Objective: To evaluate the test-retest reliability, discriminative and concurrent validity, and responsiveness of the Childhood Atopic Dermatitis Impact Scale (CADIS), a quality-of-life scale with 5 domains.

Design: Prospective, longitudinal study.

Setting: Two academic pediatric dermatology practices.

Patients: A total of 301 parents of children younger than 6 years with atopic dermatitis.

Main Outcome Measures: Participants completed the CADIS, sociodemographic items, and other clinical questions at enrollment and at a 4-week follow-up. In addition, 41 participants completed the CADIS again 48 hours after baseline. Disease severity was measured using the Severity Scoring of Atopic Dermatitis (SCORAD) index for all children.

Results: Of 301 enrolled participants, 270 (90%) completed the enrollment materials and 228 (84%) of these completed the 4-week follow-up materials. Thirty-four (83%) of the 41 participants completed the 48-hour materials. Intraclass correlation coefficients of CADIS scores at enrollment and at 48 hours ranged from 0.89 to 0.95. Correlations between CADIS scores and the SCORAD index scores (range, 0.42-0.72) demonstrated that more severe atopic dermatitis is associated with worse quality of life. Scores from all 5 domains of the CADIS significantly differentiated patients at each severity level as measured by the SCORAD index (P<.001). Participants who rated their children as “improved” at the 4-week follow-up had significantly better CADIS scores than those who rated their children as having the “same” or “worse” skin disease (P<.05).

Conclusions: These data confirm the test-retest reliability, concurrent validity, and discriminative validity of the CADIS. In addition, responsiveness evaluation demonstrates that the CADIS accurately measures change in patients whose disease improves.

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validity with a measurement of disease severity, sensitivity to differences in severity of the disease, and responsiveness across time.

**METHODS**

Eligible subjects consisted of parents or primary caregivers of children from birth to age 6 years with a diagnosis of AD; to be eligible, participants needed to be able to read and understand English. Recruitment took place at 2 pediatric dermatology practices (Children's Memorial Hospital, Chicago, Ill, and the University of California, San Francisco). A total of 301 consecutive eligible parents who were approached by one of the investigators (S.L.C. or A.J.M.) offered to participate after their child's regular appointment. The study protocol was approved by the institutional review boards at both participating centers.

Enrolled participants completed the CADIS, sociodemographic items, and other clinical questions. The CADIS is self-administered by the parent's parents. Standardized response choices consist of 5 category choices relating to frequency ("never" to "all the time"). A response of "never" is scored with zero points, and "all the time" is scored with 4 points. The CADIS inquires about the parent's perceptions during the past 4 weeks. Parents were asked to respond to additional questions about their child's skin condition, including a global question ("How would you rate the condition of your child's skin now?" [Poor, fair, good, very good, or excellent]), and items about itch and sleep loss (rated on 10-point visual analog scales).

In addition, the examining physician (S.L.C.) completed the Severity Scoring of Atopic Dermatitis (SCORAD) index for each participating child during the clinic visit. The SCORAD index is widely used, well-validated instrument that measures the severity of AD according to objective (extent and intensity of lesions) and subjective (pruritus and sleep loss) criteria. Pruritus and sleep-loss measurements are collected as patient- or parent-completed 10-point visual analog scales. The SCORAD index results can be reported as a total score (includes subjective criteria) or an objective score. The objective score excludes the subjective ratings of pruritus and sleep loss. Overall, low SCORAD scores represent mild AD, and high scores represent severe AD.

To examine the stability of items, 41 parents were asked to respond to the CADIS at initial enrollment and again in 48 hours. This time interval was chosen both to minimize complete recall of responses at baseline and to ensure that the severity of disease itself would likely be stable because childhood AD typically changes after only a few days of therapy.

To test responsiveness to clinical change, all enrolled parents received a copy of the CADIS for completion 4 weeks after enrollment. All data were entered into a SAS data set (SAS Inc, Chicago, Ill), and SAS statistical software was used for all data analysis.

Test-retest reliability of each CADIS domain score and the total score was estimated using the intraclass correlation coefficient of reliability.

Concurrent validity was assessed by comparing CADIS scores with SCORAD total and objective scores and ratings of pruritus and sleep loss using Spearman rank correlation coefficients.

To determine discriminant validity (ie, how well the CADIS discriminated subjects with AD of different clinical severity), we compared CADIS scores of patients in 3 severity groups based on their SCORAD objective scores: severe (scores >40), moderate (scores of 15-40), and mild (scores <15) (hereinafter severe, moderate, and mild groups, respectively).

For responsiveness to change over a 4-week period, responses for each patient to the global item about overall skin condition were compared. Patients whose skin conditions were rated as "improved" in at least 1 response category over 4 weeks were classified as "improved"; those whose conditions were rated as "worse" in at least 1 response category were classified as "worse."
have been published. Additional characteristics of this cohort and returned questionnaires. Of the 301 enrolled participants, 270 (90%) completed the initial CADIS and sociodemographic items. Of note, only 1 family refused participation. Of the 41 parents asked to complete the survey at 48 hours, 34 (83%) completed and returned questionnaires.

The mean (SD) age of the children was 16.0 (12.7) months (range, 1.5-71.4 months); 55% were male, 52% were white, and 21% were Asian. The mean age of the mothers was 32.8 years, 86% were married or living with their partner, 81% were privately insured, and 56% reported a yearly income higher than $75,000. Of note, parents’ education levels did not have an impact on their partner’s education levels did not have an impact on their partner, 81% were privately insured, and 56% reported a yearly income higher than $75,000. Of note, parents’ education levels did not have an impact on their partner.

“worse”; and those with no change in ratings were classified as “remained the same.” We used analysis of variance to examine the ability of the CADIS to differentiate these three subject groups.

RESULTS

SAMPLE CHARACTERISTICS

Of the 301 enrolled participants, 270 (90%) completed the initial CADIS and sociodemographic items. Of note, only 1 family refused participation. Of the 41 parents asked to complete the survey at 48 hours, 34 (83%) completed and returned questionnaires.

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TEST-RETEST RELIABILITY

The intraclass correlation coefficient of each domain score ranged from 0.89 (Social and Family Function) to 0.95 (Child Activity Limitations and Parent Sleep), and the intraclass correlation coefficient of the total CADIS scores was 0.96. These values indicate acceptable test-retest reliability of the CADIS.

CONCURRENT VALIDITY

Using Spearman rank correlation, correlations between each CADIS domain score and the total CADIS score with the total SCORAD scores ranged from 0.48 (Family and Social Function, Parent Emotions) to 0.65 (Child Symptoms); with objective SCORAD scores, from 0.42 (Child Emotions, Family and Social Function) to 0.53 (Child Symptoms); and with subjective criteria (pruritus and sleep loss), from 0.46 (Family and Social Function) to 0.72 (Child Symptoms). These results indicate that the CADIS has evidence of concurrent validity in that more severe AD was associated with worse QOL. The results also indicate, though, that the tools are not redundant and assess different aspects of disease severity; the CADIS assessed features of patients and parents that the SCORAD index did not capture.

DISCRIMINATION

Based on the SCORAD clinical severity classification scheme, 35 patients (13%) were classified as having severe AD, 173 (64%) with moderate AD, and 62 (23%) with mild AD. Figure 1 depicts the mean scores of each domain (transformed into a 0 to 5 scale for ease of comparison) for the 3 severity groups. Although score differences between the mild and moderate groups seemed not as great as those between the moderate and severe groups, analysis of variance results showed that scores from all 5 CADIS domains significantly differentiated patients at each clinical severity level ($F_{3,225,2}=46.41, 50.84, 28.01, 34.28, 24.21,$ and 48.16 for Child Symptoms, Child Activity Limitations and Behavior, Family and Social Function, Parent Sleep, Parent Emotions, and total CADIS, respectively; $P<.001$). Follow-up post hoc tests (Tukey honestly significant difference [HSD]) showed that all pairwise comparisons were significant ($P<.05$). Table 2 shows mean CADIS domain and total scores for disease severity with additional scoring information.

RESPONSIVENESS

A total of 228 (84%) of the 270 respondents completed the 4-week survey used to measure responsiveness. The mean changed scores between baseline and 4-week follow-up were −4.3, −1.8, −1.4, −1.0, −4.8, and −19.0 for Child Symptoms, Child Activity Limitations and Behavior, Family and Social Function, Parent Sleep, Parent Emotions, and total CADIS, respectively. According to the definition of the changed responses on the global skin item described in the “Methods” section, 146 patients (64%) were classified as “improved,” 61 (27%) as “remained the same,” and 21 (9%) as “worse.” Figure 2 depicts the change in CADIS domain scores at the 4-week follow-up by these 3 groups. Analysis of variance results showed that CADIS domains significantly differentiated subjects at these 3 groups ($F_{2,225,2}=28.86, 11.3, 5.53, 14.51, 9.90,$ and 20.16 for Child Symptoms, Child Activity Limitations and Behavior, Family and Social Function, Parent Sleep, Parent Emotions, and total CADIS scores, respectively; $P<.001$). Follow-up post hoc tests (Tukey HSD) indicated that “improved” subjects had significantly better scores than the other 2 groups on all domains ($P<.05$), except the Family and Social Function, whereas “improved” subjects did not significantly differ from those whose condition declined ($P>.05$). This indicates that the CADIS is most responsive to improvement in AD.
The 45-item CADIS is a hypothesis-based QOL scale developed and refined by a review of published work, interviews with families and expert medical professionals, and validity evaluation.²,¹³ This study is the second part of a multisteped process to evaluate the performance and properties of the CADIS; previous work¹³ demonstrated that the instrument has considerable evidence of face, construct, and content validity.

The domain and total CADIS scores and items in each domain are detailed in Table 2. The CADIS can be reported as a total score and individual domain scores. Table 2 includes the mean CADIS scores for each category of disease severity, and these data may be useful for interpreting CADIS scores in clinical trials and practice.

Test-retest reliability at 48 hours was confirmed with the findings described herein. In addition, responsiveness evaluation demonstrated that the CADIS most accurately measures change in patients whose disease improved. Because the group whose condition clinically worsened was small (n = 21), definitive conclusions about the CADIS responsiveness to worsening condition cannot be made. As parent-rated condition of the skin improved, CADIS scores improved. The use of CADIS for young children with AD is supported by these findings. Of note, the Family and Social Function domain was not found to differentiate improved subjects vs those whose condition worsened over the 4-week period, and a longer follow-up period with repeated measurements may be needed to explain this finding.

Quality of life worsens when children with moderate and severe AD are compared with children with mild to moderate AD, as shown graphically in Figure 1 and numerically in Table 2. This change is most notable in the Parent Sleep and Child Symptoms domains. Sleep disturbance as an important effect of AD is well documented with delayed sleep onset, frequent awakening, daytime irritability, parental sleep loss, and cosleeping.⁴,⁷,¹⁰ This study quantifies the effects on sleep in a separate domain for parents and as part of the symptom domain for children.

All patients were recruited from pediatric dermatology practices. This may imply a referral bias toward increasing disease severity. This bias was considered during study design, and all patients with AD were recruited for participation even if their visit was for other diagnoses. Mild cases were well represented (23%). However, it is unknown whether parents seeking specialty care for children with mild disease are inherently different than those who do not.

Although determination of clinically meaningful change in QOL scales is challenging owing to the lack of a gold standard to use in comparison, defining the meaningfulness of changes in CADIS scores through comparison with global health questions is the next critical step in the evaluation of the performance and properties of this scale.¹³ An understanding of changes in CADIS scores through such an analysis is critical for interpret-
This article uses statistical methods that would tax even the most well-informed reader of the Archives. It reports the important psychometric properties of the CADIS: test-retest reliability, correlation with disease severity, and responsiveness to changes in disease severity. The test-retest reliability of CADIS was very high at 48 hours. The correlation with disease severity was determined using Spearman correlation coefficients (a non-parametric test that is appropriate for data that are skewed). Correlation coefficients vary from 1 (perfect linear relationship) to –1 (perfect negative linear relationship), with 0 representing no or a random relationship. The square of the correlation coefficient can be interpreted as the percentage of variance of the dependent variable that is explained by the independent variable. (http://www2.chass.ncsu.edu/garson/apa765/correl.htm)\(^1\) The CADIS is responsive to improvement in AD severity. Cogent explanation of intraclass correlation coefficient, reliability analysis, and correlation can be found at http://www2.chass.ncsu.edu/garson/apa765/index.htm. The CADIS provides a patient-centered measurement of AD severity that should prove useful in clinical research.

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Author Contributions: Dr Chamlin had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Chamlin, Frieden, Williams, and Chren. Acquisition of data: Chamlin, Frieden, Williams, and Mancini. Analysis and interpretation of data: Chamlin, Lai, Cellu, and Chren. Drafting of the manuscript: Chamlin, Lai, Cellu, and Chren. Critical revision of manuscript for important intellectual content: Frieden, Williams, and Mancini. Statistical analysis: Lai. Obtained funding: Chamlin. Administrative, technical, and material support: Chamlin, Cellu, and Chren. Study supervision: Cellu and Chren.

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REFERENCES