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Reliability and meaningful change of the Patient-Reported Outcomes Measurement Information System Itch Questionnaire® (PIQ) Item-Banks in adults with atopic dermatitis.

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To the editor:

Itch is the most burdensome symptom in AD[1]. The Patient-Reported Outcomes Measurement Information System® Itch Questionnaire (PIQ), includes a suite of patient-reported outcome measures to assess the burden of itch in adults[2]. Scores are reported using a T-score metric ranging from 32.7-79.1 for item-bank (IB)-1, 26.9-77.4 for IB-2, 32.6-77.1 for IB-3, and 32.6-72.7 for IB-4, respectively. A T-score of 50 is the average score for people in the United States general population who recently experienced chronic itch[2]. PIQ item-banks were studied in AD patients and had good content, construct and cross-cultural validity, internal consistency and feasibility in clinical practice[3]. In this study, we sought to determine the smallest detectable change (SDC), threshold for meaningful improvement and test-retest reliability of PIQ IBs for assessing the burden of itch in adult AD.

A prospective, dermatology practice-based study of adults (≥18 years) was performed between 06/2017-04/2019 as previously described[3]. Self-administered questionnaires were completed by patients, including PIQ 8-item and abridged 4-item short forms (SFs) for IB-1 (itch interference), IB-2 (mood and sleep) and IB-3 (clothing and physical activity), and 5-item SF for IB-4 (scratching behavior)[2]. The study was approved by the institutional review board of Northwestern University. Informed consent was obtained electronically.

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An anchor-based approach was used to determine the threshold for minimal important change (MIC) at follow-up from baseline. Thresholds were determined by comparing the change of PIQ IB scores with 1-point improvement of patient-reported global AD severity (0=clear/1=almost clear/2=mild/3=moderate/4=severe) and Verbal Rating Scale (VRS) for worst-itch (0=none/1=mild/2=moderate/3=severe/4=very severe)[4]. The SDC, i.e. the smallest change that can be detected above measurement error, was determined in patients with unchanged patient-reported global AD severity or VRS worst-itch scores at follow-up using: 1.96 * √2 * standard error of measurement.

Test-retest reliability was assessed by intraclass correlation coefficient (ICC) and 95% confidence intervals (CI95), using a mixed-effects model among patients with no change of patient-reported global AD severity between the baseline and follow-up visits (ICC<0.50=poor/0.50–0.74=moderate/0.75–0.89=good/≥0.90=excellent)[5]. Statistical analyses were performed in SAS v9.4.3 (SAS Institute, Cary, IN). Complete case analysis was performed.

Overall, 351 adults (ages 18-97 years) with AD, including 233 females (66.6%), and 210 whites (59.8%), with a mean±st4andard deviation age at enrollment was 45.7±17.4 years, across a range of AD severities as rated by clinician-assessed investigator's global assessment (clear=4.4%; almost clear=9.0%; mild=28.0%; moderate=37.0%; severe=21.6%).

The SDC for raw/T-scores were similar based on no change of patient-reported global AD severity (n=164; IB-1: 1.2/2.2, IB-2: 2.1/2.7, IB-3: 1.3/1.8, IB-4: 1.4/2.7) or VRS worst-itch (n=123; IB-1: 0.9/1.6, IB-2: 1.3/2.0, IB-3: 1.7/2.3, IB-4: 0.8/2.4). MIC thresholds for IB1-4 SF8 raw/T-scores were similar based on an anchor of ≥1 point improvement of patient-reported global severity (n=102; IB-1: −1.4/−2.4; IB-2: −2.7/−3.7; IB-3: −1.6/−2.0; IB-4: −1.8/−3.7) or VRS worst-itch (n=73; −1.2/−2.2, −4.0/−4.8, −2.9/−3.6, −1.9/−3.4). All MIC thresholds were greater than their respective SDC, indicating the MIC are meaningful and able to be measured beyond measurement error.

In 164 cases with no change in self-reported global AD severity, the ICC [CI95] for the SF8 T-scores for IB-1 was 0.74 [0.61-0.82], IB-2 was 0.79 [0.68-0.86], IB-3 was 0.74 [0.62-0.82]. The ICC [CI95] were slightly lower for the SF4 (IB-1: 0.66 [0.50-0.78]; IB-2: 0.77 [0.65-0.85]; IB-3: 0.70 [0.65-0.79]). The ICC [CI95] for the SF5 T-score for IB-4 was 0.63 [0.45-0.76]. The results indicate moderate-good test-retest reliability of the PIQ item-banks. Reliability of an outcome is important so that we get the same answer every time an instrument is used in the same conditions.

This study has several strengths, including large sample size, use of multiple anchors for MIC. There are some limitations. Patients were recruited from a single academic center, which may limit generalizability to a more severe dermatology referred population.

In conclusion, PIQ SFs have acceptable test-retest reliability and we identified MIC thresholds (2-4 point T-score changes) in this referral population. These instruments may be incorporated into the assessment of adults with AD and chronic itch in clinical trials and practice.

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