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Research Article

Natural Skin Care Regimen Improves Clinical Parameters and Quality of Life in Children with Atopic Dermatitis

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Abstract

Background: Atopic dermatitis (AD) is a prevalent, chronic inflammatory skin disorder, characterized by xerosis, itching and recurrent eczematous lesions. The condition also has major psychosocial implications for patients and their families. A daily skincare regimen of gentle cleansing and moisturization is an important part of atopic dermatitis therapy.

Objective: This study evaluated the tolerability and efficacy of a nature-based shampoo/wash and moisturizer in children with mild to moderate atopic dermatitis

Methods: This open-label study involved 23 children (6 months – 13 years) with atopic dermatitis. A daily skin care regimen of nature-based shampoo/wash and moisturizer was used for 4 weeks. The primary endpoint was tolerability assessed through clinical grading of erythema, dryness and roughness. The study pediatrician graded the eczema condition using the Eczema Area and Severity Index (EASI), and assessments of stratum corneum hydration and transepidermal water loss were performed before and after treatment. Parent/guardian completed two validated quality of life questionnaires.

Results: Twenty children completed the study. Clinical evaluations showed significant improvement in subjects' atopic disease with daily use of nature-based regimen. Significant reduction in dryness and roughness was observed, indicating that both products were well-tolerated. Moisture content and transepidermal water loss measurements showed directional improvements in skin barrier function.
Parent/guardian reported significant improvements in quality-of-life assessments.

Conclusions: The study demonstrated that nature-based skin care regimen was well tolerated and improved quality of life and skin condition in children with atopic dermatitis and can be used either alone or in adjunction with traditional treatment for disease control.

Keywords: alternative medicine; herbaceous pharmaceuticals; normal remedies; complete healthcare; plant-located therapies; pharmacological projects; dispassionate evidence; control of product quality; uniformity; drug interplays

Introduction

Atopic dermatitis (AD) is a chronic, relapsing skin condition characterized by pruritus, inflammation, and xerosis. The disease is common, affecting an estimated 15-30% of children and 2-10% of adults.1,2 The specific cause of AD is unknown, but the disease is often associated with elevated serum IgE levels and a personal or family history of type I allergies, allergic rhinitis, and asthma. AD often begins in infancy, with a high percentage of children experiencing their first episode before one year of age.1–4 The disease represents a significant burden not only for those afflicted, but for family members as well.1,5
Treatment AD often requires pharmacological intervention. However, AD is associated with an epidermal barrier defect and nonpharmacological topical interventions such as moisturizer or emollient application are a mainstay of therapy, since these products help hydrate the skin and may augment barrier function and repair.6,7 Avoidance of triggering factors is also recommended. Allergens and irritants can act as triggers, and in general, limited use of non-soap cleansers is preferred.6–8 Minimizing the presence of superfluous ingredients such as perfumes and dyes in skin care products is also desirable.

We conducted a 4-week clinical study to assess the suitability of a regimen comprising liquid shampoo/wash and lotion products based on natural ingredients for daily use by children with AD. Clinical grading and bioinstrumentation were key to judging the regimen's safety and efficacy. However, the study also incorporated two validated quality of

life instruments to assess the burden of disease on the subjects and on their caregivers.

Methods

Test Articles

Subjects or parents/guardians of enrolled subjects used a natural ingredient-based liquid shampoo/wash product to cleanse themselves/their child during the study. This product combined effective cleansing and convenience; the latter was considered important given the lower end of the age range under study.

Additionally, subjects/parents used a natural ingredient-based lotion to moisturize their/their child's skin.

Ingredient listings for the natural ingredient-based shampoo/wash and moisturizer test articles are provided in Table 1.

Test Article	Ingredient Listing
Shampoo and wash product	Water, decyl glucoside, coco-betaine, lauryl glucoside, isoamyl laurate,sucrose laurate, glycerin, natural fragrance, betaine, potassium cocoyl hydrolyzed soy protein, hydrogenated palm glycerides citrate, tocopherol, lecithin, xanthan gum, citric acid, sodium chloride, coco- glucoside, glyceryl oleate, potassium sorbate, sodium benzoate, ascorbyl palmitate, phenoxyethanol, limonene.
Lotion/moisturizer product	Water, helianthus annuus (sunflower) seed oil, glycerin, cetyl alcohol, zea mays (corn) starch, avena sativa (oat) kernel flour, aloe barbadensisleaf juice, butyrospermum parkii (shea) butter, hydrolyzed jojoba esters, jojoba esters, kaolin, lecithin, xanthan gum, citric acid, sucrose stearate, zinc oxide, sodium PCA, sucrose polystearate, glyceryl laurate, sodium stearoyl lactylate, potassium sorbate, sodium benzoate, phenoxyethanol.

Table 1: Ingredient listing for the test articles used in this study.

Clinical In-Use Study

A single-center, clinical in-use study was conducted under the supervision of a board-certified pediatrician to assess the test articles' skin tolerance and efficacy over four weeks of daily use. The target study population comprised otherwise healthy infants and children aged 6 months to 12 years with mild to moderate AD. The study protocol and all associated documents were reviewed and approved by an institutional review board. A parent or legal guardian provided informed consent for each prospective subject before they underwent any study-related procedures.

Prospective subjects acclimated under controlled environmental conditions (68-75 °F, 35-65% relative humidity) for at least 15 minutes upon arriving at the clinical testing facility. The study pediatrician then evaluated each individual's skin using the Eczema Area and Severity Index (EASI) to assure that enrolled subjects had mild (EASI score from 1.1-7.0) or moderate (EASI score from 7.1-20.0) AD.9 The demographics of the enrolled study population are summarized in Table 2. The study pediatrician also scored erythema, dryness, and roughness as tolerance parameters on a 4-point scale (0 = none to 3 = severe). Qualifying subjects then had stratum corneum hydration (Corneometer CM 825, Courage + Khazaka electronic GmbH, Köln, Germany) and transepidermal water loss (TEWL, Tewameter TM300, Courage + Khazaka) measurements taken from an uninvolved area on a randomly assigned leg. Hydration measurements were made in triplicate at apposed sites and averaged; a single TEWL measurement was made.

Atopic Dermatitis Severity (EASI)	
Mild, N (%)	16 (69.6)
Moderate, N (%)	7 (30.4)
Age at Enrollment (Months)	
Mean (SD)	57 (45.3)
Median	54
Range	6 - 148
Sex	
Female, N (%)	8 (34.8)
Male, N (%)	15 (65.2)
Fitzpatrick Skin Phototype	
I	2
II	5
III	3
IV	3
V	10
Key: N = number, SD = standard deviation.	

Table 2: Demographics of enrolled subjects.

Subjects' parents/guardians completed Patient Oriented Dermatitis Measure (POEM) for children and Family Dermatology Quality of Life Index (FDLQI) questionnaires to assess subjects' perceived dermatitis severity and the impact of the subjects' disease on other family members, respectively.10,11 Completing the POEM required parents/guardians to rate how frequently, within the previous week, seven specific events/behaviors related to their child's disease had occurred. Responses were scored from 0 to 4, corresponding to 'no days' and 'every day'. The maximum POEM score is 28. Similarly, the FDLQI required parents/guardians to respond to a series of 10 questions to assess the impact of their child's disease on them during the past month. Responses are scored from 0 to 3, corresponding to 'not relevant/not at all' and 'very much'. The maximum FDLQI score is 30.

Parents or guardians of qualifying subjects were provided with the test articles along with instructions for use. The liquid shampoo/wash product was to be used at least once but not more than twice daily for cleansing the body and hair. The moisturizer was to be applied twice daily; immediately after cleansing and 10-12 hours later. An additional daily application of the test moisturizer to dry skin areas was allowed, if necessary. Parents or guardians recorded each use of the test articles in a supplied study diary.

Subjects returned to the clinical testing facility after four weeks for final evaluation. Completed study diaries were collected and checked to assure compliance. After subjects acclimated, the study pediatrician evaluated EASI and scored tolerance parameters. Stratum corneum hydration and barrier function were measured as at baseline then subjects' parents/guardian completed POEM and FDLQI questionnaires to assess perceived changes in their child's dermatitis severity and the disease's impact on other family members.

Statistical analysis

Only data for subjects who completed the study were included in the statistical analysis. Demographic data collected at the baseline visit were tabulated, and summary statistics were calculated for graded parameters, instrumental measurements, and questionnaire responses. The change-from-baseline values for each endpoint at each evaluation were calculated on a per subject basis, then mean values were tested for difference from zero using non-parametric statistical tests for grades and questionnaire data, and parametric tests for instrumental data. A two-tailed significance level of $\alpha = 0.05$ was used for all statistical analyses.

Results and Discussion

Children with mild to moderate AD were the target population for this clinical study. Consistent with this, subjects' incoming EASI scores ranged from 1.2 to 12.0, with an average baseline EASI score of 4.1 (Table 3). This reflects that the majority of enrolled subjects (~70%) had mild AD. Graded erythema was absent at baseline, but graded dryness and roughness scores were also in the 'mild' range. Twenty-three subjects qualified to enter treatment. One subject was dropped for noncompliance and one subject was lost to follow-up. There was one adverse event reported (erythema), which was mild in severity and judged possibly related to test article use. This adverse event resolved without further intervention. Thus, data from twenty subjects who completed the study were analyzed.

Clinical evaluation showed that subjects' atopic disease improved with treatment (Table 3). The average EASI score decreased significantly from 4.1 to 3.5. Erythema graded as a tolerance parameter remained absent at study end; however, the other graded parameters, dryness and roughness, both decreased significantly from baseline. These clinical results support that the regimen comprising natural-based liquid shampoo/wash and lotion products was well-tolerated, and in fact improved subjects' skin condition over 4 weeks of daily use.

Graded Endpoint	Baseline	Week 4	*P*-value[a]
EASI score, mean (SD)	4.1 (3.00)	3.6 (3.04)	0.004
Tolerance parameters			
Erythema, mean (SD)	0.0 (0.00)	0.0 (0.11)	1.000
Dryness, mean (SD)	0.6 (0.54)	0.5 (0.43)	0.025
Roughness, mean (SD)	0.7 (0.38)	0.6 (0.37)	0.025
[a]Wicoxon signed rank test. Key: SD = standard deviation.			

Table 3: Average graded endpoint values at baseline and study end.

AD is associated with skin dryness and barrier compromise. Values for these parameters tend be lower and higher, respectively, than in healthy individuals, even on uninvolved skin sites.12–14 Stratum corneum hydration values measured on uninvolved leg skin at baseline averaged about 23 AU, placing them in the range associated with 'very dry skin' (Table 4).15 Baseline TEWL values measured with the Tewameter® on uninvolved leg skin averaged 11.3 gm·m-2·hr-1, somewhat higher than the value measured with this instrument on the legs of healthy individuals.16 Thus, baseline instrumental measurements made on enrolled subjects' legs are consistent with the expectations for AD.

Instrumental Endpoint[a]	Baseline	Week 4	*P*-value[b]
Corneometer, mean (SD)	23.2 (7.42)	26.6 (8.65)	0.259
TEWL, mean (SD)	11.3 (3.39)	10.4 (3.08)	0.311
[a]Corneometer units are AU; TEWL units are $gm \cdot m^{-2} \cdot hr^{-1}$. [b]Paired t-test. Key: SD = standard deviation; TEWL = transepidermal water loss.			

Table 4: Average instrumental endpoint values measured at baseline and study end.

Stratum corneum hydration values measured on subjects' legs increased by about 2.6 AU (about 11%) from baseline to study end, suggesting that the treatment increased moisture in the stratum corneum. However, the increase was not statistically significant. TEWL values decreased by about 0.9 gm·m-2·hr-1 (about 8%) over treatment, indicating improvement in the stratum corneum barrier. But again, this change was not statistically significant. The instrumental data are consistent with directional improved skin condition as a result of using the natural-based liquid shampoo/wash and moisturizer products.

AD creates a burden not only for those afflicted, but also on those around them.1,5 In the case of children, parents or guardians are most affected. This study used two validated instruments to assess the burden of disease on the child from the parents'/guardians' standpoint (POEM), and the impact of the disease on the child's family (FDLQI). Baseline responses to the POEM showed that itching, sleep disturbances, and cracked, flaking, and dry/rough skin were the symptoms most frequently affecting subjects (Table 5). The average POEM Total Score was 12.5, which is consistent with 'moderate dermatitis'.10 Thus, disease severity was greater based on parents'/guardians' POEM ratings of their child's disease status than on clinical assessment. In terms of effect on family, time spent looking after the child and emotional distress experienced due to their atopic disease were the attributes that most affected parents'/caregivers' quality of life (Table 6). However, overall, the FDQLI responses were relatively low, with only the mean for time spent caring for the child exceeding 1.0, i.e. this attribute was rated as having

'a little' impact on the caregivers' quality of life. The relatively low baseline scores generated in the FDLQI might reflect the disease severity or the young age of the enrolled subjects, or the special bond between child and parent/guardian.

Over the last week, on how many days/nights...	**Baseline** mean (SD)	**Week 4** mean (SD)	**P-value[a]**
has your child's skin been itchy because of their dermatitis?	3.5 (1.32)	2.2 (1.76)	0.016
has your child's sleep been disturbed because of their dermatitis?	1.5 (1.67)	0.7 (1.13)	0.023
has your child's skin been bleeding because of their dermatitis?	0.6 (0.94)	0.4 (0.99)	0.406
has your child's skin been weeping or oozing clear fluid because of their dermatitis?	0.4 (0.81)	0.2 (0.49)	0.500
has your child's skin been cracked because of their dermatitis?	1.9 (1.66)	1.2 (1.51)	0.078
has your child's skin been flaking off because of their dermatitis?	2.0 (1.49)	1.0 (1.59)	0.011
has your child's skin felt dry or rough because of their dermatitis?	3.6 (0.82)	2.5 (1.64)	0.008
POEM Total Score	12.5 (6.19)	8.1 (7.08)	0.003
[a]Wilcoxon signed rank test. Key: SD = standard deviation.			

Table 5: Average parent/guardian responses to the Patient Oriented Dermatitis Measure questionnaire.

Over the last month how much...	**Baseline** mean (SD)	**Week 4** mean (SD)	**P-value[a]**
emotional distress have you experienced due to your relative/partner's skin disease (e.g. worry, depression, embarrassment, frustration)?	0.9 (0.67)	0.4 (0.49)	0.027
has your relative/partner's skin disease affected your physical well-being (e.g. tiredness, exhaustion, contribution to poor health, sleep/rest disturbance)?	0.6 (0.75)	0.2 (0.37)	0.016
has your relative/partner's skin disease affected your personal relationships with him/her or with other people?	0.2 (0.41)	0.1 (0.22)	0.375
have you been having problems with other peoples' reactions due to your relative/partner's skin disease (e.g. bullying, staring, need to explain to others about his/her skin problem)?	0.1 (0.31)	0.1 (0.22)	1.000
has your relative/partner's skin disease affected your social life (e.g. going out, visiting or inviting people, attending social gatherings)?	0.1 (0.22)	0.1 (0.31)	1.000
has your relative/partner's skin disease affected your recreation/leisure activities (e.g. holidays, personal hobbies, gym, sports, swimming, watching TV)?	0.2 (0.52)	0.2 (0.37)	1.000
time have you spent on looking after your relative/partner (e.g. putting on creams, giving medicines or looking after their skin)?	1.3 (0.98)	1.2 (0.93)	0.753
extra housework have you had to do because of your relative/partner's skin disease (e.g. cleaning, vacuuming, washing, cooking)?	0.5 (0.95)	0.2 (0.41)	0.250
has your relative/partner's skin disease affected your job/study (e.g. need to take time off, not able to work, decrease in the number of hours worked, having problems with people at work)?	0.2 (0.41)	0.1 (0.22)	0.375
has your relative/partner's skin disease increased your routine household expenditure (e.g. travel costs, buying special products, creams, cosmetics)?	0.6 (0.75)	0.2 (0.52)	0.031
FDQLI Total Score	4.6 (3.56)	2.5 (1.54)	0.035
[a]Wilcoxon signed rank test. Key: SD = standard deviation.			

Table 6: Average parent/guardian responses to the Family Dermatology Quality of Life Indexquestionnaire.

Consistent with the clinically observed improvement in subjects' atopic disease, the caregiver-assessed change in subjects' skin condition shown by the POEM also improved. Ratings for all seven questions improved from baseline and significant changes were observed for several symptoms that received high frequency ratings at baseline, i.e. the frequencies of itching, sleep disturbances, and flaking and dry/rough skin were significantly reduced. The change in frequency rating for cracked skin was nearly significant (P = 0.078). The POEM Total Score decreased significantly from 12.5 to 8.1, although this score remained in the 'moderate dermatitis' range.10 The improvement in subjects' atopic disease also lessened the burden on their caregivers, as reflected in the FDQLI. Of the ten parameters probed by this instrument, three remained the same and seven improved at study end. Respondents' emotional distress, physical well-being, and household expenditure responses were significantly improved, as was the average FLQLI Total Score, which decreased from 4.6 to 2.5.

Conclusion

A four-week clinical in-use study was conducted among children with atopic dermatitis using a regimen comprising liquid shampoo/wash and lotion products that are based on natural ingredients. Treatment effects were judged using a 3-pronged approach that included clinical grading, bioengineering measurements, and validated life-quality questionnaires. These measures consistently showed that the regimen was well-tolerated and improved subjects' skin condition and quality of life, as well as the quality of life of their caregivers. Taken together, these results show that the tested shampoo/wash and lotion products are appropriate for use as part of daily skin care in the management of atopic dermatitis.

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Disclosures

Hemali B. Gunt is an employee of Burt's Bees, Inc (Durham, NC, USA). Jeanette Jakus is a consultant to Burt's Bees, Inc.

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