Range of Secalia products for treatment of atopic dermatitis

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SUMMARY

Overview: Atopic dermatitis is a skin disease associated with xerosis and increased cutaneous permeability. Emollients and moisturizers are widely used for cutaneous dryness treatment in patients with atopic dermatitis to repair compromised skin permeability. Among available products, we find the products marketed by ISISPHARMA, SECALIA DS (an hydrolipidic emulsion containing shea butter and inca inchi oil) and SECALIA ULTRA formulated with shea butter (a strong moisturizer and emollient), inca inchi oil (anti-inflammatory and hyposensitizing, regulating lipid metabolism), glycerin and vaseline (moisturizer, emollient and protective).

Objective: To demonstrate the efficacy of SECALIA products in the treatment of patients with atopic dermatitis.

Materials and methods: A total of 61 patients with atopic dermatitis (males/females 28/33) aged 1 to 14 years old, were included in this study. Diagnosis was made on the base of anamnestic data and clinical manifestations. SCORAD score was used to standardize the diagnosis (Scoring atopic dermatitis). In accordance with SCORAD score, patients were divided in 3 groups: the 1st group included 21 patients with SCORAD <30 (mild form); the 2nd group was formed by 27 patients with SCORAD ranging from 30 to 50 (moderate form); the 3rd group was made of 13 patients with SCORAD >50 points. SECALIA DS emulsion has been applied on the face, while SECALIA ULTRA on the trunk, twice per day on dry parts of the skin. Treatment lasted for 15-20 days depending on severity of the disease. The efficacy of SECALIA products was monitored on the 10th and 20th day of treatment, using SCORAD score.

Results: SCORAD score decreased on the 10th day of treatment by 24.5% and on the 20th day by 55.7%, respectively.

Key words: atopic dermatitis, treatment, SECALIA.

INTRODUCTION

Atopic dermatitis (AD), previously named constitutional eczema, is a common chronic inflammatory skin disorder with genetic determination, commonly found in children and adults. Its prevalence is increasing, affecting around 10-20% of the population. Its aetiology is not perfectly known.

It is currently accepted that AD has clear genetic basis, but is also under influence of environmental factors such as early exposure to food (cow's milk, eggs, fish, peanuts and walnuts) or to inhaled allergens (dust mites, contact with pets, pollen) and air pollution. Atopic dermatitis involves impaired immune system and mainly features damages to skin barrier. Because of its impact on quality of life of patients and their families, AD represents a considerable social and economic burden. Recent advances in genetics and immunology bring us new perspectives in understanding the pathophysiology of this complex disease. (V. Beneactul. 2015 E. Moraru 2015).

Main features in AD

In most cases, AD begins as soon as several weeks after birth and can evolve in three clinical phases:

Phase I

Immediately after birth, around the age of 6-8 weeks, limited dry skin lesions appear on the face and extremities. In this initial phase of the disease, Ig-E mediated sensitivity cannot be detected. However, the sensitivity occurs with chronic inflammation leading to the second phase of the disease.

Phase II

Corresponds with sensitization to allergens from the environment with the occurrence of Ig-E mediated sensitivity. It can be improved and go into remission before puberty or turn to be permanent in adulthood.

Phase III
This last phase is characterized by the domination of autoimmune phenomenon in which patients develop Ig-E mediated sensitization to their own proteins. It can be seen most frequently in adults and may be associated with other atopic disorders such as allergic rhinitis and/or asthma.

The four main characteristic features of AD are:
- Skin barrier dysfunction characterized by skin xerosis and high permeability.
- Clinical or subclinical chronic inflammation.
- Cutaneous pruritus.
- Staphylococcus aureus with massive colonization.

Skin barrier function is the result of tight interactions between genetic and proinflammatory events.

Variants on three candidate genes (SPINK5, KLK7 and FLG) have been associated with atopic dermatitis. There also exists strong local impact of proinflammatory cytokines such as IL-4 or IL-13 that are capable of damaging the functionality of structural proteins and/or affect the functioning of enzymes involved in epidermal lipids and ceramides production. General effects of skin barrier dysfunction are multiple, including dehydration manifested by increased epidermal xerosis, increased permeability allowing penetration of high molecular weight allergens, a favourable microenvironment for staphylococcus aureus colonization and chronic pruritus.

Current treatments of AD
The goals of treatment of AD are mainly restoring skin barrier, combating skin inflammation and remission of pruritus. Treatment must be adapted to the extension and severity of skin lesions, to the age of the patient, and to the impact of the disease on patient's quality of life. Children are more likely to face side effects that may occur during the treatment.
Topical treatment is the first line treatment in AD. It must consider dry skin (emollient, moisturizer), superinfection (bacterial, viral or fungal) and inflammation of the skin (especially corticosteroids and immunosuppressive macrolides - tacrolimus).
Systemic treatment is only required when unresponsive to topical treatment and it includes antihistamines, antibiotics, Y-linolenic acid, photochemotherapy, corticotherapy, immunosuppressants and immunomodulators (IFN-Y, immunoglobulins).

Management of AD symptoms requires focusing on two main levels: an efficient control of chronic inflammation through anti-inflammatories and improvement of skin barrier function using emollients adapted to the skin of atopic patients. Applying a specific treatment before the onset of AD is a new concept which could impact on the evolution of this pathology. Applying an emollient on baby skin with high risk of developing AD in the first weeks of life can be effective in reducing dehydration, improving proinflammatory microenvironment, reducing S. aureus colonization and reducing the penetration of allergens.

MATERIALS AND METHODS

This was an open clinical study aimed to support the concept that early application of emollients can have long-term positive impact on the evolution of AD. This study took place at Dermatology Hospital of the State University of Medicine and Pharmacy "Nicolae Testemițanu" Chisinau, Moldova.
Study visits were as follows: a screening visit at D0, and at D10 and D20.

SUBJECTS

Eligible subjects were 1-14 years old, with symptoms of AD present for three months or more and not having received treatment for their disease during the month preceding their inclusion in the study in order to avoid any carryover effect of previous therapy. Exclusion criteria included known allergies to any component of the formula of the product under study or patients (or patients' parents) whose mental condition did not permit good compliance.

SAMPLE SIZE

61 patients were distributed in three groups: SCORAD <30 (mild form), SCORAD >30 but <50 (moderate form) and SCORAD >50 (severe form).

TREATMENT

Patients received SECALIA DS emulsion which had to be applied on the face, while SECALIA ULTRA on the trunk, twice per day on dry parts of the skin.
SECALIA DS features an hydrolipidic emulsion containing shea butter and inca inchi oil and SECALIA ULTRA is made of shea butter (a strong moisturizer and emollient), inca inchi oil (anti-inflammatory and with hyposensitizing effects, regulates lipid metabolism), glycerin and vaseline (moisturizing, emollient and protective effects).

ASSESSMENTS

Treatment efficacy was assessed by SCORAD score which is the severity score used for atopic dermatitis. It was created and validated in 1990 by a group of experts: the European Task Force on Atopic Dermatitis. SCORAD score is computing data about spread of disease (Front: face, upper limbs, trunk, lower limbs; Back: head, upper limbs, trunk and lower limbs), intensity of associated symptoms (erythema: 0 1 2 3 edema: 0 1 2 3 oozing: 0 1 2 3 excoriation: 0 1 2 3 lichenification: 0 1 2 3 Xerosis: 0 1 2 3) and subjective signs (pruritus and insomnia both graded from 0 to 10).
SCORAD was established at baseline (D0) and at D10 and D20.
Safety assessments included adverse events (AEs) throughout the study.

ETHICAL PATTERNS

This study was conducted in accordance with the ethical principles derived from the Declaration of Helsinki and ICH (International Conference on Harmonization) Good Clinical Practices and in compliance with local regulatory requirements. All subjects' parents provided a written informed consent before entering the study.

RESULTS

Demographic characteristics
A total of 61 subjects aged between 1 and 14 years old, males (28 patients, 46%) and females (33 individuals, 54%) were screened and distributed between the three groups according to their SCORAD value at baseline as shown in Table 1.

Table 1. Repartition of patients at baseline in function of their SCORAD value

	SCORAD VALUE AT D0	NUMBER OF PATIENTS
GROUP 1	<30 (mean 21.5)	21
GROUP 2	>30 and <50 (mean 43.8)	27
GROUP 3	>50 (mean 69.6)	13
TOTAL	Mean 45.0	61

All patients (100%) completed the study.
Treatment groups were comparable at baseline in terms of demographic characteristics. (Table 1)

Efficacy

Detailed results of different scores are shown in Table 2.

In all groups, it could be observed a progressive reduction of SCORAD along time.

In Group 1 (SCORAD <30 at baseline) the mean value dropped from 21.5 to 11.1 (-48.4%) at D10 and to 0 (-100%) at D20.

In group 2 (SCORAD >30 and <50 at baseline) the mean value was reduced from 43.8 to 32.5 (-25.8%) at D10 and to 14.6 (-55.1%) at D20.

Finally, among the most severe cases (SCORAD > 50 at baseline) the decrease was from 69.6 to 58.3 (-16.2%) at D10 and to 30.5 (-47.7%) at D20.

The average SCORAD including all three groups dropped from 44.9 to 33.9 (-24.5%) at D10 and to 22.3 (-55.7%) at D20.

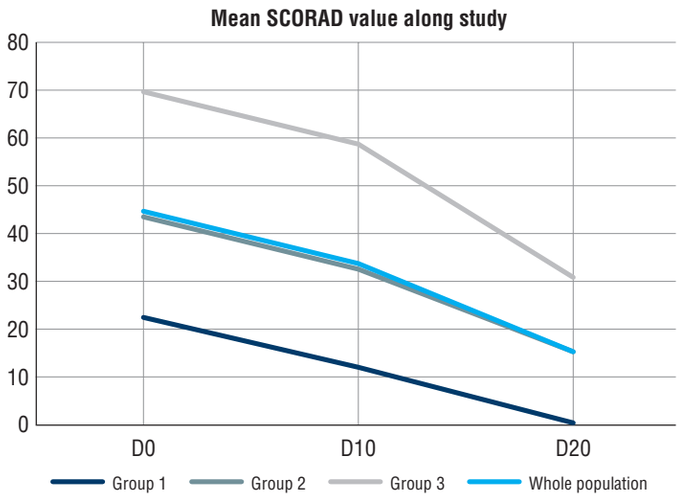
Table 2. SCORAD values at different stages of the study

	SCORAD MEAN VALUE		
	D0	**D10**	**D20**
GROUP 1	21.5	11.1	0
GROUP 2	43.8	32.5	14.6
GROUP 3	69.6	58.3	30.5
TOTAL 3 GROUPS	45.0	34.0	15

Adverse events

No noticeable adverse event was reported along this study.

Figure 1. Kinetics of evolution of SCORAD along the study.



DISCUSSION

It is well recognized that in the management of AD, the use of emollients and moisturizers is a cornerstone.

In this study, it was demonstrated that the use of a combination of two emollients/moisturizers, namely SECALIA DS and SECALIA ULTRA, has permitted a major improvement in the conditions of the patients, as observed from the evolution of SCORAD index from baseline to the different stages of this trial. The rapid and significant efficacy of both tested products is due to their capability to restore the integrity of epidermal barrier and moisturize the skin.

Shea butter is an off-white fat extracted from the nut of the African shea tree (Vitellaria paradoxa).

This is a triglyceride derived mainly from stearic acid and oleic acid. It is well known that in AD skin there is a deficiency in ceramides, these being synthesized from oleic acid. For this reason, bringing oleic acid will permit at least partial recovery of the ceramide levels, and help to restore the integrity of skin barrier. Further to its emollient and humectant properties, shea butter is also reported to have anti-inflammatory properties, necessary in AD, whose inflammatory component is high.

Inca inchi oil is extracted by pressing from the seeds and flesh of the fruit of the Plukenetia volubilis, a tree native to the area surrounding the Amazon River. It has a very high content (approximately 50%) of the omega-3 fatty acid gamma-linolenic acid (=GLA). In the skin of AD patients, concentrations of linoleic acid tend to be elevated, whereas concentrations of linolenic acid are substantially reduced. This suggests reduced conversion of linoleic acid to gamma-linolenic acid in these patients. In various studies, topical application of GLA has been found to improve the clinically assessed skin condition and objectively assessed skin roughness. Hence it is not surprising that in our study, we can observe good results. Further, inca inchi oil has a very high content of Tocopherols (176–226 mg/100 g) which consists predominately of gamma-Tocopherol (50%) and delta-Tocopherol. These compounds are the main constituents of vitamin E and possess potent antioxidant properties. As a consequence, they can block at least partially the inflammatory cascade by reducing the level of proinflammatory cytokines which have a major role in the occurrence and maintenance of inflammation in AD. For this reason, the use of vitamin E is common in AD. To complete its activity SECALIA ULTRA, contains glycerin and vaseline, which are recognized humectants and moisturizers.

CONCLUSION

In this study we were able to demonstrate the benefits obtained from the application of SECALIA DS and SECALIA ULTRA in young patients with AD. This demonstration was based on an objective criterion: the reduction of SCORAD index. Hence we could conclude that the application of SECALIA DS and SECALIA ULTRA was able to improve the condition of the skin with AD, and that, based on the new concept that applying an emollient cream on the skin of babies in the weeks following their birth could be beneficial for the avoidance or reduction of the risk of occurrence of AD, SECALIA DS and SECALIA ULTRA would certainly be the adequate products in this indication.