

Evaluating the Safety and Tolerance of a Body Wash and Moisturizing Regimen in Patients With Atopic Dermatitis

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ABSTRACT

Atopic dermatitis is an inflammatory skin disease accompanied by a variety of signs and symptoms including heightened skin sensitivity, intense pruritus, xerosis and even skin lichenification in the more advanced stages. Patients with atopy have an impaired skin barrier thus allowing a greater permeation of irritants and allergens. Even though a number of exogenous factors can trigger a patient with atopy to flare, a gentle and moisturizing daily skin care routine is important for proper hydration and maintenance of a healthy skin barrier. Body cleansers and moisturizers not only need to be free of potential irritating ingredients, allergens and fragrances but also should be formulated with ingredients that protect, hydrate and provide benefits to skin in strengthening an already compromised barrier. Special care needs to be taken when choosing ingredients and formulations need to be reviewed by dermatologists who are experts in both allergy and an atopic population. Proper safety, allergy and tolerance testing is imperative to assure that the regimen is safe and well tolerated by those with atopic dermatitis.

A regimen of a mild oatmeal based body wash and therapeutic oatmeal based cream with topical benefit agents, specifically developed for an atopic population, was tested for safety and tolerance. The cleanser and body cream was tested for allergy by the Repeated Insult Patch Test and did not cause any contact dermal sensitization in over 200 subjects tested. Additional safety testing showed this regimen was gentle to the skin and non-photoreactive when tested for phototoxicity and photoallergy.

A dermatologist controlled usage study was also performed to assess the clinical tolerance and patient acceptability of the above gentle and moisturizing skin care regimen. Upon inclusion all patients exhibited mild to moderate atopic dermatitis as determined by the criteria of Hanifin and Rajka. An independent dermatologist performed weekly clinical evaluations. This regimen was well tolerated; there were no significant changes in clinical safety parameters, while both patient and clinical assessments indicated significant skin benefits in this highly sensitive population.

INTRODUCTION

A skin care regimen consisting of a mild oatmeal based body wash and a therapeutic oatmeal based body cream with topical benefit agents was developed for use on individuals with eczema. The body wash was fragrance free and mild to prevent further insult to the stratum corneum. The therapeutic moisturizing cream contained oatmeal to soothe and protect the skin, combined with glycerin, a humectant, and ceramides to help with the skin's water retention properties. In addition, the therapeutic cream also contained panthenol to condition the skin and petrolatum that functioned as an occlusive to slow water loss. A two-week clinical study was performed by an independent dermatologist to determine the tolerance of a mild oatmeal based body wash and a therapeutic oatmeal based body cream with topical benefit agents in patients with mild to moderate atopic dermatitis.

STUDY DESIGN

Population

Twenty-one healthy patients between the ages of 15 and 60 with mild to moderate atopic dermatitis (according to the criteria of Hanifin and Rajka) and at least 5% body surface area of involvement were entered into the study. Patients with severe atopy, those with a history of recurrent cutaneous infections, or those with known allergies to ingredients in the test products were excluded from the study. Over 70% of the patients enrolled into the study were using either an OTC or prescription topical treatment to control their atopy. This protocol was approved by an IRB and informed consent was obtained from all patients.

Treatments

Patients used the mild oatmeal based body wash once a day for showering or bathing. They applied the therapeutic oatmeal based cream with topical benefit agents to their arms, legs, hands and torso twice a day for the duration of the two-week study. Patients were allowed to apply the cream more often if necessary, and were required to record usage in their diary.

Benefits of the Regimen to Skin with Eczema were Determined By

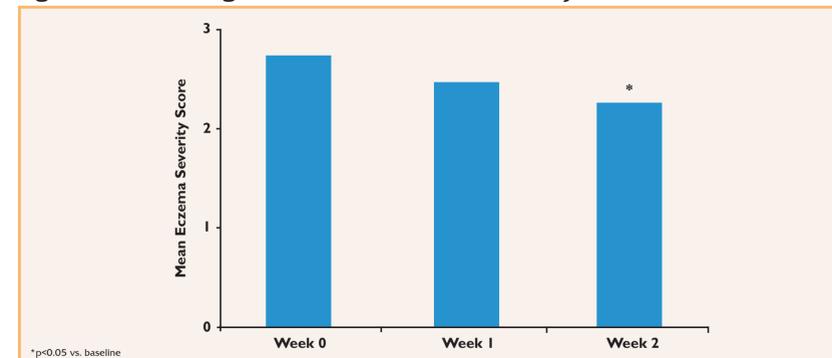
Investigator Evaluations: Performed at Day 0, 7, and 14

Final Self-assessments: Day 14

RESULTS

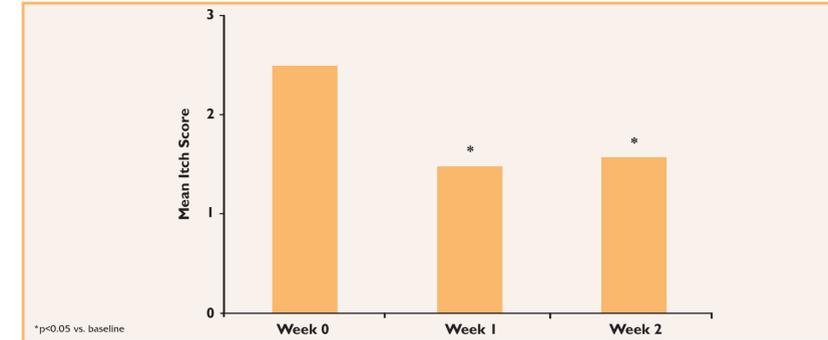
The regimen of the mild oatmeal based body wash and the therapeutic oatmeal based cream with topical benefit agents was well-tolerated by patients with mild to moderate atopic dermatitis. There were no significant increases in the mean scores for eczema severity, itch, or any of the clinical safety parameters observed during the 2-week study period.

Figure 1: Dermatologist Assessments: Eczema Severity



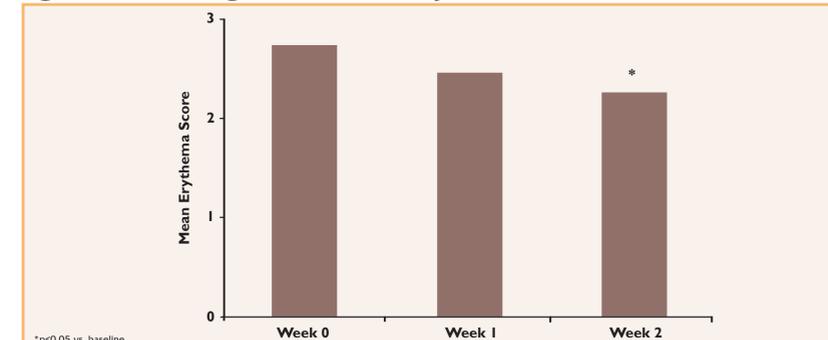
Dermatologist evaluations showed a significant improvement ($p < 0.05$) in the mean eczema severity score after 2 weeks of use of the oatmeal based body wash and the therapeutic oatmeal cream. At the 2-week time point 62% of the atopic patients actually showed an improvement in their eczema severity score when compared to baseline.

Figure 2: Dermatologist Assessments: Itch Severity



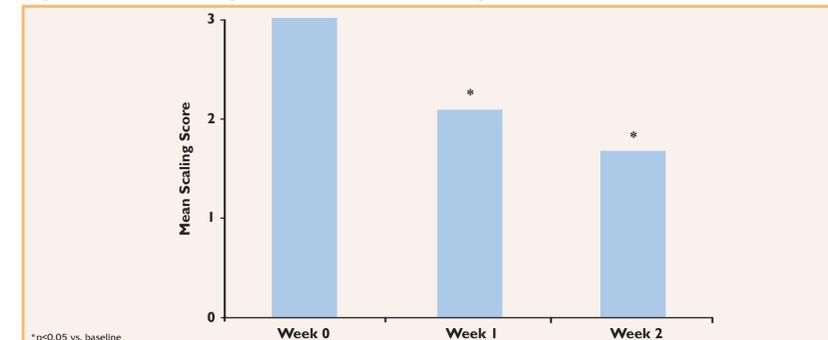
Patients perceived a significant improvement ($p < 0.05$) in itch severity as early as 1 week after using the mild oatmeal body wash and the therapeutic oatmeal cream regimen. After 1 week of using the oatmeal based regimen there was over 40% improvement in the perceived mean itch score when compared to baseline. Significant improvement in the mean itch score was maintained at the 2-week time point when compared to baseline.

Figure 3: Dermatologist Assessments: Erythema



Dermatologist evaluations showed significant improvements ($p < 0.05$) in skin redness after two weeks of using the mild oatmeal body wash and therapeutic oatmeal cream regimen.

Figure 4: Dermatologist Assessments: Scaling



Significant improvement ($p < 0.05$) in skin scaling was observed by the dermatologist after 1 week of using the oatmeal body wash and therapeutic cream regimen. After 1 week of using the regimen over 75% of the atopic patients showed an improvement in scaling. Significant improvement ($p < 0.05$) in the mean score for skin scaling was maintained at the 2-week time point when compared to baseline.

Table 1

Final Self Assessments	Percent of Patients Agreeing
Regimen	
Gentle and mild to skin	100
Effective in providing moisturization	100
Liked the regimen	75
Felt their skin was in an overall better condition	66
Cream	
Left skin feeling soft and smooth	100
Provide the right amount of moisturization	90
Was effective in relieving their itchy skin	80
Cleanser	
Gentle to the skin	100
Left skin feeling moisturized after use	100
Provided just the right amount of lather	80

CONCLUSIONS

This regimen of the mild oatmeal based body wash and therapeutic oatmeal based cream was well-tolerated and beneficial to patients with mild to moderate atopic dermatitis.

- Dermatologist evaluations showed a significant improvement in the mean eczema severity score after 2 weeks of use.
- Dermatologist evaluations showed significant improvements in skin scaling and erythema.
- Atopic patients perceived significant improvements in itch as early as 1 week after starting use of the regimen.
- Instrumental assessments proved that the cream provided 24-hour moisturization to the skin.

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