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A Clinical Study of Majoon Ushba and Marhame Safeda Kafoori in the Management of Daus Sadaf (Psoriasis)

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ABSTRACT

Psoriasis is a Greek word derived from "so-ri-a-sis" means itching while Daus Sadaf is an Arabic word derived from "Da" means "disease" and "Al-Sadaf" means "molluscum shells" (seep). It was considered as Taqash'shur-e-Jild (Ichthyosis) by Unani physicians.

Aims and Objectives:

To assess the efficacy of Majoon Ushba and Marhame Safeda-Kafoori in the management of psoriasis.

Material & Methods:

All the patients were given Majoon Ushba 5 gm twice daily for systemic administration and Marhame Safeda Kafoori for local application twice a day. The duration of therapy was 90 days with 6 visits at every 15 days. The assessment of efficacy was based on subjective and objective parameters. In subjective parameters symptoms included Itching, Erythema, Scaling and Induration etc., while the objective parameters included Psoriasis Area Severity Index (PASI) scale and Pictures of lesions. The data of clinical and laboratory findings were analyzed by using Paired "t" test.

Result: The mean value of PASI score at the time of commencement of study was 24.15 ± 14.44 which decreased significantly to 4.73 ± 4.73 (p<0,001) indicating a significant antipsoriatic effect produced by the test drug.

Conclusion: Based on the findings it can be concluded that Unani drugs, Majoon Ushba and Marham-e-Safeda Kafoori possess significant antipsoriatic effect and can be used in the management of Psoriasis.

Keywords: Daus Sadaf, MajoonUshba, Marhame Safeda-Kafoori, PASI, Psoriasis, Unani Medicine.

INTRODUCTION

Psoriasis is a Greek word derived from "so-ri-a-sis" means itching while Daus Sadaf is an Arabic word derived from "Da" means "disease" and "Al-Sadaf" means "molluscum shells" (seep) [1]. It is a skin disease characterized by a wildly accelerated cell growth process in which external as well internal beauty of skin is lost due to altered abnormal humours. Psoriasis is a common, chronically recurring papulosquamous disease characterized by varying size whitish scaly patches seen most commonly on the elbow, knees and scalp[3,4]. According to W.H.O, psoriasis is a chronic, non-communicable, painful, disfiguring and disabling disease for which there is no cure and with a great negative impact on patients' quality

of life (QoL)[4]. Unani physicians have described it under the desquamated disease of skin (Taqash'shur-e-Jild) and assigned it a specific name i.e. Daus Sadaf. Ibn Zohr, defined it as the disease of skin, in which the patient feels intensive itching over the lesions. Khilt-e-Sauda (morbid melancholic humour) accumulated in the skin causes failure of skin function which in turn leads to poor supply of nutrients to and the removal of morbid melancholic humour from the skin. As a result, skin tissues become dead and fall out in the form of scales. In 1841 AD the concept of psoriasis was first put forward by Ferdinand Hebra, who used the term psoriasis for the first time and separated it from leprosy.

Psoriasis is serious global problem with at least 100 million individuals are affected by it worldwide. It occurs in all countries

Ahmad A. Int J Pharm 2021; 11(4): 1-6 and individuals of all ages; the prevalence of psoriasis defined ranges between 0.09% and 11.43%. In India prevalence of psoriasis varies from 0.44 to 2.8%, it is two-fold more common in males in comparison of females, and most of the patients are in their 3rd or 4th decade at the time of presentation[4].

The etiology of psoriasis is unclear but the Humoral theory proposed by Bugrat (Hippocrates), appears to have a key role in the aetiopathogenesis of all the idiopathic diseases in general and psoriasis in particular. Humoral theory states that certain errors in the body functions even in the mood, emotions and behaviours were caused by an excess or shortage of humours (body fluids) and an alteration in their qualities[5]. Almost all Unani physicians believed that it is a Saudavi (Melancholic) disease. It occurs due to the Saudae-Mohtaraq, Merah-e-Safra / Balgham-e-Merari, indigestion, uncleanness, cold, and uses of dry-salty diets.6,7,8 Psoriasis has its genetic preponderance as well as of environment sensitivity, thus has variations in its clinical presentation, individual susceptibility response to a particular treatment etc[9].

Although there is no complete cure yet, psoriasis can be managed by achieving some important guidelines described by Unani system of Medicine; broadly involved the three types of therapy which are as follows. a) Ilaj Bit-Tadbeer (Regimenal Therapy) b) Ilaj Bil-Ghiza (Dietotherapy) c) Ilaj Bid-Dawa (Pharmacotherapy)

In this study we used Unani medicines "Majoon Ushba" and "Marhame Safeda Kafoori" for its anti-psoriatic effect. The efficacy of these medicines in psoriasis has never been clinically studied earlier even though the major ingredients of this compound own anti-keratolytic and anti-psoriatic actions, as have been proved in various clinical studies. Another reason for choosing this drug was its easy availability and reasonable cost as comparison with the allopathic drugs available for the treatment of psoriasis. It is a hypothesis that, "Majoon Ushba" and "Marhame Safeda Kafoori" could be effective in treatment of psoriasis based on the inherent actions of ingredients present in these drugs.

Main aim of treatment for psoriasis is to control epidermal proliferation and to expel out the abnormal altered humor from the body. Regimens, diet & different drugs which are mentioned in Unani literature act on psoriasis by expelling out the abnormal humors, thereby correcting the normal physiology of cells, tissues, organs, systems & whole body etc. Drugs are also effective in relieving the symptoms, presentations, prognosis and complications as well as relapse at larger level[10].

In view of the above, the present clinical study was designed to evaluate the efficacy of Majoon Ushba and Marhame Safeda-Kafoori which were administered simultaneously through oral and 2

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topicl routes in the management of psoriasis. The study design is randomized open clinical study.

MATERIALS AND METHODS:

The present study was conducted in the OPD and IPD of Moalejat and Amraze Jild Wa Zohrawiya of Ajmal Khan Tibbiya College Hospital for a period of 18 months from December 2017 to May 2019. Study design is Open clinical study. The proposal was approved by institutional ethics committee of AKTC, AMU Aligarh U.P with approval date 20/07/2017.

Clinically diagnosed patients of psoriasis were enrolled for the study. Patients fulfilling the inclusion criteria were provided with an information sheet having details concerning the nature of the study, the drug to be used with the mode of administration and method of treatment. Patients were given sufficient time to go through the contents of informed consent sheet. They were left free to ask whichever the query regarding the study and if they agreed to be enrolled in the study, they were asked to sign the informed consent form. A total of 50 patients were included in the study.

Aim and Objective of the Study:

To study the efficacy and safety of Majoon Ushba and Marhame Safeda-Kafoori in the management of Psoriasis

Inclusion Criteria:

- All the patients of psoriasis confirmed clinically by examination.
- Patient who are clinically stable.
- Patient having age group of 14 to 65 years.
- Patients of either sex.
- Patients not taking any other treatment.
- Patients who have left the other treatment at least 3 month back.

Exclusion Criteria:

- Patient below 14 years and above 65 years.
- Patients with complications of psoriasis like psoriatic nails, psoriatic arthropathy, pustular psoriasis and systemic ailments.
- Psoriasis with secondary infections.
- Patients with chronic renal and hepatic diseases.
- Patients with Diabetes Mellitus.
- Pregnant and lactating women's.

Methods of the Study:

For the rational and effective therapy of psoriasis potent Unani drugs Majoon Ushba (Table 01) and Marhame Safeda Kafoori(Table 02) were selected from National formulary of Unani Medicine. The

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test drugs were procured from Dawakhana Tibbiya College, A.M.U Aligarh. Patients were treated with Majoon Ushba [5]. gm twice daily orally and Marham-e-Safeda Kafoori topically twice a day. All events experienced by the patients were recorded in case report form at each visit.

Drugs (Common	Botanical Name	Quantity		
name)				
Sana	Cassia angustifolia	80 gm		
Sandal Surakh	Pterocarpus santalinus	60 gm		
Sandal Safaid	Santalum album	60 gm		
Chobchini	Smilax china	60 gm		
Gul-e-Surkh	Rosa Damascus	60 gm		
Darchini	Cinnamomum zeylanicum	40 gm		
Kababchini	Piper cubeba	40 gm		
Gaozaban	Borage officinalis	40 gm		
Aftimoon	Cuscuta reflexa	40 gm		
Bisfayej	Polypodium vulgare	40 gm		
Ushba	Hemidismus indicus	40 gm		
Post-e-Balela	Beleric myrobalan	20 gm		
Sumbul-ul-Teeb	Valirina jatamansi	20 gm		
Halela Siyah	Chebulic myrobalan	15 gm		
Post-e-Halela Zard	Chebulic myrobalan	10 gm		
Qand Safaid	Honey or Sugar	2 kg		

Table 1: Majoon Ushba: Ingredients for 2.750 kg.

Name of	Quantity
Drugs	
Mom Safaid	100 gm
Roghan-e-Gul	300 ml
Kushta-e-Qalai	50 gm
Murdar Sang	50gm
Kafoor	50gm

Table 2: Marhame Safeda Kafoori: Ingredients for 550 gm.

Follow up:

Patients were kept under strict observation and advised to come to OPD fortnightly for assessment. Ninety days study was divided into six visits of follow up. At every visit, patients were asked about the progression or regression in their symptoms, and were examined to assess the clinical findings.

Assessment of the Safety and documentation of adverse effect if

All events experienced by the patients were recorded at each visit.³

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Adverse drug reactions were kept into consideration. Routine laboratory safety tests including complete blood count with ESR, Urine- Routine and Microscopic, AEC, LFT, RFT, Serum Uric acid, and R A factor were performed before and after the treatment.

Efficacy Assessment: The assessment of efficacy was based on subjective and objective parameters. In subjective parameters the symptoms of the disease such as Itching, Erythema, Scaling, and Induration were assessed for improvement or otherwise. Objective parameters included Psoriasis Area Severity Index (PASI) scale and Pictures of the lesions.

Itching assessed through Verbal Rating Scale (VRS): A fourpoint scale consists of a list of adjectives describing various levels of symptom intensity (0= no itch, 1= mild itch, 2= moderate itch and 3= severe itch) was used to categorize the itch intensity.

Psoriasis Area Severity Index (PASI): was adopted for appropriate assessment and statistical evaluation of the efficacy of drugs. Four sites of affection, head, upper limbs, trunk and lower limbs were separately scored as shown in table-03.

Characteristic Limbs Limbs Erythema Induration/Thickness Scaling Lesion Score (Add together each of the scores for each body region to give 4 separate sum (A) 0 1 2 3 4 None Slight Moderate Severe Very Severe Lesion score sum (A)	Plaque		Head	Upper	Trunk	Lower
Induration/Thickness Scaling Lesion Score (Add together each of the scores for each body region to give 4 separate sum (A) 0	Characteristic			Limbs		Limb
Scaling Lesion Score (Add together each of the scores for each body region to give 4 separate sum (A) 0	Erythema					
Lesion Score (Add together each of the scores for each body region to give 4 separate sum (A) 0	Induration/Thickness					
give 4 separate sum (A) 0	Scaling					
0 1 2 3 4 None Slight Moderate Severe Very Severe Lesion score sum	Lesion Score (Add tog	gether ea	ch of the sc	ores for e	ach body	region to
None Slight Moderate Severe Very Severe Lesion score sum	give 4 separate sum (A	.)				
Lesion score sum	0	1	2	3	4	
Lesion score sum	None	Slight	Moderate	Severe	Very	
					Severe	
(A)	Lesion score sum					
	(A)					

% Area affected
Area Score (B)
Degree of involvement as a percentage for each body region each region with score between 0-6)

192	1	1 2245	/ -	1848		
cant		cant		cant	cant	cant

Multiply lesions score sum (A) by area score (B), for each bod	y region, to		cant	cant	cant		cant	cant	
give 4 individuals subtotals (C)	I	#				T			_

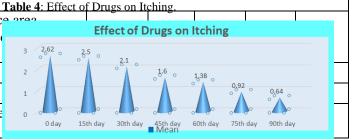
Subtotals (C)

Multiply each of the subtotals (C) by amount of the body surface area represented by that region, i.e. x 0.1 for head, x0.2 for upper boo trunk. And 0.4 for lower limbs.

Body Surface Area

Totals (D)

Add together each of the scores for each body region to give the



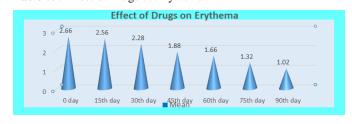
Graph 1: Effect of Drugs on Itching.

Effect of Drugs on Erythema:

The mean value of Erythema was found to be 2.66±0.473 and 1.02± 0.51 in pre and post treatment assessment, respectively showing a significant decrease (P<0.0001).

Sympt	0	15th	30th	45th	60th	75th	90th
oms	day	day	day	day	day	day	day
Erythe	2.6±	2.56±	2.28±	1.88±	1.66±	1.32±	1.02±
ma	0.47	0.50	0.57	0.47	0.51	0.62	0.51
(Mean							
±S.D.)							
Paired		P	P	P<	P	P<0.0	P=
"t" test		=0.02	< 0.00	0.000	< 0.00	001	0.000
		3	01	1	01		1
		3 t =	01 t =	1 t=	01 t =	t	1 t =
						t =14.3	_
		t =	t =	t=	t =	-	t =
Signifi		t =	t =	t=	t =	=14.3	t =
Significance		t = 2.33	t = 5.48	t= 10.88	t = 12.37	=14.3 9	t = 20.60
		t = 2.33 Signif	t = 5.48	t= 10.88 Highl	t = 12.37	=14.3 9 Highl	t = 20.60

Table 05: Effect of Drugs on Erythema.



Graph 2: Effect of Drugs on Erythema.

Effect of Drugs on Induration:

The mean value of Induration at the time of commencement of study was 2.78±0.46 and after completion was 1.04±0.60. paired't' test revealed P<0.0001, t= 17.22 which is considered highly significant.

Sympt 0 day 15th	30th	45th	60th	75th	90th
------------------	------	------	------	------	------

Grading:

0=Absent, 1=Mild, 2=Moderate, 3=Severe, 4=Very Severe.

These scores of each patient were summed up at each assessment point to obtain PASI, with a maximum value of 72 points. After the completion of treatment, the pre and post treatment values or scores were compared statistically[11].

Outcome measures: Clearly write under this heading that what will be findings when you will say that the treatment is effective.

Statistical Analysis:

Paired "t" test was applied to compare the data consist of pre and post treatment findings and to determine the level of significance.

Observation and Result:

Effect of Drugs on Itching:

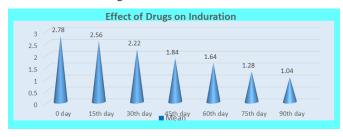
The mean value of Itching at the time of commencement of study was 2.62±0.633, which decreased significantly to 0.64±0.48 (p<0.0001).

Symp	0	15th	30th	45th	60th	75th	90th
toms	day	day	day	day	day	day	day
Itchin	2.62	2.5±	2.1±0.	1.6±0.	1.38±	0.92±	0.64±
g	±0.	0.50	58	53	0.53	0.44	0.48
	63						
(Mean							
±S.D.							
)							
Paired		P	P	P =	P =	P=	P=
"t"		=0.0	=0.00	0.000	0.000	0.000	0.000
test		001	01	1	1	1	1
		t =	t =	t =	t =	t =	t
		2.53	3.37	22.62	20.32	20.71	=25.3
							2
Signif		Sign	Highl	Highl	Highl	Highl	Highl
icance		ifica	y	y	y	y	у
level		nt	signifi	signifi	signifi	signifi	signifi ⁴

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oms	illiaa .	day	day	day	day	day	day
Indurat	2.78	2.56±	2.22±	1.84±	1.64±	1.28±	1.04±
ion	±0.4	0.54	0.54	0.50	0.56	0.60	0.60
	6						
(Mean							
±S.D.)							
Paired		P=0.0	P	P<	P	P<0.	P<0.
"t" test		005	< 0.00	0.000	< 0.00	0001	0001
			01	1	01		
		t =	t =	t=	t =	t	t =
		3.71	7.89	11.40	16.27	=16.3	17.22
						9	
Signifi		Highl	Highl	Highl	Highl	Highl	Highl
cance		у	у	у	у	у	у
level		Signi	signif	signif	signif	signif	signif
		ficant	icant	icant	icant	icant	icant

Table 6: Effect of Drugs on Induration.



Graph 3: Effect of Drugs on Induration.

Effect of Drugs On Scaling:

The mean value of Scaling at the time of commencement of study was 2.86 ± 0.49 and after completion was 0.98 ± 0.47 , paired't' test revealed P<0.0001, t= 25.53 which is considered highly significant.

Symp	0	15th	30th	45th	60th	75th	90th
toms	day	day	day	day	day	day	day
Scalin	2.86	2.52±	2.16±	1.82±	1.64±	1.24±	0.98±
g	±0.	0.50	0.46	0.52	0.62	0.59	0.47
	49						
(Mea							
n±S.							
D.)							
Paire		P<0.0	P	P<	P	P<0.0	P<0.0
d t		005	< 0.00	0.000	< 0.00	001	001
test			01	1	01		
		t =	t =	t=	t =	t	t =
		5.02	10.69	14.91	17.02	=18.0	25.53 5

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					3	
Signif	Highl	Highl	Highl	Highl	Highl	Highl
icanc	y	у	у	у	у	у
e	Signif	signif	signif	signif	signif	signif
level	icant	icant	icant	icant	icant	icant

Table 7: Effect of Drugs on Scaling.



Graph 4: Effect of Drugs on Scaling.

Effect of Drugs on PASI Score:

The mean value of PASI score at the time of commencement of study was 24.15±14.44 and after completion was 4.73±4.73. On statistical evaluation, paired 't' test revealed P<0.0001, t= 11.88 which is considered highly significant.

PASI	0 day	15th	30th	45th	60th	75th	90th
Score		day	day	day	day	day	day
Mean	24.1	21.44	18.27	14.37	10.88	7.27±	4.73±
±S.D	5±14	±13.1	±11.3	±9.62	±7.93	5.88	4.73
	.44	1	6				
Paire		P<0.0	P	P<	P	P<0.0	P<0.0
d "t"		001	< 0.00	0.000	< 0.00	001	001
test			01	1	01		
		t =	t=8.0	t=	t =	t	t =
		5.89	4	9.36	10.33	=11.3	11.88
						7	
Signi		Highl	Highl	Highl	Highl	Highl	Highl
ficanc		у	у	у	у	у	y
e		Signif	signif	signif	signif	signif	signif
	1	1	ĺ		ĺ	ĺ	

Table 8: Effect of rugs on PASI Score.



Graph 5: Effect of rugs on PASI Score.

Discussion:

The study demonstrated that the Unani treatment possesses

Ahmad A. Int J Pharm 2021; 11(4): 1-6 significant antipsoriatic effect as it alleviated the symptoms of

Psoriasis and reduced the PASI score significantly.

Improvement in itching:

May be due to emollient, antibacterial, blood purifier activity of Cassia angustifolia and Pterocarpus santalinus[11,12]. Sedative activity of Cinnamomumcamphoraand Santalinus alba. Laxative effect of Bee wax & Rosa damascene, mubarrid (cooling) and radae-mawad (alterative) effect of Roghan-e-gul[12,14].

Relieve in erythema:

Due to anti-inflammatory activity of cassia angustifolia, Santalinus alba, Rosa damascene, Piper cubeba and Hemidismus indicus[15]. Antioxidant activity of Piper cubeba and siccative effect of Cera flava. Muhallil (Resolvent) and Mudammil Qurooh (Wound Healing) activities of Marhamsafeda kafoori. Mussaffie dam (Blood Purifier) and Muhallil (Resolvent) activities of Smilax china, Polypodium vulgare Cuscutareflexa, Santalum album and Hemidismusindicus present in Majoon Ushba for systemic use [15,17].

Effect of Drugs on safety parameters in psoriasis:

In safety parameters significant reduction was found in serum uric acid as well as AEC before and after treatment. Uric acid may be reduced due to Blood purifying activity of MajoonUshba. The significant reduction was also seen in AEC. It may be due to antiallergic and antibiotic and blood purifier activity of Cassia angustifolia, Pterocarpussantalinus and Cinnamomumcamphora. Noticeable significant was seen in value of haemoglobin level of patients. The reason is that the drug might be accredited to various ingredients present in Majoonushba and MarhameSafedaKafoori, having properties of Muqqawiazaraisa (General tonic) property and hepato-protective.

CONCLUSION

On the basis of observations and results of the study, it is can be concluded that the Unani treatment comprising of MajoonUshba (p.o) and Marham-e-safeda Kafoori(topical) is safe and effective in the management of Psoriasis.

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