

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.^{2,3} 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 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 *Buqrat* (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 *Sauda-e-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 topical 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 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.

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 any: All events experienced by the patients were recorded at each visit. 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 four-point 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

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 ($p < 0.0001$). Table-04 and graph-01.

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 ($P < 0.0001$). Table 05 Graph 02.

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, Table 06 & Graph No 03.

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, Table 07 & Graph 04.

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, Table 08 & Graph No 05.

Discussion: The study demonstrated that the Unani treatment possesses 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*.¹²⁻¹³ Sedative activity of *Cinnamomum camphora* and *Santalinus alba*.¹²⁻¹⁴ Laxative effect of Bee wax & Rosa damascene, *mubarrid* (cooling) and *rada-e-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*.¹⁵ *Muhallil* (Resolvent) and *Mudammil Qurooh* (Wound Healing) activities of *Marhamsafeda kafoori*.¹⁵⁻¹⁷ *Mussaffie dam* (Blood Purifier) and *Muhallil* (Resolvent) activities of *Smilax china*, *Polypodium vulgare* *Cuscuta reflexa*, *Santalum album* and *Hemidismus indicus* present in *Majoon Ushba* for systemic use.¹⁵⁻¹⁷

Relieve in Scaling and Induration: Due to demulcent effect of *borage officinalis*, alterative effect of *smilax ornate*, laxative effect of *Terminalia chebula*, *mubarrid* and *mulayyin* effect of *Roghan-e-Gul*, *mujaffif*, antiseptic activity of *Cinnamomum camphora*.¹⁵⁻¹⁷ This marked improvement in scaling in almost all cases may also be due to the *Musaffie dam* (Blood Purifier) and *Muaddile sauda* effects of drugs, given orally leading to overall improvement in the disease process.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 *Majoon Ushba*. The significant reduction was also seen in AEC. It may be due to anti-allergic and antibiotic and blood purifier activity of *Cassia angustifolia*, *Pterocarpus santalinus* and *Cinnamomum camphora*. 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

Marham-e-Safeda Kafoori, 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 *Majoon Ushba (p.o)* and *Marham-e-safeda Kafoori (topical)* is safe and effective in the management of Psoriasis.

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1. Majoon Ushba: Ingredients for 2.750 kg

Table-01

Drugs (Common name)	Botanical Name	Quantity
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	Chebolic myrobalan	15 gm
Post-e-Halela Zard	Chebolic myrobalan	10 gm
Qand Safaid	Honey or Sugar	2 kg

2. Marhame Safeda Kafoori: Ingredients for 550 gm

Table-02

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

Table - 03

Psoriasis area and severity index (PASI) Worksheet
(British Association of Dermatologists)

Plaque Characteristic	Head	Upper Limbs	Trunk	Lower Limb
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)				

% Area affected	Area score	Hand	Upper Limb	Trunk	Lower Limb
Area Score (B) Degree of involvement as a percentage for each body region affected (Score each region with score between 0-6)	0=0%				
	1=1%-9%				
	2=10%-29%				
	3=30%-49%				
	4=50%-69%				
	5=70%-89%				
	6=90%-100%				

Multiply lesions score sum (A) by area score (B), for each body region, to give 4 individuals subtotals (C)				
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 body, x 0.3 for trunk. And 0.4 for lower limbs.				
Body Surface Area	X 0.1	X 0.2	X 0.3	X 0.4
Totals (D)				
Add together each of the scores for each body region to give the final PASI score.				

PASI Score.....



Table 04 Graph No 01 Effect of Drugs on Itching

Symptoms	0 day	15 th day	30 th day	45 th day	60 th day	75 th day	90 th day
Itching (Mean±S.D .)	2.62 ±0.6 3	2.5±0.50	2.1±0.58	1.6±0.53	1.38±0.5 3	0.92±0.4 4	0.64±0.4 8
Paired “t” test		P =0.0001 t = 2.53	P =0.0001 t = 3.37	P = 0.0001 t = 22.62	P = 0.0001 t = 20.32	P= 0.0001 t = 20.71	P= 0.0001 t =25.32
Significance level		Significant	Highly significant	Highly significant	Highly significant	Highly significant	Highly significant

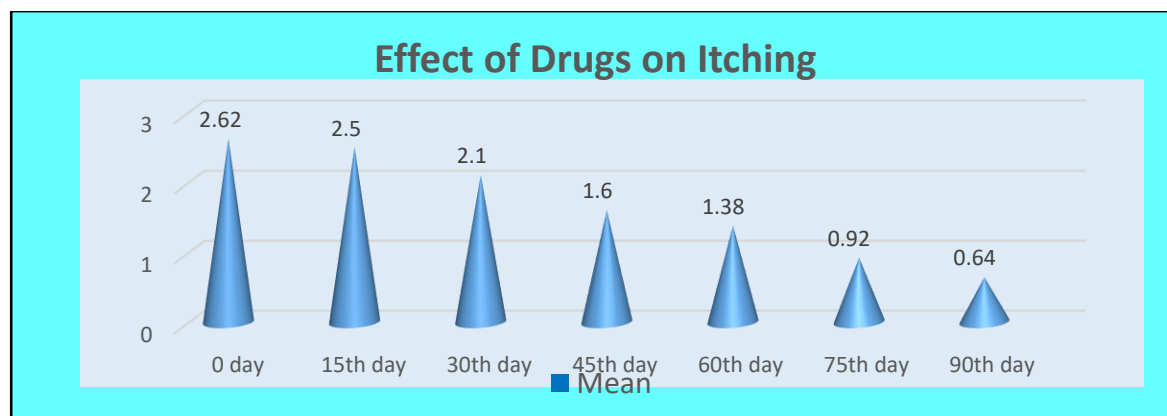


Table 05 Graph 02 Effect of Drugs on Erythema

Symptoms	0 day	15 th day	30 th day	45 th day	60 th day	75 th day	90 th day
Erythema (Mean±S.D.)	2.6±0.47	2.56±0.50	2.28±0.57	1.88±0.47	1.66±0.51	1.32±0.62	1.02±0.51
Paired “t” test		P =0.023 t = 2.33	P <0.0001 t = 5.48	P <0.0001 t = 10.88	P <0.0001 t = 12.37	P <0.0001 t =14.39	P= 0.0001 t = 20.60
Significance level		Significant	Highly significant	Highly significant	Highly significant	Highly significant	Highly significant

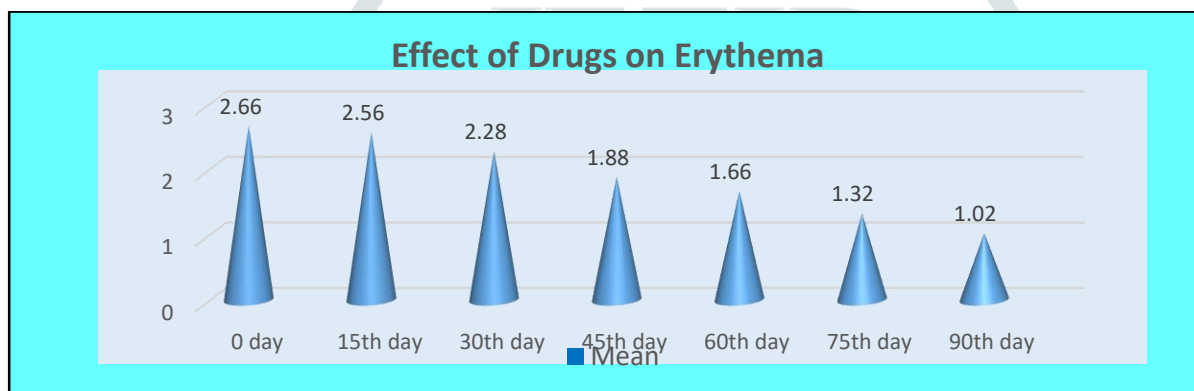


Table 06 & Graph No 03 Effect of Drugs on Induration

Symptoms	0 day	15 th day	30 th day	45 th day	60 th day	75 th day	90 th day
Induration (Mean±S.D.)	2.78±0.46	2.56±0.54	2.22±0.54	1.84±0.50	1.64±0.56	1.28±0.60	1.04±0.60
Paired “t” test		P=0.0005 t = 3.71	P <0.0001 t = 7.89	P <0.0001 t = 11.40	P <0.0001 t = 16.27	P <0.0001 t =16.39	P <0.0001 t = 17.22
Significance level		Highly Significant	Highly significant	Highly significant	Highly significant	Highly significant	Highly significant

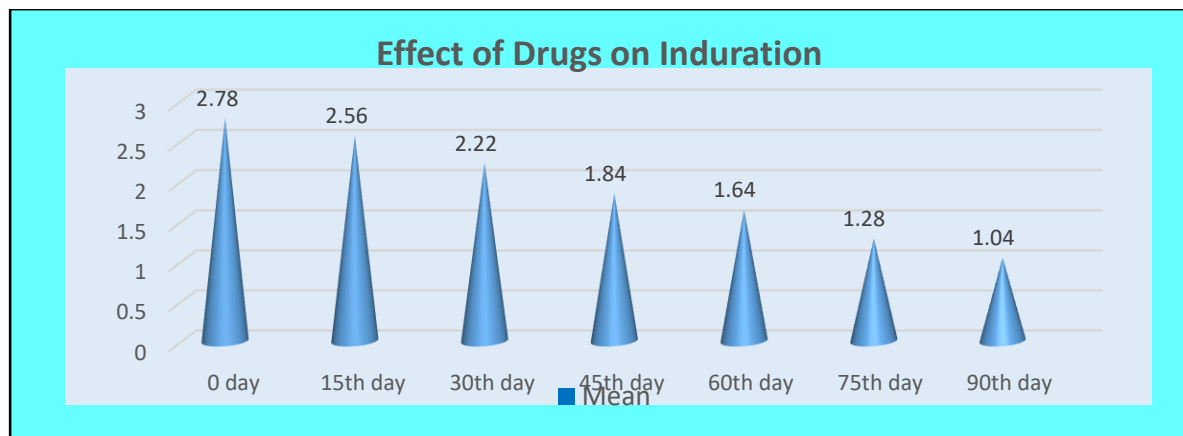


Table 07 & Graph No 04 Effect of Drugs on Scaling

Symptoms	0 day	15 th day	30 th day	45 th day	60 th day	75 th day	90 th day
Scaling (Mean±S.D.)	2.86±0.49	2.52±0.50	2.16±0.46	1.82±0.52	1.64±0.62	1.24±0.59	0.98±0.47
Paired t test		P<0.0005 t = 5.02	P<0.0001 t = 10.69	P<0.0001 t = 14.91	P<0.0001 t = 17.02	P<0.0001 t = 18.03	P<0.0001 t = 25.53
Significance level		Highly Significant	Highly significant	Highly significant	Highly significant	Highly significant	Highly significant

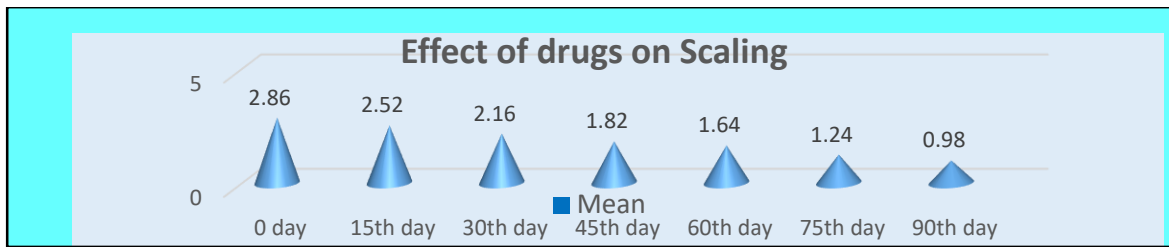
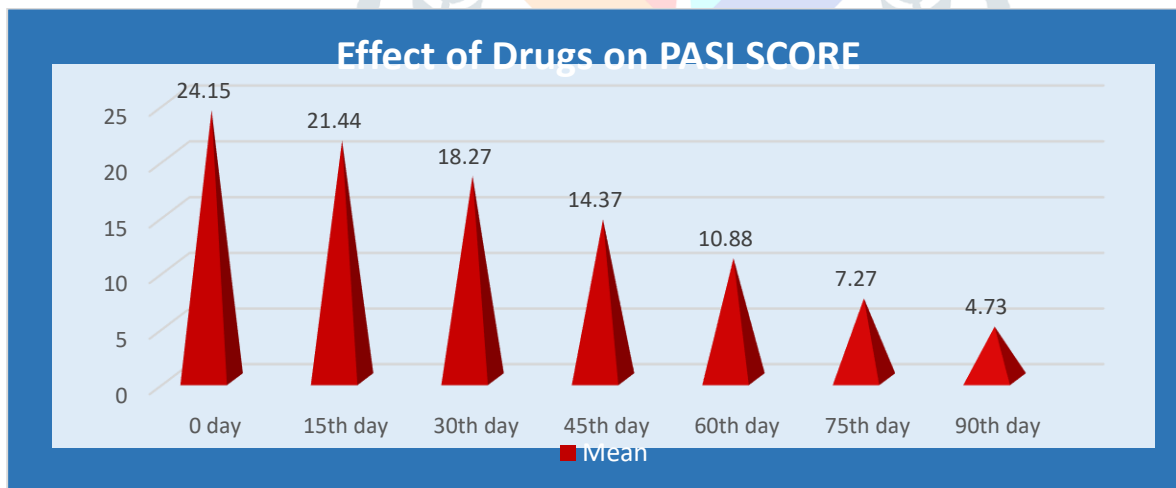


Table 08 & Graph No 05 Effect of rugs on PASI Score

PASI Score	0 day	15 th day	30 th day	45 th day	60 th day	75 th day	90 th day
Mean±S.D	24.15±14.44	21.44±13.11	18.27±11.36	14.37±9.62	10.88±7.93	7.27±5.88	4.73±4.73
Paired “t” test		P<0.0001 t = 5.89	P <0.0001 t=8.04	P<0.0001 t= 9.36	P <0.0001 t = 10.33	P<0.0001 t =11.37	P<0.0001 t = 11.88
Significance level		Highly Significant	Highly significant	Highly significant	Highly significant	Highly significant	Highly significant



PICTURES OF LESIONS:

Before

After



Before

After



Before



After



Before



After

