

ORIGINAL ARTICLE

Skin & Eye Disease

WILEY

Reliability and validity of the Atopic Dermatitis Symptom Score (ADSS)

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Funding information

This study was funded by the Environmental Health Center Project of the Ministry of Environment, Republic of Korea.

Abstract

Background: We have developed the Atopic Dermatitis Symptom Score (ADSS) by which patients or parents can easily assess and record AD symptoms on a daily basis in a smartphone application. The aim of this study was to evaluate the reliability and validity of the ADSS.

Methods: We enrolled 307 children and adolescents with AD. Parents or caregivers were asked to record daily symptoms of the patients (itching, sleep disturbance, erythema, dryness, oozing, and edema) using a scale of 0-4. Statistical analyses consisted of the test-retest reliability, concurrent validity, minimal clinically important difference (MCID), responsiveness, floor or ceiling effects, and screening accuracy. Receiver-operating characteristic analyses were conducted to evaluate the ADSS cutoff point for predicting severe AD (SCORing AD [SCORAD] ≥ 40).

Results: Test-retest reliability between daytime and night-time ADSS was good (intra-class correlation coefficient, 0.82 [95% CI: 0.70-0.90]). An increase in ADSS was significantly associated with an increase in SCORAD ($r = 0.64$, $P < .0001$) (concurrent validity). The MCID was 4.1 points for the ADSS. There was a significant association between changes in ADSS and SCORAD ($r = 0.56$, $P < .0001$), indicating good responsiveness. At the optimal ADSS cutoff value of 7.0, sensitivity, specificity, and positive and negative predictive values were 88.4%, 78.6%, 21.1%, and 99.1%, respectively (screening accuracy).

Conclusions: The ADSS can be a useful tool for self-assessment of skin symptoms in children with AD.

KEYWORDS

assessment, atopic dermatitis, reliability, severity, validity

1 | INTRODUCTION

Atopic dermatitis (AD) is one of the most common chronic skin diseases in children with an increasing prevalence in the past few decades.¹ Chronically relapsing skin symptoms in AD patients can lead to sleep deprivation, lack of concentration, and absence from school.² Adherence to treatment and behavioral interventions are essential for self-assessment and disease control of AD.³ AD patients need long-term

management, similar to other chronic diseases. In general, daily routine self-monitoring is an effective and important behavioral component of chronic disease management.^{3,4} A previous study reported that self-monitoring and management programs led to positive effects on skin care, cost-effectiveness, and quality of life in patients with AD.⁴

To date, there have been a few self-monitoring tools for AD, such as the Patient-Oriented Eczema Measure (POEM), the Patient-Oriented SCORing Atopic Dermatitis (PO-SCORAD) Score, and the

Self-Administered Eczema Area and Severity Index (SA-EASI).⁵⁻⁷ Although the international Harmonising Outcome Measures for Eczema (HOME) initiative recommended the POEM as the best core instrument to measure AD symptoms, a recent systematic review pointed out that the evidence for internal consistency was limited, and the test-retest reliability was unknown.^{8,9} Moreover, the sensitivity and specificity of POEM were only 62.1% and 66.1%, respectively, at the receiver-operating characteristic (ROC) cutoff points.¹⁰ In addition, it took more than five minutes to record all the PO-SCORAD items in half of the patients.¹¹

Recording symptom diaries in a smartphone application by patients or their caregivers may provide an effective means of collecting real-time symptom data, because smartphones are easily used anytime anywhere.¹² In addition, the connectedness of smartphones enables patients to share their conditions with health professionals.¹² Therefore, we have developed the Atopic Dermatitis Symptom Score (ADSS) by which patients or parents can easily assess and record AD symptoms on a daily basis in a smartphone application. The aim of this study was to evaluate the reliability and validity of the ADSS in children with AD.

2 | METHODS

2.1 | Study population

In this descriptive longitudinal study, we evaluated the reliability and validity of a mobile phone-based electronic symptom diary for children with AD. We enrolled patients who were 18 years or younger and who had been diagnosed with AD between November 2012 and March 2015. The diagnosis of AD was based on the Hanifin and Rajka criteria.¹ Patients visited the outpatient clinic every 1 or 2 months and were assessed by a pediatric allergist using the SCORing Atopic Dermatitis (SCORAD) index, ranging from 0 to 103.¹³ Parents were asked to complete a questionnaire about their child's demographics and past medical history. All patients were instructed to bathe once daily in warm water for approximately 10 minutes and to apply moisturizers frequently during the study period.³ Intermittent use of topical 1% hydrocortisone or prednisolone valeroacetate was allowed in patients if necessary. This study protocol was approved by the Institutional Review Board of Samsung Medical Center (SMC IRB file No. 2015-11-114).

2.2 | Atopic dermatitis symptom score (ADSS)

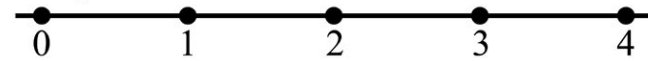
The ADSS was set in a smartphone application for self-assessment of AD symptoms on a daily basis. In order to make it simple and easy to use, the ADSS was designed by modifying previous monitoring tools.¹⁴ In other words, 2 subjective symptoms (itching, sleep disturbance) and 4 objective signs (erythema, dryness, oozing, edema) were selected, and the severity of each item was assessed on a scale of 0 (mild) to 4 (very severe) (Figure 1). The minimum and maximum scores of the ADSS were 0 and 24, respectively. The smallest detectable change (SDC) was 1 point. Parents or caregivers were instructed to record daily ADSS of the patient regardless of age. Before study enrollment, all parents and caregivers were educated on how to assess the ADSS using an illustrated guidance booklet and mobile phone application.

Do you have the following symptoms of atopic dermatitis today?

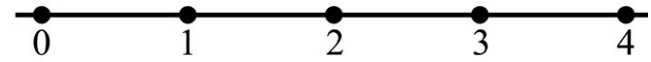
Itching



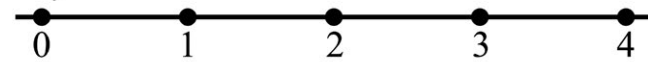
Sleep disturbance



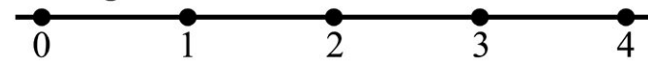
Erythema



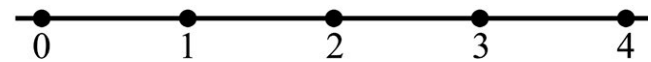
Dryness



Oozing



Edema



0: none, 1: mild, 2: moderate, 3: severe, 4: very severe

FIGURE 1 Visual analogue scale of Atopic Dermatitis Symptom Score (ADSS). Parents or caregivers select one response for all six questions every day

These records were automatically delivered to a secure website that could be accessed by only registered researchers. The dates and times of data submission were also coded. Children were excluded from the study if their caregivers had a history of psychiatric disease or other condition that would limit the validity of their data.

2.3 | Statistical analyses

Statistical analyses consisted of intraobserver reliability, internal consistency, concurrent validity, minimal clinically important difference (MCID), responsiveness, floor or ceiling effects, and screening accuracy. For validation of intraobserver reliability, the test-retest reliability of each ADSS item was assessed by estimating the intraclass correlation between daytime and night-time ADSS for 7 days in a subset of 20 patients. Internal consistency was determined by calculating the intraclass correlation coefficient (ICC) with a 95% confidence interval (CI) for each item. An ICC ≥ 0.4 was regarded as a moderate correlation, and >0.75 was considered a strong correlation.¹⁵ The concurrent validity of ADSS was evaluated using simple linear regression

to assess the association between ADSS and SCORAD. For concurrent validity, we analyzed only one baseline measurement per patient, because multiple measurements might bias the results. Responsiveness was assessed by evaluating the association between changes in ADSS and SCORAD from baseline to the next visit using simple linear regression. We used ADSS data that were recorded on the same day when SCORAD was measured for evaluation of concurrent validity and responsiveness. The presence of floor or ceiling effects was defined when the percentage of subjects who achieved the lowest or highest possible score was >15%.¹⁶

We estimated MCID using anchor-based approaches.¹⁷ ADSS and patient global assessment (PGA) were independently assessed at baseline and follow-up visits. PGA was scored using a three-point scale: 1 = better, 0 = unchanged, and -1 = worse. We calculated the mean change in ADSS of those in the minimal-change subgroup of the PGA. The minimal-change subgroup was defined when the patient was 'better' than the previous visit. We also determined the cutoff point of ADSS that most optimally discriminated between those with a PGA response of 'better' and 'no difference' by analyzing ROC curves.

To determine the cutoff point for ADSS, severity was classified as either mild to moderate (SCORAD <40) or severe (SCORAD ≥40) AD.¹⁸ The ADSS cutoff value for predicting severe AD was determined with ROC curve analysis. Performance characteristics such as sensitivity, specificity, positive predictive value, and negative predictive value were analyzed using the ADSS cutoff value that was calculated using the highest Youden's index value.¹⁹

All analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) and R 3.2.1 (Vienna, Austria; <http://www.R-project.org/>). We excluded data for the first 3 months from analysis and analyzed only complete datasets. Patient characteristics were presented as medians with interquartile ranges for continuous variables and as relative frequencies for categorical variables. A *P*-value <.05 was considered significant.

3 | RESULTS

3.1 | Study population

The study subjects included 188 boys and 119 girls. Among them, 78.7% of the subjects recorded daily ADSS for longer than 3 months. Their median age was 14.0 months (interquartile range [IQR], 6.0-41.3 months) (Table 1). The median baseline SCORAD for all patients was 15.7 (IQR, 8.2-23.6), and the median baseline ADSS was 4.0 (IQR, 2.0-7.0). Median follow-up duration was 5.4 months (IQR, 2.8-10.2 months), and the median number of visits was 2 (IQR, 1-4). All the subjects filled in the 6 items within one minute. Actually, 58.3% of subjects completed it in less than 30 seconds. The percentage of subjects who achieved the lowest or highest possible score was 7.8%.

3.2 | Test-retest reliability

Test-retest reliability of the 6 ADSS symptoms between day and night for 138 datasets was analyzed. Two measurements were

TABLE 1 Clinical characteristics of the subjects (n = 307)

Characteristic	Number of patients (%)
Gender (male)	188 (61.2)
Age (year)	
0-1	188 (61.2)
2-6	94 (30.6)
7-12	18 (5.9)
13-18	7 (2.3)
Accompanied allergic diseases	
Food allergy	129 (42.0)
Allergic rhinitis	39 (12.7)
Asthma	22 (7.2)
SCORAD at initial visit (median, IQR)	15.7 (8.2-23.6)
<15.0	133 (43.3)
15.0-39.9	156 (50.8)
≥40.0	18 (5.9)
ADSS (median, IQR)	4.0 (2.0-7.0)
Number of visits	
1	77 (34.5)
2	46 (20.6)
3	30 (13.5)
≥4	70 (31.4)

AD, atopic dermatitis; SCORAD, SCORing Atopic Dermatitis; ADSS, Atopic Dermatitis Symptom Score; IQR, interquartile range.

missing because a subject's parent forgot to record it twice during the study period. The ICCs associated with itching, sleep disturbance, erythema, dryness, oozing, and edema were 0.79 (95% CI: 0.72-0.85), 0.88 (95% CI: 0.83-0.91), 0.82 (95% CI: 0.76-0.87), 0.84 (95% CI: 0.78-0.88), 0.90 (95% CI: 0.86-0.92), and 0.94 (95% CI: 0.91-0.96), respectively, indicating strong correlation between day and night scores. Additionally, the ICC for total ADSS was 0.82 (95% CI: 0.70-0.90).

3.3 | Concurrent validity

Concurrent validity was analyzed using 223 datasets. An increase in ADSS was significantly associated with an increase in SCORAD ($r = .64$, $P < .0001$, Figure 2). In addition, regression analysis showed that a one-point increase in ADSS was associated with a 0.23 unit increase in SCORAD (95% CI: 0.20-0.26).

3.4 | Responsiveness

Of 307 subjects, data from 133 were used to evaluate the correlation between absolute changes in SCORAD and ADSS from baseline to the next visit. The median length of interval between baseline and the next visit was 1.9 months (IQR, 1.4-2.8 months). Patients who experienced decreases in SCORAD at follow-up visits

FIGURE 2 Correlations between the scoring of atopic dermatitis (SCORAD) and the Atopic Dermatitis Symptom Score (ADSS). ADSS and SCORAD were recorded on the same day. The dashed line represents the 95% confidence interval

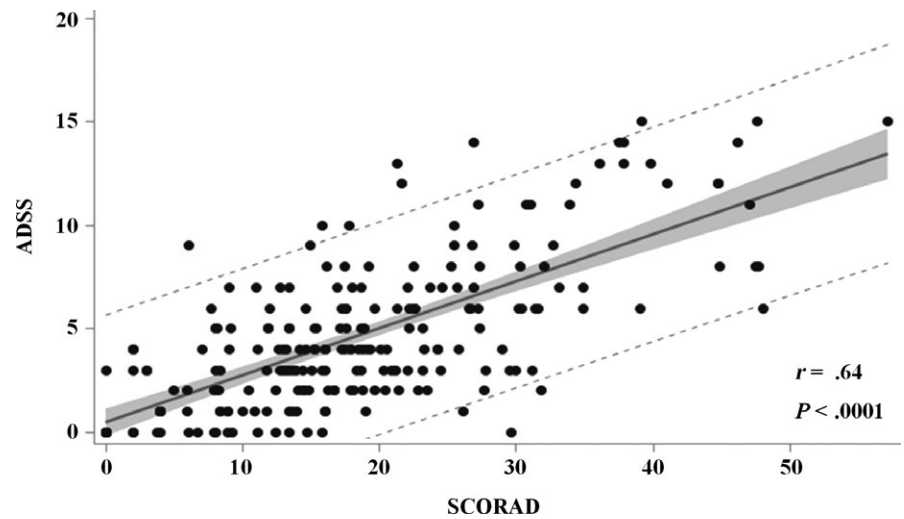
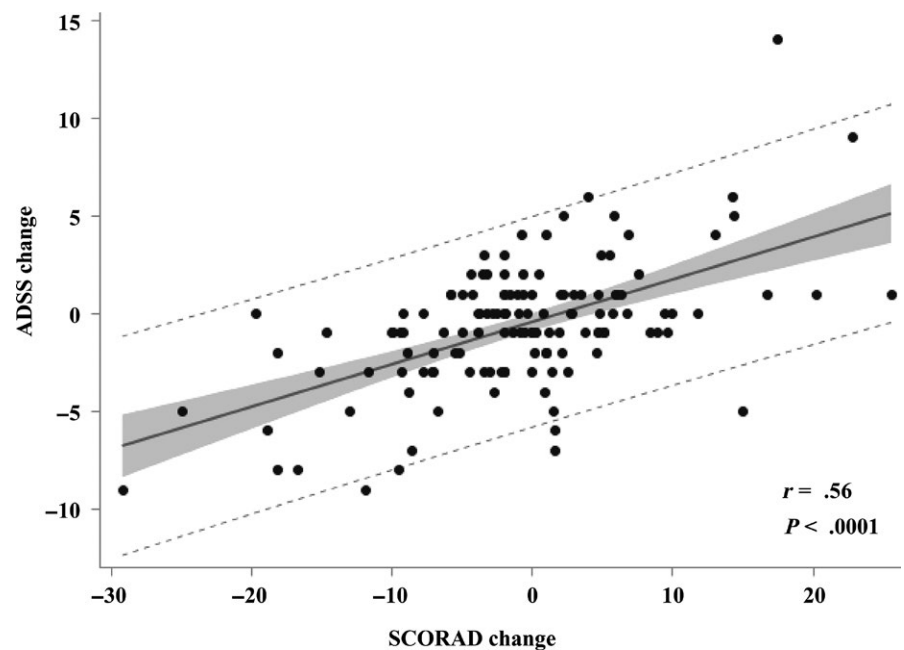


FIGURE 3 Correlation between the changes in total scoring of atopic dermatitis (SCORAD) and the changes in the Atopic Dermatitis Symptom Score (ADSS). ADSS and SCORAD were recorded on the same day. The dashed line represents the 95% confidence interval



demonstrated significant improvement in ADSS. There was a significant association between changes in ADSS and SCORAD ($r = .56$, $P < .0001$) (Figure 3).

3.5 | Minimal clinically important difference (MCID)

For assessment of MCID of ADSS, data of 89 patients were analyzed. Of 89 patients, 31 (34.8%) improved, 48 (53.9%) worsened, and 10 (11.3%) showed no change. The anchor-based mean difference in ADSS for patients with improvement in PGA was 4.1 points (standard deviation 2.7). The ROC cutoff point was 2 points on the ADSS for indicating clinical improvement, with a sensitivity of 83.9% and a specificity of 100.0%, which showed an acceptable area under the curve (AUC) of 0.95 (95% CI: 0.90–1.00).

3.6 | Screening accuracy

Overall, 705 datasets were used to calculate the cutoff point for the prediction of severe AD (SCORAD ≥ 40). In ROC analyses of ADSS for predicting severe AD, the AUC was 0.90 (95% CI: 0.85–0.94). Using an optimal cutoff value of 7.0 for ADSS, sensitivity, specificity, and positive and negative predictive values were 88.4%, 78.6%, 21.1%, and 99.1%, respectively (Figure 4).

4 | DISCUSSION

Accurate symptom monitoring by patients or their caregivers is a basic component of effective management of allergic diseases, but previous

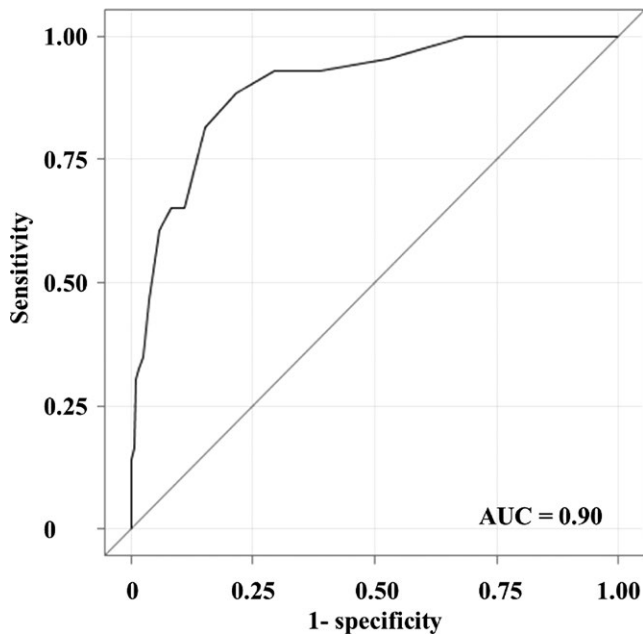


FIGURE 4 The receiver-operating characteristic (ROC) curve to identify severe atopic dermatitis (AD) using an Atopic Dermatitis Symptom Score (ADSS) cutoff value of 7.0. Severe AD was defined as SCORAD ≥ 40 . The ADSS in this figure was recorded on the same day as SCORAD. Abbreviations: AUC, area under the receiver-operating characteristic curve

monitoring tools for AD were not sufficiently sensitive.⁹ Therefore, we explored a new symptom monitoring tool, the ADSS, which would permit daily evaluation of AD status and help to determine individual-specific aggravating factors. We found strong test-retest reliability and good concurrent validity for the ADSS. The ADSS was moderately responsive to changes in skin symptoms, as reflected by an increase in ADSS as physician-assessed SCORAD increased. The ADSS had good screening accuracy, with a cutoff value of 7.0 for predicting severe AD. In addition, the ADSS had no floor or ceiling effects. To our knowledge, this is the first study to validate the assessment of skin symptom scores using mobile technology that facilitates daily monitoring of symptoms in children with AD.

There are different phenotypes of AD in which multiple triggers and mechanistic pathways are involved.¹ It is important to identify and eliminate aggravating factors in each patient's environment, although there is no effective way to find environmental triggers in each individual. Therefore, daily monitoring of AD symptoms is essential for analyzing the relationships between skin symptoms and various triggers and for implementing individualized treatment plans. In this respect, ADSS can be a useful tool in clinical practice for assessing symptom severity, identifying aggravating factors, and encouraging patients to change their behaviors. In the research field, a longitudinal panel study using ADSS allows us to overcome individual variation of symptom assessment through repeated responses from the same individuals and to find potential environmental risk factors for exacerbation of AD symptoms.^{14,20,21} In addition, mobile technology allows for efficient collection of daily symptom reports, reduction in the burden of data

processing, and better analysis of within-subject changes in long-term longitudinal studies.^{22,23}

Several objective methods have been used to assess AD severity: SCORAD, Eczema Area and Severity Index (EASI), and Six Area, Six Sign Atopic Dermatitis (SASSAD).²⁴⁻²⁶ A systematic review indicated that SCORAD and EASI were the most valid and reliable instruments to measure clinical signs of AD with adequate internal consistency and responsiveness.¹⁶ However, they are time-consuming and too complex to use every day, because they are based on physician assessment in the outpatient clinic at different intervals over a few months. The SASSAD satisfied some quality criteria in a previous study, but needs more validation studies to identify other required measurement properties such as intraobserver reliability, floor or ceiling effects, and acceptability.¹⁶ High correlation between the ADSS and SCORAD in the present study indicated adequate construct validity for the ADSS, because SCORAD is one of the best instruments for assessing AD severity objectively. Therefore, daily assessment of the ADSS can provide clinicians with useful information about daily symptom variation.

Previous studies tried to validate the symptom-based monitoring tools in AD and suggested that those tools need further evaluation to establish their reliability and validity.⁹ For example, POEM is a well-known patient assessment tool with adequate reliability, but has not been analyzed for measurement error and test-retest reliability.^{5,9,10,27} Moreover, it only allows caregivers to describe how often patients experienced skin symptoms during a 1-week period, which might provide an incomplete trend for skin symptoms.²⁸ SA-EASI estimates the amount of body surface area that is affected by AD and includes visual analogue scales for skin symptoms.²⁹ Although SA-EASI is regarded as one of the most appropriate tools to assess symptoms of AD, limited evidence is available on its construct validity.^{7,9} PO-SCORAD is a questionnaire evaluating the extent and severity of itching and sleep disturbance.¹¹ A good correlation was found between PO-SCORAD and SCORAD at both initial and follow-up visits.^{6,30} PO-SCORAD can be also used in the form of a smartphone application. However, the PO-SCORAD needs further evaluation to establish its responsiveness and MCID.⁹ In addition, mobile PO-SCORAD has not been validated and takes more time than ADSS because users have to evaluate the extent of skin symptoms over the whole body. On the other hand, all the subjects of the present study reported that ADSS was easy to record, with 58.3% of subjects completing it in <30 seconds.

A limitation of this study is that it was a single-center study and most patients presented with mild-to-moderate AD. Multicenter and cross-cultural trials using the ADSS would provide evidence of its broader validity. Another limitation is that the ADSS does not assess either chronicity or body surface area affected by AD. However, estimations of the extent of skin involvement take more time and are therefore inadequate for daily monitoring. In addition, the ADSS is easy to use because daily symptoms can be recorded and stored in a smartphone application at any time at any place. Despite the limitations, the ADSS is more practical for daily symptom monitoring than the previous tools.

In conclusion, our study demonstrated that ADSS had strong reliability, good concurrent validity and MCID (4.1 points), moderate responsiveness, and excellent feasibility. Therefore, this time-saving and

easy-to-use tool could help AD patients and their caregivers monitor daily skin symptoms, identify environmental triggers, and change their management behavior.

ACKNOWLEDGEMENTS

This study was funded by the Environmental Health Center Project of the Ministry of Environment, Republic of Korea.

CONFLICT OF INTEREST

The authors declare that there are no potential conflicts of interests with respect to the authorship and/or publication of this article.

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How to cite this article: Lee JY, Kim M, Yang H-K, et al. Reliability and validity of the Atopic Dermatitis Symptom Score (ADSS). *Pediatr Allergy Immunol*. 2018;29:290-295. <https://doi.org/10.1111/pai.12865>