

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF MANJISHTADYA TAILA AND Its MODIFIED FORM OF CREAM IN TWAK VAIVARNYA

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ABSTRACT

External beauty has gained a lot of attention & demand in ancient times as well as in today's era. *Twak Vaivarnya* refers to the abnormal pigmentation of the skin, often resulting in uneven patches or dark spots. It is a common disorder affecting any age group. It affects the sex invariably. It is not limited to any particular class of society. *Vyanga* (dark spots on face) is a condition of localized hyper melanosis which affects only the skin of the face. Topical applications mentioned in modern cosmetics containing synthetic or chemical substances are known to have several adverse effects including local hypersensitivity reactions. Hence, there is always a demand for safe and effective topical applications to manage hyperpigmented skin diseases. A total of 30 candidates were selected for the present study. In Control Group 15 candidates were given classically prepared *Manjishtadya taila* and in Study Group 15 candidates were given with *Manjishtadya taila* cream in Randomized open label parallel group exploratory study. A comparative clinical study was planned into *Twak vaivarnya* to elicit whether the modified tropical dosage form is showing equal or comparable clinical efficacy in clinical scenario. The MASI score was considered to assess the effect of treatment. Score was compared before and after treatment both in Group A and Group B, highly significant result was observed with P-0.000.

In the present study, *Manjishtadya taila* and *Manjishtadya taila* cream both showed equal effectiveness, but statistically *Manjishtadya taila* had better results.

Keywords: *Manjishtadya taila*, *Manjishtadya taila* cream, *twak vaivarnya*, Fitzpatrick's Skin Phototypes, MASI scale

INTRODUCTION

Face is the most important organ that reflects the human personality. Any minor disfigurement or anomaly at different ages of the life like scars, wrinkles, slack skin and hyper pigmentary skin problems in one's face may result in inferiority complex and sometimes isolation in the social life. Skin discoloration or hyper-pigmentation is a common dermatological concern that affects a significant portion of the global population. Sunburn and suntan are common dermatological conditions or manifestations of excessive ultraviolet (UV) radiation exposure. Sunburn manifests as a painful and reddened skin response to overexposure to UVB rays, while suntan involves the skin's natural production of melanin to protect against UV damage. Hyper Pigmentation of skin is due to over production of Melanin pigment which occurs in Melasma and the patches of these are seen especially on cheeks, nose, forehead and chin.

METHODOLOGY:

A total of 30 candidates were selected for the present study. In Control Group 15 candidates were given classically prepared *Manjishtadya taila*^[1] and in Study Group 15 candidates were given with *Manjishtadya taila* cream in Randomized open label parallel group exploratory study for a period of 15days.

➤ Diagnostic criteria:

- Based on clinical features of sunburn^[2]:
- 1) First degree sunburn: damages outer skin layer
 - Redness
 - Warm or tighten feeling.
 - Swelling

- Soreness
- 2) Second degree sunburn: penetrates outer of skin and damages dermis.
 - Deep red skin
 - Swelling and blisters
 - Wet-looking shiny skin
 - Pain
 - Whitish discoloration within burned area
- **Inclusion criteria:**
 - Candidates with signs of sunburn and suntan are selected.
 - Candidates with dull complexion and dark spots will be chosen.
 - Age group of 18-30 years.
 - Both genders.
- **Exclusion criteria:**
 - Candidates with pre-diagnosed skin allergies and wounds.
 - Candidates with other pre-diagnosed systemic diseases involving skin ailment.
- **Assessment criteria:**
 - Subjective criteria:
 - Complexion
 - Softness of skin
 - Objective criteria:
 - Lustre
 - Pigmentation
 - Dark spots
 - Based on **Fitzpatrick's Skin Phototypes** classification:^[3]

Table no. 1: Fitzpatrick's Skin Phototypes

Skin type	Score	Description
Type I	0-6	Pale white skin, burns easily, does not tan
Type II	7-13	White skin, burns easily, tans with difficulty
Type III	14-20	Light brown skin, may burn but tans easily
Type IV	21-27	Moderate brown skin, hardly burns, tans easily
Type V	28-34	Dark brown skin, usually does not burn, tans easily
Type VI	35+	Deeply pigmented dark brown skin to black skin, very unlikely to burn, becomes darker with UV radiation exposure

- Based on **Melasma area severity index** score:^[4] Melasma area severity index (MASI) is developed by Kimbrough-Green et al for the assessment of melasma. The severity of the melasma in each of the four regions (forehead, right malar region, left malar region and chin) is assessed based on three variables:
 - percentage of the total area involved (A)
 - darkness (D)
 - homogeneity (H)

Table no. 2: MASI scale

Area	Darkness	Homogeneity
0=no involvement	0=normal skin color without evidence of hyperpigmentation	0=normal skin color without evidence of hyperpigmentation
1=<10% involvement	1=barely visible hyperpigmentation	1=specks of involvement
2=10-29% involvement	2=mild hyperpigmentation	2=small patchy areas of involvement <1.5 cm diameter
3=30-49% involvement	3=moderate hyperpigmentation	3=patches of involvement >2 cm diameter
4=50-69% involvement	4=severe hyperpigmentation	4=uniform skin involvement without any clear areas
5=70-89% involvement		
6=90- 100% involvement		

To calculate the MASI score, the sum of the severity grade for darkness (D) and homogeneity (H) is multiplied by the numerical value of the areas (A) involved and by the percentages of the four facial areas (10-30%).

Total MASI score: Forehead 0.3 (D+H) A + right malar 0.3 (D+H) A + left malar 0.3 (D+H) A + chin 0.1 (D+H) A

Procedure:

- Patient written consent will be taken.
- Selected patients are randomly divided into two groups.
 - Group A - Control group:** The candidate is asked to thoroughly wash face with clean water and pat it dry. Then the face should be massaged with quantity sufficient *Manjishtadya taila* till completely absorbed. This will be allowed to stay overnight. The

candidate will be educated to follow the same for 15 days.

- Group B - Study group:** The candidate is asked to thoroughly wash face with clean water and pat it dry. Then the required amount of *Manjishtadya taila* cream is taken and dotted over the face and gently massaged in upward-outward circular motions with fingertips and allowed to stay overnight. The candidate will be educated to follow the same for 15 days.
- Concomitant medicines:** Any concomitant medicines for any systemic diseases can be continued by the candidate in the course of procedure except any facial application.
- Drop out criteria:** Candidates who develop any signs of skin irritation and sensitization during the course of study will drop out after informing the guide. For any adverse drug reaction observed prompt remedial measures will be initiated.



DISCUSSION

The majority, i.e., 50% of patients belong to age group of 21-25 years. Majority of patients were females i.e., 83.33% indicating natural concern regarding cosmetic aspect existing among the female patients. The majority were unmarried with 80%. When religion wise distribution was followed majority were Hindus with 76.66%, Muslims with 20% and then Christian with 3.33%, which looks to be simply a reflection of normal religion wise distribution observed in tested geographical area. The majority of patients were graduates i.e., 86.67%, which indicates

their awareness and also concern related with the condition. The majority of patients were students as they were the target group. It was observed that the larger proportion of patients, 56.66%, had Type III skin, followed by 40.33% with Type IV skin. Type III skin occasionally burns and tans uniformly; Type IV skin rarely burns but always tans well. Hence, the sensitivity of the skin in selected patients is intermediate. The skin type was based on Fitzpatrick's type Wolluschan's chromatic scale correlated with tanning potential [5].

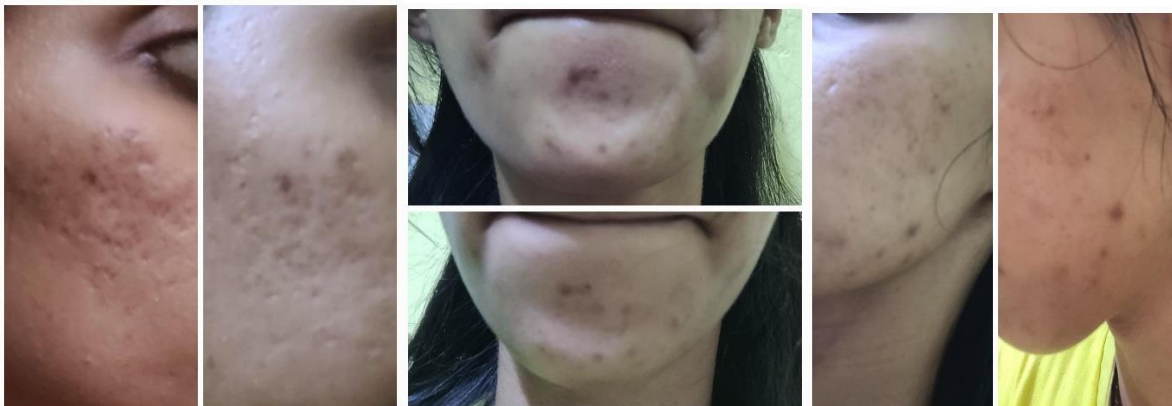
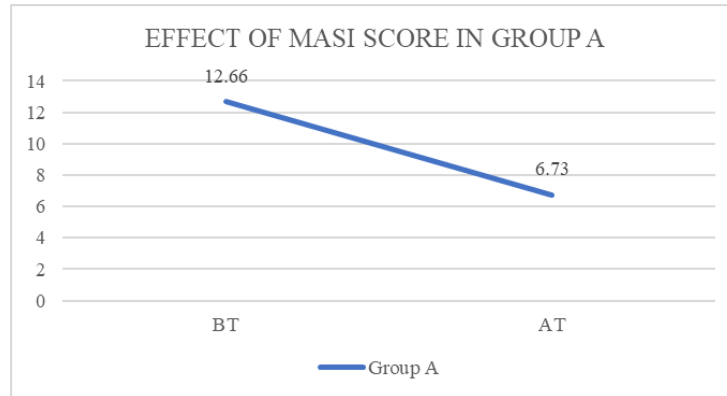


Table no. 3: Effect on MASI Score in group A

MASI SCORE GROUP A	Mean score	Difference in means	Paired t-test				Interpretation	
			% of Change	S. D	S.E.M	t		P
BT	12.66	5.93	47.07%	5.17	1.33	-6.42	0.000	HS
AT	6.73			2.31				

- The MASI Score before the treatment was 12.66 and after the treatment 6.73 and the mean difference of 5.93. which is statistically highly significant with a p-value of 0.000

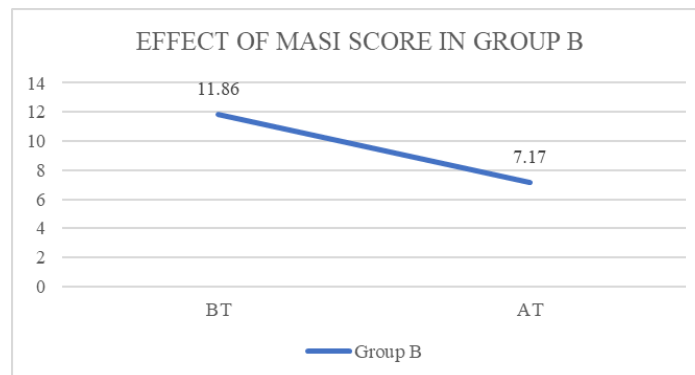


Graph no. 1: Effect of Treatment on MASI Score in Group A

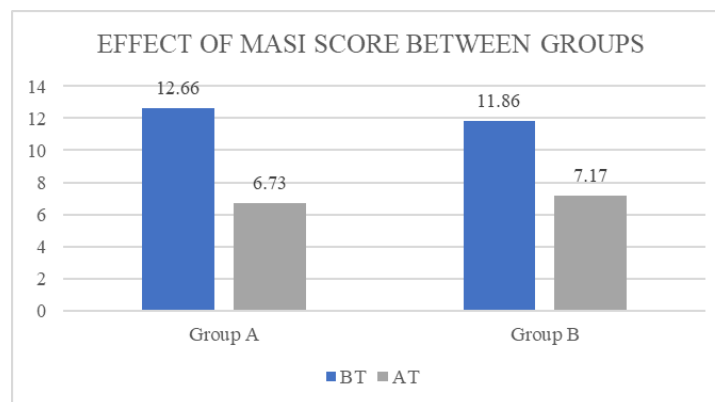
Table no. 4: Effect on MASI Score in Group B

MASI SCORE GROUP B	Mean score	Difference in means	Paired t-test				Interpretation	
			% of Change	S. D	S.E.M	t		P
BT	11.86	4.73	39.98%	4.64	1.19	-6.57	0.000	HS
AT	7.17			2.82				

- The MASI Score before the treatment was 11.86 and after the treatment 7.17 and the mean difference of 4.73. which is statistically highly significant with a p-value of 0.000



Graph no. 2: Effect of Treatment on MASI Score in Group B

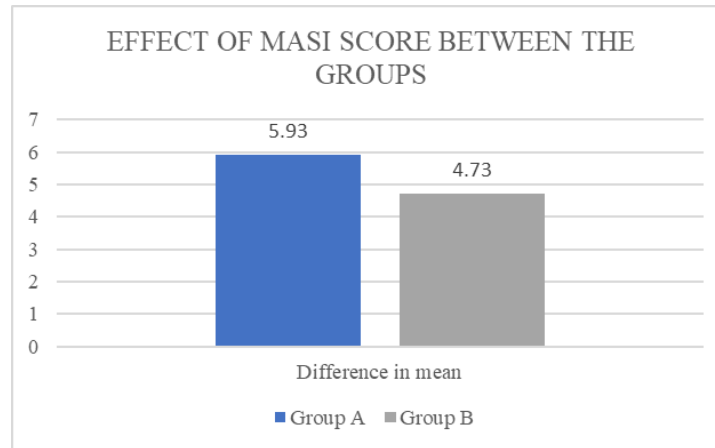


Graph no. 3: Effect of Treatment on MASI Score in Group A & Group B

Table no. 5: Comparative effect on MASI Score between the groups.

MASI Score	Group	N	Difference in mean	Unpaired t-test				Interpretation
				S. D	S.E.M	T	P	
BT-AT	Group A	15	5.93	3.57	0.92	-1.02	0.314	NS
	Group B	15	4.73	2.78	0.72			

In unpaired test, the comparative effect of MASI score showed insignificant result between the groups. However, comparatively Group A showed better results with the decrease of 5.93 of MASI score and 4.73 in Group B.



Graph no. 4: Comparative Effect of Treatment on MASI Score Between the Group

CONCLUSION

Manjishtadya taila and *Manjishtadya taila* cream showed a majority of the components to be similar in all the compounds. However, *Manjishtadya taila* had a more significant number of components.^[6] This resulted in significant changes in complexion and MASI score with notable reduction in dark spots and pigmentation. *Manjishtadya taila* and *Manjishtadya taila* cream both showed equal effectiveness, but statistically *Manjishtadya taila* had better results.

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