



## Rubber band ligation for 750 cases of symptomatic hemorrhoids out of 2200 cases

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### Abstract

**AIM:** To study the results for the treatment of symptomatic hemorrhoids using rubber band ligation (RBL) method.

**METHODS:** A retrospective study for 750 patients who came to the colorectal unit from June, 1998 to September, 2006, data was retrieved from archived files. RBL was performed using the Mc Gown applicator on an outpatient basis. The patients were asked to return to out-patient clinic for follow up at 2 wk, 1 mo, 6 mo and through telephone call every 6 mo for 2 years).

**RESULTS:** After RBL, 696 patients (92.8%) were cured with no difference in outcome for second or third degree hemorrhoids ( $P = 0.31$ ). Symptomatic recurrence was detected in 11.04% after 2 years. A total of 52 patients (6.93%) had 77 complications from RBL which required no hospitalization. Complications were pain, rectal bleeding and vaso-vagal symptoms

(4.13%, 4.13% and 1.33% of patients, respectively). At 1 mo there were a significant improvement in mean SF-36 scores over baseline in five items, while after 2 years there were improvement in all items over baseline, but not significant. No significant manometric changes after band ligation.

**CONCLUSION:** RBL is a simple, safe and effective method for treating symptomatic second and third degree hemorrhoids as an out patient procedure with significant improvement in quality of life. RBL doesn't alter ano-rectal functions.

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**Key words:** Piles; Rectal bleeding; Barron banding; Hemorrhoidectomy

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### INTRODUCTION

Hemorrhoids are the clinical manifestation of the downward disruption of normal functional structures known as the anal cushions<sup>[1]</sup>. Hemorrhoids are considered one of the most frequent diseases of the anal region with high prevalence (nearly 50% of proctological visits in a colorectal unit)<sup>[2]</sup>, involving any age and affecting both males and females equally<sup>[3,4]</sup>. They commonly occur in patients with chronic increased intra-abdominal pressure as well as in pregnancy<sup>[5]</sup>.

Numerous modalities and techniques have been

developed to treat symptomatic hemorrhoids ranging from simple dietary measures and bowel habit regulation, through a number of non-operative procedures, to different techniques of excision of diseased anal cushions. The vast amount of treatment options means none are close to perfection<sup>[6]</sup>. While many non-operative procedures are effective in controlling symptoms, at least from the patients' perspective, they all share the common problem of recurrence<sup>[7]</sup>. Although, surgical hemorrhoidectomy is more definitive in symptom control, it has a reputation for being a painful procedure for a relatively benign disorder<sup>[8]</sup>. First, second and third degree hemorrhoids can be treated by non surgical methods in outpatient clinics while severe prolapsed or circumferential hemorrhoids can be treated using a variety of surgical techniques, e.g. Milligan Morgan, Longo and others<sup>[9,10]</sup>.

Nonsurgical methods aim at tissue fixation (sclerotherapy, cryotherapy, photocoagulation, laser), or fixation with tissue excision [rubber band ligation (RBL)]<sup>[11]</sup>. RBL is considered the most widely used procedure, and it offers the possibility to resolve hemorrhoidal disease without the need for hospitalization or anaesthesia, and with lower incidence of complications<sup>[12,13]</sup>.

In this retrospective study, we analyze the effectiveness, safety, quality of life and results (early and long term) of RBL in the management of symptomatic hemorrhoids as outpatient procedure.

## MATERIALS AND METHODS

This is a retrospective analysis of data of patients diagnosed with hemorrhoids who were managed by RBL at the outpatient clinic of colorectal surgery unit, Mansoura university hospitals from June, 1998 to September, 2006. Data, from 750 patients who had symptomatic hemorrhoids and treated by RBL, were retrieved from archived files of our colorectal surgery unit out of 2200 cases of hemorrhoids. The mean age was  $39.13 \pm 14.75$  years (ranging from 15 to 90 years old). Six hundreds and twenty seven patients (82.8%) were males, while 123 patients (17.2%) were females. Sixty four patients (8%) had chronic liver disease. Supplemental information was obtained from telephone follow up.

The policy of our colorectal unit stated for the following inclusion and exclusion criteria: Patients at any age with first, second or third degree internal piles were included. While, patients with: Previous ano-rectal surgery, associated ano-rectal pathology "fissure, fistula ...*etc*", fourth degree hemorrhoids and complicated piles (infection, ulceration or strangulation) were excluded.

Patients who fulfilled inclusion criteria were subjected to: Thorough history taking including the following items; age, sex, occupation and residence, presentation (bleeding, prolapse, anal pain, discharge, and pruritus). For local examination, the patient was examined when relaxed in the left lateral position and the local examination to anal region is carried out by inspection,

palpation, P.R. examination, proctoscopic examination and sigmoidoscopic examination for patients above 50 years.

Ano-rectal manometry was performed using a standard low compliance water perfusion system and eight-channels catheters with pressure transducer connected to 5.5 mm manometric probe with spirally located ports at 0.5 cm interval. The protocol of performance is a stationary pull through technique with recording the functional length of the anal canal (FL), mean maximum resting pressure, mean squeeze pressure.

All patients received a cleansing rectal enema before the procedure to avoid bowel movement in first 24 h so ligatures would not be expelled. The procedure was done in left lateral position. No anaesthesia was used; no antibiotics were administered, except to patients with valvular heart diseases or chronic liver disease.

The procedure was performed through the proctoscope, which was inserted and placed about 1-2 cm. above the dentate line using K-Y gel as a lubricant. The hemorrhoidal cushion was allowed to prolapse into the lumen of proctoscope, after that it was sucked into the Mc Gown ligator. It was important that the patient experienced no pain when the cushion was sucked; if pain was experienced, the cup was placed in a more proximal position. The tissue was drawn into the drum until it was taut, and the trigger was released, expelling rubber O-ring with an inner diameter of about 1 mm around the base of the haemorrhoid. The policy of our unit is that all piles are ligated in the same session.

By the end of the procedure, each patient treated by RBL was kept in the outpatient clinic and observed for 1-2 h following the procedure, in order to detect any early complication as hemorrhage and pain. The patients were informed about the progress of the treatment (fall of the necrosed hemorrhoidal nodule). We recommended high residue diet, mild laxative to softening the stool, local anal hygiene, avoidance of straining, and information concerning early and late complications.

The patients were asked to return to out-patient clinic for follow up at 2 wk, 1 mo, 6 mo and then through telephone call every 6 mo for 2 years. Subsequent ligations were performed at 1 mo after the prior one, if the patients still had symptoms.

Results were classified as following; cure if the patient was asymptomatic after the end of treatment, improvement if the symptoms had been minimized, and as failure of the method if no improvement whatsoever occurred.

Post ligation complications include: pain, Vaso-vagal symptoms (dizziness or fainting), retention of urine, bleeding per rectum whether primary, secondary or reactionary and post ligation infection were recorded. Also, the patient was asked about continence and anal stricture during scheduled P.R examinations

Functional status was assessed with the medical outcomes study 36-item short-form general health survey (SF-36) questionnaire, version 2<sup>[14]</sup> (pre procedure,

1 mo post procedure and after 2 years). The SF 36 consists of eight multi-item dimensions, each of which generates a score of between 0 and 100; higher scores indicate higher levels of perceived health.

### Statistical analysis

The statistical analysis of data was done by using SPSS (Statistical Package for Social Science) version 10 under Microsoft Windows XP. The description of data was done in form of mean  $\pm$  SD for quantitative data; while frequency and proportion for qualitative data. The analysis of data was done to test the statistical significant difference between groups. For quantitative data, to compare between 2 groups Student *t*-test was used and for qualitative data  $\chi^2$  test was used.  $P < 0.05$  was considered significant.

## RESULTS

Our study includes 750 patients with hemorrhoidal disease with a mean age was  $39.13 \pm 14.75$  years (ranging from 15 to 90 years old). Six hundred and twenty seven patients (82.8%) were males, while 123 patients (17.2%) were females. Male to female ratio was 5.09:1.

Demographic data, clinical presentation and severity of hemorrhoids for all patients are shown in Table 1.

In 473 patients (63.06%), one session ligation was performed while in the remaining patients, multiple hemorrhoidal ligations were performed in two sessions for 259 patients (34.53%), and three sessions for 18 patients (2.4%) with 1 mo interval.

The total of 2122 ligations in 1045 sessions were carried out, with a mean of  $2.35 (\pm 0.49)$  per patient and  $2.03 (\pm 0.54)$  per session.

Successful results were achieved in 696 patients (92.8%), 650 patients (86.66%) were cured after the end of treatment, whereas, 46 patients (6.13%) improvement was reported. Fifty four patients (7.2%) failed to get any benefit from RBL. There was no significant difference in the outcome of RBL between second and third degree hemorrhoids ( $P = 0.31$ ) Table 2.

Two years after the end of treatment, 643 patients 85.73% came for follow up. Symptomatic recurrence was detected in 71 out of 643 patients (11.04%), with repeated treatment by RBL in 23 cases and additional surgical treatment was required in another 48 patients due to severe symptoms in 30 patients, associated anal fissure in 6 patients, and patient desire in 12 patients Tables 3 and 4.

Seventy seven complications from RBL were encountered in 52 patients (6.93%) as shown in Table 5. Pain was occurred in 31 patients (4.13), 22 cases (3.78%) had second degree hemorrhoids and 9 cases (5.35%) had third degree hemorrhoids with no statistical significance ( $P = 0.8$ ) (Table 5). Patients with multiple hemorrhoidal banding, when compared with patients with single banding had great discomfort and pain (19/277, 6.85% *vs* 12/473, 2.53% respectively). Pain was treated conservatively with analgesic and warm baths in all patients and no patient forced to remove the band.

**Table 1** Demographic and clinical data for patients *n* (%)

| Variables             | Number of patients       |
|-----------------------|--------------------------|
| Age (yr)              | 39.13 $\pm$ 4.75 (15-90) |
| Sex                   |                          |
| Male                  | 627 (82.8)               |
| Female                | 123 (17.2)               |
| Cirrhotic patients    | 64 (8.53)                |
| Child A               | 23                       |
| Child B               | 15                       |
| Child C               | 6                        |
| Grade of haemorrhoid  |                          |
| G2                    | 582 (77.6)               |
| G3                    | 168 (22.4)               |
| Clinical presentation |                          |
| Bleeding              | 612 (81.6)               |
| Prolapse              | 496 (66.13)              |
| Constipation          | 267 (35.6)               |
| Pruritus              | 64 (8.53)                |
| Pain                  | 30 (4)                   |

**Table 2** Early results of RBL in 750 patients *n* (%)

| Results     | Total       | Grade II   | Grade III   | <i>P</i> |
|-------------|-------------|------------|-------------|----------|
| Cured       | 650 (86.66) | 522 (89.7) | 128 (76.19) | 0.31     |
| Improvement | 46 (6.13)   | 24 (4.12)  | 22 (13.09)  | 0.23     |
| Failure     | 54 (7.2)    | 36 (6.18)  | 18 (10.7)   | 0.16     |
| Total       | 750         | 582        | 168         |          |

**Table 3** Long term results and follow up of patients with RBL

| Results     | Patients | Re-examined | Asymp-tomatic | Symp-tomatic | Surgery | RBL |
|-------------|----------|-------------|---------------|--------------|---------|-----|
| Cured       | 650      | 610         | 572           | 38           | 30      | 8   |
| Improvement | 46       | 33          |               | 33           | 18      | 15  |
| Failure     | 54       | -           | -             | -            | -       | -   |
| Total       | 750      | 643         | 572           | 71           | 48      | 23  |

**Table 4** Patients with recurrence

|                    | No. of patients (%) |
|--------------------|---------------------|
| Initial grade      |                     |
| Grade II (582)     | 49 (8.42)           |
| Grade III (168)    | 22 (13.1)           |
| Grade at follow up |                     |
| Grade I            | 19 (26.7)           |
| Grade II           | 42 (59.15)          |
| Grade III          | 10 (14.08)          |
| Symptoms           |                     |
| Bleeding           | 68 (95.8)           |
| Prolapse           | 50 (70.42)          |
| Pruritus           | 16 (22.53)          |
| Pain               | 15 (21.12)          |
| Associated fissure | 6 (8.4)             |
| Line of treatment  |                     |
| Re-banding         | 23 (32.4)           |
| Surgical treatment | 48 (67.6)           |
| Severe symptoms    | 30                  |
| Associated fissure | 6                   |
| Patient's desire   | 12                  |

Mild rectal bleeding was reported in 31 cases (4.13%) and it was occurred 7-14 d after the procedure. It was treated conservatively in all cases with no need for

Table 5 Post-banding complications *n* (%)

| Complication        | Degree of hemorrhoids |                       | Total      | <i>P</i> |
|---------------------|-----------------------|-----------------------|------------|----------|
|                     | 2nd ( <i>n</i> = 582) | 3rd ( <i>n</i> = 168) |            |          |
| Pain                | 22 (3.78)             | 9 (5.35)              | 31 (4.13)  | 0.8      |
| Bleeding            | 21 (2.8)              | 10 (5.95)             | 31 (4.13)  | 0.35     |
| Vaso-vagal symptoms | 8 (1.37)              | 2 (1.19)              | 10 (1.33)  | 0.23     |
| Infection           | 1 (0.17)              | -                     | 1 (0.13)   | -        |
| Fistula             | 1 (0.17)              | -                     | 1 (0.13)   | -        |
| Fissure             | 2 (0.34)              | 1 (0.59)              | 3 (0.4)    | 0.79     |
| Total               | 55 (9.45)             | 22 (13.09)            | 77 (10.26) | 0.09     |

Table 6 Quality of life using mean SF-36 scores pre-banding and at 1 mo and 2 yr follow up

| Dimension                                     | Pre-banding  | After 6 mo   | <i>P</i> | At 2 yr follow up | <i>P</i> |
|---|--------------|--------------|----------|-------------------|----------|
| Physical functioning (PF)                     | 58.98 ± 2.5  | 63.6 ± 3.4   | 0.03     | 60.12 ± 5.2       | 0.08     |
| Role limitation due to physical problem (RP)  | 64.8 ± 15.22 | 63.6 ± 11.2  | 0.67     | 63.1 ± 10.2       | 0.56     |
| Body pain (BP)                                | 60.5 ± 4.32  | 63.6 ± 6.5   | 0.04     | 61.4 ± 7.1        | 0.07     |
| General health (GH)                           | 74.8 ± 4.9   | 76.5 ± 6.7   | 0.54     | 75.8 ± 6.6        | 0.57     |
| Vitality (VT)                                 | 69.3 ± 12.5  | 70.2 ± 11.66 | 0.02     | 69.8 ± 12.3       | 0.09     |
| Social functioning (SF)                       | 73.9 ± 6.2   | 75.6 ± 5.66  | 0.05     | 74.1 ± 7.5        | 0.07     |
| Role limitation due to emotional problem (RE) | 60.4 ± 3.2   | 58.5 ± 5.6   | 0.08     | 65.2 ± 4.5        | 0.09     |
| Mental health (MH)                            | 71.9 ± 2.8   | 73.5 ± 2.3   | 0.01     | 73.6 ± 5.2        | 0.04     |

blood transfusion or hospitalization in any of these cases. Post banding bleeding occurred in 21 cases (2.8%) with second degree hemorrhoids and in third degree hemorrhoids only 10 cases (5.95%) complicated with mild bleeding after RBL with no statistical significance ( $P = 0.35$ ) (Table 5).

Post-banding vaso-vagal symptoms were reported in 10 cases (1.33%). There were no cases of urine retention that necessitate catheterization, fecal incontinence did not occur after RBL in this study, also no cases were complicated by anal stenosis (Table 5).

Perianal abscess occurred in one case (0.13%) after RBL. It was drained, but 2 mo later the patient developed low anal fistula which was treated by fistulectomy. Three patients (0.4%) complicated with anal fissure after RBL.

There was no significant difference in pre banding and post banding manometric study (pre banding and post banding mean resting pressure were  $87.29 \pm 17.44$  and  $86.45 \pm 15.46$ , respectively,  $P = 0.065$ ) and (pre banding and post banding mean squeeze pressure were  $227.82 \pm 43.82$  and  $227.04 \pm 44.12$ ,  $P = 0.193$ ).

The SF-36 questionnaires were completed by 730 patients pre banding, 720 patients at 1 mo and 630 patients at 2 years for assessment of quality of life. At 1 mo after banding there was greater improvement in mean score over baseline, the difference observed were significant for five dimensions in physical, social activity, vitality, freedom of pain and mental health. At 2 years after banding there were greater improvement in mean scores over baseline for all items, but only mental health showed significant difference Table 6.

## DISCUSSION

The need to treat hemorrhoids is based primarily on the severity of symptoms, but the type of treatment is based on the traditional classification of hemorrhoids, which may have little to do with symptom severity<sup>[15]</sup>. The best treatment remains unanswered despite of the wide variety of treatment options in use. Safety is of paramount importance, especially when treating a benign disease such as hemorrhoids<sup>[16,17]</sup>. Although surgical hemorrhoidectomy is more definitive in symptom control, it has a reputation of having a significant postoperative pain and an extended recovery time for a relatively benign disorder<sup>[7]</sup>. Nowadays, rubber-band ligation is the most widely used procedure, and it offers the possibility to resolve hemorrhoids disease without the need for hospitalization or anaesthesia, and with a lower incidence of complications when compared to conventional surgery<sup>[15]</sup>.

The success rates of the method range between 79% and 91.8%<sup>[11,16,18]</sup>. Wroblewski *et al*<sup>[19]</sup> 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<sup>[11]</sup>. In our study, successful results were achieved in 696 patients (92.8%), 650 patients (86.66%) were cured or presented great improvement after the end of treatment and 2 years later, 572 patients were cured out of 643 patients who attended follow-up. Johanson *et al*<sup>[20]</sup> 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<sup>[21,22]</sup>. Vassillios *et al*<sup>[11]</sup> 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*<sup>[23]</sup> 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. In our study, symptomatic recurrence was detected in 11.04% (71/643) after 2 years follow up, with repeated treatment by RBL in 23 cases while additional surgical treatment was required in 48 patients.

A review of 39 studies incorporating 8 060 patients undergoing RBL revealed post banding complications in the form of severe pain in 5.8%, hemorrhage in 1.7%, infection in 0.05% anal fissure and fistula in 0.4%<sup>[24]</sup>. Bat *et al*<sup>[16]</sup> showed that the complications rate after RBL was relatively low (4.2%), most of the complications were minor and self limiting, only 2.5% of his patients had severe complications that required hospitalization. Vassillios *et al*<sup>[11]</sup> reported that in 94 patients (18.8%), complications were occurred. In our series, seventy seven complications from RBL encountered in 52 patients (6.93%) were mostly minor and no hospitalization was needed. Many authors reported that post banding pain was frequently observed even during careful placement



above the dentate line<sup>[25]</sup>. Furthermore, pain and anal discomfort were reported to be greater, ranging from 28% to 79%, when multiple bandings were performed per session<sup>[26]</sup>. Gupta<sup>[18]</sup> found that out of 44 patients underwent RBL; seven patients (15.9%) reported pain and Oueidat and Jurjus<sup>[27]</sup> noted that out of 148 patients underwent RBL; twenty patients (13.5%) reported pain. We found that, pain occurred in 31 patients (4.13%), in all cases the pain appeared immediately or few hours after the ligation and lasted less than 2-3 d. Patients with multiple hemorrhoidal banding in one session had greater discomfort and pain. These results are in accordance with those of Vassillios *et al.*<sup>[11]</sup>, who reported that patients with multiple hemorrhoidal banding in a single session compared with patients with single banding had greater discomfort and pain (9.35% *vs* 1.96%). Also, Lee *et al.*<sup>[28]</sup> and Gehmy *et al.*<sup>[29]</sup> reported the same results. On the contrary, Hardwick *et al.*<sup>[30]</sup> failed to show any relationship between the number of bands applied and the degree of pain. Moreover, Khubchandani<sup>[31]</sup>, in a prospective randomized study, compared the results of single, double and triple hemorrhoidal ligation, but did not notice any difference even if they were forced to remove the elastic band in many cases in the third group.

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, bleeding in our series occurred in 31 cases (4.13%). It was mild and treated conservatively in all cases without hospitalization or blood transfusion. Band ligation is safe in patients with cirrhosis and portal hypertension as reported by Vassillios *et al.*<sup>[11]</sup>. Bat *et al.*<sup>[16]</sup> and Bayer *et al.*<sup>[23]</sup> reported that only 2.2% of his patients complicated by rectal bleeding.

Watson *et al.*<sup>[32]</sup>, in their study of 183 cases of band ligation, found that 41 patients (30%) of patients had vaso-vagal symptoms. Kumar *et al.*<sup>[33]</sup> reported that 15.3% of their studied group (98 patients) had vaso-vagal symptoms. In our study, Post-banding vaso-vagal symptoms occurred in 10 cases (1.33%). There were no cases of urine retention that necessitate catheterization, fecal incontinence or cases complicated by anal stenosis after band ligation. This also reported by Benzoni *et al.*<sup>[34]</sup> and Watson *et al.*<sup>[32]</sup>.

Bursics *et al.*<sup>[35]</sup> reported that maximum resting pressure and squeeze pressure remained unchanged after RBL, as found in our study.

Our conclusion is that RBL is a simple, safe and effective method for treating symptomatic second and third degree hemorrhoids as an out patient procedure with significant improvement in quality of life. RBL can be used to treat grade 2 and 3 hemorrhoids with similar effectiveness. RBL doesn't alter ano-rectal functions.

habit regulation, through a number of non-operative procedures, to different techniques of excision of diseased anal cushions. The vast amount of treatment options means none are close to perfection. Nonsurgical methods aim at tissue fixation (sclerotherapy, cryotherapy, photocoagulation, laser), or fixation with tissue excision [rubber band ligation (RBL)].

### Research frontiers

RBL is a simple, safe and effective method for treating symptomatic second and third degree hemorrhoids as out patient procedure with significant improvement in quality of life. RBL doesn't alter ano-rectal functions.

### Innovations and breakthroughs

RBL is effective method for treating symptomatic hemorrhoids as an out patient procedure with significant improvement in quality of life. RBL doesn't alter ano-rectal functions.

### Applications

After RBL, 696 patients (92.8%) were cured with no difference in outcome for second or third degree hemorrhoids ( $P = 0.31$ ). Symptomatic recurrence was detected in 11.04% after 2 years. A total of 52 patients (6.93%) had 77 complications from RBL which required no hospitalization. Complications were pain, rectal bleeding and vaso-vagal symptoms (4.13%, 4.13% and 1.33% of patients respectively). At 1 mo there were a significant improvement in mean SF-36 scores over baseline in five items while after 2 years there were improvement in all items over baseline but not significant. No significant manometric changes after band ligation.

### Peer review

This is an interesting study of a large series of patients with RBL and their results. Authors retrospectively analyzed the effectiveness, safety, quality of life and results of RBL in the management of symptomatic hemorrhoids. The paper is well written.

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## COMMENTS

### Background

Numerous modalities and techniques have been developed to treat symptomatic hemorrhoids ranging from simple dietary measures and bowel

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