

Comparative Study of Staging Rubber Band Ligation (RBL) and Hemorrhoidectomy in Treatment of Forth Degree Hemorrhoids

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Background: Rubber band ligation is one of the most worldwide used treatments of hemorrhoids because of its effectiveness and low complication rate. Hemorrhoidectomy is the procedure of choice for treatment of grade four hemorrhoids which is a painful method for a relatively benign disease. There are a few studies available analyzing the effectiveness of RBL as an initial treatment for grade four symptomatic internal hemorrhoids.

Objective: This study aimed to analyze the efficacy of the staging rubber band ligation in treatment of grade four hemorrhoids and comparing to hemorrhoidectomy.

Patients and Methods: A prospective randomized clinical trial was performed on all patients diagnosed with grade four symptomatic internal hemorrhoids from August 2011 to March 2013. Sixty four patients with grade four hemorrhoids were divided into two groups and underwent hemorrhoidectomy (H group) and rubber band ligation (R group). These patients were compared for any complications and recurrence in a six month period.

Results: Pain existed in 100% of the H group and 67.7% of the R group in the first visit one week postoperation ($P < 0.05$). There was a statistically significant difference between the two groups regarding the days off work. Patients' satisfaction and recurrence were similar in both groups after a period of six months.

Conclusions: This study showed that staging rubber band ligation is effective for treating grade four hemorrhoids. Few complication and low recurrence rate were noted which enable us to recommend this modality as the procedure of choice for the management of selected patients with grade four symptomatic hemorrhoids.

Keywords: Rubber band ligation; Hemorrhoidectomy; Hemorrhoids

1. Background

Hemorrhoidal disease is considered one of the most frequent pathology of the anal region (1). It has been estimated that 5% of the general population is affected by the symptoms of hemorrhoids. Studies showed that symptomatic hemorrhoids are equally affecting men and women (2). Internal hemorrhoids are classified into four degrees depending on the extent of prolapse. Grade four hemorrhoids are those with irreducible prolapsed (3).

A variety of techniques have been developed to treat hemorrhoidal disease: medical treatment (increasing dietary fiber, avoiding straining at stool, etc.), minimally invasive methods (rubber band ligation, sclerotherapy, infrared photocoagulation), and surgical techniques include Milligan- Morgan, closed Ferguson and other surgical methods that have to be used in about 10% of cases

(4, 5). Rubber band ligation (RBL) is the most frequently used nonoperative technique because of its effectiveness and low complication rate as well as its short recovery time compared to the operative procedure (6-8).

Nowadays hemorrhoidectomy is reserved for patients with grade four hemorrhoids and for whom nonsurgical treatment was not effective or those with external hemorrhoid. Although surgery is more definitive in symptom control, it is a painful procedure for a relatively benign disease and has some adverse effect on anal canal physiology (9,10).

2. Objective

There are a few studies available analyzing the effectiveness of RBL as an initial treatment for grade four symptomatic internal hemorrhoids (6, 11, 12). This study was

Implication for health policy/practice/research/medical education:

This present study describes the results of the staging rubber band ligation in treatment of grade four hemorrhoids. This article would be helpful to surgeons who treat patients with grade four hemorrhoids.

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designed to evaluate the success of staging RBL in treatment of grade four hemorrhoids, analyzing its complication and finally comparing the result with conventional hemorrhoidectomy.

3. Patients and Methods

This is a prospective randomized clinical trial study of 70 patients diagnosed with symptomatic grade 4 internal hemorrhoids from August 2011 to March 2013 in Kerman University affiliated hospitals. The hospital's ethics committee approved the randomized, controlled trial protocol. Informed consent was obtained from each patient included in the study. Patients were divided into two groups those treated with hemorrhoidectomy (H group) and those treated with rubber band ligation (R group). Patients with coexisting anorectal pathology such as fissure, polyp, cancer and previous history of anorectal operation were excluded. Detailed clinical history was taken in all patients with particular attention to bleeding, constipation, prolapse, painful defecation, and pruritus, discharge per rectum, dietary habit, and family history. General physical exam was performed and each patient underwent digital rectal exam (DRE) and recto-sigmoidoscopy.

All the patients in H group were kept fasting eight hours prior to the operation. This group required general or spinal anesthesia. They underwent Milligan-Morgan hemorrhoidectomy and received intravenous analgesia during the 24 hours postoperatively, and then it was changed to oral analgesia.

In RBL group no anesthesia was used. Rubber band ligation was performed with a Mc Gown device. In each session two or three symptomatic piles were ligated above the dentate line. Patients treated with RBL only received oral analgesia on demand. The outcome and complication of the treatment were recorded after a series of banding-a sequence of treatment between which there was still symptoms and after which further treatment has not been required. High fiber diet and warm sitz bath were prescribed for both groups after the procedure.

In our observation we administered a verbal survey which considered aspects such as control of symptoms, any complications in the form of bleeding, pain, fever, discharge, swelling in site of operation and pain level according to the numerical rating pain scale, and days off works. Final assessment was performed six months post procedure regarding the effect of treatment on rectal bleeding, prolapse, pain and the degree of patient satisfaction.

4. Results

A total of 70 patients were entered the study. We excluded six patients from the study; five patients because they presented associated anal pathology and we lost one patient during the follow-up period. All the patients had

symptomatic disease (average 35.2 months) and received medical therapy such as high fiber diet, life style modification and etc. (mean duration 16.0 months). The most common symptoms were prolapse (100 %) and bleeding (62.5%), and the least one was pruritus (14.1%). Patients often presented with more than one symptom but the indications for treatment were primarily prolapse and bleeding (60.9% and 39.1% respectively). Of all 64 patients included in this study 31 were treated by rubber band ligation and 33 by Milligan-Morgan hemorrhoidectomy. Forty seven males (73.6%) and 17 (26.4%) females were included in this study (M/F ratio: 2.8/1). Patients' age ranged from 16 to 91 years with a median age of 49.1 years. (Table 1) To maintain as much homogeneity of the groups treated, only patients with grade four internal hemorrhoids were included. There was no significant difference between the two groups regarding presenting symptom, bowel habit and diet (62.6% of the patients had low fiber diet).

Table 1. Characteristics of Patients at Diagnosis

Variable	Number of Patient No. (%)		
	H* group	R* group	Total
Age, y	43.3 (16-77)	55.4 (25-91)	49.1 (16-91)
Sex			
Male	21 (63.6)	26 (83.9)	47 (73.6)
Female	12 (36.4)	5 (16.1)	17 (26.4)
M/F ratio	1.7/1	5.2/1	2.8/1
Diet			
Low fiber	24 (72.7)	18 (58.1)	42 (65.6)
High fiber	9 (27.3)	13 (41.9)	22 (34.4)
Constipation	20 (60.6)	14 (45.2)	34 (53.1)
Clinical presentation			
Prolapsed	33 (100)	31 (100)	64 (100)
Bleeding	24 (72.7)	16 (51.6)	40 (62.5)
Pain	14 (42.4)	7 (22.6)	21 (32.8)
Discharge	10 (30.3)	4 (12.9)	14 (21.8)
Pruritus	6 (18.2)	3 (9.7)	9 (14.1)
≥ Two Symptoms	29 (87.8)	19 (61.3)	48 (75)

* Abbreviations: H Group, Treated with hemorrhoidectomy; R Group, Treated with rubber band ligation

Hemorrhoidal bandings were performed safely in all patients in R group and they were discharged one hour post procedure. For 27 patients banding was performed in one session and remainders needed two sessions for completion of treatment with an interval of three weeks between sessions. All the patients in the H group were discharged within 24 hours after the operation. One patient in this group needed readmission because of post-operative bleeding which required reoperation and hemostasis. There were no admissions in the R group. The most common complication was pain followed by bleed-

ing, discharge per rectum and urinary retention. No significant difference was observed between the continence state of the two groups either before surgery or at the end of six months post procedure. There was only one case of gas incontinence recorded after hemorrhoidectomy. Two patients developed thrombosed external hemorrhoid after RBL and both of them treated medically. No case of infection was occurred.

The pain reported by patients underwent hemorrhoidec-

tomy was clearly greater than those in R group. We observed statistically significant differences regarding postoperative pain score reported by patients between the two groups in the first week after treatment ($P < 0.05$). By assessing requirements for analgesia during the first week postoperatively we observed statistically significant differences between the two groups (H group 100% vs. R group 64.5%) These findings were significant after one month (Table 2).

Table 2. Postoperative and Follow-up Details of Patients underwent Rubber Band Ligation (R group) or Hemorrhoidectomy (H group)

	One Week, No. (%)		P Value	One Month, No. (%)		P Value
	H group	R group		H group	R group	
Pain (Total)	33(100)	21(67.7)	0.001*	9(27.3)	3(9.7)	0.075
Non	0	10		24	28	
Mild	0	11		6	3	
Moderate	9	10		3	0	
Severe	24	0		0	0	
Analgesic consumption(total)	33	20	0.000*	6	0	0.001*
Prolapse	0	0		0	0	
Discharge	8	9		3	3	
Bleeding(total)	12 (36.4)	11 (35.5)	0.943	9 (27.5)	5 (16.1)	0.758
Non	21	20		24	26	
Mild	11	11		9	5	
Moderate	0	0		0	0	
Severe	1	0		0	0	
Urinary retention	11 (33.3)	0		0	0	
Change in continence	0	0		1	0	
Thrombosed external hemorrhoid	0	2		0	0	

* Statistically significant

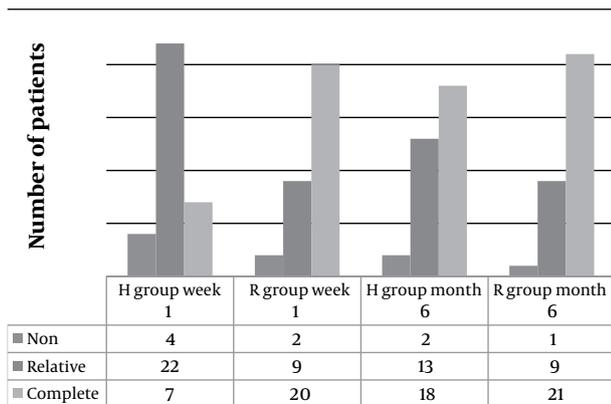


Figure 1. Comparison of Patient Satisfaction in R Group and H Group one Week and Six Months After the Procedure (Number of patients)

We observed statistically significant differences be-

tween the two groups regarding days off work; this was 17.8 days in the group treated with hemorrhoidectomy and 1.3 days in the case of rubber band ligation. Full remission of symptoms was observed in 41 patients (64.1%). Among these 70.9% were in the R group and 63.6% in the H group. Neither of the two groups reported any improvement in symptoms. Recurrence was 3.1% after six months of follow up which was similar in both groups.

Patient's satisfaction in R group was significantly better than H group after the first week post operatively ($P = 0.002$) but this difference was not observed at the end of follow up period ($P = 0.103$), (Figure 1.).

5. Discussion

There are different modalities to treat hemorrhoidal disease, but there is no perfect technique to treat this disease, although many studies have been performed to compare these techniques (9).

Surgical hemorrhoidectomy remains a very effective ap-

proach for patients with advanced hemorrhoids (grade three or four). However, it is associated with increased pain and the highest complication rate and causes significant changes in anorectal physiology when compared to other modalities (7, 10). Now it is the procedure of choice for patients who did not respond to office-based procedures or who unable to tolerate these procedures, grade three or four hemorrhoids, or patients with substantial external skin tags (5).

Rubber band ligation is also widely used because it is a safe and effective method, involves less postoperative pain, and causes a quick recovery (9, 11-13). Complications are mostly minor. However, there have been reports of severe sepsis following interventions for hemorrhoids (14). It is a safe method for treatment of symptomatic hemorrhoids in HIV positive patients and one with cirrhosis and portal hypertension (12, 15).

Because hemorrhoidal disease is a benign condition, we believe that we should try the least aggressive and safest procedure which enables quick recovery of the patient. For this reason, we decided to perform rubber band ligation on patients with grade four hemorrhoids.

Some studies analyzed the effect of rubber band ligation in treatment of grade four hemorrhoids. In two surveys performed by Iyer et al. and Longman et al. Rubber band ligation considered a safe and effective therapy for symptomatic internal hemorrhoids that can be used to treat all degrees of hemorrhoids with similar effectiveness (6, 11).

Our study contained all patients with grade four symptomatic internal hemorrhoids so it was not surprising that all of them complained of prolapse. Other most common symptoms among this group of patients were bleeding followed by pain, discharge and pruritus. This finding is similar to others {Longman, 2006, A prospective study of outcome from rubber band ligation of piles} (4, 6, 9).

The efficacy of both treatments has been proven in our study by observing that only in 3.1% of patients recurrence occurred at the end of the follow-up period and cure was obtained in 64.1% of patients upon completion of treatment in both groups without statistically significant differences between them. These results are comparable to 66% to 82% cure rate reported by others (9, 12, 16, 17)

The most significant difference found between these two groups was postoperative pain. During the first postoperative week the differences in pain reported were statistically significant between the two groups. Also we observed statistically significant differences in the analgesic consumption in a week postoperatively. No major complications occurred after rubber band ligation in this study. These findings are supported by other researches (4, 11, 16).

Also we found that patients treated with rubber band ligation could go back to work immediately compared to

those underwent hemorrhoidectomy which required a mean time of 17.8 days off works.

In this study we followed our patients in a 6 month period and during this time we found just 3.1% recurrence of symptoms. Bernal et al. reported a recurrence rate of 13.8% for 287 procedures (1) Longman et al. reported that at first short follow-up, 84% of their patients were symptom-free. Long term follow up performed by questionnaire found that 44% of responders remained asymptomatic at a median of 46 months from banding (11). This difference is due to different grade of hemorrhoids and duration of follow up period. However other studies showed that rubber band ligation is an effective method for recurrence of symptoms (6).

In our study four patients required two sessions of banding while other just received one session for completion of treatment. We had one case of recurrence in R group which belonged to those with one banding session. Iyer reported that the number of ligations performed in a treatment series seems to affect the success rate. Specifically, when more than four bands are placed, there is a 13.5% drop in success rate and 7.5% increased rate of subsequent hemorrhoidectomy. Although this is not statistically significant, it implies a trend, which is clinically relevant when deciding on further banding versus hemorrhoidectomy for subsequent treatment in a given patient (6).

Considering these results obtained together with the high degree of satisfaction revealed by patients we can conclude that rubber band ligation is effective for the treatment of grade four internal hemorrhoids and few complications and little postoperative pain enables us to recommend it as the procedure of choice for the management of this condition.

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Authors' Contribution

Main idea was proposed by Mahmoud Aghaei Afshar. Designing study and writing was performed by Mahmoud Aghaei Afshar and Maryam Kouhestani Parizi. Data collection was performed by Mahmoud Aghaei Afshar, Maryam Kouhestani Parizi. Hadi Hadavi, Mehrdad Vahedian, Bahram Poorseyedi, Hamid Zeynali nejad, Mohammad Reza Lashkari zadeh provided the conditions for referral of patients and helped in data collection.

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