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Original Research Article

Clinical assessment of novel plant-based moisturizer "Elovera" in management of dry skin conditions

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ABSTRACT

Background: Moisturizers are major component of basic daily skin care in patients with eczema/dermatitis. Botanical ingredients like aloe vera extract having anti-inflammatory property can be useful in reducing signs and symptoms along with improvement in dry skin in such patients.
Methods: It was retrospective data analysis conducted across 145 centres in India. Patients with eczema/dermatitis who were prescribed Elovera a novel plant-based moisturizer were included in the study. Effectiveness was assessed by evaluating improvement in DASI score, physicians, and patients' global assessment of disease. Safety was assessed by monitoring all the adverse events reported by the patients.
Results: 402 patients were included in the study. There was significant improvement in mean baseline DASI score with with a reduction of 40.57% and 84.8% at week 2 and week 4, respectively. 86.31% (n=347) and 85.32% (n=343) patients reported significant improvement in their disease as per physician's and patients' global assessment of disease. Elovera was well tolerated and only 5 patients reported mild irritation and erythema during treatment.
Conclusions: The result of our study proves that "Elovera" a novel plant-based moisturizer is associated with significant improvement in dry skin, signs, and symptoms of patients with eczema/dermatitis. Based on these results concomitant use of Elovera can be considered along with standard treatment for better outcome in patients with eczema/dermatitis.

Keywords: Aloe vera extract, Dry skin, Eczema/dermatitis, Moisturizer, Anti-inflammatory

INTRODUCTION

Eczema is a frequently encountered dermatologic condition characterized by inflammation resulting in erythema, scaling, induration, and lichenification.[1] Another characteristic feature of eczema is dysfunctional epidermal barrier leading to development of itching, stinging, burning, and sometimes painful skin.[1] The basis for eczema therapy is inflammation reduction followed by creation of an environment for barrier repair.[2]

Moisturizers are major component of basic daily skin care, particularly in presence of epidermal barrier alteration and reduced epidermal water content.[3] It is an important part of a dermatologist's strategy to maintain skin health as well as treating various dermatoses which co-exist with skin dryness and are linked to impaired skin barrier function, such as various types of eczemas and dermatitis.[3]

Many botanicals have been identified that possess anti-inflammatory properties.[1,4] It was theorized that a combination of botanical anti-inflammatories incorporated into a moisturizing base might be able to provide meaningful improvement in the signs and symptoms of mild-to moderate eczema.[1,4]

The Aloe vera plant has been known and used for centuries for its health, beauty, medicinal and skin care properties. Aloe vera extract contains 75 potentially active constituents such as vitamins, enzymes, minerals, sugars,

lignin, saponins, salicylic acids and amino acids.[5-8] Because of these aloe extract has multiple properties like anti-inflammatory, moisturizing, wound healing, antiseptic, etc. Multiple studies have reported the effectiveness of aloe extract in management burns, sunburns, inflammatory skin disorders, wounds and dry skin.[5-8]

However, in India there are no studies which have evaluated the effectiveness and safety of aloe vera based moisturizer in management of patients with dry skin disorders like eczema or dermatitis. Hence, we conducted this study novel plant-based moisturizer "Elovera" containing aloe extract, allantoin and vitamin E in management of dry skin associated with eczema and dermatitis.

Objective

The objective of study was to evaluate the effectiveness and safety of novel plant-based moisturizer "Elovera" in management of patients with dry skin disorders like eczema or dermatitis based on improvement in their Dry skin Area Severity Index (DASI), Physicians and Patients global assessment of disease.

METHODS

The present study was multicentre, retrospective cohort study, wherein review of medical records of patients of eczema or dermatitis were conducted from 145 dermatology centres across India. The study duration was November 2019 to March 2020. Data was collected in a structured manner which was specific for the management of eczema or dermatitis. The data charts were identified by generating a list of all patients ever prescribed Elovera at all clinics and maintaining effectiveness records with DASI Score, using the electronic medical record database.

Ethical considerations

This research was undertaken in compliance with the ICH harmonized tripartite guidelines for good clinical practice (GCP) adherence to the Helsinki declaration of ethical standards. The research was initiated after approval by the institutional ethics committee.

Patient selection criteria

Eligible patients within age group of 18-60 years and with a clinical history of dry skin associated with eczema and dermatitis were included in study. Patients with other form of dry skin disorders like atopic dermatitis, psoriasis, and ichthyosis were excluded from the study. Pregnant or nursing females, patients with known hypersensitivity to the study drugs, patients with history of other dermatological conditions which may impact the outcome of the study were also excluded from the study.

Effectiveness assessment

Effectiveness of "Elovera" was assessed by evaluating the improvement in DASI score compared to baseline and Physician global assessment of improvement in disease. Additionally, Patients' global assessment data was also captured as exploratory endpoint.

Physician global assessment was done by evaluating the improvement in signs of eczema/dermatitis (erythema, scaling, roughness and cracks) during study period. Patients' global assessment was done by evaluating the improvement in symptoms of eczema/dermatitis (itching, dryness, burning and tightness). Each sign and symptom were measured on 4-point scale (0- Clear, 1- mild, 2- moderate, 3- sever, 4- very severe). Improvement was assessed as per following scale 0 – 1: significant improvement; 1 – 2: moderate improvement; 2 – 3: mild improvement and 3 – 4: no improvement.

Safety assessment

Safety assessment was done by analysing all the AEs reported by the patients during treatment.

Data analysis

Descriptive statistics were used to summarize effectiveness and safety endpoints using GraphPad Prism version 8 (San Diego, California: GraphPad Software Inc., 20057). $P \leq 0.05$ were considered statistically significant.

RESULTS

Data of a total of 700 patients with dry skin associated with eczema or dermatitis who visited for dermatological consultation during the study period was screened. Of the 700 patients screened, 402 patients fulfilled the inclusion criteria and were included in the study.

Table 1: Baseline demographic characteristics.

Parameter	n = 402
Average age (mean ± SD)	37.55±14.46
Sex (n, %)	
Male	207 (51.49%)
Female	195 (48.50%)
Average disease duration (years±SD)	0.59±0.19
Concomitant Medications (n, %)	
Antihistamines	265 (65.92%)
Topical corticosteroids	172 (42.80%)
Immunosuppressants	32 (7.96%)
Topical calcineurin inhibitors	55 (13.68%)
Antibiotics	27 (6.71%)
Oral corticosteroids	29 (7.21%)
Multivitamins/antioxidants	34 (8.45%)
DASI	294.32±164.33

Table 2: Improvement in mean DASI score during study period.

	Baseline	Day 14	Day 28
Mean ± SD	294.32±164.33	184.90±137.70	47.04± 64.82

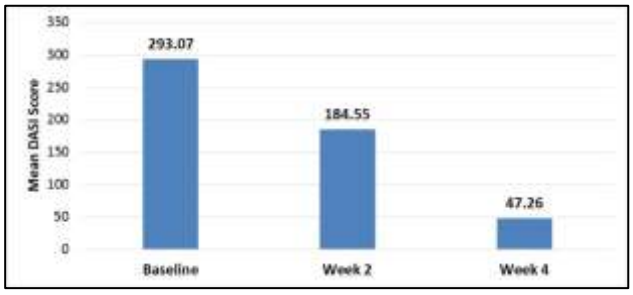

Figure 1: Improvement in mean DASI score during study period.

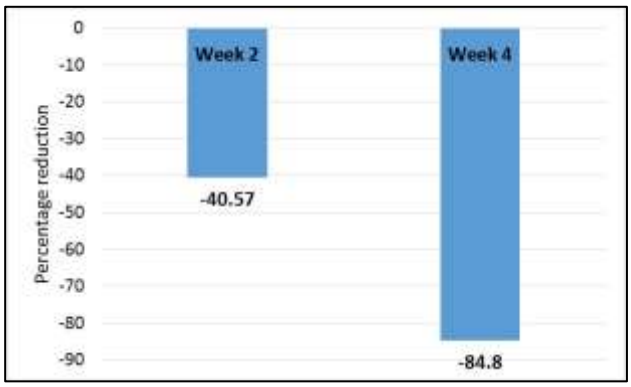

Figure 2: Percentage reduction in mean DASI score at week 2 and 4.

The baseline demographic characteristics of patients are summarized in table 1.

There was significant reduction in mean DASI score as compared to baseline at week 2 and 4 ($p<0.01$) as shown in Figure 1 and table 2. A significant reduction in DASI scores was observed at the 2nd and 4th week compared with baseline, with a reduction of 40.57% and 84.8% respectively. (Figure 2)

At the end of 4 weeks treatment period, 86.31% (n=347) patients reported significant improvement in their disease as per physician's global assessment. 12.43% (n=50) patients reported moderate improvement while 1.24% (n=5) patients reported mild improvement in their disease. Similar results were also obtained for patients' global assessment where 85.32% (n=343) patients reported significant improvement; 13.18% (n=53) patients reported moderate improvement while 1.49% (n=6) patients reported mild improvement respectively in their disease (figure 3). Elovera was well tolerated and only 5 patients reported mild irritation and erythema during treatment.

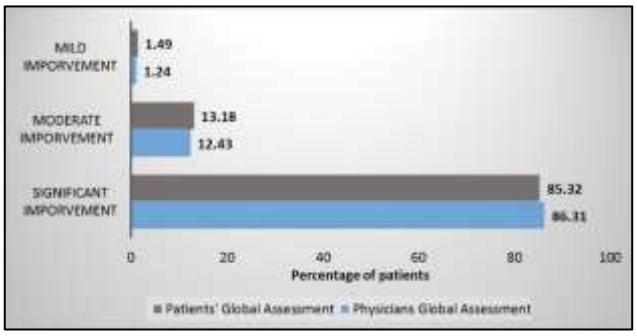

Figure 3: Proportion of patients showing improvement in their disease as per physician and patients' global assessment.

DISCUSSION

Moisturizers are major component of basic daily skin care, particularly in presence of epidermal barrier alteration and reduced epidermal water content. Moisturizers provide functional skin benefits, such as making the skin smooth and soft, increasing skin hydration, and improving skin optical characteristics; however, moisturizers also function as vehicles to deliver ingredients to the skin.[9] These ingredients may be vitamins, botanical antioxidants, peptides, skin-lightening agents, botanical anti-inflammatories, or exfoliants.[9] Botanical ingredients with anti-inflammatory activity may improve the outcomes in patients with eczema or dermatitis and may help in reducing the dose of topical corticosteroids thus reducing the chances of side effects. In our study we evaluated the effectiveness and safety of novel plant-based moisturizer "Elovera" containing aloe extract, allantoin and vitamin E.

In our study patients were evaluated for improvement in their dry skin based on DASI score. There was significant reduction of 40.57% and 84.8% in mean DASI score at week 2 and week 4, respectively. This improvement in DASI score suggests the effectiveness of Elovera in reducing dry skin associated with eczema or dermatitis. Similar results were reported by earlier studies where aloe vera containing moisturizers were associated with significant improvement in dry skin. Azizi et al in their study concluded that aloe vera containing moisturizers were associated with improvement in skin barrier function thus reducing TEWL and increasing the skin hydration.[10] Similarly, Dal'Belo et al in their study reported that aloe vera extract is a natural effective ingredient for improving skin hydration, possibly through a humectant mechanism.[11] West et al in their study substantiated that those who have, or are at risk of having, irritant contact dermatitis, particularly occupationally related, show a marked improvement in their skin quality with the use of AV gel.[12]

In our study significant improvement in signs and symptoms of eczema or dermatitis as suggested by improvement in physician and patients' global assessment of disease was observed with use of Elovera. This could be attributed to potent anti-inflammatory, wound healing and moisturizing property of aloe vera extract. Aloe vera extract contains 75 potentially active constituents such as vitamins, enzymes, minerals, sugars, lignin, saponins, salicylic acids and amino acids.[5-8]

Because of these active ingredients, aloe vera is associated with multiple properties like wound healing, anti-inflammatory, antiseptic and antipruritic.[5-8] Anti-inflammatory and wound healing properties of aloe vera extract are well established in multiple clinical studies.[13-15] Hekmatpou et al in their review concluded that aloe vera extract can be used to retain skin moisture and integrity and to prevent ulcers. Use of aloe vera, as a complementary treatment along with current methods, can improve wound healing.[16] Similarly, Pahani et al in their study reported that aloe extract containing emollient was associated with significant improvement in disease severity, quality of life and eosinophil count in patients with atopic dermatitis.[17]

Moisturizers are associated with steroid sparing effects addition of botanical extract like aloe vera can further enhance this effect.[9,18] This justifies the steroid sparing effect of Elovera. Considering all the benefits offered by Elovera, we suggest further exploration for its use as an adjuvant therapy in dry skin disorders. Although our present study had no comparator and was observational and retrospective in nature, the real-life clinical practice picture across India was duly captured.

There are certain limitations of the study, i.e., non-evaluation of the consequence of concomitant medications; no follow-up period and various confounding factors affecting the efficacy response. Future controlled comparative trials are recommended to ameliorate the above-mentioned limitations and reinforce the usefulness of Elovera in dry skin disorders.

CONCLUSION

The result of our study proves that "Elovera" a novel plant-based moisturizer is associated with significant improvement in dry skin, signs, and symptoms of patients with eczema/dermatitis. Based on these results concomitant use of Elovera can be considered along with standard treatment for better outcome in patients with eczema/dermatitis.

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Ethical approval: The study was approved by the institutional ethics committee

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