Original Article

Role of Aegle Marmelos Extract in the Management of Haemorrhoids As Compared With Daflon: A Randomized, Active Controlled, Multicentric Study

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Abstract

Objective: To evaluate the efficacy of a herbal preparation, Aegle marmelos (AM)Extract with Daflonin in haemorrhoids.

Methodology: Adouble blind, multicentric comparative clinical randomized trial was conducted with acute haemorrhoids cases divided into two equal and parallel groups (70 each) for one week through randomly selected general physicians in Lahore urban community.

Interventions: Administration of 2 capsules of AM extract twice a day for a week or Daflon (500 mg) in a dose of 6 tablets per day for the first 4 days, followed by 4 tablets per day upto one week.

Main outcome measures: Measurable relief in symptoms and signs and patient tolerance.

Results: Characteristics at baseline were near about similar between the two groups. The clinical severity of inflammation, congestion, tenesmus, hematochezia and oedema diminished in both groups, but more quicker in the AME group by the end of 24 hours. Symptoms improved in both groups from day 1 to day 7. Acceptability was good in both groups. No adverse effect was noted in both groups during and at the end of trial.

Conclusion: Both AM extract and Daflon were found equally effective in resolving clinical picture of haemorrhoids. However AM extract acted more quickly.

Keywords: Aegle Marmelos Extract, Daflon, Hemorrhoids

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How to cite:
Ahmad M, Ahmad M, Arshad S, Chughtai AS, Ahmad H, Ali M, et al. Role of Aegle Marmelos Extract in the Management of Haemorrhoids As Compared With Daflon: A Randomized, Active Controlled, Multicentric Study. JRLMC. 2023;

Received:16th Aug, 2023 Revised:28th Sep, 2023 Accepted:13th Nov, 2023

Introduction

Medicinal plants are used in herbal research. Many studies revealed that Aegle marmelos possessed ulcer healing as well asanti-inflammatory properties[1] Haemorrhoids also known as piles, are varicose veins. They are in fact swollen veins in lower rectal region and constitute about 50% of colorectal investigations.[1]

Haemorrhoids are classified into either internal and external based on location above or below dentate line respectively and are responsible for agonizing sypmtoms like burnibg, pain, itching and swelling. Internal haemorrhoidsmay be categorized into the following grades:

I. No prolapse.

II. Prolapse upon defecation and reduce spontaneously

III. Prolapse upon defecation but manually reduced.

IV. Prolapse upon defecation but manually reduction not possible.[2]

Overall estimated worldwide prevalence of haemorrhoidesranges from 2.9% to 27.9%[3] The age distribution elaborates a peak from 45 to 65 years followed by decline after 65 years of age. The disease is not common before 20 years and above 70 years of age. Males were found more affected.4 In US, haemorrhoids can be labelled as most common OPD gastrointestinal diag-

nosis.[5,8] In Japan the prevalence of haemorrhoids ranges from 4 to 55%.[6] Regarding subcontinent, India has 75% population affected.[7]

Despite numerous efforts, the true etiopathogenesis of haemorrhoidal disease still remains elusive.[9] The most common causes of haemorrhoids include straining with bowel movements either due to chronic constipation or hard stools, constant sitting, diarrhea, chronic cough, severe coughing, prolonged sitting on the toilet, heavy weight lifting, poorly managed childbirth, anal intercourse, poor muscle tone, obesity, lack of regular exercise, water retention in women having premenstrual syndrome or menstruation and poor posture.[10]

There are so many local treatments available in our community mostly herbal. Bael (Aegle marmelos) has been documented as an effective therapy for chronic dysentery and irritable bowel syndrome (IBS). Till today there has been no study on the effectiveness of Aegle marmelos extract in haemorrhoidesinspite of its documented alterative, anodyne, antioxidant, astringent and laxative action .Bael fruit itself is a bit laxative due to its mucilage content. It may arrest bleeding. This forms a coating on the stomach mucosa and thus helps heal ulcers.[11] There have been so many studies conducted in human beings.[12,13,14,15]

As already mentioned there is very little information available regarding effective role of Aegle marmelos in acute haemorrhoids so there is dire need to determine the safety profile of AM extract in humans, find out the efficacy of AM extract in haemorrhoids, compare efficacy of AM extract with Daflon and render the community aware of the efficacy of Aegle marmelos extract in haemorrhoids .

Methodology

100 grams dry pulp powder of Aegle marmelos was undergone anaerobic sublimation followed by ethanolic-aqueous extraction. The resulting extract was kept in open place to evaporate alcoholic content. The residual pulp extract was used in 5 ppm concentration given in the undergoing trial.

The control preparation, Dafloncontained 450 mg of diosmin, and 50 mg of hesperidine per tablet.

A prospective clinical study was conducted on consecutive 140 patients suffering from haemorrhoids with the objective of compare its efficacy against Daflon in patients suffering from acute haemorrhoids.

Institutional Review Board(IRB) Rashid Latif Medical College, Lahore approved the study. Eligibility criteria was to include male patients above the age of 18 years suffering from haemorrhoids complaining of hematochezia, pain, burning ,swelling and itching were included in this study. Patients already under treatment process and non-willing persons were excluded from the study. It was a community based pilot study, multicentric, randomized, double blind, active controlled, comparative clinical trial of 1 week duration conducted in randomly selected community settings with the help of family physicians. Calculation through Epi-info at at 95% confidence level with 3.823% current prevalence rate of hemorrhoids in Pakistan and keeping the worst acceptable at 7%, the sample size was estimated as 140. Informed consent duly signed by eligible patients was taken before participation in the trial. All personal informations were kept confidential. Participants were assigned randomly (1:1) either to receive AM extract (trial group) 2 capsules twice a day for a week or to receive Daflon 500 mg (control group) in a dose of 6 tablets per day for the first 4 days, followed by 4 tablets per day for a week. After taking due history, the trial was started. The patients were instructed to visit after 24 hours, 3 days and at the end of 1st week. Efficacy criteria were based on clinical signs & symptoms Data was collected, compiled and analyzed through SPSS version 25. Routine bloodtests (CBC, Hb%, LFT, RFT, Lipid profile ,BS and) were carried out before start and after completion of trial.

Results

After recording base line data where there was no significant difference in Trial and Daflon group regarding haemorrhoidal symptoms, first observation was made after 24 hours followed by after 3 days and finally after one week. It was evident that there was reduction in symptoms but there was no significant difference in symptoms in two groups except swelling and irritation In the study, difference in Itching/ Irritation after defecation between both groups was statistically significant at day 3 (p-value 0.049) and day 7(p-value 0.044). AM extract group was providing better compliance. Similarly difference between both groups regarding swelling was statistically significantly different after 24 hours (p-value 0.004) and after 3 days (p-value 0.049) and AM extract group was better than Daflon group. See Table 01. Also there was no difference in various blood para-meters in both groups before and after trial. See Table 02.

Discussion

Bioflavonoids found in herbshave been used haemorrhoides but not adequately described in the literature. In developed countries herbal products are gaining importance and taking place of costly modern medications having adverse effects.[1,2] A randomized control trial was conducted in randomly selected community settings with the help of general physicians. The clinical picture was recorded for control and trial group before

Table 1: *Efficacy Profile of AMextract and Daflon Groups*

Symptoms	Time	Drug		Total	p-value
		Aegle	Daflon		
Pain	Baseline	40(57.1%)	38(54.3%)	78(55.7%)	0.734
	After Day 1	10(14.3%)	12(17.1%)	22(15.7%)	0.642
	After Day 3	6(8.6%)	6(8.6%)	12(8.6%)	1.000
	After Day 7	0(0.0%)	2(2.9%)	2(1.4%)	0.248
Bleeding	Baseline	16(22.9%)	18(25.7%)	34(24.3%)	0.693
	After Day 1	2(2.9%)	5(7.1%)	7(5.0%)	0.245
	After Day 3	1(1.4%)	3(4.3%)	4(2.9%)	0.310
	After Day 7	0(0.0%)	0(0.0%)	0(0.0%)	
Tenesmus	Baseline	62(88.6%)	57(81.4%)	119(85.0%)	0.237
	After Day 1	10(14.3%)	12(17.1%)	22(15.7%)	0.642
	After Day 3	6(8.6%)	7(10.0%)	13(9.3%)	0.771
	After Day 7	0(0.0%)	2(2.9%)	2(1.4%)	0.154
Itching/ Irritation after defecation	Baseline	59(84.3%)	60(85.7%)	119(85.0%)	0.813
	After Day 1	13(18.6%)	20(28.6%)	33(23.6%)	0.163
	After Day 3	7(10.0%)	14(20.0%)	21(15.0%)	0.049*
	After Day 7	0(0.0%)	4(5.7%)	4(2.9%)	0.044*
Swelling	Baseline	58(82.9%)	54(77.1%)	112(80.0%)	0.398
	After Day 1	14(20.0%)	30(42.9%)	44(31.4%)	0.004*
	After Day 3	7(10.0%)	14(20.0%)	21(15.0%)	0.049*
	After Day 7	0(0.0%)	3(4.3%)	3 (2.1%)	0.080

Chi Square test p-value significant at 0.05

Table 2: *Safety Profile.Comparison of Blood Parameters before and after Trial in each Group*

		CPE Group			Placebo Group		
		Before	After	p-value	Before	After	p-value
Parametre	**Desirable Range**	**Mean±SD**	**Mean±SD**		**Mean±SD**	**Mean±SD**	
Hb	13-18 gm/dL	12.16±1.41	12.22±1.33	>0.05 (NS)	12.11±1.31	12.68±1.08	>0.05 (NS)
RBC	4.4-5.8million/ml	4.9±0.28	5.8±0.31	>0.05 (NS)	4.9±0.28	5.6±0.27	>0.05 (NS)
TLC	4000-11000/mcL	7865±15976	7867±1364	>0.05 (NS)	7855±1567	7859±1453	>0.05 (NS)
Platelets	150000-450000 cells/mcL	328234±41877	328412±43523	>0.05 (NS)	328114±41502	328124±38775	>0.05 (NS)
Blood sugar	<140 mg/dL	128.2.34±21.87	129.54±20.77	>0.05 (NS)	130.34±20.88	131.34±21.87	>0.05 (NS)
Bilirubin	0.2 to 1.2 mg/dL	.81±.15	.80±.33	>0.05 (NS)	.82±.08	.82±.09	>0.05 (NS)
ALT (SGPT).	<50 U/L	30.29±7.14	30.22±6.88	>0.05 (NS)	31.29±7.15	30.21±7.04	>0.05 (NS)
AST (SGOT)	<50 U/L	29.99±6.87	28.98±6.15	>0.05 (NS)	30.02±6.89	29.24±6.42	>0.05 (NS)
ALP	<258 U/L	132.77±12.04	132.68±11.09	>0.05 (NS)	131.66±12.31	131.11±12.78	>0.05 (NS)
Blood urea	15-43 mg/dL	14.66±4.34	13.32±3.13	>0.05 (NS)	14.97±4.33	15.21±5.23	>0.05 (NS)
S.Creatinine	0.5-1.5 mg/dL	.747±.08	.731±.07	>0.05 (NS)	.748±.07	.752±.09	>0.05 (NS)
Total Cholesterol	<200 mg/dL	174.58±14.87	174.16.±12.23	>0.05 (NS)	172.20±13.73	171.591± 15.63	>0.05 (NS)
S.Triglyceride	<150 mg/dL	160.23±11.67	159.11±16.08	>0.05 (NS)	160.11±11.52	158.29±21.65	>0.05 (NS)
HDL	>45 mg/dL	39.66±6.66	39.56±6.32	>0.05 (NS)	39.87±6.23	39.76±6.18	>0.05 (NS)
LDL	<130 mg/dL	129.72±11.74	129.73±12.37	>0.05 (NS)	130.52±11.78	130.63±11.54	>0.05 (NS)

start of trial followed by visit after 24 hours, 3 days, and 7 days of treatment. Symptomatic relief was observed and recorded i.e., reduction in bleeding, swelling, pain, tenesmus, itching and irritation. The study results revealed that the AM extract was quite effective in allieviating haemorrhoidal complaints.

The study, although with a limited sample size highlighted more efficacy of AM extract over Daflon 500 mg, in improving the haemorrhoidal symptoms in the patients. Prompt resolution of bleeding symptom, pain and swelling within 24 hours was remarkable feature of AM extract in comparison with Daflon. The study highlighted the significance of herbal medicine in the normal routine of a haemorrhoidal patient till the need felt for surgery.[12,13,14,15]

Conclusion

AM extract was found to be more effective as compared with Daflon in improving haemorrhoidal conditions rather its remarkable effect of being prompt in action. AM extract may be considered as novel alternative remedy for patients with haemorrhoids.

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