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IP Indian Journal of Clinical and Experimental Dermatology

Journal homepage: www.innovativepublication.com

Original Research Article

Safety and efficacy of skimune tablet and gel with respect to psoriasis

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ARTICLE INFO

Article history:
Received 19-12-2019
Accepted 16-01-2020
Available online 21-04-2020

Keywords:
Skimune
Psoriasis
Ayurveda
Inflammation
Chronic

ABSTRACT

Psoriasis is an autoimmune disorder. It is characterized by chronic inflammatory condition of skin. It leads to thick, scaly plaques on skin . Current medication involves symptomatic treatment by the various moisturizers, however, the effects do not last long and recurrence occurs. Based on several ancient text a combination of herbs was formulated and named as Skimune tablet and Gel. Preclinical safety was conducted which was found to be safe for the dose above 5000 mg/kg of body weight. The beneficial effects of Skimune Tablet and Gel was clinically evaluated on patients with mild to moderate psoriasis. The Dermatology Life Quality Index (DLQI) and Psoriasis area & severity index (PASI) score was evaluated to understand the effects of tablet and Gel. Skimune tablet was found to be safe upto 5000mg/kg of body weight in animals and was well tolerated in patients too. Skimune Tablet and Gel showed significant improvement ($P < 0.05$) before and after treatment with patient with psoriasis

1. Introduction

Psoriasis is a common dermatologic disease, affecting up to 1% of the World's population.[1] Psoriasis is a non - infectious, chronic inflammatory disease of skin, characterized by well - defined erythematous plaques with silvery white scale with a predilection for the extensor surface and scalp, and a chronic fluctuating course. In psoriasis, main abnormality is of increased epidermal proliferation due to excessive multiplication of cells in the basal layers. The transit time of keratinocyte is shortened and epidermal turnover is reduced to 5 - 6 days from 28- 30 days.[2] Even though the aetiology is unknown, the factors involved are genetic, biochemical and immunopathological.[3] Precipitating factors like trauma, infections, sunlight, some drugs and emotions may flare up the disease.

Treatment in allopathic uses various moisturizer either in creams or lotion form. Recurrence is the major setback with this therapy. Apart from physical problems, mental and social distress is the major concern of the treatment . Ayurveda has the answer to all the problems associated with skin and is most widely accepted alternative medicine. Various ayurvedic combination have been reported to have positive effects on skin, also it keeps mental stress at bay.[4] Skimune Tablet and Gel was formulated on the basis of Ayurved and ancient texts. The Tablet formulation is the balanced combination of Ghandak rasayan, Khadirstakam Ext, Navakashya guggul processed in Manjistha and Anantmool. All these ingredients have reference in ancient text to be used in kusth roga (Psoriasis). The Gel formulation is based on Sneh Paka vidhi with the use of Mustard oil as the base.

2. Aims and Objectives

To assess the Safety and Efficacy of Skimune Tablets and Gel in the management of Psoriasis (Kustha roga).

3. Material and Methods

Pre-clinical Toxicity study as per OECD guidelines no. 420 was conducted at Bombay college of Phar-

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https://doi.org/10.18231/j.ijced.2020.001

macy, Kalina , Mumbai with registration number as 242/PO/RE/S/2000/CPCSEA; 01/08/2000 vide protocol approval number as CPCSEA-BCP-/2017-01/11.

3.1. Clinical study design

Sample size - 40

Study conducted from May, 2016 and ended on 16/02/2017

3.2. Study duration

9 weeks Follow up every 15 days till end of the study

3.3. Drug formulation

Skimune Tablets 2 bid and Skimune Gel applied liberally 2 times a day.

3.4. Screening and Criteria for assessment of patients

Psoriasis was diagnosed clinically by a consultant dermatologist or experienced general practitioner. It was characterized by a Psoriasis Area and Severity Index (PASI) score of >10 and Dermatology Life Quality Index (DLQI)

3.5. Inclusion criteria

1. Patients between age group 16-60 years.
2. Patients with psoriasis which had been stable for at least 2 months and is not any therapy for last 2 weeks.

3.6. Exclusion criteria

1. Patients who had been treated aggressively by beta blockers or those patients with other complications such as lymphoma and infections were excluded.
2. Patients having Diabetes Mellitus, Cancer, AIDS, TB and other skin diseases like seborrhic dermatitis, lichen simplex chronicus, etc.
3. Age less than 13 years and more than 70 years.

3.7. Statistical analysis

Standard Paired ‘ t’test was used to find out significance between the various results.

P value • $P > 0.05$ - Not significant or not quite significant • $P < 0.05$ – Significant • $P < 0.01$ - Very significant • $P < 0.001$ - Highly significant

4. Results

4.1. Pre-clinical Acute Toxicity Studies

Toxicity studies was carried out as per the OECD Guidelines no. 420 on three different dose levels viz Low (8.5mg/kg), Medium (85 mg/kg) and High (850 mg/kg). No clinical signs of toxicity were observed. Even n o mortality was observed at any of the observation time points (14 days) following the administration of oral doses of Skimune tablets. All animals survived during the entire period of observation. Animals sacrificed at the end of the study did not show any pathological changes.

4.2. Clinical Outcome of the study

4.2.1. No of Patients completed the study

40 patients were screened and enrolled for the study with the help of questionnaire filled by the doctors. 34 patients completed the 9 week treatment and results were been evaluated on the basis of 34 patients.

4.2.2. History and Sex wise distribution of patient:

52.94% were males and 47.05% were females. 35.29 % of patients were diagnosed before the age of 30 years old and 47.05 % were diagnosed after the age of 30 (Table 2). Majority of the patient reported Stress as the major factor for diseases followed by Temperature changes and then sun burn.

4.2.3. Questionnaire based on Dermatology life quality index (DLQI)

Questionnaire based on Dermatology life quality index (DLQI) provides qualitative and validated results from patient with psoriasis. The effect of Skimune tablets and Gel on DLQI was analyzed before and after treatment using different questions. It was observed that DLQI index significantly increased from 41.90% to 74.26 %, which means 74.26% relief of the symptoms were reported by the patients.

4.2.4. Effect on Psoriasis Area and Severity Index (PASI) score

The Psoriasis Area and Severity Index (PASI) is a quantitative rating score for measuring the severity of psoriatic lesions based on area coverage and plaque appearance. The PASI score was used to measure the average redness, thickness, and scaliness of the lesions (0 – 4 scale for each parameter) and the areas of involvement (0 – 6 scale). The effect of Skimune tablet and Gel on PASI Score was analyzed before treatment and after treatment of 9 weeks.

- **Erythema:** After treatment of 9 weeks, the mean erythema reduced from 1. 28 to 0. 42 on upper limbs. This indicates 67.23 % relief with the treatment with skimune tablet and gel. Similarly redness of lesion was reduced in lower limb too, gradually with mean results from 1.35 to 0.41, which indicates 69.62 % relief with the patients.
- **Induration:** After treatment, induration (thickness of lesions) was reduced from 0.8 to 0.1 in upper limbs and the thickness of lesion in lower limb reduced from

Table 1: Clinical Signs and Mortality in animals

Observation	Vehicle Control	Low dose	Medium dose	High Dose
Ataxia	NO	NO	NO	NO
Convulsion	NO	NO	NO	NO
Exophthalmos	NO	NO	NO	NO
Lacrimation	NO	NO	NO	NO
Oral Discharge	NO	NO	NO	NO
Nasal Discharge	NO	NO	NO	NO
Diarrhoea	NO	NO	NO	NO
Piloerrection	NO	NO	NO	NO
Rough Coat	NO	NO	NO	NO
Mortality	NO	NO	NO	NO

Note: NO – Not Observed

Table 2: Sex wise distribution:

Distribution	No of Patients	% distribution
Male	18	52.94
Female	16	47.05
Minimum years of disorder		
Age less than 30	12	35.29
Age more than 30	22	64.70
Family history of psoriasis		
Yes	12	35.29
No	22	64.70

Table 3: Dermatology Life Quality Index (DLQI) Questionnaire (Before Treatment (0) After Treatment (9)).

	Very much	A lot	A little	Not at all
Inflamed skin with itch				
Before Treatment (0)	8(23.52 %)	10(29.41 %)	10(29.41%)	6(17.64 %)
After Treatment (9)	0(0%)	4(11.76 %)	4(11.76 %)	26(76.47 %)
Mental issue				
Before Treatment (0)	5(14.70%)	9(26.47%)	12(35.29%)	8(23.52%)
After Treatment (9)	1(2.94%)	2(5.88%)	8(23.52%)	23(67.64%)
Day to day work				
Before Treatment (0)	4(11.76%)	2(5.88%)	10(29.41%)	18(52.94%)
After Treatment (9)	1(2.94%)	0(0.0%)	7(20.58%)	26(76.47%)
Difficulty in dressing				
Before Treatment (0)	6(17.64 %)	6(17.64%)	12(35.29%)	10(29.41%)
After Treatment (9)	2(5.88%)	1 (2.94%)	6(17.64%)	25(73.52%)
Social issues				
Before Treatment (0)	4(11.76%)	5 (14.70%)	10(29.41%)	15(44.11%)
After Treatment (9)	0(0%)	3 (8.82%)	8(23.52%)	24(70.58%)
Social issues with relatives and friends				
Before Treatment (0)	0(0.0%)	5(14.7%)	14(41.11%)	15(44.11%)
After Treatment (9)	0(0%)	2(5.88%)	7(20.58%)	25(73.52%)
Sexual difficulties				
Before Treatment (0)	1(2.94%)	3(8.82%)	4(11.76%)	26(76.47%)
After Treatment (9)	0(0%)	2(5.9%)	3(8.8%)	29(85.3%)
Consumption of Time				
Before Treatment (0)	0(0%)	7(20.58%)	11(32.35%)	16(47.05%)
After Treatment (9)	0(0%)	3(8.82%)	7(20.58%)	24(70.58%)

0.85 to 0.06. Mean reduction in upper limb was found to be 87.5% whereas in lower limb it was 92.94%. This showed that treatment with Skimune tablet and Gel significantly ($P<0.05$) reduced thickness of lesion in psoriatic patients.

- **Scaling:** Treatment with Skimune tablet and Gel for 9 weeks significantly ($P<0.05$) reduced scaling of lesion in upper limb as well as lower limb. It was noticed that scaling in upper limb was reduced from 1.2 to 0.25 whereas in lower limb it was reduced from 1. 1 to 0.10 . Mean relief found in patient was 85.0%
- **Area:** Area of psoriatic lesion was assessed before and after treatment with Skimune Tablet and Gel. Significant reduction ($P<0.05$) in the area of lesion was found with the treatment of Skimune Tablet and Gel. It may considered as the important as well as final outcome of the PASI score. Mean reduction in the score was seen from 0.94 to 0.33 in upper limb and in case of lower limb from 1.25 to 0.42.

5. Discussion

Skimune Tablet and Gel was well tolerated in patients and did not have any major side effects. Majority of the patients (more than 70% patients) claimed to be benefited from the treatment. It remarkably improved the mental and social status of the patient.

The mechanism of action of ingredients of Skimune Tablet possesses Kusthaghna (Herbs acting on Skin diseases), Kandughna (Anti-Pruritic Herbs) and Krimighna (Anthelmintic Herbs) properties. Due to its Krimighna and Vishaghna properties it directly affect the skin, prevents infection and Hyperkeratinisation .

All the ingredients are mainly Katu, Tikta and Kashaya rasa Pradhan which decreases kapha dosha. Tikta rasa stimulates Agni (Metabolism) by promoting samana vata and absorbing kapha which is responsible for mandagni (sluggish metabolism). Katu , Tikta rasa has property of Srotoshodhan (Metabolic Pathways) by expelling the obstructive material. It also penetrates in the micro channels and helps to remove obstruction.

The Deepana and Pachana effect corrects the vitiated Bhrajakka pitta (Which imparts colour to the skin) of the skin, via correction of pachaka pitta. Rasayana (Immunomodulator) properties which improve immunity status of skin thus total health of the skin improve significantly. Tikta Rasa has property of Deepana and Pachana (Metabolism), which potentiates Jatharagni and Dhatvagni, and in this way it reduces the formation of Ama (Metabolic Waste) resulting in arresting of progression in Dhatu shaithilya (Premature degeneration of tissues)

Tikta rasa acts as anthelmintic, blood purifier, eliminates toxins and is useful in various skin diseases. Kashaya rasa has healing property and helps in normalizing skin pigmentation. Prasadana property of Sheeta Veerya also helps to purify the accumulated Doshas. Laghu and Ruksha guna helps to relieve vata and kapha.

Based on our findings, we believe that the Skimune tablet and Gel showed significant beneficial effects in the patients with psoriasis.

6. Source of funding

None.

7. Conflict of interest

None.

References

1. Fauci, Braunwald, Kasper, Hauser, Longo J, et al. Harrison's Principal of Internal Medicine. vol. 1. McGraw Hill Companies; 315.
2. Davidson's. Principles and practice of medicine. In: and others, editor. (Diseases of the skin). Churchill livin stone publication; 2010.
3. Hertl M. Autoimmune diseases of skin. Wein New York: Springer;. p. 328–331.
4. Charmi M, Dave A, Shukla V. Ayu. 2011;32(3):333–339.

Cite this article: Vador N, Vador B. **Safety and efficacy of skimune tablet and gel with respect to psoriasis**. *IP Indian J Clin Exp Dermatol* 2020;6(1):1-4.