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Quality of Life of Parents Living with a Child Suffering from Atopic Dermatitis Before and After a 3-Month Treatment with an Emollient

Carlo Gelmetti, M.D., Ph.D.,* Franck Boralevi, M.D.,† Sophie Seité, Ph.D.,‡ Ramon Grimalt, M.D.,§ Philippe Humbert, M.D., Ph.D.,¶ Thomas Luger, M.D., Ph.D., Jean-Francois Stalder, M.D., Ph.D.,†† Alain Taïeb, M.D., Ph.D.,† Dominique Tennstedt, M.D., Ph.D.,‡‡ Rita Garcia Diaz, M.D.,§§ and André Rougier, Ph.D.‡**

**Scienze Dermatologiche, Università degli Studi di Milano, Fondazione IRCSS Ospedale Maggiore Policlinico, Milan, Italy, †Hôpital Pellegrin Enfants, Bordeaux, France, ‡La Roche-Posay Pharmaceutical Laboratories, Asnières, France, §University of Barcelona, Barcelona, Spain, ¶Department of Dermatology, Franche-Comté University, Besançon, France, **Department of Dermatology, University of Münster, Münster, Germany, ††Service de Dermatologie, Hôtel-Dieu, Nantes, France, ‡‡Department of Dermatology, University Hospital Saint-Luc, Brussels, Belgium, §§Hospital P. Garrahan, Buenos Aires, Argentina*

Abstract: Atopic dermatitis (AD) can be extremely disabling and may cause psychological problems for affected children and their families. Moisturizers and emollients are important in the baseline daily skin care of patients with AD. To assess the effect of a 3-month, twice-daily treatment with an emollient on the quality of life (QoL) of parents with a child with mild to moderate AD (SCORing Atopic Dermatitis [SCORAD] ≤30, a multicenter open trial was performed by eight dermatologists on 191 volunteers. Evaluation by the dermatologist of the child's clinical condition (SCORAD) and of the efficacy and overall safety of the treatment was associated with a QoL questionnaire completed by one parent of the atopic child. A self-assessment of the global QoL and of the efficacy and overall safety was also performed. During the study, mean SCORAD dropped from 28 to 12 ($p < 0.001$), with good improvement in skin dryness and pruritus criteria. At the same time, the self-assessment of the global parent QoL scores dropped from 4.4 to 2.1 ($p < 0.001$) with 60%, 48% and 79% favorable parent opinions regarding wellbeing or improvement of the health condition, quality of sleep, and efficacy of the emollient, respectively. This trial revealed the efficacy of the product in improving parent QoL (85% of parents noted improvement in QoL), and its global safety was considered to be very good or good, with 80% favorable opinions in parents' declarative judgements and dermatologists' assessments. The emollient evaluated improves the course of AD and can improve the QoL of patients and their families.

Address correspondence to Professor C. Gelmetti, M.D., Clinica Dermatologica, Via Pace 9, 20122 Milan, Italy, or e-mail: carlo.gelmetti@unimi.it.

S. Seité and A. Rougier have been working exclusively for La Roche-Posay for longer than 5 years.

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Atopic dermatitis (AD) is a common, chronic inflammatory skin disease characterized by dry skin, impaired integrity of the skin barrier, and disturbing pruritus. Proper emollient usage is an important part of AD management, and patients are encouraged to use emollients generously (1). Patient education has been shown to be important. A study demonstrated that repeated education and demonstration of appropriate use of topical therapies by specialized dermatology nurses reduced the severity of AD by 89%. During this study, an 800% increase in the use of emollients and no overall increase in the use of topical steroids was noted. This type of study reinforces the idea that the most important interventions in the management of AD include explaining the causes of AD, demonstrating how to apply topical therapies in proper quantities, and listening to patient and family concerns (2).

AD is often described as a skin disease, but it can be extremely disabling and may cause psychological problems for affected children and their families. Quality of life (QoL) assessment in patients with AD has demonstrated that this disease can be rated among the worst. Moreover, patients with severe AD in childhood showed significantly delayed social development over the course of their life (3).

AD is a chronic disease that may span from infancy to adulthood. Educational programs focusing on the parents of young children with the disease can improve their QoL (4,5). No data exist regarding the effect of the regular use of emollients on the QoL of parents of patients. Improvement in the condition of the children's skin with daily use of an emollient improves the children's QoL, and can also enhance that of their parents.

Shea butter (also known as Karite Butter) is a yellow–white to ivory-colored substance with a high content of nonsaponifiable fatty acids. It is absorbed rapidly into the skin without leaving a greasy feeling (6). Clinical observations suggest that Shea butter may have some antiinflammatory properties (7,8), and is an excellent vehicle for dermatologic preparations (6).

Considering the global virtues of this natural lipid, our aim was to assess the effect of a 3-month treatment regimen with an emollient rich in Shea butter. The emollient was administered in two daily doses, and the change in the QoL of parents with children with mild to moderate AD (SCORing Atopic Dermatitis [SCORAD] ≤30) was evaluated.

METHODS

This was an open-label, multicenter, noncomparative study with a direct, individual benefit (6). It was conducted with 191 parents of children with mild to moderate AD (SCORAD ≤30) and involved two visits to the investigating centers: one for the inclusion of volunteers and a second after the onset of treatment with the emollient. The emollient evaluated in this study contains La Roche-Posay spa water, Shea butter or Karite butter, glycerin, and rapeseed oil (Lipikar Baume La Roche-Posay Pharmaceutical Laboratories, Asniéres, France). Parents applied the product in the morning and evening to the entire body of the child. The study also checked the following preset concepts: efficacy of the product in the treatment of moderate AD and good product safety.

A class IV dermocorticoid (weak) could be used if < 5% of the body surface area was affected. The prescription of a more-active dermocorticoid automatically induced the subject's withdrawal from the study. If patients were prescribed a dermocortocoid, they were asked to report the name of the drug and the number of applications in a diary.

The children's clinical condition (SCORAD) was determined at baseline and at the end of the study, and the same parent completed the QoL questionnaire at the two visits and self-assessed his or her global QoL. The questionnaire was derived from the validated Dermatitis Family Impact scale (9) and included 10 questions regarding the emotional, psychological, and social effect of the child's disease on the parent's QoL and that of the entire family (five-point scale: enormous, considerable, moderately, minor, no effect, and no opinion-0–4). A self-assessment of global QoL of the last 2 weeks was measured on a visual analog scale from 0 (good) to 10 (very bad). After the 3-month treatment, the dermatologist and the parent gave their overall efficacy assessments, and the parent also evaluated improvement in health-enhancing and quality of sleep of his or her child (five-point scale from 0 [no improvement] to 4 [greater improvement]) and an overall safety assessment (five-point scale from 0 (no tolerance or bad tolerance) to 4 (excellent tolerance)) of the investigational product (10).

The data were expressed as means with standard errors of the mean and percentages. Analysis of scores was performed using the Wilcoxon test. Differences were considered to be statistically discernible with an alpha risk value of 5% for efficacy and 1% for distances from normality. Statistics were determined using SPSS 15 (SPSS, Inc., Chicago, IL, USA).

RESULTS

One hundred ninety-one cases were eligible for analysis (Table 1), and 180 completed the study. Seven dropped out because of adverse events (eczema flare-up needing the use of a more-potent corticosteroid) and four were

TABLE 1. *Characteristics of the Population*

	Parents*	Children
Female, *n* (%)	156 (82)	96 (50)
Male, *n* (%)	34 (18)	95 (50)
Age, years, mean ± SEM (range)	37 ± 0.5	4.8 ± 0.3 (1–12)
Duration of the disease, years, mean ± SEM		3.3 ± 0.2

*1 sex undocumented.
SEM, standard error of the mean.

lost to follow-up. Patients enrolled for the whole study tolerated the emollient well. Global safety was considered to be very good or good in 80% of parents' declarative judgements and dermatologists' assessments.

At baseline, the patients were slightly affected by their AD, with an average SCORAD of 28 ± 0.9 (≤30). The QoL of the parents was also slightly altered (mean self-assessment of global QoL 4.4 ± 0.1, range 0–10). After the 3-month treatment, mean SCORAD dropped from 28 to 12 (Table 2, $p < 0.001$), with the greatest improvement noticed for skin dryness and pruritus criteria, with 83% of patients improved. Seventy-nine percent of parents and 69% of dermatologists judged the emollient overall to be very efficient or efficient.

The improvement in the QoL of the patients' parents from baseline to 3 months is detailed in Table 3. The emollient showed very good and statistically significant efficacy with regard to QoL; from baseline to 3 months, the self-assessment of the global scores dropped from 4.4 to 2.1, and 85% of parents noted an improvement of their QoL. We found 60% and 48% favorable parent opinions (very strong or strong improvement) regarding enhancement of health and child's quality of sleep, respectively.

CONCLUSION

The course of AD is chronic and it can last many years. AD, even in its mildest form, is not trivial; the frequent and disturbing pruritus and the loss of sleep can make AD extremely disabling, causing psychological problems for children and their families (11).

Recent figures indicate a doubling or tripling in AD over the past 30 years (12), resulting in more children with this debilitating and underestimated skin condition. Children and parents find managing eczema on a daily basis to be challenging.

Educational programs devoted to the parents of young children with the disease have been developed (13). This type of program may help to improve the QoL of families with children with AD, but requires a high degree of integration between doctors and careful and expensive organizational work. Programs with the explanation and demonstration of topical therapies by a specialized dermatology nurse are much cheaper but can offer valuable results (2). Large differences exist between emollients. Similar to other products, the efficacy is likely to depend on the quality, dosage, and adherence; a strong odor from ingredients and greasiness can be disagreeable to patients. Recent findings indicate that active substances or active ingredients and excipients may have more-pronounced effects on the skin than previously considered and may reduce the likelihood of further

TABLE 2. *Scores of Clinical Signs and Symptoms at Baseline and After 3 Months Treatment*

Dermatologic examination score (scale 0–4)	Baseline (*n* = 191) Mean ± SEM	Month 3 (*n* = 180)	Children showing improvement, %
Area involved (A)	12.17 ± 0.7	5.25 ± 0.5*	81
Intensity of symptoms (composite score B)†	5.63 ± 0.2	2.32 ± 0.2*	87
Erythema/darkening (0–3)	1.27 ± 0.1	0.69 ± 0.1*	53
Edema/papulation (0–3)	0.49 ± 0.1	0.20 ± 0.04*	28
Oozing/crust (0–3)	0.43 ± 0.1	0.21 ± 0.04*	25
Excoriations (0–3)	0.77 ± 0.1	0.27 ± 0.04*	47
Lichenification/prurigo (0–3)	0.71 ± 0.1	0.24 ± 0.04*	40
Dryness (0–3)	2.02 ± 0.1	0.71 ± 0.1*	83
Intensity of subjective symptoms (score C, 0–20)‡	6.18 ± 0.2	2.82 ± 0.2*	83
Pruritus (0–10)	4.30 ± 0.1	2.07 ± 0.2*	83
Sleep loss (0–10)	1.97 ± 0.1	0.75 ± 0.1*	60
SCORAD (A/5 + 7B/2 + C)	28.2 ± 0.9	12.0 ± 0.8*	89

Comparison of mean scores obtained at baseline and 3 months.
*$p < 0.001$.
†Composite score B includes each criterion (erythema, edema, oozing, excoriation, lichenification, dryness) scored between 0 (absence) to 3 (severe).
‡Composite score C includes subjective symptoms (pruritus and sleep loss).

TABLE 3. *Scores of Quality of Life Items at Baseline and After 3 Months of Treatment*

Questionnaire items (scale 0–4)	Baseline (N = 191) Mean ± SEM	Month 3 (N = 180)	Children showing improvement, %
During the last 2 weeks, did the atopic dermatitis of your child:			
1 Have consequences on your emotional state (is it source of depression, of a feeling of impotence, of fault, of frustration…)?	1.56 ± 0.07	0.76 ± 0.06*	64
2 Have consequences on your physical state (is it source of fatigue, exhaustion, change of the quality and the duration of your sleep…)?	1.35 ± 0.07	0.60 ± 0.06*	62
3 Have consequences on your relations with your child, your spouse or partner or with the other members of the family?	1.25 ± 0.07	0.55 ± 0.05*	60
4 Engendered relational problems towards persons outside your family (is it source of gene or shyness of your part, of need to explain the state of your child, of particular glances or questions on behalf of the others…)?	1.19 ± 0.08	0.50 ± 0.06*	53
5 Have consequences on your social life (does it affect the number of your outings, of your visits at the other persons, of your invitations of the other persons…)?	1.00 ± 0.07	0.38 ± 0.05*	53
6 Have consequences on your leisure activities and those of all the family (does it affect the choice of the place and the duration of your holidays, your personal entertainments, the sports practiced by your family, the choice and the number of entertainments and outings….)?	1.48 ± 0.08	0.73 ± 0.06*	62
7 Have consequences on the time you spend to take care of your child (taking charge of his skin, treating him, applying cream to him….)?	1.99 ± 0.07	1.20 ± 0.07*	67
8 Have consequences on the time you spend to make domestic tasks (housework), washing, and preparation of meals….)?	1.17 ± 0.08	0.55 ± 0.06*	53
9 Have consequences on your professional life (does it affect the number of your demands of leaves, the number of your days or of hours worked your relations with your working colleagues….)?	0.73 ± 0.07	0.38 ± 0.06*	37
10 Have consequences on the family spending (expenditure connected to the treatment of your child, to the purchase of particular hygiene products and care, particular clothes, particular food, works in the house...)?	2.14 ± 0.07	0.93 ± 0.08*	71
Self-assessment of global quality of life (0–10)	4.4 ± 0.1	2.1 ± 0.1*	85

Comparison of mean scores between baseline and 3 months.
*$p < 0.001$.

aggravation of the disease. The emollient used in this study has previously been shown to be effective in treating xerosis and the major symptoms of atopic eczema in children.

The clinical assessment of the efficacy and safety qualities of the emollient administered in this study, after 3 months of use and two successive examinations, demonstrated its remarkable effect on the skin of children with mild to moderate AD. We found 92%, 87%, and 93% favorable parent opinions regarding enhancement of health, quality of sleep, and global efficacy, respectively. In addition, this clinical trial revealed the great efficacy of the product in improving parent QoL. Furthermore, 85% of volunteers were favorable responders in a self-assessment of global QoL. Finally, global safety was considered to be excellent (with minor to unexpected adverse effects attributable to the test product), with 91% favorable opinions of parents' declarative judgements and dermatologists' assessments. Nevertheless, this study was not a comparative study; perhaps similar improvement could be obtained with another emollient, and the improvement noticed may be partly due to changes in the usual hygienic or body care practice (twice daily treatment with an emollient) during the study or to parents' perceptions of their child' disease.

In summary, a 3-month treatment with an emollient rich in Shea butter decreased the severity and improved the course of AD and the QoL of patients and their parents.

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