Severity strata for five patient-reported outcomes in adults with atopic dermatitis

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Abstract

Background—Multiple patient-reported outcomes have been used to assess the burden of atopic dermatitis (AD). Some are disease specific, e.g. the Patient Oriented Eczema Measure (POEM). While others pertain to itch, e.g. Numerical Rating Scale (NRS)-itch, ItchyQoL and 5-D itch, or dermatologic disease in general, e.g. Dermatology Life Quality Index (DLQI). Development of severity strata is essential for proper interpretability of these assessments. We sought to confirm previously developed strata for POEM, DLQI and raw ItchyQoL, and develop strata for the NRS-itch, mean ItchyQOL and 5-D itch scale for use in adults with AD.

Methods—Self-administered questionnaires were completed by 210 adults with AD in a dermatology practice setting. Strata were selected using an anchoring approach based on patient-reported disease severity.

Results—We confirmed the existing strata for POEM (mild=0–7, moderate=8–16, severe=17–28) (kappa=0.440), DLQI (mild=0–5, moderate=6–10, severe=11–30) (kappa=0.398) and NRS-itch (mild=0–3, moderate=4–6, severe=7–10) (kappa=0.499). However, the preferred band for *raw*

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ItchyQoL was mild=22–58, moderate=59–74 and severe=75–110 (kappa=0.379) and *mean* ItchyQOL was mild=1–2.9, moderate=3.0–3.9, severe=4.0–5.0 (kappa=0.374). The preferred band for 5-D itch scale was mild=0–11, moderate=12–17 and severe=18–25 (kappa=0.331).

Conclusions—Existing strata for POEM and DLQI perform well in adult AD. Previously reported strata for VAS-itch performed best for NRS-itch. We identified banding for the raw ItchyQoL for our AD population that varies slightly from the banding published for a more heterogeneous population. Finally, we proposed strata for mean ItchyQOL and 5-D itch scale in adult AD.

Keywords

atopic dermatitis; eczema; severity; patient-reported outcomes

Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease that is associated with a significant patient-burden. AD is associated with pruritus, sleep disturbance[1,2], impaired quality of life (QoL), including limitations of function and activities of daily living, poor school and work performance[3–7], and impaired mental health[8,9]. Some aspects of AD can be reliably assessed using objective assessments, accounting for the extent and severity of skin lesions[10]. However, many of the symptoms and detrimental aspects of the disease are subjective and may not be adequately reflected by investigator-derived assessments of disease severity.

Patient-reported outcomes (PRO) are becoming increasingly incorporated into clinical practice and trials in dermatology[11]. PRO are particularly useful in the assessment of the symptoms of AD. The symptoms of AD are multidimensional and not comprehensively assessed by any single PRO instrument. A variety of PRO have been used in AD, including those that measure intensity and frequency of symptoms, patient-reported signs, QoL impairment and disease control. Recently, Harmonizing Outcome Measures in Eczema (HOME), an international consensus group aimed at standardizing outcomes in clinical trials of AD, selected the Patient-Oriented Eczema Measure (POEM) as the preferred PRO of AD symptoms in clinical trials of AD[12]. However, POEM does not assess the intensity of pruritus, or quality of life (QoL) impairment secondary to AD. No QOL assessment met sufficient rigor for selection in AD, though DLQI and QoLIAD were potential candidates in adults[13].

Itch intensity is commonly assessed in clinical research and practice for AD. A recent systematic review by the HOME group found that the visual analog scale (VAS-itch) was the most commonly used PRO for itch, followed by the numerical rating scale (NRS-itch)[14]. However, another study showed there was less missing data for NRS[15] compared to VAS, and that patients preferred NRS over VAS[16].

Multiple PRO have been used to assess QoL impairment in AD, including Dermatology Life Quality Index (DLQI)[17], ItchyQOL[18,19] and 5-D itch scales[20]. The former assesses QoL across dermatologic disease, whereas the latter two assess itch-related QoL impairment.

Each of these PRO has been used in clinical research for AD and has a potential role for the assessment of AD in clinical practice. The HOME group deemed that no QOL instruments met their criteria for recommendation to be included in AD RCT,[13,21] but that the CADIS in children [21] and DLQI and QoLIAD in adults [13] have the potential to be recommended based on further validation studies.

One challenge of using these PRO is interpretability, i.e. how to interpret a given PRO score, when each PRO has a different numbers of questions, response options, and scoring systems. Severity strata or bands have been developed for some of these instruments to improve interpretability of results and help determine clinical meaningfulness[15,22–24]. Additional studies are warranted to confirm that previously proposed severity strata are reproducible in other cohorts. Further, previously reported strata for DLQI, VAS-itch and raw ItchyQOL were determined in broader cohorts of dermatologic and pruritic disease, respectively[15,22,23,25]. It is unclear how well strata developed in more heterogeneous cohorts perform in an AD-specific population. Similar strata identified in a cohort of AD patients would suggest that these strata perform well in AD. Moreover, several instruments are still lacking interpretable severity strata altogether, e.g. 5-D itch scale[20] and *mean* ItchyQOL scores[25]. Further, while severity strata for VAS-itch have been developed, no severity strata have been formally proposed for NRS-itch. There are a number of advantages of applying severity strata to outcome measures, which have recently been discussed in a recent study of AD[26]. We sought to confirm whether previously reported strata for POEM and DLQI are applicable to adults with AD. We also sought to develop interpretable severity strata for NRS-itch, mean ItchyQOL and 5-D itch scale.

Methods

Study design

We performed a prospective dermatology practice-based study of adults (18 years) with AD as defined by the Hanifin & Rajka diagnostic criteria[27]. Self-administered questionnaires were completed by patients of the eczema clinic prior to their encounter. At each encounter, questionnaires included a validated question assessing self-reported severity of AD ("Would you describe your atopic dermatitis or eczema as mild, moderate, or severe?")[28], the Patient Oriented Eczema Measure (POEM) (7 questions, range: 0–28), Dermatology Life Quality Index (DLQI) (10 questions, range: 0–30)[17], Numerical Rating Scale for average itch (NRS-itch) (1 question, range: 0–10)[15], Itchy Quality of Life (ItchyQoL) (22 questions; range for raw scores: 22–110; range for mean scores: 1.0–5.0)[18], including symptoms (6 questions; range for raw scores: 6–30; range for mean scores: 1.0–5.0), physical functioning (7 questions; range for raw scores: 7–35; range for mean scores: 1.0–5.0) and emotion (9 questions; range for raw scores: 9–45; range for mean scores: 1.0–5.0) subscores, and 5–dimensions (5-D) itch scale (5 domains, range: 5–25)[20]. Surveys were administered between January, 2014 and June, 2016. The study was approved by the institutional review boards of Northwestern University and informed consent was waived.

Data Processing and Statistical Methods

An anchor-based approach was used as recently described[26]. Briefly, the thresholds for severity strata were determined by comparing the assessments with a global assessment. POEM, DLQI, NRS-itch, raw and mean ItchyQOL and 5-D itch scores were stratified against the self-reported AD severity, which was used as the severity anchor. Missing or invalid responses occurred in <1% of subjects for any of the assessments. A detailed description of the methods can be found in the Supplemental Methods.

Results

Patient characteristics

Overall, 210 adults (ages 18–93 years) with 728 encounters were included in the study, including 131 self-reported women (62.7%) and 128 Caucasian/white (61.2%) (Table 1). The mean ± std. dev. age at enrollment was 39.8 ± 17.8 years. All subjects met the Hanifin and Rajka criteria for AD. Forty-eight subjects (22.9%) reported mild, 64 (30.5%) moderate and 98 (46.7%) severe disease upon initial encounter. POEM, DLQI, ItchyQoL and 5-D itch scale were all significantly correlated with each other, with Spearman rho statistics ranging from 0.36–0.73 (P<0.0001).

Self-reported AD severity (the anchor) was most strongly correlated to NRS-itch (Spearman correlation; rho=0.61), followed by POEM (rho=0.57), DLQI (rho=0.51), raw total ItchyQoL (rho=0.51), mean total ItchyQOL (rho=0.52), and 5-D itch scale (rho=0.28) (P 0.0005 for all). In addition, self-reported AD severity correlated most with the raw and mean symptoms subscores of ItchyQOL (rho=0.55 and 0.55), followed by functioning limitations (rho=0.50 and 0.50) and emotion (rho=0.40 and 0.41) subscores, respectively.

Strata

The distribution, mean, median and mode of self-reported AD severity for each POEM, DLQI, NRS-itch, raw and mean ItchyQoL total score and symptoms, functioning limitation and emotion subscores, and 5-D itch are presented in Supplemental Tables 1–12. An illustration of the anchor-based approach is presented in the Supplemental Results.

Based on assessment of mean, median and mode POEM values, lower thresholds of 7 or 8 were identified for moderate and 17 and 19 were identified for severe disease. In combination, four different strata were tested. Multiple strata were selected for testing for DLQI (n=16), NRS-itch (n=3), raw total ItchyQOL (n=9), mean ItchyQOL (n=6), and 5-D itch scale (n=4). Optimal severity strata for each scale are presented in Table 2.

For POEM, the first band was 0–6=mild, 7–16=moderate and 17–28=severe and had the highest k coefficient (0.443) (Supplemental Table 13). However, the second band of 0–7=mild, 8–16=moderate and 17–28=severe had an almost identical k coefficient (0.439), and was similar to the stratum previously reported for POEM[22].

For DLQI, the previously reported band[23] of 0–5=mild, 6–10=moderate and 11–30=severe had the highest k coefficient (0.398). For NRS-itch, the previously reported band (for VAS-itch[15]) of 0–3=mild, 4–6=moderate and 7–10=severe had the highest k coefficient for NRS-

itch (0.499). For 5-D itch, the band of 0–11=mild, 12–17=moderate and 18–25=severe had the highest k coefficient (0.331).

For raw total ItchyQOL, the stratum of 22–58=mild, 59–74=moderate and 75–110=severe had the highest k coefficient (0.379). The previously reported raw ItchyQoL strata[25] had a lower k coefficient (0.332). For mean ItchyQOL, the stratum with the highest k coefficient was 1–2.6=mild, 2.7–4.2=moderate and 4.3–5.0=severe. Since these thresholds are uneven and potentially difficult to remember, we also tested the stratum 1–2.9=mild, 3.0–3.9=moderate and 4.0–5.0=severe to see if there was similar concordance. In fact, this band had the highest k coefficient (0.374).(Supplemental Table 13).

Robustness of strata

Eighteen patients (3.5%) had a self-reported AD severity score >1 point outside of that predicted by the final POEM strata. There were 92 (17.7%) of patients whose severity score was 1 point higher and 116 (22.3%) with 1 point lower than the final POEM strata predicted. Fifty-nine patients (9.3%) had an AD severity score >1 point outside of that predicted by the final DLQI strata. There were 117 (18.5%) of patients whose severity score was 1 point higher and 100 (15.8%) with 1 point lower than the final DLQI strata predicted. Forty-nine patients (7.6%) had an AD severity score >1 point outside of that predicted by the final NRS-itch strata. There were 61 (9.4%) of patients whose severity score was 1 point higher and 132 (20.4%) with 1 point lower than the final NRS-itch strata predicted. Forty-three patients (8.6%) and 39 (7.8%) had AD severity scores >1 point outside of that predicted by the final total and mean ItchyQOL strata, respectively. There were 82 (16.4%) and 119 (23.8%) of patients whose severity score was 1 point higher, and 100 (20.0%) and 58 (11.6%) with 1 point lower than the final total and mean ItchyQOL strata predicted, respectively. Patients falling outside the possible strata had a similar distribution of sex, age, race/ethnicity as the overall study cohort.

Discussion

The present study determined potential severity strata for POEM and DLQI in adults with AD, which were consistent with previously reported strata[22,23]. In addition, we found potential severity strata for NRS-itch that were very similar to previously reported strata for VAS-itch[15]. Severity strata for DLQI and VAS-itch were previously determined in broad cohorts, including multiple disorders, and found similar potential strata [15,23]. The potential strata identified in this study were categorized as mild, moderate and severe. This is a notable difference from the previously reported strata, which also included categories for clear or almost clear, and very severe. This was an a priori decision based on preliminary feedback from participant stakeholders that these categories were less meaningful to patients[26]. Another noteworthy difference of this study is that the anchoring question used in the study was worded differently than those used in prior studies. Despite these subtle differences, the optimal severity strata observed in the present study for POEM, DLQI and NRS-itch align almost perfectly with those previously reported. Together, the present study confirms that these strata are indeed optimal for adults with AD.

In addition, we found potential severity strata for the raw ItchyQOL score. This banding scheme performed better in our cohort of adult AD than strata determined using anchors from the Global Itch Severity Questionnaire (GISQ) (scale of 0–10 for itch severity) in 54 US veterans with chronic pruritus of unspecified etiology[25]. Both banding schemes may be valid in different contexts, but the strata determined in the present study appear to be optimal for the interpretation of ItchyQOL scores in adults with AD. Further, we developed novel severity strata for the mean ItchyQOL score, which are both intuitive and applicable to the original ItchyQOL scoring approach. We also developed strata for the raw and mean symptom, functioning disturbance and emotion subscores of ItchyQOL. Finally, we developed potential severity strata for the 5-D itch scale.

An interesting observation of this study is that the banded scores for NRS-itch had the greatest concordance with patient-reported AD severity. This suggests that patients' report of AD severity is most strongly influenced by the intensity of their itch. Alternatively, more severe AD could be associated with more intense itch, potentially because it is often more widespread. The stronger correlation of patient-reported AD severity with NRS-itch than POEM in intriguing. The HOME consensus group has recently selected POEM as the preferred PRO to assess AD symptoms. The results of the present study confirm that POEM correlates fairly well with overall disease severity. However, they also suggest that NRS-itch correlates with AD severity as well or perhaps even better than POEM in some populations. NRS-itch, as a single question instrument, is shorter, simpler, and more feasible than virtually any of the currently available PRO for AD symptoms. While the NRS has been well validated for rating pruritus [16,29], it is possible that a multi-item instrument, e.g. POEM, may be more reliable than NRS-itch. POEM has been well validated and shown to demonstrate construct validity, convergent validity, divergent validity, internal consistency, sensitivity to change, and test-retest reliability[30,31]. POEM was chosen by the HOME group at the fourth international consensus meeting as the preferred core instrument to assess patient-reported symptoms in future AD trials [32,33]. We concur with this recommendation, and suggest that NRS-itch is an additional assessment to consider for the symptoms in AD.

The concordance of self-reported AD severity with POEM, NRS-itch, DLQI, ItchyQOL and 5-D itch scale were all modest at best. This underscores the heterogeneity of AD and its multidimensional impact on patients, including disturbances of function, activities of daily living, sleep, and emotional well-being. Each of these instruments assesses different aspects of these disturbances, with only partial overlap. Thus, each instrument has its merits and no one instrument can replace the others. Selection of an instrument in clinical practice or trials will depend on feasibility and specific domains to be probed.

This study has several strengths, including large sample size, and good representation across gender, race/ethnicity and AD severity. However, there are some limitations of this study. The study cohort was recruited from a single academic center, which may limit generalizability. However, the remarkable consistency between potential strata for POEM, DLQI and NRS-itch identified in our cohort and previous cohorts is reassuring that this is not a major issue. This suggests that the results from our cohort are generalizable to the broader population of AD patients. Despite their common use in clinical trials and research of AD, there are limited data available for ItchyQOL, NRS-itch, and 5-D itch in AD patients.

We studied the interpretability of these PRO because of their commonality and potential utility in AD. Nevertheless, future studies are needed to elaborate on the measurement properties of these assessments in AD.

In conclusion, the present study confirmed that previously determined severity strata for POEM and DLQI are optimal in adults with AD. We also found that previously reported strata for VAS-itch were optimal for NRS-itch. Moreover, we found a different banding scheme for raw ItchyQOL to be optimal in adult AD, and developed novel strata for mean ItchyQOL and 5-D itch scale. We recommend these strata be used in clinical practice and/or research studies of adult AD. These strata can be used to improve interpretation of clinical and research data using these instruments.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Abbreviations used

AD	atopic dermatitis
POEM	Patient Oriented Eczema Measure
NRS	Numeric Rating Scale
DLQI	Dermatology Life Quality Index

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What's already known about this topic?

- Severity strata were previously developed for POEM, DLQI and total ItchyQOL, but lack confirmation in atopic dermatitis.

- Mean ItchyQOL, NRS-itch, and 5-D itch scales currently do not have accepted severity strata.

What does this study add?

- The present study confirmed that previously developed severity strata for POEM and DLQI perform well in adults with AD.

- We also developed novel severity strata for NRS-itch, mean ItchyQoL and 5-D itch scales.

Table 1

Subject characteristics.

Variable	Value
Age – mean ± std. dev.	39.8 ± 17.8
Female sex – freq (%)	131 (62.7%)
Race/ethnicity – freq (%)	
Caucasian/white	128 (61.2%)
African-American/black	28 (13.4%)
Hispanic	9 (4.3%)
Asian	42 (20.1%)
Multiracial/other	2 (1.0%)

Table 2

Concordance of final proposed severity strata with self-reported AD severity.

Scale	Self-reported AD severity			κ-coefficient
	Mild	Moderate	Severe	
POEM	0–7	8–16	17–28	0.440
DLQI	0–5	6–10	11–30	0.398
NRS-itch	0–3	4–6	7–10	0.499
Raw ItchyQOL				
Total	22–58	59–74	75–110	0.379
Symptoms	6–18	19–21	22–30	0.433
Functioning	6–18	19–27	28–35	0.413
Emotion	7–26	27–33	34–45	0.327
Mean ItchyQOL				
Total	1–2.9	3.0–3.9	4.0–5.0	0.374
Symptoms	1–2.9	3.0–3.9	4.0–5.0	0.402
Functioning	1–2.6	2.7–3.9	4.0–5.0	0.413
Emotion	1–2.9	3.0–3.9	4.0–5.0	0.314
5-D itch	0–11	12–17	18–25	0.331