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Rubber Band Ligation in the Treatment of Grade II and III Hemorrhoids: A Prospective Study

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Abstract

Introduction: Hemorrhoids (HD) is one of the most common anorectal disorders. Although multiple treatment options exist, each treatment option has its limitations. Rubber band ligation (RBL) is a non-operative outpatient treatment of internal Hemorrhoids (IHD). It does not require anesthesia and has less risk of complications.

Aim: to determine the efficacy of RBL in treating grade II and III HD.

Materials and methods: this is a prospective study of 90 patients with grade II and III HD. RBL was applied to all HD patients at the same session in an outpatient clinic. After 3 weeks symptomatic patients had a proctoscopy examination and a second RBL session was repeated if HD was present. After 6 weeks, all patients had proctoscopy. Asymptomatic patients with negative proctoscopy were declared cured. All patients who had symptoms and /or with positive proctoscopy were stated failure. Follow-up of cured cases continued until the end of the 12th week to detect the recurrence cases.

Results: the cure rate, failure rate, and recurrence rates were 83.33%, 13.34 %, and 3.33 % respectively. Pain and bleeding were the most common complications. Both were limited and resolved with conservative management.

Conclusion: RBL has low morbidity and fewer complications which can be managed conservatively. It has a low short-term recurrence rate. The success rate may increase by elongating the follow-up period with repeated sessions for non-responding or recurrent HD patients.

Keywords: Hemorrhoids, Rectal bleeding, Band ligation, Hemorrhoidectomy.

Introduction:

HD is one of the most common disorders in surgical practice. It is the symptomatic enlargement and/or distal displacement of the normal anal cushions [1]. Internal hemorrhoids (IHD) lie above the dentate line. It is innervated by visceral nerve fibers. It does not cause pain. This is why we can treat IHD by RBL with no need for anesthesia. [2,3]. IHD is classified into 4 grades based on the degree of prolapse (Goligher classification) (**table 1**). [4]



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In spite of the vast number of methods and techniques developed to treat HD, no one can be regarded as ideal [5]. Many office-based procedures are proven effective, but they all have a recurrence problem [6]. On the other hand, surgical procedures are more definitive treatments with lower recurrence rates. However, they are painful and harbor the risks and complications of surgery and anesthesia [7,8].

The American Society of Colon and Rectal Surgeons (ASCRS) Guidelines for the management of hemorrhoids (2018) strongly recommend office-based treatments for patients with grade I and II hemorrhoids, and some with grade III hemorrhoids [9].

Nonsurgical office-based treatments of HD include; infrared photocoagulation, sclerotherapy, cryotherapy, electrocoagulation, laser, and RBL. A lot of studies found that RBL is more effective and has a lower recurrence rate than the other available nonsurgical office-based treatments. [10] In studies comparing RBL with surgical intervention in treating IHD, studies found that RBL had the same results as excisional hemorrhoidectomy (EH) but without the adverse effects of EH. Some studies advised choosing RBL as the treatment of choice for grade II HD and reserving EH for grade III HD or recurrence after RBL. [11,12].

In compares with the Hemorrhoidal Artery Ligation procedure, Brown et al. found that multiple sessions of RBL have the same effectiveness and complications as that of the HLA while the pain is less with RBL in the early postoperative period [9]. The present study was done to determine the efficiency of RBL in grade II and III HD treatment.

Material and methods:

The study was performed in an outpatient clinic in Basra governorate in the south of Iraq, from August 2017 till August 2019. The total follow-up period of the study was 12 weeks.

The study included 90 patients with grade II and III symptomatic HD who underwent RBL. Distribution of age, sex, chief complaint, and count of HD in each patient are shown in **tables (2,3)**. A full history, clinical general and anal examination, and proctoscopy were carried out for every patient. Golligher's grading system was used to classify IHD. Patients having other associated anorectal pathology, complicated HD, and patients on anticoagulation were excluded. No bowel preparation was required. The patient was asked to go to the toilet to empty his rectum just before the procedure. After informed consent, RBL procedure was performed in the steps mentioned in **table (4)**.

The patients were given instructions to have Sitz bath, a high fiber diet, stool softeners, and oral analgesia on need. Patients follow up visits were scheduled 3, 6, 9, and 12 weeks of the procedure. During each visit, the patients were assessed for symptomatic relief, recurrence, and the presence of any complication. At the 3rd weeks visit, symptomatic patients had proctoscopy examination followed by a second RBL session if the proctoscopy was positive.



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At the end of the 6th week, all the patients were subjected to proctoscopy and according to the findings; they were divided into 2 groups:

1. The cured group: asymptomatic and with negative proctoscope exam.
2. The failure group: the presence of hemorrhoids with or without symptoms.

Cured group patients had follow-up visits at 9 and 12 weeks post-procedure. The reappearance of symptoms and /or the presence of hemorrhoids was declared recurrence.

Statistical analysis:

The statistical analysis was done using SPSS Statistics version 22 under Microsoft Windows XP. The data description was done in the form of the mean for quantitative data and frequency and proportion for qualitative data.

The data analysis was done to test the statistically significant difference between groups. A chi-square test was used, p p-value less than 0.05 was considered significant.

Results: (Table 5)

The study included 90 patients. According to the grade of HD: Sixty patients had grade II HD (group II), and 30 patients had grade III HD (group III). Regarding the numbers of HD in the patients: thirty-five patients had a single HD, and 55 patients had multiple HD.

At the end of 3rd weeks, seventy-three patients were cured, while 17 patients remained symptomatic and were found having HD by proctoscopy. These 17 patients underwent a second banding session.

At the end of the 6th week, 78 patients were asymptomatic with no HD by proctoscopy. All these patients were declared cured and followed up for 12 wks. In the last visit, three patients complained of recurrent bleeding and were found to have HD on proctoscopy. These 3 patients were declared recurrence. So; at the end of the 12th week, the success rate was 83.33 % (75 / 90), the failure rate was 13.34 % (12/ 90), and the recurrence rate was 3.33 % (3 / 90).

The success rate for group II was 85 % and for group III was 80 %. The success rate was 91.42 % for the single HD group and 78.18 % for the multiple HD group.

Complications: (Tables 6 , 7) Pain was experienced by 12 patients and was limited to the first 48 hrs. Mild bleeding occurred in 8 patients. Two patients had urine retention which was treated by temporary catheterization. All the complications were limited and resolved by conservative measures without surgical intervention or hospitalization.

Discussion:

Although a lot of new techniques are available, RBL is still one of the most effective and preferred method to treat II and III grade HD [8, 15].



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It was found that the success rate of the RBL is between 79 and 91.8 % [13]. In our study, the success rate was 81.11 %, which is consistent with other studies.

Lu et al. found no significant difference between also there was no significant statistical difference between them. the success rate of RBL in grade II and grade III HD [14]. In our study; the success rates were 85 % and 80 % for grade II and grade III HD respectively and Various studies reported rates of repeat RBL sessions from 6% to 20% [14,15]. In our study a second RBL was performed in 17 patients (18.89%) at the end of the 3rd week. Cure rate in our study was 76.67 % after a single RBL session and (86.67%) after two sessions; the success rate increased by 10% by the second session. V S Iyer et al. found that treating of recurrent HD by multiple RBL sessions resulted in increasing success rate from 70.5% to 80.2% [16]. The recurrence rate in our study was 3.33 %. However, 12 weeks is too short of a period to comment upon the overall recurrence rate.

Lu et al. reported a 41% pain incidence within 48hs of the session.[14] In our study, pain occurred in 13.33 % of patients and lasted not more than 48hs.

Hardwick and Durdey showed no relationship between the number of HD banded and the degree of pain [17]. On the contrary Vassilios et al. reported that patients with multiple HD banding in a single session had greater discomfort and pain compared with patients with single banding [13]. In our study we found no significant difference in pain, neither between single and multiple HD nor between grade II and grade III patients. These findings probably suggest that pain is a subjective finding and perhaps is more patient specific regardless of the procedure itself.

El Nakeeb et al. and Lu et al. reported 4% and 2% incidences of mild rectal bleeding in their studies respectively [14,18]. In our study there was self-limited bleeding in 8 cases (8.89 %). Two patients developed urine retention that resolved by temporary catheterization.

A lot of studies found that, compared to operative procedures, RBL is more economical even if it is done in multiple sessions [19, 20]. Through our study the economic aspects were not considered.

Limitation of the study

Our study has its own limitations:

1. The follow up time was 12 weeks; a longer time is better to predict more accurate recurrence rates.
2. Repeating RBL session to recurrent HD was done once in the 3rd week visit, if we repeated it in the next visits, that might increase the success rate.
3. The economic aspects through this study were not considered.



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Conclusion

From the results of our and other studies, the RBL settled as an effective, simple, and cheap method to treat Grade II and Grade III IHD. RBL can be done effectively as an outpatient procedure with no need for anesthesia or sedation and with less equipment. It has low morbidity and fewer conservatively manageable complications. Multiple HD can be treated in the same session with no significant increase in post procedure complications. The short-term recurrence rate after successful RBL is low. Elongating the follow up period with re-banding of the not responded or recurrent HD is a good option to increase the success rate. More researches are still required to better understand the role of RBL in the treatment of HD.

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Table 1: Goligher classification of IHD:

Grade I: the anal cushions bleed but does not prolapse.

Grade II: the anal cushions prolapse throws the anus on straining but reduce spontaneously.

Grade III: the anal cushions prolapse throw the anus on straining and require manual replacement into the anal canal.

Grade IV: the prolapse stays out at all times and is irreducible.



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Table 2: Demography and clinical presentation:

Variables	Number	Percentage
Number of patients	90	100%
Sex		
Male	53	58.9
Female	37	41.1
Age (years) Range 15 - 75 Mean 42.4		
Grade of hemorrhoids		
Grade II	60	66.67
Grade III	30	33.33
Number of hemorrhoids		
Single:	35	38.89
Multiple:	55	61.11
Chief Complain:		
Bleeding:	39	43.33
Prolapse:	9	10
Bleeding and Prolapse:	42	46.67

Table 3 – Distribution of patients according to grade and count of HDs:

	Grade II	Grade III	Total
Number of patients	60 (66.67 %)	30 (33.33 %)	90
Count of hemorrhoids			
Single	20	15	35 (38.89 %)
Multiple	40	15	55 (61.11 %)

Table 4 – Our practical steps in performing RBL in this study:



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1. The patient was kept in left lateral position.
2. The instruments required in the procedure were Mcgown 10 mm 30 deg Suction Hemorrhoid Ligator and a metallic proctoscope.
3. The proctoscope was introduced till 1-2 cm above the dentate line.
4. Gentle manipulation and outward pulling of the proctoscope was practiced till the HD mass was seen through the proctoscope.
5. In some cases we used a sponge forceps with a piece of gauze for swabbing if blood or fecal material was found in the field.
6. The Ligator was introduced in the proctoscope till its cup covered the doom of the HD mass.
7. Suction was applied till the HD mass became sucked completely in the Ligator cup.
8. Pulling the shooting trigger, the rubber band slipped to round the base of the HD mass.
9. It is important to note that if the patient feels pain on suction, the cup must be released and placed in a more proximal point before shooting.
10. All HD were ligated in the same session.
11. The patient was kept in the clinic for about one hour, to detect and manage any early complication like bleeding and pain

Table 5 – Success rates in each visit and second RBL session rates according to count of HD and grade of HD, and the P value to find if the difference in the success rates is statistically significant:

	Grade II	Grade III	Total
Success at end of 3rd wk.: Single = 30/ 35 (85.71%) Multiple = 43/ 55 (78.18%)	50/60 (83.33 %)	23/30 (76.67 %)	73/90 (81.11%)
Re-banding end of 3th wk.: Single =5/35(14.29%) Multiple= 12/55(21.81%)	10/60 (16.67%)	7/30 (23.33%)	17/90 (18.89%)
Success at end of 6th wk.: Single=32/35(91.42%) Multiple=46/55(83.63%)		25/30 (83.33%)	78/90(86.67%)



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	53/60 (88.33%)		
<p><i>For the difference between Group II and Group III : P Value = 0.5107 > 0.05 No significant difference</i></p> <p><i>For the difference between single and multiple HD : P Value = 0.2890 > 0.05 No significant difference</i></p>			
Success at end of 12th wk.: Single = 32/35(91.42%) Multiple = 43/55(78.18%)	51/60(85%)	24/30(80%)	75/90(83.33%)
<p><i>For the difference between Group II and Group III : P Value = 0.5485 > 0.05 No significant difference</i></p> <p><i>For the difference between single and multiple HD : P Value = 0.1002 > 0.05 No significant difference</i></p>			

Table 6 – Distribution of complications after RBL according to grades of hemorrhoids:

Complication	Grade II (n= 60)	Grade III(n= 30)	Total(n= 90)	P value
Pain	6 (10%)	6 (20 %)	12 (13.33 %)	P = 0.1883 > 0.05
Bleeding	4 (6.67%)	4 (13.33%)	8 (8.89 %)	P = 0.2948 > 0.05
Urine retention	0	2 (6.67 %)	2 (2.22 %)	

Table 7 – Distribution of complications after RBL according to number of hemorrhoids:

Complication	Single (n=35)	Multiple (n= 55)	Total (n = 90)	P value
Pain	3 (8.57 %)	9 (16.36 %)	12 (13.33 %)	P = 0.2890 > 0.05
Bleeding	2 (5.71 %)	6 (10.91 %)	8 (8.89 %)	P = 0.3985 > 0.05
Urine retention	0	2 (3.64 %)	2 (2.22 %)	