Psychometric properties of the Itch Numeric Rating Scale in patients with moderate-to-severe plaque psoriasis*

A.B. Kimball,1 A.N. Naegeli,2 E. Edson-Heredia,2 C.-Y. Lin,2 C. Gaich,2 E. Nikai,2 K. Wyrwich3 and G. Yosipovitch4

1Massachusetts General Hospital and Harvard Medical School, Boston, MA, U.S.A.
2Eli Lilly and Company, Indianapolis, IN, U.S.A.
3Evidera, Inc., Bethesda, MD, U.S.A.
4Temple University, Philadelphia, PA, U.S.A.

Background Itching is a profoundly distressing symptom for many patients with psoriasis, but it has not been rigorously studied using validated tools for this condition.

Objectives This study investigated the psychometric properties of the Itch Numeric Rating Scale (Itch NRS), a single-item patient-reported outcome (PRO) measuring the worst itching severity due to psoriasis in the past 24 h.

Methods Using disease-specific clinician-rated and PRO data from one phase II and three phase III randomized clinical studies of subjects with moderate-to-severe plaque psoriasis, the Itch NRS was evaluated for test–retest reliability, construct validity and responsiveness. A responder definition was explored using anchor-and distribution-based methods.

Results Test–retest reliability analyses supported the reproducibility of the measure (intraclass correlation coefficient range 0.71–0.74). To support the construct validity of the Itch NRS, large cross-sectional correlations with the Dermatology Life Quality Index (DLQI) Symptoms and Feelings domain (r ≥ 0.60 at baseline and r ≥ 0.80 at week 12) supported a priori hypotheses, while large correlations (r ≥ 0.71) between changes in Itch NRS scores and changes in DLQI Symptoms and Feelings domain scores from baseline to week 12 established responsiveness. A 4-point change was optimal for demonstrating a level of clinically meaningful improvement in itch severity after 12 weeks of treatment, which corresponds with marked clinical improvements in plaque psoriasis.

Conclusions The Itch NRS demonstrated sufficient reliability, validity and responsiveness, and appropriate interpretation standards for evaluating change over time in itch severity among patients with moderate-to-severe plaque psoriasis when validated using clinical trial data for this condition.

What’s already known about this topic?
- Itching is a profoundly distressing symptom for many patients with psoriasis, but has not been rigorously studied using validated tools for this condition.
- The Itch Numeric Rating Scale is a single-item instrument that assesses the severity of itch due to psoriasis.

What does this study add?
- The Itch Numeric Rating Scale demonstrated sufficient reliability, validity and responsiveness, and appropriate interpretation standards for evaluating change over time in itch severity among patients with moderate-to-severe plaque psoriasis.
Plaque psoriasis is a chronic skin disorder with an estimated prevalence of 2–3% worldwide.1,2 Itching is a highly prevalent3–5 and troublesome symptom6 for patients with psoriasis, and has a negative impact upon patients’ health-related quality of life.3,5,7–11 Patients with psoriasis report that itching is their most important symptom compared with other symptoms, including pain and flaking.6

Despite the importance of itching to patients with psoriasis, clinician-rated primary instruments that evaluate treatment efficacy for this condition, like the Psoriasis Area and Severity Index (PASI),14,15 do not measure itch severity. The Itch Numeric Rating Scale (Itch NRS) was developed as a single-item patient-reported outcome (PRO) designed to capture the severity of a patient’s itching due to their psoriasis, and has demonstrated strong content validity.16 The objective of the current study was to evaluate the psychometric properties (reliability, validity and responsiveness) and to establish an appropriate responder definition for the Itch NRS using the wealth of disease-specific clinician-rated and PRO data in four randomized clinical trials of patients with moderate-to-severe plaque psoriasis.

Materials and methods

Patient population

Study JADP

Study JADP was a global phase II, randomized, double-blind, placebo-controlled, dose-ranging trial of baricitinib in patients with moderate-to-severe plaque psoriasis (NCT01490632). Patients were aged ≥ 18 years; had chronic plaque psoriasis for ≥ 6 months prior to entry; were candidates for systemic therapy and/or phototherapy; and had ≥ 12% body surface area (BSA) involvement, a PASI score ≥ 12 and a static Physician’s Global Assessment (sPGA) score ≥ 3 at the time of entry.

Studies RHAZ, RHBC and RHBA

With the same context of use17 as study JADP, three global ixekizumab phase III, randomized, double-blind, placebo-controlled clinical studies (RHBA and RHBC also had etanercept as a comparator) were conducted in patients with moderate-to-severe plaque psoriasis (RHAZ, NCT01474512; RHBC, NCT01646177; RHBA, NCT01597245). Patients in studies RHAZ, RHBC and RHBA had the same entry criteria as for study JADP, with the exception of BSA ≥ 10%, PASI ≥ 12 and sPGA score ≥ 3 at screening and baseline.

Study end points

For all four clinical studies, key end points that are well known and widely used in the treatment of plaque psoriasis assessed change from baseline to 12 weeks postrandomization. All clinical studies were conducted with informed consent, under institutional review board approval, and in accordance with the Declaration of Helsinki.

Instruments

Itch Numeric Rating Scale

The Itch NRS is a simple, self-administered PRO questionnaire that was administered at each clinic visit in the four clinical studies. Patients indicated itch severity by circling the integer that best described the worst level of itching due to psoriasis in the past 24 h on an 11-point scale anchored at 0, representing ‘no itching’ and 10, representing ‘worst itch imaginable’.

Dermatology Life Quality Index

The Dermatology Life Quality Index (DLQI) assesses health-related quality of life and covers six domains: Symptoms and Feelings, Daily Activities, Leisure, Work and School, Personal Relationships, and Treatment.19 Response categories for all 10 items include ‘not at all’, ‘a lot’ and ‘very much’, scored as 1, 2 and 3, respectively, with unanswered (‘not relevant’) responses scored as 0. DLQI total scores range from 0 to 30 (less to more impairment).

Other scales

Other well-described instruments used in the evaluation of the psychometric properties of the Itch NRS included (i) PASI;14,15,20 (ii) the Short Form 36 (SF-36);21 (iii) a Patient’s Global Assessment (PATGA) for ranking the severity of their psoriasis ‘today’ (0 clear, no psoriasis to 5 severe, the worst their psoriasis has ever been); and (iv) an sPGA using physician’s assessment of the patient’s overall severity of disease based on plaque elevation, scaling and erythema (0 clear to 5 very severe).

Statistical analyses

Test–retest reliability

Test–retest validity was assessed in patients with stable disease during the interval between screening (7–30 days before baseline) and baseline prior to randomization, in studies JADP and RHAZ. Stable patients were defined as those with the same sPGA ratings at screening and baseline. An intraclass correlation coefficient (ICC) was calculated between the initial and retest scores to evaluate test–retest reliability. An ICC ≥ 0.70 is considered acceptable.22 In studies RHBA and RHBC, Itch NRS data were collected only once prior to randomization/treatment initiation; therefore, test–retest reliability was not examined.

Convergent and discriminant validity

Convergent validity was assessed by Pearson correlations at baseline and week 12 between scores of the Itch NRS and the
Responsive was evaluated by correlating calculated changes from baseline to week 12 in scores on the Itch NRS with changes in the DLQI Symptoms and Feelings domain and PATGA scores. Large correlations were hypothesized based on Cohen’s conventions. Additionally, responsiveness was evaluated using one-way ANOVA for overall and paired comparisons, with Scheffé’s correction-based post hoc tests in distinguishing between subgroups defined on the basis of PASI scores at week 12: (i) PASI improved ≥ 75%; (ii) PASI improved ≥ 50% to < 75%; and (iii) PASI got worse or improved < 50%. An overall statistically significant difference (P < 0.05) with statistically significant subgroup comparisons was hypothesized.

### Known-groups validity

The known-groups validity of the Itch NRS was evaluated using two-sample t-tests to distinguish the Itch NRS scores between subgroups defined on the basis of the sPGA score at week 12 (sPGA 0 or 1 vs. ≥ 2) in the phase III studies.

### Responsiveness

Responsiveness was evaluated by correlating calculated changes from baseline to week 12 in scores on the Itch NRS with changes in the DLQI Symptoms and Feelings domain and PATGA scores. Large correlations were hypothesized based on Cohen’s conventions. Additionally, responsiveness was evaluated using one-way ANOVA for overall and paired comparisons, with Scheffé’s correction-based post hoc tests in distinguishing between subgroups defined on the basis of PASI scores at week 12: (i) PASI improved ≥ 75%; (ii) PASI improved ≥ 50% to < 75%; and (iii) PASI got worse or improved < 50%. An overall statistically significant difference (P < 0.05) with statistically significant subgroup comparisons was hypothesized.

### Table 1 Patient demographics and disease characteristics at baseline for studies JADP, RHAZ, RHBC and RHBA

| Characteristic                  | Baricitinib JADP (n = 271) | Ixekizumab RHAZ (n = 1296) | RHBC (n = 1346) | RHBA (n = 1224) |
|--------------------------------|----------------------------|---------------------------|----------------|----------------|
| Age (years), n                 | 271                        | 1296                      | 1341           | 1221           |
| Mean ± SD                      | 47.3 ± 13.3                | 45.7 ± 12.9               | 45.8 ± 13.1    | 45.0 ± 13.0    |
| Sex, n                         | 271                        | 1296                      | 1246           | 1224           |
| Male, n (%)                    | 197 (72.7)                 | 883 (68.1)                | 918 (68.2)     | 821 (67.1)     |
| Race, n                        | 270                        | 1296                      | 1346           | 1215           |
| White, n (%)                   | 215 (79.6)                 | 1199 (92.5)               | 1248 (92.7)    | 1125 (92.6)    |
| Black or African American, n (%) | 7 (2.6)                  | 26 (2.0)                  | 32 (2.4)       | 39 (2.2)       |
| Asian, n (%)                   | 45 (16.7)                  | 62 (4.8)                  | 41 (3.0)       | 37 (3.0)       |
| Native Hawaiian or other Pacific Islander, n (%) | 0 (0)          | 1 (0.1)                   | 6 (0.4)        | 3 (0.3)        |
| American Indian or Alaskan native, n (%) | 1 (0.4)                 | 3 (0.2)                   | 10 (0.7)       | 6 (0.5)        |
| Multiple, n (%)                | 2 (0.7)                    | 5 (0.4)                   | 9 (0.7)        | 5 (0.4)        |
| Weight (kg), n                 | 271                        | 1296                      | 1339           | 1220           |
| Mean ± SD                      | 90.8 ± 22.3                | 92.3 ± 23.8               | 91.2 ± 23.5    | 91.6 ± 22.2    |
| Height (cm), n                 | 271                        | 1295                      | 1340           | 1217           |
| Mean ± SD                      | 171.8 ± 10.6               | 173.3 ± 9.5               | 172.8 ± 9.7    | 172.7 ± 9.8    |
| Body mass index (kg m⁻²), n    | 271                        | 1295                      | 1338           | 1216           |
| Mean ± SD                      | 30.7 ± 6.8                 | 30.7 ± 7.4                | 30.5 ± 7.2     | 30.7 ± 7.0     |
| Psoriasis duration (years), n  | 271                        | 1296                      | 1343           | 1224           |
| Mean ± SD                      | 17.3 ± 12.0                | 19.6 ± 11.9               | 18.1 ± 12.2    | 18.7 ± 12.5    |

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demographics and disease characteristics are provided in Table 1, and baseline scores for the Itch NRS and other assessments are presented in Table 2.

**Test–retest reliability**

Test–retest analysis was conducted in a subsample of patients in study JADP ($n = 222$) and study RHAZ ($n = 1101$) using data from their first two Itch NRS assessments. The ICCs for the Itch NRS scores were 0.74 (JADP) and 0.71 (RHAZ), indicating acceptable reproducibility.\(^\text{22}\)

**Convergent and discriminant validity**

There was a large relationship between the Itch NRS and DLQI Symptoms and Feelings domain at baseline ($0.60 \leq r \leq 0.67$) in the four studies, demonstrating the convergent validity of this single-item measure. This domain continued to have the strongest association with Itch NRS of all other study measures in all four studies at week 12 ($0.80 \leq r \leq 0.88$).

As hypothesized, statistically significant moderate-to-large correlations were observed between the Itch NRS and PATGA at baseline ($0.37 \leq r \leq 0.46$) and week 12 ($0.80 \leq r \leq 0.87$), and small-to-moderate correlations with SF-36 Physical Component Summary scores at baseline ($−0.35 \leq r \leq −0.27$) and week 12 ($−0.41 \leq r \leq −0.37$), indicating that the Itch NRS scores related well to the patients’ assessments of their disease severity and physical health.

Consistent with other studies,\(^\text{3,25}\) correlations between the patient-reported Itch NRS and clinician-reported PASI and sPGA were small at baseline ($0.11 < r < 0.19$). However, these correlations became substantially more robust at week 12, ranging from $r = 0.52$ to $r = 0.79$. In contrast, small (at baseline: $−0.24 \leq r \leq −0.19$) and nonsignificant correlations (at week 12: $−0.28 \leq r \leq −0.24$) were observed with the SF-36 Mental Component Summary scores, supporting the discriminant validity of the Itch NRS measure.

**Known-groups validity**

Statistical tests evaluated the ability of the Itch NRS to discriminate between subgroups of patients at week 12 with different underlying disease severity as measured by the sPGA (Table 3). As hypothesized, patients with more severe plaque psoriasis ($sPGA \geq 2$) generally experienced more severe itching ($P < 0.001$).

**Responsiveness**

Large correlations were observed between changes in Itch NRS scores and changes in the DLQI Symptoms and Feelings

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**Table 2. Clinical outcome assessment scores at baseline for studies JADP, RHAZ, RHBC and RHBA**

| Outcome assessment                        | Baricitinib (JADP, n = 271) | Ixekizumab (RHAZ, n = 1296) | RHBC (n = 1346) | RHBA (n = 1224) |
|------------------------------------------|-----------------------------|-----------------------------|----------------|----------------|
|                                         | Sample size | Mean ± SD | Sample size | Mean ± SD | Sample size | Mean ± SD | Sample size | Mean ± SD |
| Itch NRS                                 | 270          | 7.3 ± 2.39 | 1296        | 7.1 ± 2.49 | 1340        | 6.3 ± 2.61 | 1219        | 6.6 ± 2.55 |
| sPGA                                     | 271          | 3.3 ± 0.54 | 1296        | 3.6 ± 0.62 | 1343        | 3.5 ± 0.59 | 1224        | 3.6 ± 0.60 |
| PATGA                                    | 267          | 4.1 ± 0.86 | 1291        | 4.1 ± 0.92 | 1338        | 4.0 ± 0.96 | 1217        | 4.0 ± 0.92 |
| PASI                                     | 271          | 20.0 ± 8.3 | 1296        | 20.2 ± 8.0 | 1343        | 20.9 ± 8.2 | 1224        | 19.6 ± 7.2 |
| DLQI Total Score                         | 270          | 9.3 ± 7.61 | 1294        | 13.1 ± 7.05| 1340        | 12.0 ± 6.93| 1218        | 12.3 ± 6.91|
| DLQI Symptoms and Feelings               | 263          | 4.2 ± 1.47 | 1294        | 4.1 ± 1.53 | 1339        | 3.7 ± 1.49 | 1220        | 3.9 ± 1.46 |
| DLQI Daily Activities                    | 271          | 2.9 ± 1.79 | 1294        | 2.9 ± 1.73 | 1338        | 2.6 ± 1.76 | 1220        | 2.7 ± 1.77 |
| DLQI Leisure                             | 271          | 2.2 ± 1.94 | 1295        | 2.3 ± 1.91 | 1340        | 2.1 ± 1.90 | 1211        | 2.1 ± 1.91 |
| DLQI Work and School                     | 242          | 0.7 ± 0.71 | 1294        | 0.9 ± 1.04 | 1339        | 0.9 ± 0.99 | 1214        | 0.9 ± 1.00 |
| DLQI Personal Relationships              | 271          | 1.6 ± 1.82 | 1295        | 1.9 ± 1.88 | 1340        | 1.7 ± 1.81 | 1217        | 1.7 ± 1.79 |
| DLQI Treatment                           | 271          | 1.1 ± 1.08 | 1295        | 1.2 ± 1.07 | 1340        | 1.1 ± 1.04 | 1218        | 1.1 ± 1.05 |
| SF-36 PCS                                | NA           | NA          | 1288        | 47.0 ± 9.4 | 1299        | 47.9 ± 9.0 | 1215        | 47.6 ± 9.1 |
| SF-36 MCS                                | NA           | NA          | 1288        | 48.1 ± 11.5| 1299        | 48.2 ± 11.5| 1215        | 48.4 ± 11.0|

DLQI, Dermatology Life Quality Index, range 0–30 for Total Score with higher score indicating worse health-related quality of life; 0–6 for DLQI domains of Symptoms and Feelings, Daily Activities, Leisure, and Personal Relationships; and 0–3 for DLQI domains of Work and School, and Treatment, with higher DLQI domain scores indicating greater quality-of-life impairment; Itch NRS, Itch Numeric Rating Scale, range 0–10 with higher scores representing worse itch; MCS, Mental Component Summary, range 0–100 with higher scores indicating better health-related quality of life; NA, not applicable; PATGA, Psoriasis Area and Severity Index, range 0–72 with higher scores indicating greater disease severity; PATGA, Patient’s Global Assessment, range 0–5 with higher scores indicating more severe psoriasis; PCS, Physical Component Summary, range 0–100 with higher scores indicating better health-related quality of life; SF-36, Medical Outcomes Study 36-Item Short Form Health Survey, with lower scores indicating more disability; sPGA, static Physician’s Global Assessment, range 0–5 with higher scores indicating more severe psoriasis lesions overall.
domain \((0.80 \leq r \leq 0.88)\) and PATGA scores from baseline to week 12 \((0.80 \leq r \leq 0.87)\).

The responsiveness of the Itch NRS was further examined by the level of change in the Itch NRS among different degrees of improvement in psoriasis as measured by PASI. The ability of the Itch NRS to discriminate between subgroups of patients whose PASI score improved \(\geq 75\%\) vs. those whose PASI score improved \(\geq 50\%\) and \(< 75\%\) vs. those whose PASI score got worse or improved \(< 50\%\) are shown in Figure 1. In all analyses, the Itch NRS was able to differentiate significantly \((P < 0.001)\) between the three subgroups.

**Responder definition**

In study JADP, evaluations using the YI suggested that a \(\geq 4\)-point reduction is optimal in predicting sPGA, and denotes a marked clinically important improvement over 12 weeks of treatment.

**Table 3** Known-groups validity of the Itch Numeric Rating Scale (Itch NRS) using static Physician’s Global Assessment (sPGA) groups at week 12 for studies JADP, RHAZ, RHBC and RHBA

| Study   | sPGA category at week 12 | P-value |
|---------|--------------------------|---------|
|         | sPGA 0–1 | sPGA ≥ 2 |         |
| JADP, n per group | 67 | 168 | < 0.001 |
| Mean ± SD change in Itch NRS | −5.4 ± 2.92 | −2.9 ± 3.10 | < 0.001 |
| RHAZ, n per group | 698 | 592 | < 0.001 |
| Mean ± SD change in Itch NRS | −6.0 ± 2.69 | −1.4 ± 3.18 | < 0.001 |
| RHBC, n per group | 773 | 563 | < 0.001 |
| Mean ± SD change in Itch NRS | −5.1 ± 2.70 | −2.5 ± 3.31 | < 0.001 |
| RHBA, n per group | 675 | 538 | < 0.001 |
| Mean ± SD change in Itch NRS | −5.4 ± 2.72 | −2.2 ± 3.15 | < 0.001 |

Similarly, in studies RHAZ, RHBC and RHBA, the YI was maximized at a 3-point reduction in studies RHAZ and RHBC, while the YI yielded the same maximum value \((YI = 0.41)\) at both a 4- and 5-point change in study RHBA, confirming a 4-point reduction as a conservative yet effective threshold for defining an Itch NRS responder after 12 weeks of treatment.

**Discussion**

The results from these four studies support the usefulness and validity of the Itch NRS for evaluating change over time in the clinical trial setting. This study incorporated the wealth of relevant clinical outcome assessments and represents the largest and most thorough analysis of the Itch NRS instrument performed to date.

Test–retest reliability analyses revealed substantial agreement in scores among stable patients and provide confidence in the repeatability of patients’ assessments when no change has occurred. Correlations with other clinical outcome assessments and known-groups testing supported a priori hypotheses and the construct validity of the Itch NRS. Consistently with other studies of itch in plaque psoriasis, correlations between the PRO Itch NRS and clinician-reported PASI and sPGA were small at baseline \((0.11 \leq r \leq 0.19)\). This phenomenon is also observed in clinical practice, where some patients experience substantially more itching than others. The Itch NRS appears to assess a different concept from the PASI and sPGA and captures unique information that complements standard clinician-reported end points in understanding the efficacy of psoriasis treatments. These differences are especially important considering the unmet need to address the significant effects of pruritus on quality of life.\(^1,2\)

The large correlations observed between changes from baseline to week 12 in Itch NRS scores and changes in the DLQI Symptoms and Feeling domain and PATGA scores demonstrated the responsiveness of the Itch NRS. Responsiveness was further demonstrated through the Itch NRS score’s ability to discriminate \((P < 0.001)\) between subgroups of patients based on improved PASI scores.

![Fig 1. Mean change in Itch Numeric Rating Scale (Itch NRS) scores from baseline at week 12 among Psoriasis Area and Severity Index (PASI) improvement groups at week 12 for studies JADP, RHAZ, RHBC and RHBA.](attachment:image.png)
Finally, anchor- and distribution-based analyses using data from study JADP yielded a 4-point change as being optimal for demonstrating a clinically meaningful itch response in patients with moderate-to-severe plaque psoriasis, which was confirmed in the ixekizumab phase III studies. This magnitude of change (4 points) demonstrates a marked improvement in plaque psoriasis and is also linked to a qualitatively meaningful change on the 0–10-point Itch NRS, based on other independent investigations.26

Despite the rich data available for this investigation, a key limitation was that no other direct measures of itch were included in the four clinical studies. The DLIQI item addressing this symptom (itchy) also assessed other skin symptoms (sore, painful or stinging) and used a longer recall period (the past week). In addition, the responder definition derived and confirmed in this investigation describes a responder achieving a marked improvement in her/his plaque psoriasis over 12 weeks of treatment as measured by PASI and sPGA, and meaningful improvement in the itch symptom may occur at a lower level of change.

Prior work by Phan et al.27 demonstrated the cross-sectional reliability and validity of a 0–10-point Itch NRS in a broad sample of patients with chronic pruritus (>6 weeks) of any origin. The work presented here extends those results and provides evidence that the Itch NRS is a well-defined, reliable, valid and responsive PRO instrument for use in clinical trials of patients with moderate-to-severe plaque psoriasis. It allows measurement of change over time in itch severity and evaluation of treatment efficacy for this most troubling and severe symptom of psoriasis. Additionally, these results support the use of the Itch NRS in routine clinical practice, to help clinicians to assess and manage psoriasis-related itch in their patients.

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