

Hemoroidde lastik band ligasyonu sonuçlarını etkileyen faktörler

Factors affecting the success rate of rubber band ligation in haemorrhoid treatment

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ÖZ

GİRİŞ ve AMAÇ: Lastik band ligasyonu yaptığımız hastalarımızın bulgularını ve sonuçlarını istatistik olarak değerlendirmek, tedavinin sonucunu etkileyen faktörleri belirlemek ve hangi hastalarda bu yöntemin daha uygun olduğu konusunda kanaat oluşturmaktır.

YÖNTEM ve GEREÇLER: Hastanemiz genel cerrahi kliniğinde haziran 2015 ve haziran 2018 tarihleri arasında band ligasyonu yapılan ve takibe gelen hastalar dahil edildi. Hasta cinsiyeti, yaşı, BMI, şikâyet süresi, tedavi süresi, hemoroidin evresi, işlem tarihi, takip süresi, tekrar bandlama yapılması, muayane bulguları, komplikasyonlar, kabızlık skoru ve hasta memnuniyeti parametrelerine bakıldı.

BULGULAR: Çalışmaya 80 erkek (%75,5) ve 26 kadın (%24,5) olmak üzere toplam 106 hasta alınmıştır. Ortalama takip süresi $29,9 \pm 13,5$ ay, hastaların yaş ortalaması $44,2 \pm 12,5$ ve BMI ortalaması $29,2 \pm 4,7$ dir. Ortalama şikâyet süresi $8,9 \pm 7,6$ yıldır. Tedavi süresi ortalama $6,5 \pm 6,2$ aydır. Hastalardan 49 (%47,1) unda grade 2, 55 (%52,9) unda grade 3 hemoroid tespit edildi. Nüks olan hastalar incelendiğinde hemoroidin derecesi, kabızlık skoru ve anal tonus artışının nükste anlamlı derecede etkili olduğu bulundu. Ayrıca kabızlık skoru yüksek olan veya anal tonusu yüksek olan hastalarda memnuniyet oranları anlamlı derecede düşük bulundu.

TARTIŞMA ve SONUÇ: Band ligasyonu kolay uygulanabilir, başarılı ve güvenli bir yöntemdir. Ancak bütün hastalar için ilk seçenek olmayabilir. Bazı hasta gruplarında başarıyı etkileyen faktörlerin tespiti durumunda tedavide alternatif ofis prosedürü seçenekleri düşünülebilir.

Anahtar Kelimeler: komplikasyon, hemoroid, lastik band ligasyonu

ABSTRACT

INTRODUCTION: The aim of this study was to statistically evaluate the use of rubber band ligation (RBL) for the treatment of haemorrhoids, as well as to determine the factors affecting the success of this treatment and to provide recommendations for the most appropriate treatment methods based on those factors

METHODS: The study included patients who received a follow up after undergoing a band ligation procedure between June 2015 and June 2018 in the hospital's general surgery clinic. Patient's sex, age, BMI and satisfaction were assessed, along with duration of symptoms, duration of treatment, haemorrhoid grade, follow up period, rebanding rate, examination findings, complications, and constipation score.

RESULTS: A total of 106 patients, 80 males (75.5%) and 26 females (24.5%), were included in the study. The mean follow up period was 29.9 ± 13.5 months, the mean age of patients was 44.2 ± 12.5 years and the mean BMI was 29.2 ± 4.7 . The mean duration of symptoms was 8.9 ± 7.6 years and the mean duration of treatment was 6.5 ± 6.2 months. Forty-nine patients (47.1%) had grade 2 haemorrhoids and 55 patients (52.9%) had grade 3 haemorrhoids. Haemorrhoid grade, constipation score and increase in anal tonus were determined to be factors that significantly affected haemorrhoid relapse. Moreover, patient satisfaction was lower in patients with higher constipation score or increased anal tonus.

DISCUSSION AND CONCLUSION: Band ligation is a safe, effective treatment for haemorrhoids that can be applied easily to most patients, however, it may not be the first choice for all patients. Alternative procedures may be recommended for patients with higher constipation scores or increased anal tonus, as these factors may affect success for those patient groups.

Keywords: Complications, Haemorrhoids, Rubber band ligation,

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INTRODUCTION

A haemorrhoid is the clinical sign of a downward distortion of enlarged anal submucosal veins, which are known as anal cushions, and normal functioning structures (1). The incidence of haemorrhoids increases with age (2), and they affect both males and females (3). Haemorrhoids typically occur in patients with conditions that can lead to a chronic increase of intraabdominal pressure, such as pregnancy (4). Many different treatment modalities were introduced to address symptomatic haemorrhoids, including simple dietary interventions and regulation of intestinal habits, various non-operative procedures and different methods for excision of diseased anal piles (5). The presence of so many different treatment choices may imply that none are the perfect solution. Most patients with grade 1, 2 and 3 internal haemorrhoids that have not responded to medical treatment may be effectively treated with office procedures, such as rubber band ligation (RBL), sclerotherapy and infrared coagulation (6).

The RBL method for treating haemorrhoids was first described in 1958, by Blaisdell, who noted its ease of use in office conditions (7). In 1963, Barron simplified the procedure and the modified form he described is the method that is currently used (8). Ligation of haemorrhoid tissue results in ischemia of the prolapsed mucosa and its ensuing necrosis; this is followed by fixation of the scar to the rectal wall. This rapid method is well tolerated by patients because ligation is performed over the dentate line, which lacks somatic sensitivity (6). Band ligation is superior to and more efficient than sclerotherapy (9). It is a simple, reliable and effective treatment method that can lead to a significant improvement in quality of life (2).

The aim of this study was to statistically evaluate the use of RBL in the treatment of haemorrhoids, as well as to determine the factors affecting the success of this treatment and to provide recommendations for the most appropriate treatment methods based on those factors.

MATERIAL AND METHODS

This retrospective study was performed With the approval of the hospital ethics committee (Kartal Koşuyolu Yüksek İktisas Training and Research Hospital, n:70). We included patients (n=106) who had undergone an RBL procedure in the hospital's general surgery clinic between June 2015 and June 2018. The procedures were performed by a single surgeon who had previously performed more than 50 band ligations and was, thus, experienced in its use. Band ligation was done for patients who had symptoms for at least one year and who did not have any clinical improvement despite having one month of medical therapy. The procedure was not used in patients < 18 years old or in pregnant women. Patients with an additional diagnosis of anal fissures, perianal fistulas, or inflammatory bowel disease, were also excluded from the study.

All patients were given a digital and anosopic examination before the procedure. Depending on the clinical condition, a sigmoidoscopy or colonoscopy was also performed. Band ligation was performed without local or general anaesthesia and while patients were in the knee-elbow position. A 23 mm diameter flute-beaked anoscope, with a ligature attached to a suction device, was used for the procedure and the suction device was adjusted for a maximum 200-220 mm/Hg. Patients received an enema as preparation prior to the procedure. A rubber band was placed around the base of the haemorrhoid cushion pedicle, at least 1 cm proximal of the dentate line, via the vacuum suction ligature. The most piles treated during a single procedure was 3. After a follow-up in the recovery room, an hour after the procedure, patients were prescribed pain medication and laxatives and discharged from the hospital.

Control visits were scheduled for day 10, day 30 and month 6. For assessment of long-term relapse and other complications, an additional control visit was planned for 3 years post-procedure. Patients with rectal bleeding or patients with pathological haemorrhoid piles (as determined by anal or anosopic examination) were considered to have relapsed. For patients without haemorrhoid piles, but who continued to experience periodic symptoms

despite significant improvement of their clinical condition, the procedure was considered to be relatively unsuccessful. Anal tonus was considered normal if there was no resistance during digital examination or examination by a 23 mm anoscope and considered increased if resistance was encountered.

Patient's sex, age, BMI and satisfaction were assessed, along with duration of symptoms, duration of treatment, haemorrhoid grade, follow up period, rebanding rate, examination findings, complications, and constipation score. Patient satisfaction was rated on a scale from 1 to 4, where 1 is not satisfied at all, 2 is somewhat satisfied, 3 is satisfied, and 4 is very satisfied. The constipation score was assessed based on responses to questions suggested by Wexner et al., and included constipation duration and severity, bowel habits, stool consistency, intake of fibre, frequency and amounts of laxatives used, use of suppositories, digitation or enemas, duration and frequency of assistance, length of straining time per attempt, unsuccessful attempts at evacuation per 24 hours, and sensation of incomplete evacuation (minimum score 0 , maximum score 30) (10).

Statistical analysis of the results was performed using SPSS version 17.0. Normal distribution of the variables was assessed using histogram graphics and the Kolmogorov-Smirnov test. Mean, standard deviation, median and minimum-maximum values were used for descriptive analysis. Categorical variables were compared using Pearson Chi Square and Fisher's Exact Tests. The Mann Whitney U Test was used for binary comparison of variables with non-normal distributions (non-parametric) and the Kruskal Wallis test was used for triple comparison of these variables. The Spearman correlation test was used to compare measured data. Results with P-value <0.05 were considered statistically significant.

RESULTS

One hundred and six patients, 80 males (75.5%) and 26 females (24.5%), were included in this study. The mean follow up period was 29.9 ± 13.5 months, the mean patient age was 44.2 ± 12.5 years and the mean BMI was 29.2 ± 4.7 .

The mean duration of symptoms was 8.9 ± 7.6 years and the mean duration of treatment was 6.5 ± 6.2 months. The mean Wexner constipation score was 3.2 ± 2.0 . Forty-nine patients (47.1%) had grade 2 haemorrhoids and 55 patients (52.9%) had grade 3 haemorrhoids (Table 1).

	Mean	s.d.	Median	Minimum	Maximum
Age	44,2	±12,5	44,0	18,0	80,0
BMI	29,2	±4,7	28,9	19,3	38,9
Durations of symptoms (month)	8,9	±7,6	6,0	1,0	40,0
Durations of treatment (year)	6,5	±6,2	6,0	1,0	30,0
Constipation score	3,2	±2,0	2,0	0,0	9,0

The incidence of early complications included rebanding in 4 patients (3.8%), urge to defecate in 16 patients (15.5%), procedural pain in 41 patients (38.7%), and urinary retention in 11 patients (10.4%). No patients experienced post-operative headaches or infections. The incidence of late complications included relapse in 8 patients (7.7%) and 6 patients (5.8%) whose procedure was considered relatively unsuccessful (Table 2).

	n	%
Early complications	Postop headache	0 (0,0)
	Infection	0 (0,0)
	Rebanding	4 (3,8)
	Urge to stool	16 (15,5)
	Procedural pain	41 (38,7)
	Urinary retention	11 (10,4)
Late complications	Relapse	8 (7,7)
	Relatively unsuccessful	6 (5,8)

In the final control visit with the patients, anal tonus was considered increased for 9 patients (8.5%) and 9 patients (8.5%) experienced slight anal pain during defecation. Rectal bleeding was observed in 10 patients (9.4%), protrusion of piles in 9 patients (8.5%) and 8 patients (7.6%) reported itching. A survey of patient satisfaction revealed that 80 patients (75.5%) were very satisfied, 20 patients (18.9%) were satisfied, 4 patients (3.8%) were somewhat satisfied, and 2 patients (1.9%) were not satisfied at all. Eight patients (7.7%) experienced a

relapse and, for 6 patients, the procedure was considered relatively unsuccessful.

For patients with relapses, BMI, duration of symptoms and constipation score were compared. The constipation score of patients with relapse (5.0 ± 1.3) was higher than the score for patients without relapses (2.9 ± 1.9) ($p = 0.004$). There was no difference, however, between the two groups in terms of BMI or duration of symptoms (Table 3).

Table 3. BMI, duration of symptoms and constipation score according to relapse

	RELAPSE									p ¹
	No			Yes			Relatively unsuccessful			
	mean	s.d.	Median	mean	s.d.	Median	Ort	s.d.	Median	
BMI	29,5	±4,6	29,4	27,2	±3,1	28,5	30,0	±6,8	30,2	0,426
Duration of symptoms	9,2	±8,0	6,0	6,5	±5,5	5,0	10,8	±3,8	10,0	0,246
Constipation score	2,9	±1,9	2,0	5,0	±1,3	4,5	4,3	±2,6	4,0	0,004

¹Kruskal Wallis test

Grade of haemorrhoid and anal tonus were also compared for patients with relapses. All 8 patients with relapses had grade 3 haemorrhoids, while patients with grade 2 haemorrhoids experienced no relapses. Five of the patients whose procedures were deemed relatively unsuccessful had grade 3

haemorrhoids; only 1 had a grade 2 haemorrhoid. Relapses occurred more frequently in patients with grade 3 haemorrhoids as compared to grade 2 ($p < 0.001$). In patients with relapses, increase in anal tonus (50.0%) was significantly more frequent than in patients without relapses (5.6%) (Table 4).

Table 4. Grade and anal tonus rate according to relapse

		RELAPSE						RELAPSE
		No		Yes		Relatively unsuccessful		
		n	%	N	%	n	%	
Grade	2	46	(52,3)	0	(0,0)	1	(16,7)	0,006
	3	42	(47,7)	8	(100,0)	5	(83,3)	
Anal tonus	Normal	85	(94,4)	4	(50,0)	6	(100,0)	<0,001
	Elevated	5	(5,6)	4	(50,0)	0	(0,0)	

¹Chi-square Test

Patient satisfaction was also found to be higher for patients with normal anal tonus than for patients with increased anal tonus ($p < 0.001$) (Table 5).

Assessment of the correlation between constipation score and patient satisfaction revealed a moderate significant ($p:0.002$) moderate negative correlation ($r:0.304$). The results of the patient satisfaction assessment for patients without relapses were as follows: 14 patients (15.56%) were satisfied and 76 patients (84.44%) were very satisfied.

DISCUSSION

There are many alternatives for treating haemorrhoids, depending on the grade and symptoms of the disease and on the condition of the patient. The band ligation procedure can be used with similar levels of effectiveness in all haemorrhoid grades which did not respond to other medical treatment (11). However, symptomatic relapses may occur in some patients and rebanding may be needed (11).

Table 5. Patient satisfaction rate according to anal tonus

		Anal tonus				p ¹
		Normal		Elevated		
		n	%	n	%	
Patients satisfaction	Not satisfied at all	2	(2,1)	0	(0,0)	<0,001
	Somewhat satisfied	2	(2,1)	2	(22,2)	
	Satisfied	13	(13,4)	7	(77,8)	
	Very satisfied	80	(82,5)	0	(0,0)	

Band ligation was evaluated in many studies, both alone and in comparison with other methods (12, 13). The success rates in these studies varied, which may have been due to differences in the number of band ligations performed in a single procedure, criteria for relapse, and duration of follow up. After 5 years, most studies reported an average remission rate of 70% (14). Vassilios et al. reported a symptomatic relapse rate of 11.9% after two years, and 9.2% of the cases required rebanding or surgery (15). Some studies reported a success rate of up to 92% (16). In our study, when procedures deemed relatively unsuccessful were also considered as a relapse, the success rate averaged 86.5% after 30 months of follow up. In the study by Lu et al., there was no significant difference in the success rate of patients with grade 2 and grade 3 haemorrhoids (17). In the study by Nikam et al., the success rate was significantly higher in patients with grade 2 haemorrhoids, compared to patients with grade 3 haemorrhoids, which was similar to our study findings (18).

Various studies reported a repeat rate for RBL between 4-20%. Bayer et al. found that 18% of patients required one or more additional RBL procedures; 2.1% could not be treated by RBL and were directed to undergo a conventional haemorrhoidectomy (19). In our study, only one procedure used multiple banding. Only 3.8% of the patients needed rebanding and this was usually due to the band falling off early. In the study by Nikam et al., it was reported that subsequent rebanding did not increase the procedure's success rate (18).

A large meta-analysis of RBL procedures has shown that the incidence of severe pain was 5.8%, bleeding 1.7%, development of fistula or fissure 0.3%, infection 0.05%, incontinence 0.9%, and stenosis 0.06% (20). Lu et al. observed mild or moderate pain in 41% of patients and, in only 1% of

the cases, conventional haemorrhoidectomy was required one week after RBL because of severe pain (17). Bat et al. reported a complication rate of 4.2% and 2.5% had complications severe enough to require hospitalization (21). In our study, the rate of mild or moderate procedural pain was 38.7%. Vasovagal symptoms occurred in 15.5% of the patients and transient urinary retention occurred in 10.4%. All patients were treated with oral analgesics and sitz baths. There were no infections or incidence of anal stenosis in our patients and none were hospitalized due to complications.

RBL is an easy and reliable method for treating grade 2 and 3 haemorrhoids, however, it may not be an optimal choice for grade 1 haemorrhoids. Absence of sufficient mucosal protrusion for banding may decrease the success rate of the procedure in grade 1 haemorrhoids. In their study, Bhimani et al. reported that sclerotherapy was the treatment of choice for symptomatic grade 1 haemorrhoids or early grade 2 haemorrhoids (22).

In our study, the constipation score was found to be significantly higher in patients with relapses. Moreover, patient satisfaction scores were significantly lower as the constipation score increased. To decrease the likelihood of relapse and increase the satisfaction of patients undergoing the band ligation procedure, we suggest providing them with adequate information about constipation and bathroom behaviours.

In our study, increase in anal tonus was significantly higher in patients with relapses compared to patients without relapses. Moreover, the patient satisfaction score was significantly lower in patients with higher anal tonus. In a retrospective study by Nakeep et al., manometry results did not reveal any significant difference when performed before or after the RBL procedure (16). Patients with

higher anal tonus during the initial examination, therefore, should seek alternative treatment options.

A significant correlation was found between constipation score and anal tonus, and the success of the band ligation procedure and patient satisfaction. . Limitation of our study is its design being retrospective. We think that conducting larger prospective studies, using anal manometry to measure anal tonus and measuring constipation scores before the procedure and during the follow up, may be of use.

In conclusion, the band ligation procedure is a safe and easily applied method for successfully treating patients with haemorrhoids, however, it may not be the first choice for all patients. Alternative treatment options should be considered in cases where factors affecting success have been identified, such as higher anal tonus, higher constipation scores and lower constipation scores.

Informed consent was obtained from all patients for being included in the study.

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