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Original Article

Comprehensive Skin Care Regimen of Moisturizer with Broad-Spectrum Sunscreen as an Adjuvant in Management of Acne (CHARISMA)

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Abstract

Introduction: Both acne and topical anti-acne therapies are associated with cutaneous reactions, thereby jeopardizing patient adherence, and thus compromising treatment efficacy. In addition, many acne therapies are associated with thinning of skin and predispose to ultraviolet damage which has been implicated in acne flares. Use of photoprotecting moisturizer may help to alleviate these reactions thus benefiting the patients.

Methods: This was a multicenter, open-label retrospective questionnaire-based survey designed primarily to assess the cutaneous tolerability, overall performance, and cosmetic acceptability of Episoft AC, a moisturizer with broad-spectrum sunscreen activity as an adjuvant in the management of acne. Each doctor was given a survey questionnaire booklet containing survey forms. Patients were evaluated for their skin tolerability by analyzing the responses from both patients (subjective assessment) and investigator (objective assessment).

Results: A total of 100 doctors participated in a survey involving 340 patients. There was a significant improvement in all the parameters of facial skin tolerability (subjective assessment), i.e., itching, burning, stinging, and tightness at day 28 compared to a baseline which was maintained until day 56 with continued therapy with Episoft AC. Similarly, objective facial skin tolerability assessments determined by the investigator showed significant improvement in dryness and erythema at day 28 relative to a baseline which was maintained until day 56 with continued use of Episoft AC. Majority of patients felt that the treatment regimen was easy to use, were satisfied with the treatment regimen, and would continue to use it.

Conclusion: The results of this survey signify that incorporating a comprehensive skin care regimen of moisturizer with broad-spectrum sunscreen in the overall management plan of acne may help in improvement of cutaneous tolerability and overall patient satisfaction with acne treatment.

Key words: Moisturizer, Sunscreen, Acne

INTRODUCTION

Acne is a chronic inflammatory disease of the pilosebaceous unit that affects almost all teenagers between the ages of 15 and 17 years.[1] Clinical features include open and closed comedones, papules, and pustules.[2] Increased sebum production, follicular hyperkeratinization, propionibacterium acnes proliferation, and inflammation are four main processes in the pathogenesis of the disease.[3]

Multiple therapies, both topical and systemic are available for the treatment of acne vulgaris (AV).[4,5] Even though anti-acne therapies are efficacious and safe in the management of acne, one of the major limitations of topical therapies for AV is the relatively high potential for cutaneous reactions characterized by signs (erythema, dryness, roughness, etc.) and symptoms (stinging, burning, etc.).[6-9] These reactions can result from direct effects of

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active ingredient or acne itself leading to epidermal barrier damage.[10-13] In addition, many acne therapies are associated with thinning of the skin and predispose to ultraviolet (UV) damage which has been implicated in acne flares.[14]

Non-adherence to the treatment regimen is most common problem associated with these undesirable effects of acne and acne therapies leading to suboptimal therapeutic outcomes. Many patients lose follow-up with dermatologists after experiencing skin irritation which further reduces the efficacy of treatment regimen and recurrence of acne.[15]

These undesirable dermatological effects can be taken care by moisturizers and photoprotectants which may be beneficial for AV patients.[14-16] These moisturizers and photoprotectants should be non-comedogenic, devoid of skin irritants and compatible with therapeutic regimens.[16] However, many acne patients neither find it intuitive nor consider it necessary to use a moisturizer or photoprotection as part of their skin care regimen, because of conventional beliefs. Therefore, it is crucial to counsel acne patients regarding both moisturization and sun protection.[16]

Numerous skin care moisturizers are available in the market; however, there is a paucity of studies that have evaluated their efficacy and compatibility specifically in AV patients especially in a country like India. Consequently, AV patients are left with multiple over-the-counter skin care products to complement their treatment, but in many cases, these products may magnify the side effects of treatment regimens exacerbating the patient's AV.

Hence, considering these scenarios, we conducted this survey with the aim to assess the cutaneous tolerability, overall performance, and cosmetic acceptability of Episoft AC, a photoprotecting moisturizer specifically designed for acne-prone skin as an adjuvant skin care regimen in management acne.

MATERIALS AND METHODS

This was a multicenter, open-label retrospective questionnaire-based survey designed primarily to assess the cutaneous tolerability, overall performance, and cosmetic acceptability of Episoft AC, a moisturizer with broad-spectrum sunscreen activity as an adjuvant in the management of acne. The survey was conducted in compliance with the Declaration of Helsinki and current Good Clinical Practice guidelines.

Dermatologists involved in the management of AV were identified through "SCRIP intelligence" database. Among these 100 doctors who were maintaining the patients' clinical record including the sensorial profile of cosmetic products were selected across 4 zones (east, south, west, and north) each by convenient sampling to have a uniform representation of population across the country.

Each doctor was given a survey questionnaire booklet containing survey forms. The questionnaires' booklets were collected after the end of survey period, and data from all the patients were assessed to evaluate cutaneous tolerability, overall performance, and cosmetic acceptability of Episoft AC. Each patient was evaluated at baseline (day 0), day 28, and day 56. The total survey period was from July 2017 to December 2017.

Patients more than 12 years of age with mild to moderate acne on stable anti-acne therapy along with Episoft AC, with facial skin symptoms (itching, burning, erythema, dryness, etc.) and keeping monthly follow-up with dermatologists were included in the survey. Patients with severe acne (presence of nodules and cysts) were excluded from the survey. Patients who changed their anti-acne therapy or who underwent any dermatological procedures (e.g., chemical peeling, and lasers) during the survey period were also excluded from the final analysis. Individuals with any visible dermatological disorder or abnormal skin pigmentation that may have interfered with subjective or objective assessments were also excluded from the final analysis.

Skin Tolerability Assessment

Skin tolerability assessment was done by analyzing the responses from both patients (subjective assessment) and investigator (objective assessment). For subjective assessment, data regarding various symptoms such as itching, burning, stinging, and skin tightness experienced by the patients during the previous 8 weeks were analyzed. Similarly for objective assessment, data regarding visible signs such as erythema, dark spots, dryness, and roughness evaluated by the investigators during the previous 8 weeks were analyzed. Each parameter was measured on 4 points Likert Scale (0–3) ranging from no evidence of any facial skin symptom to severe facial skin symptom. The parameters were evaluated at baseline, on days 28 and 56. All the patients were further evaluated for satisfaction with the treatment regime by analyzing the questionnaires regarding sensorial parameters at the end of 8 weeks of therapy.

Safety Assessment

Safety assessment was done by analyzing all the reported adverse events during the survey period.

RESULTS

A total of 120 doctors participated in the survey, from whom a total of 480 completed survey forms were collected at the end of 6 months period. Out of 480 forms collected, 340 forms fulfilling all the inclusion criteria were

considered for further evaluation. The average age of the population was 17.6 years. Out of total 340 patients evaluated, 56% (n = 190) were male while 44% (n = 150) were female patients. All the patients were taking some form of topical therapy for management of their acne. In this survey, combination of adapalene and benzoyl peroxide was most commonly prescribed anti-acne therapy (43% n = 146) followed by a combination of adapalene and clindamycin which was prescribed to 37% (n = 129) patients. Less commonly prescribed anti-acne therapies were combination of clindamycin and nicotinamide, monotherapy with either tretinoin or adapalene.

Subjective Assessment

Improvement in mean facial tolerability score was reported by each patient during each visit relative to baseline. There was a significant improvement in all the parameters of facial skin tolerability, i.e., itching, burning, stinging, and tightness at day 28 compared to baseline which was maintained until day 56 with continued therapy with Episoft AC [Figure 1].

Objective Assessment

Objective facial skin tolerability assessments determined by the investigator showed improvement in mean scores relative to baseline for erythema, dark spots, dryness, and roughness during each visit. There was a significant improvement in dryness and erythema at day 28 relative to a baseline which was maintained until day 56 with continued use of Episoft AC [Figure 2].

Subject Satisfaction

Patients satisfaction with the treatment regime was assessed by analyzing the data regarding sensorial parameters evaluated by the investigators. Majority of patients felt that the treatment regimen was easy to use, were satisfied with the treatment regimen, and would continue to use it. Figure 3 depicts the data from subject satisfaction questionnaire.

In this survey, more than 90% of patients reported very good or excellent adherence to treatment. None of the patient reported any adverse event related to survey drug. There were no discontinuations from the survey related to adverse events including skin tolerability reactions.

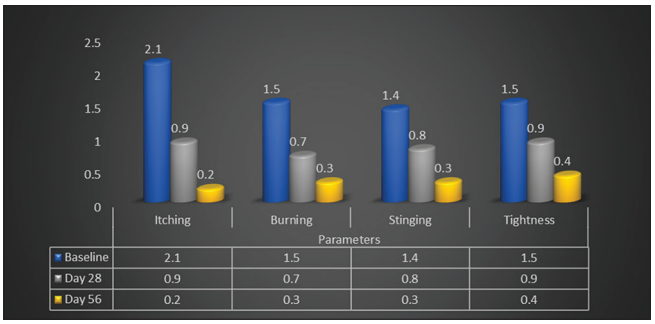

Figure 1: Mean facial skin tolerability assessment (subjective)

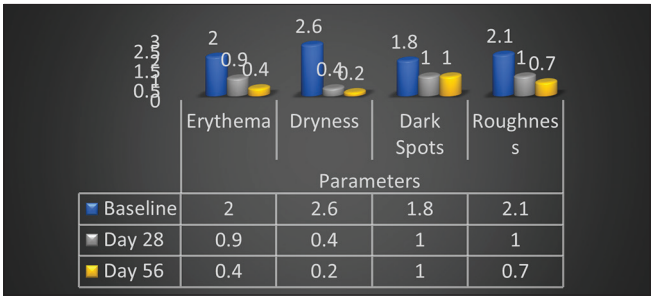

Figure 2: Mean facial skin tolerability assessment (objective)

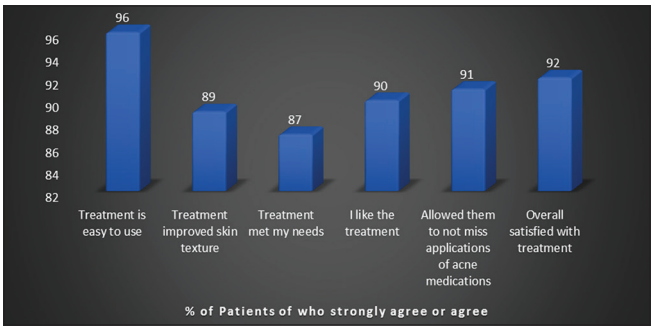

Figure 3: Subject satisfaction questionnaire at week 8: Regimen satisfaction

DISCUSSION

One of the major limitations of topical therapies for AV is the relatively high potential for cutaneous reactions characterized by signs (erythema, dryness, roughness, etc.) and symptoms (stinging, burning, etc.).[6-9] These reactions can result from direct effects of active ingredient or acne itself leading to epidermal barrier damage.[10-13] Thiboutot *et al.* in their review highlighted that AV itself is associated with some inherent epidermal barrier impairments.[10] Similarly, Thiboutot and Del Rosso,[10] Del Rosso and Brandt[17] highlighted the role of anti-acne therapy in epidermal barrier damage. Trautinger *et al.* in their review reported that many acne therapies are associated with phototoxicity and increased risk of UV damage.[18]

Hence, focusing on photoprotection and moisturization are very important adjuvant skin care strategies to a complete anti-acne regimen that serves to optimize therapeutic outcomes for the patient. This is especially true in those using topical AV therapy and in those treated with oral antibiotics associated with increased risk of photosensitivity. Various clinical trials have shown the effectiveness of photoprotection and moisturizers to mitigate the cutaneous reactions associated with acne.[14,15,19,20]

The moisturizer component assists in mitigating epidermal barrier impairment and its related skin sensitivity and irritation.[21-23] Both the moisturizer and sunscreen components can assist in the prevention of residual hyperpigmentation, which can result from skin irritation and inflammation, especially in individuals with darker skin.[23,24] The sunscreen component may also protect against photosensitivity induced by UV radiation in patients using certain Rx medications for AV.[23-25]

It must be noted that both moisturizers and sunscreen can cause irritation and can be comedogenic leading to flare up of acne in some patients, hence while choosing these components dermatologist must be sure that the adjuvant therapy should be non-comedogenic.[17,23,26,27] Episoft AC is one such novel photoprotecting moisturizer which has shown to be non-comedogenic and did not exacerbate or worsen AV with continued use, including in subjects using a variety of Rx products for AV.

We conducted this survey to find out cutaneous tolerability, overall performance, and cosmetic acceptability of Episoft AC as adjuvant skin care in the management of acne. In this survey continued use of Episoft AC was associated with improvement in mean facial skin tolerability scores as determined by both patients and dermatologists. There was a significant improvement in both signs such as erythema, dryness, and symptoms such as itching and burning associated with anti-acne treatment during the survey.

These results were in accordance with earlier results reported by various authors. Bowe and Kircik in their study highlighted the importance of photoprotection and moisturization in the management of acne. Authors concluded that moisturizer with broad-spectrum sunscreen was associated with better therapeutic outcomes in the management of acne.[14] Laquieze *et al.* reported that Retinoid-induced skin irritation can be relieved by the regular use of a gentle moisturizing cream as an adjunctive treatment.[19] Kircik *et al.* highlighted that a comprehensive skin care regimen of moisturizer and sunscreen may maximize efficacy and tolerability and contribute to the armamentarium for treating both photodamage and acne at the same time.[20]

All the patients participated in the survey were highly satisfied with the treatment regimen, with the following percent of subjects noting specific observations with Episoft AC. 96% - easy to use, 89% - improvement in skin texture, 87% - treatment met their need, 91% - allowed them to not to miss their acne medication, and 92% - overall satisfied with Episoft AC as an adjuvant. These results were also in accordance with published reports from various investigators.[17,23]

Another important observation seen in this survey was very good or excellent adherence to entire treatment regimen over a period of 8 weeks which is very important since poor adherence to treatment is one of the most common problems associated with acne management. Multiple clinical trials by Gollnick *et al.*,[28] Yentzer *et al.*,[29] Koo *et al.*,[30] and Tan *et al.*[31] reported that one of the central reasons for nonadherence is dryness and irritation associated with topical acne treatment. In our survey, Episoft AC was associated with improvement in signs and symptoms of cutaneous irritation which may have resulted in increased adherence to treatment. Hayashi *et al.* reported similar results and concluded that "the concomitant use of a moisturizer with adapalene from the beginning of treatment did not affect its therapeutic effects and helped to improve adherence to treatment with adapalene."[32]

In this survey Episoft AC was well tolerated by the patients, none of the patients reported any adverse event related to Episoft AC. There were no discontinuations from the survey because of adverse events including skin tolerability reactions.

This survey has certain limitations. Due to the observational and retrospective design of the survey, the possibility of selection bias cannot be ruled out. Long-term prospective comparative studies to address the shortcomings of the present survey are warranted.

CONCLUSION

The results of this survey signify that incorporating a comprehensive skin care regimen of moisturizer with broad-spectrum sunscreen in the overall management plan of acne may help in improvement of cutaneous tolerability and overall patient satisfaction with acne treatment.

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