

# Competence of *Althaeaofficinalis* Seed Extract in control of Haemorrhoids in comparison with Daflon

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## ABSTRACT

**Background:** The use of medicinal plants in herbalism has been documented for thousands of years, with evidence dating back to ancient civilizations such as the, Chinese, Greeks and Egyptians<sup>1</sup>. Extensive clinical studies have demonstrated that *Althaeaofficinalis* has properties that promote healing of ulcers<sup>2</sup>.

**Aim:** To evaluate effectiveness of *Althaeaofficinalis* seed extract compared to Daflon (diosmin plus hesperidin) in treating hemorrhoids.

**Methods:** A double-blind, randomized clinical trial was carried out in Lahore's urban community. Patients with acute hemorrhoids were randomly divided into two parallel groups, each with 60 participants, for a one-week period. The selection of family physicians for the study was done randomly.<sup>6,7,8</sup>

**Interventions:** In the beginning, the participants were given either two capsules of 500mg *Althaea* seed extract or two tablets of Daflonin morning and evening for four days, followed by two capsules/tablets daily for the next three days. The primary measure of effectiveness was the alleviation of symptoms and signs.<sup>9,10</sup>

**Results:** Both groups demonstrated similar improvement from first day to last day. The intensity of symptoms such as itching, tenesmus, and bleeding, swelling, pain etc reduced markedly in both groups, but the reduction was fast in the *Althaeaofficinalis* seed extract group observed initial days of the trial.

**Practical Implications:** Estimated prevalence of haemorrhoids ranges from 2.9% to 27.9% worldwide.<sup>11,12,13</sup> However, due to cultural practices, it is often ignored and left untreated, It is therefore essential to design preventive measures and control strategies for hemorrhoids.

**Conclusion:** Both *Althaea* and Daflon were found relieving haemorrhoidal signs and symptoms of hemorrhoids. However, the use of *Althaea* seed extract resulted in quicker relief and it may be used as good alternative to Daflon.

**Keywords:** Haemorrhoids, *Althaea* seed extract, *Althaeaofficinalis*, double blind, tenesmus, bleeding,

## INTRODUCTION

Herbalism is an ancient practice that has been used by many cultures throughout history.<sup>1</sup> Numerous studies have shown that *Althaeaofficinalis* is effective in promoting healing of ulcers<sup>2</sup>. Hemorrhoids refer to the presence of varicose veins in the anorectal region of the gastrointestinal tract.<sup>3</sup> Hemorrhoids make up approximately 50% of the investigations related to the colon and rectum<sup>4</sup>. Hemorrhoids typically do not cause pain or itching on their own, but they are often associated with the symptoms that are commonly heard of, such as pain, burning, swelling, itching or a combination of these<sup>5</sup>.

Hemorrhoids are categorized into four grades based on the degree of prolapse, which are classified as 1 to 4. Grade 1 indicates no prolapse, Grade 2 indicates prolapse that spontaneously reduces, Grade 3 indicates prolapse that can be manually reduced, and Grade 4 indicates prolapse that cannot be reduced<sup>6</sup>.

Hemorrhoids are more commonly found in the age group of middle to old age<sup>7</sup>. The occurrence of hemorrhoids tends to decrease after the age of seventy<sup>8</sup>. Hemorrhoids tend to affect males more frequently than females<sup>9</sup>. Hemorrhoids are the third most frequently occurring gastrointestinal diagnosis made on an outpatient basis in the United States<sup>10</sup>. In Japan, the occurrence rate of hemorrhoids varies between 4% and 55%.<sup>11</sup> In the subcontinent, specifically India, around 75% of the population is affected by hemorrhoids<sup>12</sup>. Despite the documented alternative, antioxidant, and astringent properties of *Althaeaofficinalis* extract, there has been no study to date on its effectiveness in treating

hemorrhoids. Numerous studies have been conducted through human trials to determine the efficacy of *Althaeaofficinalis* in treating various diseases<sup>13</sup>.

However, there is limited information available on the effective use of *Althaeaofficinalis* in treating acute hemorrhoids. As a result, there is a pressing need to establish the safety profile of *Althaea* seed extract in humans, evaluate its efficacy in treating hemorrhoids, compare its effectiveness with Daflon, and increase awareness in the community about the efficacy of *Althaeaofficinalis* extract in treating hemorrhoids..

## MATERIAL & METHODS

A double-blind, randomized clinical trial was carried out in Lahore's urban community. To obtain an ethanolic-aqueous extract, 100 grams of *Althaeaofficinalis* seed powder was anaerobically sublimated and added to an ethanolic-aqueous mixture. The extract was then allowed to evaporate in an open environment to remove the alcohol content. The remaining seed extract was administered in 500mg capsules at a concentration of 5 ppm for the trial. Daflon®, a medication consisting of 500mg of micronized purified flavonoid extracts from the Rutaceae family, with an equivalent of 450mg diosmin and 50mg hesperidin was used as control. A randomized control trial was conducted on 120 males, aged 18 years or older, who were suffering from acute hemorrhoids and experiencing symptoms such as itching, pain, swelling, tenesmus, and bleeding. The study aimed to evaluate the effectiveness of *Althaea* seed extract and compare it to Daflon® 500 mg in treating hemorrhoids. Patients who were already receiving treatment or unwilling to participate were excluded. The study was conducted for one week, and it was a randomized, double-blind, controlled pilot study conducted in community

Received on 13-09-2022

Accepted on 27-02-2023

settings with the assistance of family physicians. The sample size was determined based on a 3.8% prevalence rate of hemorrhoids in Pakistani population and a worst-acceptable rate of 7%, using a 95% confidence level calculated through Epi-info. Participants were randomly assigned in a one to one ratio to either Althaeaofficinalis seed extract (trial group) or Daflon (control group). Confidentiality of personal information was ensured. Clinical signs and symptoms were used to evaluate the efficacy, and data was collected, compiled, and analyzed using SPSS version 25. The categorical variables between the groups were compared -squared using a chitest.

**RESULTS**

Baseline data was recorded, which showed that difference was found insignificant between Trial and Control groups. Observations were recorded after 24 hours, 3 days and 7 days. It was clear that both groups experienced a reduction in symptoms. Regarding

pain, in trial group there was marked relief after 24 hours and 3 days. Similarly there was reduction in swelling in the trial group.. Regarding tenesmus, a noticeable relief was found in trial group after 24 hours but after 3 days no significant difference was observed between trial and control group In trial group bleeding was promptly controlled and there was marked difference between these two groups.Observations in various blood parameters before and after the trial did not reveal any difference To summarize both groups resulted into clinical picture of disease but it is also apparent that no difference was observed by the end of trial regarding pain, tenesmus, itching and swelling in both groups.Based on improvement in both groups, Althaea seed extract may be recommended as an better alternative to Daflon (Table 1).

Furthermore, there was no difference observed in various blood chemistry parameters between the two groups before and after the trial (Table 2).

Table 1: Efficacy profile of Althaea extract and Daflon groups

Symptom	Time	Drug		P value
		Trial Group(Althaea extract) Out of 60	Control Group (Daflon) Out of 60	
Pain	Baseline	56(93.34%)	54(90.5%)	0.510
	After One Day	11(18.33%)	22(36.66%)	0.001*
	After Three Days	4(6.66%)	14(23.33%)	0.002*
	After Seven Days	1(1.66%)	1(1.66%)	0.497
Bleeding	Baseline	55(91.67%)	54(90.2%)	0.751
	After One Day	19(31.66%)	32(53.33%)	0.001*
	After Three Days	7(11.66%)	17(28.337%)	0.007*
	After Seven Days	2(3.33%)	10(16.66%)	0.033*
Tenesmus	Baseline	58(96.67%)	56(93.34%)	0.403
	After One Day	20(33.33)	33(55%)	0.042*
	After Three Days	10(16.66%)	14(23.33%)	0.344
	After Seven Days	3(5%)	3(5%)	0.404
Swelling	Baseline	58(96.67%)	56(93.34%)	0.678
	After One Day	14(23.34%)	28(46.66%)	0.011*
	After Three Days	6(9.9%)	16(26.66%)	0.030*
	After Seven Days	1(1.67%)	2(3.33%)	0.365
Itching	Baseline	59(98.34%)	58(96.65%)	0.560
	After One Day	24(40%)	32(53.33%)	0.143
	After Three Days	10(16.66%)	23(38.33%)	0.024*
	After Seven Days	2(3.33%)	3(5%)	0.365

Table 2. Blood parameters comparison before and after study

Parametre	Desirable Range	Althaea Group			Daflon Group		
		Value Before	Value After	p-value	Value Before	Value After	Value After
Hb	12.8-17.8 gm/dL	12.16±1.43	12.16±1.391	>0.05	12.68±1.07	12.68±1.07	>0.05
RBC	4.4-5.8 million/ml	5.7±0.30	5.6±0.31	>0.05	5.7±0.27	5.7±0.26	>0.05
TLC	4000-11000/mcL	7875±1599	7877±1366	>0.05	7876±1577	7876±1464	>0.05
Platelets	150000-450000 cells/mcL	328244±41879	328244±43525	>0.05	328124±41506	328124±39785	>0.05
Blood sugar	<140 mg/dL	126.23±21.88	125.12±19.78	>0.05	129.34±20.12	129.35±21.97	>0.05
Bilirubin	Upto 1 mg/dL	0.78±0.16	.78±0.17	>0.05	.79±.084	.79±.091	>0.05
ALT (SGPT)	10-55 U/L	35.81±7.15	35.82±6.88	>0.05	34.29±9.17	34.98±7.16	>0.05
AST (SGOT)	10-40 U/L	32.99±6.76	32.98±6.57	>0.05	29.23±6.88	29.24±6.72	>0.05
ALP	45-115 U/L	134.78±11.04	134.69±11.09	>0.05	131.67±12.32	131.66±12.33	>0.05
Blood urea	15-43 mg/dL	13.66±4.33	13.66±4.24	>0.05	14.98±5.31	14.98±5.24	>0.05
S.Creatinine	upto1.5 mg/dL	.758±.08	.757±.07	>0.05	.757±.07	.756±.08	>0.05
Total Cholesterol	Less than 200 mg/dL	175.19±13.67	175.16±13.85	>0.05	176.20±14.59	176.591±14.54	>0.05
S.Triglycerides	40-150 mg/dL	139.33±11.56	139.31±11.07	>0.05	140.23±12.63	140.22±12.64	>0.05
HDL	>45 mg/dL	39.66±5.45	39.65±5.39	>0.05	39.86±6.24	39.86±6.27	>0.05
LDL	<130 mg/dL	129.62±11.98	129.62±11.71	>0.05	130.62±11.77	130.63±11.84	>0.05

**DISCUSSION**

Many natural products have been discovered from traditional medicines, including aspirin from willow bark, artemisinin from sweet wormwood, and morphine from the opium poppy<sup>1</sup>. These compounds have been used to develop drugs for a variety of conditions, including pain, inflammation, and malaria<sup>4</sup>.

Researchers have been exploring traditional medicines as a potential source for introducing new natural drugs. Traditional medicines have been used for centuries in many cultures, and they often have a long history of safe use. They may also contain bioactive compounds that have therapeutic effects. There are some evidence-based studies based on personal observations that describe the medicinal uses of various herbs containing bioflavonoids for treating hemorrhoids. However, there is a

significant lack of studies in this field, despite growing interest in developed and developing countries<sup>6</sup>.

Researchers are exploring traditional medicines as a potential alternative source for introducing new and effective natural therapies, given that there are effective therapeutic options available.

An experiment of comparative clinical trial was carried out on individuals experiencing acute hemorrhoids using a design that was randomized, active-controlled, double-blind, and multicenter<sup>7</sup>. The patients were randomly allocated into two parallel groups, with each group comprising of 60 patients who received treatment for a period of one week<sup>8</sup>. The trial was carried out with the assistance of family physicians who were handpicked at random from the urban community of Lahore<sup>9</sup>.

At the onset of the treatment, as well as on the 1st, 3rd and 7th day of the medication, the clinical indications and manifestations of hemorrhoids were evaluated for both sets of patients. The research highlighted the significance of conventional medicine by juxtaposing it against a herbal treatment. Interestingly, it concluded that the herbal therapy was not an inferior alternative<sup>10</sup>. On the contrary, it was found to be more effective than the traditional medication in managing certain aspects of the condition, such as bleeding. Furthermore, other clinical indications and manifestations were also treated more efficiently using the herbal remedy. Thus, the extract derived from the seeds of *Althaea* can be deemed a new and innovative substitute for individuals who are afflicted by hemorrhoids.

## CONCLUSION

The efficacy of *Althaea* seed extract in ameliorating the ano-rectal conditions that arise due to hemorrhoids was noted. Its ability to expedite the process of healing renders it a noteworthy substitute for the medicines that are presently in circulation.

**Conflict of interest:** Nil

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