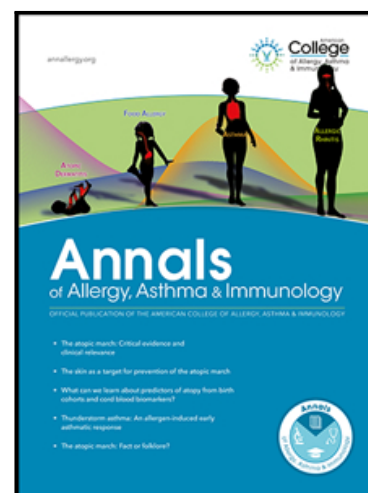


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Pilot study of the CAPS (Clinical extent, Area, Pruritus, Sleep) measure for atopic dermatitis severity.,☆☆☆,☆☆☆

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Pilot study of the CAPS (Clinical extent, Area, Pruritus, Sleep) measure for atopic dermatitis severity

CAPS pilot study

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Keywords: Eczema; atopic dermatitis; outcome measures; severity; symptoms; itch

Abbreviations: AD: atopic dermatitis; BSA: body surface area; CAPS: Clinical extent, Area, Pruritus, Sleep; DLQI: Dermatology Life Quality Index; EASI: Eczema Area and Severity Index; IGA: Investigator Global Assessment; POEM: Patient-Oriented Eczema Measure

As new treatments are developed, tested and approved for atopic dermatitis (AD), valid and practical tools are needed to assess their effectiveness in clinical trials and in routine practice. AD severity is usually assessed clinically in two different ways: physician-assessed signs of the disease and patient-reported symptoms. Commonly used outcome measures include the Eczema Area and Severity Index (EASI) for signs and Patient-Oriented Eczema Measure (POEM) for symptoms; these are recommended by the Harmonizing Measures for Eczema initiative.^{1,2} However, current measures of AD severity, particularly signs, are cumbersome and difficult to use in routine clinical practice; they are time-consuming and utilize complex scoring systems.

In order to address the need for a practical assessment of the signs and symptoms of AD in clinical trials and routine clinical practice, we have developed and pilot-tested the CAPS (Clinical extent, Area, Pruritus, Sleep) measure (Supplementary figure 1). This tool has 4 questions, each with a maximum score of 10. Two of the questions relate to clinical signs of the disease (clinician-assessed) and two are related to symptoms (patient-assessed). The signs subscale includes an assessment of (1) representative lesion severity and (2) body surface area (BSA). The representative lesion is defined as the worst lesion for that patient at that assessment, with involvement of the face, hands or genitals or the presence of impetiginization increasing the score. The symptoms subscale includes assessments of pruritus and sleep, each on visual analogue scales, which have been identified as major drivers of AD morbidity and are similar to the patient-reported component of the SCORAD.³⁻⁵ The signs and symptoms subscales are given equal weight, with each scored out of 20 for a total score out of 40.

In a pilot study to assess internal consistency and criterion validity, we administered CAPS to a convenience sample of adult AD patients in two academic dermatology practices in Providence, RI.

The study was approved by the Lifespan and Brown University IRBs. All patients met Hanifin and Rajka diagnostic criteria.⁶ CAPS was administered at the conclusion of the clinic visit along with an Investigator Global Assessment (IGA), EASI, POEM and two quality of life instruments, the Dermatology Life Quality Index (DLQI) and SKINDEX-16.⁷ We hypothesized that CAPS would positively correlate with the other outcome measures, and that the signs and symptoms subscales would correlate with other physician-reported measures and patient-reported outcomes, respectively.

We had 25 patients in our pilot study, 10 (40%) of whom were males. The median age was 34 years-old (range 20 – 75 years-of-age). Median scores and ranges for each assessment are presented in supplementary table 1. Cronbach's alphas were high for the signs (0.94) and symptoms (0.88) components and the overall score (0.93), indicating good internal consistency. Pearson correlation coefficients were all moderate-to-strong and statistically significant for the signs and symptoms components of CAPS and the overall instrument with the other outcome measures (Table 1).

Our study is limited by its small sample size and conduct at tertiary care clinics in one US state only. Larger studies in more diverse settings are necessary to replicate our findings and to assess other measurement properties of CAPS including feasibility/efficiency, responsiveness, inter- and intra-rater reliability and interpretability. Future assessments of criterion validity would benefit from other outcome measures, including the SCORAD. We did not collect data on patient race/ethnicity, which will be important for future studies given that AD appears differently in different skin types. The original CAPS used for this pilot study did not include explicit completion instructions; these have been added to the reformatted CAPS (Supplementary Figure 1b) and measurement properties of the reformatted instrument must be assessed. One may argue that a representative lesion should be

described as an average lesion, but we have interpreted it in these instructions to be the worst lesion. Additionally, CAPS does not account for all elements of the disease, including oozing, which is assessed in the SCORAD.⁴ Further, CAPS will be most efficient if it is converted to a digital format, such as a tablet. Nevertheless, CAPS has potential as an efficient, patient- and physician-friendly instrument to measure AD severity in routine clinical practice.

Acknowledgments

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Table 1. Pearson correlation coefficient matrix of the CAPS signs subscale, symptoms subscale, and overall scale with other outcome measures (n=25).

Outcome measures	CAPS		
	Signs subscale	Symptoms subscale	Overall
IGA	0.958 ($p = 5.4\text{e-}14^{***}$)	Not assessed	0.826 ($p = 3.6\text{e-}07^{***}$)
EASI	0.775 ($p = 5.5\text{e-}06^{***}$)	Not assessed	0.640 ($p = 0.00057^{***}$)
DLQI	Not assessed	0.605 ($p = 0.0014^{***}$)	0.871 ($p = 1.5\text{e-}08^{***}$)
POEM	Not assessed	0.549 ($p = 0.0045^{**}$)	0.745 ($p = 2.0\text{e-}05^{***}$)
Skindex-16	Not assessed	0.602 ($p = 0.0019^{**}$)	0.789 ($p = 4.6\text{e-}06^{***}$)

Supplementary figure 1a. Original CAPS (Clinical extent, Area, Pruritus, Sleep)
Eczema Severity Scale used by investigators in this study

Representative lesion severity

Score	Severity	Description
0	Clear	
1	Almost clear	
2	Mild	Mild erythema OR few excoriations
3	Moderate ()	Moderate erythema OR numerous excoriations OR mild lichenification
4	Severe	Prominent erythema OR thick lichenification
5	Very severe	Crusting or bleeding
Add +1: involvement of face, hands or genitals; impetiginization		

Area

Score	Body Surface Area (1% estimated by area of the palm+fingers)
0	0%
1	1-5%
2	6-10%
3	11-15%
4	16-20%
5	21+%

Patient reported outcome (B)

On the scale below, please mark where you would rate your itch over the last week?



No itch



Very itchy

On the scale below, please mark how much your sleep has been disturbed in the last week.



Sleeping great



Terrible sleep

28 Supplementary figure 1b. Reformatted CAPS (Clinical extent, Area, Pruritus, Sleep)
 29 Eczema Severity Scale to include a reverse page with scoring and completion
 30 instructions

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32 Clinician reported outcomes

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Score	Representative lesion Severity	Description
0	Clear	
1	Almost clear	
2	Mild	Mild erythema OR few excoriations
3	Moderate	Moderate erythema OR numerous excoriations OR mild lichenification
4	Severe	Prominent erythema OR thick lichenification
5	Very severe	Crusting or bleeding
Add +1: involvement of face, hands or genitals; impetiginization		

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Score	Body Surface Area (1% estimated by area of the palm+fingers)
0	0%
1	1-5%
2	6-10%
3	11-15%
4	16-20%
5	21+%

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38 Patient reported outcomes

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40 On the scale below, please mark where you would rate your itch over the last week?

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No itch



Very itchy

On the scale below, please mark how much your sleep has been disturbed in the last week.



Sleeping great



Terrible sleep

Scorer use only

Raw lesion score ____/5	Final lesion score (raw x2) ____/10 (A)
Raw area score ____/5	Final area score (raw x2) ____/10 (B)
	Itch score ____/10 (C)
	Sleep score ____/10 (D)
	Overall Signs score (A)+(B) ____/20
	Overall Symptoms score (C)+(D) ____/20
	Overall score (A)+(B)+(C)+(D) ____/40

Elaboration on the completion and scoring of CAPS

- CAPS consists of 4 questions with a maximum score of 10, 2 to be completed by the clinician and 2 by the patient
- The 2 clinician questions are summed together for a maximum Signs score of 20
- The 2 patient questions are summed together for a maximum Symptoms score of 20
- The entire assessment can be combined for a total score of 40
- The higher the score, the more severe the atopic dermatitis.

Question 1: Representative lesion severity

- The representative lesion is defined as the worst lesion for that patient at that assessment
- Crusting is defined as hemorrhagic or serous crusting
- Bleeding is defined as fresh bleeding
- Involvement of the face, hands or genitals or the presence of impetiginisation adds an additional point to this assessment; however, the maximum raw score for this question is 5 (i.e., it cannot be elevated to 6)
- The raw score for this question is multiplied by 2 to achieve the final score for this question

Question 2: Body Surface Area

- Using the surface area of a hand to estimate, select the category of body surface area involvement the patient has; this gives a raw score out of 5
- The raw score for this question is multiplied by 2 to achieve the final score for this question

Patient reported outcomes (questions 3 and 4: itch and sleep)

- The patient marks on each 10 cm visual analog scale their level of itch and sleep disturbance
- The distance from the left side of the line to the patient's mark in cm is measured and is their final score for each question

103 Supplementary Table 1. Median scores and ranges for each quality of life measure
 104 (IGA, EASI, DLQI, POEM, Skindex-16) (n=25).
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		Median	Range
Outcome measures			
CAPS	Signs	12	0 - 20
	Symptoms	11.55	2.2 - 20
	Overall	23.55	2.2 - 40
IGA		3	0 - 5
EASI		6.3	0 – 52.5
DLQI		13	0 - 24
POEM		16	2 - 27
Skindex-16		66	3 - 96

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