

# Efficacy of Daflon in the treatment of hemorrhoids

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## ABSTRACT

**Objective:** To demonstrate the value of Daflon in the management of hemorrhoidal symptoms in Saudi patients attending the Surgical clinic.

**Methods:** This is a prospective clinical study of 105 consecutive patients suffering from hemorrhoidal problems including thrombosed piles. Detailed history and proctoscopic examination to determine position, size, and degree of hemorrhoids was conducted in all patients attending the Surgical Clinic at Dammam Central Hospital, Dammam, Kingdom of Saudi Arabia (KSA). The study was conducted over a 6-months period (December 2000 to May 2001). All were started on Daflon; 2 tablets twice daily for 4 weeks and were followed up weekly during the study period and proctoscopic examination was conducted at each consultation.

**Results:** The mean age was 35 (range 19-70) years. The majority (77%) suffered congested hemorrhoidal disease

and only 8% had thrombosed piles. Previous surgery for piles was noted in 11%. Concomitant medical diseases were present in 10%. The degrees of piles were first degree (23 patients), 2nd degree (73), 3rd degree (9) and 4th degree (0). There was a statistically significant ( $p < 0.001$ ) improvement in pain, heaviness, bleeding, pruritus, and mucosal discharge from baseline to last visit. There was also a significant ( $p < 0.001$ ) improvement on the proctoscopic appearance. Five patients failed to improve on Daflon; therefore, they underwent surgery. The side effects of Daflon (mainly gastrointestinal symptoms) were encountered in 5 patients but did not force interruption of the medication.

**Conclusion:** Daflon is a very safe and effective drug in the treatment of all hemorrhoidal symptoms in the population of Eastern KSA.

**Saudi Med J 2002; Vol. 23 (12): 1496-1498**

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**H**emorrhoids and their symptoms are common surgical afflictions throughout the world<sup>1-3</sup> and the Saudi population is no exception. The exact data on its incidence in the Kingdom of Saudi Arabia (KSA) is however lacking. In the author's surgical unit, a good percentage of patients attending the General Surgical Outpatient Clinic are due to piles or pile-related problems. Furthermore, the number of surgical procedures performed for piles in the Department of General Surgery at Dammam Central Hospital, Dammam, KSA have an average of 120 procedures per year; making hemorrhoidectomy the 3rd most common elective surgical procedure

performed in our department after cholecystectomy and hernia repairs. The best treatment of hemorrhoids is prevention. This can be achieved by avoiding constipation, intake of high fibre diet and administration of bulk laxatives if necessary. Local symptoms such as anal irritation and pain can be alleviated by some soothing creams and suppositories, but they hardly provide long term benefit. On the other hand, surgical treatment of hemorrhoids is often associated with morbidity that makes it of bad reputation and unpopular among patients.<sup>4,5</sup> Although non-surgical treatments of piles such as rubber band ligation, sclerotherapy,

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Received 27th May 2002. Accepted for publication in final form 31st July 2002.

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photocoagulation and cryotherapy are well accepted and very popular to the patients, they are not suitable for all grades of piles.<sup>1-3</sup> Therefore, an effective medical treatment for symptoms of piles would be a very attractive option to patients and surgeons. Daflon (Les Laboratoire Servier, Orleans, France) is a new flavonoid vasoprotector venotonic agent whose active principle is a micronized flavonoid fraction that contains flavonoid extracts of rutaceae equivalent to 150 mg diosmin expressed as hesperidin. It is a phlebotropic agent that has a proven efficacy in the treatment of various venous disorders.<sup>6</sup> Considering piles as a venous disease, as bleeding occurs from presinusoidal arterioles,<sup>7</sup> the use of Daflon for treatment of piles would be a very attractive option. This article studies the efficacy of Daflon in the treatment of hemorrhoids of various grades in patients attending the General Surgical Clinic at Dammam Central Hospital with various hemorrhoidal symptoms.

**Methods.** The study was conducted over a 6-months period (December 2000 to May 2001). 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 was also conducted. Baseline proctoscopic examination was carried out and the size, grade, and position of piles were clearly noted. 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. Daflon 4 tablets in 2 divided doses were given per day with meals (each tablet contains 0.375gm flavonoid extracts of rutaceae equivalent to 150mg diosmin) for 4 weeks. 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.

Statistical analysis comparing symptoms and proctoscopic improvement at first and last visits was carried out using Wilcoxon Signed Ranks test and Chi squared test. The study was approved by the Credential and Scientific Research Committee of the Hospital.

**Results.** There were 105 patients (70 males and 35 females) who completed the treatment and the data was available for analysis. Their mean age was 35 (range 19-70) years. Eighty-one patients (77%) suffered congested hemorrhoidal disease, 16 (15%) acute hemorrhoidal attacks and 8 (8%) thrombosed piles. Twelve patients (11%) had previous surgery

for piles and 25 (24%) were already on anti-hemorrhoidal medications with no apparent benefit. Ten (10.5%) had some associated medical diseases such as diabetes, hypertension, Behcet's disease and others. Twenty-three patients (22%) had 1st degree hemorrhoids, 73 (70%) had 2nd degree, 9 (8%) had 3rd degree and none for 4th degree. 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; 26 patients had an excellent improvement, 51 good, 16 moderate and 7 nil. Two patients; a pregnant female in the 3rd trimester and a patient with Behcet's disease on warfarin reported marked improvement in symptoms due to congested piles after 2 and 3 weeks of Daflon therapy. There were 5 patients whose symptoms failed to improve on Daflon; therefore, they underwent surgery. Minor side effects of Daflon (mainly gastrointestinal symptoms) were encountered in 5 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 77 out of 105 patients. Significant improvement in symptomatology was also evident. This study also confirms Daflon efficacy in various degrees of piles except for the 4th degree. Non of the patients in this study had 4th degree piles. The use of Daflon compares favorably with rubber band ligation in controlling bleeding from non-prolapsed piles and it is even cheaper.<sup>8</sup> 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. Furthermore, the use of Daflon in pregnancy; a period when piles is common and surgery is relatively contraindicated, is safe.<sup>9</sup> This safety is explained by the minimal transplacental passage.<sup>10</sup> Daflon is usually given 4-8 weeks before and for 4 weeks after delivery.<sup>9</sup> This study included a pregnant female in her 3rd trimester presented with congestive hemorrhoidal disease. A course of Daflon alleviated all her symptoms within 2 weeks. Using Daflon during lactation is also safe, as its passage in milk is minimal.<sup>10</sup> Another advantage of Daflon is the lack of interaction with anticoagulants such as warfarin and other coumarins. 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. Although this is a prospective study, certain pitfalls can be addressed. It was a non-randomized study and control groups, and the investigators were not

blinded so a degree of bias may be inevitable. Furthermore, not all the proctoscopic examinations was carried out by the same investigator at each visit as this was practically impossible; leaving some room for subjective variations. Moreover, improvement in symptoms relied on subjective measures. Also, compliance of patients can not be accurately determined. Some patients, albeit a small percentage, showed some reluctance in joining this trial and were favoring surgery as the treatment of choice. They were given trial of Daflon but their compliance was questionable. Approximately 24% of the patients in this study were already using some other antihemorrhoidal treatments. Hence the improvement in symptoms may not entirely be due to Daflon although those patients did not report any effective benefits from topical agents. Such pitfalls however, cannot undermine the significant improvement of all hemorrhoidal symptoms and the proctoscopic appearance of piles by a month course of treatment in a very good number of patients (approximately 75%). A prospective randomized study would have settled all these reservations and would have added greater strength to the study. As the long-term effect of Daflon treatment on hemorrhoids was not studied, it would be very interesting to follow-up patients included in this study to see if symptoms recurred and how long after the initial treatment has been stopped. It would be of interest also to determine the percentage of the study patients who eventually come to surgery. The author believes that recurrent symptoms can be similarly treated by another course of Daflon. Failure to control symptoms is an indication for other forms of treatment modalities that are available to the surgeon. A new promising operation that is suitable for piles especially that accompanied by mucosal prolapse is stapled hemorrhoidectomy. This was introduced by Longo<sup>11</sup> and it has been gaining popularity due to its numerous advantages. Daflon may play a role in reducing post-hemorrhoidectomy bleeding even after the stapled procedure.<sup>12</sup> This study confirms the efficacy of Daflon in treating various hemorrhoidal symptoms in Saudi patients attending the surgical clinic. It also confirms its significant efficacy in

improving the proctoscopic appearance of piles after a month course of Daflon. This calls for an initial trial treatment of piles with Daflon before embarking on surgical management with all its attendant risk of morbidity.

**Acknowledgment.** I am thankful to all my colleagues in the Department of General Surgery, Dammam Central Hospital, Dammam, Kingdom of Saudi Arabia. Special thanks to Drs. Hussain Al-Abkari, Ramadhan Jomaa, Heitham Shamout and Abbass Al-Qassab for allowing me to include their patients in this study.

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