

Daflon use in the hemorrhoids treatment

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Abstract

The aim of this study was to assess the medical treatment in the management of primary grade-4 internal hemorrhoidal disease (IH) and external hemorrhoidal disease (CH). Detailed history and proctoscopic examination to determine position, size, and degree of hemorrhoids was conducted in all patients attending our private clinic and Salah Aden General hospital .The study was conducted over a one_ year period. All were started on Daflon, with dosage of 6 tablet per day for 4 days, 4 tablet per day for 3 days, and 2 tablet per day until the signs and symptoms clinically disappear or the end of observation time of 2months were followed up weekly during the study period and proctoscopic examination was conducted at each consultation.

Results: The mean age was 35 (range 20_60) years. The majority (58%) suffered primary grade IV internal hemorrhoidal disease and 42% with external hemorrhoidal disease. 56% patient had an excellent improvement, 28% good, 12% moderate and 4% nil.

Minor side effects of Daflon (mainly gastrointestinal symptoms) were encountered in 8% patients.

Keywords: internal hemorrhoidal disease, external hemorrhoidal disease, medical treatment, hemorrhoidectomy, flavonoid

Introduction

Hemorrhoidal illness represents one of the most common surgical and medical conditions through out the world [1-3]. The most recent statistics indicate a prevalence of about 25% in the adult population, and higher than 50% for those older than 50. However, the prevalence and incidence are most probably higher, considering the fact that, in certain patients, the illness begins in an asymptomatic fashion. The origin of hemorrhoidal disease can be either mechanical or vascular (hemodynamic).

Hemorrhoid is a normal anatomic structure in the anal canal in the form of vascular cushion of both sexes in all ages. Its function is to improve closure of the anal canal to prevent against improper flatus and soiling, thus have important contribution in social living. Internal hemorrhoids have three cushions normally found in the submucosal area of dentate line, and each cushion containing a hemorrhoidal plexus. External hemorrhoids arise from inferior hemorrhoidal plexus covered by squamous epithelium under the anal skin [4,5,6]. The most important part of the cushion is its blood vessels which are bright red in color as a result of high oxygen saturation in blood, and are more suitable for an arterio-venous anastomosis [6]. The submucosal cushions are held in place by the anchoring and supporting connective

tissue (ligament of Parks) and the muscular is submucosae. During the act of normal defecation the cushions are filled with blood and it protects the anal canal from injury [7]. During defecation, prolonged straining may cause dilatation and stretching of the cushions, and in combination with the weakness of supporting tissue render the dilated cushions prolapsed down through the anal canal. Hard fecal mass has a tendency to rupture the dilated cushions and bleeding [7]. The origin of hemorrhoidal disease can be either mechanical or vascular (hemodynamic) [8]. Treatment of hemorrhoids is divided by the cause of symptoms, into internal and external treatments. Accurately classifying a patient's symptoms and the relation of the symptoms to internal and external hemorrhoids is important [9,10,11]. Internal hemorrhoidal disease is usually classified into four-degrees of severity: Grade I-bleeding; grade II-bleeding and pile that reduces spontaneously; Grade III-the prolapsed pile outside the anus during defecation, can be manually reduced back into the anal canal; Grade IV-irreducible prolapse [12].

The treatment for internal hemorrhoids by grade

Grade I hemorrhoids are treated with conservative medical therapy and avoidance of nonsteroidal anti-inflammatory drugs (NSAIDs) and spicy or fatty foods. Grade II or III

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hemorrhoids are initially treated with nonsurgical procedures. Very symptomatic grade III and grade IV hemorrhoids are best treated with surgical hemorrhoidectomy. Treatment of grade IV internal hemorrhoids or any incarcerated or gangrenous tissue requires prompt surgical consultation[13]. Nowadays, many literatures have suggested conservative treatment for hemorrhoidal disease in conservative way. Many hemorrhoidal patients were afraid or reluctant to be operated. Excisional hemorrhoidectomy is not a minor operation, has many significant complications, and should be used only as a last resort [12].

Daflon

Daflon is a micronized purified flavonoid fraction containing 90% diosmin and 10% other flavonoids expressed as hesperidin.[14]the flavonoids,(Daflon 500 mg), have been demonstrated to restrain lysosome enzymes and interfere with enzymes involved in the flow of arachidonic acid, which causes inflammation.[15]Daflon 500 mg has also demonstrated an antioxidant activity, which allows it to oppose free radicals,[16] as well as a decreasing effect on the synthesis of PGE-2 and TXA-2 by the macrophage(the main inflammatory mediators, whose level are higher during attacks which lead to pain and bleeding).[17]All these effects result in a reduction of the

pericapillar permeability and an increase in the capillary resistance to blood extravasation in the interstitium.[18]The hemodynamic effect manifests itself through an increase in venous tone demonstrated both experimentally and clinically.[19,20]It is recommended for treating Chronic venous insufficiency and for treating Hemorrhoidal diseases. [21]Daflon is also beneficial in the reduction of symptoms after operation for hemorrhoidal disease.[22]

Side effects: Possible side effects include routine gastric disorders and neurovegetative disorders.

Dosage: For acute hemorrhoidal attack, the dosage is 6 tablets daily for 4 days, followed by 4 tablets daily over the next 3 days.[21].

Methods

This is a prospective study of the patients suffering primary grade IV internal hemorrhoidal disease and external hemorrhoidal disease, were selected as patients in our Privet clinics and Salah Al Din General Hospitaland in Tikrit city. The study was conducted over a one year period. All patients presenting with symptoms related to hemorrhoidal disease were recruited. Detailed history including duration of symptoms, current medications for piles and previous surgery for piles was noted.Physical examination to exclude concurrent medical illnesses

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was also conducted. Baseline proctoscopic examination was carried out and the size, grade, and position of piles were clearly noted.

Fifty patients between 20 to 60 years old were chosen based on inclusion and exclusion criterias. Inclusion criteria: male or non-pregnant female suffering ambulatory chronic grade-IV internal hemorrhoidal disease and external hemorrhoidal disease . patients that choosing medical treatment, informed consent voluntary signing, non-smoker. Exclusion criteria: secondary hemorrhoidal disease, pregnant woman, suffer serious organ disease. Patients were then consented for inclusion in the study after thorough explanation of Daflon and the possible side effects. General advice on how to avoid constipation and regulation of bowel habits was also given Medical treatment means using oral 500 Daflon, produced by Servier, France), with dosage: 6 tablets perday (3 dd 2 tablets) for 4 days, 4 tablets perday (2 dd 2 tablets) for 3 days, and 2 tablets perday (2 dd 1 tablet) consecutively for 2 months. Patients were seen on a weekly basis during the treatment period and inquiries were made of worsening or improvement of symptoms, and any side effects to Daflon. Proctoscopic examination was also conducted at each visit to determine the degree of improvement.

Results

There were 50 patients 37(74%) males and 13(26%) females who completed the treatment and the data was available for analysis. Their mean age was 35 (range 20-60) years. Twenty-nine (58%) suffered primary grade IV internal hemorrhoidal disease and 21 (42%) external hemorrhoidal disease. 11 patients (22%) had previous surgery for piles and 25 (50%) were already on antihemorrhoidal medications with no apparent benefit. Eight patients (16%) had some associated medical diseases such as Diabetes, hypertension, one of them with Behcet's disease.

There was a statistically significant ($p<0.001$) improvement in pain, heaviness, bleeding, pruritis and mucosal discharge from the 1st (baseline) to the last visit. There was also a significant ($p<0.001$) improvement in proctoscopic appearance of piles; 28 (56%) patients had an excellent improvement 14(28%) good response , 6(12%) moderate and 2(4%) with no response . One patients with Behcet's disease on warfarin reported marked improvement in symptoms after 2 and 3 weeks of Daflon therapy. There were 2(4%) patients whose symptoms failed to improve on Daflon; therefore, they underwent surgery.

Minor side effects of Daflon (mainly gastrointestinal symptoms) were

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encountered in 4(8%) patients but did not force interruption of medication.

Discussion

This prospective trial confirms the safety and efficacy of Daflon in the treatment of all symptoms of hemorrhoids. Good-excellent proctoscopic improvement was achieved in 48 out of 50. Significant improvement in symptomatology was also evident. This study confirms Daflon efficacy in IV degree of piles. The use of Daflon controlling bleeding from non-prolapsed piles and it is even cheaper. Another advantage of Daflon is its trivial side effects that are mainly gastrointestinal and can be easily averted by taking tablets with or after meals. Another advantage of Daflon is the lack of interaction with anticoagulants such as warfarin. This study also included a patient with Behcet's disease who was on warfarin and whose hemorrhoidal symptoms were controlled with a month course of Daflon, which has averted surgery with all its attendant risks.

Daflon oral tablet has an important contribution in correcting vein integrity that are caused by varying combination of predisposing factors [23,24,25]. The results of a clinical investigation Godeberge shows that the signs and symptoms involved in hemorrhoidal disease of grade-I to III were significantly improved for almost 100 % of the patients after 2 months

treatment with daflo [25]. In other study, a double blind placebo controlled study involving 100 patients of acute hemorrhoidal disease, shows that MPFF in comparison with placebo result in significant improvement of objective and subjective signs and symptoms [26]. The clinical intensity of acute signs and symptoms such as bleeding, pain, rectal discomfort, anal exudation and proctoscopic rectal inflammation were significantly decreasing. Those investigation-results have indicated that the efficacy of MPFF in fighting the impairment of vascular cushion in hemorrhoidal disease. The efficacy is based on facts that Daflon has mode of action in improving venous tone, improving lymphatic flow, protects the microcirculation, reducing local inflammation, decreasing capillary hyperpermeability and increasing capillary resistance [27, 28, 29].

Cooperative attitude of well-informed patients are the important point to bringing the successful conservative medical therapy in primary hemorrhoidal disease. Daflon may reduce the frequency, duration and intensity of symptoms of acute internal hemorrhoidal disease [30].

The good results of medical treatment of primary grade IV internal hemorrhoidal disease and external hemorrhoidal disease are supporting the claim that operative treatment or any ablative treatment should be used only as a last resort due to high

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complication rates [12]. Many reports have mentioned about recurrences after non-stapled hemorrhoidectomy or stapled hemorrhoidectomy [31]. Even after successful medical treatment, the hemorrhoidal disease may recur, but medical treatment will however be a good management for healing. In follow-up of medical treatment, it was found that the patient who become vegetarian and rarely consume spicy foods heal faster, and there was a significant correlation between low fiber diet and recurrence of hemorrhoidal disease ($p < 0.05$, $OR = 0.16$) [32].

Medical treatment is more cost effective and does not cause side effect or complaints such as pain, bleeding, and other typically encountered in surgical treatment. Results of many studies showing the success of the medical treatment of hemorrhoidal

disease using Daflon without any adverse reaction. Of course it should be informed clearly to the patient, so that they can choose wisely which is the best treatment. Hemorrhoidal disease is a disease that is easy to recur after successfully treated, especially if lifestyle is not maintained properly. Recurrence can be treated by the same medical treatment.

Conclusion

Daflon is a very safe and effective drug in the treatment of all hemorrhoidal symptoms. and this study suggested that all cases of internal hemorrhoidal disease and external hemorrhoidal disease can be managed

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