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Measurement properties of three assessments of burden used in atopic dermatitis in adults

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Abstract

Background: Standardized quality of life (QOL) assessments can provide important and clinically relevant information. There is currently a lack of standardization in QOL assessments used in AD. We sought to determine the content validity, construct validity, internal consistency, differential reporting, responsiveness, floor or ceiling effects, and feasibility of Dermatology Life Quality Index (DLQI), ItchyQOL and 5-dimensions (5-D) itch scales for assessing burden of AD in adults and compare their performance.

Methods: Self-administered questionnaires and skin-examination were performed in 340 adults with AD in a dermatology practice setting.

Results: DLQI, ItchyQOL and 5-D all had good content validity. DLQI, mean ItchyQOL and 5-D itch all had strong correlations with frequency of AD symptoms (POEM), intensity of itch (NRS-itch), and moderate correlations with AD severity (EASI and SCORAD) (Spearman correlations, $P<0.0001$ for all). DLQI and 5-D itch showed good internal consistency (Cronbach's alpha: 0.88 and 0.82), though ItchyQOL appeared to have several redundant items (alpha=0.96).

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Uniform and non-uniform differential item functioning by age, sex and/or race/ethnicity was found for multiple items in DLQI, ItchyQOL and 5-D itch. DLQI, ItchyQOL and 5-D itch scores all demonstrated responsiveness, though ItchyQOL demonstrated the greatest responsiveness. There were no floor or ceiling effects for total scores. The median time to completion of DLQI, ItchyQOL and 5-D itch was 2 minutes.

Conclusions: DLQI, ItchyQOL and 5-D itch scales all showed good content and construct validity, and responsiveness in the assessment of AD in adults, and were feasible for use in clinical trials and practice.

Keywords

atopic dermatitis; eczema; severity; patient-reported outcomes; quality of life; burden

Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease that is associated with a significant patient-burden and quality of life (QOL)-impact. Patient-burden of AD is related to the complex overlap of AD signs and symptoms, and cannot be merely assessed by disease activity and intensity of itch alone[1]. Current dermatology guidelines for AD[2] and an international consensus of AD experts[3] recommend that QOL assessment should be included into therapeutic decision-making among other considerations in AD, e.g. before commencing systemic therapy[3]. Standardized QOL assessments can provide important and potentially clinically relevant information.

There is a lack of standardization in the assessment of patient-burden in AD, with different scales used to assess AD signs, symptoms and QOL-impact[4–11]. The Harmonizing Outcome Measures for Eczema (HOME) international consensus group deemed that no QOL instruments met their criteria for recommendation to be included in AD RCT[9,10], but that Dermatology Life Quality Index (DLQI) and Quality of Life Index for Atopic Dermatitis (QoLIAD) were candidates in adults[9]. A major reason for the lack of consensus was the dearth of available studies assessing the performance of QOL assessments in AD. Any QOL instrument used in AD RCT should be valid, reliable, and feasible for use in AD patients[5].

There are different approaches to assess QOL impairment in AD, including AD-, symptom- and dermatology- specific assessments; each has its strengths and weaknesses. QoLIAD is an example of an AD-specific assessment, including 25 yes/no items related to impact of AD on patient-needs[12]. While QoLIAD appears to be valid for assessing AD, it cannot be used to assess QoL impairment in other disorders. This is a major limitation for uptake in clinical practice, where ideally a single assessment could be incorporated into the clinical workflow to assess multiple pruritic and/or other dermatologic disorders. DLQI[13] is a 10-item questionnaire that assesses QoL across dermatologic disease in general. DLQI is the most frequently used QOL instruments in AD studies[5,14], with established interpretability bands for severity[15], and extensive validation and use across a wide array of dermatologic disease. These are potential advantages for use in clinical practice. There are limited data supporting the validity of DLQI particularly in AD. Itchy Quality of Life (ItchyQOL)[16,17] and 5-dimensions (5-D) itch scales[18] assess QOL-impact related to itch. Itch is the most

common[19–21] and burdensome symptom in AD[22]. A previous systematic review of the patient-burden of chronic itch found considerable overlap between the associated signs and symptoms of itch in general[23] with those of AD in particular[24]. Further, patient-concerns and QOL impacts in chronic itch overlap considerably with those in AD[23,25]. While these instruments are not specific to AD, they capture much of its disease burden. These assessments have been used in AD trials, though less frequently than DLQI[5,14]. They may have utility for assessing AD and other pruritic disorders in clinical practice. These assessments were not validated in AD *per se*, thus were not even considered by the HOME group owing to a lack of existing validation studies. In this study, we sought to determine the content validity, construct validity, internal consistency, differential item functioning, responsiveness, floor or ceiling effects, and feasibility of DLQI, ItchyQOL and 5-D itch scales for assessing AD in adults and compare their performance.

Methods

Study design

We performed a prospective, dermatology practice-based study of adults (≥18 years), male or female, with AD as defined by the Hanifin & Rajka diagnostic criteria[24]. Self-administered questionnaires were completed by patients of the eczema clinic at an academic medical center prior to their encounter. Exclusion criteria included those without a definite diagnosis of AD and being unwilling or unable to complete the assessments. Virtually all (>99%) patients who were invited agreed to participate. Patients received standard of care follow-up and treatment, including emollients, prescription topical, systemic and/or phototherapy, where appropriate.

At each encounter, questionnaires included the Patient Oriented Eczema Measure (POEM) (7 questions, range: 0–28)[26], DLQI (10 questions, range: 0–30)[13], Numerical Rating Scale for average itch (NRS-itch) in the past 3 days (1 question, range: 0–10)[27], ItchyQoL (22 questions; range for mean scores: 1.0–5.0)[16], and/or 5-D itch scale (5 domains, range: 5–25)[18]. Content validity was assessed in the first 50 patients with an additional 2 questions asked after each survey: “Did this questionnaire address the issues related to your eczema that are most important to you? (yes/no)”. If they answered no, they were instructed to answer “What are the most important issues to you?”. Similar open-ended questions have been used in qualitative research[28].

Patients were assessed with full body skin examination by a dermatologist (JS), EASI (4 signs [erythema, excoriation, swelling, lichenification] on 4 body sites, range: 0–72)[29] and Scoring AD (SCORAD; 6 signs [erythema, excoriation, swelling, oozing/crusting, lichenification, dryness] on 8 body sites, pruritus and sleeplessness; range: 0–103)[30]. Surveys were administered between January, 2014 and June, 2017. The study was approved by the institutional review boards of Northwestern University and informed consent was obtained electronically.

Statistical analysis

Wilcoxon rank sum test was used to determine if there were group differences of DLQI, ItchyQOL or 5-D itch by age (quartiles) or sex (m/f). To address potential confounding effects of AD severity, multivariable log-linear models were constructed with DLQI, ItchyQOL or 5-D itch as the dependent variable and age, sex, EASI, NRS-itch and POEM as the independent variables.

Convergent and discriminant construct validity of DLQI, ItchyQOL and 5-D itch were established using Spearman correlations and Wilcoxon rank sum tests, respectively. Internal consistency was determined using Cronbach's alpha and Spearman correlation between individual questions. Differential item functioning was assessed by sex, age and race/ethnicity (Supplemental methods). Responsiveness of scores was determined using Cohen's D between the first and follow-up visit among those with a ≥1 and ≥3.4-point improvement or worsening of POEM scores based on previous studies showing the MCID be 3.4[31]. Floor or ceiling effects of total scores and individual items were considered present if 15% of responses fell in the lowest or highest scores[32,33]. Feasibility was examined by survey completion rates and time to completion. All statistical analyses were performed in SAS version 9.4.3 (SAS Institute, Cary, IN). A two-sided P-value of 0.05 was taken to indicate statistical significance.

Results

Patient characteristics

Overall, 340 adults (ages 18–93 years) with 1216 encounters were included in the study, including 229 self-reported women (67.4%), 220 Caucasian/white (64.7%), with a mean ±std. dev. age at enrollment of 42.8±16.5 years. Group differences of DLQI, ItchyQOL and 5-D itch by age, sex and race/ethnicity are presented in the Supplemental Results.

Content validity

Most patients reported that DLQI, ItchyQOL and 5-D itch addressed the issues related to their AD that were most important to them (92%, 96% and 88%, respectively). Sleep disturbances were the most important issues in the 4 patients who reported that DLQI did not assess their most important issues. Some reported that skin pain (n=2) and impaired physical activity or exercise (n=2) were most important to them and not reflected in ItchyQOL and/or 5-D.

Some reported that items from DLQI related to impact on sexual activity (n=5) and sports (n=5) were not important to them because of their baseline characteristics, i.e. they don't regularly play sports or are not sexually active. None reported that the items assessed in DLQI, ItchyQOL or 5-D, were conceptually irrelevant to AD.

Construct validity

Regarding convergent validity, DLQI, mean ItchyQOL and 5-D itch had strong correlations with each other, POEM, and NRS-itch, and moderate correlations with EASI and SCORAD

(Spearman correlations, P<0.0001) (Table 1). 5-D itch had the strongest correlations with these assessments.

Regarding discriminative validity, there were significant and stepwise increases of DLQI, ItchyQOL and 5-D itch scores at each level of severity for POEM, NRS-itch, EASI and SCORAD (Wilcoxon rank sum test, P<0.0001) (Supplemental Figure 2).

Internal consistency

Both DLQI and 5-D itch showed good internal consistency (Cronbach's alpha: 0.89, and 0.84, respectively). For DLQI, all items showed fair to moderate correlations with each other (rho: 0.28–0.60) (Supplemental Table 1). For 5-D itch, most items the items showed fair to moderate correlations with each other (rho: 0.27–0.76) (Supplemental Table 2).

ItchyQOL had a very high Cronbach's alpha score (0.96), suggesting there are redundant items. In particular, the items "my skin hurts…" and "my skin burns…" showed strong correlations (rho=0.84), as well as "I am embarrassed by…", "I worry about what other people think about me…", and "I feel self-conscious" (rho=0.81–0.85) (Supplemental Table 3).

Differential item functioning

Significant uniform and non-uniform DIF by gender, age and race/ethnicity were found in logistic regression and/or IRT approaches for multiple items from DLQI, ItchyQOL and 5-D itch (Table 3).

Responsiveness

Overall, DLQI, ItchyQOL and 5-D itch scores, changed significantly between baseline and the next visit (Table 4). ItchyQOL demonstrated the greatest responsiveness among patients with ≥1-point and ≥3.4-point improvement and ≥1-point worsening of POEM. DLQI was the least responsive among patients with ≥1-point and ≥3.4-point improvement of POEM and most responsive in those with ≥3.4-point worsening of POEM.

Floor or ceiling effects

The proportions of patients with lowest and highest values for DLQI (8.2% or 0.7%), ItchyQOL (2.2% or 1.2%) or 5-D itch (4.3% or 0.3%) were below 15%, indicating there were no floor or ceiling effects overall. However, >15% of patients reported the lowest value (not relevant/not at all) for individual DLQI-items 2, 3, 4, 5, 6, 7A, 7B, 8, 9 and 10, and highest value (very much) for DLQI-items 1, 2 and 4 (Supplemental Table 4). In addition, >15% of patients reported the lowest value (never) for ItchyQOL-items 1, 4, 9, 17, 18, 19 and 22 and highest value (all of the time) for items 2, 3, 4, 5, 6, 7, 8, 10, 12, 13, 14, 15, 16, 17, 19, 20 and 21 (Supplemental Table 5). Finally, >15% of patients reported the lowest values for 5-D-items 1, 4A, 4B, 4C, 4D, and 5 and highest values for 5-D-items 1 and 3 (Supplemental Table 6).

Feasibility

DLQI, ItchyQOL and 5-D itch were completed by 98.4%, 92.2%, and 98.4%, respectively of subjects. Survey length / high number of items accounted for virtually all incomplete surveys. Among completed surveys, the median time to completion of DLQI, ItchyQOL and 5-D itch was 2 minutes, with maximum times of completion being 15, 5 and 9 minutes, respectively. Only 4.4%, and 4.3% of subjects took longer than 5 minutes to complete the DLQI and 5-D itch, respectively.

Discussion

This study demonstrated that DLQI, ItchyQOL and 5-D itch had overall good content validity, convergent validity, discriminative validity for severe vs. moderate vs. mild AD, good responsiveness, and similar amounts of time for completion in the assessment of AD, with no observed floor or ceiling effects for total scores. All 3 instruments had multiple items that suffered from DIF by age, sex and race/ethnicity. Items with DIF may perform differently across various demographic subgroups. If these results are confirmed by future multicenter studies, then scores for these different patient groups should neither be combined nor compared during analysis of clinical trials or research studies. Each instrument had distinct advantages and/or disadvantages. 5-D showed the strongest correlation with objective and PRO assessments of AD. ItchyQOL demonstrated the greatest responsiveness, but also appeared to have redundant items. DLQI has a feasibility advantage over ItchyQOL and 5-D itch, as it can be used across all dermatologic disease. Together, the results of the present study suggest that DLQI, ItchyQOL and 5-D itch all are imperfect, but have sufficient validity and feasibility to be used as assessments of burden in AD.

These results are consistent with previous findings of good internal consistency for DLQI in AD patients (Chronbach's alpha 0.83)[34]. DLQI had strong correlations with the SCORAD assessment in AD patients[35], moderate correlations with multiple Short-Form 36 domains and the objective-SCORAD[36], moderate inverse correlations with the Patient Generated Index[37], but only low-moderate correlations with the Nottingham Health Profile domains (spearman correlation coefficients ranged from 0.12–0.32)[34]. Other studies showed strong internal consistency, good reliability, and responsiveness in cohorts that included AD patients, but did not specifically examine the measurement properties in AD patients by themselves[38,39]. Two studies found differences of DLQI scores in AD by gender[40,41]. We found significantly higher DLQI and ItchyQOL scores in females, but lower DLQI scores with age. It is unclear if these are true gender differences or artefacts of DIF observed for many DLQI and ItchyQOL items. DLQI was also found to be sensitive to change with large effect-sizes[34,36].

ItchyQOL previously demonstrated construct validity, internal consistency and responsiveness in a mixed cohort of patients with AD and other pruritic disorders[16]. 5-D itch scale demonstrated convergent validity, test-retest reliability, and sensitivity to change in a mixed cohort of patients with pruritic disorders[18]. While none of these instruments assesses the burden of AD *per se*, they include concepts that are highly relevant to the patient-burden of AD. The attributions of QOL impact to "your skin" in DLQI and "my itchy skin condition" in ItchyQOL are sufficiently broad to reflect all aspects of AD. Feedback from

multiple AD patients revealed that they interpreted DLQI and ItchyQOL questions to refer to AD and all its sequelae, and not just skin or itch *per se*. In contrast, 5-D itch specifically assesses the dimensions of itch *per se*. While the patient-burden of AD may be attributable to the multiple signs and symptoms, previous studies found that itch is the most burdensome symptom[22]. Thus, there may be face validity for using a multi-dimensional assessment of itch, e.g. 5-D itch, in AD patients.

A previous study suggested that multiple questions from DLQI may be irrelevant to AD based on weak correlations with Patient Generated Index, another PRO[37]. We found that a number of items had floor effects and/or were considered not relevant to individual patients. Floor or ceiling effects were most commonly observed among items from DLQI and least from 5-D itch items. These phenomena were attributable to patient baseline characteristics and not to lack of conceptual validity in AD. Most patients reported that all three PRO assessed the most important issues related to their AD. Though, sleep disturbance, skin pain and/or physical activity were not addressed in at least one assessment. Taken together, it appears that all three of these instruments are sufficiently valid and appropriate for assessment of the patient-burden of AD.

All three instruments were time-efficient and may be integrated into day-to-day practice. The median time to completion was 2 minutes, with most or all completed in ≤5 minutes. In order to be “acceptable” or “adequate” for use in clinical practice, a severity score should not take longer than 3 or 3–5 minutes, respectively[42]. Previous studies found that DLQI and 5-D itch take 1–3 and <5 minutes to complete, respectively[43,18]. All three assessments would be “acceptable” and “adequate” for clinical practice. In contrast, previous studies found that SCORAD and EASI, objective assessments of AD used in clinical trials, took 3[44]-10[30] and 2[45]-6[46] minutes to perform, respectively. Completion-time for untrained dermatologists was >3 minutes[30,47,48]. Reliability and completion-time of these assessments is user-dependent and varies based on experience and training. DLQI, ItchyQOL and 5-D itch may be more “acceptable” and “adequate” in clinical practice than EASI and SCORAD. EASI and SCORAD, as well as POEM, provide important information about AD severity, with entirely different constructs than QOL. Thus, DLQI, ItchyQOL and 5-D itch can be used in clinical practice by themselves or in conjunction with POEM, EASI or SCORAD.

DLQI and 5-D itch have one-page short-forms and ItchyQOL has a three-page short-form that can be easily incorporated into clinic practice. Despite being 3 pages long, ItchyQOL had the shortest maximum completion time. However, no computerized adaptive test administration options are available. DLQI has a simple scoring approach based on the sum of responses for all 10 questions. ItchyQOL requires the sum or average of 22 items. 5-D itch has a complex scoring approach involving the sum of the duration, degree, and direction domains, maximum score for the burden domain, and number of itch body parts converted into an ordinal scale. The latter two scoring approaches may be too cumbersome for manual scoring in clinical practice. All three assessments can be implemented in an electronic health record and administered and scored fairly seamlessly.

Clinician assessments of disease severity may not align with QOL and other PRO assessments.[49] Clinician assessments may not capture the symptom burden in some clinical

encounters of AD patients. Incorporation of QOL assessments may improve therapeutic-decision making. A recent consensus statement of the International Eczema Council recommended assessing the QOL-impact of AD among other considerations before commencing systemic therapy in AD[3]. Some QOL-impacts of AD may not be well-appreciated by clinicians. A recent systematic review of QOL impairment in pruritus[23], found only partial concordance between the prioritization of symptom burden, such as functional limitations and relationship/social effects in clinical review publications vs. qualitative patient-research studies. We recommend that structured and validated QOL and/or other PRO assessments be used complementarily with clinician assessments of AD in clinical practice. We defer to the consensus of the upcoming HOME group meeting as to the preferred instrument for clinical practice.

This study has several strengths, including large sample size, and good representation across gender, race/ethnicity and AD severity. However, there are some limitations. The study cohort was recruited from a single academic center, which may limit generalizability. We did not assess test-retest reliability. We examined some elements of content validity, but there is no gold-standard approach and additional studies are warranted to address content validity of specific items and their response options[50]. We did not study the QoLIAD or other AD-specific QOL assessments as we initiated this study prior to the decision of the HOME group on QOL assessments. Future studies are needed to explore the structural validity of DLQI, ItchyQOL, 5-D itch and QoLIAD. Larger multicenter studies may be needed to explore and potentially adjust redundant items and DIF. Future studies are also needed to determine how the information provided by these QOL assessments impacts clinical decision-making.

In conclusion, this study demonstrates that DLQI, ItchyQOL and 5-D itch scales may have good content validity, construct validity, responsiveness, and feasibility in the assessment of AD, with no overall floor or ceiling effects. These instruments may be incorporated into the assessment of AD patients, as they provide important information about the burden of AD that can guide therapeutic decision-making.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations used:

AD	atopic dermatitis

POEM	Patient Oriented Eczema Measure
NRS	Numeric Rating Scale
DLQI	Dermatology Life Quality Index
5-D	5 dimensions of itch
SCORAD	SCORing Atopic Dermatitis
EASI	Eczema Area and Severity Index
PRO	Patient-reported outcomes
QOL	quality of life

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What's already known about this topic?

- DLQI, 5-D itch and ItchyQOL are quality of life assessments that have been used to assess the burden of inflammatory and/or pruritic skin disorders.
- However, conflicting and/or limited results have been demonstrated about their validity, reliability and feasibility particularly in atopic dermatitis.

What does this study add?

- This study demonstrated that DLQI, ItchyQOL and 5-D itch had good construct validity, responsiveness, and similar amounts of time for completion in the assessment of adult atopic dermatitis, with no observed floor or ceiling effects.
- DLQI, ItchyQOL and 5-D itch all appear to have sufficient validity and feasibility to be used as assessments of burden in adults with atopic dermatitis in clinical practice.

Table 1.

Subject characteristics

Variable	Value
Age – mean ± std. dev.	42.8 ± 16.5
Female sex – freq (%)	229 (67.4%)
Race/ethnicity – freq (%)	
Caucasian/white	220 (64.7%)
African-American/black	40 (11.8%)
Hispanic	18 (5.3%)
Asian	56 (16.5%)
Multiracial/other	6 (1.8%)
POEM – median (min, max)	9 (0, 27)
NRS-itch – median (min, max)	6 (0, 10)
EASI – median (min, max)	6.45 (0, 66.7)
SCORAD – median (min, max)	35.3 (0, 103)
DLQI – median (min, max)	6 (0, 30)
Mean Itchyqol – median (min, max)	2.9 (1, 5)
5-D itch – median (min, max)	12 (5, 23)

Table 2.

Spearman correlation of DLQI, ItchyQol and 5-D with each other, atopic dermatitis symptoms and severity.

QOL assessment	Spearman rho					
	POEM	NRS-itch	EASI	SCORAD	Mean ItchyQOL*	5-D itch
DLQI	0.61*	0.59*	0.44*	0.55*	0.79*	0.77*
Mean ItchyQOL	0.69*	0.66*	0.45*	0.57*	1.00	0.77*
5-D itch	0.74*	0.70*	0.46*	0.62*		1.00

*Mean ItchyQOL is the mean score across all responses to items.

*$P<0.0001$

Table 3.

Differential Item Functioning (DIF) by sex and race/ethnicity of items in DLQI, ItchyQOL and 5-D itch.

Assessment	Item	DIF by sex			DIF by race/ethnicity			DIF by age		
		Regression approach		IRT approach	Regression approach		IRT approach	Regression approach		IRT approach
		Uniform DIF	Non-uniform DIF	Uniform DIF	Uniform DIF	Non-uniform DIF	Uniform DIF	Uniform DIF	Non-uniform DIF	Uniform DIF
DLQI	Q1	P=0.16	**P=0.003**	P=0.16	P=0.23	P=0.20	**P=0.02**	P=0.12	P=0.24	P=0.30
	Q2	**P=0.02**	**P=0.005**	**P=0.01**	P=0.42	**P=0.004**	**P=0.0002**	**P=0.007**	**P=0.002**	**P<0.0001**
	Q3	P=0.19	**P=0.001**	P=0.56	P=0.27	P=0.98	P=0.05	P=0.53	**P=0.02**	P=0.17
	Q4	P=0.69	**P<0.0001**	**P=0.0007**	P=0.72	P=0.74	P=0.89	P=0.44	P=0.16	P=0.10
	Q5	P=0.65	**P=0.004**	P=0.99	P=0.89	P=0.31	**P=0.007**	P=0.32	P=0.17	P=0.09
	Q6	P=0.84	**P=0.0005**	P=0.72	P=0.91	P=0.09	P=0.97	P=0.45	P=0.82	P=0.46
	Q7A	P=0.18	**P<0.0001**	P=0.69	P=0.37	P=0.34	**P<0.0001**	P=0.81	**P=0.008**	**P=0.03**
	Q7B	P=0.67	P=0.97	P=0.64	P=0.11	P=0.38	**P=0.0003**	**P<0.0001**	P=0.26	**P<0.0001**
	Q8	P=0.39	P=0.39	P=0.36	P=0.13	P=0.51	P=0.44	P=0.26	P=0.92	P=0.18
	Q9	**P=0.004**	**P=0.001**	**P=0.01**	P=0.22	P=0.35	P=0.46	P=0.42	P=0.10	P=0.75
	Q10	P=0.24	**P=0.02**	Reference	**P=0.004**	P=0.74	Reference	P=0.27	P=0.15	Reference
ItchyQOL	Q1	P=0.08	P=0.07	P=0.79	**P=0.01**	**P=0.02**	P=0.63	P=0.20	**P<0.0001**	**P=0.002**
	Q2	P=0.99	**P<0.0001**	P=0.68	P=0.77	P=0.12	P=0.46	P=0.55	**P=0.0001**	**P=0.005**
	Q3	P=0.93	**P<0.0001**	P=0.62	P=0.68	P=0.24	**P=0.047**	P=0.53	**P<0.0001**	**P=0.01**
	Q4	P=0.94	**P=0.02**	P=0.70	P=0.20	**P=0.04**	**P<0.0001**	P=0.08	P=0.31	P=0.65
	Q5	P=0.12	**P<0.0001**	P=0.75	**P<0.0001**	**P=0.02**	**P<0.0001**	P=0.23	**P=0.02**	**P=0.001**
	Q6	P=0.91	**P<0.0001**	P=0.21	P=0.90	P=0.99	**P=0.01**	P=0.19	**P=0.03**	**P=0.006**
	Q7	P=0.68	P=0.56	P=0.49	P=0.79	**P=0.02**	**P=0.004**	P=0.97	**P=0.002**	**P=0.005**
	Q8	**P=0.008**	**P=0.004**	P=0.24	P=0.30	P=0.73	P=0.05	P=0.46	**P=0.0004**	**P=0.003**
	Q9	**P=0.009**	P=0.32	P=0.21	**P=0.047**	P=0.63	P=0.56	P=0.24	**P=0.003**	**P=0.007**
	Q10	**P=0.01**	P=0.24	P=0.09	P=0.64	P=0.40	**P=0.02**	P=0.88	**P=0.04**	P=0.88
	Q11	**P=0.001**	P=0.64	P=0.09	P=0.97	P=0.99	P=0.07	P=0.57	P=0.10	**P=0.04**
	Q12	P=0.99	**P<0.0001**	**P=0.003**	P=0.76	P=0.49	P=0.06	P=0.93	**P=0.002**	P=0.10
	Q13	P=0.49	P=0.90	P=0.81	**P=0.009**	**P=0.01**	P=0.52	P=0.11	P=0.05	**P=0.0007**
	Q14	P=0.12	**P<0.0001**	P=0.52	P=0.22	P=0.39	**P=0.039**	**P=0.01**	P=0.10	P=0.52
	Q15	P=0.32	**P<0.0001**	P=0.89	P=0.91	P=0.10	**P=0.0001**	P=0.17	**P=0.002**	**P=0.04**

Assessment	Item	DIF by sex			DIF by race/ethnicity			DIF by age		
		Regression approach		IRT approach	Regression approach		IRT approach	Regression approach		IRT approach
		Uniform DIF	Non-uniform DIF	Uniform DIF	Uniform DIF	Non-uniform DIF	Uniform DIF	Uniform DIF	Non-uniform DIF	Uniform DIF
5-D itch	**Q16**	P=0.38	**P<0.0001**	P=0.29	P=0.18	P=0.52	**P=0.03**	P=0.56	P=0.30	P=0.64
	Q17	**P=0.04**	**P<0.0001**	P=0.20	P=0.08	P=0.67	**P=0.01**	P=0.56	**P=0.002**	P=0.15
	Q18	P=0.20	**P<0.0001**	P=0.24	P=0.28	P=0.73	P=0.10	P=0.79	P=0.09	P=0.23
	Q19	P=0.40	**P=0.0003**	P=0.79	P=0.50	P=0.16	**P<0.0001**	P=0.51	**P<0.0001**	**P<0.0001**
	Q20	P=0.82	**P<0.0001**	**P=0.02**	P=0.09	P=0.62	P=0.06	**P=0.0002**	P=0.06	P=0.93
	Q21	**P=0.002**	**P<0.0001**	P=0.79	P=0.32	P=0.17	**P<0.0001**	P=0.44	**P=0.001**	**P=0.04**
	Q22	P=0.70	**P=0.002**	Reference	P=0.41	P=0.06	Reference	P=0.22	**P=0.047**	Reference
	Q1	P=0.42	P=0.29	P=0.40	P=0.22	P=0.89	**P=0.0002**	**P=0.02**	P=0.70	P=0.27
	Q2	P=0.55	**P<0.0001**	**P=0.046**	P=0.30	**P=0.004**	**P=0.02**	P=0.20	**P=0.0002**	P=0.59
	Q3	P=0.30	P=0.06	P=0.58	P=0.09	P=0.22	**P=0.01**	P=0.84	P=0.06	P=0.87
	Q4A	P=0.09	P=0.07	P=0.27	P=0.84	P=0.93	**P=0.003**	P=0.45	**P=0.002**	P=0.46
	Q4B	P=0.87	**P=0.009**	**P=0.0002**	P=0.66	P=0.32	**P<0.0001**	P=0.26	P=0.38	P=0.74
	Q4C	P=0.46	P=0.0006	**P=0.0006**	P=0.91	P=0.23	**P<0.0001**	P=0.61	P=0.64	P=0.70
	Q4D	P=0.26	**P=0.03**	P=0.07	P=0.93	P=0.13	P=0.07	P=0.46	P=0.07	P=0.32
	Q5	P=0.07	P=0.14	Reference	**P=0.003**	P=0.60	Reference	P=0.57	P=0.35	Reference

Table 4.

Responsiveness of DLQI, ItchyQOL, and 5-D itch in patients with changes of POEM scores at next visit.

Assessment	POEM											
	Improvement						Worsening					
	≥1-point			≥3.4-point (MCID)			≥1-point			≥3.4-point (MCID)		
	Freq	Mean Δ	Cohen's D	Freq	Mean Δ	Cohen's D	Freq	Mean Δ	Cohen's D	Freq	Mean Δ	Cohen's D
DLQI	51	−46.9%	−0.74	40	−47.7%	−0.72	32	+20.9%	+0.28	19	+54.8%	+0.65
Mean ItchyQOL	43	−30.2%	−1.26	34	−33.0%	−1.44	35	+8.8%	+0.31	23	+10.2%	+0.43
5-D itch	38	−31.6%	−1.19	29	−34.7%	−1.27	29	+8.5%	+0.27	19	+9.1%	+0.34

MCID, Minimal Clinically Important Difference. Previous studies found the MCID for POEM to be 3.4 points[31].