The Psoriasis Symptom Inventory: An Effective Patient-reported Outcome Measure of Psoriasis Severity

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ABSTRACT. There is a need for simple, practical, and reliable measurement instruments for use in clinical trials, registries, and clinical practice to assess psoriasis severity and the change in symptoms with treatment. The Psoriasis Area and Severity Index (PASI) is the standard measure of psoriasis used in clinical trials, but it is rarely used in clinical practice and it is not readily used in clinical registries because of its complexity. The Physician Static Global Assessment score is a simpler measure also used in clinical trials and less frequently in registries and practice, but like the PASI, it requires some degree of experience to score. The Psoriasis Symptom Inventory (PSI) was developed as a simple measure to enable patients to self-score psoriasis severity. It has been demonstrated to be reliable and discriminative, and it correlated with the PASI score in a psoriasis clinical trial. It also was recently validated to assess psoriasis in a psoriatic arthritis (PsA) clinical trial. The PSI may be a useful and practical measure of psoriasis severity in psoriasis and PsA clinical trials, registries, and in clinical practice. (J Rheumatol 2015;42:1034–6; doi:10.3899/jrheum.150127)

Key Indexing Terms:
PSORIASIS
PSORIASIS SEVERITY MEASURE
PATIENT-REPORTED OUTCOME MEASURES
PSORIATIC ARTHRITIS

The Psoriasis Symptom Inventory (PSI) is an 8-item patient-reported outcome (PRO) measure that assesses the severity of psoriasis signs and symptoms[1,2]. The PSI was developed through contributions from literature review, expert clinicians, patient focus groups, and interviews with individual patients, resulting in a "saturation" of concepts regarding psoriasis signs and symptoms. The 8 questions address itching, redness, scaling, burning, stinging, cracking, flaking, and pain, with response categories of not present, mild, moderate, severe, and very severe. Wording and recall period appropriateness, comprehension, and item interpretation were confirmed through individual patient cognitive interviews. The measure can be used with either a 24-h recall period (for clinical trials) or a 7-day recall (for clinical practice).

In a brodalumab phase 2 trial in psoriasis, the PSI results closely mirrored those of the PASI (Figures 1-3). It demonstrated content, convergent, discriminant, and known groups validity, unidimensionality, and reliability, and was responsive and able to detect change in psoriasis severity (Table 1)[3,4].

In a brodalumab phase 2 trial in PsA, the PSI recorded rapid and significant change in psoriasis[5], and again demonstrated content, convergent, discriminant, and known groups validity, unidimensionality, and reliability, and ability to detect change (Table 2)[5,6].

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Currently, phase 3 trials of brodalumab are being conducted in which both the PASI and PSI are being measured to establish the correlation of these 2 instruments in patients with PsA.

It appears that the PSI can be a reliable, simple, and practical PRO to measure psoriasis severity in clinical trials, registries, and practice.

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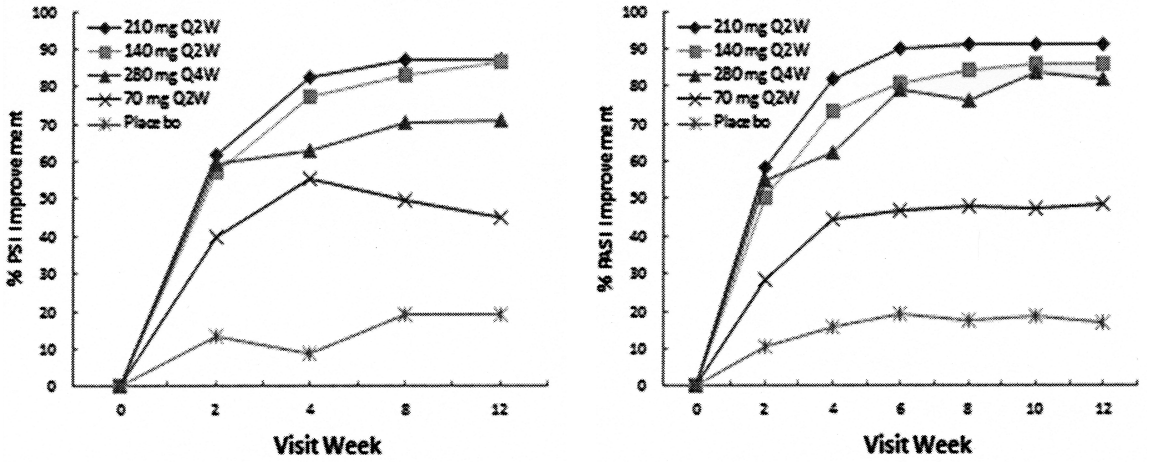

Figure 1. Percentage of Psoriasis Severity Index (PSI) improvement (left panel) and Psoriasis Area and Severity Index (PASI; right panel) in a psoriasis trial. Right panel is reproduced from Papp, *et al*: N Engl J Med 2012;366:1181-93[3]; with permission.

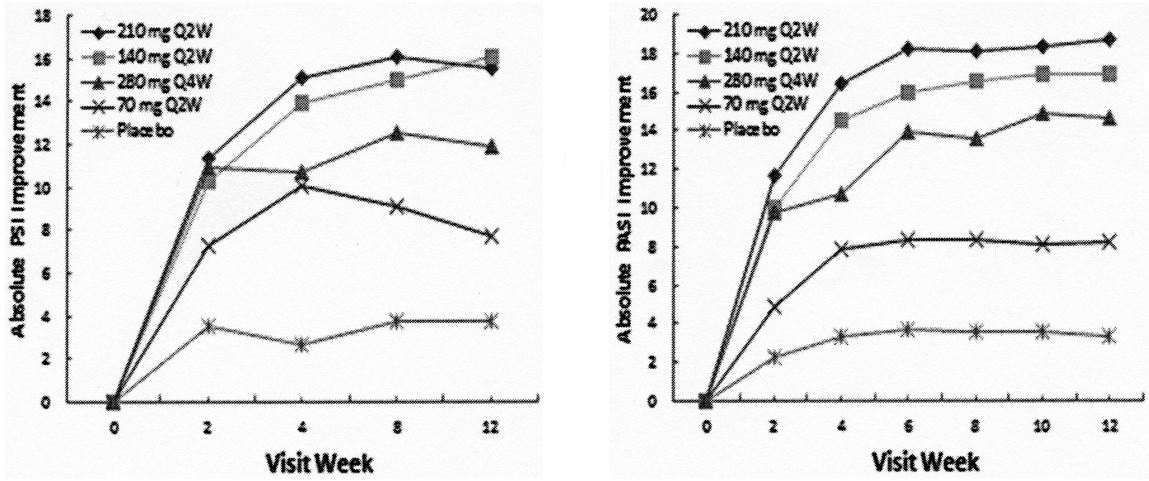

Figure 2. Absolute improvement in Psoriasis Severity Index (PSI; left panel) and Psoriasis Area and Severity Index (PASI; right panel) over time in a psoriasis trial.

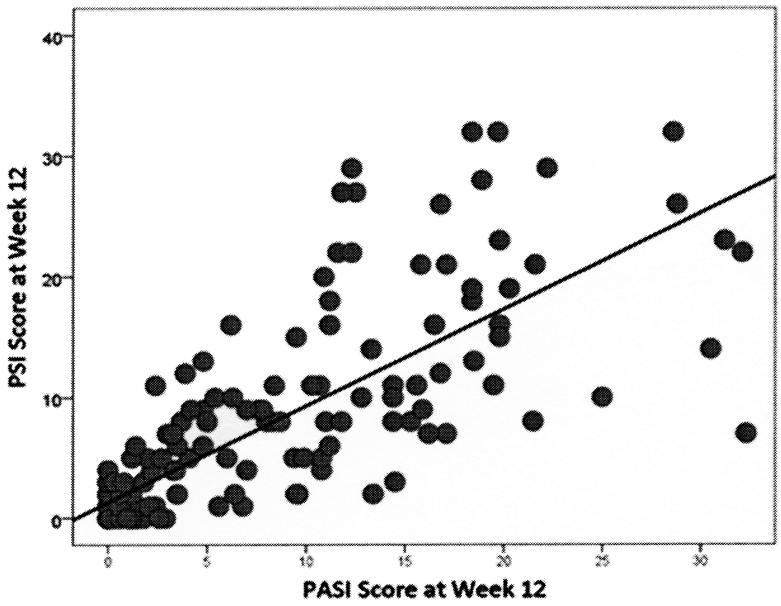

Figure 3. Psoriasis Severity Index (PSI) total score versus absolute Psoriasis Area and Severity Index (PASI; as observed) at Week 12 in a psoriasis trial.

Table 1. Psychometric properties of the PSI in plaque psoriasis clinical trial.

Property	Supportive Evidence
Content validity	Extensive patient concept elicitation focus groups and interviews, cognitive interviews, clinician input, and input from measurement experts
Unidimensionality	Confirmed using factor analysis and Rasch analysis
Reliability	Excellent internal consistency (Cronbach's alpha coefficient = 0.92) Good test-retest reliability (ICC ranging from 0.70 to 0.80 for items) for PSI scores between Week 1 and Week 2
Convergent validity	Supported by significant moderate correlations with DLQI items (r from 0.31 to 0.73) and SF-36v2 pain domain ($r = –0.59$)
Discriminant validity	Supported by significant low correlations ($r \leq –0.3$) with SF-36v2 domains of role limitations due to emotions
Known groups validity	Supported by significant differences ($p < 0.001$) among PSI scores for subjects with DLQI scores (2–10, 11–20, 21–30), PASI scores (< 12, 12 to 18, > 18), and sPGA scores (0–2, 3, 4, 5)
Ability to detect change	Supported by significant differences ($p < 0.001$) in PSI scores among subjects with ≥ 1-point Δ in the patient global assessment from Day 0 to Day 7, and Day 7 to Day 14
Responsiveness	Supported by significantly different Δ in mean PSI scores among subjects with PASI improvements of ≥ 75, 50–74, < 5, sPGA scores of 0–2, 3, 4, 5 from baseline to Week 12
PSI responders	Anyone achieving a PSI total ≤ 8, with no item score > 1

PSI: Psoriasis Severity Index; DLQI: Dermatology Life Quality Index; PASI: Psoriasis Area and Severity Index; SF-36v2: Medical Outcomes Study Short Form-36, version 2; sPGA: static physician's global assessment.

Table 2. Psychometric properties of the PSI in PsA clinical trials.

Property	Supportive Evidence
Content validity	Initial concept elicitation interviews in PsO included patients with PsA
Unidimensionality	Confirmed using factor analysis and Rasch analysis
Item analysis	Supported by good item fit and correctly ordered categories based on Rasch analysis
Reliability	Excellent internal consistency (Cronbach's alpha coefficient = 0.95) Good test-retest reliability (ICC = 0.70 for total scores and ranging from 0.67 to 0.81 for items) for PSI scores at Week 2 and Week 4 in stable subjects [i.e., ≤ 1 Δ on the subject global assessment (SGA) of disease]
Convergent validity	Supported by moderate correlations with BSA ($r = 0.50$) and SF-36v2 pain domain ($r = –0.45$)
Discriminant validity	Supported by significant low correlations ($r < –0.3$) with SF-36v2 domains of role limitations due to emotions
Known groups validity	Supported by significantly lower mean PSI scores ($p < 0.001$) between subjects with BSA < 5% compared to those with BSA > 10%
Ability to detect change	Supported by significantly greater ($p < 0.001$) change in mean PSI score in subjects with ≥ 30% SGA improvement than subjects with < 30% SGA improvement

PSI: Psoriasis Severity Index; PSA: psoriatic arthritis; SF-36v2: Medical Outcomes Study Short Form-36, version 2; PsO: psoriasis; BSA: body surface area.