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A prospective study of efficacy and safety of rubber band ligation in the treatment of Grade II and III hemorrhoids – a western Indian experience



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ABSTRACT

Background: Hemorrhoids are one of the most frequent diseases of the anal region with high prevalence involving all age groups. Multiple treatment options exist with none being perfect. Rubber band ligation of hemorrhoids is a non-operative treatment which can be performed on outpatient basis.

Objective: The study was undertaken to determine efficacy of banding in treatment of Grade II and III hemorrhoids and to follow-up patients treated by banding to evaluate for symptomatic relief, recurrence and complications.

Study design: A prospective, interventional study with clearance from the institutional ethics committee was undertaken over the period of 2 years in a tertiary referral center with a sample size of 60.

Result: Out of 60 patients, 41 patients (68.30%) had Grade II and 19 patients (31.7%) had Grade III hemorrhoids. At first follow up, success rate for Grade II hemorrhoids was 85% (35/41) as compared to 21% (4/19) in Grade III. The unsuccessful 20 patients were re-banded, however only 2 of them responded to procedure. At the end of 6 weeks, 36 patients with Grade II hemorrhoids (88%) were cured. Failure rate was higher for Grade III hemorrhoids (68.42%, n = 13). Success rate was 86.6% for single hemorrhoid. There were no major complications. Anemia reverted significantly with successful band ligation.

Conclusion: Rubber band ligation is a simple, safe and effective method for treating symptomatic second and third degree hemorrhoids as an outpatient procedure. It gives better results for Grade II and single hemorrhoids. Recurrence rate after successful band ligation is low.

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Estudo prospectivo da eficácia e segurança da ligadura elástica no tratamento de hemorroidas de Grau II e III – uma experiência na Índia ocidental

R E S U M O

Palavras-chave:

Hemorroidas
Sangramento retal
Ligadura elástica
Hemorroidectomia

Background: As hemorroidas são uma das doenças mais frequentes da região anal, com alta prevalência envolvendo todas as faixas etárias. Existem várias opções de tratamento, sendo que nenhuma é perfeita. A ligadura elástica de hemorroidas é um tratamento conservador que pode ser realizado em ambulatório.

Objetivo: O estudo foi realizado para determinar a eficácia da ligadura no tratamento de hemorroidas de Grau II e III e para acompanhamento dos pacientes tratados por ligaduras para avaliar o alívio sintomático, a recorrência e as complicações.

Design do estudo: Estudo prospectivo e intervencionista com liberação do comitê de ética institucional foi realizado durante o período de 2 anos em um centro de referência terciário com um tamanho de amostra de 60.

Resultado: Dos 60 pacientes, 41 (68,30%) apresentaram hemorroidas de Grau II e 19 (31,7%) de Grau III. No primeiro seguimento, a taxa de sucesso para hemorroidas de grau II foi de 85% (35/41), em comparação com 21% (4/19) no Grau III. Os 20 pacientes sem sucesso foram novamente submetidos a ligadura, mas apenas 2 deles responderam ao procedimento. Ao final de 6 semanas, 36 pacientes com hemorroidas de Grau II (88%) foram curados. A taxa de falha foi maior para as hemorroidas de grau III (68,42%, n = 13). A taxa de sucesso foi de 86,6% para hemorroida única. Não houve grandes complicações. A anemia reverteu significativamente com ligadura elástica bem-sucedida.

Conclusão: A ligadura elástica é um método simples, seguro e eficaz para o tratamento de hemorroidas sintomáticas de segundo e terceiro graus, como procedimento ambulatorial. Ela promove melhores resultados para hemorroidas de Grau II e únicas. A taxa de recorrência após ligadura elástica bem-sucedida é baixa.

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Introduction

Hemorrhoids occur due to downward displacement of the normal anal cushions. Hemorrhoids are very commonly encountered in clinical practice and involve any age. Both sexes are affected equally.^{1,2} 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 number of treatment options means that there is no gold standard.³ Although, surgical hemorrhoidectomy is more definitive in symptom control, it is a relatively painful procedure.² First, second and third degree hemorrhoids can be treated by non-surgical methods. Nonsurgical methods aim at tissue fixation (sclerotherapy, cryotherapy, photocoagulation, laser), or fixation with tissue excision (Rubber Band Ligation – RBL). RBL is a modality which can resolve hemorrhoidal disease on outpatient basis without the need for anesthesia, with lower incidence of complications.^{3,4} We conducted a prospective study to determine efficacy and safety of RBL in Grade II and III hemorrhoids at a tertiary referral center.

Material and methods

A prospective and interventional study was conducted on 60 patients of Grade II and III symptomatic hemorrhoids presenting to the outpatient department of department of Surgery in a tertiary referral center over a period of 2 years. Only the new cases presenting to the outpatient department were included. Patients having Grade I and IV hemorrhoids, recurrent hemorrhoids, external hemorrhoids, thrombosed and infected hemorrhoids were excluded. Modified Goligher grading system was used to classify the hemorrhoidal disease.⁵

After informed consent, a detailed history and examination was carried out for every patient. Patients fulfilling the inclusion criteria were subjected to RBL with all proper precautions on outpatient basis. Standard technique for RBL was used with patient in lithotomy position. All hemorrhoids were banded at the same session. RBL was supplemented with the blood transfusion/oral hematinic (as required), warm Sitz bath, high fiber diet, plenty of oral fluids, stool softeners. Patients were then followed up to assess symptomatic relief and look for any complication. Patients not willing to follow up were withdrawn from the study.

At the 1st follow-up scheduled 3 weeks post procedure, symptomatic patients were subjected to proctoscopy with repeat band ligation of hemorrhoids. Both symptomatic and asymptomatic groups were advised to continue warm sitz bath and stool softeners.

At 6 weeks post procedure all patients were subjected to proctoscopy and based on the findings, they were divided into 3 groups:

Asymptomatic and no evidence of hemorrhoids. This group was declared as cured.

Asymptomatic but hemorrhoids present.

Symptomatic and hemorrhoids present.

Patients in the second and third group were considered failure of treatment.

The patients in first group were followed up 9 weeks post procedure to determine recurrence of hemorrhoids.

Hemoglobin of each patient was measured at the primary visit and at the first and second follow up visits thereafter.

Symptomatic relief with eradication of hemorrhoids was considered endpoint for cure. Persistence of hemorrhoids despite presence or absence of symptoms was failure and reappearance of hemorrhoids after being cured was recurrence.

Statistical analysis

The statistical analysis of the data was done by using SPSS (Statistical Package for Social Science) version 10 under Microsoft windows XP. The description of the 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's *t* test was used and for qualitative data Chi-square test was used; $p < 0.05$ was considered significant.

Results

In our study 60 patients with symptomatic Grade II and III hemorrhoidal disease were included.

Out of these 60 patients, 41 patients (68.30%) had Grade II and 19 patients (31.7%) had Grade III hemorrhoids. 15 patients (25%) had a single hemorrhoid mass on proctoscopy. 45 patients (75%) had 2 or more hemorrhoidal masses.

All 60 patients were subjected to rubber band ligation.

At first follow up, 40 of 60 patients (66.66%) were asymptomatic. Of these, 36 had Grade II hemorrhoids whereas 4 had Grade III hemorrhoids. Thus success rate for first follow-up for Grade II hemorrhoids was 88% compared to 21% for Grade III hemorrhoids. The difference was statistically significant. Twenty patients remained symptomatic and had persistent bleeding per rectum during defecation. Fifteen of these were Grade III (33.34%, 15–19) and 5 were Grade II. All the 15 patients having grade III hemorrhoids also had multiple hemorrhoidal masses at the primary visit.

Of the 20 patients with persistent symptoms, 7 patients noticed extrusion of the rubber band applied at the primary

sitting of band ligation. Band extrusion was noticed at 2–10 days post procedure. None had significant symptoms that required urgent follow up or hospitalization. Re-banding was done in all the patients with persistent symptomatic hemorrhoids at the first follow up visit.

At the second follow up visit at 6 weeks, 42 patients (70%) were asymptomatic for bleeding per rectum with no evidence of hemorrhoids. These included all the asymptomatic patients at first follow-up, i.e. the patients who became asymptomatic after the banding at the primary sitting, remained so, even after an interval of 6 weeks, with complete resolution of hemorrhoids. To this 2 more patients were added after they underwent re-banding procedures at the first follow up visit.

Eighteen out of 20 patients who underwent re-banding at the first follow up visit, had persistence of hemorrhoids on proctoscopy at the second follow up. Of these 18 patients, 12 patients (66.7%) had persistent symptoms of bleeding per rectum, and 6 patients (33.3%) were symptom free. All these were considered failure of treatment.

The distribution of patients on grade, number of hemorrhoids, rebanding rate and cure rate is given in Table 1.

All 42 patients who were asymptomatic at 6 weeks were followed up at 9 weeks in order to determine the rate of recurrence. Only 1 of 42 patients in this group reported to have bleeding per rectum after a disease free interval of almost 6 weeks and was found to have hemorrhoids on proctoscopy. This patient had undergone a re-banding at the first follow up visit for persistent symptoms at the time.

Hence, after an interval of 9 weeks, 41 patients (68.33%) were declared cured, 19 patients (31.67%) were considered failure of treatment and there was recurrence in 1 patient.

Improvement in anemia (increase in hemoglobin concentration)

In the 42 patients with no evidence of hemorrhoids after 6 weeks, mean hemoglobin concentration at 6 weeks was 9.8 g/dL compared to 7.3 g/dL at the primary visit. This 2.2 g/dL increase in mean hemoglobin concentration was found to be statistically significant ($p < 0.05$).

Complications

Complications after rubber band ligation were encountered in 22 of 60 patients (36.66%). Pain was experienced by 12 patients (20%). Eleven of these underwent band ligation of multiple hemorrhoids in one setting, while one patient had single hemorrhoidal mass ($n = 1$, 6.6%). There was significant difference in pain between single or multiple bandings. Mild bleeding per rectum post rubber band ligation was observed by 10 patients; bleeding was of a mild degree and conservative treatment was successful in all cases, without the need for blood transfusion or hospitalization. Four patients (6.7%) had urinary retention which was treated in all cases by temporary catheterization. Band slippage was seen to occur in 7 patients (11.70%) post rubber band ligation. The patients reported extrusion of rubber band at a variable interval of 2–10 days post procedure. All these patients had a failure of treatment at the first follow-up visit, and underwent a re-banding procedure in this visit.

Table 1 – Distribution of patients according to grade, number, re-banding rate and cure rate.

	Grade II	Grade III	Significance
Number of patients	41 (68.3%)	19 (31.7%)	
Number of hemorrhoids			
Single	13	2	
Multiple	28	17	
Re-banding at 1st			
Follow-up	5 (12.2%)	15 (78.94%)	$\chi^2 = 22.69$ DF = 1 p-value < 0.05 (Significant)
Cured at 3rd			
Follow-up	36 (85.3%)	6 (31.57%)	$\chi^2 = 22.01$ DF = 1 p-value < 0.05 (Significant)

Discussion

There is no single best treatment for hemorrhoids and various options are available depending upon symptoms and grading. Any treatment has to be safe especially while treating non-life threatening conditions such as hemorrhoids. Rubber-band ligation has been studied in many clinical studies alone or in comparison to other procedures.^{6,7} The average success rates of the method are around 75%; however rates as high as 92% are reported in some studies.^{2,8} In our study, the overall success rate was 68.33% (41/60).

In a retrospective analysis of short and long term efficacy of RBL for hemorrhoids, Lu et al.⁴ observed that at the end of two months 92% of II-degree patients and 76% of III-degree patients showed no residual symptoms and the difference in success rate was not significantly different ($p = 0.32$) for both grades. Contrary to this, in our study there was a statistically significant difference in success rates of RBL in II and III degree hemorrhoids.

Varying rates of repeat RBL from 6%⁴ to 20%⁹ have been reported by various studies. Bayer et al.¹⁰ 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 re-banding was performed in 33.37% ($n = 20$) patients at the end of first follow up out of which most belonged to grade III hemorrhoids ($n = 15$). Of these 20 patients only 2 showed resolution at 2nd followup. Thus overall cure rate was 66.66% after first session of RBL and 68.33% after re-banding. There was not much addition to the success rate after first session.

Most of the studies report a 70% cure rate at the end of 5 years.^{8,11} Vassilios et al.¹² reported that symptomatic recurrence was 11.9% two years after RBL, with 9.2% requiring repeat RBL or surgery. In our study, we have found one symptomatic recurrence within 9 weeks post procedure. However it is too small a period to comment upon overall recurrence rate.

A review of 39 studies incorporating 8060 patients undergoing RBL revealed post banding complications in the form of severe pain in 5.8%, hemorrhage in 1.7%, infection in 0.05%.¹³ Lu et al.⁴ observed a 41% incidence of mild to moderate pain 24 or 48 h after the initial treatment, which could be alleviated through warm sitz baths and oral analgesia. For four patients (1%), conventional haemorrhoidectomy was required to perform one week after RBL owing to considerable pain. Bat et al.¹⁴ have reported a 2.5% incidence of severe complications requiring hospitalization among the overall 4.2% complication rate. In our series 33 complications from RBL encountered in 22 patients (36.66%) were minor and no hospitalization was

needed. Pain occurred in 12 patients (20%). In all cases the pain appeared immediately or few hours after the ligation and lasted less than 2–3 days. Of these 12 patients, 11 had multiple bandings and 1 had single hemorrhoidal ligation. These results are in accordance with those of Vassillios et al.,¹² 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%). On the contrary, Hardwick and Durdey¹⁵ failed to show any relationship between the number of bands applied and the degree of pain. In fact multiple ligations at one sitting has been found by some to be better in control of bleeding.¹⁶

Bleeding occurs after RBL as result of the falling off of the hemorrhoid and local inflammation. In our series bleeding occurred in 10 cases (16.7%). It was mild and treated conservatively in all cases without hospitalization or blood transfusion. El Nakeeb et al.⁸ and Lu et al.⁴ have reported 4% and 2% incidence of self-limiting rectal bleeding in their studies. Four patients required temporary urinary catheterization in our study.

Compared to any other operative procedure RBL is more economical and saves large number of hospitalization days and operating room time.^{9,17} We have not studied the economic aspects of the same.

Conclusion

Rubber band ligation is a simple and can be done with less equipment and expertise, safe can be done safely in high-risk ICU group of patients and also who are high risk group to tolerate anesthesia, it can be effectively done in outpatient basis.

It is more effective for Grade II than for Grade III hemorrhoids. Banding is a procedure with low morbidity; and complications, which are few, can be managed with conservative measures. Immediate recurrence rate after successful RBL is low. Success rate for banding procedure is most evident after the first session. There was no additional improvement in the success rate after repeated banding procedures at further follow up visits. The patients in whom one session of banding is unsuccessful, alternative treatment options should be offered. There is a significant improvement in levels of hemoglobin after RBL.

Conflicts of interest

The authors declare no conflicts of interest.

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