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Impact of an Emollient Containing Nicotinamide on Moderate Atopic Eczema and Quality of Life in Paediatric Patients

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Introduction

Moderate atopic eczema is characterised by recurrent inflammation and itching, affecting the patient's quality of life. It often requires repeated courses of topical steroids to control. This study examines the efficacy of Adex® Gel (DENI), an emollient with an ancillary anti-inflammatory substance nicotinamide, in improving eczema symptoms and associated quality of life, using SCORAD* and CDLQI** as key measures.

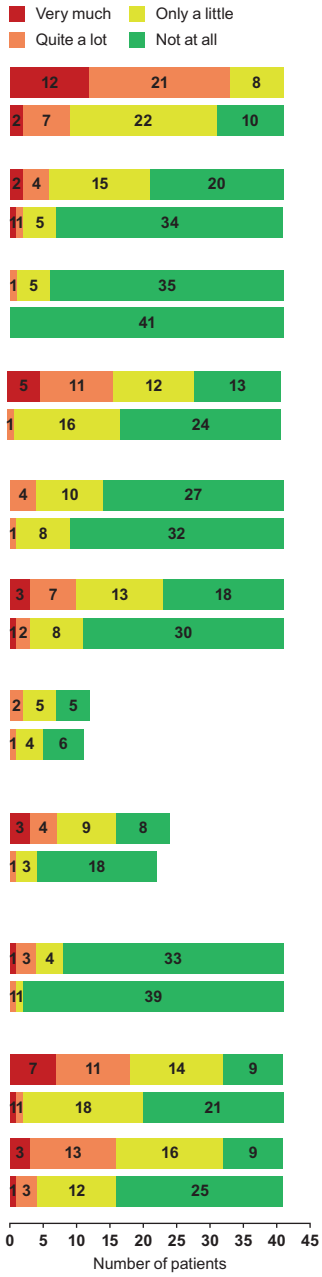
Methodology

This was a prospective, open-label study conducted in 11 GP centres across the UK, involving 60 screened children (aged 1 year to 15 years) with moderate atopic eczema. DENI was used three times daily for 4 weeks instead of their usual emollient or as the first-line treatment for moderate atopic eczema, in both scenarios, without supplementary use of any topical (or oral) corticosteroids or immunomodulators (topical calcineurin inhibitors). The clinical endpoints were the change from baseline in SCORing Atopic Dermatitis (SCORAD)* measurements after 2 and 4 weeks of treatment and the change from baseline in Children's Dermatology Life Quality Index (CDLQI) questionnaire after 4 weeks of treatment.

Results

The mean disease severity score (SCORAD – scored by the investigator) improved significantly from 37.14 (moderate atopic eczema) at baseline, to 22.56 (mild atopic eczema) after 2 weeks and to 18.48 (mild atopic eczema) after 4 weeks, in the per protocol (PP) analysis of 41 children. The improvements were statistically significant at both week 2 and week 4 (p<0.0001, n=41). The total CDLQI score (as scored by patients) improved from 9.3 (moderate effect on child) at baseline to 3.7 (small effect on child) at week 4 showing a statistically significant improvement of 5.6 (p<0.0001). Related adverse events were reported, with stinging, itching, redness and worsening of the eczema symptoms being the most common, but these are expected adverse events when using emollients in children with moderate eczema.

Question	Time point	Very much	Quite a lot	Only a little	Not at all
1. Over the last week, how itchy, "scratchy", sore or painful has your skin been?	Baseline	12	21		8
	Week 4	2	7	22	10
2. Over the last week, how embarrassed or self conscious, upset or sad have you been because of your skin?	Baseline	2	4	15	20
	Week 4	1	1	5	34
3. Over the last week, how much has your skin affected your friendships?	Baseline	1		5	35
	Week 4				41
4. Over the last week, how much have you changed or worn different or special clothes/shoes because of your skin?	Baseline	5	11	12	13
	Week 4	1		16	24
5. Over the last week, how much has your skin trouble affected going out, playing, or doing hobbies?	Baseline		4	10	27
	Week 4		1	8	32
6. Over the last week, how much have you avoided swimming or other sports because of your skin trouble?	Baseline	3	7	13	18
	Week 4	1	2	8	30
7a. If school time: Over the last week, how much did your skin problem affect your school work? *where applicable	Baseline		2	5	5
	Week 4		1	4	6
7b. If holiday time: How much over the last week, has your skin problem interfered with your enjoyment of the holiday? *where applicable	Baseline		3	4	9
	Week 4		1	3	18
8. Over the last week, how much trouble have you had because of your skin with other people calling you names, teasing, bullying, asking questions or avoiding you?	Baseline	1	3	4	33
	Week 4	1	1		39
9. Over the last week, how much has your sleep been affected by your skin problem?	Baseline	7	11	14	9
	Week 4	1	1	18	21
10. Over the last week, how much of a problem has the treatment for your skin been?	Baseline	3	13	16	9
	Week 4	1	3	12	25



Conclusion

DENI gel, an emollient with an ancillary anti-inflammatory substance nicotinamide, significantly reduced eczema severity and improved quality of life in paediatric patients over 4 weeks. These results highlight its potential as an effective treatment option for moderate atopic eczema, improving both clinical symptoms and quality of life outcomes in NHS GP settings.

*SCORAD is a tool used in clinical trials to assess atopic dermatitis severity based on disease area, intensity and subjective symptoms (itch and sleeplessness). SCORAD-Index = Mild 0-24; Moderate 25-50; Severe 51-100 (Willemsen, M.G., *et al.*, Determining the severity of atopic dermatitis in children presenting in general practice: an easy and fast method. *Dermatol Res Pract,* ***2009:*** *357046*).

**CDLQI is designed to measure the impact of any skin disease on the lives of children. For the CDLQI the within-patient change of 6 is considered the Minimal Clinically Important Difference (MCID).

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