Egyptian Journal of Surgery Vol 27, No 3, July, 2008

ORIGINAL ARTICLE

RUBBER BAND LIGATION FOR 550 PATIENTS OF SYMPTOMATIC HAEMORRHOIDS OUT OF 2200 PATIENTS RETROSPECTIVE STUDY

By

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Aim: ***This retrospective study was conducted to elucidate the results of the treatment for symptomatic haemorrhoids using rubber band ligation (RBL) method.***

Method: ***a retrospective study for 550 patients who came to the colorectal unit from June 1998 to June 2006, data was retrieved from archived files. Forty four patients with haemorrhoid had liver cirrhosis.RBL was performed using the Mc Gown applicator on an outpatients basis. The patients were asked to return to out-patient clinic for follow up at 2 week, 1, 6, months and through telephone call every 6 month for 2 years).***

Results: ***After RBL 496 patients (90.18%) were cured with no difference in outcome for first, second or third degree haemorrhoids (P value = 0.31). symptomatic recurrence was detected in 16.03 % after 2 years then repeated RBL or surgery were done for them. A total of 88 patients (16%) had 155 complications from RBL which required no hospitalization. Complications were registered; pain in 10.37 %, rectal bleeding in 8.36% and vaso-vagal symptoms in 7.81 %.***

Conclusion: ***RBL is a safe and successful method for treating symptomatic haemorrhoids, even in cirrhotic patients.***

Keywords: ***Piles, rectal bleeding, Barron.***

INTRODUCTION

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

Numerous modalities and techniques have been developed to treat symptomatic haemorrhoids 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.[6] While many non operative procedures are effective in controlling symptoms at least from the patient's perspective, they all share the common problem of recurrence.[7] Although, surgical haemorrhoidectomy is more definitive in symptom control, it has a reputation for being a painful procedure for a relatively benign disorder.[8] First, second and third degree haemorrhoids can be treated by non surgical methods in outpatients' clinic while severe prolapsed or circumferential haemorrhoids can be treated using a variety of surgical

techniques e.g. Milligan Morgan, Longo and others.[9-10]

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

In this retrospective study we analyze the effectiveness, safety and results (early and long term) of RBL in the management of symptomatic haemorrhoids.

PATIENTS AND METHODS

This is a retrospective analysis of data of patients diagnosed with haemorrhoids who were managed by RBL at the outpatient clinic of colorectal surgery unit, Mansoura university hospitals from June 1998 to June 2006. Data of 550 patients who had symptomatic haemorrhoids and treated by RBL were retrieved from archived files of our colorectal surgery unit out of 2200 patients of haemorrhoids. The mean age was 39.13+14.75 years (ranging from 15 to 90 years old). Four hundred and twenty seven patients (77.64%) were males, while 123 patients (22.36%) were females. Forty four patients (8%) had chronic liver disease .Supplemental information was obtained from telephone follow up.

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 haemorrhoids 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 pruritis). 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.

All patients received a cleansing rectal enema before the procedure to avoid bowel movement in first 24 hours 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 haemorrhoidal 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 rubber band ligation was kept in the outpatient clinic and observed for 1-2 hours 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 haemorrhoidal 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 two weeks, one month, 6 months and then through telephone call every 6 months for two years. Subsequent ligations were performed at one month 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 wether 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

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 ± 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, to compare between more than 2 groups "One way Anova" test was used and for qualitative data Chi-square test was used. P value < 0.05 was considered significant.

RESULTS

Our study includes 550 patients with haemorrhoidal

disease with a mean age was 39.13 + 14.75 years (ranging from 15 to 90 years old). Four hundred and twenty seven patients (77.64%) were males, while 123 patients (22.36%) were females. Male to female ratio was 3.47:1

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

Table 1. Demographic and clinical data for patients.

Variables	Number of Patients
Age	39.13+14.75 (15-90) years
Sex Male	427(77.64%)
Female	123 (22.36%)
Cirrhotic Patients	44 (8%)
Child A	23
Child B	15
Child C	6
Grade of Haemorrhoid	
G1	38 (6.9%)
G2	432 (78.5%)
G3	80 (14.6%)
Clinical Presentation	
Bleeding	502 (91.27%)
Prolapse	397 (72.18%)
constipation	137 (24.91%)
Pruritis	44 (8%)
pain	30 (5.5%)

In 473 patients (86%) single haemorrhoidal ligation was performed while in the remaining patients, multiple haemorrhoidal ligations was performed in two sessions for 69 patients (12.55%) and three sessions for 8 patients (1.45%) with one month interval Table 2.

Table 2. Number of sessions of RBL in 550 patients.

Number of sessions	Number of patients
One session	473 patients (86%).
Two sessions	69 patients (12.55%
Three sessions	8 patients (1.45%)

The total of 1291 ligations in 635 sessions were carried out, with a mean of 2.35(+ 0.49) per patient and 2.03 (+ 0.54) per session.

Successful results were achieved in 496 patients (90.18%), 450 patients (81.82%) were cured after the end of treatment, whereas, 46 patients (4.18%) improvement was reported. Fifty four patients (9.82%) failed to get any benefit from RBL and haemorrhoidectomy was done for them. There was no significant difference in the outcome of rubber band ligation between first, second and third degree haemorrhoids (P value = 0.31) Table 3.

Table 3. Early results of RBL in 550 patients.

Results	Total	Grade I	GradeII	Grade III	P value
Cured	450 (81.82%)	32	357	61	
		84.32%	82.63	76.25%	
Improvement	46 (4.18%)	4	34	8	0.31
		10.52%	7.88%	10%	
Failure	54 (9.82%)	2	41	11	
		5.26%	9.49%	13.75%	
Total	550	38	432	80	

One hundred and fifty five complications from RBL were encountered in 88 patients (16%) as shown in table (4). Pain was occurred in 59 patients (10.73), 3 patients (7.89%) had first degree haemorrhoids, 47 patients (10.88%) had second degree haemorrhoids and 9 patients (11.25%) had third degree haemorrhoids with no statistical significance (P value = 0.8) Table 4. Patients with multiple haemorrhoidal banding when compared with patients with single banding had great discomfort and pain (13/77, 16. 88% vs 46/473, 9.72% respectively). Pain was treated conservatively with analgesic and warm baths in all patients and no patient forced to remove the band.

Mild rectal bleeding had been reported in 46 patients (8.36 %) and it was occurred 7-14 days after the procedure. It was treated conservatively in all patients with no need for blood transfusion or hospitalization in any of these patients. Post banding bleeding occurred in 3 patients (7.89%) with 1st degree haemorrhoids, 33 patients (7.64%) with second degree haemorrhoids and in third degree

haemorrhoids only 10 patients (12.5%) complicated with mild bleeding after RBL with no statistical significance (P value = 0.35) Table 4.

Table 4. Post-banding complications.

Complication	Degree of Haemorrhoid			P value	Total
	1st (N = 38)	2nd (N = 432)	3rd (N = 80)		
Pain	3 7.89%	47 10.88%	9 11.25%	59 (10.73%)	0.8
Bleeding	3 7.89%	33 7.64%	10 12.5%	46 8.36%	0.35
Vaso-vagal symptoms	4 10.52%	34 7.87%	5 6.25%	43 7.81%	0.23
Infection	– –	1 0.23%	– –	1 0.18%	–
Fistula	– –	1 0.23%	– –	1 0.18%	–
Fissure	– –	4 0.93%	1 1.25%	5 0.92%	0.79
Total	10 26.31%	120 27.78%	25 31.25%	155	0.09

Post-banding vaso-vagal symptoms reported in 43 patients (7.81 %).There were no patients of urine retention that necessitate catheterization, faecal incontinence did not occur after rubber band ligation in this study also no patients complicated by anal stenosis Table 4.

Perianal abscess occurred in one case (0.18%) after RBL. It was drained but 2 months later the patient developed low anal fistula which was treated by fistulectomy. Five patients (0.92 %) complicated with anal fissure after rubber band ligation.

Two years after the end of treatment, 443 patients 80.56% came for follow up .Symptomatic recurrence was detected in 71 out of 443 patients (16.03%), with repeated treatment by RBL in 23 patients 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 5,6.

Table 5. Long term results and follow up of patients with RBL.

Results	Patients	Re-examined	Asymptomatic	Symptomatic	Surgery	RBL
Cured	450	410	372	38	30	8
Improvement	46	33		33	18	15
Failure	54	-	-	-	-	-
Total	550	443	372	71	48	23

Table 6. Patients With Recurrence.

No of patients (%)	
Symptoms	
Bleeding	68 (95.8 %)
Prolapse	30 (42.25 %)
Pruritis	16 (22.53%)
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

DISCUSSION

The need to treat haemorrhoids is based primarily on the severity of symptoms, but the type of treatment is based on the traditional classification of haemorrhoids, which may have little to do with symptom severity.[14] 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 haemorrhoids.[15,16] Although surgical haemorrhoidectomy 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.[7] Nowadays, rubber-band ligation is the most widely used procedure, and it offers the possibility to resolve haemorrhoidal disease without the need for hospitalization or anaesthesia, and with a lower incidence of complications when compared to conventional surgery.[14]

The success rates of the method range between 79 and 91.8%.[11,15,25] Wrobleski et al.[17] 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 haemorrhoids.[11] In our study, successful results were achieved in 496 patients (90.18%), 450 patients (81.82%) were cured or presented great improvement after the end of treatment and 2 years later, 372 patients were cured out of 443 patients who attended follow up. Johanson and Rimm[18] 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 haemorrhoidectomy.[19,20] Vassilios et al[11] reported that symptomatic recurrence was 11.9% (53/445) 2 years after RBL, with repeat RBL or surgery in (41/445) 9.2% patients. Bayer et al[21] 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 haemorrhoidectomy. In our study, symptomatic recurrence was detected in 16.03 % (71/443) after 2 years follow up, with repeated treatment by RBL in 23 patients while additional surgical treatment was required in 48 patients

A review of 39 studies incorporating 8060 patients undergoing rubber band ligation 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%.[22] Bat et al[15] 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 require hospitalization. Vassillios et al[11] reported that in 94 patients (18.8%), complications were occurred. In our series one hundred and fifty five complications from RBL encountered in 88 patients (16%) 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.[23] Furthermore, pain and anal discomfort were reported to be greater, ranging from 28% to 79%, when multiple bandings were performed per session.[24] Gupta[25] found that out of 44 patients underwent rubber band ligation; seven patients (15.9%) reported pain and Oueidat and Jurjus[26] noted that out of 148 patients underwent rubber band ligation; twenty patients (13.5%) reported pain. We found that, pain occurred in 59 patients (10.73%), in all patients the pain appeared immediately or few hours after the ligation and lasted less than 2-3 days. Patients with multiple haemorrhoidal banding in one session had greater discomfort and pain. These results are in accordance with those of Vassilios et al,[11] who reported that patients with multiple haemorrhoidal 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[27] and Gehmy and Weakley[28] reported the same results. On the contrary, Hardwick and Durdley[29] failed to show any relationship between the number of bands applied and the degree of pain. Moreover, Khubchandani[30] in a prospective randomized study compared the results of single, double and triple haemorrhoidal ligation, but did not notice any difference even if they were forced to remove the elastic band in many patients 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 haemorrhoidal nodule and local inflammation, bleeding in our series occurred in 46 patients (8.36%). It was mild and treated conservatively in all patients without hospitalization or blood transfusion. Band ligation is safe in patients with cirrhosis and portal hypertension as reported by Vassilios et al.[11] Bat et al[15] al and Bayer et al[21] reported that only 2.2% of his patients complicated by rectal bleeding.

Watson et al[31] in their study of 183 patients of band ligation found that 41patients (30%) of patients had vaso-vagal symptoms. Kumar et al[32] reported that 15.3% of their studied group (98 patients) had vaso-vagal symptoms. In our study Post-banding vaso-vagal symptoms occurred in 43 patients (7.81%).There were no patients of urine retention that necessitate catheterization, faecal incontinence or patients complicated by anal stenosis after band ligation. This also reported by Benzoni et al[33] and Watson et al.[31]

Our conclusion is that RBL for haemorrhoids is a safe, effective, and easy to use with acceptable results. RBL can be used to treat grade 1,2 and 3 haemorrhoids with similar effectiveness. It seems to be safe for patients with liver cirrhosis

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