


Daflon 500mg is used for the treatment of all grades of hemorrhoids

Saman Taher Barzinjy ¹

¹ Department of Surgery, Faculty of General medicine, Koya University, Koya, Erbil, Iraq

OPEN ACCESS

Correspondence Address: Saman Taher Barzinjy

Email: saman.taher@koyauniversity.org

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Website:

<https://djm.uodiyala.edu.iq/index.php/djm>

Received: 23 March 2023

Accepted: 30 April 2023

Published: 25 April 2024

Abstract

Background: Hemorrhoidal diseases are very common diseases found in surgical outpatient clinics, affecting populations all over the world. Treatments for the different grades of hemorrhoids include lifestyle changes, conservative medical therapy, and operative interventions.

Objective: To assess the conservative treatment response of all grades of hemorrhoidal disease (grades 1-4) to a venotonic agent (Daflon 500mg).

Patients and Methods: This is a prospective observational study of 196 patients with hemorrhoids, conducted during the period from January 2015 to January 2020, All treated with the standard dose of a venotonic agent (Daflon 500mg). An observation of the reduction and disappearance of the signs and symptoms of the different grades of the disease was done at 1, 3, and 6 months.

Results: The mean age of the patients was 46.6 (range 14–85) years. The majority (41.84%) were diagnosed with grade III hemorrhoidal disease and 30.1% with grade II disease; Grade I and Grade IV constitute 9.69% and 18.37%, respectively. excellent improvement observed in about 72.45%, temporary response seen in 15.82% of cases.

Conclusion: Daflon 500 mg is an effective first-line conservative treatment for all four grades of hemorrhoidal diseases, including grade 4, which has a 44.74% permanent response rate. This medical treatment, in turn, reduces the chance of surgical intervention and its complications.

Keywords: hemorrhoidal disease, pile, medical treatment of pile, hemorrhoidectomy, flavonoid, Daflon 500mg.

Introduction

Hemorrhoidal disease (HD) is a very common disease affecting populations all over the world [1]. The global prevalence of hemorrhoids among the general population is estimated at approximately 4.4% [2]. The prevalence of hemorrhoids is higher in Australia (38.93%) than in Israel (16%) and South Korea (14.4%) [3]. Few attempts have been made to estimate the prevalence of hemorrhoids in Africa; the prevalence of hemorrhoids in Egyptian patients undergoing

colonoscopy was 18% [4]. Studies conducted in other countries to assess the causes of this global disease have found that inadequate dietary fiber intake, constipation, diarrhea, high blood pressure, a high body mass index (BMI), pregnancy, and aging are among the risk factors for the development of hemorrhoids [4,5]. Hemorrhoids are not always a disease because they are normal anatomical structures in the anal canal in the form of vascular cushions that are present

among both male and female sexes and are also present in all age groups. The function of these cushions is to close the anal canal in order to prevent inappropriate or involuntary passing of flatus and soiling of the perianal region, thus having an important role in the social aspect of human life. Internal hemorrhoids consist of three cushions, which are found in the sub-mucosal layer near the dentate line, and each cushion contains a plexus of veins. On the contrary, the external type of hemorrhoids is made from the inferior hemorrhoidal plexus of veins, which is covered by a squamous type of epithelium underneath the anal skin [6]. During the mechanism of stool passage, prolonged straining and pressure will lead to edema, dilatation, and stretching of the mentioned vascular cushions, and this, in combination with the laxity and weakness of the tissue supporting the anal region, will lead to downward prolapse of the dilated cushions throughout the anal canal. Solid stool may lead to injury to the dilated cushions, which in turn may lead to hemorrhage [7]. The origin of hemorrhoidal disease may be mechanical or vascular (hemodynamic) [8]. We can say that the hemorrhoid is formed by the anastomoses between the superior rectal artery (terminal branch of the inferior mesenteric artery) and the superior (tributary of the inferior mesenteric vein), middle, and inferior rectal veins (tributaries of the internal iliac vein); all of these veins surround the distal rectum and anal canal. Then, hemorrhoid is a distal displacement and venous swelling of the hemorrhoidal cushions [9]. Hemorrhoids are broadly classified into internal and external hemorrhoids. Internal hemorrhoids arise

above the dentate line and are lined with columnar epithelium, whereas external hemorrhoids arise below the dentate line and are lined with squamous epithelium [10]. The accurate classification of the severity of hemorrhoids is important [11]. Hemorrhoidal disease is usually divided into four grades. In Grade I, there is only bleeding without any prolapse or feeling of lumpiness in the perianal region; in Grade II, there is bleeding and a pile protruding outside but can be reduced by itself; in Grade III, the prolapsed or protruded pile is outside the anus during stool passage but can be reduced back into the anal canal manually but not spontaneously; and in Grade IV, there is irreducible or permanent prolapse that cannot be reduced by itself nor manually [12]. Regarding the treatment of the different grades of hemorrhoid, grade I hemorrhoid is usually treated by only conservative medical therapy in combination with providing instructions to avoid non-steroidal anti-inflammatory drugs (NSAIDs) and avoidance of fatty or spicy foods. This grade usually does not need surgical intervention if the treatment coincides with the management of the risk factors and the causes of the disease. Conservative treatment should be tried first in both grade II and III hemorrhoids. Severely symptomatic grade III and IV hemorrhoids are usually nonresponsive to conservative medical treatment, and most of them require treatment by surgical interventions. Radical surgical treatment is required for symptomatic grade IV hemorrhoids or in the case of the development of complications such as incarceration or gangrene. [13]. Nowadays, a lot of literature is available concluding that

treatment of hemorrhoidal disease conservatively is feasible for all grades. Many patients with symptomatic hemorrhoidal diseases are afraid of doing surgery for their diseases, or they refuse to do surgery. Hemorrhoidectomy has different annoying complications like post-operative pain, bleeding, urinary retention, constipation, etc. It should be applied only as a last resort and for the patient's reluctance to conservative medical treatments [12]. Prolapsed hemorrhoids are usually managed by procedures at outpatient clinics or by operative interventions [14]. Complications of operative interventions may include severe bleeding and pain; less common but disaster complications include fecal incontinence, abscess formation, and septicemia [15]. Conservative treatment includes lifestyle and diet modifications in the form of increasing fluid and fiber intake, avoiding straining during defecation, increasing physical activity, and avoiding constipation and constipating agents. Local treatments with creams containing corticosteroids, anti-inflammatory agents, and anesthetic agents may relieve the symptoms of HD. Venoactive or phlebotonic drugs for treating chronic venous insufficiency such as varicose veins, have also been used to treat and relieve the symptoms of HD [16]. The most commonly used agents are flavonoids. Micronized purified flavonoid fraction (MPFF; Daflon [Server, France]) is a venoactive drug that is commonly prescribed to relieve the symptoms of chronic venous insufficiency, especially in France [17]. Daflon is a micronized, purified flavonoid fraction that contains approximately 90% diosmin and 10% other flavonoids in the form of

hesperidin. [18] The flavonoids (Daflon 500 mg) have been demonstrated to restrain lysosome enzymes and interfere with those enzymes having roles in the flow of arachidonic acid, which has a role in the inflammatory process and causes inflammation. [19] It is observed that Daflon 500 mg also has antioxidant properties; this property can affect function and have a negative impact on free radicals [20]. Daflon 500mg is recommended for treating hemorrhoidal disease [21]. Daflon has also had beneficial effects on the reduction of symptoms in post-hemorrhoidectomy cases [22]. The treatment schedule for acute hemorrhoidal attacks is to start with a daily dosage of six tablets for four days, followed by four tablets daily over the next three days [21].

Patients and Methods

In this prospective study, 196 cases were included from the out-patient clinic in the east emergency hospital in Erbil city (the capital of the Kurdistan region in the north part of Iraq) and the private clinic in the same city between the periods of January 2015 and January 2020. Signed consent forms were obtained from all patients. Assessment and diagnoses based on clinical features such as constipation, itching, and discomfort; perianal reducible and irreducible lumps and protrusion; per anal bleeding; per anal soiling; per anal pain, etc. Some cases were on irregular oral and local medications for the pile treatment; others had a past surgical history of perianal conditions, including hemorrhoidectomy (open technique, closed technique, etc.), but recurrence happened. Some have a surgical history of operations for anal fissures and fistulas, and some cases

underwent two to three times hemorrhoidectomy previously. A thorough clinical examination, including a digital rectal examination, was performed to see the perianal lump, bleeding, anal stenosis, and perianal soiling for the diagnosis of hemorrhoids. Those who still have a vague diagnosis are sent for further assessment, including a proctoscopy, sigmoidoscopy, or colonoscopic examination.

All patients were treated with Daflon 500 mg: 2 tablets every 8 hours or 1 tablet every 4 hours for 4 days, then 2 tablets every 12 hours or 1 tablet every 6 hours for another 3 days, followed by 1 tablet every 12 hours for 2 months. Symptomatic treatments coincide with Daflon 500 mg as a laxative for constipation, treating underlying causes of diarrhea, chronic cough, and BPH by the relevant specialties (internists and urologists, respectively). The patients were instructed to avoid lifting heavy weights for heavy workers and the avoidance of long standing for those who stand for a long duration.

Instructions were provided to avoid precipitating factors. Pregnancy counseling was done for those ladies who were diagnosed with hemorrhoids. Lifestyle counseling is provided to avoid foods aggravating the constipation; analgesia is also provided to relieve the symptom of pain. Follow-up for all patients done after 1 month, 3 months, 6 months, and 2 years is assessed for the response to the medication through clinical and digital rectal examinations, either via visiting out-patient departments or private clinics or via phone contact.

Statistical Analysis

Data entry and analysis are performed via Microsoft Excel 2010 for calculating frequencies, percentages, means, S.D.s, and tables.

Results

Among all 196 cases, 101 cases (51.53%) were male, and the remaining 95 cases (48.47%) were female Table (1).

Table (1): Gender distribution among the sample

Gender	No	%
Male	101	51.53
Female	95	48.47
Total	196	100

The mean age of the patients involved in the study was 46.6 years with SD of 46.6±15.47 (range 14-85). Eighteen (9.18%) patients were included in the age group of 14-25 years, 74 cases (37.76%) in the age group 26-45 years. The majority of patients (78 cases, 39.8%) were in the age range 46-65 years;

the remaining 26 cases (13.27%) were in the range of 66-85 years Table (2).

Risk factors such as chronic constipation, chronic diarrhea, chronic cough, family history, pregnancy, and BPH are all assessed and estimated as the causes and risk factors of the disease Table (3).

Table (2): Distribution of patients according to the age groups

age ranges (year)	number	percentage
14-25	18	9.18
26-45	74	37.76
46-65	78	39.80
66-85	26	13.27
Total	196	100.00

Table (3): Numbers and percentages of risk factors patients presented with hemorrhoids

risk factors	Number	Percentage
Pregnancy among female	19	20
BPH among male	50	49.50
Constipation	86	43.88
Diarrhea	2	1.02
family history	48	24.49
chronic cough	51	26.02
Idiopathic	15	7.65

The majority (82 patients, 41.84%) were diagnosed with grade III hemorrhoidal disease, 59 patients (30.1%) with grade II

hemorrhoidal disease, 19 (9.69%) patients with grade I, and 36 (18.37%) patients with grade IV Table (4).

Table (4): Distribution of the sample according to the grades of hemorrhoids

Pile grade	Number	Percentage
Grade 1	19	9.69
Grade 2	59	30.10
Grade 3	82	41.84
Grade 4	36	18.37
Total	196	100.00

Excellent improvement of the hemorrhoidal disease and permanent response to the drug used were observed in 142 patients (72.45%); 31 cases (15.82%) temporarily responded and

were then managed by other treatment modalities; meanwhile, 23 patients (11.73%) got no benefit from the drug Table (5).

Table (5): number and percentages of case responsiveness to Daflon 500mg treatment

Response	Number	Percentage
Permanent	142	72.45
Temporary	31	15.82
No response	23	11.73

Also, we observed that 17 cases (44.74%) of grade IV disease permanently responded to the treatment, while 54 cases (91.53%) of grade II and 16 cases (84.21%) of grade I disease responded completely, followed by a

permanent response of 55 cases (67.07%) for grade III Table (6). Very few minor side effects of Daflon 500mg were observed during the follow-up period (mainly gastrointestinal upset symptoms).

Table (6): Permanent response distribution according to the grades of hemorrhoids

Grade	permanent response (No.)	(%)
I	16	84.21
II	54	91.53
III	55	67.07
IV	17	44.74

Discussion

Daflon 500mg oral medication has an important role in correcting the integrity of the veins, which is due to various combinations of predisposing and risk factors [23]. The Godesberg's results revealed that the clinical features included in hemorrhoidal disease in nearly all patients with grades I, II, and III significantly responded to Daflon 500mg following 2 months of treatment [23]. This is in contrast to our study, in which a permanent response rate was observed in 84.21%, 91.53%, and 67.07% for grades I, II, and III, respectively. Despite our observation of a range of response rates for grade IV disease, this significant response rate in our study may be due to two points: firstly, the smaller sample size of this grade in comparison to the other grades, and secondly, the well-compliance of the patients with using the drug and following the instructions to minimize the risk factors of failure of the conservative treatments and operative complications. The lower response rate of grade I to III disease in comparison to the mentioned study may be due to the ignorance of some patients in these groups to strictly follow the instructions because of the lower grade of their piles and fewer signs and symptoms. In the current study, the responses were nearly equal for grades I and II (84.21% and 91.53%, respectively). The effects of Daflon on the reduction and disappearance of

the clinical features of hemorrhoids overall in our study were the same. Cooperation and well-informed patients are essential for achieving successful conservative drug therapy among patients with primary hemorrhoidal disease. Daflon will decrease the intensity, duration, and frequency of symptoms [24].

The good results of drug treatment of both grade IV primary internal hemorrhoid and external hemorrhoid are regarded as supporting data for those conservative surgeons who think that operative treatment or any ablative treatment should be used only as a last method of treatment because of high rates of complications [12]. In our study, the same aim was obtained since most of the patients of different grades well responded to the conservative management with an observation of 44.74% complete response rate of the grade IV disease. Non-stapled hemorrhoidectomy, or stapled hemorrhoidectomy, is mentioned in many reports in regard to recurrences [25]. Even after successful drug treatment, the hemorrhoidal disease has a rate of recurrence; however, medical treatment is a good way of managing it, especially for healing. In follow-up of conservative treatment, it was found that those patients who change their lifestyle by increasing vegetable and high-fiber diets and decreasing spicy foods heal more rapidly, and there was a clear relation between decreasing high-fiber diet intake and the

recurrence rate of hemorrhoids ($p < 0.05$, OR = 0.16). [26], in spite of focusing the patients in our study on drug treatment, instructions for increasing a high-fiber diet were also provided to those patients in whom constipation was found to be a major cause and risk factor for their disease. In our study, we observed that 27.55% of all cases (15.82% were temporary responders and 11.73% were non-responders) underwent surgical intervention after follow-up. A trial to compare the effects of Daflon 500mg versus placebo was done for 90 cases. Daflon 500 mg was given to the patients with acute hemorrhoid symptoms (proctorrhagia, and anal pain). The result was a significant decrease in the symptoms of acute hemorrhoid for the Daflon 500mg group in comparison to the placebo group [27]. The same results have been observed in our study that revealed an overall excellent response to treatment by the same dose of Daflon 500 mg, particularly for grade II, in which a 91.53% response rate was observed with only two months of treatment. A meta-analysis of 14 studies in 2006 investigated flavonoid treatment (MPFF, Ruto sides, or diosmin) for hemorrhoids. The results were that flavonoids increased the chance of success and response rate globally by 58%, with an obvious decrease in the risks of pain, recurrence, bleeding, and itching [17]. Different results were seen in our study since an overall 72.45% had a complete response and improvement of the signs and symptoms of different grades of hemorrhoids, with the majority of grades I and II having an excellent permanent response. Another Cochrane meta-analysis for the treatment of hemorrhoid by the use of phlebotonics, which

involve different kinds of drugs, including MPFF, revealed that phlebotonics provided essential benefit in statistically significant results for hemorrhage and all main symptom improvement in acute hemorrhoid and in post-hemorrhoidectomy hemorrhage as well [28].

Conclusions

Hemorrhoid is a common disease among populations in the age range of 46–65 years. Daflon 500 mg is an effective first-line conservative treatment for all grades of hemorrhoidal diseases, including grade 4, which has a 44.74% permanent response rate. It can also be tried for grade IV hemorrhoids before rushing to surgery so as to reduce the chance of surgical intervention and its complications. Daflon 500 mg is also associated with minimal side effects when used for the treatment of hemorrhoidal diseases.

Recommendations

We recommend the use of a Daflon 500mg tablet in a standard dose for all grades of hemorrhoids, provided that the patient is stable and not complaining of severe symptoms, in order to minimize the rate of surgical interventions and their complications.

Source of funding: The current study was funded by our charges with no any other funding sources elsewhere.

Ethical clearance: Koya University/ Faculty of Medicine- scientific Research Ethics Committee granted approval for this study (date: 22.12.2022, number: 1130). (No.2023STB741).

Conflict of interest: Nil

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استخدام دافلون ٥٠٠ ملغم لجميع درجات البواسير الشرجية

سامان طاهر برزنجي^١

الملخص

خلفية الدراسة: تعد أمراض البواسير من الأمراض الشائعة جدًا الموجودة في العيادات الخارجية الجراحية والتي تؤثر على السكان في جميع أنحاء العالم، وتشمل علاج مختلف درجات البواسير؛ عادة ما يتم علاج البواسير من الدرجة الأولى بالعلاج الطبي المحافظ فقط، ويمكن علاج البواسير من الدرجة الثانية والثالثة في البداية بطرق محافظة وغير جراحية. عادةً ما تفشل البواسير المصحوبة بأعراض شديدة من الدرجة الثالثة والرابعة في الاستجابة للعلاج الطبي المحافظ ويتم علاج معظمها بالتدخلات الجراحية.

اهداف الدراسة: لتقييم الاستجابة العلاجية المحافظة لجميع درجات مرض البواسير (الدرجة ١-٤) لعامل مقوي للأوردة (دافلون ٥٠٠ ملغم).

المرضى والطرائق: سجل كامل لجميع المرضى البالغ عددهم ١٩٦ مريضًا الذين يزورون قسم الجراحة الخارجية في مستشفى الطوارئ شرق أربيل والعيادة الخارجية الخاصة. أجريت الدراسة بين فترات من يناير ٢٠١٥ إلى مارس ٢٠٢٠. تم وضع جميع المرضى على دواء دافلون ٥٠٠ ملغم بجرعة قياسية، ولاحظت الدراسة انخفاض واختفاء علامات وأعراض درجات المرض المختلفة في نهاية ٦ أشهر المتابعة.

النتائج: كان متوسط عمر هذه الدراسة ٤٦,٦ سنة (المدى ١٤-٨٥) سنة مع $SD 46.6 \pm 15.47$. الغالبية (٤١,٨٤٪) تم تشخيصها على أنها مرض البواسير من الدرجة الثالثة و٣٠,١٪ بمرض البواسير من الدرجة الثانية، وفي الوقت نفسه شكلت الدرجة الأولى والرابعة ٩,٦٩٪ و١٨,٣٧٪ من المرضى على التوالي. لوحظ تحسن ممتاز لمرض البواسير الشرجية واستجابة دائمة للدواء المستخدم في حوالي ٧٢,٤٥٪، ١٥,٨٢٪ من الحالات استجابت مؤقتًا مما ادت الى اجراء طرق اخرى للمعالجة، بينما ١١,٧٣٪ من المرضى لا يستفيدون من الدواء.

الاستنتاجات: دواء دافلون ٥٠٠ ملغم هو علاج محافظ فعال للخط الأول لجميع الدرجات الأربع لأمراض البواسير بما في ذلك الدرجة الرابعة الذي يحتوي على معدل استجابة دائم ٤٤,٧٤٪، وهذا العلاج الطبي بدوره يقلل من فرصة التدخل الجراحي ومضاعفاته.

الكلمات المفتاحية: مرض البواسير، بواسير شرجية، علاج طبي للبواسير، استئصال البواسير، فلافونويد، دافلون ٥٠٠ ملغم

البريد الإلكتروني: saman.taher@koyauniversity.org

تاريخ استلام البحث: ٢٣ آذار ٢٠٢٣

تاريخ قبول البحث: ٣٠ نيسان ٢٠٢٣

^١قسم الجراحة - كلية الطب - جامعة كويه - أربيل - العراق