



A Real-World, Non-interventional Indian Study Evaluating Intensive Plant-Based Butter Moisturizing Cream in Psoriasis

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ABSTRACT

Introduction: Psoriasis is estimated to affect 0.44–2.8% of the Indian population. Moisturizers are a key adjuvant psoriasis treatment strategy, but data regarding their effectiveness, safety and compliance pattern in an Indian context are lacking. Hence, this real-world study on an intensive plant-based butter

moisturizing cream (Venusia[®] Max) was conducted among Indian patients with psoriasis.

Methods: This was an observational, patient-reported outcomes (PRO) study in patients with psoriasis aged 18–75 years who were prescribed the cream in routine clinical practice, as per clinician's discretion, over 4 weeks. The primary outcome measure was improvement from baseline in quality of life assessed using the Dermatology Quality of Life Index (DLQI) at 4 weeks of the study period. The secondary outcome measures were improvement in dryness using the Dry Skin/Ichthyosis Area and Severity Index (DASI) score at 4 weeks, safety and compliance. The DLQI and DASI scores were recorded by the clinicians at baseline and after 2 (optional) and 4 weeks of starting the

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cream. Safety was assessed throughout the study.

Results: The study included 400 patients from 9 outpatient dermatology centers across India. Of 400 patients, 384 completed the study. A significant reduction in both the mean DLQI score (66.7%; $p < 0.001$) and mean DASI score (84.6%; $p < 0.001$) was observed at week 4 after starting the cream vs. baseline in the overall population. Overall, the cream showed a good safety and compliance profile during the study period. There were no serious adverse events or deaths.

Conclusions: The evidence from the PRO study suggests that use of the intensive plant-based butter moisturizing cream in a real-world scenario has a noticeable impact on improving the quality of life and reducing the skin dryness associated with psoriasis over 4 weeks. The moisturizing cream may serve as a valuable adjuvant treatment option for the management of psoriasis.

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INTRODUCTION

Psoriasis is a chronic autoimmune condition predominantly linked to genetic factors and to a lesser extent to environmental factors [1]. According to various hospital-based studies, the prevalence of psoriasis in India varies from 0.44 to 2.8%, and it is more common in males than females [2, 3]. The disease is characterized by the presence of well-defined erythematous plaques with silvery scales that arise most commonly on the extensor surfaces of the elbows, knees, lumbosacral region and scalp [4, 5]. Various forms of psoriasis include psoriasis vulgaris, guttate form, erythrodermic form, pustular and palmoplantar psoriasis [2, 4, 5]. The clinical classification of the disease ranges from mild, wherein skin plaques cover $< 3\%$ of the body surface area, to moderate (3–10% of body surface area affected) and severe ($> 10\%$ of

body surface area affected) [6]. The impact of psoriasis on a patient primarily depends on the affected areas of the patient's body [6]. The disease is incurable and requires lifelong control to minimize the development of skin lesions and to relieve existing symptoms [7]. Numerous topical and systemic therapies are available for the disease, and the selection of therapy depends primarily on the severity of disease, cost of therapy, adverse-effect profile of the therapeutic agent, patient preference and availability of the treatment agents (Fig. 1) [4, 6, 8, 9].

Topical agents remain the standard of care for treating mild-to-moderate psoriasis and are used as an adjuvant with ultraviolet (UV) light or systemic agents in moderate-to-severe cases [8, 10–12]. American and European guidelines highly recommend topical agents such as vitamin D analogs, corticosteroid monotherapy or combination therapy based on consistent, high-quality clinical evidence [6, 13]. The presence of dry skin in psoriasis, in addition to being distressing to patients, can further cause adverse consequences such as fissures and infections [6]. These, in turn, contribute to a decreased quality of life (QoL), reduced productivity, lost work days, increased incidence of comorbidities and social isolation in some cases. Hence, the treating agents should be able to improve upon the patient's QoL [6, 14, 15].

In psoriasis, breakdown of the skin barrier leads to exaggeration of inflammation along with release of proinflammatory mediators [16]. Therefore, moisturizers that have established compatibility with topical agents serve as a promising modality to improve the signs and symptoms of dry skin [17, 18]. They help maintain the hydration and overall integrity of the skin. The improvement in the skin barrier function and the hydration status of the stratum corneum makes the epidermis more resistant to external irritants [19]. Though many internal guidelines are available, there is no well-defined Indian guideline for the effective management of the disease, and data regarding the use of moisturizers and their effectiveness are lacking.

The cream investigated in this study is an intensive moisturizing cream with a

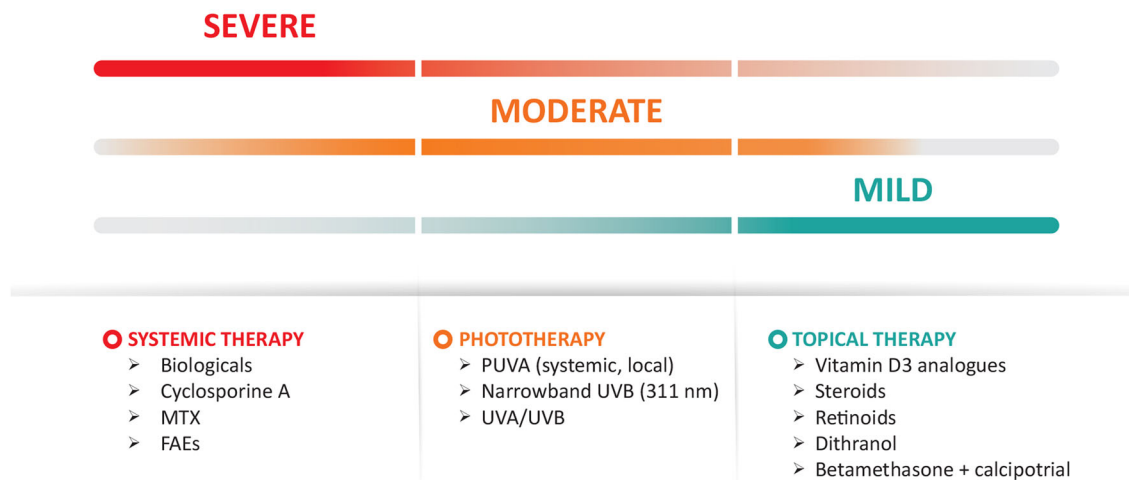


Fig. 1 Various topical and systemic therapies available for the management of psoriasis [6]. *FAE* fumaric acid ester; *MTX* methotrexate; *PUVA* psoralen + UVA treatment; *UVA* ultraviolet A; *UVB* ultraviolet B. Narrow band UVB

combination of plant-based butters (shea, aloe, mango, cocoa); it provides hydration and softens and heals dry skin. It previously demonstrated an improvement in skin hydration in patients with dry skin conditions and had a good safety profile [20]. Our study aimed to contribute to the real-world evidence of the effectiveness and safety of the intense moisturizing cream in the overall management of Indian patients with psoriasis.

METHODS

This was a real-world, multicentric, non-interventional, observational study conducted in outpatient dermatology departments/clinics across various regions of India.

Study Participants

Adult male and female patients with psoriasis aged between 18 and 75 years and for whom the physician decided to prescribe the intensive plant-based butter moisturizing cream for psoriasis were enrolled in the study. Patients with known hypersensitivity to any ingredient or component of the cream were excluded from the study.

Compliance with Ethics Guidelines

The study was approved by the independent/institutional ethics committee(s) at all the participating centers and was conducted in compliance with the International Conference on Harmonisation (ICH) E6 Guideline for Good Clinical Practice (GCP), the Declaration of Helsinki (October 1996) and applicable country laws [Indian Council of Medical Research (ICMR) regulations]. Please see the supplementary material for a complete list of ethics committees. The patients received a detailed explanation of the trial and were further encouraged to raise any queries about the study. Written informed consent was obtained from all patients before enrollment in the study, which was registered on the Clinical Trials Registry of India (CTRI): CTRI/2017/03/008023; registered on: 07/03/2017).

Study Treatments

Patients who were prescribed the intensive plant-based butter moisturizing cream (Venusia[®] Max cream, Dr. Reddy’s Laboratories Ltd., India) for a 4-week period at the physician’s discretion were enrolled. Patients were allowed to continue other concomitant medications. The Venusia[®] Max cream consists of shea

butter, aloe butter, mango butter and cocoa butter along with propylene glycol, glycerin, glycol, emulsifying wax, cyclomethicone, dimethicone, cetyl alcohol, stearic acid, ethyl paraben, propyl paraben, disodium edetate, zinc oxide and fragrance.

Study Procedures

A detailed medical history of all the enrolled patients was obtained, and the clinical examination was carried out as per routine clinical practice by the clinicians at baseline. The patient-reported effectiveness and compliance outcome data for the cream were recorded by the clinicians at baseline and after 2 weeks (optional) and 4 weeks of introducing the cream. The effectiveness of the moisturizing cream in improving the QoL was recorded by the Dermatology Life Quality Index (DLQI) Questionnaire. The DLQI questionnaire is a ten-item validated questionnaire for assessing QoL in patients with dermatologic conditions [21, 22]. The DLQI scoring was used to assess the effect of psoriasis on the patient's QoL: no effect at all on patient's life (score 0–1), a small effect on patient's life (score 2–5), a moderate effect on patient's life (score 6–10), a very large effect on patient's life (score 11–20) and an extremely large effect on patient's life (21–30). The effect of the cream regarding the reduction in dryness associated with psoriasis was recorded by the Dry Skin/Ichthyosis Area and Severity Index (DASI) score. DASI scores of 0–4 are considered for each body region separately. Assessed areas included the head and neck (10% of total area), upper extremities (20% of total area), trunk (30% of total area) and lower extremities (40% of total area). The scaling/roughness/fissure and cracks were graded as absent (0), slight (1), moderate (2), severe (3) and very severe (4) with eczema. The DASI score was calculated as the sum of the four body regions [23].

Study Outcomes

The primary outcome of the study was to assess the reduction in DLQI scores from baseline at the end of the 4-week study period. Secondary

outcomes were the reduction in DASI score at the end of 4 weeks, compliance with and safety of the cream. Safety assessment was based on spontaneous reports generated by the clinician.

Statistical Analysis

To evaluate the role of the moisturizer in improvement of scores as measured by the Quality of Life (DLQI) questionnaire at 4 weeks from baseline, we required 400 subjects with the assumptions of margin of error = 5%, confidence level = 95% and percentage of mean change from baseline = 50%. Therefore, a total of 400 subjects were proposed.

Data from all the study centers were pooled for analysis. The data were analyzed using R software version 3.2.3. Continuous variables are presented as mean and standard deviation. Categorical variables are presented as count and percent. Comparison of means between two time points was made using the paired *t*-test. Comparison of means among three time points was made using one-way repeated measure analysis of variance (ANOVA). $p < 0.05$ was considered statistically significant.

RESULTS

Demographics and Patient Characteristics

A total of 400 patients were enrolled from 9 study centers, of whom 16 were discontinued since they were lost to follow-up. Among the 384 patients completing the study, 179 completed the week-2 follow-up, and 384 patients completed the week-4 follow-up. Demographic details for all the enrolled patients are presented in Table 1. The frequency of cream application was decided by the treating physician based on patient characteristics. The details concerning the concomitant medication use by the patients are presented in the supplementary material (Tables S1 and S2). A total of 151 patients were on moisturizing cream alone without any concomitant therapy (37.75%).

Table 1 Patients characteristics and concomitant treatment at baseline

Patient characteristics	Mean ± SD/count (%)
Sex	
Male	203 (50.8)
Female	197 (49.2)
Age (years) (n = 400)	43.9 ± 13.9
Smoking	
Never	320 (80.0)
Former	37 (9.3)
Current	42 (10.5)
NA	1 (0.25)
Alcohol	
Yes	92 (23.0)
No	307 (76.8)
NA	1 (0.3)
Clinically relevant pre-existing condition (other than psoriasis)	
Cardiovascular disease	12 (3.0)
Diabetes	24 (6.0)
Hypertension	43 (10.8)
Lower urinary tract symptoms	2 (0.5)
Hypothyroidism	1 (0.3)
Thyroid	1 (0.3)
Umbilical hernia	1 (0.3)
No	320 (80.0)
NA	2 (0.5)
Has the patient been newly diagnosed with psoriasis?	
Yes	114 (28.5)
No	271 (67.75)
NA	15 (3.75)
Severity of psoriasis	
Mild	127 (31.75)
Moderate	220 (55.0)
Severe	49 (12.25)

Table 1 continued

Patient characteristics	Mean ± SD/count (%)
NA	4 (1)
Type of treatment received for psoriasis	
Systemic therapy	35 (8.75)
Topical therapy	335 (83.75)
NA	30 (7.5)
Has the patient received treatment with moisturizers and emollients previously?	
Yes	294 (73.5)
No	96 (24)
NA	10 (2.5)

Efficacy Outcomes

Tables 2 and 3 show the descriptive data for the DLQI and DASI scores. The post-treatment scores at week 2 and week 4 for DLQI and DASI were significantly lower than the baseline scores ($p < 0.0001$). The percentage reductions from baseline in DLQI scores and DASI scores are presented in Figs. 1 and 2, respectively.

Dermatology Life Quality Index (DLQI) Score

Based on the DLQI scores at baseline ($n = 400$), psoriasis significantly affected patients' life with 12% and 29% of patients reporting an extremely large and very large effect on their life. After starting the intensive plant-based butter moisturizing cream at 4 weeks ($n = 383$) only 0.5% and 15.9% of patients had an extremely large effect and very large effect on life. Significant ($p < 0.0001$) improvement (reduction in mean DLQI scores) was observed at both week-2 and week-4 follow-ups. All individual items of the DLQI questionnaire also showed a significant reduction from baseline over a period of 4 weeks ($p < 0.001$). A 66.6% and 54.4% reduction was observed in the mean DLQI score for patients with moderate and severe psoriasis,

Table 2 Effect of the cream on DLQI scores over the treatment period

	Baseline (<i>n</i> = 400) Mean (\pm SD)	Week 2 (<i>n</i> = 178) Mean (\pm SD)	Week 4 (<i>n</i> = 383) Mean (\pm SD)
DLQI scores	10.5 (7.44)	5.4 (4.29)	4.2 (5.09)
% Reduction change in DLQI scores	–	29.8%	63.0%
<i>p</i> value (vs. baseline)	–	< 0.001	< 0.001
DLQI score according to psoriasis severity			
Mild	6.3 (4.52)	5.0 (4.51)	2.7 (3.2)
Moderate	11.4 (7.47)	5.4 (4.22)	4.2 (5.25)
Severe	17.1 (7.12)	6.2 (4.21)	7.9 (6.07)
<i>p</i> value (vs. baseline for all psoriasis severity)	–	< 0.001	< 0.001

Table 3 Effect of the cream on DASI scores over the treatment period

	Baseline (<i>n</i> = 399) Mean (\pm SD)	Week 2 (<i>n</i> = 178) Mean (\pm SD)	Week 4 (<i>n</i> = 384) Mean (\pm SD)
DLQI scores	430.5 (255.5)	207.3 (142.1)	150.3 (159.8)
% Reduction change in DASI scores	–	73.5% ^a	84.6% ^a
<i>p</i> value (vs. baseline)	–	< 0.001	< 0.001
	Baseline (<i>n</i> = 399) Mean (\pm SD)	Week 4 (<i>n</i> = 384) Mean (\pm SD)	Percentage mean change (week 4 vs. baseline) (%)
DASI score according to psoriasis severity			
Mild	257.2 (179.79)	78.9 (79.53)	69.6% ^a
Moderate	465.0 (213.95)	156.5 (163.05)	73.9% ^a
Severe	734.3 (251.33)	300.4 (187.17)	86.4% ^a
<i>p</i> value (vs. baseline for all psoriasis severity)	–	< 0.001	< 0.001

^a Values are mean of difference in DASI score for individual patients

respectively, compared with baseline, at the 4th week of the study (Table 2; Fig. 3).

Dry Skin/Ichthyosis Area and Severity Index (DASI) Score Assessment

The mean DASI score significantly reduced to 84.6% at the 4th week (*n* = 384) after starting the intensive plant-based butter moisturizing cream compared with baseline (*n* = 399). A

significant reduction in DASI scores was observed at the 4th week compared with baseline, with a reduction of 69.6%, 73.9% and 86.4% reported in patients with mild, moderate and severe disease, respectively (Table 3).

Compliance Assessment

It was observed that 96.6% and 92.1% of patients, as assessed at the 2nd and 4th week,

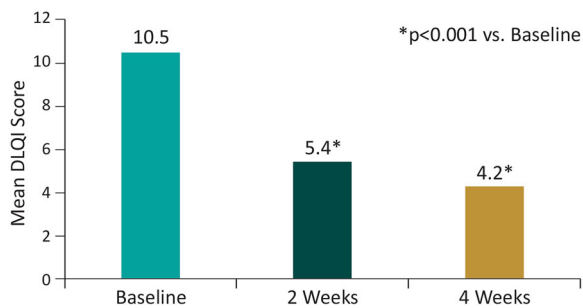


Fig. 2 Effect of treatment with cream on DLQI scores over study period

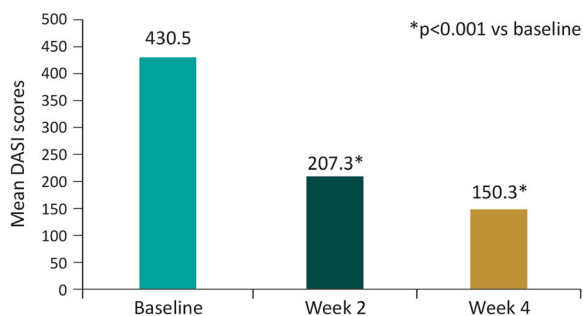


Fig. 3 Effect of treatment with cream on DASI scores over study period

respectively, had used the intensive plant-based butter moisturizing cream as instructed by the physician (Table 4).

Safety Outcomes

A total of 8 out of 400 patients reported an adverse event (AE) in the study. The majority of AEs were mild to moderate in severity and did

Table 4 Compliance with the cream over the study period

Usage of moisturizer as per the physician’s instruction	Week 2 (n = 179)		Week 4 (n = 384)	
	No. of patients	%	No. of patients	%
Yes	173	96.6	350	91.1
Most days	3	1.7	8	2.1
A few days	0	0	2	0.5
Missing	3	1.7	24	6.3

Table 5 Frequency of adverse events occurring in subjects (all causalities)

System organ class—preferred term	All patients (n = 400)
Overall total	8 (9) [2.0%]
Skin and subcutaneous tissue disorders	
Itching and darkening of skin	1 (1) [0.25%]
Soothing, itching	1 (1) [0.25%]
Post-inflammatory hyperpigmentation to psoralen and ultraviolet A (PUVA) therapy	1 (1) [0.25%]
New lesions	1 (1) [0.25%]
Exacerbation of lesions	1 (1) [0.25%]
Nervous system disorders	
Mild headache	1 (1) [0.25%]
Infections and infestations	
Mild fever	1 (2) [0.25%]
Fever	1 (1) [0.25%]

N number of subjects studied, [percentage of subjects with adverse events], (number of adverse events)

not require treatment interruption. Nine adverse events occurred in the study, of which five were categorized under the skin and subcutaneous tissue disorder system organ class, three to the infection and infestation class and one to nervous system disorders. There was no age and/or gender predilection for AEs in the study. No serious AEs or deaths occurred during the study (Table 5).

DISCUSSION

As the chronic condition of psoriasis has a detrimental effect on patients’ overall QoL, it is crucial that the treating agents should have a positive impact on the patients’ QoL. The impact on patients’ social and personal life is thus a crucial factor in determining the choice of therapy [24]. In a placebo-controlled study conducted by Syed et al. among 60 patients with psoriasis, to evaluate the clinical

effectiveness and tolerance of aloe vera extract (0.5%) in a hydrophilic cream, the Psoriasis Area and Severity Index (PASI) score was used. Patients were randomized to receive either the hydrophilic cream or matching placebo. Results from the study showed statistically significant lowering in mean PASI score in the aloe-treated group compared with the placebo group (9.3–2.2) [25]. To check the impact on QoL, our study used the DLQI score. The validated DLQI is predominantly a patient-reported questionnaire covering every aspect of a patient's life and provides more information than other methods regarding the outcomes of the treatment modality [24, 26]. The findings from our study based on DLQI assessment showed mean DLQI scores were significantly reduced by 63% at the 4th week ($p < 0.001$) after introducing the cream compared with baseline. The study results also showed an improvement in skin dryness associated with psoriasis as evaluated by the DASI score: the mean DASI score significantly decreased by 84.6% ($p < 0.001$) 4 weeks after introducing the cream compared with baseline. These improvements in skin dryness results were in line with the results obtained from a 4-week study conducted among 30 patients with mild-to-moderate plaque psoriasis [27].

Clinical studies on one of the constituents of our formulation, cocoa, which contains a mixture of bioactive components, have shown its tremendous potential to treat and prevent skin disease [28]. A study conducted among 12 adult patients with psoriasis assessed the effectiveness of a plant-based preparation containing olive oil, tea tree oil and cocoa butter. Treatment success was determined by the PASI score, and a PASI score reduction of $> 75\%$ was observed in 83% of patients, proving the cocoa-based formulation's effective in the management of psoriasis [29]. In addition to the effectiveness and safety of the treatment agent, another key factor influencing the success of a treatment strategy in chronic conditions is the adherence or compliance rate [30]. Among the several factors involved in poor patient compliance, patient's perception of therapy being not aggressive or effective is crucial. Additionally, a good safety profile, i.e., less frequent occurrence

of adverse events by a primary therapeutic agent, leads to good compliance in patients [31]. Hence, a safe and tolerable treatment with a good patient adherence rate can boost the success of chronic disease therapy. Our plant-based butter moisturizing cream in addition to having a favorable safety profile had a good compliance profile similar to compliance results obtained in the study by Syed et al. using an aloe vera-based cream [25]. Considering all the benefits offered by the intensive plant-based butter moisturizing cream for the psoriasis condition, we suggest further exploration of the use of an intense moisturizing preparation as an adjuvant therapy in the Indian population with psoriasis. Although our present effort had no comparator and was observational in nature, the real-life clinical general practice picture from various regions of India was duly captured. We acknowledge certain limitations of the study, i.e., non-evaluation of the consequence of continuing anti-psoriatic agents; short duration of follow-up for a chronic condition such as psoriasis; non-assessment of the PASI score and various confounding factors affecting the efficacy response. We sincerely believe that future controlled comparative trials will remediate the above-mentioned limitations and reinforce the usefulness of the cream for the management of psoriasis in an Indian scenario.

CONCLUSIONS

Based on the real-world evidence, generated from the study, an intense moisturizing cream can be considered a valuable adjuvant therapy for efficient management of psoriasis in India.

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Data Availability. The manuscript has no associated data or the data will not be deposited.

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