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Assessment of the American Academy of Dermatology Diagnostic Criteria for Pediatric Atopic Dermatitis and Modification into a Checkbox Form: A Cross-Sectional Study

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Abstract

Background/Objectives: Diagnostic criteria for atopic dermatitis (AD) are limited in their performance and/or usability. The American Academy of Dermatology (AAD) consensus criteria include hierarchical categories of disease features to improve these metrics but have not been validated. Our objective was to create and validate a checkbox form of the AAD consensus criteria in the pediatric population.

Methods: We performed a cross-sectional study of 100 pediatric patients with AD (n=58) and diseases in the differential diagnosis of AD (n=42).

Results: Having three or more "Essential," ≥2 "Important," ≥1 "Associated" features of the AAD criteria was optimal for the diagnosis of AD in children. This combination was 91.4% (95% CI, 84.2–98.6%) sensitive and 95.2% (88.8%−100%) specific. The UK working party criteria and the Hanifin-Rajka criteria had sensitivities of 96.6% (95% CI 91.9–100%) and 98.3% (95% CI 94.9–100%) and specificities of 83.3% (95% CI 72.1–94.6%) and 71.4% (95% CI 57.8–85.1%),

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respectively. The AAD criteria had significantly greater specificity than the Hanifin-Rajka criteria (P=0.002).

Conclusions: This study represents an important step in validating the AAD consensus criteria and formulating a useable checkbox form for diagnosing AD in the pediatric population.

Keywords

Atopic dermatitis; diagnostic criteria; pediatrics

Introduction

Atopic dermatitis (AD) affects 15–20% of children in developed countries and has significant impact on these patients, their families and the healthcare system.[1–3] Determining a diagnosis of AD with a high degree of specificity in clinical trials and practice is crucial, especially with the cost of newer medications like systemic biologic agents. Highly specific diagnostic criteria ensure that studies are reliable and reproducible by defining an appropriate and consistent patient population for study.

The “gold standard” for diagnosing AD is a clinical diagnosis by a physician,[4] and for many years, this was the only way to diagnose AD. The Hanifin and Rajka (HR) diagnostic criteria and the United Kingdom Working Party’s (UK) criteria were subsequently created, and while these criteria represented a large advance in the field, they are limited by their usability and poor sensitivity, respectively.[4–8] Due to their shortcomings, the American Academy of Dermatology (AAD) Consensus Conference on Atopic Dermatitis (2001) created revised HR criteria (AAD consensus criteria) that removed many of the poorly performing minor criteria.[9,10] The AAD criteria utilize a hierarchical three-tiered system that includes “Essential,” “Important,” and “Associated” features of AD. The consensus criteria have been used in clinical trials for over a decade,[11] yet, these criteria remained a qualitative assessment with no validation to confirm their diagnostic accuracy.

Thus, we set out to determine the number of diagnostic features from each of the hierarchical groups of AAD criteria necessary to diagnose AD in the pediatric population with optimal sensitivity and specificity and to validate these criteria. Additionally, we sought to develop an optimized checkbox form of the AAD consensus criteria and compare the sensitivity and specificity of these criteria to the HR and UK criteria.

Materials and Methods

We conducted a cross-sectional study of pediatric patients with AD and diseases considered in the differential diagnosis of AD presenting to the Rady Children’s Hospital - Pediatric and Adolescent Dermatology outpatient clinic according to the STARD (Standards for Reporting of Diagnostic Accuracy Studies) 2015 reporting guidelines.[12] In total, 100 subjects from the outpatient dermatology clinic were recruited and examined for this study—60 for the criteria creation phase and 40 for the validation phase. The target population included patients with unequivocal cases of AD, diseases that resembled AD, or those considered in the differential diagnosis. A convenience sample of male and female patients from 3 months to 18 years

of age presenting to our clinic for routine care were considered for the study. Referring physicians were aware that a study pertaining to atopic dermatitis was being conducted and they inquired whether patients were interested in participation. Patients with chronic AD that lacked cutaneous manifestations of disease at the time of the visit were excluded. One of seven board-certified pediatric dermatologists determined the patient's eligibility for inclusion in the study and whether they met the gold-standard, clinical diagnosis of AD, at which time the diagnosis was then verified by an additional healthcare practitioner.

A single, non-physician observer (medical student) performed clinical assessments using a questionnaire and physical exam criteria formed from the AAD, UK and HR criteria. This observer was selected to minimize inter-observer variability and to avoid introducing clinical bias based on prior clinical experiences. After subject recruitment for the criteria creation phase was complete, the patient's medical record was accessed to extract the patient's diagnosis from the physicians' clinical note. Diagnoses such as "eczema" that did not specify the diagnosis of AD were clarified with the physician.

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Power analysis

Given an approximated sensitivity and specificity of 90% based on prior validation studies of the HR criteria,[6] an *a priori* power analysis was conducted centered around achieving a 95% confidence interval with less than +/−10% variability and determined that this could adequately be achieved with under 100 total subjects.[13]

Data input and management

Microsoft® Excel® was utilized for data processing and IBM® SPSS (version 24, IBM Corp, Armonk, NY) and R statistical software (version 3.3.2, Vienna, Austria)[14] for statistical analysis.[14] We used the gold-standard diagnosis from the electronic medical record to compute the true positive, true negative, false positive, false negative, sensitivity, and specificity values for each criterion and each combination of criteria from the AAD criteria. We utilized a normal approximation[13] or "exact" Clopper-Pearson[15] binomial proportion (with less than 30 samples) to create 95% confidence intervals.

AAD Criteria Combinations

Criteria creation—Using data from the first 60 subjects, we examined all 54 possible AAD consensus criteria combinations created from the three "Essential", three "Important," and six "Associated" criteria [Supplemental Figure 1]. Each criterion was assessed for its sensitivity, specificity, and Youden's J statistic to ensure that the "Essential," "Important," and "Associated" criteria were ordered with decreasing levels of importance.

The 54 possible combinations were then concatenated into discrete variables, "E" representing "Essential," "I" representing "Important" and "A" representing "Associated" criteria followed by the number of each of these criteria at the respective cut point. An algorithm was created using Boolean logic that considered all cases that had at least the

count of the concatenated variables and calculated the sensitivity and specificity at and above each of these cut points based on the gold standard diagnosis and the predicted values. Youden's J statistic, which integrates and equally weights both sensitivity and specificity to summarize the performance of diagnostic criteria, was used to rank and select the best performing criteria.

The best criteria from the criteria creation phase above was then validated on the subsequent 40 subjects. Spearman and Kendall tau (b) correlations were performed to detect differences between the 54 ranked "criteria creation" phase and "validation" phase criteria to determine if both datasets were similar enough to perform an aggregated analysis. The probability of both cohorts sharing one of the two best combinations due to chance alone is 0.037 (2/54). This was our *a priori* threshold prior to dataset combination. Finally, the entire dataset was used to calculate the sensitivity and specificity values for each criteria combination and to create a check-box form of the AAD consensus criteria using the highest ranked criteria.

A general definition for "eczema" as stated in the AAD consensus criteria guidelines[9] was created from variables within the HR[16] and UK[4] criteria. The definition was "Patches or plaques of dermatitis composed of raised or flat poorly defined erythema with surface changes that include fine scaling, papules, vesicles, fissures, lichenification, oozing, crusting or hyperlinearity" and each variable was recorded separately to allow for modification of this definition.

During the criteria creation phase and once the dataset was complete, we performed sensitivity analysis of the definition statement by removing each morphology from the final definition. To determine the robustness of the final diagnostic criteria, each criterion was interrogated for its sensitivity and specificity and its overall effect on final criteria.

HR and UK Criteria

The sensitivity and specificity values for the UK and HR criteria were calculated for the entire subject cohort. The discordant values between these criteria and the modified AAD consensus criteria were then compared with the McNemar statistical test using a binomial distribution.

Results

Subject characteristics

The subjects examined had 22 different primary diseases and 58% had AD [Figure 1]. The mean age of patients with AD was 5.0 years [Table 1]. The average age of AD onset per parental report was 7.3 months of age. The subjects with AD trended towards developing disease earlier in life (Cochran-Armitage test, P=0.005) than those without AD [Supplemental Figure 2].

Criteria Selection

The diagnostic characteristics for each of the AAD criteria were tabulated [Table 2]. The "Essential" criteria all demonstrated higher sensitivity (>95%) with a trend towards lower sensitivity in the "Important" (85–95%) and "Associated" (<85%) categories. The

hierarchical nature of the AAD criteria were demonstrated with partial ROC arcs that show increasing importance from the “Associated” to “Important” to “Essential” criteria [Supplemental Figure 3]. This trend was less evident with regard to specificity, as the criteria ranged from 28.6–71.4% for “Essential”, 42.9–59.5% for “Important”, and 19.0–66.7% for “Associated” criteria.

Using the criteria creation algorithm described above, E3I2A1 had the largest Youden’s J value (indicating best performance) in the 60-subject criteria creation cohort (82%, 72–92%) and the 40-patient validation arm (88%, 77–98%). The probability of both cohorts demonstrating this same combination due to chance alone is 0.019 (1/54), which is less than our a priori threshold. Additionally, the Spearman correlation coefficient between the two data sets was 0.97 and Kendall’s tau (type b) was 0.88, with $P<0.001$ in favor of concordance. Due to this high degree of concordance, the two datasets were combined for final analysis. For E3I2A1, the overall Youden’s J value was 86.6% (95% CI, 79.9–93.3%), sensitivity was 91.4% (95% CI 84.2–98.6%), and specificity was 95.2% (95% CI 88.8–100%). The positive and negative likelihood ratios for E3I2A1 were 18.83 and 9.21 respectively. Although E3I2A1 was the best criterion, other criteria that performed well include E3I2A2, E3I1A1 and E3I1A2 [Table 3]. Finally, we created a simplified checkbox form of the optimal AAD consensus criteria [Figure 2].

HR and UK criteria comparison

The UK criteria achieved a sensitivity of 96.6% (95% CI 91.9–100%) and specificity of 83.3% (95% CI 72.1–94.6%) on the entire cohort, while the HR criteria had a sensitivity of 98.3% (95% CI 94.9–100%) and specificity of 71.4% (95% CI 57.8–85.1%). The AAD checkbox criteria had significantly higher specificity than the HR criteria ($P=0.002$) but not significantly different sensitivity ($P=0.125$). The UK criteria had sensitivity ($P=0.375$) and specificity ($P=0.125$) that were not significantly different from the AAD checkbox criteria. The UK and HR criteria did not differ statistically in both sensitivity ($P=1.000$) and specificity ($P=0.109$) [Supplemental Table 4].

Discussion

Our analysis utilized a unique approach to evaluate the efficacy of a hierarchical set of diagnostic criteria. While the UK criteria used logistic regression to distill the important predictors from a large list of criteria, our study examined combinations of predictors that were ranked by order of importance. Our analysis demonstrated that ≥3 “Essential,” ≥2 “Important,” ≥1 “Associated” criteria (E3I2A1) from the AAD consensus criteria are optimal for diagnosing AD in pediatric patients from 3 months to 18 years old—coined the “3-2-1 rule.” To our knowledge, this is the only conversion of the AAD consensus criteria into a checkbox format and the only validation study of these criteria. While inter-observer validation is required, it is our hope that the check box criteria will be useful for both pediatric and non-pediatric dermatologists in the clinical setting.

In our analysis, the AAD checkbox criteria had superior specificity over the HR criteria ($P=0.002$), an important factor in clinical trials and practice, where the incorrect labeling of a diagnosis of AD may have negative consequences. However, in epidemiologic and

prevalence studies, sensitivity may be more important than specificity. The UK criteria had similar sensitivity to the AAD checkbox criteria and does not require a physical examination for diagnosis. Therefore, in its present form, the AAD checkbox criteria cannot be recommended over the currently available criteria for epidemiologic and prevalence studies.

It should also be noted this study aimed to identify active AD. Accordingly, the sensitivity and specificity would likely be altered by using the AAD checkbox criteria on quiescent disease. Active AD is also important in confirming the diagnosis using the UK criteria (criteria of "visible flexural dermatitis") and the HR criteria ("typical morphology and distribution").

Limitations

Although the "gold standard" diagnosis for AD has little inter-observer variability, some variability may still be present,[17] and is a potential limitation to our study. The AAD checkbox criteria will need to be further examined for inter-observer variability and validated on a larger cohort. An additional limitation of our study is the generalizability of the study population. Although we attempted to create a demographically diverse cohort, we only had 7 non-Hispanic, African American subjects. African American patients are thought to be at an increased risk for developing AD and may have some morphologic differences than other races with less noticeable erythema on physical examination.[18] Further study of the AAD criteria in a larger, more representative cohort is needed.

Conclusions

This study represents an important step in developing, refining, and validating the AAD consensus criteria. Although further studies are required, our results indicate that having ≥3 "Essential," ≥2 "Important," ≥1 "Associated" criteria from our modified AAD consensus criteria allows a practical and very specific diagnosis of AD in pediatric patients. This may be helpful in future clinical trials and clinical practice.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

AAD criteria (includes hierarchical categories: Essential, E; Important, I; Associated, A)
American Academy of Dermatology criteria

AD
Atopic dermatitis

HR criteria
Hanifin-Rajka criteria

UK criteria
U.K. working party criteria

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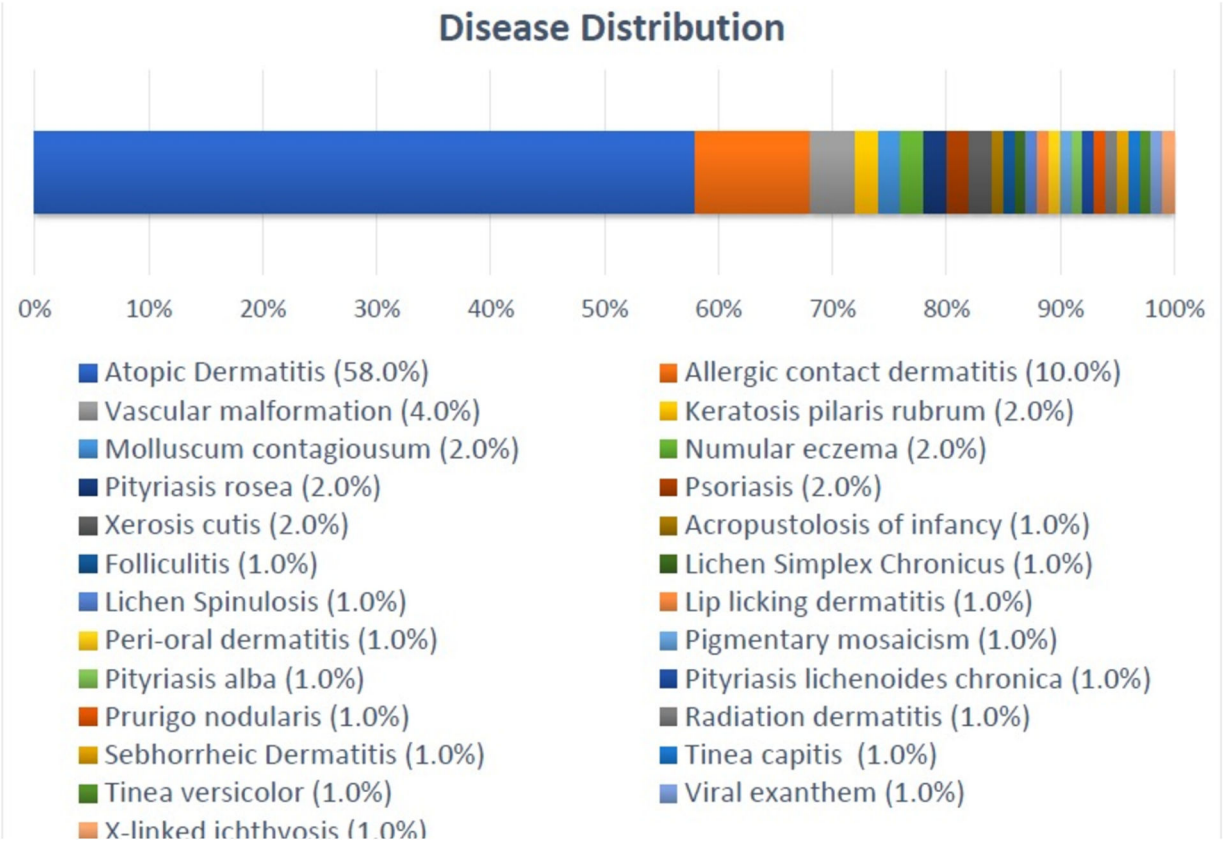

Figure 1:
Breakdown of diseases included in the study. Diseases included in the study and their percent prevalence.

Checkbox form of the AAD consensus criteria

Essential features (any 3 required)

- □ Mild to severe pruritus (or scratching/rubbing of the skin per parental report)
- □ Eczema[1] in age-specific patterns:
  - □ Bilateral Facial, midline anterior neck, or bilateral extensor involvement up to 4 years of age
  - □ Current or previous flexural lesions in any age group
- □ Rash that follows a chronic[2] or relapsing course

Important features (2 or more required)

- □ Age of onset less than 2 years of age
- □ Child or any relative with allergic rhinitis, asthma, food allergies, or atopic dermatitis
- □ Child suffering from dry skin within the last year

Associated features (1 or more required)

- □ Atypical vascular response on physical exam: Facial pallor and/or erythema without secondary surface change, white dermatographism and/or delayed blanche response, erythroderma
- □ Atypical keratinization: Keratosis pilaris, palmar hyperlinearity, ichthyosis[3], pityriasis alba
- □ Ocular changes: Periorbital darkening or lichenification, bilateral periorbital eczema, Dennie-Morgan lines under the lower eyelid
- □ Other regional findings: Bilateral periauricular eczema lesions, perioral eczema or darkening or lichenification, prurigo nodules or papules
- □ Other perifollicular abnormalities: Perifollicular accentuation, perifollicular lichenification
- □ Sparing of the groin and/or axilla

1. Patches or plaques of dermatitis composed of raised or flat poorly defined erythema with surface changes that include fine scaling, papules, vesicles, fissures, lichenification, oozing, crusting or hyperlinearity.
2. Longer than 6 months
3. Dry thickened "fish scale" skin

Figure 2:

Checkbox form of the AAD consensus criteria. Checkbox form to be used in clinical practice and research settings. The "3-2-1 rule" of ≥3 "Essential," ≥2 "Important," ≥1 "Associated" criteria is optimal for diagnosing atopic dermatitis.

Table 1:

Demographic characteristics

Characteristic	Total	AD	Control
N	100	58	42
Mean age in years (SD)	6.3 (5.4)	5.0 (5.1)	8.2 (5.4)
Male sex, % (N)	57% (57)	57.9% (33)	42.1% (24)
Race, % (N)			
Hispanic	41% (41)	37.9% (22)	45.2% (19)
White	27% (27)	24.1% (14)	31% (13)
Asian	16% (16)	24.1% (14)	4.8% (2)
Black	7% (7)	6.9% (4)	7.1% (3)
Pacific Islander	2% (2)	1.7% (1)	2.4% (1)
Other or mixed	7% (7)	5.2% (3)	9.5% (4)
Atopic Dermatitis		58%	
Other Diagnoses:			42%
Allergic Contact Dermatitis			10%
Vascular Malformation			4%
Nummular eczema			2%
Molluscum contagiousum			2%
Pityriasis rosea			2%
Xerosis cutis			2%
Keratosis pilaris rubrum			2%
Folliculitis			1%
Lichen spinulosis			1%
Peri-oral dermatitis			1%
Pityriasis alba			1%
Prurigo nodularis			1%
Sebhorrheic dermatitis			1%
Tinea versicolor			1%
X-linked ichthyosis			1%
Acropustolosis of infancy			1%
Lichen simplex chronicus			1%
Lip licking dermatitis			1%
Pigmentary mosaicism			1%
Pityriasis lichenoides chronica			1%
Tinea capitis			1%
Viral exanthem			1%

* not significant with correction for multiple comparisons

Table 2:

Diagnostic parameters of AAD consensus criteria

Statistic	Sensitivity	Specificity	Youden's J Statistic	PPV
Essential Criteria				
Pruritus	100.0%	40.5%	40.5%	69.9%
Typical AD pattern	100.0%	71.4%	71.4%	82.9%
Chronic/Relapsing course	96.6%	28.6%	25.1%	65.1%
Important Criteria				
Early age of onset	87.9%	59.5%	47.5%	75.0%
Atopy	89.7%	42.9%	71.4%	82.9%
Xerosis	94.8%	57.1%	25.1%	65.1%
Associated Criteria				
Atypical vascular response	72.4%	19.0%	−8.5%	55.3%
Atypical keratinization	67.2%	40.5%	7.7%	60.9%
Ocular changes	81.0%	42.9%	23.9%	66.2%
Other regional changes	84.5%	66.7%	51.1%	77.8%
Perifollicular changes	50%	31%	−19%	50.0%
Sparing of the groin/axilla	53.4%	42.9%	−3.7%	56.4%

PPV, positive predictive value

Table describing the diagnostic characteristics of each individual criterion in the AAD consensus criteria arranged by hierarchical criteria.

Table 3:

Sensitivity, specificity, Youden's J statistic and Positive Predictive Values for the 10 top performing criteria across all 100 subjects

Criteria	Sensitivity (95% CI)	Specificity (95% CI)	YJS (95% CI)	PPV (95% CI)
E3 I2 A1	**91.4% (84.2–98.6%)**	**95.2% (88.8–100%)**	**86.6% (79.9–93.3%)**	96.4% (91.4–100%)
E3 I2 A2	89.7% (81.8–97.5%)	95.2% (88.8–100%)	84.9% (77.9–91.9%)	96.3% (91.3–100%)
E3 I1 A1	96.6% (91.9–100%)	85.7% (75.1–96.3%)	82.3% (74.8–89.8%)	90.3% (83.0–93.1%)
E3 I1 A2	94.8% (89.1–100%)	85.7% (75.1–96.3%)	80.5% (72.8–88.3%)	90.2% (82.7–93.2%)
E3 I1 A3	81% (70.9–91.1%)	90.5% (81.6–99.4%)	71.5% (62.7–80.4%)	92.2% (84.8–97.9%)
E3 I2 A3	75.9% (64.8–86.9%)	95.2% (88.8–100%)	71.1% (62.2–80%)	95.7% (89.8–100%)
E1 I3 A1	77.6% (66.9–88.3%)	92.9% (85.1–100%)	70.4% (61.5–79.4%)	93.8% (86.9–99.7%)
E2 I3 A1	77.6% (66.9–88.3%)	92.9% (85.1–100%)	70.4% (61.5–79.4%)	93.8% (86.9–99.7%)
E3 I3 A1	74.1% (62.9–85.4%)	95.2% (88.8–100%)	69.4% (60.3–78.4%)	95.6% (89.5–100%)
E1 I3 A2	75.9% (64.8–86.9%)	92.9% (85.1–100%)	68.7% (59.6–77.8%)	93.6% (86.6–99.8%)

95% CI, 95% confidence interval; PPD, positive predictive value; YJS, Youden's J Statistic **Youden's J Statistic**