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ORIGINAL ARTICLE SKIN AND EYE DISEASES

Patient-Oriented SCORAD (PO-SCORAD): a new self-assessment scale in atopic dermatitis validated in Europe

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Abstract

Background: Patient-oriented medicine is an emerging concept, encouraged by the World Health Organization, to greater involvement of the patient in the management of chronic diseases. The Patient-Oriented SCORing Atopic Dermatitis (PO-SCORAD) index is a self-assessment score allowing the patient to comprehensively evaluate the actual course of atopic dermatitis (AD), using subjective and objective criteria derived mainly from the SCORAD, a validated AD severity clinical assessment tool.

Objectives: To validate the PO-SCORAD index in a large European population of patients exhibiting all forms of AD severity by assessing its correlation with the SCORAD index.

Patients/methods: Four hundred and seventy-one patients (185 adults, 286 children) consulting for AD in hospitals from 9 European countries were recruited. The investigators and the patients used the SCORAD and PO-SCORAD scales, respectively, to assess AD severity at inclusion (D0) and 28 ± 7 days later (D28).

Results: Patient-Oriented SCORing Atopic Dermatitis and SCORAD scores were significantly correlated at D0 [$r = 0.67$ (95% CI: 0.62; 0.72), $P < 0.0001$]. Consistency was confirmed at D28, with a stronger linear correlation between both scales [$r = 0.79$ (95% CI: 0.75; 0.83), $P < 0.0001$]. Absolute changes from baseline in SCORAD and PO-SCORAD scores were also significantly correlated [$r = 0.71$ (95% CI: 0.64; 0.76), $P < 0.0001$]. Although no specific intervention was investigated, AD improved over the study, with a decrease of PO-SCORAD and SCORAD scores from D0 to D28 by −19.19% and −24.39%, respectively. The consistency of the correlations was similar in the adult and children groups.

Conclusions: This study validated the use of PO-SCORAD to self-assess AD severity and demonstrated its good correlation with SCORAD.

Atopic dermatitis (AD) is a chronic/relapsing pruritic inflammatory skin disease generally associated with dry skin. This common condition (1–4) affects 10–20% of all children and 1–3% of adults in industrialised countries (2–4). It has a significant impact on the quality of life of patients (5) and on public health costs (6).

To assess the severity of this disease and to provide better management of patients, in 1992, the European Task Force on Atopic Dermatitis (ETFAD) developed the SCORing Atopic Dermatitis (SCORAD) index, which has been validated in many studies in AD clinical research (7–9). This method is useful to assess the efficacy of a treatment at a given time point. However, a characteristic of AD is its uneven course with flares and remissions inducing clinical variations between two consultations. Consequently, the periodical assessment by a doctor is insufficient to evaluate comprehensively the course of the disease or the efficacy of the treatment.

Self-assessment, if reliable, could allow a better monitoring of disease status. Moreover, self-assessment scores (SAS) can be an effective tool for communication between patients and physicians regarding daily life issues in disease management and could be a valuable adjunct to a therapeutic education programme. Self-assessment scores require greater patient's involvement in the treatment process, which is highly recommended by health authorities (10–13). Few self-assessment tools for AD have been proposed; they include the Self-Administered Eczema Area and Severity Index (SA-EASI) rating scale (14), the Skin Detective scale (15), the Atopic Dermatitis Quickscore (ADQ) (16) and the Patient-Oriented Eczema Measure (POEM) scale (17). According to Schmitt et al. (18), POEM is the only adequately validated scale, but it does not allow comparisons between patient's and doctor's evaluations.

A self-assessment scale for atopic patients has been developed by the ETFAD to meet the demand for a tool integrating objective and subjective symptoms evaluation. The patient-oriented SCORAD (PO-SCORAD) uses basically the same criteria as SCORAD featured in an illustrated document adapted for patients (19). In a pilot study, the PO-SCORAD has been shown to be simple to understand, and quick and easy to use by the patients and their family (20).

The aim of this study was to validate this scale in a large European population of adults and children exhibiting the whole range of AD severity [mild to severe, according to the criteria of the United Kingdom Working Party (21)]. Therefore, study objectives were to assess the consistency between SCORAD measured by physicians and PO-SCORAD measured by patients and to confirm that PO-SCORAD is quick and easy to use by patients in different countries and languages.

Patients and methods

This prospective, observational study was conducted from February 2009 to January 2010 in hospital departments of nine European countries: Belgium, Denmark, Finland, France, Germany, Italy, the Netherlands, Sweden and Switzerland. It was carried out in accordance with applicable regulatory requirements of each country involved in the study. The protocol was validated by an independent scientific committee including members of the ETFAD. Informed consent was obtained from the patients, or the child's parents, prior to study inclusion.

Patients and study procedures

Investigators included all adults (≥18 years old) and children (< 18 years old) consulting at the hospital for AD and being able to understand and complete the PO-SCORAD questionnaire. Each patient was managed without specific study requirements by the same investigator, as during a normal visit and a 4-week follow-up. Disease severity was assessed at inclusion (D0) and at follow-up visit (D28) 28 ± 7 days later, by both the investigators and the patients, using the SCORAD and the PO-SCORAD scales, respectively. The investigators of the study were all previously trained to use the SCORAD index routinely, whereas the patients assessed the PO-SCORAD index after reading of an illustrated guidance booklet. The SCORAD (8) and PO-SCORAD (20) scales have previously been described. In both scales, the evaluation of AD severity is based on the same items and comprises objective and subjective symptoms: surface area of skin affected by eczema in the last 3 days, dryness of the skin without eczema, evaluation of the severity of the eczema over the last 3 days (redness of skin affected by eczema, swelling, oozing/crust, scratching and thickening), pruritus and sleep loss. The PO-SCORAD questionnaire was completed by the patients or by the parents on behalf of children < 8 years old or unable to complete the form themselves. According to our pilot study (20), time for filing out the form was less than 5 min for 96% of patients. The PO-SCORAD and SCORAD questionnaires were previously translated in the language of the nine participating countries, and the translation was validated by AD expert dermatologists.

Evaluation criteria and plan of analysis

The consistency between the two rating scales was determined using the correlation between PO-SCORAD and SCORAD indexes at D0 for the overall population as the main criterion. This criterion was analysed in the subjects having a paired measure of their SCORAD and PO-SCORAD at D0 (time period between the evaluations of SCORAD and PO-SCORAD ≤3 days). To conclude on consistency between both scales, the coefficient of correlation had to be ≥0.7 with a lower limit of the 95% confidence interval (CI) ≥0.65.

The consistency between the two scales was also evaluated according to the following secondary criteria:

- Correlation between PO-SCORAD and SCORAD indexes at D28 for the overall population. The analysis was performed in the population of patients assessable having a paired measure of their SCORAD and PO-SCORAD at D28 and a time period between the D0 and D28 visits ≥21 days and ≤35 days
- Correlation between absolute changes in SCORAD and PO-SCORAD scores from D0 to D28, which was analysed

in the population having a paired measure of their SCORAD and PO-SCORAD at D0 and D28 and a time period between the D0 and D28 visits ≥21 days and ≤35 days.
- The same correlations were also determined for adult and children subgroups.

Statistical analysis

Statistical analysis was performed using SAS® software (9.13 version, pack 4, SAS Institute Inc., Cary, NC, USA). Quantitative data were described using the number of patients, missing data, mean and standard deviation, minimum and maximum. Between-group comparisons were made using Student's *t*-test or the Wilcoxon rank sum test for nonparametric data. Qualitative data were described as available data, missing data, total numbers and percentage by category. Comparisons between adults and children were performed using a chi square test or an exact Fisher test when the assumptions of the chi square test were not met. Correlations between the PO-SCORAD and SCORAD scores at D0 and D28 were analysed using the Bravais–Pearson correlation coefficient (r), and confidence was computed using the Fisher transform. All tests were two-sided, and the alpha risk was set at 5% for the whole study.

Results

The distribution of the study subjects is summarised in Fig. 1. Of the 486 subjects included, 471 were eligible and analysed. A total of 438 subjects were assessable at D0 for the main criterion, 289 were assessable for the correlation between both scales at D28 and 271 for the correlation between absolute changes from D0 to D28 in SCORAD and PO-SCORAD scores.

The patients' sociodemographic and clinical characteristics at inclusion are presented in Table 1. The population was well balanced in terms of gender, with a similar proportion of male and female subjects (48.62% and 51.38%, respectively). The mean age of subjects suffering from severe AD was significantly higher than that of subjects suffering from mild to moderate AD (20.87 ± 17.15 years *vs* 15.82 ± 16.61 years, $P = 0.0024$). Severe AD was significantly more frequent in adults than in children ($P = 0.005$) (Table 1), and among the children group, it was also more prevalent in children above the age of 2 than in infants (18.75% *vs* 13.63%), indicating that the prevalence of severe AD increases with age. Likewise, a treatment of AD was more commonly prescribed in adults than in children, whether it was before or at inclusion (Table 1). By contrast, topical treatment, which is the main AD treatment in all age groups, was significantly more frequently prescribed to children at inclusion than to adults (91.83% *vs* 65.54%, $P < 0.0001$).

Analysis of the correlation between SCORAD and PO-SCORAD scores at D0

SCORing Atopic Dermatitis and PO-SCORAD scores in the population assessable at D0 and by age class are presented in Table 2. The mean SCORAD score at D0 was significantly higher in adults than in children (40.49 ± 16.84 *vs* 35.78 ± 13.72, $P = 0.01$), whereas the mean PO-SCORAD scores in the respective subgroups were similar (39.32 ± 18.07 and 37.73 ± 15.82, $P = 0.69$). Pearson's correlation coefficient between SCORAD and PO-SCORAD scores at D0 was 0.67 (95% CI: 0.62; 0.72), with a highly significant consistency ($P < 0.0001$). The linear relationship between both scales was confirmed in the scatter plot of SCORAD and PO-SCORAD measures at D0 (Fig. 2). The same consistency was observed in adult and children subgroups with similar correlation coefficients in both groups (Table 2).

Analysis of the correlation between SCORAD and PO-SCORAD scores at D28

As it was the case at D0, the mean SCORAD at D28 was significantly higher in adults than in children (32.42 ± 19.20 *vs* 26.28 ± 13.61, $P = 0.03$) and the mean PO-SCORAD scores at D28 in both groups were not statistically different ($P = 0.865$) (Table 2). A highly significant correlation was observed between the two scores at D28, with a Pearson's correlation coefficient above the threshold of 0.70 assumed in the protocol to conclude on consistency between both scales [$r = 0.79$ (95% CI: 0.75; 0.83), $P < 0.0001$]. The linear relationship between SCORAD and PO-SCORAD scores at D28 is shown in Fig. 3.

Analysis of the correlation between changes from baseline in SCORAD and PO-SCORAD scores

Between D0 and D28, the mean SCORAD and PO-SCORAD scores decreased by −24.39 ± 38.35% and −19.19% ± 47.26, respectively, in the overall population with a mean absolute change from baseline of −10.61 ± 13.51 and −9.12 ± 15.70, respectively, indicating an improvement of AD. This decrease was similar in adult and children groups (Table 2). As for SCORAD and PO-SCORAD scores at D0 and D28, absolute changes from baseline in SCORAD and PO-SCORAD scores were significantly correlated [$r = 0.71$ (95% CI: 0.64; 0.76), $P < 0.0001$].

Discussion

In this prospective observational study, we validated the ability of PO-SCORAD to self-assess AD severity and confirmed the results obtained in our previous pilot study (20) in a large population of 471 patients, representative of the range of AD severities observed in a hospital outpatient clinic (about 75% of mild to moderate AD and 25% of severe AD). PO-SCORAD and SCORAD were well correlated at the two evaluation time points and across the different age classes. A very good statistical consistency was shown in all analyses.

In the population assessable at D0, there was a good correlation between the two scales at D0, although the correlation was slightly lower than that assumed in the design of the protocol ($r = 0.67$ *vs* $r = 0.70$). Correlation coefficients were homogeneous in the 2 age groups. Furthermore, in a post hoc analysis carried out in the patients assessable at

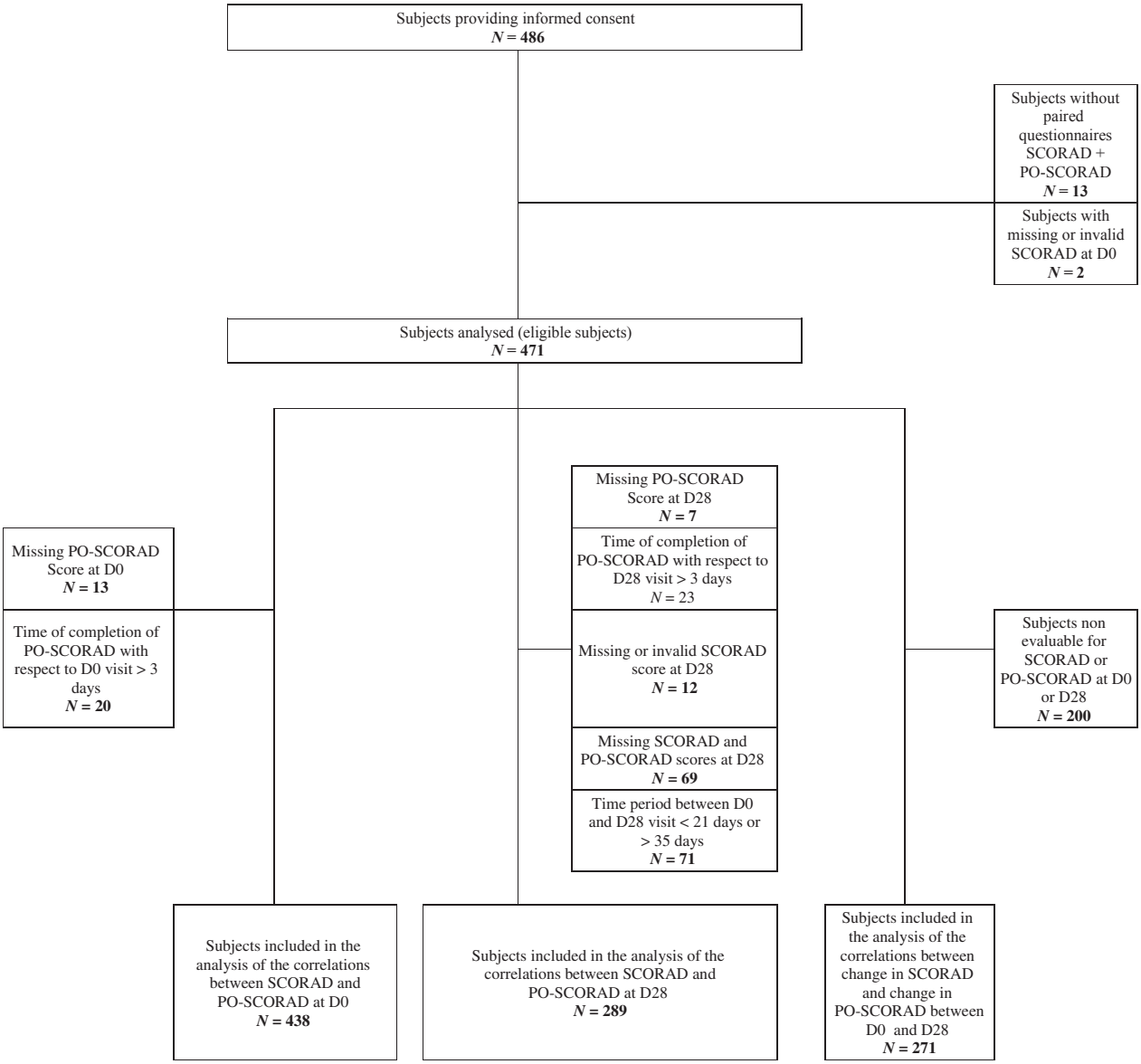

Figure 1 Flow chart of the overall study population.

both D0 and D28, the correlation between SCORAD and PO-SCORAD at D0 was even higher [$r = 0.71$ (95% CI: 0.64; 0.75), $P < 0.0001$]. This may be attributed to a higher involvement of the patients in the management of their disease. They may acquire a better knowledge of AD and thus may be more confident with the definition of their symptoms. Therefore, the patients who dropped out between D0 and D28 were probably less compliant and did not necessarily concentrate on the proper completion of the PO-SCORAD form. At the second evaluation, the correlation between both scales improved, with a coefficient of 0.79, largely exceeding the prespecified threshold of 0.70. This may reflect a learning-by-doing effect: the patients might require a short adaptation period to adjust and learn how to use the PO-SCORAD scale properly. The high correlation also obtained between absolute changes from baseline in SCORAD and PO-SCORAD confirms the ability of the PO-SCORAD to accurately assess AD severity. It represents a valuable tool for physicians as it gives them a good estimate of the evolution of AD severity between the visits.

In the present study, the correlation between both scales was much stronger and more significant than in the previous study (20). This improvement is certainly because of the fact that in this study, the patients received from the investigator an illustrated tutorial along with the PO-SCORAD questionnaire to guide them in grading AD severity, with each intensity grade for each item being illustrated by a reference image. Therefore, understanding the items and grading the severity were much easier than in the pilot study in which the patients were not provided visual explanations to help them

Table 1 Sociodemographic and clinical characteristics of patients at inclusion

		Subgroup analysis		
	Overall population	Children (<18 years old)	Adults (≥18 years old)	*P*-value
Gender, *N*	471	286	185	0.713*
Male	242 (51.38%)	145 (50.70%)	97 (52.43%)	
Female	229 (48.62%)	141 (49.30%)	88 (47.57%)	
Missing	0	0	0	
Severity of atopic dermatitis, *N*	471	286	185	0.005*
Mild to moderate (SCORAD < 50)	372 (78.98%)	238 (83.22%)	134 (72.43%)	
Severe (SCORAD ≥ 50)	99 (21.02%)	48 (16.78%)	51 (27.57%)	
Missing	0	0	0	
Duration of AD (years), *N*	463	283	180	<0.0001†
Mean ± SD	13.1 ± 14.9	4.12 ± 4.28	27.11 ± 14.85	
Range	0–75	0–16.92	0–75	
Missing	8	3	5	
Subjects already treated at D0, *N*	469	285	184	0.041*
Yes	407 (86.78%)	240 (84.21%)	167 (90.76%)	
No	62 (13.22%)	45 (15.79%)	17 (9.24%)	
Missing	2	1	1	
Prescription of a treatment at D0, *N*	465	283	182	0.013*
Yes	436 (93.76%)	259 (91.52%)	177 (97.25%)	
No	29 (6.24%)	24 (8.48%)	5 (2.75%)	
Missing	6	3	3	
Type of AD treatment prescribed at D0, *N*	434	257	177	<0.0001‡
Topical	352 (81.11%)	236 (91.83%)	116 (65.54%)	
Systemic	11 (2.53%)	1 (0.39%)	10 (5.65%)	
Topical + systemic	71 (16.36%)	20 (7.78%)	51 (28.81%)	
Missing	2	2	0	

*Chi-square test. †Wilcoxon rank sum test. ‡Fischer exact test.
AD, atopic dermatitis; SCORAD, SCORing Atopic Dermatitis.

filling out the study form. This study also confirms that PO-SCORAD is easy to understand and feasible for everybody, even for children who answered the questionnaire themselves. Indeed, no significant difference was observed in the correlations between SCORAD and PO-SCORAD according to the age classes.

Compared to other tools available for the self-assessment of AD severity, PO-SCORAD is the only one to measure the severity of AD both subjectively and objectively in a standardised way, with the help of an illustrated tutorial allowing the patient to accurately compare his/her symptoms with standardised photographs. The POEM scale is the only one that is adequately validated (17), but it does not allow comparison between patient's and physician's scores. Indeed, it is only based on subjective outcome measurements, which might introduce biases when they are used for rating quality of life impairment or the influence of comorbidity. The SA-EASI scale is fairly well correlated with the EASI scale (22), its counterpart for physicians, but it may be difficult for some patients with mild AD to distinguish between acute and chronic lesions (14). This has been confirmed in a recent study evaluating the relation of SA-EASI with the objective SCORAD in 60 children with moderate to severe eczema (23). Although the total SA-EASI and the SCORAD were

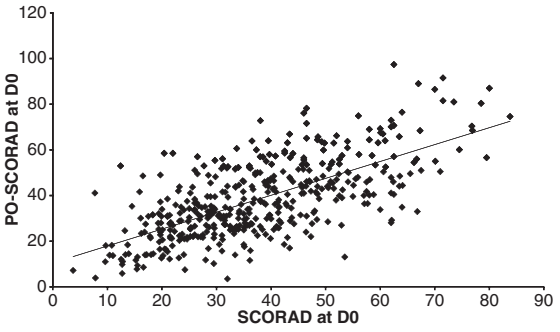

Figure 2 Scatter plot of Patient-Oriented SCORing Atopic Dermatitis (PO-SCORAD) and SCORing Atopic Dermatitis (SCORAD) scores at D0. Correlation between PO-SCORAD and SCORAD measures at D0 was good and highly significant [$r = 0.67$ (95% CI: 0.62; 0.72), $P < 0.0001$].

Table 2 Analysis of SCORAD and PO-SCORAD scores at D0 and D28 and evolution from baseline

Population		SCORAD	PO-SCORAD	Pearson's correlation coefficient (95% CI) *P*-value
Population assessable at D0				
Total (*N* = 438)	Mean ± SD	37.60 ± 15.15	38.34 ± 16.72	0.67 (0.62; 0.72)
	Median	36.00	36.00	*P* < 0.0001
	Min/max	3.70/83.80	3.50/97.40	
Adults (*N* = 169)	Mean ± SD	40.49 ± 16.84	39.32 ± 18.07	0.68 (0.59; 0.76)
	Median	38.00	35.90	*P* < 0.0001
	Min/max	11.00/83.80	3.50/97.40	
Children (*N* = 269)	Mean ± SD	35.78 ± 13.72	37.73 ± 15.82	0.66 (0.59; 0.73)
	Median	34.80	36.10	*P* < 0.0001
	Min/max	3.70/71.50	3.90/81.50	
Population assessable at D28				
Total (*N* = 289)	Mean ± SD	28.70 ± 16.30	29.98 ± 17.65	0.79 (0.75; 0.83)
	Median	25.50	25.60	*P* < 0.0001
	Min/max	3.50/84.50	0.00/80.90	
Adults (*N* = 114)	Mean ± SD	32.42 ± 19.20	31.03 ± 19.72	0.81 (0.74; 0.87)
	Median	28.35	25.75	*P* < 0.0001
	Min/max	4.54/84.50	1.20/80.90	
Children (*N* = 175)	Mean ± SD	26.28 ± 13.61	29.31 ± 16.17	0.79 (0.73; 0.84)
	Median	24.00	25.60	*P* < 0.0001
	Min/max	3.50/71.50	0.00/78.10	
Population assessable at both D0 and D28				
Total (*N* = 271)	Mean ± SD	−10.61 ± 13.51	−9.12 ± 15.70	0.71 (0.64; 0.76)
	Median	−10.30	−8.20	*P* < 0.0001
	Min/max	−53.90/28.00	−53.30/40.00	
Adults (*N* = 103)	Mean ± SD	−9.19 ± 13.22	−8.04 ± 15.65	0.69 (0.57; 0.78)
	Median	−8.40	−5.60	*P* < 0.0001
	Min/max	−53.90/28.00	−51.20/40.00	
Children (*N* = 168)	Mean ± SD	−11.48 ± 13.65	−9.79 ± 15.75	0.72 (0.64; 0.78)
	Median	−11.15	−9.20	*P* < 0.0001
	Min/max	−49.90/25.00	−53.30/35.30	

SCORAD, SCORing Atopic Dermatitis; PO-SCORAD, Patient-Oriented SCORing Atopic Dermatitis.

well correlated ($r = 0.61$, $P < 0.001$), only a moderate correlation was found between the severity scores of SA-EASI and SCORAD scales ($r = 0.37$, $P = 0.003$), indicating that with the SA-EASI, the parents have difficulty in assessing the severity of their child's AD. Like in our study, the authors highlight the value of AD grade illustrations and educative leaflets for training parents in grading AD severity and thus enhancing the correlation between the self-assessment score and the physician score. By contrast, a study evaluating the ADQ (16), another parent-administered scoring tool, showed a marked decrease in the correlation between ADQ and SCORAD after one week of an interventional programme (including therapeutic treatment and education) compared to inclusion ($r = 0.39$ *vs* $r = 0.64$), suggesting that ADQ is a poor assessment tool responding in a different manner to changes in skin condition with time.

The Skin Detective scale, which includes items matching SCORAD, was designed, like PO-SCORAD, to allow a correlation between the perception of skin condition by the patient and the physician, respectively (15). However, the scale was difficult to understand by children under the age of 10, in particular for recording the extent of the disease on their body.

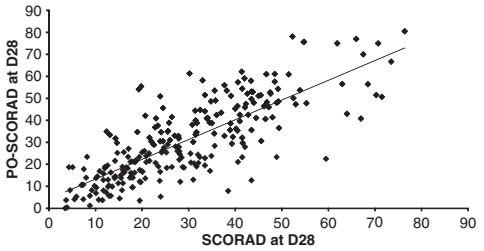

Figure 3 Scatter plot of Patient-Oriented SCORing Atopic Dermatitis (PO-SCORAD) and SCORing Atopic Dermatitis (SCORAD) scores at D28. Correlation between PO-SCORAD and SCORAD measures at D28 was strong and highly significant [$r = 0.79$ (95% CI: 0.75; 0.83), $P < 0.0001$].

Furthermore, it has not been evaluated in children under the age of 7 years, the age group that accounts for most of paediatric AD prevalence. By contrast, PO-SCORAD is easy to implement and to understand, and it shows a strong correlation with SCORAD in all age classes. Therefore, it is a valuable tool for large-scale epidemiological studies on the assessment of AD severity and its impact on the quality of life of the patient and his/her family, especially in paediatric populations.

For the physician, the PO-SCORAD is also a convenient mean to improve the communication with his/her patient. As PO-SCORAD is based on SCORAD, both the physician and his/her patient use the same language for the description of AD severity and have the same understanding of the words. As PO-SCORAD was shown to be as accurate as SCORAD to assess AD severity, the physician may follow the evolution of the disease and the long-term effect of the treatment, without necessarily having to see his patient frequently. PO-SCORAD could be of particular value in the assessment of structured education programmes, by providing patient evaluation of the impact of education on the real course of the disease. Moreover, filling out PO-SCORAD questionnaire could be a real mean for enhancing the compliance of the patient. A software dedicated to SCORAD/PO-SCORAD for helping doctors, patients/parents to fill out the questionnaires is currently in progress. Such software (widget), available on Internet, will offer the patient the possibility of creating automatically a curve of PO-SCORAD score changes with time representing the real course of the disease. He/she will then be able to send this curve to his/her doctor.

In conclusion, this study validated the use of PO-SCORAD for the self-assessment of AD in a large European population of patients exhibiting the whole range of AD severity. The PO-SCORAD correlates well with SCORAD, considered as the most internationally used AD severity assessment tool for physicians. With the help of standardised pictures providing the patients with illustrations of AD symptoms and severity, this scale is easy to understand and to complete by all. It represents a valuable tool for everyday clinical practice as well as for clinical and epidemiological studies in AD. The long-term correlation of SCORAD and PO-SCORAD has not yet been explored, but the concept of a self-assessment score opens numerous paths in clinical research.

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