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Original Article

Psoriasis Symptom Inventory (PSI) as a patient-reported outcome in mild psoriasis: Real life data from a large psoriatic arthritis registry

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Abstract

Objective: Our aim is to test the validity of the Psoriasis Symptom Inventory (PSI), a patient-reported outcome, to assess the psoriasis severity within the scope of rheumatology.
Methods: Within the PsA international database (PSART-ID), 571 patients had PSI, while 322 of these also showed body surface area (BSA). Correlations between PSI, BSA, and other patient- and physician-reported outcomes were investigated.
Results: There was a good correlation between PSI and BSA ($r=0.546$, $p<0.001$), which was even higher for mild psoriasis (BSA<3 ($n=164$): $r=0.608$, $p<0.001$). PSI significantly correlated with fatigue, pain, and patient and physician global parameters ($p<0.001$).
Conclusion: PSI has a good correlation with other patient- and physician-reported outcomes, and our findings support its use in rheumatology practice.
Keywords: Psoriatic arthritis, registry, psoriasis, disease activity

Introduction

Psoriatic arthritis (PsA) is a heterogeneous disease affecting not only the joints but also the skin, nails, and various tendons and their insertions. A patient is considered to have minimal disease activity only when five of the seven criteria are met, one of which is the Psoriasis Activity and Severity Index (PASI), having a score of ≤1 or the physician-reported body surface area (BSA) score of ≤3 (1). Therefore, skin assessment has been recognized as an important outcome measure in PsA, but is still not frequently measured by rheumatologists.

The Psoriasis Symptom Inventory (PSI) is a relatively new patient-reported outcome measure consisting of eight items that assess skin symptoms (2, 3). The options to respond on a 5-point Likert-type rating scale include itching, redness, scaling, burning, stinging, cracking, flaking, and pain. The validity of PSI has previously been demonstrated in psoriasis (4). A phase 2 clinical trial that evaluated the efficacy of the drug brodalumab showed that PSI has excellent reliability and responsiveness in moderate-to-severe chronic plaque psoriasis (5). In this study, patients with a BSA score of more than 10 and a PASI score of ≥12 were recruited in the study, excluding patients with mild psoriasis. Similarly, in the original study developing PSI, only patients with BSA>3 were included and initially and was further tested in patients with BSA≥10 (3). Recently, another PSI-related study investigated the differences in the severity of psoriasis signs and symptoms between patients with clear and almost clear skin, which showed that PSI could discriminate between these two groups (6). In PsA, there had been one study using PSI as a patient-reported outcome, which was also a phase 2 clinical trial on brodalumab (7). That study supported the use of PSI, citing that it had good reliability, adequate construct, and discriminative validity in the patient group with a mean SD BSA score of 10.4 (15.6). However, in clinical practice, most of the PsA patients in rheumatology departments have a BSA of <3, while the most important limitation of the PASI is that it is insufficient to measure and discriminate between these patients (8).

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In this study, we aimed to understand whether PSI is a valid tool to accurately assess the patients with mild psoriasis and PsA in real life. If a patient-reported outcome tool has good construct validity in comparison to physician-reported outcomes, this would increase the assessment of skin disease in the rheumatology practice.

Methods

An observational multi-center web-based registry of PsA (PsArtID: PsA International Database) was launched in 2014, the details of which have been extensively described previously (9, 10). With extension of the registry, the data have now been collected in two countries (Turkey and Canada) since 2017. Ethics approval was obtained from the local ethical committees board (Hacettepe University Ethics Board, Ankara (GO 14/578); Ottawa Health Science Network Research Ethics Board, Ottawa (20160436-01H) and all patients gave informed consent prior to data collection. Briefly, the data included demographics, records on psoriasis and PsA, and physician- and patient-reported outcomes. BSA and PSI were collected to evaluate skin disease activity. PSI was not included in the registry at the start of the study and was added subsequently. The severity of the skin psoriasis assessment is not mandatory and was only recorded by investigators who were familiar with the scoring. For this reason, the analysis in this study only included patients that had available PSI data.

Main Points

- Skin involvement is an important outcome measure in psoriatic arthritis, which is not frequently measured by rheumatologists due to time constraints.
- PSI (Psoriasis Symptom inventory) is a patient-reported outcome measure used to assess the severity of skin psoriasis.
- PSI has good construct validity in comparison with body surface area, which is a physician-reported outcome, even in patients with mild psoriasis.

Statistical analysis

Descriptive statistics are given as numbers (percentages) for categorical variables and as mean (SD) for continuous variables. The demographics of patients whose PSI data were available were compared to those of patients who had no data to assess whether the choice of PSI being filled was affected by any factors. Continuous variables were compared by the Student's t test or the Mann-Whitney U test, depending on the type of data. *Pearson's correlation coefficients* were calculated to compare the PSI with other outcome measures. BSA data was further categorized as <3 and ≥3 and the correlations were were also investigated in these subgroups, also by dividing the data according to genders. Finally, the correlation between BSA and PSI was done separately for patients recruited from Turkey and Canada to see the differences that could be generated on the basis of different backgrounds and language. The IBM Statistical Package for the Social Sciences software version 24.0 (IBM SPSS Corp.; Armonk, NY, USA) was used as the analytical software.

Results

At the time of analysis, 1372 patients had been recruited to the registry and of these, 571 had available PSI data (41.6% of all patients). The mean (SD) age of the patients with PSI information was 47 years (13) with a disease duration of 181.7 (136.3) months for psoriasis and 62.1 (74.8) months for PsA. Within these patients, 331 (58%) were women and 252 (44%) showed nail involvement. Regarding the types of arthritis, 236 patients (41.6%) had axial disease, 218 (38.4%) had symmetrical polyarthritis, 242 (42.7%) had asymmetrical oligo or monoarthritis, 119 (21%) had DIP joint disease, and 0.2% had arthritis mutilans. Patient- and physician-reported outcomes are given in Table 1.

When demographics of patients with PSI data were compared with the rest of the registry, where PSI was not available, the age and duration of psoriasis were similar, whereas patients without PSI data had PsA for a longer duration (71.9 (87.3) years vs. 62.2 (74.9) years; p=0.04).

Table 1. Patient- and physician-reported outcomes.

	n	mean (SD)
Tender joint counts	475	3.3 (4.4)
Swollen joint counts	477	1.9 (3.1)
PSI	571	7.5 (7)
BASDAI	434	41.6 (24.8)
BASFI	411	30.5 (24.3)
Patient Global Assessment (VAS: 0-100 mm)	482	43.1 (26.5)
Physician Global Assessment (VAS: 0-100 mm)	462	36.1 (24.3)
Fatigue VAS (VAS: 0-100 mm)	496	42.9 (27.2)
Pain VAS (VAS: 0-100 mm)	495	42.6 (28.4)
ESR (mm/hour)	463	25.3 (19.4)
CRP (mg/lt)	480	11.9 (18.7)

N: number of patients with available data; PSI: Psoriasis symptom inventory; BASDAI: Bath ankylosing spondylitis disease activity index; BASFI: Bath ankylosing spondylitis function index; VAS: visual analogue scale; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein.

Table 2. Correlation of the Psoriasis Symptom Inventory with other outcome measures.

	N	Whole group (r)	Women	Men
BSA	322	0.546	0.46	0.68
Patient global	482	0.402	0.34	0.49
Physician global	462	0.375	0.29	0.50
Fatigue	496	0.283	0.22	0.37
Pain	495	0.360	0.24	0.38

N: number of patients with available data; r: correlation coefficient; BSA: body surface area.
p<0.001 for all given correlations.

Skin assessment

The mean (SD) PSI was found 7.5 (7) and 100 patients (17.5 %) had a PSI of 0. BSA data were available for 322 of these patients with a mean (SD) of 6.6 (11.8). BSA of <3 was found in164/322 (50.9 %), 88/322 (27.3%) had BSA≥3 to <10 and 70/322 (21.7%) had a BSA ≥10.

There was a moderate correlation between PSI and BSA (r=0.546, p<0.001), with a higher correlation coefficient in men than in women (Table 2). When compared with other physician- and patient-reported outcomes, PSI was found to be significantly correlated to global patient and physician parameters, fatigue, and pain (p<0.001 for all, Table 2). Then, the PSI data was analyzed separately for patients who had BSA scores of <3 and ≥3.The correlation between PSI and BSA in patients that showed a BSA score of <3 was even higher than patients with a higher psoriasis activity (For patients with BSA<3 (n=164): r=0.608, p<0.001; BSA≥3 (n=158): r=0.170, p=0.03).

When patients from two different countries were compared, the correlation was higher for patients recruited from Canada (n=74; r=0.705, p<0.001) as compared to Turkey (248; r=0.470, p<0.001), however, both were still significant.

Discussion

This is the first study that shows a good correlation between PSI, a patient-reported outcome, and BSA, a physician-reported outcome, for skin disease activity in clinical rheumatology practice. Rheumatologists agree on the importance of skin assessment, however, the increasing workload proves to be a time constraint and has become a big concern in rheumatology practice across the world. Therefore, tools that are feasible within this framework would increase the diagnosing power. The advent of an easy patient-reported outcome tool that can easily be filled by the patient while waiting to be seen by the rheumatologist could increase the acceptance of this method by rheumatologists. Many studies have tried to identify the validation of PSI in comparison to BSA and PASI in higher disease activity levels for psoriasis, both in clinical trials and in clinical settings. Our observations add to these by proving the validity of PSI for patients that have a milder psoriasis activity, which is more common in rheumatology practice.

Our data showed that there is also a good correlation between PSI and other patient-reported outcomes, such as patient and physician global parameters, fatigue, and pain. This may represent the impact of the skin manifestations on the patients' global assessment, which can easily be captured by a patient-reported outcome tool.

The major strengths of this study are the wide representation of the rheumatology practice in real life and the large sample size. As consecutive patients were recruited, the data represented by the patient population seen in rheumatology clinics was without any selection bias. Approximately 51% of the patients had a BSA score of <3, which supported the concept of a mild psoriatic activity for skin involvement in PsA in routine rheumatology practice.

Our study has some limitations. PASI was not one of the outcomes included in the registry as the purpose was to collect data from real life. Most of the rheumatologists do not have enough experience with PASI unless they are doing research in the field of PsA, therefore, not including PASI in this registry was a deliberate decision. Another limitation is that BSA data was not available for all the patients. This may be due to several reasons, such as with the time concerns, reluctance of physicians to assess skin disease, etc. Linked to this, patients may not get undressed during a rheumatology follow-up exam, thereby not allowing for the calculation of BSA. Alternatively, rheumatologists may not be comfortable about their skills in truly assessing skin activity using BSA, despite it being an easier tool to use as compared to PASI.

In summary, this study shows that PSI is valid tool when compared to a physician-reported outcome targeting the same aspect of the disease, has good correlation with other patient-reported outcomes, and is well-received by rheumatologists. The validity has been shown for patients who have mild psoriasis in real life, suggesting its use in clinical practice.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of the Hacettepe University Ethics Board, Ankara (GO 14/578) and Ottawa Health Science Network Research Ethics Board, Ottawa (20160436-01H).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

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