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Clinical evaluation of efficacy of *Majoon Ushba* and *Roghane Hindi* in the management of psoriasis: A randomized single-blind, placebo-controlled study

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ABSTRACT

Psoriasis is a common dermatological disease affecting up to 1–2% of the world's population. It is associated with both organic and psychosocial complications like psoriatic arthropathy, nephritis, infection, hyperuricemia, hypoproteinemia, depression, and stress, and is responsible for hindering patients' daily activities. The present study was conducted to assess the safety and efficacy of two pharmacopeial Unani formulations (*Majoon Ushba* and *Roghane Hindi*) in the management of psoriasis on scientific parameters. Thirty diagnosed psoriasis patients, satisfying the inclusion criteria, were selected for a randomized, single-blind, placebo-controlled study in the Department of Moalajat (Medicine), National Institute of Unani Medicine, Bangalore. The patients were divided by the method of Random Table Numbers into test and control groups after obtaining informed consent. The experimental group comprised 20 patients to whom *Majoon Ushba* 5 g was administered orally twice daily and *Roghane Hindi* was applied locally twice daily. The control group comprised 10 patients who were given placebo drugs orally and topically. The duration of the trial was 8 weeks and follow-up was done fortnightly. The severity of psoriasis and efficacy of the drug was assessed by the Psoriasis Area and Severity Index (PASI) Scale. The results of both groups were compared and analyzed statistically. The study showed significant reduction in the PASI score in the test group ($P < 0.01$) as compared to placebo. No obnoxious side effects were observed in the test group: toxicological parameters were within normal limits even after 2 months of treatment. It was therefore concluded that *Majoon Ushba* and *Roghane Hindi* are safe and effective in the management of psoriasis

Key words: *Majoon Ushba*, Psoriasis Area and Severity Index Scale, psoriasis, *Roghane Hindi*, Unani formulations

INTRODUCTION

Psoriasis is a common dermatological disease affecting up to 1–2% of the world's population. It is a chronic inflammatory skin disorder clinically characterized by erythematous, sharply demarcated papules and rounded plaques, covered by silvery micaceous scale. The skin lesions are variably pruritic.[1-8] It often occurs in families and has a multifactorial inheritance. It affects both sexes equally and occurs mostly in the second to fourth decade of life. It is unusual before the age of 5 years.[9] It is often precipitated by trauma, emotional stress, winter season, infections, medication, etc.[10] In classical Unani literature, psoriasis, termed as *Taqashshure jild,* is a common skin disorder characterized by dryness of skin and scale formation just like the scales of a fish.[11] It is caused by aggravated dosha resulting from *hiddat* and *taufun dam* as well as *safra* (impairment of blood and bile).[12,13] It is a skin disorder in which there is formation of plaques along with scales and dryness.[14] In Unani, psoriasis is said to occur due to burnt melancholic humor having an irritant nature that destroys the skin and produces intense itching, roughness and scaling.[13,15-23] Psoriasis vulgaris is an inflammatory disease characterized by red scaling plaques on the skin. It may present in various morphological forms and may affect either a few areas of skin or the whole skin.

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Plaque type psoriasis is the most common type, manifesting as plaques that are well circumscribed with a sharply demarcated border. The plaques vary considerably in size and thickness, ranging from those barely perceptible by palpation to dramatic plateau like elevation.[24] Psoriasis is a noninfectious, chronic inflammatory skin disease characterized by well-defined erythematous plaques with silvery scales, which have a predisposition for the extensor surfaces and scalp, and follow a chronic fluctuating course. The scales are dry, loose, abundant and silvery white or micaceous. On grattage, characteristic coherence of scales can be seen as if one scratches a wax candle (*signe de la tache de bougie*). When the scales are completely scraped off, a membrane with a moist, red surface becomes visible (membrane of Bulkeley) through which dilated capillaries can be seen as red spots. On further scraping, multiple bleeding points can be seen (Auspitz sign).[10,24-27] The objective of the study was to assess the safety and efficacy of two pharmacopeial Unani formulations *(Majoon Ushba* and *Roghane Hindi)* in the management of psoriasis using modern scientific parameters and to reduce patients' anxiety and cosmetic problems.

MATERIALS AND METHODS

The trial was conducted in the Department of Moalajat (Medicine), National Institute of Unani Medicine (NIUM), Bangalore India. It was a randomized, single-blind, placebo-controlled study approved by NIUM's ethical committee. Patients were enrolled in the study from the OPD of Medicine and Dermatology, at the NIUM Hospital, and were clinically assessed and diagnosed on the basis of a thorough history, dermatological examination and skin biopsy of the affected area. Diagnosed patients were included in the trial on the basis of subjective parameters[24-26] such as sharply demarcated papules and round plaques, silvery micaceous scales, itching and erythema, and objective parameters[24-26] including PASI Scale, *Signe de la tache de bougie*, membrane of Bulkeley, Auspitz sign and Woronoff's ring. Patients of both sexes in the age range 11–60 years were enrolled in the trial. Patients below 11 years and above 60 years, pregnant and lactating mothers, mentally retarded persons, patients who refused to give consent, diabetic patients and patients suffering from other concomitant diseases like vitiligo, dermatophytosis, pityriasis, and eczema were excluded from the study. Patients who had taken any local or systemic antipsoriatic treatment in the past, 2 months prior to the trial were also excluded from the study.

A total of 30 patients was enrolled in the study and divided randomly by the method of Random Table Numbers into test and control groups after giving written informed consent. The test group comprised 20 patients to whom *Majoon Ushba* 5 g was administered orally on an empty stomach twice daily and *Roghane Hindi* 5–10 ml was applied locally twice daily. *Majoon Ushba* and *Roghane Hindi* are poly herbomineral pharmacopeial formulations selected for the study from Anonymous, National Formulary of Unani Medicine. They were procured from the Saidla (Pharmacy) Department of NIUM. The control group comprised 10 patients who were given placebo drugs (wheat flour orally and coconut oil topically) at the same doses as test drugs and for the same duration. The duration of this trial was 8 weeks and follow-up was done fortnightly. All the patients were thoroughly observed and clinical improvements in subjective and objective parameters were recorded in the case report proforma designed for the study. Routine investigations including hemogram, urine, stool, Liver Function Tests (LFTs), Renal Function Tests (RFTs), and blood sugar (random) were carried out before and after treatment, in order to exclude the other systemic ailments, and to assess any adverse effects of the drug formulation on liver and kidney. Skin biopsy was done before treatment as a supportive confirmation of clinical diagnosis.

RESULTS AND DISCUSSION

Clinical evaluation was done by observing the regression of subjective and objective parameters and using the Psoriasis Area and Severity Index (PASI) Scale.[28,29] Demographic data are not of much value since it was a short duration study carried out on a small sample size. However, it was observed that out of 30 patients included in the trial, the highest incidence (33.33%) was found in the age group of 31–40 years while the least incidence (10%) was seen in the age group of 11–20 years. Besides, 21 (70%) patients were male and 9 (30%) patients were female. As far as dietary habits are concerned, 18 (60%) patients were nonvegetarians and 12 (40%) were vegetarians [Table 1].

Table 1: Distribution of patients according to age, gender and dietary habits

Contents	No. of patients	Percentage
Age (years)		
11–20	3	10
21–30	8	26.6
31–40	10	33.3
41–50	4	13.3
51–60	5	16.6
Total	30	100
Gender		
Male	21	70
Female	9	30
Dietary habits		
Vegetarian	12	40
Nonvegetarian	18	60

Effect of test drugs and placebo on itching

In the test group, 8 (26.66%) patients had severe itching, 8 (26.66%) patients had moderate itching and 4 (13.33%) patients complained of mild itching before treatment. After treatment, there was a marked improvement in itching as 10 (33.33%) patients showed complete cure, 4 (13.33%) patients complained of moderate itching, 6 (20%) patients had mild itching and no patients complained of severe itching at the end of the trial. This improvement in itching may be attributed to the refrigerant, emollient, analgesic and sedative effect of various ingredients of the test drugs, such as *Sandal surkh, Sandal safaid, Gule surkh, Roghane Sarson* and *haldi.*[30-38] In the control group, 3 (10%) patients had severe itching, 2 (6.66%) patients had moderate itching and 5 (16.66%) patients complained of mild itching before treatment. There was no improvement in itching and it remained the same even after the end of treatment [Table 2].

Effect of test drugs and placebo on scaling

In the test group, 10 (33.33%) patients had severe scaling, 6 (20%) patients had moderate scaling and 4 (13.33%) patients complained of mild scaling before treatment. After treatment, there was a marked improvement in scaling as 12 (40%) patients showed complete cure, 1 (3.33%) patient complained of moderate scaling, 6 (20%) patients had mild scaling and only 1 (3.33%) patient complained of severe scaling at the end of the trial. This improvement in scaling may be attributed to the emollient, detergent and stripping effect of *Nila tutiy*a, *Murdar sangh, Chob chini, Ushba* and *Aabe bargh neem.*[30-38] In the control group, 3 (10%) patients had severe scaling, 5 (16.66%) patients had moderate scaling and 2 (6.66%) patients complained of mild scaling before treatment. There was no improvement in scaling and it remained the same even after the end of treatment [Table 3].

Effect of test drugs and placebo on erythema

In the test group, 12 (40%) patients had severe erythema, 6 (20%) patients had moderate erythema and 2 (6.6%) patients complained of mild erythema before treatment. After treatment, there was a marked improvement in erythema as 10 (33.33%) patients showed complete cure, 2 (6.66%) patients complained of moderate erythema, 7 (23.33%) patients had mild erythema and only 1 (3.33%) patient complained of severe erythema at the end of the trial. This improvement in erythema may be attributed to the anti-inflammatory, blood purifying and detergent effect of *Chob chini, Ushba, Gaozuban, Darchini, Sana makki* and *Kabab chini.*[30-38] In the control group, 4 (13.3%) patients had severe erythema, 3 (10%) patients had moderate erythema and 3 (10%) patients complained of mild erythema before treatment. There was no improvement in erythema and it remained the same even after the end of treatment [Table 4].

Table 2: Effect of test drugs and placebo on itching

Group	Severity	Days				
		0	15	30	45	60
Test (20)	Mild	4 (13.3)	4	6	8	6 (20)
	Moderate	8 (26.6)	9	9	5	4 (13.3)
	Severe	8 (26.6)	7	5	3	0
	Cured	0	0	0	4	10 (33.3)
Control (10)	Mild	5 (16.6)	5	5	5	5 (16.6)
	Moderate	2 (6.6)	2	2	2	2 (6.6)
	Severe	3 (10)	3	3	3	3 (10)
	Cured	0	0	0	0	0

Values in parenthesis indicates percentage

Table 3: Effect of test drugs and placebo on scaling

Group	Severity	Days				
		0	15	30	45	60
Test (20)	Mild	4 (13.3)	4	4	5	6 (20)
	Moderate	6 (20)	6	6	5	1 (3.33)
	Severe	10 (33.3)	10	8	6	1 (3.33)
	Cured	0	0	2	4	12 (40)
Control (10)	Mild	2 (6.6)	2	2	2	2 (6.6)
	Moderate	5 (16.6)	5	5	5	5 (16.6)
	Severe	3 (10)	3	3	3	3 (10)
	Cured	0	0	0	0	0

Values in parenthesis indicates percentage

Table 4: Effect of test drugs and placebo on erythema

Group	Severity	Days				
		0	15	30	45	60
Test (20)	Mild	2 (6.6)	2	3	8	7 (23.33)
	Moderate	6 (20)	6	7	4	2 (6.66)
	Severe	12 (40)	12	10	6	1 (3.33)
	Cured	0	0	0	2	10 (33.33)
Control (10)	Mild	3 (10)	3	3	3	3 (10)
	Moderate	3 (10)	3	3	3	3 (10)
	Severe	4 (13.3)	4	4	4	4 (13.3)
	Cured	0	0	0	0	0

Values in parenthesis indicates percentage

Table 5: Effect of test drugs and placebo on psoriasis area and severity index score

Group	Psoriasis area and severity index	
	Before treatment	After treatment
Test	7.75	3.25
Control	6.80	6.80

Table 6: Composition of the test drugs

Composition of *Majoon Ushba*[39-42]		
Drug	**Scientific name**	**Dose (g)**
Sana makki	Cassia angustifolia	80
Sandal surkh	Pterocarpus santalinus	60
Sandal safaid	Santalum album	60
Chob chini	Smilax china	60
Gule surkh	Roasa damascene	60
Darchini	Cinnamomum zeylanicum	40
Kabab chini	Piper cubeba	40
Gaozuban	Borage officinalis	40
Aftimoon	Custa reflexa	40
Bisfaij	Polypodium vulgare	40
Ushba	Smilax officinalis	40
Post balela	Terminalia belerica	20
Sumbulutteeb	Nardostachys jatamansi	20
Halela siyah	Terminalia chebula	15
Post halela zard	Terminalia chebula	10
Qand safaid	White sugar	2 k
Composition of *Roghane Hindi*[39]		
Aabe barg neem	Azadirachta indica	250
Nila tutiya	Copper sulfate	10
Murdar sang	Monoxide of lead	10
Mayeen khurd	Tamarica gallica	10
Halela siyah	Terminalia bellerica	10
Haldi	Curcuma longa	10
Roghane Sarson	Mustard oil	250

Effect of test drugs and placebo on PASI score

PASI[28,29] is a measure of overall psoriasis severity and is the best tool for the evaluation of efficacy of test drugs in the management of psoriasis. It is a commonly used measure in clinical trials of psoriasis treatments. PASI Score was calculated for all patients in the test and control groups before and after treatment according to the method described by Louden *et al.*[28] In the control group, the mean PASI Score was 7.75 before treatment; after treatment, it reduced to 3.25. In the case of the placebo control group, the mean PASI Score was 6.80 both before and after treatment. Then, the data of both the test and control groups were tabulated and statistically analyzed by applying paired Student's *t*-test.

The effect of test drugs was found to very significant ($P < 0.01$) as compared to the placebo control group ($P > 0.05$). In this way, the test drugs were demonstrated to a significant effect on PASI Scale [Table 5].

The test drugs, the composition of which is given in Table 6, showed good response on other symptoms and signs like plaques, papules, Wornoff's ring sign and Auspitz sign. Out of 20 patients in the test group, 18 had plaques and pustules, all had positive Auspitz sign while none showed *Signe de la tache de bougie*, Membrane of Bulkeley or Woronoff's ring signs. But after completion of treatment, there were remarkable effects from the test drugs as both plaques and papules disappeared in 14 patients, and 16 patients showed negative Auspitz sign. The improvement in plaques and pustules may be due to the anti-inflammatory and detergent effects of *Chob chini, Ushba, Gaozuban, Darchini, Sana makki* and *Kabab chini*.[30-38] The most probable reason for improvement in Auspitz sign is the cicatrization effect by *Nila tutiy*a, *Murdar sang* and *Haldi* and may also be due to hemostatic properties of *Sandal surkh, Sandal safaid* and *Kabab chini*.[34-37] Overall improvement may be due to *nuzj wa tanqiyahe sauda* (concoction and expulsion of black bile, which is the main culprit for psoriasis) by *Aftimoon, Bisfaij*, *Postbalela, Sana makki, Mayeen khurd* and *Halela siyah, tasfeyahe dam* (blood purification) by *Chob chini, Ushba* and *Aabe barg neem*. It may also be attributed to *indimale zakhm* (cicatrization) by *Nila tutiy*a, *Murdar sang* and *Haldi, taskeene jild* (demulcification) by *Sandal surkh, Sandal safaid* and *Gule surkh*, and *tahleele auram* (resolution of inflammation) by

Gule surkh, *Gaozuban, Darchini* and *Kabab chini* of the test drugs. This is in consonance with the properties described by Ibn Sina[22] and Najmul Ghani.[34]

Laboratory investigations were carried out to observe any systemic adverse affects of the drug formulation on the body. No significant changes were observed in the laboratory investigations [Hb%, total leukocyte count (TLC), differential leukocyte count (DLC), erythrocyte sedimentation rate (ESR), blood sugar, LFT, RFT, urine and stool tests] done after 2 months of treatment and these safety parameters remained within the normal limits.

CONCLUSIONS

This study provided important information regarding the usefulness of Unani drugs in the treatment of psoriasis. It demonstrated that these Unani formulations produce significant improvements in subjective and objective parameters and PASI. The test group's overall response was statistically significant, giving a P value of <0.05 on a chi-square test, whereas no response was observed in the control group treated with placebo for the same duration. This clearly indicates the effectiveness of the Unani formulations. Further, no significant changes were observed in the laboratory investigations (blood sugar, LFT, RFT) after 2 months of treatment and these parameters remained within normal limits. This indicates that the Unani formulations do not have systemic side effects. Moreover, results were more significant in less chronic cases and in younger age groups. Diagnosis at an early stage followed by appropriate treatment should give remarkable results. Hence, it may be concluded that the test drugs can be used safely and effectively for the treatment of psoriasis. However, more advanced studies need to be carried out.

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