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Role of calcium dobesilate in management of internal haemorrhoid: An interventional study

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Abstract

Introduction: Internal Haemorrhoids are symptomatic anal cushions. These anal cushions are normal, vascular tissue within the submucosa located in the anal canal. Caudal displacement, structural distortions and mucosal trauma of anal cushions leads to the symptoms of this disease. A randomised, double blind controlled study was conducted to investigate the efficacy of oral and local application of calcium dobesilate in management of acute attacks of internal haemorrhoid.

Methods: 40 patients of 1st and 2nd degree internal haemorrhoid were treated with calcium dobesilate along with high fibre diet and stool softeners for 4 weeks, while 40 patients received only high fibre diet and stool softeners to serve as control. Patients were kept on followup and both symptoms and anoscopic inflammation were scored on a scale from 0 to 2 before and after 4 weeks of treatment.

Results: With calcium dobesilate oral and local therapy for 4 weeks, a success rate of 77.5% with cessation of bleeding plus lack of severe anitis on anoscopic examination was achieved and the reduction of symptoms and anoscopic inflammation were also significantly better than those with diet therapy only.

Conclusion: In addition to dietary management and proper bowel habits, oral and local supplementation of Calcium dobesilate provides an effective and fast relief from acute symptoms of 1st and 2nd degree haemorrhoid. This symptomatic relief is associated with significant improvement in anoscopically observed inflammation.

Keywords: Calcium dobesilate, haemorrhoid

Introduction

Internal Haemorrhoids are symptomatic anal cushions^[1]. These anal cushions are normal, vascular tissue within the submucosa located in the anal canal^[2]. They are thought to aid in anal continence by providing bulk to the anal canal^[3]. Current theories about the development of haemorrhoid consider the nature of anal cushions. Such cushions are aggregates of blood vessels (arterioles, venules, and arterio-venular communication) smooth muscles and elastic connective tissue in the submucosa that reside in the left lateral, right posterolateral and right anterolateral anal canal with small discrete secondary cushion residing between the main cushion^[4].

It was originally reported that the vascular cushions from the termination of the vascular supply within the anal canal contributed to the maintenance of anal continence^[5]. Shearing forces acting on the anus lead to the caudal displacement of the anal cushion and mucosal trauma. With time fragmentation of the supporting structures (a normal consequence of ageing but perhaps accelerated in those with haemorrhoid) leads to loss of elasticity of cushions such that they no longer retract following defaecation^[6].

Anatomic studies have revealed that the anchoring and supporting subepithelial tissue deteriorates with ageing and the descended loose lining becomes more sensitive to trauma from stool, resulting in venous distension, inflammation, erosion, bleeding and/or thrombosis^[7, 8].

The finding of proctoscopic anitis correlates with enlarged lamina propria, capillaries with inflammation is associated with occurrence of haemorrhoid bleeding and/or pain^[9, 10].

The treatment is grouped into conservative (dietary modification, stool softener and vascular tonification), non surgical (sclerotherapy, cryotherapy, manual anal dilatation, diathermy, electrocoagulation) and surgical methods (ligation and haemorrhoidectomy). Non surgical treatment has the advantage that they can be performed on opd basis with minimal complications, pain and control approx 90% of symptoms^[11, 12]. Conservative policy is based on the fact that haemorrhoids are normal anatomic structures with age related changes occurring in every person but they become symptomatic in few^[13].

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Calcium dobesilate (calcium 2,5 dihydroxybenzenesulfonate) is a drug with demonstrated efficacy in the treatment of diabetic retinopathy and chronic venous insufficiency [14-17].

The beneficial effect of the drug are attributed to its ability to decrease capillary permeability, platelet aggregation and blood viscosity and to increase capillary transport. Because of these properties of calcium dobesilate, it was expected to contribute to acute inflammatory attack of disease. a randomised double blind study was carried to investigate and verify the efficacy of calcium dobesilate in treating acute attacks of haemorrhoid disease [18].

Method

80 patients of first- and second-degree haemorrhoid were selected on the basis of clinical symptoms and anoscopy findings from opd in our institute and were included in study.

Inclusion criteria: In all patients symptoms attributable to haemorrhoid had existed for over six months and rectal bleeding was present. Haemorrhoid that bleed but do not prolapsed outside the anal canal were labelled as first degree haemorrhoid and those haemorrhoid that bleed and prolapse outside the anal canal and reduce spontaneously are labelled as second degree haemorrhoid were included.

Exclusion criteria

1. Patients of rectal bleeding with prolapse that required manual repositioning (third degree haemorrhoid) and in whom prolapsed was not reducible (fourth degree haemorrhoid).
2. Patients of concurrent anal fistula or anal fissure, inflammatory bowel disease, diabetes, coagulation disorders, abnormal sexual habits, previous anorectal surgery or previous treatment of haemorrhoid disease by any method other than dietary modification and or topical agents.

After initial anoscopy examination the patients were randomly divided into study and control group.

Group A: (Diet only group) (control group = 40 patients) with diet modification, stool softener and lifestyle advice.

Group B: (calcium dobesilate = 40 patients) with calcium dobesilate 500mg tablet twice a day for 1 week followed by 1 tab daily for 3 week along with calcium dobesilate ointment local application twice a day, diet modification, stool softener and change in lifestyle advised. These patients were examined every week to see the improvement from the various symptoms of haemorrhoid as in the patients of control group.

Diet Modification: a high fibre diet was advised to all patients and importance of fibre (fruits and vegetables) in healthy nutrition was explained. Stool softeners were advised to facilitate easy passage of stool and minimise trauma due to hard stool. Consumption of heavy spice was not allowed. Encouragement was given to correct unhealthy defecation habit

like avoid straining to pass stool, ignoring to pass stool, irregular meals and lack of physical exercise.

Patient follow up and evaluation: The patients were re-examined every weekly. The day on which symptomatic relief was observed was recorded.

Symptomatic relief was graded as

1. Complete relief of symptoms,
2. Partial relief of symptoms with minimal bleeding per rectum and
3. No relief from symptoms and persistent bleeding per rectum.

The anoscopy examination was graded as

1. Normal pink healthy mucosa
2. Mild inflammatory changes with minimal engorged veins and
3. Engorged veins with signs of inflammation in the mucosa.
4. For patients having more than one haemorrhoid the worst lesion was considered for outcome. If bleeding persisted for more than 2 weeks after starting of either therapy with no improvement of symptoms was regarded as treatment failure. In view of improvement of symptoms and anoscopically measured inflammation with use of calcium dobesilate at 2 weeks. calcium dobesilate was further continued for 2 weeks and patients were asked to come immediately if symptoms recurred.

Results and Analysis

Calcium dobesilate oral and local application therapy along with dietary management was given to 40 cases. Whereas only dietary management was advised in 40 cases.

In calcium dobesilate group there were 27 males and 13 females, in diet only group there were 24 males and 16 females and the age group of patients in both group was 20 to 60 yrs.

All the patients had rectal bleeding along with other symptoms for a duration of 3 months to 2 years.

Bleeding per rectum 80(100%)

Anal pain 26(32.5%)

Anal discomfort 24(30%)

Anal pruritus 47(58.75%)

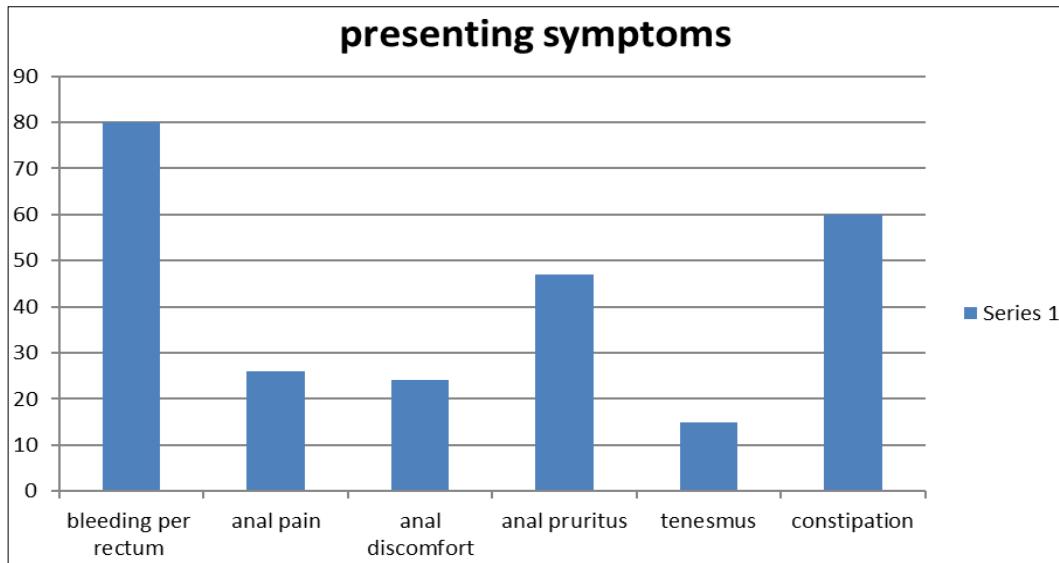
Tenesmus 15(18.75%)

Constipation/ Irregular bowel habit 60(75%)

Group A (Diet only group): After 4 weeks of diet therapy, 17 of 40 patients (42%) had Complete or partial relief of symptoms with improvement in anoscopically observed inflammation whereas no relief of symptom was seen in 23 patients.

Group B (Calcium Dobesilate group): After 4 weeks of calcium dobesilate oral and local application therapy along with dietary management.

Complete relief of symptoms along with significant improvement in anoscopically observed inflammation was observed in 31 of 40 patients (77.5%). Results after 4 weeks

**Fig 1:** Presenting symptoms.

Discussion

Calcium dobesilate (oral and local application therapy) appear to be highly effective in controlling the symptoms and improvement in anoscopically observed inflammation in haemorrhoid. A Success rate of 77.5% was observed with 4 weeks therapy of calcium dobesilate as compared with unsatisfactory success rate of 42% with diet only therapy. These results show that diet therapy alone is not effective for management of symptoms of haemorrhoid but should be used as an adjunct to medical therapy.

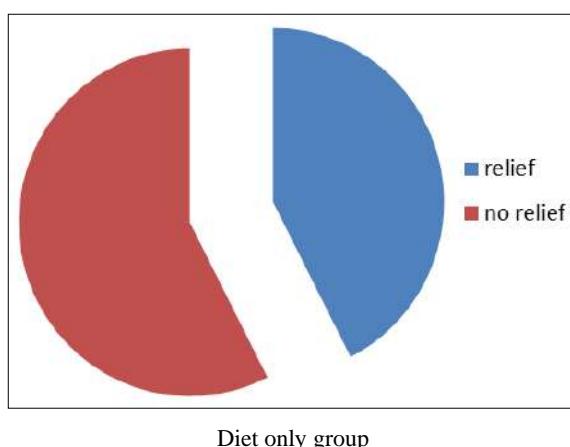
During follow up the patients were encouraged for fibre rich diet and dietary management Encouragement was given for proper bowel habits and amount of fibre in diet [19, 20].

Conclusion

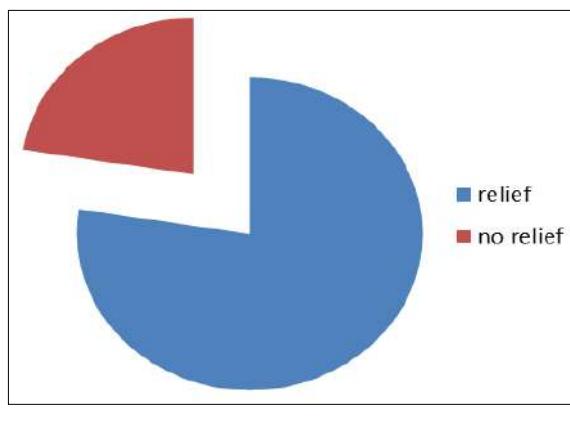
Calcium dobesilate treatment supplemented with high fibre diet and proper defaecation habits is highly effective in symptomatic acute attacks of 1st and 2nd degree haemorrhoid. The improvement is superior to that observed in control diet only group.

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Diet only group



Calcium dobesilate group

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