Clinics of Surgery

Research Article ISSN 2638-1451 | Volume 5

Treatment of Hemorrhoids with Rubber Band Ligation (Rbl) In A Single Outpatient Centre. Suggestions of Treatment in Sars-Covid Age

Gentile M*, Vitiello A, Velotti N, Berardi G and Schiavone V

Department of General Surgery, Endocrinology, Orthopedics and Rehabilitation, Federico II University of Naples- Naples, Italy

***Corresponding author:**

Maurizio Gentile,
Department of General Surgery, Endocrinology, Orthopedics and Rehabilitation, Federico II University of Naples-Via S.Pansini 5, 80131. Naples, Italy, E-mail: magentil@unina.it

Received: 18 Apr 2021
Accepted: 08 May 2021
Published: 14 May 2021

Citation:

Gentile M. et al., Treatment of Hemorrhoids with Rubber Band Ligation (Rbl) In A Single Outpatient Centre. Suggestions of Treatment in Sars-Covid Age. Clin Surg. 2021; 5(9): 1-6

Keywords:

Haemorrhoids; COVID; Rubber band ligation; Complications; Haemorroidectomy

1. Abstract

Haemorrhoids are the most common proctological disorder with a high incidence per year and a prevalence up to 39% in the general population [1]. This condition often leads to disruption in an individual's personal and working life. Management has considerable cost implications, and therefore, economic consequences [2].

Due to the fear of SARS-COVID infection the most of patients actually regret hospitalization for surgery and choose to delay the time of treatment. RBL can be proposed as successful procedure to patients with II-III grade with a short stay in the hospital. Treatment consists initially of conservative measures such as lifestyle advice, diet and toilet behavior. When conservative hemorrhoid therapy is ineffective, many physicians may choose other non-surgical modalities: rubber band ligation injection sclerotherapy, cryotherapy, manual dilation of the anus infrared photocoagulation, bipolar diathermy, direct current electrocoagulation [3]. Rubber Band Ligation (RBL) was established as one of the most important, cost-effective and commonly used treatments for first- to third-degree internal hemorrhoids. It is a very effective non-surgical treatment for internal hemorrhoids. causing fibrosis, retraction, and fixation of the hemorrhoidal cushions. Rubber band ligation is also more effective than sclerotherapy and infra-red coagulation, but more painful. Overall complications occur in less than 10%. A retrospective study of 186 patient's outpatients who underwent RBL with a minimum follow-up of 12 months is reported. Results confirmed it is effective until 1 year with a low rate of complications and could be offered as conservative treatment for I to III grade haemorrhoids.

2. Introduction

Hemorrhoids are a common anal condition defined as the symptomatic engorgement and distal displacement of the anal cushions. Millions of people are affected around the world, and this represent a major medical and socioeconomic problem An epidemiologic study by Johanson et al [4] in 1990 showed that 10 million people in the United States complained of hemorrhoids, corresponding to a prevalence rate of 4.4%. Due to SARS-COVID infection in the last two years a lot of patients regret to refer to the hospital and delay the solution of their problems until the end of pandemic. At the same time the availability of beds in the hospitals was dramatically reduced for benign diseases. In this context would be wise to reconsider the opportunity of treatment in order to offer to patients an effective and safe solution.

Multiple factors have been claimed etiologic in the pathogenesis of hemorrhoidal disease, including constipation and prolonged straining. A dilatation and distortion of the vascular channel, followed by destructive changes in the supporting connective tissue of the anal cushion, is a the main finding of hemorrhoidal disease [5].

External hemorrhoids lie below the dentate line and are innervated by somatic nerves that can produce pain. External hemorrhoids are generally asymptomatic unless they thrombose. Thrombosed hemorrhoids are acutely painful. For many years the theory which postulated that hemorrhoids were caused by varicose veins in the anal

canal was accepted, but now it is obsolete since hemorrhoids are proven to be distinct entities by varices. In fact, patients with portal hypertension and varices do not have an increased incidence of hemorrhoids [6]. Internal hemorrhoids are usually located above the dentate line, innervated by visceral nerve fibers and are devoid of pain. Internal hemorrhoids are classified into four grades depending on their position in the anal canal: third and fourth grade usually concern with a surgical treatment.

Traditional treatment methods for haemorrhoids are divided into two broad groups: less invasive techniques which tend to produce minimal pain, and the more radical techniques like Excisional Haemorrhoidectomy (EH), which are more painful [7]. Non-surgical methods aim to remove or cause sloughing of excessive haemorrhoid tissue along with scarring that fixes the residual tissue to underlying anorectal muscular ring. These include sclerotherapy, cryotherapy, photocoagulation, laser, and rubber band ligation. Surgical methods include Miligan - Morgan and Ferguson's haemorrhoidectomy, doppler guided haemorrhoidal artery ligation with mucopexy and circular stapler techniques.

In the 1950s, Blaisdell [8] described a new technique for the ligation of bleeding internal hemorrhoids which can be performed in the office without the need for hospitalization.

The technique of office ligation of internal hemorrhoids was later modified and simplified using rubber bands by Barron [9] in the 1960s. Since then, Rubber Band Ligation (RBL) was established as one of the most important, cost-effective and commonly used treatments for first- to third-degree internal hemorrhoids, Rubber band ligation of hemorrhoids is a very effective non-surgical treatment for internal hemorrhoids. causing fibrosis, retraction, and fixation of the hemorrhoidal cushions [3].

RBL may be complicated by pain, rectal bleeding, vasovagal symptoms (dizziness or fainting), and severe perianal sepsis in some occasions.

Degree I and II symptomatic hemorrhoids should be treated initially with a rich-fiber diet [10]. Barron's technique is effective to treat haemorrhoids, degrees I, II, and many cases with III [11], especially in elderly patients with comorbidity or with moderate prolapse. and for selected patients with grade IV hemorrhoids.

In this retrospective study, we analyze the effectiveness, safety, quality of life, and results of RBL as outpatient procedure in the management of symptomatic haemorrhoids.

2.1. Rationale

The core idea was to reconsider the treatment of haemorrhoids in SARS-COVID era, since patients regret hospitalization for a benign disease such haemorrhoids and the availability for recovery is dramatically reduced. The aim was to verify if an alternative and effective method of treatment could be proposed. So, this is a retrospective study of 186 outpatients with haemorrhoids diagnosed and treated with RBL from January 2017 to January 2020 (minimum follow-up 12 months). Were considered the data of all patients with haemorrhoids from I to III grade treated by rubber band ligation. Excluded from the study were thrombosed and grade IV hemorrhoids or received other primary treatment modalities for haemorrhoids.

The study variables included symptoms, short-term and long-term outcome and complications after treatment such as pain, bleeding, and any other adverse effect. The limit of the study is the sample size but results were compared with the largest experience in literature.

2.2. Statistical Analysis

Statistical analysis was performed using the SPSS 23 system (SPSS Inc., Chicago, IL, USA). Continuous data were expressed as the means ± standard deviation (SD), and categorical variables were expressed as the % changes. The Kruskal-Wallis test was used to analyse categorical data. All results are presented as two-tailed values with statistical significance defined as p values <0.05.

3. Methods

The data refer to a single outpatient center with all patients following the same procedure. No more than two procedures were repeated in the same patient.

All treatments were preceded by a recto sigmoidoscopy which excluded the presence of rectal lesions. A small enema was prescribed on the evening before the procedure. Sedation wasn't required: in some cases, 5-10 drops of diazepam b.m. were administered before the procedure.

All treatments were performed by LEM, disposable haemorrhoid ligation suction and banding instrument by Sapimed-Italy. The suction instrument was Aspeed 3.0 by GIMA -Italy, and the latex free bands were from CS Surgical Louisiana US. Patients using ASA or clopidrogel or non-steroidal anti-inflammatory drugs (NSAID) were asked to interrupt these drugs one week before and two weeks after treatment.

Using the suction ligature device, with a pre-mounted double row of rubber bands the protrusion was suctioned into device and rubber bands deployed to the base of tissue at 1-2 cm proximal to the dentate line.

If patient experienced pain, the band was released, and was replaced in a more proximal position. A maximum of 3 sites were banded per session. At the end of the procedure a fibre-rich diet, avoidance of straining, daily sitz bath, and information concerning early, and late complications were given to each patient. A non-opioid analgesia was administered if necessary.

A note of complications including anal pain, chronic ulcer, difficulty in urination, perianal sepsis incontinence and anal stricture was made at controls. A proctoscopy was done at follow-up visit to confirm resolution or repeat band application in same or fresh sites

done. Follow-up visit was established one month after procedure and outpatients control or phone calls were made at 6-month and 1-year interval post-banding. Patients with poor results or slight improvement were invited to repeat the procedure.

4. Results

A total of 455 rubber band ligation were performed as primary treatment in 186 patients. The age ranged from 21 to 82 years old (mean 48.3 +/- SD). They were 112 (60,21%) male and 74 (39,78%) female Based on the grade of the haemorrhoids they were 37 (19,898%) patients with I grade symptomatic haemorrhoids 124 II grade (66,66%) and 25 III grade (13,44%) (Table 1, Table 2).

Table 1: Sex, distribution and grade of haemorrhoids

SEX DISTRIBUTION AND GRADE	NUMBER	%
TOTAL PATIENTS	186	
MALE	112	60,21
FEMALE	74	39,78
I GRADE	37	19,89
II GRADE	124	66,66
III GRADE	25	13,44

Table 2: Rubber band ligation as first treatment: number of sites in one session

3 sites	106	318
2 sites	57	114
1 site	23	23
Total banding	186	455

In 106 patients three ligations were performed in one session, two in 54 and only one site in 23: the total banding was 455 at the first session. Bleeding was the major complaining symptom in 57 (30,46%), anal protrusion in 41 (22,04%), pain 35 (18,1%), obstructed defecation/ constipation 22 (11,82%). The most of patients had one or more of these symptoms associated with the main one.

As secondary complaints tenesmus was recorded in 73 (39,24%) and discharge with pruritus ani in 44 (23,65) (Table 3).

Table 3: Major complaints in 186 patients

Major complaints and associated symptoms	
Prolapse	
Bleeding	**57 (30,64%)**
Pain	**35 (18,81%)**
Prolapse/Constipation	
	41 (22.04%)
Associated Tenesmus	**73 (39,24%)**
Associated Pruritus Ani	**44 (23,65%)**

A note of complication was taken after one hour and ten days from treatment: these are usually classified as minor complications and are reported in table on a total of 231 procedures including a second treatment in 45 patients.

No patient required hospitalization after the procedure.

The main complication was the pain with a high rate of incidence after the procedure and a significant improvement in the following days. Patients with repeated banding experienced more discomfort and pain (27/45). The pain was severe and persistent in 22 cases of prolapsed trombosed haemorroids. Vaso-vagal symptoms occurred in the immediate time after procedure and are frequent among young ladies; in about 25% of cases there was a difficulty in urination needing catheterization: the incidence was higher in patients with prostatic hypertrophy. In our series two episodes of priapism were registered with a short-time resolution.

Major complications were recorded in only three cases: one patient developed a perianal abscess after severe pain and fever, one had persistent severe pain requiring opioid analgesia and finally one patient required surgical haemostasis under local anesthesia (Table 4).

Table 4: Complications after RBL in 231procedures

MINOR	Within 4 hrs	Within 10 days
Pain (oral analgesia)	**215 (93,07%)**	**22 (9,52%)**
Bleeding (mild)	**25 (10,82%)**	**11 (4,76%)**
Vaso-vagal sympt	**41 (17,74%)**	-
Slippage	**2 (0,86%)**	-
Urinary difficult	**34 (14,71%)**	-
Need catheter	**8 (3,46%)**	-
Trombosed Haem	-	**22 (9,52%)**
MAJOR		
Perianal abscess, severe pain, late bleeding	-	**3 (1,29%)**

Six months after procedure 145 patients were examined out of 184 (78,1%). In this second group 105 (72,41%) had resolution with an improved condition in 28 (20,74%). 12 (8,88%) patients showed the persistence of original complaints. One year after the first treatment 121 of 135 patients were scheduled (76,56%) and 93 of them (76,85%) showed a persistent resolution, 15 a further improvement (14,85%) but 13 (12,87%) a complete failure (Table 5).

Concerning the grade of haemorrhoids the most of patients with resolution had II grade disease (Table 6). It is evidenced that at 1 and 6 months' control, patients with grade II had higher incidence of resolution if compared to other grades. This is not evidenced after 12 months but this could be due to the number of patients lost to follow-up.

From these results there is no statistically significant difference in terms of resolution between the three steps of follow-up.as reported in table 7.

Table 5: Outcome after 1, 6, 12 months

FOLLOW-UP	1 MONTH	6 MONTHS	12 MONTHS
RESOLUTION	148 (80,4%)	105 (72,41%)	93 (76,85%)
IMPROVED	27 (14,5 %)	28 (20,74%)	15 (14,85%)
FAILURE	9 (4,89%)	12 (8,88%)	13 (12,87%)
TOTAL	**184**	**145**	**121**
LOST F.U.	2 (1,07%)	39 (21,9%)	34 (23,44%)

Table 6: Grade of haemorrhoids in patients with resolution

RESOLUTION	PATIENTS	%	I GRADE	II GRADE	III GRADE	P
1 MONTH	148/186	79,5	37	90	21	0.003
6 MONTHS	105/145	72,4	27	60	18	0.007
12 MONTHS	93/121	76,8	24	58	13	0.15

Table 7: Significativity of resolution at different stages of follow-up

RESOLUTION	p. value	
1 month vs 6 months	0.18	n.s
1 month vs.12 months	0.96	n.s
6 months vs 12 months	0.4	n.s

The procedure was repeated in 19 patients within one month after the first procedure with an improvement of the condition in 14 and no change/ failure in 5. A second session was made after 6 months from the first treatment in 16 patients, with 11 improved, and 5 poor results.

Finally, at twelve months 10 patients were retreated with 7 improvements and 3 failures. A group 21 patients of 186 went to surgical haemorroidectomy due to persistence of bleeding with a disconfort.

5. Discussion

Surgical hemorrhoidectomy is the best option in symptom control, but is related to significant postoperative pain and the recovery time is sometimes too extended for a benign condition [12].

Murie et al [13] performed a patient assessment in which 93%of patients undergoing haemorrhoidectomy had an excellent to moderately successful result versus 88% of patients after rubber band ligation: this is the most widely used procedure, safe and very effective, with severe complication being uncommon. A Cochrane review evaluated the efficacy of RBL with respect to grade of hemorrhoids and found that excisional hemorrhoidectomy was superior to RBL for grade III hemorrhoids (2 trials, 116 patients, RR = 1.23 (95% CI, 1.04–1.45); p = 0.01) [14].

Moreover, it offers the possibility of resolution without the need for hospitalization or anaesthesia, and enables the patient to immediately return to his normal working activity with a limited recovery time. Awad et al. [15] reported a hospital stay of 2.5 days after haemorrhoidectomy versus 1 day after RBL. Loss of working days was reported by Murie et al. [13] favouring RBL (32 vs. 3 days): this difference was statistically significant. Overall postoperative complications were more frequent after haemorrhoidectomy: pain and bleeding were evaluated in all studies with a higher incidence after surgical haemorrhoidectomy.

Thus RBL is regarded as the most effective and safe outpatient procedure for all grades of hemorrhoids in terms of short- and long-term results and less complications [16, 17]. In our experience RBL was applied to patients from first to third grade in the opinion that surgery is mandatory for IV grade haemorrhoids.

In our series 186 patients were evaluated with a minimum follow-up of 12 months. A resolution is reported in 76,8% after 12 months' even if only 121out 186 patientes were re-examined: these results could be even better if the total of patients could be re-examined.

The procedure was repeated in about 24% of the patients at different stages of the follow-up. There is some uncertain if repeated banding must be considered as recurrence or part of treatment. For rebanding two or three sessions are common and patients may find this a more agreable than one operation if the results are comparable in the long period. In our experience repeated banding were limited to two sessions: in literature, except for 2 trials which performed 1 session RBL, none out of the 8 trials reported by Dekker describes the exact number of sessions. Finally, surgical hemorrhoidectomy was offered in, 21 patients out 186 (11%).

RBL is considered as the gold standard for conservative methods such as haemorrhoidectomy is for surgical procedures. Reliable

outcome measurements relate to the definition of haemorrhoids. and the choice of treatment is based on Goligher classification of haemorrhoids but symptoms are not reliably related to Goligher's gradation [18]. It should be more useful a solid definition of failure or recurrence by a validated score of symptoms.

The success rates of the method in literature range between 79% and 91.8% [19]. Wrobleski et al [20] reported that 80% of their patients improved and 69% were symptom-free at a mean follow-up of 5 years.

There was no difference in success rates of RBL in 1st, 2nd and 3rd degree hemorrhoids and Johanson et al [21] showed that 6.6%-14% of the patients undergoing RBL will require additional treatment, due to the recurrence of symptoms.

Many authors reported that recurrence rate may be as high as 68% at 4 or 5 years of follow-up and symptoms usually respond to repeated ligation, but only 10% of such patients require excisional hemorrhoidectomy [22]. Vassillios et al [23] reported that symptomatic recurrence was 11.9% (53/445) 2 years after RBL, with repeat RBL or surgery in (41/445) 9.2% cases. Bayer et al [24] found that 18% of their patients required one or more additional sessions of RBL while 2.1% failed to be cured by RBL and were referred for conventional hemorrhoidectomy. Bleeding is a significant complication of RBL, and it cannot be prevented. It is the result of the fall of the hemorrhoidal nodule and local inflammation; in our series it is about 10% but always mild and not requiring hospitalization neither transfusion. One patient went to emergency room 8 days after procedure for three repeated episodes of bleeding and was observed for one night without any transfusion. Ayman et al. [25] in their study of 750 cases found that 31 patients (4.13 %) had bleeding which is lower than our results.

We reported 41 patients with vaso-vagal symptoms (dizziness or fainting) after RBL mainly occurring in young ladies. In Aram [26] study on 890 patients post-banding vasovagal symptoms occurred in five cases (0.6 %) that is very low incidence but the Author doesn't report if any sedation was administered before the procedure.

Difficulty in urination were observed in 14% of cases with 8 (3,46%) patients need catheter just to void the bladder: in Aram [25] there were no cases of urine retention that necessitate catheterization.

This result is lower than Ayman et al. [25] who found this complication in ten cases (1.33 %) in their study. Dekker [2] reported a urinary retention more often after haemorrhoidectomy (2-34%) than after RBL (0-0.4%).

Pain is a common complication after RBL and is present up to 50% as mild pain for the first 48 hours [27, 28]. In a prospective study pain was the most common symptom occurring in almost 90% with the pain scores higher 4 hours following the procedure and after 1 week 75% of patients did not experienced any pain at all [29, 30]. From HubBle trial pain was lower after RBL than HAL surgical procedure either compared after 1 day either after 1week [31].

As reported in literature no patient with incontinence was observed [2]. In 3 studies anal incontinence was reported from 0 to 7.7% after surgical haemorrhoidectomy but this was not reported after RBL [31-33]. Anal stenosis is reported in one patient by Bakhtawar in 2017 out 471 patients while is reported in 26 cases after haemorrhoidectomy [34].

Septic complication has been reported including pelvic sepsis, Fournier's gangrene, liver abscess and bacterial endocarditis. The hypotheses are related to transmural necrosis that facilitates the spread of sepsis to adjacent tissues [28]. We reported only one case of little perianal abscess drained in outpatient room.

Finally, data regarding health-care costs from other studies is sparse. Cost analysis has been carried out in one trial comparing stapled haemorrhoidopexy with RBL, with the cost of stapled haemorrhoidopexy being substantially higher and unlikely to be considered cost-effective at 1 year [2].

6. Conclusions

Haemorrhoidectomy seems to provide better symptom control but at the cost of more pain and complications.

Due to the fear of infection the most of patients actually regret hospitalization for surgery and choose to delay the time of treatment. RBL can be proposed as successful procedure to patients with II-III grade with a short stay in the hospital.

Rubber band ligation is an efficacious, cost-effective and simple treatment for the first to third degree hemorrhoids without rectal mucosal prolapse Rubber band ligation is also more effective than sclerotherapy and infra-red coagulation, but more painful. Overall complications occur in less than 10%.

The cure rate is high with low rates of recurrence. Most patients with grade I and II and select patients with grade III internal hemorrhoidal disease who fail medical treatment can be effectively treated with office-based procedures, such as banding, sclerotherapy, and infrared coagulation (IRC). Hemorrhoid banding is typically the most effective option [35, 36].

7. Acknowledgement

Supported by Sapi Med -Alessandria- Italy.

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