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Original Research Article

Open label, single arm, interventional multi-centered study to evaluate the efficacy and biophysical response of topical Soteri Skin cream in following skin conditions: atopic dermatitis, eczema, psoriasis and rosacea

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ABSTRACT

Background: Eczema, also known as dermatitis, is characterized by skin inflammation, which presents as pruritus, skin dryness and erythema. Soteri cream, which was used in the study, contains *Helianthus annus* oil, glycerin, sodium hyaluronate, niacinamide and various ceramides. Niacinamide upregulates epidermal ceramide synthesis; thereby, strengthening epidermal barrier.
Methods: The study was conducted on 30 patients in total, out of which, 5 patients were of scalp (3) and palmar psoriasis (2), 10 of eczema, 10 of atopic dermatitis and 5 of rosacea. The above patients were the ones coming to Aayna clinic for their respective skin concerns. After doing clinical examination and taking written consent, patients were given Soteri skin cream, to apply twice daily on the area of concern. Follow up was done fortnightly for a month. Patient's assessment in follow up visits was done with clinical photographic, along with dermoscopic photographic assessment after a month and by filling proforma for effects and side effects using VAS and SCORAD score (for atopic dermatitis).
Results: Complete symptomatic and visual improvement was seen in 3 patients of eczema, 2 of rosacea, 1 of scalp psoriasis and 6 of atopic dermatitis.
Conclusions: Soteri skin cream with its unique formulation of ceramides and niacinamide resulted in significant improvement in psoriasis, hand and nummular eczema, atopic dermatitis and rosacea. It is a steroid free, valuable line of treatment for chronic eczema.

Keywords: Eczema, Atopic dermatitis, Psoriasis, Rosacea, Soteri cream

INTRODUCTION

Eczema, a term derived from the Greek word 'ε′κζεμα' meaning 'to boil', is a clinical and histological pattern of inflammation of the skin seen in a variety of dermatoses with widely diverse etiologies. Clinically, eczematous dermatoses are characterized by variable intensity of itching and soreness, and, in variable degrees, a range of signs including dryness, erythema, excoriation, exudation, fissuring, hyperkeratosis, lichenification, papulation, scaling and vesiculation.[1] Niacinamide up-regulates epidermal ceramide synthesis with concurrent epidermal barrier benefits.[2]

Hand eczema is a common and distressing condition, and has a particular impact on quality of life due to its effects on dexterity, appearance and social functioning.[3]

Atopic eczema is an itchy, chronic or chronically relapsing inflammatory skin condition that often starts in early childhood (usually before 2 years of age).[4,5] The rash is characterized by erythema, itchy papules/papulovesicles (occasionally vesicles in infants) which may become excoriated and lichenified, and typically has a flexural distribution. The eruption is frequently associated with other atopic conditions in the individual or other family members.[4-6] Filaggrin insufficiency predisposes to barrier dysfunction but additionally T helper 2 (Th2) cytokines (interleukin (IL)-4 and IL-13) can also down-regulate filaggrin expression [7], indicating a complex interplay in which the epithelia and the immune system regulate each other. In adults, a distribution on the face, upper arms and back may correlate with areas of maximal thermal sweating or Malassezia sensitivity.

Scalp is one of the commonest areas to be affected by plaque psoriasis and often the site first affected. The whole scalp may be diffusely involved or multiple discrete plaques of varying size may be seen.[8] Plaques tend to be restricted to hair-bearing areas, extending a short distance beyond the hairline and around the ears. The rate of hair growth is normal and common scalp psoriasis is not a frequent cause of alopecia, although it may occur.[9,10] A morphological entity consisting of plaques of asbestos-like scaling, firmly adherent to the scalp and associated hair, has been termed pityriasis (tinea) amiantacea.[11] It is most common in children and young adults, and is best regarded as a non-specific reaction pattern, which may be seen in other scaling scalp conditions.

On the palms and soles, psoriasis may present as typical scaly patches on which a fine silvery scale can be evoked by scratching; as less well-defined plaques resembling lichen simplex or hyperkeratotic eczema; or as a pustulosis. Mixed forms occasionally occur.[12] It is often difficult to distinguish between psoriasis and eczema, with which it may sometimes appear to alternate. A sharply defined edge at the wrist, forearm or palm and absence of vesiculation are helpful. On the dorsal surface, the knuckles frequently show a dull-red thickening of the skin. Elsewhere on the hands and feet, psoriasis retains its typical character. There may be a relationship to trauma or occupational irritants.[13]

Rosacea is a chronic disorder with fluctuating severity. In the past it was assumed that rosacea was a single entity and a disorder that evolved progressively through stages, beginning with flushing and terminating in phymatous changes.[14] Rosacea is a disorder that predominantly affects fair, pale-skinned, sun-sensitive individuals. Treatment of rosacea varies according to the type of rosacea. Sunscreen and emollients form the mainstay of treatment for erythematotelangiectatic rosacea.

All of the above conditions are chronic and require long-term treatment with emollients and topical steroids. In order, to avoid the side effects that come in handy with the long-term use of topical steroids, new modalities of treatment for such conditions, which help in re-storing the skin pH, have come into picture. Nicotinamide containing moisturizers have been shown to be effective in the treatment of atopic dermatitis. In atopic dermatitis, there is a decrease in ceramides, increase in trans epidermal water loss (TEWL) and impaired skin barrier. An in vitro study showed that nicotinamide caused 2-3 fold increase in free fatty acids and 1.5-fold increase in cholesterol.[15] Nicotinamide has a potential role in the treatment of psoriasis because of its anti-inflammatory effect, inhibition of the expression of ICAM-1 and MHC-II, and production of IL-12, TNF- α, and IL-1.[16]

As the Soteri Skin cream used in our study, contains nicotinamide along with essential ceramides that help in re-storing the skin pH and epidermal barrier; thereby, helping in the above mentioned conditions. The patients in our study were told not to use any other cream during the study duration and were advised to use the cream twice daily on the area of concern.

Objective

The objective was to evaluate the efficacy and biophysical response of topical Soteri Skin cream in following skin conditions: atopic dermatitis, eczema, psoriasis and rosacea.

METHODS

Study type

The study conducted was an open label interventional single arm study.

Study duration

The study was done from June 2022 to August 2022.

Study place

The study was performed at Aayna clinic, Mehrauli and Khan market, New Delhi, India.

Ethical clearance was taken in accordance to the principles of harmonization good clinical practice (ICH-GCP) guidelines and Indian Regulatory Guidelines (Indian Council of Medical Research and Indian GCP guidelines). All patients were provided with written consent in their patient authorization form prior to participating in the study.

A total of 30 patients were included in the study, with 10 patients of eczema, 10 of atopic dermatitis, 2 and 3 patients of palmar and scalp psoriasis respectively and 5 patients of rosacea.

Soteri Skin cream was given to them for duration of a month, to apply twice daily on the area of concern.

Inclusion criteria

Age group of 18-55 years, all sexes included, mild to moderate severity of illness, individuals that were willing to provide written informed consent and were able to read, speak, write and understand English, individuals willing to have their photographs taken during the study and were willing to sign a photography release, willing to stop all facial treatments during the course of the study including botulinum toxin, injectable fillers, microdermabrasion, intense pulsed light (IPL), peels, facials, waxing, laser treatments and tightening treatments, willingness to cooperate/follow all study requirements for the duration of the study and to report any changes in health status or medications, adverse events, symptoms or reactions immediately, willingness to not begin using any new cosmetic facial make-up during the study. If one regularly uses cosmetic facial make-up, one must have used the product(s) without any issues for at least 2 weeks prior to starting the study, willingness to apply sunscreen daily to the face as much as possible, (including avoiding tanning beds), especially from 10 AM to 2 PM, protective clothing (i.e. hats, scarfs when stepping in the sun).

Exclusion criteria

Age below 18 years, using any other topical medication during the study period, individuals diagnosed with known allergies to ingredients in the study provided skin care products, individuals who are nursing, pregnant, or planning to become pregnant during the study, individuals with a history of skin cancer, having other debilitating health conditions, immunosuppression/immune deficiency disorders (including (human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)) or currently using immunosuppressive medications and/or radiation, individuals with an uncontrolled disease such as asthma, diabetes, hypertension, hyperthyroidism or hypothyroidism, individuals with any planned surgeries and/or invasive medical procedures during the course of the study, individuals who were currently participating in any other facial usage study or had participated in any clinical trial within 4 weeks prior to inclusion into the study, individuals who had observable sun tan, scars, nevi, excessive hair, individuals who started hormone replacement therapies (HRT) or hormones for birth control less than 3 months prior to study entry or who plan on starting, stopping, or changing doses of HRT or hormones for birth control during the study, individuals who used any of the following medications or had any of the listed procedures within the listed time frame prior to the study start date: had a light-depth chemical peel or microdermabrasion within 1 month; had a medium-depth chemical peel, medium-depth microdermabrasion, any systemic steroids, non-ablative laser, light and/or radio frequency or fractional laser resurfacing of the face and neck within 3 months; any systemic retinoid within12 months; any topical tretinoin product or derivative, imiquimod, 5-fluorouracil or diclofenac on their face within 1 month; prescription strength skin lightening products (e.g. 4% hydroquinone, tretinoin, alpha hydroxy acid (AHA), beta hydroxy acid (BHA) and polyhydroxyacids, 15% or 20% azelaic acid, tretinoin, etc.) within 1 month; any non-prescription cosmetic anti-wrinkle, skin lightening products, or any other product or topical or systemic medication known to affect skin aging or dyshcromia (products containing alpha/beta/poly-hydroxy acids, vitamin C, hydroquinone) within 2 weeks; have undergone plastic surgery, dermabrasion, a deep chemical peel or ablative laser resurfacing of the face and neck within 3 months.

Procedure

All patients were clinically examined and diagnosed, after the informed consent. A baseline clinical photograph along with dermoscopic picture was taken. For digital photography, 16.1 megapixel camera was employed. The DermLite DL4 was utilized for dermoscopy.

Patients were given Soteri Skin cream to apply twice daily on the area of concern for a month.

Patients were followed up fortnightly and were given a proforma to grade the symptomatic and visual improvement in the condition (via VAS scoring for all skin conditions and SCORAD scoring for atopic dermatitis), along with a photographic record of the same.

At the end of the study, photographic images along with dermoscopic pictures were taken to grade the visual improvement in the skin lesion via grading system for each of the above parameters.

The statistical analysis the study was given in percentages and mean values, based on global photographic and dermoscopic assessment score. Bar charts were used for demographic representation of patients in the study.

RESULTS

In our study, maximum number of patients was between 30-50 years of age with mean age of 35. Figure 1 and 2 depict age group and sex of the patients enrolled in the study.

Most common concern for which the Soteri Skin cream was given was atopic dermatitis.

Table 1: Improvement in various skin conditions.

Skin disorder	Complete improvement (no. of patients)	Partial improvement (no. of patients)
Atopic dermatitis	6	4
Eczema	3	7
Psoriasis	1	4
Rosacea	2	3

Table 2: Improvement in psoriasis patients.

Psoriasis	Complete improvement (no. of patient)	Partial improvement (no. of patients)
Scalp	1	2
Palmar	Nil	2

Table 3: Improvement in patients with eczema.

Eczema	Complete improvement (no. of patients)	Partial improvement (no. of patients)
Hand eczema	3	2
Nummular dermatitis	Nil	5

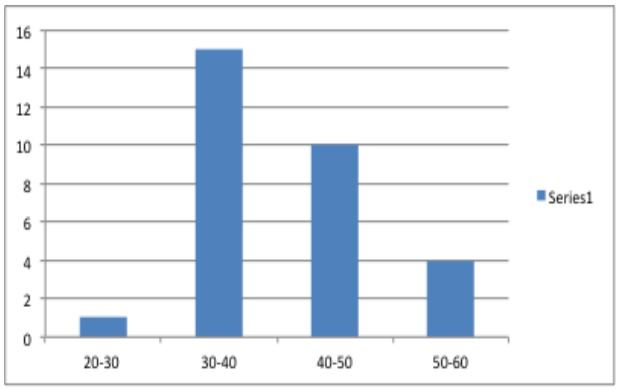

Figure 1: Age distribution of patients in the study.

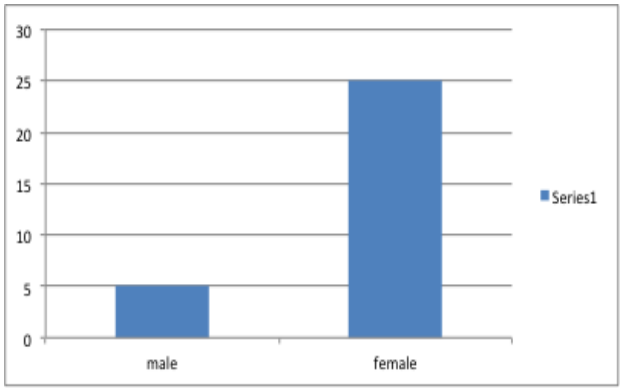

Figure 2: Sex distribution of patients in the study.

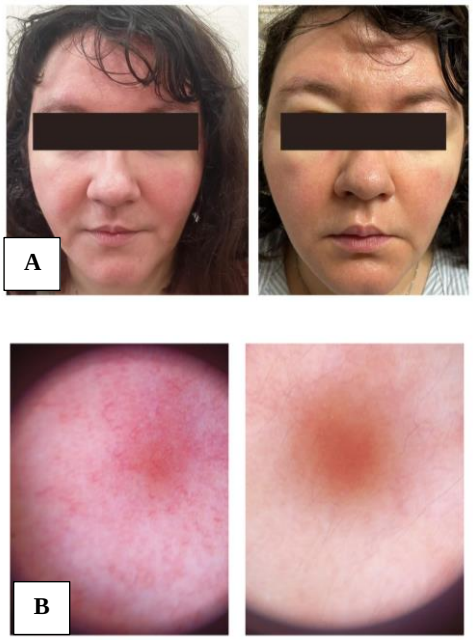

Figure 3 (A): Improvement in erythematotelangiectatic rosacea, left; after 30 day usage of Soteri Skin cream, right; (B) improvement in erythematotelangiectatic rosacea, dermoscopic view left: before, right: after 30 day usage of Soteri Skin cream.

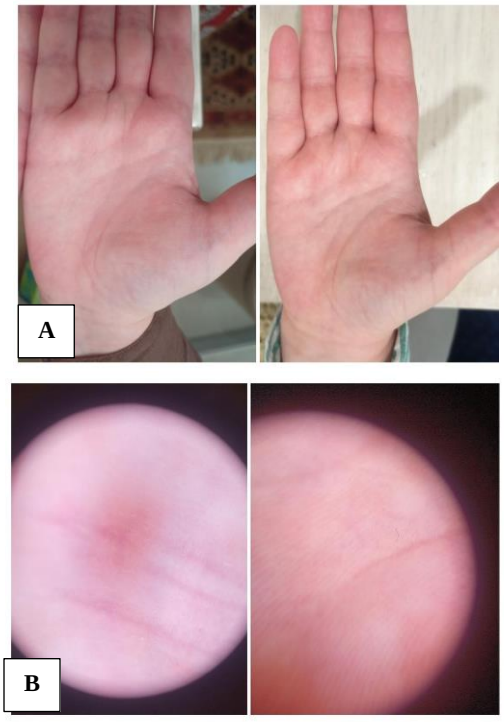

Figure 4: (A) Improvement in hand eczema left: before, right: after 30 day usage of Soteri Skin cream; (B) improvement in hand eczema, dermoscopic view left: before, right: after 30 day usage of Soteri Skin cream.

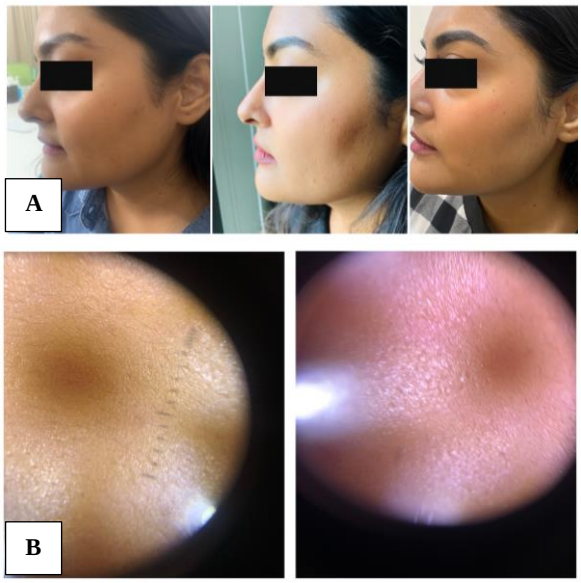

Figure 5: (A) Marked improvement in atopic skin left: before, middle: after 15 days, right: after 30 day usage of Soteri Skin cream; (B) marked improvement in atopic skin, dermoscopic view, left: before, right: after 30 day usage of Soteri Skin cream.

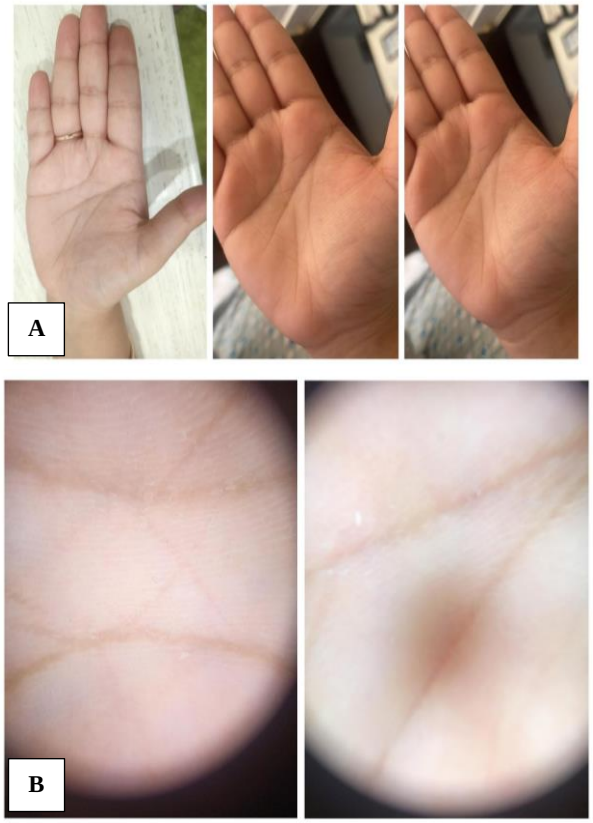

Figure 6: (A) Improvement in hand eczema left: before, middle: after 15 days, right: after 30 day usage of Soteri Skin cream; (B) improvement in hand eczema, dermoscopic view, left: before, right: after 30 day usage of Soteri Skin cream.

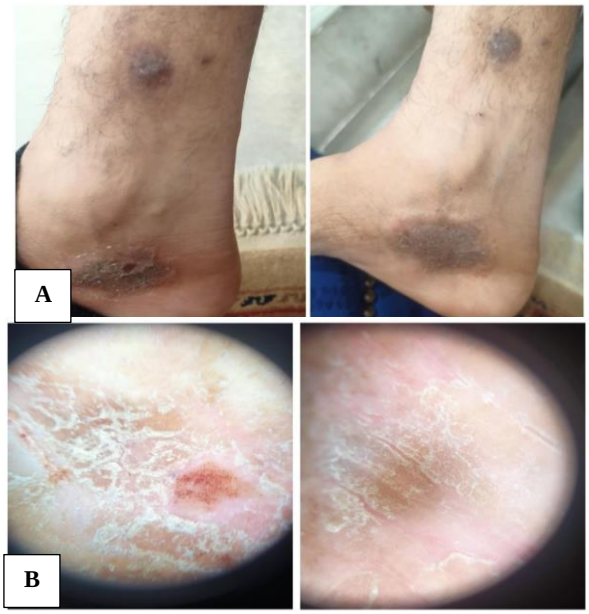

Figure 7: (A) Improvement in nummular eczema, left: before, right: after 30 day usage of Soteri Skin cream; (B) improvement in nummular eczema, dermoscopic view left: before, right: after 30 day usage of Soteri Skin cream.

Figure 8: (A) Improvement in atopic dermatitis left: before, right: after 30-day usage of Soteri Skin cream; (B) improvement in atopic dermatitis, dermoscopic view, left: before, right: after 30 day usage of Soteri Skin cream.

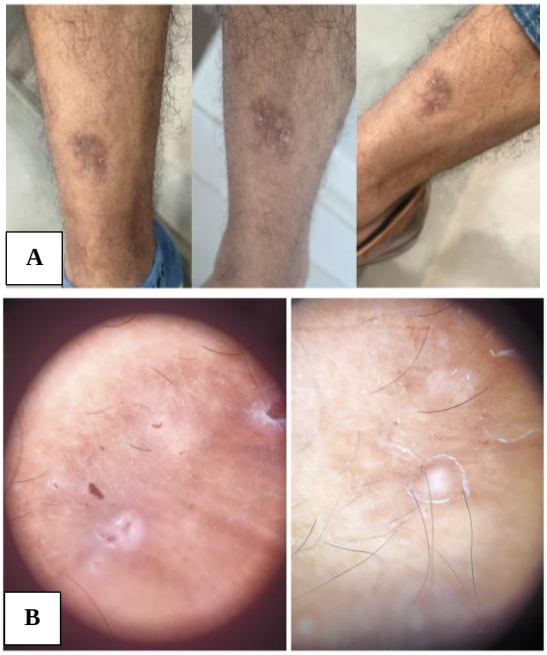

Figure 9: (A) Improvement in atopic dermatitis, left: before, middle: after 15 days, right: after 30 day usage of Soteri Skin cream; (B) improvement in atopic dermatitis, dermoscopic view, left: before, right: after 30 day usage of Soteri Skin cream.

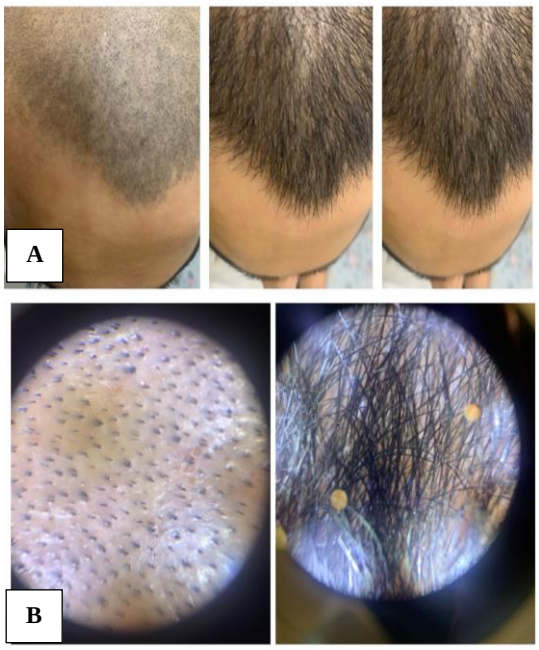

Figure 10. A) Marked improvement in scalp psoriasis, left: before, middle: after 15 days, right: after 30 day usage of Soteri Skin cream; (B) marked improvement in scalp psoriasis, dermoscopic view, left: before, right: after 30 day usage of Soteri Skin cream.

Complete improvement in 6 patients of atopic dermatitis was seen, in terms of symptoms like itching, dryness and visual improvement, by the end of study.

Improvement in various skin conditions is given in Table 1.

Figure 5A and B, Figure 8A and B and Figure 9A and B show marked improvement in atopic skin after 30 days of usage of Soteri Skin cream.

Complete improvement in 1 patient of scalp psoriasis, with 96% improvement in symptoms of itching and scaling, over scalp. Partial improvement in 2 patients of palmar psoriasis, with 60% reduction in cracks and peeling of palmar skin, after a month of Soteri cream application.

Figure 10A and B show photographic and dermoscopic improvement in scalp psoriasis respectively, after 30 days of Soteri cream application.

Improvement in psoriasis patients is given in Table 2.

Complete improvement in 3 patients of hand eczema, along with symptomatic relief in itching; within 2 weeks of Soteri cream application.

Partial improvement in 5 patients of nummular eczema, after a month of Soteri cream application, in terms of 60% improvement in itching and erythema and induration of the skin lesion.

Figure 4A and B and Figure 6A and B show photographic and dermoscopic improvement in hand eczema after 30 days of Soteri cream application.

Figure 7A and B show improvement in nummular eczema, after 30 days of usage Soteri Skin cream.

Improvement in patients with eczema is given in Table 3.

Photographic and dermoscopic improvement in erythematotelangiectatic rosacea, are given in Figure 3A and B, after 30 days of Soteri cream application.

DISCUSSION

The skin conditions (eczema, atopic dermatitis, rosacea & psoriasis) covered in the study have a common underlying disorder of defective skin barrier.

Niacinamide stimulates fibroblast proliferation and epidermal re-epithelialization via the promotion of lipids, fatty acids, cholesterol, ceramide and sphingolipid synthesis, which are crucial in maintaining skin barrier function and integrity.[17]

In our study, niacinamide containing moisturizing cream enriched with various ceramides, Soteri cream was used. The patient was made to apply Soteri cream, twice daily for a month. VAS (visual analogue score) was used to grade the improvement in symptoms of itching, dryness, scaling and erosions with a score of 0 for no

improvement and a score of 10 for complete improvement.

Global (clinical) photographic assessment: mean percentage improvement in lesions via dermoscopy was graded into 4 classes as following:[18] grade 1: 0-25% reduction; grade 2: 26-50% reduction; grade 3: 51-75% reduction; grade 4: 76-100% reduction.

Dermoscopic assessment: mean percentage improvement in lesions via dermoscopy was graded into 4 classes as following:[18] grade 1: 0-25% reduction; grade 2: 26-50% reduction; grade 3: 51-75% reduction; grade 4: 76-100% reduction.

Patient's global satisfaction: patient satisfaction was classified as (1) excellent, (2) good (3) fair (4) poor.[19]

The SCORAD index formula is: A/5+7B/2+C.

In this formula A is defined as the extent of involvement based on the rule of 9 (0-100), B is defined as the intensity based on 6 clinical findings in atopic dermatitis, of erythema, edema or papulations, oozing or crusting, excoriation, lichenification, dryness graded on a scale of 0-3 (0-18) and C is defined as the subjective symptoms of pruritus and sleep loss graded on a VAS of 0-10 (0-20).[20] The mean SCORAD score was of 18.3 with maximum score of 30 in one patient of atopic dermatitis. There was a significant reduction in SCORAD score by the end of the study, by 70-80%.

Out of 30 patients enrolled in the study, 12 patients had complete improvement in symptoms and signs with global photographic and dermoscopic assessment score of grade 4.

In scalp psoriasis, one out of 3 patients had complete improvement and two had partial improvement as per the VAS score and global photographic and dermoscopic assessment score of grade 2, by the end of a month of treatment. There was a significant improvement in the symptom of tightness around the scalp, which was the first to respond to treatment.

Partial improvement (60% improvement in VAS score, grade 2 improvement in global photographic and dermoscopic assessment score) in both the 2 patients of palmar psoriasis within a month of treatment. There was a 60% improvement in the symptoms of itching and dryness in hands. Patients witnessed 65% improvement in their current cracks on their hands with development of no new cracks and erosions on hands while using the cream.

Complete improvement in 3 out of 5 patients of hand eczema, and partial improvement in the other 2, after a month of treatment. Itching was the first to respond to treatment followed by improvement in roughness by about 80-90%.

Partial improvement in induration and erythema of nummular eczema, after a month of treatment in all the 5 patients of the same. Induration responded earliest to the treatment followed by erythema and itching.

Complete improvement in 6 out of 10 patients of atopic dermatitis with grade 4 improvement in global photographic and dermoscopic assessment score. 50% improvement in itching and dryness was observed from day 14 of treatment, in the above patients.

90% improvement in the redness and 92% reduction in the episodic flare up in 2 out of 5 patients of rosacea after a month of treatment. There was 90% reduction in telangiectasia on dermoscopic evaluation after a month of Soteri Skin cream application with grade 4 improvement in clinical and dermoscopic evaluation.

Skin barrier was visibly improved in almost all the candidates, unless triggered by emotional factors, which caused the skin condition to return and improvement to dip. One patient who had chronic atopic dermatitis and was on Elidel (Pimecrolimus) for several years, showed marked improvement, in clinical pictures as well as in quality of life and satisfaction. Exceptional results were seen in scalp psoriasis, as the tissue was not sensitive, burning sensation was usually not felt on the scalp.

Almost all the patients who had broken skin barrier complained of intense burning sensation for 3-5 days, which subsided after the skin healed. Candidate with rosacea felt the cream was drying and felt the need of additional moisturizing cream. Burning sensation and slow results were the chief complains, however, it was already counseled to them that this was a product for long-term skin barrier repair and protection.

As the sample size of psoriasis and rosacea patients were less as compared to eczema and atopic dermatitis; it's efficacy in psoriasis and rosacea is not as significant as in the other two conditions. Soteri cream could not be used in acute eczema conditions as it caused burning sensation on erosions and fissures.

CONCLUSION

We can conclude that Soteri Skin cream is a valuable treatment option for chronic hand eczema, scalp and palmar psoriasis, atopic dermatitis and rosacea. Its unique formulation of niacinamide and ceramides helps in strengthening the epidermal barrier and maintaining the epidermal pH, which plays an essential role in the pathogenesis of the above skin conditions.

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Soteri Skin Inc (USA) gave the Soteri Skin creams for the study.

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Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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