

Original Article

Therapeutic evaluation of a Unani herbo-mineral formulation in chronic urticaria

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Abstract *Background* Chronic urticaria (*Shara*) often poses a therapeutic challenge. Alternative medicine, including herbal treatment is gaining popularity for the treatment of refractory skin diseases.

Objective To assess the safety and efficacy of a Unani herbo-mineral formulation in the management of chronic urticaria.

Patients and methods The randomized, single-blind, placebo-controlled study was carried out at outpatient department of Medicine, National Institute of Unani Medicine Hospital, Bangalore, from 15th April, 2009 to 15th April, 2010. Diagnosed patients of chronic urticaria, qualifying the inclusion criteria, were enrolled in the clinical trial. The patients were divided randomly into test and control groups after obtaining their informed consents. Test group (20 patients) was administered a herbo-mineral formulation twice daily whereas control group (10 patients) were given placebo orally. The duration of this trial was 4 weeks and follow up was done weekly. The efficacy of the test drug was assessed by the total sign and symptom score (TSSS) and severity of itching, whealing and erythema.

Results The test drug produced significant effect on itching, wheals, erythema and on TSSS without causing any untoward effect or adverse reactions as observed by the safety parameters.

Conclusion The herbo-mineral formulation can be used safely and effectively for the treatment of chronic urticaria.

Keywords

Urticaria, *Shara*, Unani herbo-mineral formulation.

Introduction

Urticaria is a skin reaction pattern characterized by transient, pruritic, edematous, erythematous papules or wheals, frequently with central clearing, which may vary in size from a few millimeters to many centimeters in diameter. Individual lesions are transient, lasting 12 to 24 hours or less and in most cases

less than 4 hours.¹ Urticarial lesions can involve any area of the body from the scalp to the soles of feet. The most common sites for urticaria are the extremities and face. It may occur separately or may be associated with angioedema.¹ It is a common skin disorder and affects 15-25% of all people at least once in their life time.² Although persons of any age group may experience urticaria and/or angioedema, the urticaria occurs most frequently after adolescence, with the highest incidence in young adults (20-40 years). Clinically, urticaria is classified into acute (duration <6 weeks) and chronic (duration >6 weeks) and may be caused by numerous factors both immunologic and non-

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immunologic, that result in vasodilatation and transudation of fluid from small coetaneous blood vessels.³ Chronic urticaria is twice as common in women as in men. A study showed that out of 500 cases of urticaria, 37% were suffering from physical urticaria.³

The major etiological factors include drugs⁹ (aspirin, penicillin, sedatives, tranquilizers etc), foods and food preservatives (cheese, fish, eggs, milk, nuts, benzoic acid derivatives etc), inhalant allergens (pollens, mold spores, animal dander etc), infections (teeth, tonsils, sinuses, chest etc), insect bites and stings (fleas, mites, bedbugs etc), penetrants and contactants (foods, textiles, medicaments, chemicals cosmetics etc), physical stimuli (friction, pressure, vibration, heat, cold, sweat etc), internal diseases and psychological factors.⁴

In Unani system of medicine *Shara* is synonymously described as urticaria. It was first described by Hippocrates.⁵ The actual cause of *Shara* is believed to be the *fassade dam* (blood impairment) caused by the *vapors of dame merari* (bilious blood) or *balghame boraqi* (acidic phlegm) coming towards the skin or periphery of the body.^{6,7,8}

A number of therapeutic measures have been proposed by the modern medicine to treat the urticaria. Most of them provide symptomatic relief to the patient but the long term use of these drugs have been reported however, to cause many side effects. In this back drop, it is being realized that the traditional systems of medicine in general and Unani system in particular, which are known for their healing properties particularly in the chronic diseases, can be used effectively in this disease. In this system of medicine a number of single and compound drugs are being used in the management of urticaria since Greco-Arabic period. The principle of treatment is aimed at the alteration or removal of morbid matter,

which is the actual culprit for the genesis of pathology leading to development of the disease. In view of the above fact, a compound formulation possessing *musakkin (sedative)*, *tadeele dam wa safra* and *tasfiya dam* (blood purifier)^{9,10,11} properties was selected for the study as it has been observed that abnormal *safra (bile) and dam (blood)* are mostly responsible for the disease.¹²

The objective of present study was to evaluate the therapeutic efficacy and safety of a Unani formulation in the management of chronic urticaria.

Patients and methods

This was a randomized single-blind, placebo-controlled study conducted at the outpatient department of National Institute of Unani Medicine, Bangalore, India, from 15th April, 2009 to 15th April, 2010. 44 patients of chronic urticaria (> 6 weeks duration), in the age group of 10-60 years, diagnosed clinically were enrolled in the study. The patients were selected on the basis of history, physical examination and investigations. All the findings were recorded on the case record pro forma. Patients fulfilling the inclusion criteria were asked to sign the informed consent. Pregnant and lactating women, patients below 10 and above 60 years of age and those with scabies, eczema, urticarial vasculitis etc. were excluded from the study. Similarly, patients who had taken any local or systemic treatment for their disease in the past one month prior to the trial were also excluded.

Routine investigations including hemogram, urine, stool, liver function tests, renal function tests, blood sugar (random) were carried out before and after treatment in order to exclude the other systemic ailments and to assess the adverse effects of the drug formulation on liver and kidney.

The patients were randomly allocated into test and control groups by employing computer generated random table. The test group comprised of 22 patients in which test drug was administered orally twice daily while control group comprised of 22 patients who were given placebo drug orally. The duration of this trial was 4 weeks and follow up was done weekly. But 2 patients from test group and 12 patients from control group did not follow up and hence were excluded from the study, leaving behind 20 patients in test and 10 patients in control group who completed the protocol duration completely.

Statistical analysis was done only on 30 patients who completed the course of treatment. The severity of 3 different symptoms and signs (itching, wheals and erythema) was rated on a 4-point scale (0=absent, 1=mild, 2=moderate, 3=severe for itching and erythema; 0=absent, <10=mild, >10=moderate, whole body covered with wheals=severe for wheals). These were summed for each patient at each assessment stage to obtain a total symptom and sign scale (TSSS) with a maximum value of 9 points. TSSS is an arbitrary grading scale. Then the results were tabulated and analysed by a suitable statistical test (Students t test).

Composition of test drug

Kushta sadaf (pearl shell) and *sufoofe bekhe asrol* (powder of *Rauwolfia serpentina*) were mixed together in equal quantity and the patients were advised to take 1gm of it twice a day on empty stomach with *zulale* of 10gm *tamarhindi* (decanted infusion of *Tamarindus indica*) for 4 weeks; whereas 1gm of wheat flour was given to placebo group for the same duration.

Results

Demographic data of both groups is shown in

Table 1 Distribution of patients according to age, gender, dietary habits and duration of illness.

	Test group N=20	Controls N=10
<i>Age (years)</i>		
11-20	2	1
21-30	5	3
31-40	6	4
41-50	4	1
51-60	3	1
Total	20	10
<i>Gender</i>		
Male	7	3
Female	13	7
Total	20	10
<i>Dietary habits</i>		
Vegetarian	8	4
Non Veg.	12	6
Total	20	10
<i>Duration of illness</i>		
2-5 months	3	1
6 months-1 year	10	6
2-5 years	7	3

Table 1. The effect of test drug and placebo on itching, erythema and whealing is depicted in **Tables 2-4**. A gradual reduction in the severity of these three parameters was seen with the test drug. **Table 5** shows a significant difference between the efficacy of test drug over placebo ($p<0.05$).

No clinical side effects and hematological or biochemical derangements were seen in either group.

Discussion

The test drug in our study showed a significant effect on itching as compared to the placebo. The relief in the itching may be due to *tadeele dam wa safra* properties of *tamarhindi*¹³⁻¹⁶ and *kushta sadaf*¹³ and *musakkin* effect¹⁷⁻²⁸ of *asrol*. These drugs lessened the *hiddat* of *safra* and *dam* that is primarily responsible for itching.

Similarly, there was a marked improvement in wheals formation as 75% patients got complete relief. This improvement may be attributed to the *mudir (diuretic)*²⁴ effect of *asrol* and *muhallil (antiinflammatory)* and

Table 2 Effect of test drug and placebo on itching.

Group	Severity	Day 0	Day 14	Day 28
Test N=20	Mild	4 (20%)	8 (40%)	5 (25%)
	Moderate	6 (30%)	7 (35%)	0
	Severe	10 (50%)	2 (10%)	0
	Cured	0	3 (15%)	15 (75%)
Controls N=10	Mild	3 (30%)	3	3 (30%)
	Moderate	2 (20%)	2	2 (20%)
	Severe	5 (50%)	5	5 (50%)
	Cured	0	0	0

Table 3 Effect of test drug and placebo on wheals.

Group	Severity	Day 0	Day 14	Day 28
Test N=20	Mild	2(10%)	7	5(25%)
	Moderate	7(35%)	6	0
	Severe	11(55%)	2	0
	Cured	0	5	15(75%)
Control N=10	Mild	5(50%)	5	5(50%)
	Moderate	2(20%)	2	2(20%)
	Severe	3(30%)	3	3(30%)
	Cured	0	0	0

Table 4 Effect of test drug and placebo on erythema.

Group	Severity	Day 0	Day 14	Day 28
Test N=20	Mild	4 (20%)	8	3 (15%)
	Moderate	7 (35%)	5	0
	Severe	9(45%)	2	0
	Cured	0	5	17(85%)
Control N=10	Mild	3(30%)	3	3(30%)
	Moderate	4(40%)	4	4(40%)
	Severe	3(30%)	3	3(30%)
	Cured	0	0	0

Table 5 Effect of test drugs and placebo on total symptom and signs scale (TSSS)

TSSS	Test	Drug
Before treatment	7	6.6
After treatment	1	6.6

tadeele safra effects of *tamarhindi*.^{13-16,19-28} In placebo group, there was no improvement in wheals and it remained same even after the end of treatment (**Table 3**).

As far as erythema is concerned, there was a marked improvement in erythema as 85% of patients showed complete cure. In contrast, in the placebo group, there was no improvement in erythema and it remained same as at baseline (**Table 4**). This improvement in erythema might be due to *muhali*¹⁹⁻²⁸ and *tadeele safra* effects¹³⁻¹⁶ of *tamarhindi* and *musakkin* effect¹⁷⁻²⁸ of *asrol*.

In test group, the mean TSSS was 7 at baseline and it reduced to 1 after treatment ($p < 0.1$) whereas the mean TSSS in placebo group did not change from 6.6. The effect of test drugs was found to be significantly superior over placebo ($p > 0.01$). The overall improvement might be due to reduction of the *hiddat* (excessive heat) of *khilte safra*. This is in consonance with the properties of *zulale tamarhindi* and *kushta sadaf* as described by Najmul Ghani. It may also be due to the *mussakin* (tranquilizing) properties of *asrol* that suppress the psychogenic factor of urticaria. *Kushta sadaf* (calcium oxide) may probably produce mast cell stabilizing effect responsible for the relief of symptoms.

Results of our study showed that the safety

profile of test drugs is similar to that of placebo.

Conclusion

Our study concludes that herbal medicines have a promising role in the treatment of chronic urticaria in terms of efficacy and safety.

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