

Evaluation of safety and efficacy of skimune tablet and gel in patients with psoriasis

Palak Garg¹, Gaurav Rajauria², Kishor Singh³

¹⁻³ Department of Dermatology and Venereology & Leprosy, Nims Medical College & Hospital Rajasthan, Jaipur, India

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. The beneficial effects of Skimune Tablet and Gel were 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 well tolerated in patients. skimune Tablet and Gel showed significant improvement ($P < 0.05$) before and after treatment with patient with psoriasis.

Keywords: Skimune, psoriasis, DLQI, safety, efficacy

Introduction

Psoriasis is a chronic, immune mediated, inflammatory and proliferative condition of the skin in which both the genetic and environmental factors plays a critical role. Initiation of disease and exacerbation of disease occur by many environmental factors like the trauma, infection, medication, metabolic factors and psychogenic factors, alcohol, smoking 2,3,4. The duration of illness is chronic in nature with intermittent exacerbation and disfigurement can cause further increase in the sufferings of the patients [1, 2, 3, 4, 5].

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. 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 Anantmol. All these ingredients have reference in ancient text to be used in kuth roga (Psoriasis). The Gel formulation is based on Sneh Paka vidhi with the use of Mustard oil as the base [6, 7, 8, 9, 10].

Aim

To evaluate the safety and efficacy of skimune tablet & gel in the treatment of psoriasis.

Material and Methods

A prospective observational single centered study of three months conducted in the dermatology department in a tertiary care teaching hospital of northern region of India. A total 40 patients diagnosed with psoriasis with both gender male and female.

Drug formulation

Skimune Tablets bid and Skimune Gel applied twice in a

day.

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)

Selection criteria

Inclusion criteria

- Patients between age group 18-60 years.
- All newly diagnosed cases, as well as old cases of psoriasis with exacerbations will be evaluated under study.

Exclusion criteria

- All psoriasis patients who are handicapped or having other chronic debilitating diseases or other associated chronic skin disorders will be excluded from the study.

Data was compiled in excel sheet and statistical analyze the data, to prepare table, graph with the help of SPSS 22.0. The level of significance was 5%.

Results

40 patients were screened and enrolled for the study with the help of questionnaire filled by the dermatologist.

Table 1: demographic details of all CKD patients

	Frequency (%)
Gender	
Male	24 (60.0%)
Female	16 (40.0%)
Age Group	
<20	6 (15.0%)
21-40	16 (40.0%)
41-60	18 (45.0%)

(n=40) are summarized in table no. 1. The study population consisted of 24 (60.0%) males and 16 (40.0%) females. Frequency of patients falls under age group 41-60 year.

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. Result summarize in table no. 2

Table 2

Parameter	After Treatment	Mean	Frequency
Erythema	Reduced	1.25	33 (82.5%)
Induration	Reduced	0.86	37 (92.5%)
Scaling	Reduced	1.2	34 (85.0%)
Area	Reduced	0.94	38 (95.0%)

Questionnaire based on Dermatology life qualityindex (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 70.0% to 84.0% which means 77.0% relief of the symptoms was reported by the patients. Result summarized in table no. 3

Table 3

	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%)	70(70.58%)

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 ^[1, 2].

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 ^[3, 4].

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 ^[5].

The Deepana and Pachana effect corrects the vitiated Bhrajakk 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) ^[6, 7].

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 ^[8, 9].

Based on our findings, we believe that the Skimune tablet and Gel showed significant beneficial effects in the patients with psoriasis [10, 11, 12].

Conclusion

It was concluded that Skimune tablet and Gel showed significant beneficial effects in the patients with psoriasis.

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 living stone publication, 2010.
3. Hertl M. Autoimmune diseases of skin. Wein New York: Springer, 328-331.
4. Charmi M, Dave A, Shukla V. Ayu. 2011; 32(3):333-339.
5. Krieger GG, Eyre RW. Trigger factors in psoriasis, Dermatology clinics, edited by G. weinstien, J Voorhees, Philadelphia, Saunders, 1984, p313.
6. CEM Griffiths, RDR. Camp and J.N.W.N. Barker. Psoriasis Chapter 25. in: Tony Burns, Stephen Breathnach, Neil Cox, Christopher Griffiths. Rooks Textbook of Dermatology. Cotterill JA, Millard LG. Psychocutaneous disorders. In: Champion RH, Burton JL, Burns DA, Breath nach SM. eds. Text book of Dermatology 6th ed. Oxford: Blackwell Science, 1998, 2785-9.
7. Park BS, Youn Ji. Factors influencing psoriasis: an anlysis based upon the extent of involvement and clinical type. J Dermatol. 1998; 25:97-102.
8. Sampogna F, Chren MM, Age, gender, quality of life and psychological distress in patients hospitalised with psoriasis. Br J Dermatol. 2006; 154(2):325-31.
9. Finlay AY, Coles EC. The effect of severe psoriasis on quality of life of 369 patients. Br J Dermatology, 1995; 132:236-44.
10. Fortune DG, Main CJ, Sullivan OTM, *et al.* Quality of life in patients of psoriasis: the contributions of clinical variables and psoriasis specific stress. Br J Dermatol, 1997, 755- 760.
11. Feldman SR, Fleischer AB Jr, Reboussin DM, Rapp SR, Bradham DD, Exum ML, *et al.* The economic impact of psoriasis increases with psoriasis severity. J Am Acad Dermatol. 1997; 37:564-9.
12. Finlay AY, Coles EC. The effect of severe psoriasis on the quality of life of 369 patients. Br J Dermatol. 1995; 132:236-44.