

The 12-item Psoriatic Arthritis Impact of Disease Questionnaire: Construct Validity, Reliability, and Interpretability in a Clinical Setting

Marco Di Carlo, Andrea Becciolini, Valentina Lato, Chiara Crotti, Ennio Giulio Favalli, and Fausto Salaffi

ABSTRACT. Objective. To study, in a real-life setting, the construct validity, the reliability, and the interpretability of the 12-item Psoriatic Arthritis Impact of Disease (PsAID-12) questionnaire in patients with psoriatic arthritis (PsA).

Methods. In 144 consecutive patients with PsA (81 men and 63 women, mean age of 51.4 ± 12.8 yrs, and 77 receiving biologic treatment), the PsAID-12 and other patient-reported outcomes (PRO) were collected, such as the Dermatology Life Quality Index. Each patient underwent articular and skin assessment.

Results. Construct validity: Factor analysis revealed a 2-factor result defined as the PsAID Symptom Score and the PsAID Skin Score. In determining convergent validity, significant correlations were found between the PsAID-12 and the clinical Disease Activity index for Psoriatic Arthritis (cDAPSA; $\rho = 0.867$, $p < 0.0001$). Multivariable analysis showed that the PsAID-12 is determined by the articular disease activity (cDAPSA, $p < 0.0001$), severity of psoriasis (PsO; physician's global assessment, $p < 0.0001$), and the presence of a coexisting fibromyalgia (FM; $p < 0.0001$). Reliability: Cronbach's alpha coefficient was 0.93 for the total PsAID-12. Interpretability: Applying the cDAPSA categorization of disease activity states, the PsAID-12 cutoff values resulted in 1.4 between remission and low disease activity (LDA), 4.1 between LDA and moderate disease activity (MDA), and 6.7 between MDA and high disease activity.

Conclusion. The PsAID-12 is an excellent PRO to evaluate the effect of PsA. It should be carefully handled in patients with coexisting FM. (First Release December 1 2016; J Rheumatol 2017;44:279–85; doi:10.3899/jrheum.160924)

Key Indexing Terms:

PSORIATIC ARTHRITIS

PsAID-12

PATIENT-REPORTED OUTCOMES

During the last decades, the approach to outcome measures has changed profoundly, moving toward a patient-centered perspective, not only in the field of rheumatic diseases¹. The patient involvement in research led to better knowledge of the importance of clinical studies and improved research recruitment and retention rates, and ameliorated the substance and the construct validity of new instruments². Riding on this innovative wave, the European League

Against Rheumatism (EULAR) endorsed the development of a new patient-reported outcome (PRO) for subjects with psoriatic arthritis (PsA): the Psoriatic Arthritis Impact of Disease (PsAID)³ questionnaire. This innovative tool is a patient-derived PRO. In PsAID development, patient representatives (patient research partners) made a substantial contribution to the building process of the final instrument⁴. A previous EULAR-guided similar experience in rheumatoid arthritis (RA) led to the Rheumatoid Arthritis Impact of Disease⁵ questionnaire. Although the detection of all RA expressions is complicated, this issue is even more difficult in PsA because of the protean features of this pathology.

Thus, the main aim of a patient-derived PRO in PsA is to identify the full burden on all the multifaceted disease domains of health. Recently, the Group for Research in Psoriasis and Psoriatic Arthritis (GRAPPA) treatment recommendations for PsA highlighted that the ideal clinical assessment should include patient-reported measures, next to the metrics instruments validated for PsA⁶. The most common indices currently used to evaluate disease activity in PsA are composite measures, such as the Composite

From the Rheumatology Department, Polytechnic University of Marche, Jesi; Rheumatology Department, Istituto Ortopedico Gaetano Pini, Milan; Clinical and Community Sciences Department, University of Milan, Milan, Italy.

M. Di Carlo, MD, Rheumatology Department, Polytechnic University of Marche; A. Becciolini, MD, Rheumatology Department, Istituto Ortopedico Gaetano Pini; V. Lato, MD, Rheumatology Department, Polytechnic University of Marche; C. Crotti, MD, Clinical and Community Sciences Department, University of Milan; E.G. Favalli, MD, Rheumatology Department, Istituto Ortopedico Gaetano Pini; F. Salaffi, MD, PhD, Rheumatology Department, Polytechnic University of Marche.

Address correspondence to Dr. M. Di Carlo, Rheumatology Department, Polytechnic University of Marche, Carlo Urbani Hospital, Via Aldo Moro 25, 60035, Jesi, Ancona, Italy. E-mail: dica.marco@yahoo.it

Accepted for publication October 27, 2016.

Personal non-commercial use only. The Journal of Rheumatology Copyright © 2017. All rights reserved.

Psoriatic Arthritis Disease Activity Index (CPDAI)⁷, the Psoriatic Arthritis Disease Activity Score⁸, the minimal disease activity criteria⁹, and the Disease Activity index for Psoriatic Arthritis (DAPSA)¹⁰. These instruments show good concurrent validity¹¹, are validated tools in clinical trials^{8,12,13}, and consist of many health domains, but their routine use is unfeasible in daily clinical practice because they are quite complex and time-consuming. The DAPSA is the easiest in computation, but it does not consider the skin assessment.

The PsAID 12-item domain of health (PsAID-12) is fast and simple, made up of 0–10 numerical rating scale (NRS) questions with a final result included between 0 and 10 (higher results indicate a worse condition). The 12 domains examine different perspectives, both physical and psychological, that are considered important in patients with PsA. Each domain has a different weight: pain, fatigue, and skin problems are those with a greater effect.

Recently, we preliminarily evaluated the clinimetric properties of the PsAID-12 administered in a touch-screen format¹⁴. Even if it is not a disease activity index, the PsAID-12 showed a good convergent validity with the DAPSA and a very good discriminant validity for minimal disease activity: 2.5 is the cutoff value, under which patients can be considered to fulfill these criteria.

Given the aforementioned preliminary data, the aims of our study were to evaluate the construct validity of the PsAID-12 in a clinical setting, to appraise its reliability, and to define its interpretability.

MATERIALS AND METHODS

Patients. There were 144 consecutive patients in the cohort of our cross-sectional study. Patients were recruited from the outpatient clinics of 2 Italian tertiary rheumatology centers (Rheumatology Department, Polytechnic University of Marche, Jesi, Italy, and the Rheumatology Department, Istituto Ortopedico Gaetano Pini, Milan, Italy) from January 2016 to July 2016 in real-world clinical settings. Inclusion criteria were represented by age > 18 years, a diagnosis of PsA fulfilling the CIASSification for Psoriatic ARthritis criteria¹⁵ with peripheral inflammatory involvement, and the agreement to sign the informed consent for the anonymous analysis of the data. Patients with coexistent sacroiliitis or psoriatic spondylitis were included. Local ethics committee approval was not necessary because all patients underwent clinical and clinimetric examination per our local protocols. Patients were excluded if they had active skin disease other than psoriasis (PsO) and concomitant inflammatory joint conditions (such as gout or calcium pyrophosphate deposition).

Measurements. After the collection of sociodemographic data [age, sex, yrs of school attendance, yrs of articular disease duration, yrs of cutaneous disease duration, treatment, and body mass index (BMI)], patients were requested to fill in a 10-cm visual analog scale for pain and disease activity assessment (patient's global assessment), the Dermatology Life Quality Index (DLQI)¹⁶, and the PsAID-12³. Comorbidities were ascertained through the Self-administered Comorbidity Questionnaire (SCQ)¹⁷. The original list of this questionnaire consisted of 13 common diseases, including osteoarthritis and RA, with 2 empty lines at the end to write in other medical problems. We modified the authentic list by removing RA and including inflammatory bowel disease. Moreover, for each patient, the presence of a concomitant fibromyalgia (FM) was assessed using the 2010 American College of Rheumatology criteria¹⁸. Acute-phase reactants, such as

C-reactive protein (mg/dl) and erythrocyte sedimentation rate (mm/h), were also registered.

Patients underwent clinical examination performed by 2 experienced rheumatologists blinded to the questionnaire results. The following variables were evaluated: the 68-joint tender joint count (TJC) and the 66-joint swollen joint count (SJC), the Leeds Enthesitis Index (LEI)¹⁹, and the dactylitis digit count. The severity of the cutaneous manifestations was estimated through the physician's global assessment (PGA) for PsO. We chose this scoring method for its easy application in a rheumatologic clinical setting. Even though the Psoriasis Area and Severity Index is more detailed and better validated²⁰, these 2 tools demonstrated to be highly correlated^{21,22}.

At the completion of the questionnaires and clinical examination, the DAPSA and clinical DAPSA (cDAPSA) were calculated. According to cDAPSA value, patients were categorized into 4 disease activity states: remission (REM) ≤ 4 , low disease activity (LDA) > 4 and ≤ 13 , moderate disease activity (MDA) > 13 and ≤ 27 , and high disease activity (HDA) > 27 ²³.

Statistical analysis. Data were stored in a Microsoft Excel database and have been processed with SPSS 11.0, and MedCalc 7.1.02 for statistical software packages for Windows XP. Parametric techniques may be applicable for certain ordinal level data; however, our data were generally not normally distributed (Kolmogorov–Smirnov test for normal distribution) and therefore the use of nonparametric techniques provided a more conservative statistical significance estimation. Where appropriate, median and interquartile ranges were presented as well as means and SD.

The construct validity of the PsAID-12 in patients with PsA was investigated in 3 ways. First, we analyzed the underlying component structure of the items. We performed a principal component factor analysis using main axis extraction with varimax rotation method, which maximizes the independence of the factors. An eigenvalue criterion of 1.0 was used to select factors, and the results have been given in terms of the percentage of variance in the scale score explained by the principal factor. Second, we examined convergent validity by correlating the scores of the index with the other measures applied in our study. To quantify these relationships, we obtained Spearman rho correlation coefficients. Third, we investigated a possible influence on pain grade of some patient characteristics, such as age, sex, educational level, and the number of comorbidities on the PsAID-12; this analysis was made using the chi-square test (discriminant validity). The Kruskal–Wallis and Wilcoxon tests were performed to study the relationship between the different PsAID score levels and these sociodemographic risk factors. A multivariable analysis was constructed to adjust for factors potentially associated with poor health-related quality of life (HRQOL) in patients with PsA. Covariates chosen by *a priori* analysis were the following: sex (as a dichotomous variable), coexistence of FM (as a dichotomous variable), age (as a continuous variable), years of school attendance (as a continuous variable), years of PsA duration (as a continuous variable), BMI (as a continuous variable), SCQ (as a continuous variable), cDAPSA, LEI, and PGA scores (as continuous variables). All these factors were introduced as covariates in multiple regression models, in which the PsAID-12 scores were dependent variables. All variables were entered simultaneously. The level of statistical significance was set at 0.01 to reduce increasing risk of reporting errors because of multiple comparisons.

The reliability was assessed in terms of the internal consistency of the PsAID subscales. If the PsAID-12 is internally consistent in the PsA population, we would expect items within the individual scales (or dimension) to be highly correlated with each other. Two techniques were used to evaluate the internal consistency of the PsAID questionnaire. Cronbach's alpha statistic measures the overall correlation between items within a scale. A 0.8 value is usually considered acceptable. Interitem correlations compare scores on individual items with the total score of the scale. Items with item–total correlations < 0.4 should be considered rejects.

The interpretability was evaluated by categorizing patients in the 4 disease activity states of the cDAPSA. In each cDAPSA disease activity state, the PsAID-12 arithmetic means with SD, medians, and the 25th and

75th percentiles were calculated. To define the PsAID-12 cutoff values, the following approach was applied: the cutoff between REM and MDA was obtained by taking the PsAID-12 mean value of the 75th percentile of REM and the PsAID-12 mean value of the 25th percentile of LDA. After this step, we calculated the arithmetic mean between these 2 values, and if necessary the mean was rounded off to the first decimal number. The resulting number represents the cutoff value in the transition from REM to LDA. The same method (arithmetic mean), rounded off to the first decimal number, between the mean PsAID-12 values of the 75th percentile of the lower disease activity status and the 25th percentile of the adjacent higher disease activity rank, was used to define the PsAID-12 cutoff in the transition from LDA to MDA, and from MDA to HDA.

RESULTS

The study cohort consisted of 81 men (56.2%) and 63 women (43.8%), with a mean age of 51.4 ± 12.8 years and 11.7 ± 4.2 years of school attendance. The cohort was mildly overweight (mean BMI 26.0 ± 4.2). The mean PsA duration was 10.3 ± 8.0 years and the mean PsO length was 16.5 ± 12.9 years. Actual synovitis (TJC or SJC ≥ 1) was observed in 79 patients (54.9%). Dactylitis was present in 15 subjects (10.4%), enthesitis (defined as LEI ≥ 1) was detectable in 38 patients (26.4%), and axial disease was registered in 23 participants (16.0%). Seventy-seven patients (53.5%) were treated with a biologic drug; 73 (50.7%) were receiving antitumor necrosis factor (anti-TNF) blockade and 4 (2.3%) were receiving antiinterleukin 12/23 (ustekinumab). Of the patients taking anti-TNF agents, 23 (16.0%) were taking adalimumab, 23 (16.0%) infliximab, 13 (9.0%) golimumab, 13 (9.0%) etanercept, and 1 (0.7%) certolizumab pegol. Seventy-three patients (50.7%) were receiving therapy with traditional disease-modifying antirheumatic drugs. Specifically, 56 (38.9%) were taking methotrexate, 7 sulfasalazine (4.9%), 5 (3.5%) leflunomide, and 5 (3.5%) cyclosporine. The mean SCQ score registered was $2.76 (\pm 3.49)$. A concomitant FM was present in 27 of the subjects (18.8%).

Construct validity. Factor analysis was carried out to examine the factorial structure of the Italian version of the PsAID-12. Items were accepted on the final factors if they had a loading of > 0.6 on the corresponding factor. The analysis revealed a 2-factor result (eigenvalues 7.201 and 1.617). The factors consisted of 9 and 3 items, respectively. The first factor, which we named the PsAID Symptom Score, accounted for 51.4% of the explained variance and represented the patient's rating for the articular disease effect on different daily life areas. The second factor, called the PsAID Skin Score, accounted for 22.1% of the explained variance, representing the patient's rating of PsO effect on HRQOL. Table 1 shows the loading of each item after varimax rotation with Kaiser normalization on the 2 factors.

The PsAID Symptom Score factor consists of 9 items focused on the articular disease (pain, fatigue, and sleep disturbance), the work and physical disability, and psychosocial aspects (coping, social participation, anxiety, and depression). Its calculation is explained as follows:

Table 1. Factor analysis of the PsAID-12 items. Rotated component matrix using the principal component analysis extraction method and varimax rotation with Kaiser normalization (n = 144).

Rotated Component Matrix	Component	
	PsAID Symptom Score	PsAID Skin Score
1. Pain	0.888	0.123
2. Fatigue	0.838	0.124
3. Skin problems	0.101	0.824
4. Work and/or leisure activities	0.891	0.191
5. Functional capacity	0.926	0.146
6. Discomfort	0.521	0.710
7. Sleep disturbance	0.803	0.221
8. Coping	0.792	0.150
9. Anxiety	0.782	0.304
10. Embarrassment and/or shame	0.191	0.901
11. Social participation	0.690	0.377
12. Depression	0.611	0.491

The highest loading (> 0.60) of each item is in bold face. PsAID-12: Psoriatic Arthritis Impact of Disease 12 items; PsAID: Psoriatic Arthritis Impact of Disease; extraction method: principal component analysis; rotation method: varimax with Kaiser normalization.

$$(\text{NRS pain} \times 3 + \text{NRS fatigue} \times 2 + \text{NRS work and/or leisure activities} \times 2 + \text{NRS functional capacity} \times 2 + \text{NRS sleep disturbance} \times 2 + \text{NRS coping} + \text{NRS anxiety} + \text{NRS social participation} + \text{NRS depression}) \div 15$$

The PsAID Skin Score is more likely to represent the interference caused by PsO in daily life (items 3, 6, and 10). Its calculation is the following:

$$(\text{NRS skin problems} \times 2 + \text{NRS discomfort} \times 2 + \text{NRS embarrassment and/or shame}) \div 5$$

During the test phase for convergent validity (Table 2), we found higher significant correlations comparing the PsAID-12 to composite indices of disease activity such as the cDAPSA ($\rho = 0.867$, $p < 0.0001$; Figure 1), with a high ability to measure pain and physical health (convergent construct validity). Of special interest are the correlations between the comparable dimension of the PsAID Skin Score and the DLQI ($\rho = 0.684$, $p < 0.0001$) and PGA ($\rho = 0.638$, $p < 0.0001$). Lower significant correlations were seen when the PsAID-12 was compared with sociodemographic variables (divergent construct validity). In particular, no correlation was found with PsA and PsO duration, and a small correlation was revealed with BMI ($\rho = 0.240$, $p = 0.0038$) and with comorbidities measured with SCQ ($\rho = 0.275$, $p = 0.0009$; Supplementary Table 1, available from the authors on request).

According to a multivariable analysis, these factors were associated with a significant relevance on the final score of the PsAID-12: the articular disease activity (cDAPSA,

Table 2. Correlations among PsAID-12, PsAID subscales, and disease activity indices for psoriatic arthritis and for psoriasis (n = 144; Spearman rank correlation coefficient). Values are correlation coefficient (significant p level).

Variables	DAPSA	DLQI	PGA	PsAID-12	PsAID Symptom Score	PsAID Skin Score
cDAPSA	0.996 (< 0.0001)	0.392 (< 0.0001)	0.406 (< 0.0001)	0.867 (< 0.0001)	0.880 (< 0.0001)	0.711 (< 0.0001)
DAPSA		0.405 (< 0.0001)	0.412 (< 0.0001)	0.868 (< 0.0001)	0.879 (< 0.0001)	0.717 (< 0.0001)
DLQI			0.747 (< 0.0001)	0.531 (< 0.0001)	0.449 (< 0.0001)	0.684 (< 0.0001)
PGA				0.489 (< 0.0001)	0.409 (< 0.0001)	0.638 (< 0.0001)
PsAID-12					0.986 (< 0.0001)	0.897 (< 0.0001)
PsAID Symptom Score						0.819 (< 0.0001)

PsAID-12: Psoriatic Arthritis Impact of Disease 12 items; PsAID: Psoriatic Arthritis Impact of Disease; cDAPSA: clinical Disease Activity index for Psoriatic Arthritis; DAPSA: Disease Activity index for Psoriatic Arthritis; DLQI: Dermatology Life Quality Index; PGA: physician's global assessment of psoriasis.

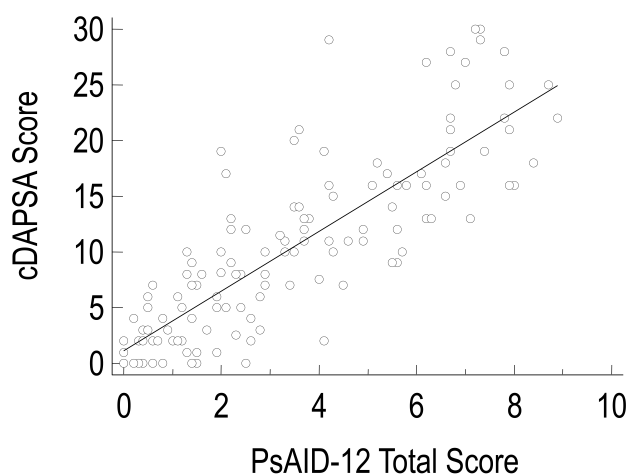


Figure 1. Scatter plot showing the correlation between the PsAID-12 (X-axis) and the cDAPSA (Y-axis; correlation coefficient 0.867, $p < 0.0001$). PsAID-12: Psoriatic Arthritis Impact of Disease 12 items; cDAPSA: clinical Disease Activity index for Psoriatic Arthritis.

$p < 0.0001$), the severity of PsO (PGA, $p < 0.0001$), and the presence of a coexisting FM ($p < 0.0001$; Table 3).

Reliability. Cronbach's alpha was 0.93 (95% lower confidence limit = 0.92) for the total PsAID-12. Both subscales of the PsAID showed satisfying to good internal consistency. Cronbach's alpha was 0.95 (95% lower confidence limit = 0.93) for the first factor (PsAID Symptom Score) and 0.83 (95% lower confidence limit = 0.78) for the second factor (PsAID Skin Score).

Interpretability. Following the cDAPSA definition, 43 patients (29.8%) reached REM, 54 subjects (37.5%) LDA, 41 patients (28.5%) MDA, and 6 subjects (4.2%) HDA.

The PsAID-12 median values for each disease activity status were 0.5 for REM, 2.6 for LDA, 6.2 for MDA, and 7.3 for HDA. Focusing on the approach of the 75th and 25th percentile mean values of adjacent categories to define the cutoff values, the percentile values considered in the passage from REM to LDA were 1.27 (mean value of the PsAID-12 at 75th percentile of REM) and 1.53 (mean value of the

PsAID-12 at 25th percentile of LDA). The arithmetic mean of these 2 numbers was 1.4 (without rounding off), the PsAID-12 cutoff value for REM. The PsAID-12 cutoff values resulted in 4.1 between LDA and MDA (4.125 being the arithmetic mean of the mean values of the PsAID-12 at 75th percentile of LDA and at 25th percentile of MDA), and of 6.7 between MDA and HDA (6.67 being the arithmetic mean of the mean values of the PsAID-12 at 75th percentile of MDA and at 25th percentile of HDA). The differences obtained among the 4 levels resulted in significance (Kruskal-Wallis test, $p < 0.0001$; Figure 2). Figure 3 sums up the cutoff values obtained in our analysis.

DISCUSSION

The patient-centered perspective has become a new model not only in healthcare delivery, but also in healthcare research. The reasons to include patient-centeredness in research are mainly related to the improved selection and refinement of the outcomes¹.

The PsAID is a patient-derived PRO in PsA, translated and validated across 13 countries. In the international validation study, Gossec, *et al* described the satisfactory psychometric properties of the instruments and obtained a patient-acceptable symptom state cutoff of 4, while a change of ≥ 3 points is considered a significant absolute change³.

In a previous work, we proved the feasibility and the equivalence of the questionnaire, even in touch-screen format compared with the paper-administered version. In the same study, we defined a PsAID-12 cutoff value of 2.5 for the fulfillment of the minimal disease activity criteria and we showed in a preliminary way the correlation between the PsAID-12 and the DAPSA¹⁴.

Searching for the perfect clinimetric tool for this complex disease that is feasible for daily clinical practice use, we decided to define the properties of the PsAID-12 more extensively.

Our study upheld the reliability of the PsAID-12, confirming the good internal consistency of the 12 items^{5,14}, and introduced many new considerations about the instrument.

Table 3. Multivariable analysis comparing the total score of PsAID-12 (dependent variable) to the potential variables influencing the quality of life in patients with PsA (n = 144).

Independent Variables	Coefficient	SE	r _{partial}	t	p
Constant	-0.5848				
Age, yrs	0.003444	0.01165	0.02664	0.296	0.7681
BMI	-0.001544	0.02796	-0.004981	-0.0552	0.9560
cDAPSA	0.2242	0.01551	0.7935	14.461	< 0.0001
Dactylitis	-0.1443	0.3276	-0.03970	-0.441	0.6602
Fibromyalgia	1.7071	0.3101	0.4446	5.505	< 0.0001
LEI	-0.001770	0.1418	-0.001126	-0.0125	0.9901
PsA disease duration, yrs	0.02754	0.01459	0.1678	1.888	0.0613
PsO disease duration, yrs	-0.01576	0.01032	-0.1365	-1.528	0.1291
Educational level, yrs	0.05237	0.02741	0.1698	1.911	0.0583
PGA	0.4739	0.09512	0.4097	4.982	< 0.0001
SCQ	-0.001721	0.03590	-0.004322	-0.0479	0.9618

PsAID-12: Psoriatic Arthritis Impact of Disease 12 items; PsA: psoriatic arthritis; BMI: body mass index; cDAPSA: clinical Disease Activity index for Psoriatic Arthritis; LEI: Leeds Enthesitis Index; PsO: psoriasis; PGA: physician's global assessment of psoriasis; SCQ: Self-administered Comorbidity Questionnaire; SE: standard error.

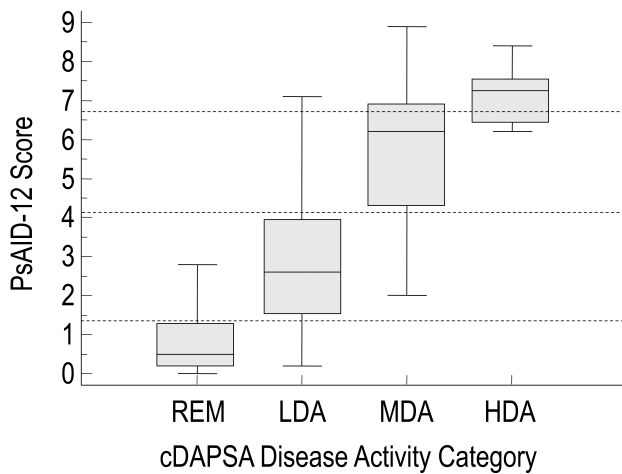


Figure 2. Box-and-whisker plots of the PsAID-12 scores (Y-axis) for each disease activity category defined by cDAPSA (X-axis; Kruskal-Wallis test, $p < 0.0001$). The boxes represent the values from the 25th to the 75th percentiles of PsAID-12 for each disease activity status, respectively REM, LDA, MDA, and HDA. The middle lines inside the boxes represent the medians. The dotted lines are the cutoff values. PsAID-12: Psoriatic Arthritis Impact of Disease 12 items; cDAPSA: clinical Disease Activity index for Psoriatic Arthritis; REM: remission; LDA: low disease activity; MDA: moderate disease activity; HDA: high disease activity.

Intriguingly, the factor analysis distinguished 2 components in the main structure of the questionnaire. The first one connects the features related to the articular disease (such as pain, fatigue, work ability, functional capacity, and sleep disturbance) to those related to the psychosocial sphere (such as coping, social participation, anxiety, and depression). The second one purely characterizes skin disease (skin problems, discomfort, and embarrassment). This significance persuaded us to calculate 2 separate PsAID subscales: the PsAID Symptoms Score and the PsAID Skin Score. This dichotomy could facilitate the PsO assessment, given that the PsAID Skin Score correlates well with DLQI and PGA.

The PsAID-12 confirmed its correlation with the DAPSA and cDAPSA. We are aware that scores without cutoffs are useful, but probably lack in interpretation²⁴. To enhance the PsAID-12 meaning, the cutoff values between disease activity states have been obtained using the cDAPSA categories as external criterion²³. Given that our cohort was distinguished for the peripheral joint involvement, we used the cDAPSA categories for their simple use in clinical practice and for their easy evaluation in a predominant peripheral disease involvement. The approach has been adopted by Schoels, *et al* to define cutoff values calculating the arithmetic mean between the 75th percentile mean value

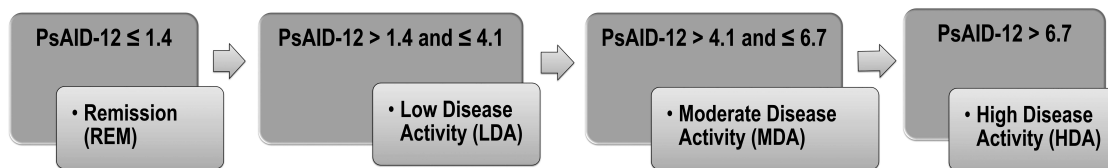


Figure 3. PsAID-12 cutoff values for the disease activity states using the cDAPSA categories as external criterion. PsAID-12: Psoriatic Arthritis Impact of Disease 12 items; cDAPSA: clinical Disease Activity index for Psoriatic Arthritis.

of a lower disease activity status and the 25th percentile mean value of the adjacent higher rank, and was also chosen to determine the cutoff points for the DAPSA and cDAPSA themselves²³. It must be emphasized that PsAID-12 is not a disease activity index. However, it showed excellent metric properties in terms of correlation with the DAPSA and cDAPSA. Further, the questionnaire is poorly influenced by the comorbidities and by the sociodemographic variables. Taking all these data, we can suppose its involvement to be a “patient-reported disease activity index”. Moreover, the recent GRAPPA guidelines encouraged the use of PRO in PsA monitoring, confirming that the ideal assessment should include patient-reported measures as an overarching principle⁶. According to this request, we think that the cutoff determination enriches these tool qualities.

The multivariable analysis revealed that the final score of the PsAID-12 is determined by PsO severity, measured through the PGA. This result confirms the effectiveness of this instrument, even in patients with strong skin involvement.

Nevertheless, the multivariable analysis highlighted a potential critical aspect in PsAID-12 interpretation, which is the presence of a coexisting FM. FM is associated with the final score of PsAID-12. This condition should always be evaluated in everyday clinical practice, especially if we consider its high prevalence in patients with PsA. In a previous report, we detected the presence of FM in the 17.2% of patients with axial PsA²⁵, and a latest study measured a 17.8% FM frequency in patients with PsA²⁶. In our cohort, the FM prevalence is similar (18.7%). In a recent paper, Brikman, *et al* revealed that the CPDAI, DAPSA, Disease Activity Score at 28 joints, LEI, and Health Assessment Questionnaire are significantly higher in patients with PsA with FM, influencing a lower likelihood ratio to achieve MDA²⁶. As with all the other indices, the interpretation of the PsAID-12 is almost nullified if there is a coexisting FM, so it is mandatory to rule out this condition in all patients, especially those evaluated through PRO. Indeed, it is always necessary for clinical judgment, next to the patient-derived measures.

We are aware of the main limitations of our cross-sectional study. In particular, the consecutive cohort of patients with PsA was nonrandomly selected, and we also performed a single visit assessment without the possibility to collect any data about the responsiveness (ongoing evaluation).

In our work, we demonstrated the usefulness of the PsAID-12 in clinical practice. For its approving properties, we recommend its routine use in patient with PsA.

REFERENCES

1. Frank L, Basch E, Selby JV; Patient-Centered Outcomes Research Institute. The PCORI perspective on patient-centered outcomes research. *JAMA* 2014;312:1513–4.
2. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al. A systematic review of the impact of patient and public involvement on service users, researchers and communities. *Patient* 2014;7:387–95.
3. Gossec L, de Wit M, Kiltz U, Braun J, Kalyoncu U, Scivo R, et al; EULAR PsAID Taskforce. A patient-derived and patient-reported outcome measure for assessing psoriatic arthritis: elaboration and preliminary validation of the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire, a 13-country EULAR initiative. *Ann Rheum Dis* 2014;73:1012–9.
4. de Wit MP, Kvien TK, Gossec L. Patient participation as an integral part of patient-reported outcomes development ensures the representation of the patient voice: a case study from the field of rheumatology. *RMD Open* 2015;1:e000129.
5. Gossec L, Paternotte S, Aanerud GJ, Balanescu A, Boumpas DT, Carmona L, et al. Finalisation and validation of the Rheumatoid Arthritis Impact of Disease score, a patient-derived composite measure of impact of rheumatoid arthritis: a EULAR initiative. *Ann Rheum Dis* 2011;70:935–42.
6. Coates LC, Kavanaugh A, Mease PJ, Soriano ER, Laura Acosta-Felquer M, Armstrong AW, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. *Arthritis Rheumatol* 2016;68:1060–71.
7. Mumtaz A, Gallagher P, Kirby B, Waxman R, Coates LC, Veale J D, et al. Development of a preliminary composite disease activity index in psoriatic arthritis. *Ann Rheum Dis* 2011;70:272–7.
8. Helliwell PS, Fitzgerald O, Fransen J, Gladman DD, Kreuger GG, Callis-Duffin K, et al. The development of candidate composite disease activity and responder indices for psoriatic arthritis (GRACE Project). *Ann Rheum Dis* 2013;72:986–91.
9. Coates LC, Fransen J, Helliwell PS. Defining minimal disease activity in psoriatic arthritis: a proposed objective target for treatment. *Ann Rheum Dis* 2010;69:48–53.
10. Schoels M, Aletaha D, Funovits J, Kavanaugh A, Baker D, Smolen JS. Application of the DAREA/DAPSA score for assessment of disease activity in psoriatic arthritis. *Ann Rheum Dis* 2010;69:1441–7.
11. Salaffi F, Ciapetti A, Carotti M, Gasparini S, Gutierrez M. Disease activity in psoriatic arthritis: comparison of the discriminative capacity and construct validity of six composite indices in a real world. *Biomed Res Int* 2014;2014:528105.
12. FitzGerald O, Helliwell P, Mease P, Mumtaz A, Coates L, Pedersen R, et al. Application of composite disease activity scores in psoriatic arthritis to the PRESTA data set. *Ann Rheum Dis* 2012;71:358–62.
13. Coates LC, Helliwell PS. Validation of minimal disease activity criteria for psoriatic arthritis using interventional trial data. *Arthritis Care Res* 2010;62:965–9.
14. Salaffi F, Di Carlo M, Carotti M, Farah S, Gutierrez M. The Psoriatic Arthritis Impact of Disease 12-item questionnaire: equivalence, reliability, validity, and feasibility of the touch-screen administration versus the paper-and-pencil version. *Ther Clin Risk Manag* 2016;12:631–42.
15. Taylor W, Gladman D, Helliwell P, Marchesoni A, Mease P, Mielants H; CASPAR Study Group. Classification criteria for psoriatic arthritis: development of new criteria from a large international study. *Arthritis Rheum* 2006;54:2665–73.
16. Mazzotti E, Picardi A, Sampogna F, Sera F, Pasquini P, Abeni D; IDI Multipurpose Psoriasis Research on Vital Experiences study group. Sensitivity of the Dermatology Life Quality Index to clinical change in patients with psoriasis. *Br J Dermatol* 2003;149:318–22.
17. Sangha O, Stucki G, Liang MH, Fossel AH, Katz JN. The Self-administered Comorbidity Questionnaire: a new method to assess comorbidity for clinical and health services research. *Arthritis Rheum* 2003;49:156–63.
18. Wolfe F, Clauw DJ, Fitzcharles MA, Goldenberg DL, Katz RS, Mease P, et al. The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. *Arthritis Care Res* 2010;62:600–10.

19. Healy PJ, Helliwell PS. Measuring clinical enthesitis in psoriatic arthritis: assessment of existing measures and development of an instrument specific to psoriatic arthritis. *Arthritis Rheum* 2008;59:686–91.
20. Robinson A, Kardos M, Kimball AB. Physician Global Assessment (PGA) and Psoriasis Area and Severity Index (PASI): why do both? A systematic analysis of randomized controlled trials of biologic agents for moderate to severe plaque psoriasis. *J Am Acad Dermatol* 2012;66:369–75.
21. Cappelleri JC, Bushmakina AG, Harness J, Mamolo C. Psychometric validation of the physician global assessment scale for assessing severity of psoriasis disease activity. *Qual Life Res* 2013; 22:2489–99.
22. Langley RG, Ellis CN. Evaluating psoriasis with Psoriasis Area and Severity Index, Psoriasis Global Assessment, and Lattice System Physician's Global Assessment. *J Am Acad Dermatol* 2004; 51:563–9.
23. Schoels MM, Aletaha D, Alasti F, Smolen JS. Disease activity in psoriatic arthritis (PsA): defining remission and treatment success using the DAPSA score. *Ann Rheum Dis* 2016;75:811–8.
24. Machado PM. Measurements, composite scores and the art of 'cutting-off'. *Ann Rheum Dis* 2016;75:787–90.
25. Salaffi F, De Angelis R, Carotti M, Gutierrez M, Sarzi-Puttini P, Atzeni F. Fibromyalgia in patients with axial spondyloarthritis: epidemiological profile and effect on measures of disease activity. *Rheumatol Int* 2014;34:1103–10.
26. Brikman S, Furer V, Wollman J, Borok S, Matz H, Polachek A, et al. The effect of the presence of fibromyalgia on common clinical disease activity indices in patients with psoriatic arthritis: a cross-sectional study. *J Rheumatol* 2016;43:1749–54.