COMPARISON OF AN ANHYDROUS OTC BALM CONTAINING 15% ZINC OXIDE, 2% COLLOIDAL OATMEAL, AND 1% ALLANTOIN VERSUS 1% HYDROCORTISONE CREAM IN SUBJECTS WITH MILD TO MODERATE DERMATITIS

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INTRODUCTION

Topical corticosteroids are recommended for the treatment of atopic dermatitis (AD). Corticosteroid efficacy has been demonstrated with a wide variety of preparations and strengths but these agents have the potential for topical and systemic side effects, including striae, skin atrophy, perioral dermatitis, acne rosacea, and adrenal suppression [1,2]. Patients' fears about these side effects have important implications for compliance with corticosteroid treatment [3,4]. An anhydrous, preservative-free, fragrance-free, over-the-counter (OTC) eczema balm containing 15% zinc oxide, 2% colloidal oatmeal, 1% allantoin, and natural oils was developed for targeted treatment of dermatitis lesions. The objective of this trial was to compare clinical efficacy and safety of this balm to hydrocortisone cream.

STUDY DESIGN

Subjects

Volunteer subjects were recruited from a pool of healthy men and women, 18-65 years of age with Fitzpatrick skin type I-VI. Subjects had clinically determined mild-to-moderate eczema or AD with a SCORing Atopic Dermatitis (SCORAD) score <50, <10% of total body area affected, and at least one active lesion.

Design

This was a 4-week, single-center, double-blind, randomized, controlled clinical trial in Colorado Springs, Colorado. The study consisted of a visit at baseline and again after two and four weeks. At each visit, SCORAD, Investigator's Global Improvement Assessment (IGIA), Dermatology Life Quality Index (DLQI), and transepidermal water loss (TEWL) were used to evaluate efficacy. Safety and tolerability were evaluated by recording adverse events and assessing signs and symptoms, including erythema, dryness/scaling, peeling, edema, burning, stinging, tightness, and tingling in the area adjacent to the target lesion.

Treatment

Subjects were randomized (1:1) to the eczema balm (EB; Skinfix Eczema Balm) or 1% hydrocortisone cream (HC). Subjects were provided with a pre-weighed unit of their assigned treatments and instructed to apply a sufficient amount of the test material to all affected areas and adjacent skin 2 times per day (ideally morning and evening) to clean dry skin, especially after bathing. The EB ingredients include zinc oxide, colloidal oatmeal, allantoin, sweet almond oil, shea butter, soybean oil, jojoba oil, beeswax, petrolatum, paraffin, and tocopherol.

Assessments

Efficacy assessments included the SCORAD, IGIA (score from 1-5 with 1= worse and 5 = markedly improved), and the DLQI.

Triplicate Tewameter (TM300, Courage + Khazaka, Germany) measurements were taken on the target lesion area after acclimating to ambient temperature (68-75˚F) and humidity (35-65%) for ≥15 minutes; the target area was chosen by the board-certified dermatologist.

Safety was evaluated by recording adverse events (AEs). Local cutaneous tolerability was determined by assessing the signs and symptoms of erythema, dryness/scaling, peeling, edema, burning, stinging, tightness, and tingling in the area adjacent to the target lesion. Each of these symptoms was scored on a 4-point scale (0 = none, 1 = mild, 2 = moderate, and 4 = severe).

RESULTS

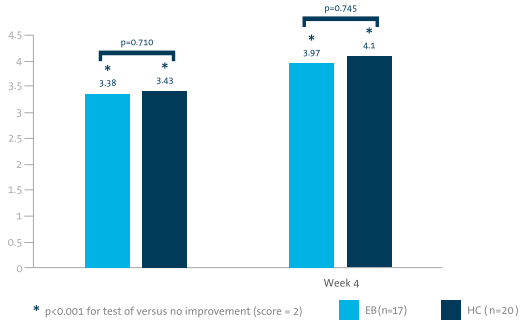
Subjects

A total of 38 subjects were enrolled and 37 completed the trial and comprised the per protocol population (EB = 17, HC = 20). One subject randomized to EB requested withdrawal and was discontinued. The mean age was 45.9 ± 9.8 years and the majority of subjects were female (75.7%) and Caucasian (75.7%); subjects in the two treatment groups were well matched for age, sex, race, ethnicity, and skin type.

Global Improvement

Both treatments resulted in significant improvements from baseline in IGIA at weeks 2 and 4 (all p <0.001) and there was no significant difference between treatments at either time point (Figure 1).

Figure 1. IGIA



Extent and severity of eczema

Both treatments were associated with significant improvements from baseline in area score "A", intensity score "B", subjective symptoms score "C", and overall SCORAD score at weeks 2 and 4 (all p<0.05). There were no significant differences between treatments for changes from baseline in any of these composites at weeks 2 or 4 (Table 1).

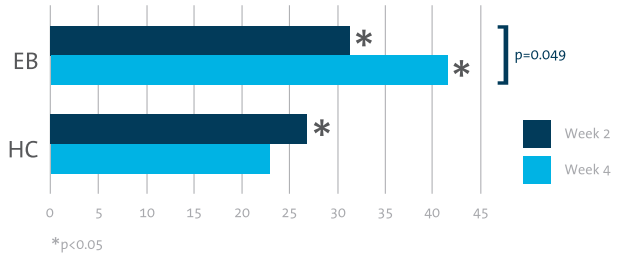
Table 1. SCORAD scores

Score	Mean change % from baseline at week 2	p-value	Mean change % from baseline at week 4	p-value
Area score "A" (%)				
EB	-37.2	0.031	-53.8	0.004
HC	-34	0.004	-56.6	<0.001
Intensity score "B"				
EB	-54.2	<0.001	-69.6	<0.001
HC	-52.3	<0.001	-75.2	<0.001
Subjective symptoms score "C"				
EB	-64.9	<0.001	-81.3	<0.001
HC	-70.2	<0.001	-84.6	<0.001
Overall SCORAD score				
EB	-56.5	<0.001	-72.2	<0.001
HC	-56.9	<0.001	-77.5	<0.001

Skin barrier

Assessments of TEWL indicated that EB treatment resulted in significant reductions from baseline at both weeks 2 and 4 (p=0.036 and p=0.004, respectively). EB treatment also resulted in a significant reduction from week 2 at week 4 (p=0.049). Treatment with HC resulted in a significant reduction in TEWL at week 2 only (p=0.029). There were no significant differences between treatments for changes from baseline in TEWL at weeks 2 or 4 (Figure 2).

Figure 2. Tewameter



Quality of life

There were no significant differences between treatments in response to the DLQI questionnaire at either time point (all p>0.05). The exception was the question "Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?" whereby HC had a better improvement than EB at week 2 (p=0.027).

Safety and tolerability

No AEs related to the study treatment were noted throughout this 4-week trial. Results of the tolerability evaluation showed that use of EB and HC produced statistically significant improvements in scores for erythema, dryness/scaling, peeling, edema, burning, stinging, tightness, and tingling at weeks 2 and 4 when compared with baseline scores (all p <0.05). Comparisons of mean changes from baseline indicated no statistically significant differences between treatments (all p>0.05).

CONCLUSION

The results from this single-center, double-blind, randomized, controlled clinical trial indicate that application of EB to affected areas and adjacent skin for 4 weeks in patients with eczema resulted in significant decreases from baseline in the signs and symptoms of this disease.

This balm, which contains 15% zinc oxide, 2% colloidal oatmeal, 1% allantoin, and natural oils is as safe and effective as 1% hydrocortisone cream for the treatment of eczema. The equivalence of this nonsteroidal preparation versus a corticosteroid cream supports the efficacy of a steroid-sparing approach for the treatment of eczema. Therefore, this balm can be a valuable addition to the dermatologic armamentarium, offering an additional avenue for enhancing the safety of treatment for this disease.

References
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Disclosures
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