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Original Research Article

Evaluation of effectiveness and tolerability of a moisturiser as an adjuvant to isotretinoin therapy for acne: a real-world evidence

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ABSTRACT

Background: Moisturizers are recommended as an adjuvant to acne therapies especially topical/systemic retinoids to counteract their cutaneous side-effects. Moisturisers also reduce inflammation and the intensity of acne. The compliment study was designed to evaluate effectiveness and tolerability of moisturiser (Excela, Cipla Ltd., Mumbai, India) in patients prescribed isotretinoin for managing their acne in real-world scenario.
Methods: This open-label, observational, prospective, non-comparative multicentre study was conducted between June 2019 and January 2020. Patients who were prescribed Excela moisturiser as an adjuvant to isotretinoin for acne management were enrolled. After four weeks, the investigator graded the patient's skin on smoothness and softness on a five-point scale and dryness, scaling and redness on a four-point scale. Its organoleptic characteristics and tolerability were evaluated using the subject assessment questionnaire.
Results: We enrolled 200 patients (average age: 24.02±5.44 years). Investigators rated smoothness and softness of the skin as very good to excellent in 129 (64.5%) and 113 (56.5%) patients. No patient reported severe skin dryness, scaling or redness. Very good to excellent spreadability and appeal was rated by 132 (66.0%) and 133 (66.5%) patients, respectively. Eighty (40%) patients rated the moisturiser as non-greasy/non-sticky. Itching (1%), redness (0.5%), cold (0.5%), and cough (0.5%) were reported as adverse events but were of mild intensity and unrelated to the study product. No patient experienced serious adverse event or moisturiser-related adverse event.
Conclusions: Overall, Excela moisturiser was effective and tolerable in patients with acne who were prescribed isotretinoin at the end of 4-week-long treatment period.

Keywords: Acne vulgaris, Dermocosmetic, Moisturiser, Retinoids, Psychological, Side-effect

INTRODUCTION

Acne or acne vulgaris is a chronic inflammatory disease of the pilosebaceous unit. It is one of the most common skin diseases treated by dermatologists worldwide and has the highest prevalence during adolescence. Clinical manifestations of the disease are oily skin, noninflammatory lesions (open and closed comedones), inflammatory lesions (papules and pustules), erythema, discomfort and various degrees of scarring.[1] Conventional pharmacological treatments for acne include topical benzoyl peroxide, systemic/topical antibiotics, systemic/topical retinoids and hormonal therapy. However, their success is often limited owing to reduced patient adherence. One of the major determinants of poor adherence is the occurrence of treatment related cutaneous

side-effects particularly, skin dryness, erythema, scaling, itching and stinging.[2-6] Hence, recent treatment approaches focus on using dermocosmetics as an adjuvant to conventional pharmacological therapies for managing treatment-related side-effects which ultimately help to increase treatment adherence and effectiveness.[7-9] Moisturisers with effective constituents and biological activities reportedly have auxiliary effects on acne treatment i.e., prevent skin dryness, reduce skin irritation associated with acne treatment and retards transepidermal water loss.[7,10-13] In addition, they are associated with treatment adherence and high level of patient satisfaction.[14,15] Excela (Cipla Ltd., Mumbai, India) moisturiser has been developed for oily and acne-prone skin. This dermocosmetic moisturiser recreates the skin's own natural moisture, reduces sebum secretion and possesses anti-inflammatory effects. Oral isotretinoin (13-cis isomer of retinoic acid) is the prescribed retinoid for treating acne. One of the major disadvantages associated with isotretinoin therapy is severe dryness of skin, especially during the first month of treatment. The complementary effects of Excela moisturiser with oral isotretinoin has not been evaluated so far. Hence, the compliment study was designed to assess effectiveness and tolerability of Excela moisturiser in patients with acne who were prescribed isotretinoin in daily clinical practice. The assessment of effectiveness and tolerability was based on the investigators' as well as patients' feedback on the moisturiser.

METHODS

Study design and patient population

The compliment study was an open-label, observational, prospective, non-comparative multicentre study. It was conducted from June 2019 to January 2020 at 18 clinical centres across India. This study enrolled 200 adult patients (aged ≥18 years) who had been recently prescribed isotretinoin and Excela moisturiser (as an adjuvant therapy) for managing their acne and voluntarily provided a written signed data sharing consent form. However, patients were excluded from the study if they had used isotretinoin one month prior to enrollment, if they had any skin allergy or a serious skin condition that made them unsuitable to participate in the study, if they had participated in any clinical trial one month prior to screening and if they were pregnant or lactating.

Procedure

We enrolled 200 patients in the study. Data sharing consent was obtained and relevant data (including baseline clinical characteristics and demographics) were collected using an approved case record form. Isotretinoin dosage was prescribed at the investigator's discretion. The enrolled patients were thoroughly explained the side-effects of isotretinoin and thereby the importance of applying a moisturiser on a daily basis. All patients were advised to apply moisturiser (1gm) twice daily for four weeks, and they were followed-up clinically post treatment at week 4 (±2 days) to determine effectiveness and tolerability of the moisturiser. The effectiveness was assessed through clinical assessment of signs and symptoms (dryness, scaling and redness). They were each rated on four point Likert scale (none, mild, moderate and severe) by the investigator over the course of the study. Smoothness and softness of the skin were also taken into consideration for assessing the efficacy of the moisturiser using the investigator assessment questionnaire using a five-point scale (rated excellent, very good, good, fair and none). The patients were asked to rate organoleptic characteristics and tolerability of the moisturiser (greasy/sticky, spreadability, appeal and overall satisfaction) on a four- to five-point scale. Patients' overall liking of the moisturiser was also evaluated after four-week treatment. Adverse events were monitored throughout treatment period.

The study was conducted in accordance with the declaration of Helsinki (Brazil, October 2013), good clinical practices for clinical research in India 2005, new drugs and clinical trials rules 2019, ICH E6 (R2), guidance on good clinical practice, and with ICMR's National ethical guidelines for biomedical and health research involving human participants-2017. The approval of independent ethics committee was also obtained for each centre before commencement of the study. All the patients included in the study provided written informed consent. The study was registered with the clinical trials registry of India (CTRI/2019/07/020458).

Excela moisturiser

Active constituents of the moisturiser are Revidrate™ (Sederma SAS, Le Perray-en-Yvelines, France), glycerine, Evermat™ (Sederma SAS, Le Perray-en-Yvelines, France), niacinamide, zinc, L-pyrrolidone carboxylic acid (PCA) and Sepitonic M3 (Seppic, Courbevoie, France).

Statistics

Descriptive analysis was performed. Continuous variables were presented as mean±SD and categorical variables were presented as frequency and percentages. All the statistical analysis was performed by using SPSS version 20.

RESULTS

A total of 200 patients who were prescribed isotretinoin and Excela moisturiser for acne management were enrolled in this study. No patient discontinued the treatment. Average age of the patients was 24.02±5.44 years. Of included patients, 51.5% of patients were male (Table 1). The effectiveness of the moisturiser as was measured by the investigator assessment questionnaire is depicted in (Table 2).

Table 1: Demographic and baseline clinical characteristics of the study population (n=200).

Variables	Observation
Age (years), mean±SD	24.02±5.44
Gender, N (%)	
Male	103 (51.5)
Female	97 (48.5)
Height (cm), mean±SD	162.93±8.42
Weight (kg), mean±SD	63.22±9.80

Table 2: Evaluation of effectiveness of the moisturiser using investigator assessment questionnaire (n=200).

Grade	Investigator assessment N (%)		
	Smoothness	**Softness**	
Excellent	22 (11)	17 (8.5)	
Very good	107 (53.5)	96 (48.0)	
Good	67 (33.5)	83 (41.5)	
Fair	2 (1.0)	4 (2.0)	
None	2 (1.0)	-	
Grade	**Dryness**	**Scaling**	**Redness**
None	59 (29.5)	112 (56.0)	141 (70.5)
Mild	93 (46.5)	65 (32.5)	49 (24.5)
Moderate	48 (24.0)	23 (11.5)	10 (5.0)
Severe	-	-	-

Table 3: Investigator's assessment of the overall clinical impression of the product in patients after four weeks of treatment (n=200).

Overall clinical impression	N (%)
Excellent/Good	90 (45)
Consistent use of moisturiser (Excela) is recommended	21 (10.5)
Dryness reduced	9 (4.5)
Satisfactory	9 (4.5)
Excellent product to take care of retinoid-induced dryness	6 (3.0)
Reduces scaling	6 (3.0)
Reduces skin redness	5 (2.5)
Smoothness	3 (1.5)
Soft	3 (1.5)
Irritation reduced	2 (1.0)
Well accepted and appreciated by the patient	2 (1.0)
After application of moisturiser (Excela), skin looks soft	1 (0.5)
Non-greasy	1 (0.5)
Spreadability	1 (0.5)
Non-sticky	1 (0.5)
Skin is hydrated	1 (0.5)
Very good to apply	1 (0.5)
Patient feels better as far as lesion and suppleness of skin is concerned	1 (0.5)
Patient tolerated it nicely with minimum complaints	1 (0.5)

At the end of 4-week treatment period, 129 (64.5%) and 113 (56.5%) patients were found to have very good to excellent smoothness and softness of the skin, respectively.

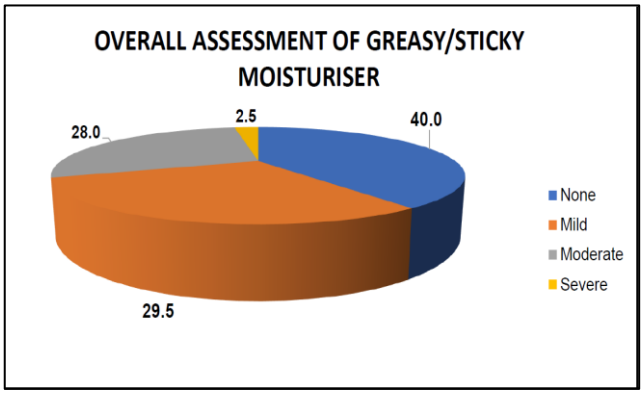

Figure 1: Assessment of organoleptic characteristics (greasy/sticky) of the moisturiser using the subject assessment questionnaire.

Two (1.0%) patients acquired fair skin smoothness after treatment. Investigators assessed some level of softness in their skin in all the participants. Evaluating signs and symptoms demonstrated that none of the patients had severe dryness, scaling or redness of skin after 4-week treatment. The investigator's assessment on the overall clinical impression about the moisturiser after four weeks of treatment as depicted in (Table 3).

Table 4: Evaluation of organoleptic characteristics and tolerability of the moisturiser using the subject assessment questionnaire.

Grade	Organoleptic and tolerability of moisturiser, N (%)		
	Spreadability	**Appealing**	**Overall satisfaction**
Excellent	37 (18.5)	36 (18)	70 (35)
Very good	95 (47.5)	97 (48.5)	112 (56)
Good	52 (26)	57 (28.5)	17 (8.5)
Fair	14 (7)	10 (5)	1 (0.5)
None	2 (1)	-	-

Nine (45%) investigators found the moisturiser either good or excellent. When the organoleptic characteristics of Excela moisturiser were assessed on a 4-point scale, 80 (40.0%) patients found the moisturiser to be non-greasy or non-sticky whereas 59 (29.5%) patients found it to be mildly greasy/sticky (Figure 1). The organoleptic characteristics and tolerability of the moisturiser was assessed using a subject assessment questionnaire at five-point scale (Table 4). Of all patients, 37 (18.5%) and 95 (47.5%) patients opined that the spreadability of the moisturiser to be excellent and very good, respectively. A total of 133 (66.5%) patients rated the product appeal to be excellent to very good, 57 (28.5%) rated it to be good and

10 (5%) patients found it fair. While measuring satisfaction, 70 (35.0%), 112 (56.0%) and 17 (8.5%) patients appraised the moisturiser to be excellent, very good and good, respectively. Of 200 patients enrolled in the study, 3 (1.5%) patients complained about the moisturiser and only 1 patient elaborated the complaint and lodged it owing to its lack of easy availability. The other 2 patients did not mention their reasons. Rest of the patients liked the moisturiser. Of all enrolled patients, only 4 (2%) patients experienced at least one adverse event (AE) and the reported AEs were itching (N=2; 1%), redness (N=1; 0.5%), cold (N=1; 0.5%) and cough (N=1; 0.5%). All AEs were of mild intensity and were unlikely to be related to the study product. No serious AEs were reported in the study.

DISCUSSION

The present study evaluated Excela moisturiser in acne patients treated with isotretinoin. Effectiveness and tolerability of the moisturiser were studied using the investigator's clinical assessment and subject's assessment questionnaires, respectively. To the best of our knowledge, we believe, we are the first to report on its effectiveness and tolerability as an adjuvant to isotretinoin therapy for acne in real-world settings. The investigator rated positively for smoothness and softness of the skin that was achieved after regularly using Excela. It also had a positive impact on reliving signs and symptoms experienced by acne patients treated with isotretinoin. Most noteworthy was the acceptable rating from end-users regarding characteristics of the moisturiser. No incidence of serious AE or moisturiser-related AE was reported. Current guideline strongly recommends oral isotretinoin for the management of moderate or severe papulopustular/ nodular acne, at a dose of 0.3-0.5 mg/kg/day, and acne conglobata, at a dose of ≥0.5 mg/kg/day.[16] Despite of superiority of oral isotretinoin over other acne treatments in terms of disease clearance, improved quality of life and reduction in psychosocial damage, it remains underutilised for acne treatment.[17] One of the major concerns related to oral isotretinoin therapy is dose-dependent cutaneous side effects. Cutaneous side effects of oral isotretinoin are attributed by its impact on barrier functions which ultimately results into loss of the homeostatic control of water content and flux.[1] Increased epidermal turnover, loss of desmosomes, reduced tonofibrils, skin fragility and altered sebaceous lipids were also reported after regular use of oral isotretinoin.[1,18] All these factors together contribute to transepidermal water loss. It is noteworthy to mention that xerotic and desquamative cutaneous changes observed in patients receiving oral retinoid therapy are of greater magnitude than that with topical retinoid therapy.[19] Nearly 90% of patients treated with isotretinoin experienced dose-dependent cutaneous side-effects.[17] Suboptimal treatment response as a consequence of low treatment adherence has been reported.[1,20] The consensus of dermatologists explicitly delineates the importance of maintaining an intact skin barrier and thereby the requirement for an adjuvant moisturiser to increase retinoid treatment adherence and thereby successful acne treatment outcomes.[11]

A growing body of evidence recommends concomitant use of moisturiser with topical retinoid therapy in patients with acne.[21-26] The utility of a moisturiser as an adjuvant to isotretinoin in those patients was also evaluated. Laquieze et al assessed efficacy of the moisturiser in 30 patients who were treated with either oral isotretinoin for at least 2 months or with topical tretinoin for at least 1 month. The authors reported significant improvement in skin dryness, roughness and desquamation with concomitant use of the moisturiser. Clinical appraisal of the moisturiser was supported by biophysical measurements. After consistent use for 15 days, patients were also satisfied with the moisturiser and rated positively for their skin properties and skin comfort.[14] A study conducted by Haren et al. systematically assessed the impact of a specific hydrating gel-cream containing hyaluronic acid, biosaccharide gum-2 and glycerine in patients treated with isotretinoin for inflammatory acne. There was a significant reduction in seborrhoea in both groups. It should be noted that as compared to placebo, the patients treated with the gel-cream were reported to have significantly increased hydration (41.88 vs. 47.44; $p<0.01$).[27] Hence, we hypothesized that concomitant use of Excela moisturiser with isotretinoin from beginning of the treatment would alleviate cutaneous side-effects of the later. The results of the present study support our hypothesis. It is possible that concomitant use of this dermocosmetic moisturiser with other acne topical/systemic medications may reduce cutaneous side-effects and also improve adherence to acne treatment. Moreover, its active constituents yield therapeutic benefits. However, further studies are required to support these assumptions. Our study had few limitations. Firstly, the study design was observational and non-comparative, and the findings are not supported by histological evaluation or objective/quantitative assessments. However, our findings provide comprehensive knowledge to dermatologists regarding the effectiveness, safety and tolerability of Excela moisturiser in a real-world scenario.

CONCLUSION

Results of this compliment study suggest that Excela when used in a real world scenario is an effective and tolerable moisturiser in patients with acne who are treated with isotretinoin. As it is able to mitigate cutaneous side-effects such as dryness, erythema and scaling, it can be considered as an effective option among dermocosmetic moisturisers, and can be used as an adjunct to pharmacotherapy for management of acne.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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