RESEARCH ARTICLE

A COMPARATIVE STUDY OF RUBBER BAND LIGATION AND FLAVONOIDS (DAFLON) IN THE TREATMENT OF HAEMORRHOIDS

Sudhir Navadiya, Harish Chauhan, Yagnesh Vaghani
Surat Municipal Institute of Medical Education & Research, Surat, Gujarat, India

Correspondence to: Sudhir Navadiya (drsudhir13@yahoo.com)

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ABSTRACT

Background: Haemorrhoids is a common disease affecting people of all ages and both sexes. Though there is no confusion on the treatment of 3rd and 4th degree haemorrhoids, there is still confusion regarding the ideal treatment for 1st and 2nd degree haemorrhoids.
Aims & Objective: To compare the safety, efficacy, advantages and disadvantages of Rubber Band Ligation and Micronized Flavonoids in the treatment of internal haemorrhoids.
Material and Methods: Two hundred patients of haemorrhoids were treated, One hundred cases with Rubber Band Ligation and rest hundred with Daflon 500 mg. The outcome measured in term of relief from bleeding and duration of treatment.
Results: 82% of patients on Daflon and 60% of patients undergoing Rubber Band Ligation were completely cured ($P<0.01$) on the 7th day but on follow up there is no statistical significance.
Conclusion: Daflon gives rapid relief from symptoms of haemorrhoids as compared to Rubber Band Ligation but the long duration and higher cost of treatment patient acceptability and compliance is less.

KEY-WORDS: Haemorrhoids; Rubber Band Ligation; Flavonoids; Piles

Introduction

Haemorrhoids are not varicose veins, and not everyone has haemorrhoids. But everybody has anal cushions. The anal cushions are composed of blood vessels, smooth muscle and elastic connective tissue in the sub mucosa. They are located in the upper anal canal, from the dentate line to the anorectal ring. Three cushions lie in the following constant sites: left lateral, right anterolateral, and right postero-lateral.[1] They have been defined as a mass of dilated tortuous veins in the anorectum involving the venous plexus of the area.[2]

Haemorrhoids are classified in degrees as following[3]:
1st Degree: Bleeding, with haemorrhoids that prolapse into but not out of the anal canal.
2nd Degree: Bleeding and seepage, with haemorrhoids that prolapse on defecation but reduce spontaneously.
3rd Degree: Bleeding with seepage, with haemorrhoids that require digital reduction.
4th Degree: Haemorrhoids that cannot be reduced into the anal canal, or are strangulated.

The treatment of 1st and 2nd degree haemorrhoids is more controversial. Sclerosant injection therapy, Lord's procedure, Rubber Band Ligation, Infrared coagulation, bipolar electro coagulation, Cryosurgery all are some of the treatment modalities used for 1st and 2nd degree haemorrhoids.[4]

Daflon, which is 90% Diosmin and 10% Hesperidin (Daflon 500), was introduced in France by Bensaude[5] for the treatment of haemorrhoids and other capillovenous diseases.

Daflon acts at the following levels: (1) It increases the duration of the contraction of veins.[6] (2) It decreases the synthesis of prostaglandin like PGE2 and thromboxane B2 which are responsible for the inflammatory process.[7] (3) It increases the local lymphatic drainage.[6]

According to Bayer[4] Rubber Band Ligation is a safe, cheap and convenient method and can save hundreds of hospitalization days. The various disadvantages include: (1) Operator's skill; (2) Severe pain if the bands in low placed band.[8] (3)

Can cause difficult micturition. (4) Fever and life-threatening soft tissue infections, rarely.[9]

This study was done to compare the commonly used treatment for 1st and 2nd degree haemorrhoids i.e. Rubber Band Ligation with Daflon.

Materials and Methods

The study was prospective and was conducted on 200 patients presenting in the outpatient department of SMIMER Hospital during year 2010-2011. The patients selected were of both sexes and above 18 years of age and had presented with the chief complaint of bleeding per rectum because of 1st and 2nd degree haemorrhoids and with associated pain, tenesmus, discomfort, pruritis or anal discharge. The status of the internal haemorrhoids was confirmed by proctoscopy.

Exclusion criteria were, (1) Patient having any anorectal diseases; (2) Inflammatory bowel disease; (3) Pregnancy; (4) Any previous history of surgery for haemorrhoids.

Written informed consent from patient and approval from institutional ethical committee was taken. After the preliminary assessment of patients i.e. detailed history of the disease and general and systemic examination, the patients were subjected to a few baseline investigations (CBC, coagulation profile, and complete urine examination). The patients were randomly subjected to Daflon or Rubber Band Ligation depending on their choice, after discussing the advantages and disadvantages of both methods with them.

100 patients each were either given Daflon 500 mg or underwent Rubber Band Ligation. Daflon 500 mg was given in the dose of 1 tablet thrice a day. At 1 week the symptoms and any relief was recorded. Consequent follow-ups were done on the 3rd week, 6th week and 12th week. In patients undergoing rubber band ligation, no prior preparation was required and the procedure was done in the outpatient department. Only one pile was banded at a time and in patients with multiple piles, every other pile was banded after a week's interval. Follow-up was done on the 3rd week, 6th week and 12th week. No other preparation like stool softener was given. The patients were followed up in term of cured, improved, and no relief.

Data analyzed statistically by IBM SPPS version 16.0. The primary outcome measure was the number of patients with no bleeding on the 7th day, while the secondary outcome measure was the average days taken for complete cessation of bleeding in both groups. Categorical data was compared by the standard error of difference in proportions and the changes were compared by the t-test. Significance was defined by $P<0.05$. Apart from primary outcome measure and secondary outcome measure, statistical comparison between relief obtained from associated complaints was also made and conclusions drawn.

Results

In present study, 67.5% were males and 32.5% were females (Table 1). 63% of the patients had mild bleeding in the form of drops of bright red blood during the act of defecation, while 32.5% patients had moderate bleeding i.e. in the form of streak of bleeding during defecation and 4.5% of patients had severe bleeding i.e. in the form of stream or pool of blood during defecation. A record of associated symptoms i.e. anal pain, constipation, diarrhea, pruritis ani and mucous discharge per rectum was kept. On proctoscopy, 1st degree haemorrhoids were found in 21% of patients (18 patients in the Rubber Band Ligation group and 23 in the Daflon), and 79% of patients had 2nd degree haemorrhoids. In the Daflon group 82% of patients (n=100) gave history of complete cessation of bleeding on the 1st week of treatment while only 60% of the patients in the Rubber Band Ligation group were cured of the symptoms, 1st week after the last haemorrhoids had been ligated. This difference was statistically significant ($P<0.01$) but this significance was not maintained in the later days of the follow-up (Table-2). A record of relief obtained from other symptoms was also kept. The relief obtained was statistically significant on the 1st week, but this significance was lost in the subsequent days of follow-up.

In the Rubber Band Ligation group, five patients relapsed by the end of the study while in the Daflon group three patient had relapse of symptoms.

Table-1: Characteristics of the Two Groups

Characteristics		Rubber Band Ligation (n=100)	Daflon 500 (n=100)
Sex	Males	65	70
	Females	35	30
Duration of Bleeding (Days)		2.5 ± 1.5	2.4 ± 1.2
Severity of Bleeding	Mild	66	60
	Moderate	29	36
	Severe	5	4
Associated Symptoms	Anal pain	18	16
	Constipation	34	37
	Diarrhoea	1	3
	Pruritus ani	22	18
	Mucous discharge	20	18
Haemorrhoids on Proctoscopy	1st degree	18	23
	2nd degree	82	77

Table-2: Statistical Analysis of Relief of Bleeding in Both Groups according to the Day of Follow-Up

Week of Follow-up	RBL Group	Daflon Group	P Value
1st week	60	82	<0.001
3rd week	74	84	N.S.
6th week	79	86	N.S.
12th week	84	90	N.S.

P value <0.05 is significant; RBL – Rubber band ligation; N.S. – not significant

Discussion

The wall of the anorectum contains the terminal branches of the superior haemorrhoidal artery in the internal haemorrhoidal plexus and the enlargement of these results in internal haemorrhoids. The three principal haemorrhoids are found at the 3, 7 and 11 o'clock position.[10]

There is no confusion regarding the treatment for 3rd and 4th degree haemorrhoids and it is haemorrhoidectomy. The best treatment for 1st and 2nd degree haemorrhoids though is still an enigma. The various modalities of treatment include Sclerosant injection therapy, Lord's procedure of anal dilatation, cryotherapy, infrared coagulation, laser therapy, direct electro-cautery, bipolar coagulation and Rubber Band Ligation. Rubber Band Ligation is the safest, cheapest and the most convenient treatment. Daflon focuses on the inflammatory pathology of haemorrhoids by increasing the duration of the contraction of veins and local lymphatic drainage[11] and by decreasing the synthesis of prostaglandins like PGE2 and thromboxane B2. The anti-inflammatory effects of Daflon are reflected in the reduction of capillary hyper permeability[12] and fragility in controlled clinical studies.

In our study internal haemorrhoids have male to female ratio as 2.1:1. The average duration of bleeding at presentation was 2.5 days ± 1.5 in the Rubber Band Ligation group and 2.4 days ± 1.2 in the Daflon group. This suggests that for most patients of haemorrhoids, haemorrhoidal bleeding and other associated symptoms constitute an emergency and they would prefer a rapid relief from it. Daflon by the virtue of its anti-inflammatory properties, led to rapid relief from the primary complaint i.e. bleeding per rectum. The difference in patients who were totally relieved of bleeding per rectum, on the 1st week of treatment was statistically significant among the two groups i.e. P <0.001 (Table 2). This significance though was lost during the subsequent follow-up. The same pattern of relief was also seen in the associated symptoms. Bleeding was the presenting complaint in all 200 patients. By the end of the study 90.0% patients in the Daflon group were satisfied with the treatment while this figure was 84% in case of the Rubber Band Ligation group. This difference was statistically insignificant.

Conclusion

We conclude that Daflon leads to the rapid cessation of haemorrhoidal bleeding, alleviation of the associated symptoms and gives objective relief from haemorrhoids. In the present study, Daflon leads to rapid relief of various associated symptoms. Daflon was more effective than Rubber Band Ligation during the acute phase of the disease. A limitation of the drug is the lack of patient compliance due to the long duration of treatment and the high cost of the drug.

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