Utilization of the validated Psoriasis Epidemiology Screening Tool to identify signs and symptoms of psoriatic arthritis among those with psoriasis: a cross-sectional analysis from the US-based Corrona Psoriasis Registry

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Abstract

Background Despite increasing awareness of the disease, rates of undiagnosed psoriatic arthritis (PsA) are high in patients with psoriasis (PsO). The validated Psoriasis Epidemiology Screening Tool (PEST) is a five-item questionnaire developed to help identify PsA at an early stage.

Objectives To assess the risk of possible undiagnosed PsA among patients with PsO and characterize patients based on PEST scores.

Methods This study included all patients enrolled in the Corrona PsO Registry with data on all five PEST questions. Demographics, clinical characteristics and patient-reported outcomes were compared in Corrona PsO Registry patients with PEST scores \( \geq 3 \) and \(<3\) using \( t \)-tests for continuous variables and chi-squared tests for categorical variables; scores \( \geq 3 \) may indicate PsA.

Results Of 1516 patients with PsO, 904 did not have dermatologist-reported PsA; 112 of these 904 patients (12.4%) scored \( \geq 3 \) and were significantly older, female, less likely to be working, and had higher BMI than patients with scores \(<3\). They also had significantly longer PsO duration, were more likely to have nail PsO and had worse health status, pain, fatigue, Dermatology Life Quality Index and activity impairment.

Conclusions Improved PsA screening is needed in patients with PsO because the validated PEST identified over one-tenth of registry patients who were not noted to have PsA as having scores \( \geq 3 \), who could have had undiagnosed PsA. Appropriate, earlier care is important because these patients were more likely to have nail PsO, worse health-related quality of life and worse activity impairment.

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Conflicts of interest

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Diagnosis of PsA. Patients with PsO may have undiagnosed PsA. For example, observational studies have shown that even larger proportions of patients with PsO have arthritis (PsA) is one of the conditions most frequently associated with PsO; up to 30% of patients with PsO may have a concurrent diagnosis of PsA. The presence or absence of PsA plays a major role in determining which therapy should be used in patients with PsO. In most patients with PsO who develop PsA, arthritis usually occurs within 10 years following the first manifestation of their skin disease. Scalp and flexural skin involvement, nail lesions, certain HLA alleles and increased levels of acute-phase proteins and matrix metalloproteinase 3 in the sera have been implicated as risk factors for the development of PsA in patients with PsO. Enthesitis and dactylitis are characteristic features of PsA and are indicative of erosive forms of the disease and worse prognostic outcomes.

However, undiagnosed PsA is common in patients with PsO. A meta-analysis revealed that between 10.1% and 15.5% of patients with PsO may have undiagnosed PsA, while other observational studies have shown that even larger proportions of patients with PsO may have undiagnosed PsA. For example, of 949 patients with PsO evaluated at 34 dermatology centres across seven countries in North America and Europe, 285 (30%) had PsA, 117 (41%) of whom were not previously diagnosed. Undiagnosed PsA, or even a delay in diagnosis of PsA by 6 months, may lead to physical disability and peripheral joint erosion. Patients with PsA must see a rheumatologist for a definitive diagnosis; therefore, patients in consultation with a general practitioner or a dermatologist for their PsO and joint pain may not receive a timely diagnosis of PsA. The Classification Criteria for Psoriatic Arthritis was developed for use by rheumatologists to classify inflammatory musculoskeletal disease, using rheumatologist assessment, diagnostic measures for inflammatory articular disease and patient-reported symptoms. However, because most patients with PsO are under the care of a dermatologist or general practitioner, it is necessary to have a simple and sensitive tool that can be used by these providers to identify patients who may have early-stage PsA and prompt a timely referral to a rheumatologist for PsA evaluation.

The currently available screening tools for PsA have been validated in various clinical settings; these tools include the Early Arthritis for Psoriatic Patients (EARP), German PsO Arthritis Diagnostic questionnaire, PsO Assessment Questionnaire (PAQ), Psoriatic Arthritis Screening and Evaluation (PASE), PsO and Arthritis Screening Questionnaire (PASQ), Psoriasis Epidemiology Screening Tool (PEST), Toronto Psoriatic Arthritis Screening (ToPAS) and ToPAS 2. For this analysis, the validated PEST questionnaire was selected because it is an effective tool that can be used in clinical practice, is easy to use (just five questions) and is available in the Corrona PsO Registry. This questionnaire can be effectively used in non-rheumatology practices to detect possibly undiagnosed PsA and identify patients who may benefit from consultation with a rheumatologist.

In this analysis of the US-based Corrona PsO Registry, we aimed to determine the proportion of patients with possibly undiagnosed PsA based on PEST scores (≥3) and compared demographic and clinical characteristics of patients with a PEST score ≥3 with those of patients with a PEST score <3.
Methods

Data source
The Corrona PsO Registry is a large, independent, prospective, observational cohort of patients with PsO, launched in April 2015. Patients in this analysis were recruited from 114 private and academic practice sites across 34 states in the United States, with 263 participating dermatologists. As of 10 May 2018, the Corrona PsO Registry had enrolled 4864 patients, with data on 11 562 patient visits and 3890.8 patient-years of follow-up observation time. The mean time of patient follow-up was 1.36 years (median, 1.28 years).

All participating investigators were required to obtain full institutional review board (IRB) approval for conducting research involving human subjects. Sponsor approval and continuing review were obtained through a central IRB (IntegReview, Corrona-PSO-500). For academic investigative sites that did not receive a waiver to use the central IRB, full board approval was obtained from the respective governing IRBs and documentation of approval was submitted to the Sponsor prior to initiating any study procedures. All registry subjects were required to provide written informed consent prior to participating.

Study population
Study inclusion criteria were the same as those used for enrolment in the Corrona PsO Registry: ≥18 years old, diagnosed with PsO by a dermatologist, and initiated or switched to a systemic (biologic or non-biologic) PsO treatment on the enrolment date or within 12 months preceding the enrolment date. This descriptive study included all patients with PsO and non-missing data on all five questions of the PEST questionnaire (Table 1) at time of enrolment in the Corrona PsO Registry, between April 2015 and June 2016. The PEST consists of five simple yes/no questions. Each ‘yes’ answer has a value of 1 point, and a score of ≥3 indicates risk of having PsA and that a rheumatology referral may be needed.

Study outcomes
Data on patient demographics, treatment history, clinical characteristics, patient-reported outcome measures and work productivity were collected using questionnaires from patients and their treating dermatologists at the enrolment visit. Demographics included age, sex, race/ethnicity, bodyweight, body mass index (BMI), physician-reported history of comorbidities, work status, family history of PsO and smoking status. Treatment history included prior and current use of biologic and non-biologic systemic therapies. Clinical characteristics evaluated included PsO morphology, affected body surface area (BSA; 0–100%), Investigator Global Assessment (IGA; 0–4) and PsO Area and Severity Index (PASI; 0–72), which measures disease severity. Patient-reported outcome measures included patient-reported pain and fatigue visual analog scale (VAS; 0–100), the Dermatology Life Quality Index (DLQI; 0–30) and EuroQol VAS (EQ VAS; 0–100). Work productivity was measured by the Work Productivity and Activity Impairment (WPAI) questionnaire.

Data analysis
Among patients without a diagnosis of PsA at enrolment, a descriptive summary of patient demographics, treatment history, clinical characteristics and patient-reported outcome measures (including quality of life measures and work productivity) was provided. Continuous variables were summarized by the number of observations, the mean and the SD, or the median and interquartile range; categorical variables were summarized using frequency counts and percentages. Statistical comparisons between PEST groups (PEST score <3 and PEST score ≥3) were made using two-sample t-tests for continuous variables and chi-squared or Fisher’s exact tests for categorical variables.

Results
As of June 2016, 1516 of 1529 patients (99.1%) in the Corrona PsO Registry had non-missing data on all five PEST questions. A total of 612 patients (40.4%) had dermatologist-reported PsA at enrolment. Of the remaining 904 patients (59.6%) without dermatologist-reported PsA, 112 (12.4%) had a PEST score ≥3 (Fig. 1). Of the 112 patients without dermatologist-reported PsA who had a PEST score ≥3, patients most commonly

Table 1 Psoriasis Epidemiology Screening Tool (PEST)

| Question                                      | Yes (%) | No (%) |
|-----------------------------------------------|---------|--------|
| Have you ever had a swollen joint (joints)?   | 24.2    | 75.8   |
| Has a doctor ever told you that you have arthritis? | 23.5    | 76.5   |
| Do your fingernails or toenails have holes or pits? | 20.8    | 79.2   |
| Have you had pain in your heel?               | 20.0    | 80.0   |
| Have you had a finger or toe that was completely swollen or painful for no reason? | 22.4    | 77.6   |

Figure 1 Distribution of Psoriasis Epidemiology Screening Tool (PEST) scores among patients with and without a diagnosis of psoriatic arthritis (PsA) in the Corrona Psoriasis Registry.
answered ‘yes’ to ‘Have you ever had a swollen joint (or joints)?’ (89%) and ‘Has a doctor ever told you that you have arthritis?’ (86%), followed by ‘Do your finger nails have holes or pits?’ (63%), ‘Have you ever had pain in your heel’ (62%) and ‘Have you had a finger or toe that was completely swollen and painful for no apparent reason?’ (52%).

Demographics and treatment history
As shown in Table 2, patients with a PEST score ≥3 were significantly older than patients with a PEST score <3 [mean (SD), 52.9 (14.4) vs. 49.2 (15.2) years, respectively; \( P = 0.016 \)]. They were also more likely to be female (55.4% vs. 42.8%; \( P = 0.012 \)) and have a higher BMI [mean (SD), 32.2 (8.0) vs. 29.5 (6.9) kg/m²; \( P = 0.001 \)], and were less likely to have a full- or part-time job (53.2% vs. 70.9%; \( P < 0.001 \)). Patients with a PEST score ≥3 were also more likely to have certain comorbidities (cardiovascular disease, serious infection, depression/anxiety, hypertension and hyperlipidemia) and a family history of PsO than patients with a PEST score <3 (all \( P < 0.05 \)). No differences in use of treatments for PsO and smoking status were observed between groups (Table 2).

Clinical characteristics
Patients with a PEST score ≥3 had a longer duration of PsO [mean (SD), 17.3 (14.8) vs. 14.6 (13.2) years; \( P < 0.001 \)] than patients with a PEST score <3 (Table 2). Additionally, patients with a PEST score ≥3 were more likely to exhibit nail PsO (21.4% vs. 10.9%; \( P = 0.001 \); Fig. 2). However, the groups did not differ significantly in terms of other PsO morphology subgroups or PsO disease severity, as measured by categorical IGA score, per cent of affected BSA, and mean PASI score (Fig. 3).

Patient-reported outcome measures
Among the 904 patients without dermatologist-reported PsA, those with a PEST score ≥3 had significantly worse mean (SD) pain [28.3 (30.6) vs. 21.3 (28.7)] and fatigue [41.7 (27.8) vs. 25.0 (26.8)] than patients with a PEST score <3 (\( P = 0.015 \) and \( P < 0.001 \)), respectively; Table 3). Patients with a PEST score ≥3 also demonstrated significantly worse mean (SD) health status [EQ VAS, 67.0 (22.9) vs. 76.4 (21.2); \( P = 0.002 \)] and DLQI score [8.1 (6.5) vs. 6.2 (5.9); \( P = 0.002 \)]. Higher proportions of patients with a PEST score ≥3 had DLQI scores of 11–20 or 21–30 (‘very large’ and ‘extremely large’ effects on quality of life, respectively) than patients with a PEST score <3. In the WPAI domains, patients with a PEST score ≥3 had significantly worse mean (SD) activity impairment than those with a PEST score <3 [24.0% (28.6%) vs. 15.0% (23.6%); \( P < 0.001 \)]; the other WPAI domains (work time missed, impairment while working and overall work impairment) were also worse in patients with a PEST score ≥3, but the differences were not statistically significant.

| Characteristic | PEST ≥3 | PEST <3 | \( P \) value |
|----------------|--------|--------|--------------|
| **Age** (years) | 52.9 (14.4) | 49.2 (15.2) | 0.016 |
| **Female** (%) | 62 (55.4) | 339 (42.8) | 0.012 |
| **White** (%) | 96 (85.7) | 593 (74.9) | 0.012 |
| **Hispanic** (%) | 7 (6.5) | 75 (9.6) | 0.289 |
| **Bodyweight** (kg) | 94.1 (25.3) | 86.4 (22.6) | 0.052 |
| **BMI** (kg/m²) | 32.2 (8.0) | 29.5 (6.9) | 0.001 |

Table 2 Demographic, clinical and treatment characteristics of patients with PsO and no diagnosis of PsA, stratified by PEST score

- Combined histories of myocardial infarction, acute coronary syndrome, congestive heart failure and peripheral artery disease.
- Includes non-melanoma of the skin.
- Infections that led to hospitalization or intravenous antibiotics, including joint/bursa, cellulitis, sinusitis, Candida infections, diverticulitis, sepsis, pneumonia, bronchitis, gastroenteritis, urinary tract infection, tuberculosis or others as specified by a physician.
- Physician-reported depression from the adverse event portion of enrolment form.
- Prior biologic use included adalimumab, alefacept, certolizumab, efalizumab, etanercept, golimumab, infliximab, ixekizumab, secukinumab, ustekinumab and other non-biologic therapies.
- Prior non-biologic use included acitretin, aminolast, cyclosporine, hydroxyurea, methotrexate, mycophenolate mofetil, sulfasalazine, 6-thioguanine, tofacitinib and other non-biologic therapies.
- BMI, body mass index; IQR, interquartile range; PEST, Psoriatic Arthritis Screening Tool; PsA, psoriatic arthritis; PsO, psoriasis.
Discussion
Among the 904 patients without dermatologist-reported PsA in the US-based Corrona PsO Registry as of June 2016, 112 (12.4%) had a PEST score ≥3 at enrolment, indicating a need for further evaluation for a possible diagnosis of PsA. Patients with PEST score ≥3 were more likely to have nail disease, a longer duration of PsO, a higher BMI, and worse pain, fatigue and health-related quality of life. Given current opinion that nail disease and obesity are among the strongest predictors for development of PsA, these results also suggest that further evaluation for a possible diagnosis of PsA is needed for patients with a PEST score ≥3.

Results of screening questionnaires administered by dermatologists, such as PEST, may allow for timely rheumatologist referral and lead to earlier diagnosis of PsA in patients with PsO.

Figure 2  Psoriasis (PsO) morphology in patients stratified by Psoriasis Epidemiology Screening Tool (PEST) score; *P < 0.05.

Figure 3  Disease severity among patients with Psoriasis Epidemiology Screening Tool (PEST) scores ≥3 and <3 as measured by (a) categorical Investigator’s Global Assessment (IGA) score, (b) per cent of affected body surface area (BSA) and (c) mean Psoriatic Arthritis Severity Index (PASI) score.

Table 3  Patient-reported outcome measures for patients with PsO and no diagnosis of PsA, stratified by PEST score

| Characteristic                  | PEST ≥3 n = 112 | PEST <3 n = 792 | P value |
|--------------------------------|-----------------|-----------------|---------|
| Patient pain (VAS 0–100), mean (SD) | 28.3 (30.6)     | 21.3 (28.7)     | 0.015   |
| Patient-reported fatigue (VAS 0–100), mean (SD) | 41.7 (27.8)     | 25.0 (26.8)     | <0.001  |
| EQ VAS (0–100), mean (SD)       | 67.0 (22.9)     | 76.4 (21.2)     | <0.001  |
| DLQI (0–30), mean (SD)          | 8.1 (6.5)       | 6.2 (5.9)       | 0.002   |
| DLQI (‘effect on life’), n (%)  | n = 112         | n = 792         |         |
| None (0–1)                      | 21 (18.8)       | 196 (24.7)      | 0.035   |
| Small (2–5)                     | 27 (24.1)       | 258 (32.6)      |         |
| Moderate (6–10)                 | 27 (24.1)       | 160 (20.2)      |         |
| Very large (11–20)              | 33 (29.5)       | 145 (18.3)      |         |
| Extremely large (21–30)         | 4 (3.6)         | 33 (4.2)        |         |
| WPAI summary scores            |                 |                 |         |
| Currently employed, n (%)       | 60 (53.6)       | 561 (71.0)      |         |
| WPAI domains, mean (SD) [n]     |                 |                 |         |
| % Work time missed              | 2.9 (7.9) [n = 57] | 2.6 (10.7) [n = 505] | 0.795 |
| % Impairment while working      | 13.3 (21.9) [n = 57] | 10.2 (18.7) [n = 502] | 0.238 |
| % Overall work impairment       | 14.8 (23.5) [n = 57] | 11.5 (20.2) [n = 502] | 0.251 |
| % Activity impairment           | 24.0 (28.6) [n = 111] | 15.0 (23.6) [n = 787] | <0.001 |

DLQI, Dermatology Life Quality Index; EQ VAS, EuroQol visual analogue scale; PEST, Psoriasis Epidemiology Screening Tool; PsA, psoriatic arthritis; PsO, psoriasis; VAS, visual analogue scale; WPAI, Work Productivity and Activity Impairment.
Because joint erosions have been documented in 27% of patients within 10 months of PsA onset and in 47% of patients within 2 years, early screening and diagnosis of PsA may result in earlier therapeutic intervention
d; observational studies have shown improved patient outcomes in patients with PsA who are treated soon after a diagnosis of PsA. Two ‘head-to-head’ PE
PEST, EARP and PASE, respectively) in to-head’ evaluations of three screening tools (comparing PASQ, and detection of PsA. Some of the screening tests developed for PsA present unique features that may be advantageous in clinical settings. For instance, the PASE can also be used to monitor a patient’s response to therapy,
while the PEST, PASQ and ToPAS questionnaires include visual aids so that patients can quickly and easily identify areas of pain, stiffness or swelling. The PEST showed high specificity and sensitivity during its development, with similar results in one real-world study of patients with PsO evaluated by a dermatologist. Lower specificity of PEST was observed in another real-world study, but this may have been related to study design and patient population, and the results were still comparable to those with other screening tools. The PEST demonstrated superior performance compared with PAQ, with a sensitivity of 0.92 and a specificity of 0.78. Two ‘head-to-head’ evaluations of three screening tools (comparing PASQ, PEST and ToPAS and PEST, EARP and PASE, respectively) in detecting PsA concluded that the PEST had the most favourable balance between sensitivity and specificity to screen for PsA. Additional head-to-head comparisons with other available tools should be performed to determine the optimal tool to identify patient populations at risk for developing PsA, thus leading to earlier accurate diagnosis and treatment of PsA in clinical practice.

The use of screening tools can be beneficial in the detection of PsA, and comprehensive efforts to validate them in multiple clinical settings must continue, along with collection of critical feedback from patients and clinicians.

As with any observational study, there are possibilities of other unmeasured confounding variables. Care received by patients enrolled in the Corrona registry may not be representative of the frequency or type received by the general population of patients with PsO. All diagnoses of PsA were reported by dermatologists, and confirmation by a rheumatologist is not reported. Some patients may have had musculoskeletal symptoms that resulted in evaluation for PsA by their dermatologists and a subsequent diagnosis of another non-PsA musculoskeletal disorder (e.g. osteoarthritis or fibromyalgia). Additionally, all patients initiated or switched to a systemic biologic or non-biologic for treatment of PsO within 12 months of enrolment, which may have selected for patients with unstable or more active disease. Some of these agents are indicated for both PsO and PsA, and as such, select subclinical PsA symptoms may already have been treated, thus affecting the patients’ responses to the PEST and potentially reducing their scores. Furthermore, no corrections for potential confounders in the multivariate analyses were performed. Further research is needed to characterize patients by individual PEST score and to assess outcomes over time.

In conclusion, using the validated PEST, over one-tenth of patients with PsO enrolled in the US-based Corrona PsO Registry were classified as having PEST scores of ≥3, raising the possibility that many of these patients could have undiagnosed PsA and highlighting a need for improved screening for PsA in dermatology settings. Appropriate and earlier care of these patients with possible undiagnosed PsA is important because they are more likely to have nail PsO, higher activity impairment and worse health-related quality of life.

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