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ORIGINAL ARTICLE

Clinical Study to assess the tolerability and effectiveness of *Haridradya Taila* in Acne and Acne-induced Post-inflammatory Hyperpigmentation

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Abstract

Introduction: Acne is a condition of the pilosebaceous glands of skin characterized by anomalies in the production of sebum which includes both non-inflammatory lesions such as comedones (open and closed) and inflammatory lesions like pustules, papules and nodules. Patients with acne frequently seek treatment in inflammatory lesions state. *Haridradya Taila* is a classical preparation mentioned in *kshudra rogadhikar* of *Chakradatta*. The present study aimed to evaluate the safety and efficacy of *haridradya taila* in acne and acne induced post inflammatory hyperpigmentation. Total fifty patients in the age group of 18–45 years having mild to moderate acne and acne induced post inflammatory hyperpigmentation were enrolled. The statistical significance of the data was examined using SPSS. Clinical trial results were statistically significant for acne and acne induced post inflammatory hyperpigmentation. The results of this study suggest *Haridradya Taila* is safe and effective in the treatment of mild to moderate acne and acne induced post inflammatory hyperpigmentation.

Introduction

Acne is a condition affecting sebaceous glands of skin that is multifactorial in etiology. It is characterized by lesions present on face, chest and back region that appear when skin pores become blocked with bacteria, oil, and dead skin cells. Severity of acne can be graded according the number of lesions, type of lesion, and extent of the involvement of lesion and can result in post inflammatory hyperpigmentation and scarring.[1]

There are two types of acne lesions :

1. No inflammation: The open comedones (blackheads) or closed comedones (whiteheads) are non- inflammatory lesions .

2. Inflammation : pustules, papules and nodules are example of inflammatory lesions.[2]

The mild and moderate forms of acne include lesions only, whereas nodules, cysts, and eventually open lesions are seen in severe acne.

Erythema, desquamation, burning, itching, dyschromia, and discomfort are just a few of the other symptoms that are constantly present with acne. [3]

According to epidemiological studies, acne can develop in any age, despite the fact that it often starts during puberty and gets worse throughout the adolescence.

The incidence of post inflammatory hyperpigmentation (PIH) is especially concerning in acne patients with darker skin tones.[4] When the inflammatory lesions break off the epidermal basal layer, melanocytes produce more melanin.[5] Affected people's health-related quality of life may be significantly impacted by the emotional and psychological distress caused by dyschromias, such as PIH.[6]

Haridradya Taila is a classical preparation mentioned in *kshudra rogadhikar* of *Chakradatta*. This *taila* is indicated in conditions of acne (*Mukhadushika*) as well as hyper pigmentation of facial skin. [7]

This study was taken up to evaluate the safety and efficacy of local application of ***Haridradya Taila*** in the treatment of acne and post inflammatory hyperpigmentation .

Materials and Methods

Materials

Haridradya Taila (Table no. 1) was prepared and provided by Ozone Pharmaceutical Ltd, New Delhi and was analyzed in a NABL accredited laboratory for various physiochemical parameters relating to its identity, purity and strength.

Inclusion criteria

Patients of either sex having mild to moderate facial acne and mild to moderate acne induced PIH in clinical features.

Patients of age between 18-45 years.

Willing to take part in study.

Exclusion criteria

With Present History of Skin Disease e.g. Psoriasis, Dermatitis, Vitiligo etc. related to face.

Person suffering from any infective or contagious skin disease.

Under medication with antibiotics, antifungal and steroid during last one month.

Women on Oral contraceptives.

Patients of known uncontrolled hormonal disease.

Any kind of diagnosed hereditary skin disorder.

Patient who had undergone any type of skin treatment like laser therapy in last 6 months.

Study Design

Interventional, single arm, open label, prospective clinical trial was conducted in skin and hair care opd, Arogyashala, National Institute of Ayurveda, Jaipur. For the proposed work ethical clearance was taken from Institutional Ethical Committee NIA, Jaipur **(IEC/ACA/2021/01/05 Dt 9/6/2021)** and trial was registered in CTRI, New Delhi, (**CTRI/2022/01/039493**). A total of fifty patients 11 males and 39 females in 18–45 years of age group were enrolled.

Procedure of Application

After washing the face, patients was instructed to apply the study oil using the amount of oil and technique of application they normally use at home when applying a facial cream.

Patients was instructed to apply the study oil twice per day (morning and bedtime).

They were also instructed to discontinue all current serum, moisturizer or any other skincare products.

Clinical evaluation

Subjects were selected on screening visits and an informed consent in written form was taken from subjects for their involvement in the study. Subjects were advised not to do any facial makeup or application of any kind of skin care products or sunscreen on the face and neck area on the day of first visit. On the baseline visit after acclimatization of 15 min, sides and front photograph was taken. Baseline individual lesion count and overall lesion count in acne were done.

A single physician recorded all the clinical observations in patients using Investigator's Global Assessment scale [8] (table no. 2) for acne, lesion count and grading according to acne induced post inflammatory hyperpigmentation severity scale [9] (table no. 3) for evaluation.

Tolerance assessments:

Tolerance tests were carried out at the baseline, weeks 4 and 8. Local skin comfort was assessed by looking at the overall erythema, edema, dryness, and peeling (table no. 4) signs and symptoms as well as the subject's reports of the overall intensity of burning, stinging, itching, and tingling (table no. 5). [10]

STATISTICAL ANALYSIS

Statistical data was analyzed by One-Sample Chi-Square Test using SPSS 25.0 software (IBM Corporation, Armonk, NY, USA). All diagrams were generated using excel sheet.

Results were expressed as mean, chi-square test value with significance accepted at $P < 0.001$.

Results

Assessment was done on the base of Investigator's Global Assessment (IGA) Scale for Acne Severity, Lesion counting (non inflammatory, inflammatory and total), Acne induced Post inflammatory hyperpigmentation severity scale (For efficacy) and Tolerance assessment (0 to 3 point assessment scale): Erythema, edema, scaling, dryness, burning, stinging & itching (For Safety and Tolerance) before and after treatment.

Assessment parameters for efficacy

Patients were scored on the scale of 0 to 4 before and after treatment on the basis of Acne severity. Mean score reduced from 2.3 to 1.08 which was statistically significant result as described in table no. 6.

Total lesion count was done in each of 50 subjects and was categorized as inflammatory and non inflammatory lesions. More than 77 percent reduction in inflammatory lesion count and more than 74 percent reduction was observed in non inflammatory lesion count in 8 week study (table no. 7). Statistically significant improvement was seen in chi square test.

Out of 50 patients 23 patients had (80-100 %) complete relief, 11 patients show moderate (60-80 %) relief, 8 patients show mild (40-60%) relief in inflammatory lesions.

Further 20 patients reported (80-100%) complete relief, 23 patients had moderate (60-80%) relief, 4 patients had mild (40-60%) relief in non-inflammatory lesions.

Haridradya taila was assessed on acne induced post inflammatory hyperpigmentation severity scale. It shows significant results in reducing Overall Disease Severity, Pigmentary Intensity of hyperpigmented lesions, Area of hyperpigmented lesions (% Facial Area) and Degree of hypopigmentation. There was significant reduction in Erythema, Burning, Peeling, Dryness(table no. 8)

Assessment parameters for safety and tolerance :

Tolerance parameters (assessed by investigator)

Test sample was assessed for its safety and tolerance on scale of 0 to 3. Trial drug has soothing effect on all patients and Erythema, Edema, Dryness and Peeling was reduced in 85.96%, 72%, 83.53%, 75.86% patients respectively (table no. 9).

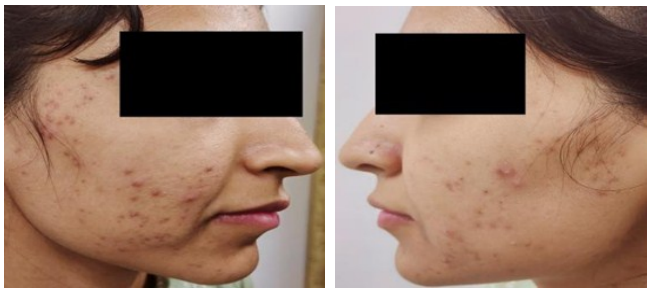
Tolerance parameters (scoring done by subject himself)

No new adverse features was seen in patients but the patients who have already these symptoms reported significant changes as described in table no. 10.

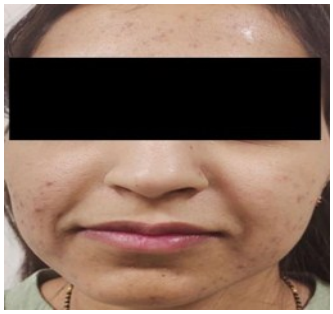
Haridradya Taila (ref. *Chakradutta*) by Ozone Pharmaceutical Ltd. has shown statistically significant results reducing in Acne Severity (IGA acne severity score), lesion count (inflammatory and non inflammatory lesions) and post acne hyperpigmentation marks. It has also shown significant reduction in Erythema, Edema, Dryness, Peeling, Burning, Stinging, Itching and Tingling. No adverse reaction was reported in any of the patient through out the study. Thus local application of *Haridradya Taila* is safe and effective in management of mild to moderate acne.

Some before and after photographs of patients.

Case no. 1

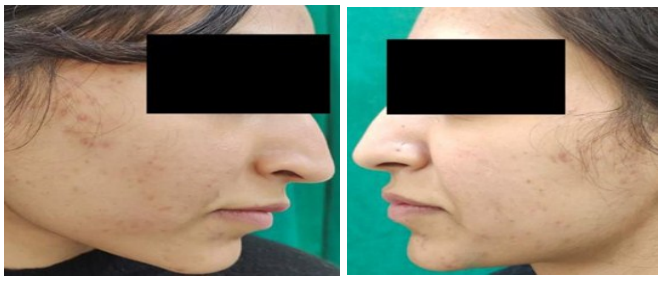


(a) - Lateral view of face (right) (b)- Lateral view of face (left)

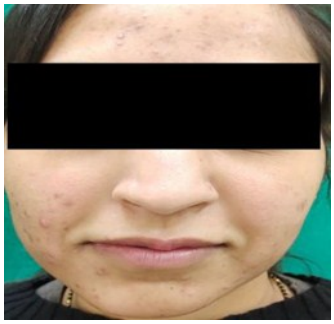


(c) – Front view of face

Figure 1: (a), (b), (c) Images taken before treatment of patient no. 1.



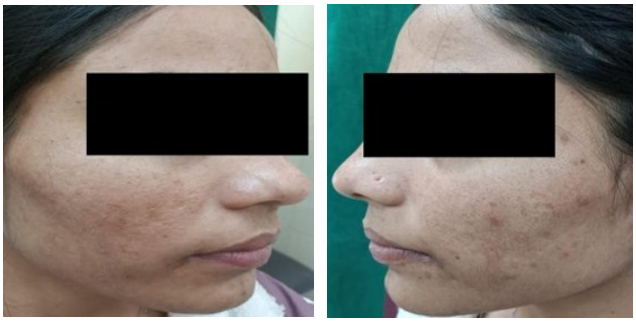
(a) - Lateral view of face (right) (b)- Lateral view of face (left)



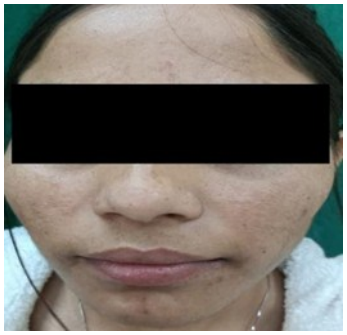
(c) – Front view of face

Figure 2: (a), (b), (c) Images taken after treatment of patient no. 1.

Case no. 2

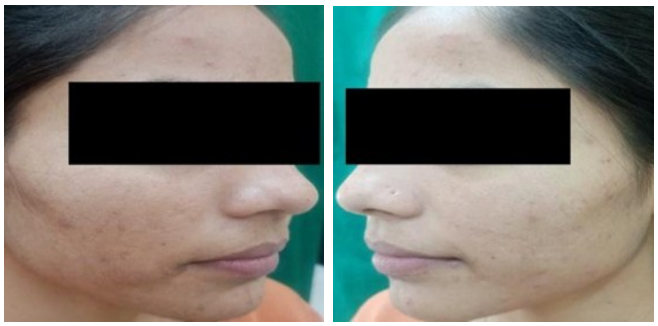


(a) - Lateral view of face (right) (b)- Lateral view of face (left)

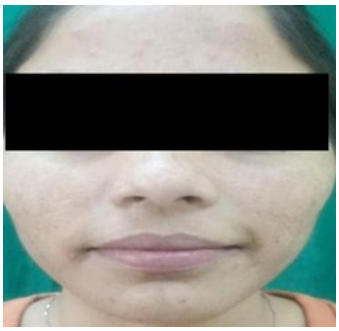


(c) – Front view of face

Figure 3: (a), (b), (c) Images taken before treatment of patient no. 2.

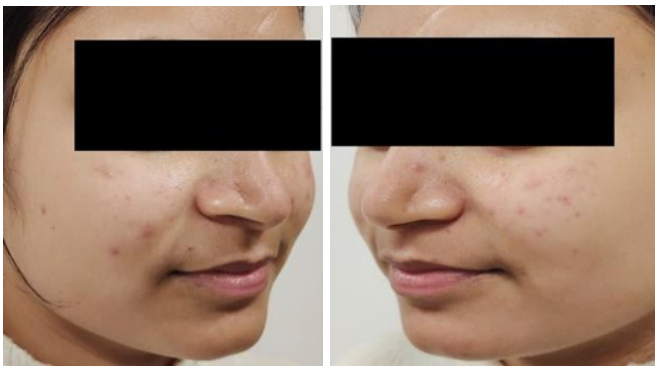


(a) - Lateral view of face (right) (b)- Lateral view of face (left)



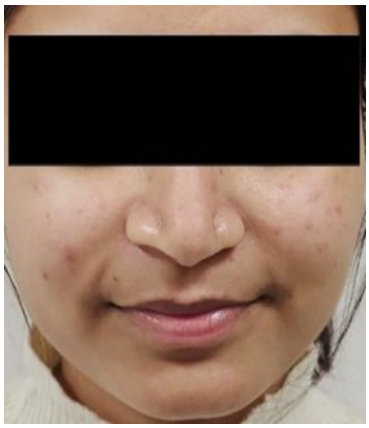
(c) – Front view of face

Figure 4: (a), (b), (c) Images taken after treatment of patient no. 2.



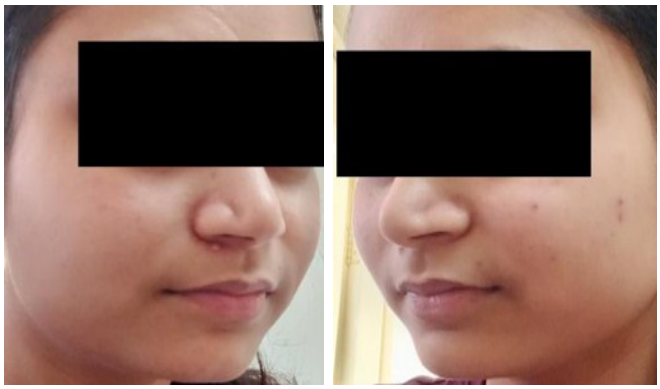
(a) - Lateral view of face (right) (b)- Lateral view of face (left)

Case no. 3

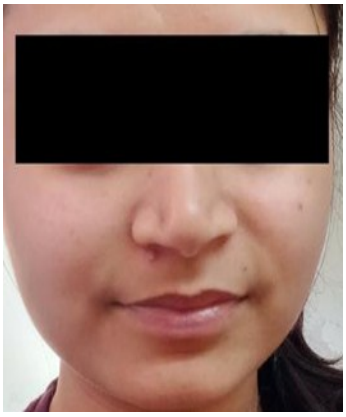


(c) – Front view of face

Figure 5: (a), (b), (c) Images taken before treatment of patient no. 3.



(a) - Lateral view of face (right) (b)- Lateral view of face (left)



(c) – Front view of face

Figure 6: (a), (b), (c) Images taken after treatment of patient no. 3.

Figure. 1, 2, 3, 4, 5, 6. Patients with acne vulgaris: before treatment with the *Haridradya taila*, and 8 weeks after treatment . Clinical improvement was observed after treatment with the *Haridradya taila*.

MODE OF ACTION

Ayurveda explains the development of *Mukhadushika* due to vitiation of *vata* and *kapha* dosha. [11] These vitiated doshas also vitiate *rakta* dhatu, which inturn vitiates medodhatu. Due to this *medodhatu dushti*, excessive *sweda* is formed, which is deposited in *romakupa* and produce *swedavaha srotas dushti* which eventually results in *Mukhadushika*. We selected *Haridradya taila* for the study. *Haridradya taila* is described in the Ayurvedic classical text *Chakrdutta* under the *kshudra rogadhikara*. Describing the properties of this oil, it is said that applying *Haridradya taila* to the skin every day will remove *vyanga*, *nilika*, *tilakalka*, and *mukhdushika*. *Haridradya taila* contains 14 herbal drugs. These include *Haridra , Daruharidra, Yashti , Kaliyak, Kuchandana , Manjishtha, Kamal , Kumkum, Padmak, Kapitha , Tinduka , Plaksha, Vata, Tila taila .* Both *haridra, daruharidra* have *kapha* and *pitta* pacifying, cleansing, anti-inflammatory, and wound healing properties. *Yashti* contain anti-itching and complexion improving properties as well as pacify *pitta* and *vata. Manjishtha* pacifies *pitta* and *kapha* and *kumkuma* pacifies *vata* and *kapha* has the ability to improve the complexion.[12] *Kamal* and *padmaka* pacify *pitta, kapha. Kapitha, tinduka, plaksha* and *vata* pacify *kapha* and *pitta* and promote wound healing hence helpful in scar. [13] *Kaliyak* and *kuchandan* removes *pitta,* useful in wound, alleviates iching and poison. *Tila taila* has ability to penetrate the skin layers, as well as possess healing properties and balances *tridoshas* to keep skin healthy and nourished. The effect of these drugs is antiseptic, antibacterial, anti-inflammatory that reduce redness associated with acne.

Haridradya taila show better results in patients with less oily skin. Better results were observed after washing face before application of oil.

Conclusion

Although the empiric evidences for the efficacy of herbal medicines in acne is not enough, the results of the present study suggest that the *haridradya taila* was useful in the treatment of *acne vulgaris*.

Table no. 1. Contents of *Haridradya taila*:

S.No	Ingredients	Botanical Name	Part Used
1.	*Haridra*	*Curcuma longa* Linn.	Rhizome
2.	*Daruharidra*	*Berberis aristata* DC.	Root
3.	*Yashti*	*Glycirrhiza glabra* Linn	Stolon
4.	*Kaliyak*	*Cocculus hirsutus* (L) Diels	Stem
5.	*Kuchandana*	*Pterocarpus santalinus* L.f.	Heartwood
6.	*Manjishtha*	*Rubia cordifolia* Linn.	Root
7.	*Kamal*	*Nelumbo nucifera* Gaertn	Flower
8.	*Kumkum*	*Crocus sativa* Linn.	Stigma
9.	*Padmak*	*Prunus cerasoides* D. Don	Stem
10.	*Kapitha*	*Limonia acidissima* Linn.	Fruit
11.	*Tinduka*	*Diospyrous montana* Roxb.	Fruit
12.	*Plaksha*	*Ficus lacor* Buch.-Ham	Bark
13.	*Vata*	*Ficus benghalensis* Linn.	Leaves
14.	*Tila taila*	*Sesamum indicum* Linn.	Seed oil

Table no. 2: Investigator's Global Assessment scale:

Grade	Symptoms
0	Skin clear, indicates no lesions, whether they are inflamed or not
1	Almost clear, Rare non-inflammatory lesions that are nearly clear and not have more than one minor inflammatory lesion
2	Mild, with a few non-inflammatory lesions and a limited number of inflammatory lesions
3	Moderate, with several non-inflammatory lesions, some inflammatory lesions, but not more than one nodule lesion
4	Severe, with numerous non-inflammatory and inflammatory lesions, but not more than a few nodular lesions.

Table no. 3. Post-inflammatory hyperpigmentation severity scale:

GRADE	OVERALL DISEASE SEVERITY	PIGMENTARY INTENSITY OF HYPER-PIGMENTED LESIONS	AREA OF HYPER-PIGMENTED LESIONS (% FACIAL AREA)	DEGREE OF HYPO-PIGMENTATION	ERYTHEMA, BURNING, PEELING, DRYNESS
0	Normal	None	None	None	None
1	Present, but <mild	Trace (mild and localized)	Trace (1–10%)	Trace (slight and localized)	Trace
2	Mild (slightly noticeable)	Mild (mild and diffuse)	Mild (1–25%)	Mild (slight and diffuse)	Mild
3	Between mild and moderate	Moderate (moderate and diffuse)	Moderate (26–40%)	Moderate (noticeable and diffuse)	Moderate
4	Moderate (noticeable)	Marked (moderate and dense)	Marked(41–50%)	Marked (noticeable and dense)	Marked
5	Between moderate and marked	Severe (prominent and dense)	Severe (>50%)	Severe (complete lack of melanin pigmentation)	Severe
6	Marked (distinctive)	–	–	–	–
7	Between marked and severe	–	–	–	–
8	Severe (very distinctive)	–	–	–	–

Table no. 4. Irritation Parameters (assessed by investigator):

Erythema	
0 = None	No erythema in the treated area
1 = Mild	The treated area has a faint but definite redness
2 = Moderate	Clearly visible redness in the treatment area
3 = Severe	Extremely noticeable redness in the treatment area
Edema	
0 = None	No edema or swelling in the treated area
1 = Mild	Slight noticeable edema in the treatment area
2 = Moderate	Definite edema in the treated area
3 = Severe	Extremely marked edema in the treatment area
Dryness	
0 = None	No dryness in the treated area
1 = Mild	Slight noticeable dryness of the treatment area
2 = Moderate	Definite dryness in the treated area
3 = Severe	Extremely marked dryness of the treatment area
Peeling	
0 = None	No peeling in the treated area
1 = Mild	Slight noticeable peeling in the treatment area
2 = Moderate	Definite peeling in the treated area
3 = Severe	Extremely noticeable peeling of the treatment area

Table no. 5. Irritation Parameters (scoring done by subject himself):

Burning	
0 = None	No burning in the treated area
1 = Mild	Slight burning sensation in the treated area
2 = Moderate	Definite burning sensation in the treated area
3 = Severe	Severe hot burning sensation in the treated area that is definitely uncomfortable and may interrupt daily activities and/or sleep
Stinging	
0 = None	No stinging in the treated area
1 = Mild	Slight stinging sensation in the treated area
2 = Moderate	Definite stinging sensation in the treated area
3 = Severe	Severe stinging sensation in the treated area that is very uncomfortable and may interrupt daily activities and/or sleep
Itching	
0 = None	No itching in the treated area
1 = Mild	Slight itching sensation in the treated area
2 = Moderate	Definite itching sensation in the treated area
3 = Severe	Marked itching sensation in the treated area that is extremely uncomfortable and may interrupt daily activities and/or sleep
Tingling	
0 = None	No tingling sensation in the treated area
1 = Mild	Slight tingling sensation in the treated area
2 = Moderate	Definite tingling sensation in the treated area
3 = Severe	Marked tingling sensation in the treated area that causes definite discomfort

Table no. 6. Results showing IGA scale for acne severity:

Parameter	No. of Patients	Mean		% Relief	Chi-Square Test Value	P	Remarks
		BT	AT				
IGA Scale for Acne Severity	50	2.3	1.08	53.04	24.280a	<0.001	Significant

Table no. 7. Results showing lesion count:

	Parameter	No. of Patients	Mean		% Relief	Chi-Square Test Value	P	Remarks
			BT	AT				
Lesion count	Inflammatory Lesion	50	7.44	1.68	77.42	22.000a	<0.001	Significant
	Non-Inflammatory Lesion	50	15.4	3.98	74.16	19.120a	<0.001	Significant

Table no. 8. Showing results of acne induced post inflammatory hyperpigmentation severity scale:

	Parameter	No. of Patients	Mean		% Relief	Chi-Square Test Value	P	Remarks
			BT	AT				
Acne induced Post inflammatory hyper pigmentation severity scale	Overall Disease Severity	50	2.82	1.4	50.36	32.600a	<0.001	Significant
	Pigmentary Intensity of hyperpigmented lesions	50	2.16	0.94	56.48	13.480a	<0.001	Significant
	Area of hyperpigmented lesions (% Facial Area)	50	2.06	0.84	59.23	24.280a	<0.001	Significant
	Degree of hypopigmentation	50	0.88	0.24	72.72	25.680a	<0.001	Significant
	Erythema, Burning, Peeling, Dryness	50	1.4	0.4	71.43	16.080a	<0.001	Significant

Table no. 9. Showing results of tolerance parameters assessed by investigator:

Parameter	No. Of Patients	Mean		% Relief	't'	P	Remarks
		BT	AT				
Erythema	50	1.14	0.16	85.96	37.520a	<0.001	Significant
Edema	50	0.5	0.14	72	18.760a	<0.001	Significant
Dryness	50	1.7	0.28	83.53	16.720a	<0.001	Significant
Peeling	50	0.58	0.14	75.86	13.480a	<0.001	Significant

Table no. 10. Showing results of tolerance parameters assessed by subject himself:

Parameter	No. Of Patients	Mean		% Relief	't'	P	Remarks
		BT	AT				
Burning	50	0.98	0.06	93.88	6.280a	<0.001	Significant
Stinging	50	0.54	0.12	77.78	16.360a	<0.001	Significant
Itching	50	1.64	0.32	80.48	18.800a	<0.001	Significant
Tingling	50	0.56	0.12	78.57	15.520a	<0.001	Significant

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