

Malva Sylvestris in the treatment of hand eczema

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Background: Hand eczema is one of the most common dermatologic diseases requiring treatment but common therapeutics such as corticosteroids and anti-histamines have numerous side effects. So, use of herbal agents, which generally have no major side effects, may be useful especially if their efficacy is established. *Malva Sylvestris* (MS) is a tropical plant in Iran with cooling characteristics. Hence, in this study, its efficacy in of the treatment of hand eczema was evaluated.

Methods: In this randomized clinical trial, 50 patients with hand eczema who were visited at Shohada-e Tajrish and Loghman hospitals, Tehran, Iran, between 2006 and 2008, were recruited and divided into two groups. In the first group, MS 4% ointment was applied twice a day and in the other group, placebo ointment was used. The efficacy and side effects were evaluated three and six weeks after beginning of the treatment.

Results: Mean age of the patients was 37.3 years and 35.6 years in MS and placebo groups, respectively ($P > 0.05$). There were no therapeutic adverse effects in the groups. There was a statistically significant difference in all measured scores between two groups in the first and second follow-up sessions ($P < 0.0001$).

Conclusion: *Malva Sylvestris* seems to be a safe and effective therapeutic modality for the treatment of hand eczema and can be used as an optimal substitute for corticosteroids and anti-histamines.

Keywords: *Malva Sylvestris*, herbal drugs, dermatitis, eczema, treatment

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INTRODUCTION

Hand eczema is one of the most common dermatological diseases requiring treatment^{1,2} but the treatment usually fails due to the relapsing feature of hand eczema³. On the other hand, use of conventional drugs such as corticosteroids and anti-histamines for a long time is not without adverse effects⁴⁻⁶. Hence, using some natural drugs, especially herbal ones, would be beneficial. Also, there has been a resurgence in public's demand for herbal remedies in recent years⁷. Three categories of herbs used for people with hand eczema: anti-inflammatory and herbs that affect the immune

system (immunomodulators), astringents (herbs that bind to fluids and exudates so they are only helpful when weeping eczema is present), and herbs that affect the liver (also called alterative, are poorly researched). Herbal drugs are usually without considerable side effects and if their efficacy is established, they can be of use for the treatment of atopic dermatitis and hand eczema⁸.

Among available herbal derivatives, the efficacy of some such as *Phenol*, *Chamomile*, *Calendula*, *Chickweed*, *Menthol* and *Aloe Vera* has been established, especially due to their cooling characteristics and few side effects⁸. However, the efficacy of other herbal agents with cooling

properties may also be evaluated in clinical settings among volunteer subjects. One of these plants is *Malva Sylvestris* (MS). This plant is a tropical species which grows in some regions of the Middle East, especially Iran. It is also one of the most important medicinal species in southern Italy. MS is important in topical remedies for the treatment of heat- and diaper- rash, bruise and some other common diseases in Italy ^{9,10}. It is documented that phytoalexin, malvone A (2-methyl-3-methoxy-5,6-dihydroxy-1,4-naphthoquinone) is also induced in MS ¹¹. MS leaves and flowers contain high amounts of mucilage which is made up of complex carbohydrates and gives MS most of its soothing activity, though flavonoids and anthocyanidins may also contribute. In herbal medicine, MS is classified as a demulcent—a soothing agent that counters irritation and mild inflammation ^{12,13}. Although this plant is used as a drug in traditional medicine, there is no academically performed clinical trial about it and therefore, this study was conducted to compare the efficacy of this agent with placebo.

PATIENTS AND METHODS

In this randomized clinical trial, 123 patients with hand eczema who were visited at Shohada-e-Tajrish and Loghman-e-Hakim hospitals, Tehran, Iran, from 2007 to 2008, were recruited. Among them, 50 patients with hand eczema were included based on clinical symptoms, physical examination, and personal and family history. Two dermatologists examined all patients to exclude other differential diagnoses, such as hand psoriasis, and confirmed the clinical diagnosis of hand eczema. Pregnant women, patients with allergic reactions/anaphylaxis to MS, and history of corticosteroid or anti-histamine consumption in the last six weeks or use of topical steroid in the last three weeks were excluded.

After receiving explanation regarding the study protocol, all participants signed informed consent forms (according to Helsinki Declaration). We then divided the patients into two groups using a table of random numbers. Group A received MS 4% ointment in a tube without a label and group B received placebo in a similar tube which only contained eucerin. Both groups were given with similar instructions to use the ointments twice

Table 1. Eczema Area and Severity Index (EASI) scoring system

Severity	erythema, infiltration/population, lichenification, and excoriation	Score
	None	1
	Mild	2
	Moderate	3
	Severe	4

daily. Only one finger tip unit was used for each affected 2-3% of the body surface which was equal to one hand (four FTUs for both hands every day). All patients were followed up for six weeks after treatment.

Both groups were similar regarding demographic features ($P > 0.05$). The therapeutic results for erythema, edema, excoriation, lichenification, dryness, oozing, and itching (according to calculated scores) were compared between the two groups three and six weeks after beginning of the treatment. The severity of erythema, excoriation and lichenification was evaluated according to the eczema area severity index (EASI) scoring (Table 1) ¹⁴. Edema, dryness, itching, and oozing were also scored similar to the EASI severity section.

Statistical analysis

Data were analyzed using SPSS (version 13.0) software [Statistical Procedures for Social Sciences; Chicago, Illinois, USA]. Independent-sample T, Chi square, and Fisher Exact tests were used for comparison. P values less than 0.05 were considered significant.

RESULTS

Thirty-eight patients were female and 12 were male. Both groups were sex-matched (18 and 20 female patients in MS and placebo groups, respectively). Mean age of the patients was 37.3 and 35.6 years in MS and placebo groups, respectively ($P > 0.05$). No therapeutic adverse effects were seen in the two groups. Table 2 shows the outcomes at baseline and after three and six weeks. There was a statistically significant difference between two groups for all measured scores at the first and second follow-up sessions ($P < 0.0001$).

Table 2. Severity scores at baseline and after three and six weeks in the two groups*

	MS			Placebo		
	Baseline	3 rd week	6 th week	Baseline	3 rd week	6 th week
Mean erythema score	1.5	1.1	0.6	1.4	1.3	1.2
Mean edema score	0.8	0.5	0.3	0.8	0.8	0.7
Mean excoriation score	1.5	1	0.6	1.6	1.5	1.5
Mean lichenification score	1.6	1.2	0.7	1.7	1.8	1.7
Mean dryness score	2	1.4	0.9	2.1	2	1.9
Mean itching score	0.2	0.1	0.1	0.3	0.4	0.4
Mean oozing score	1.7	1.2	0.8	1.7	1.6	1.5

*There was a statistically significant difference between two groups in all features ($P < 0.0001$)

DISCUSSION

Hand eczema is a common dermatologic disease worldwide ^{1,2}. The relapsing characteristic of the disease is the main issue of concern in patients ⁴. In this study, 50 patients were evaluated. Our results showed that MS had a good efficacy without side effects in the treatment of hand eczema in comparison with placebo.

MS is a tropical plant which grows in Southern Europe and Asia. Its leaves, flowers, and shoots are used for therapeutic reasons. It has been historically used as a medicine, internally as a demulcent using its seed extract or boiled young leaves, and externally as an emollient ^{15,16}. There are few reports regarding its efficacy in the treatment of dermatologic disorders, especially hand eczema and it has proved to be a safe and effective therapeutic modality ^{9,15,16}.

Corticosteroids and anti-histamines, as conventional therapeutics, are generally used with caution due to their side effects while herbal agents are generally well-tolerated.

Previous studies have documented the efficacy of MS in the treatment of some other diseases, especially febrile ones ^{16,17}. Also, this agent has been used as a softener in some conditions ¹⁶. Although MS is classified as a demulcent, our study proved its efficacy in successful treatment of hand eczema for the first time. Hence, the importance of our study lies in introducing a new herbal modality for treating hand eczema. Another interesting finding was that this medicine caused no side effects, even allergic reactions. Also, all patients were willing to attend the follow-up sessions.

In conclusion, our study showed that MS, as a safe and effective therapeutic modality, can be used as an optimal substitute for corticosteroids and anti-histamines for the treatment of hand eczema.

Finally, it is suggested that further studies with longer follow-up periods be conducted to confirm our findings.

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