Patient Global Assessment in Psoriatic Arthritis: A Multicenter GRAPPA and OMERACT Study

ALBERTO CAULI, DAFNA D. GLADMAN, ALESSANDRO MATHIEU, IGNAZIO OLIVIERI, GIOVANNI PORRU, PAUL P. TAK, CLAUDIA SARDU, ILONA UJFALUSSY, RAFFAELE SCARPA, ANTONIO MARCHESONI, WILLIAM J. TAYLOR, ANTONIO SPADARO, JOSE L. FERNÀNDEZ-SUEIRO, CARLO SALVARANI, JOACHIM R. KALDEN, ENNIO LUBRANO, SUELI CARNEIRO, FRANCESCA DESIATI, JOHN A. FLYNN, SALVATORE D'ANGELO, ALESSANDRA VACCA, ARNO W.R. VAN KUIJK, MARIA GRAZIA CATANOSO, MATHIAS GRUENKE, ROSARIO PELUSO, WENDY J. PARSONS, NICOLA FERRARA, PAOLO CONTU, PHILIP S. HELLIWELL, and PHILIP J. MEASE; for the GRAPPA 3PPsA Study Group

ABSTRACT. ***Objective.*** During OMERACT 8, delegates selected patient global assessment (PGA) of disease as a domain to be evaluated in randomized controlled trials in psoriatic arthritis (PsA). This study assessed the reliability of the PGA, measured by means of 0–100 mm visual analog scale (VAS), and the additional utility of separate VAS scales for joints (PJA) and skin (PSA).

Methods. In total, 319 consecutive patients with PsA (186 men, 133 women, mean age 51 ± 13 yrs) were enrolled. PGA, PJA, and PSA were administered at enrolment (W0) and after 1 week (W1). Detailed clinical data, including ACR joint count, Psoriasis Area and Severity Index (PASI), and Hospital Anxiety and Depression Scale, were recorded.

Results. Comparison of W0 and W1 scores showed no significant variations (intraclass correlation coefficients for PGA 0.87, PJA 0.86, PSA 0.78), demonstrating the reliability of the instrument. PGA scores were not influenced by patient anxiety or depression, but were dependent on PJA and PSA ($p = 0.00001$). PJA was dependent on the number of swollen and tender joints ($p < 0.00001$). PSA scores were influenced by the extent of skin psoriasis and by hand skin involvement ($p = 0.00001$). Joint and skin disease were found not to correlate in terms of disease activity as evidenced by the swollen joint count compared to PASI ($r = 0.11$) and by the PJA compared to PSA ($r = 0.38$).

Conclusion. PGA assessed by means of VAS is a reliable tool related to joint and skin disease activity. Because joint and skin disease often diverge it is suggested that in some circumstances both PJA and PSA are also assessed. (J Rheumatol First Release Feb 15 2011; doi:10.3899/jrheum.100857)

Key Indexing Terms:
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From the Department of Medical Sciences, Policlinico of the University of Cagliari, Monserrato, Italy; The University of Toronto, Toronto Western Hospital, Toronto, Ontario, Canada; Rheumatology Unit, Policlinico di Monserrato, University of Cagliari; Rheumatology Department of Lucania, San Carlo Hospital of Potenza and Madonna delle Grazie Hospital, Matera, Italy; Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands; Department of Public Health, University of Cagliari; Department of Rheumatology, Semmelweis University, Budapest, Hungary; Rheumatology Research Unit, Department of Clinical and Experimental Medicine, University "Federico II," Naples, Italy; Rheumatology Department, Istituto Ortopedico G. Pini, Milano, Italy; Rehabilitation Teaching and Research Unit, Department of Medicine, Wellington School of Medicine and Health Sciences, University of Otago, Wellington, New Zealand; Department of Clinical and Medical Therapy, Sapienza University, Rome, Italy; Rheumatology Division, Hospital Universitario Juan Canalejo, La Coruña, Spain; Rheumatology Unit, Arcispedale Santa Maria Nuova, Reggio Emilia, Italy; Medizinische Klinik III mit Poliklinik, Friedrich-Alexander Universität, Erlangen-Nuernberg, Germany; Rheumatology Unit, Fondazione Maugeri, Istituto Scientific Telese Terme (BN), Telese Terme, Italy; Sector of Dermatology, HUCFF School of Medicine, Federal University of Rio de Janeiro, and Sector of Dermatology, HUPE School of Medical Sciences, State University of Rio de Janeiro, Rio de Janeiro, Brazil; Spondyloarthritis Program, Johns Hopkins University, School of Medicine, Baltimore, Maryland, USA; University of Munich, Unit for Rheumatology / Clinical Trials, Muenchen, Germany; Department of Health Science, University of Molise, Campobasso, Italy; Leeds Institute of Molecular Medicine, University of Leeds, Leeds UK; and Swedish Medical Centre and University of Washington School of Medicine, Seattle, Washington, USA.

A. Cauli, MD, PhD, Department of Medical Science, Policlinico di Monserrato, University of Cagliari; D.D. Gladman, MD, FRCPC, Professor of Medicine, University of Toronto, Senior Scientist, Toronto Western Research Institute, Director, Psoriatic Arthritis Program, University Health Network, Toronto; A. Mathieu, MD, Professor of Rheumatology, Head, Rheumatology Unit, University of Cagliari; I. Olivieri, MD, Director, Rheumatology Department of Lucania, San Carlo Hospital of Potenza and Madonna delle Grazie Hospital of Matera; G. Porru, MD, Department of Medical Science, Policlinico di Monserrato, University of Cagliari; C. Sardu, MD, Department of Public Health, University of Cagliari; P.P. Tak, MD, Professor of Rheumatology, Academic Medical Center, University of Amsterdam; I. Ujfalussy, MD, Department of Rheumatology, Semmelweis University; R. Scarpa, MD, Rheumatology Research Unit, Department of Clinical and Experimental Medicine, University "Federico II"; A. Marchesoni, MD, Rheumatology Department, Istituto Ortopedico G. Pini; W.J. Taylor, MBChB, FRACP, FAFRM, Rehabilitation Teaching and Research Unit, Department of Medicine, Wellington School of Medicine and Health Sciences, University of Otago; A. Spadaro, MD, Associate Professor, Chair, Rheumatology, Department of Clinical and Medical Therapy, Sapienza University of Rome; J.L. Fernàndez-Sueiro, MD, Rheumatology Division, Hospital

Universitario Juan Canalejo; C. Salvarani, MD, Rheumatology Unit, Arcispedale S. Maria Nuova; J.R. Kalden, MD, Medizinische Klinik III mit Poliklinik, Friedrich-Alexander Universität Erlangen-Nuernberg; E. Lubrano, MD, PhD, Consultant Rheumatologist, Rheumatology Unit, Fondazione Maugeri, Istituto Scientifico Telese Terme (BN); S. Carneiro, MD, PhD, Dermatologist and Rheumatologist, HUCFF Federal University of Rio de Janeiro, Associate Professor of Dermatology, School of Medical Sciences, State University of Rio de Janeiro; F. Desiati, MD, Rheumatology Department, Istituto Ortopedico G. Pini; J.A. Flynn, MD, MBA, FACP, FACR, Professor of Medicine, Director, Spondyloarthritis Program, Johns Hopkins University, School of Medicine; S. D'Angelo, MD, Rheumatology Department of Lucania, San Carlo Hospital of Potenza and Madonna delle Grazie Hospital of Matera; A. Vacca, MD, Rheumatology Unit, University of Cagliari; A.W.R. van Kuijk, MD, Academic Medical Center, University of Amsterdam; M.G. Catanoso, MD, Rheumatology Unit, Arcispedale S. Maria Nuova; M. Gruenke, MD, Medizinische Klinik III mit Poliklinik, Friedrich-Alexander Universität Erlangen-Nuernberg; R. Peluso, MD, Rheumatology Research Unit, Department of Clinical and Experimental Medicine, University "Federico II"; W.J. Parsons, PhD, Fondazione Maugeri, Istituto Scientifico Telese Terme (BN); N. Ferrara, MD, Professor, Chair of Internal Medicine, Department of Health Science, University of Molise, Fondazione Maugeri, Istituto Scientifico Telese Terme (BN); P. Contu, MD, Department of Public Health, University of Cagliari; P.S. Helliwell, MD, PhD, Leeds Institute of Molecular Medicine, University of Leeds; P.J. Mease, MD, Seattle Rheumatology Associates, Chief, Swedish Medical Center, Rheumatology Research Division, Clinical Professor, University of Washington School of Medicine.

Address correspondence to Dr. A. Cauli, Dipartimento di Scienze Mediche, Università di Cagliari, ss 554, Monserrato 09042, Italy. E-mail: cauli@medicina.unica.it

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Psoriatic arthritis (PsA) is a systemic chronic inflammatory disease affecting principally the joints and skin. It is generally seronegative for rheumatoid factor and its main features, apart from skin psoriasis, include peripheral joint arthritis with or without inflammatory back disease, as well as enthesitis, dactylitis, and other extraarticular features that are common to the spectrum of spondyloarthritis[1,2].

Significant efforts have been focused on the attempt to better classify PsA[3] and on development of accepted outcome measures for treatment response[4]. The efficacy of biologic drugs in PsA has been demonstrated in several randomized controlled trials (RCT) by means of non-disease-specific instruments[5], underlining the need for strictly developed new assessment tools, to assess response to treatment not only in RCT and longitudinal observational studies, but also in daily practice.

The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) was founded in 2003 and includes rheumatologists, dermatologists, and other investigators[6]. Goals of GRAPPA include the validation and standardization of outcome assessment tools in PsA and psoriasis, both for basic clinical and therapeutic studies and for routine clinics. In an early approach, key domains to be assessed in PsA and psoriasis in research trials were identified through a literature review[4] and a Delphi exercise[7]. The issue was also widely discussed during GRAPPA meetings, where a preliminary set of recommended domains was identified for assessment of patients with PsA[8]. During the OMERACT 7 (Outcome Measures in Rheumatoid Arthritis Clinical Trials)[9] and OMERACT 8[10,11] meetings, specific sessions were designed to identify domains appropriate for inclusion in RCT and longitudinal observational trials in PsA. Six domains were considered a core set to be measured in all clinical trials. These included peripheral joint activity, skin activity, pain, patient global assessment (PGA), physical function and health-related quality of life. Several other domains (spinal disease, dactylitis, enthesitis, fatigue, nail disease, radiography, physician global assessment, and acute-phase reactants) were considered important, not mandatory, but preferably to be assessed at some point in a clinical trial development program. Notably, it was also recommended that a specific study should be performed to determine if PGA of disease activity, taking into account both joint and skin disease, is sufficient or if we should assess the global effects of skin and joint involvement segregated into 2 separate questions (skin and joints evaluated individually). GRAPPA set up a working group of 18 centers in 10 countries in order to assess this issue. The main aim of our study was therefore to assess the reliability of the PGA, measured by means of 0–100 mm visual analog scale (VAS), and the additional utility of separate VAS for joints (PJA) and skin (PSA).

MATERIALS AND METHODS

Patients. Consecutive patients fulfilling the Classification Criteria for Psoriatic Arthritis (CASPAR) were invited to participate in the study (56% were available to return for the followup visit); 319 patients were enrolled in 18 centers from 10 countries worldwide (Italy n = 174, USA 28, Canada 26, The Netherlands 25, Hungary 23, New Zealand 16, Germany 9, Brasil 9, Spain 8, United Kingdom 1). PsA patients were included in the study regardless of disease activity, treatment, and clinical subsets, as defined according to Moll and Wright[1].

Questionnaires. Patients' perception of disease was investigated following specific questions by means of 0–100 mm VAS as a global score (PGA), encompassing both joints and skin, as well as a question specific to joints and skin (PJA and PSA, respectively) (Table 1a, 1b, 1c). The questionnaires were elaborated by "expert opinion" consensus among GRAPPA members. In non-English-speaking countries the coordinator of the center was

Table 1. Patient global assessment (PGA), joint assessment (PJA), and skin assessment (PSA) questionnaires.

Global (PGA)
In all the ways in which your PSORIASIS and ARTHRITIS, as a whole, affects you, how would you rate the way you felt over the past week?
Excellent_____Poor

Joints (PJA)
In all the ways your ARTHRITIS affects you, how would you rate the way you felt over the past week?
Excellent_____Poor

Skin (PSA)
In all the ways your PSORIASIS affects you, how would you rate the way you felt over the past week?
Excellent_____Poor

responsible for the translation/backtranslation of the questionnaires; for all Italian centers A. Cauli was in charge. The questionnaires related to the degree of disease activity were administered at baseline and after 1 week, without any change in treatment, in order to test the reliability of the instrument. The 1-week interval was selected as a good compromise in order to avoid the simple repetition of the previous score by the patients and changes in disease activity. The 3 different VAS questionnaires were administered in a changing random order to exclude bias, on the same day as the physician examination.

Further, in order to rule out a possible influence of mood disorder on patient VAS scores, the Hospital Anxiety and Depression Scale (HADS) instrument was also administered to all patients, and anxiety and depression scores were calculated[12]. Scores of 0–7 in respective subscales are considered normal, with 8–10 borderline, and 11 or over indicating clinical case status.

Clinical assessment. Detailed clinical evaluation was performed according to a specific protocol using a dedicated clinical record form. Demographic data and medical history were taken at baseline. Joint disease clinical subsets were defined according to Moll and Wright[1]. The American College of Rheumatology (ACR) joint count (68 tender, 66 swollen joints) was employed for peripheral joint evaluation and the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) was employed in patients with axial involvement because they have been shown to be reliable in PsA[13]; the Psoriasis Area and Severity Index (PASI) score was used for skin psoriasis[14]. Presence of dactylitis and enthesitis was clinically assessed. Drug treatment at time of recruitment was also recorded.

Statistical analysis. Descriptive analysis was performed expressing variables as mean ± standard deviation, or median with 25th and 75th percentiles, according to data distribution. Intraclass correlation coefficient (ICC) was used to assess the concordance between VAS score at Week 0 and at Week 1. Pearson correlation analysis was carried out in order to evaluate the strength of association between joint counts and PASI score, between BASDAI and PASI in the axial subset, and between PJA and PSA. The strength of linear association was expressed through the correlation coefficient r and through R^2 values (ranging from 0 to 1) that express the extent to which the score expressed for one variable explains the variability in the score expressed for the other variable considered in the analysis.

The influence of PJA, PSA, anxiety (presence vs absence), and depression (presence vs absence) on PGA was analyzed through a multiple linear regression. PJA, PSA, anxiety, and depression were considered as exposure variables, while PGA was the outcome variable. Multiple linear regression allowed an estimate of the exposure effect for each variable, adjusting or controlling for the effects of the other variables included in the model. The best-fitting model was identified through a backward stepwise procedure, eliminating the exposure variables nonsignificantly associated ($p > 0.05$). Results were expressed through an R^2 value (ranging from 0 to 1) that revealed the extent to which the joint effect of exposure variables explained the variation in the outcome variable. Additionally, the effect of each exposure variable was quantified through a regression coefficient B, expressing the increase of the outcome variables produced by a unitary increment of the exposure variable. A multiple linear regression was also carried out to estimate the influence of sex, age, occupation (manual, intellectual, contact with public), dactylitis (presence vs absence), enthesitis (presence vs absence), number of tender joints, number of swollen joints, and arthritis duration on PJA.

Analogously, a multiple linear regression was performed to estimate the influence of sex, age, occupation (manual, intellectual, contact with public), PASI score, body surface areas involved (face, genitals, hands, buttocks and/or intergluteal, feet), and psoriasis duration on PSA.

Kruskal-Wallis test was performed to analyze differences in values of a continuous variable (PJA, PSA) between clinical subsets.

Ethical approval was provided in the different centers, according to the local legislation.

RESULTS

In total, 319 patients from 10 countries were recruited for the study. The median number of tender joints was 5 (range 1–13), median number of swollen joints was 1 (range 0–5), and the median PASI score was 2.80 (range 0.75–6.57). Median baseline values for the 3 questionnaires were as follows: PGA 49 (range 25–66), PJA 47 (range 22–69), and PSA 30 (range 11–60). Median total HADS resulted in the cumulative score of 10 (range 6–15), accounting for the median anxiety subscale of 5 (range 4–8) and median depressive subscale of 4 (range 2–8). Detailed clinical data from the patients are shown in Table 2.

Test/retest. The ICC revealed very good reproducibility for the VAS measures. ICC for PGA was 0.87 (95% CI 0.83–0.90), for PJA 0.86 (95% CI 0.81–0.89), and for PSA 0.78 (95% CI 0.72–0.83).

Patient global assessment. In order to quantify the specific influence of arthritis and dermatitis in the PGA of disease, we performed a multiple linear regression analysis; anxiety and depression scores were inserted as independent vari-

Table 2. Baseline clinical data of the 319 patients recruited.

Characteristic	
Male/female ratio, n	186/133
Mean age, yrs	52 ± 13
Arthritis duration, yrs (median)	10 (5–17)
Psoriasis duration, yrs (median)	17 (10–27)
Clinical subsets, %	
Polyarticular	46
Oligoarticular	25
Axial	8
Distal	4
Mutilans	2
More subsets	15
Swollen joints (median)	1 (0–5)
Tender joints (median)	5 (1–13)
Dactylitis, %	7
Enthesitis, %	21
Dactylitis + enthesitis, %	6
PASI score (median)	2.8 (0.75–6.57)
Defined areas of involved skin, %	
Face	13
Hands	24
Buttocks/intergluteal	18
Genitals	5
Feet	19
Positive family history, %	
Skin psoriasis	45
Psoriatic arthritis	14
Drug treatment at time of recruitment, %	
Traditional DMARD	63
Anti-TNF-α	23
NSAID	37
Oral steroids	9

PASI: Psoriasis Area and Severity Index; DMARD: disease modifying antirheumatic drug; TNF-α: tumor necrosis factor-α: NSAID: nonsteroidal antiinflammatory drug.

ables, in order to rule out a mood disorder bias in patient responses. The backward stepwise procedure showed that anxiety and depression were not significantly associated, in that they did not show confounding effects, and therefore they were eliminated from the model. The final regression model was statistically significant ($p < 0.00001$, $R^2 = 0.73$). The analysis showed B coefficient = 0.63 (95% CI 0.57–0.69) for PJA and B coefficient = 0.30 (95% CI 0.27–0.37) for PSA, meaning that the articular component was perceived as the dominant discomfort (with a stronger influence compared to psoriasis).

Patient assessment of joint disease. In order to test the specific influence on PJA of swollen and tender joints, dactylitis, enthesitis, arthritis duration, sex, age, and occupation, a multiple linear regression was performed. Enthesitis, arthritis duration, sex, age, and occupation were not significantly associated with PJA, and therefore were eliminated from the model. The final regression model ($p < 0.00001$) included swollen joints, tender joints, and, although with borderline association, dactylitis ($p = 0.052$). The R^2 value was 0.24; the regression coefficients were B = 0.88 (95% CI 0.24–1.52) for swollen joints, B = 0.76 (95% CI 0.47–1.06) for tender joints, and B = 9.45 for dactylitis (95% CI –0.10 to 18.99).

The detailed median PJA in the different clinical subsets were as follows: polyarticular 47 (range 22–71), oligoarticular 50 (range 20–71), axial 45 (range 21–60), distal 58 (range 29–77), mutilans 54 (range 32–73), more than one subset 36 (range 20–60); with no statistically significant differences.

Patient assessment of skin disease. In order to test the specific influence on patient assessment of skin disease of PASI score, involvement of face, genitals, hands, buttocks and/or intergluteal and feet, psoriasis duration, sex, age, and occupation, a multiple linear regression was performed. Face, genitals, buttocks and/or intergluteal, and feet involvement, psoriasis duration, sex, age, and occupation were not significantly associated with PSA, and therefore were eliminated from the model. The final regression model ($p < 0.00001$) included the 2 independent variables PASI score and hand skin involvement ($R^2 = 0.35$). The regression coefficients were B = 2.33 (95% CI 1.93–2.74) for PASI and B = 10.85 (95% CI 4.66–17.04) for hand skin involvement.

The detailed median PSA in the different clinical subsets were as follows: polyarticular 30 (range 14–62), oligoarticular 20 (range 9–51), axial 30 (range 14–68), distal 58 (range 25–77), mutilans 34 (range 4–74), and more than one subset 30 (range 15–50), with no statistically significant differences.

Arthritis versus psoriasis. In order to investigate the clinical course of joint inflammation compared to skin inflammation, we correlated objective scores (joint count and PASI) in patients without axial disease, and BASDAI and PASI in patients with axial disease. The analysis revealed that joint and skin disease do not correlate in terms of disease activity as shown by swollen joints versus PASI (r = 0.11), tender joints versus PASI (r = 0.12), and BASDAI versus PASI (r = 0.28). The correlation coefficient between PJA and PSA was r = 0.38, with a scattered pattern revealed on the dot plot (Figure 1).

DISCUSSION

The assessment of PsA poses a challenge to the clinician because of its varied manifestations including peripheral joints, axial disease, enthesitis, dactylitis, and skin and nail disease. In the past, instruments to assess PsA were "borrowed" from other diseases, mainly rheumatoid arthritis (RA), ankylosing spondylitis, and skin psoriasis. Recently, the GRAPPA and OMERACT organizations have reached a consensus on a core set of domains to be evaluated in randomized controlled trials, longitudinal observational trials[11], and hopefully in most of the rheumatology clinics for detailed and careful followup of patients with PsA, in search for the quality of care patients require[15]. Having defined the domains, the next step was to validate the proper instruments, according to a scientific approach by a consortium of physicians with a particular interest in PsA.

Patient and physician global assessments were both included among the core domains for the assessment of PsA by OMERACT[11]. PGA is important because it helps physicians to appreciate patient discomfort and to calibrate a more patient-centered clinical and therapeutic approach. PGA is also important because it has been included in several composite indices developed for RA but also employed in PsA. These measures include the ACR response criteria[16], the Disease Activity Score (DAS)[17], and the Psoriatic Arthritis Response Criteria (PsARC)[18].

The 100 mm VAS was selected over a 5-point Likert and 11-point numeric rating scale as the instrument for the PGA domain because of demonstrated psychometric quality in RA and osteoarthritis[19,20]. Reliability was determined by test-retest.

Our study demonstrated that PGA assessed by means of

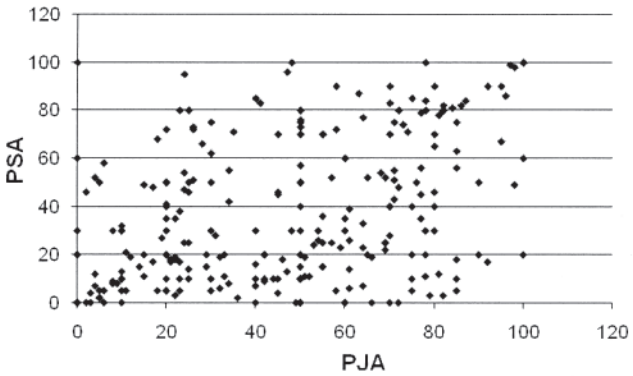

Figure 1. Patient perception of joint disease versus patient perception of skin disease. A scattered pattern is clearly visible.

VAS is a reliable tool related to both joint and skin disease activity. Because joint and skin disease VAS scores often diverge it is suggested that both PJA and PSA also be assessed separately for a more comprehensive analysis of the patient perspective.

One major concern that emerged during preliminary discussion among members of the GRAPPA consortium was the possibility that psychological factors could substantially affect the perception of the disease by patients. The results of the HADS measurement, employed to evaluate patients' anxiety and depression, suggest that they were able to discriminate and rate their disease manifestations regardless of mood disorders. In our cohort of PsA patients the results were not affected significantly by psychological problems, as only 13.4% (anxiety) and 11.6% (depression) of patients had pathological scores above the cutoff. However, it is recognized that the HADS is only a screening tool and cannot make a precise evaluation of mood in these patients, therefore further studies are required with respect to the role of psychological factors in PsA for confirmation of this result.

The specific influence of the joint and skin components in the patient global perception of disease was evaluated by multiple linear regression analysis. It should be emphasized that PJA and PSA explain nearly all the variance in PGA ($r^2 = 0.73$). It also showed a preponderance of the arthritis symptoms over those of skin, which is not surprising given the low PASI scores in the majority of the patients attending rheumatology clinics, and broadly speaking in the PsA population in general. It is notable that 17 out of 18 centers of the consortium were rheumatology units rather than dermatology units; this could represent a bias in the recruitment process that may explain a finding of more severe joint disease. On the other hand, many patients recruited by the rheumatologists were also followed by a dermatologist, and patients with arthritis are very rarely followed only by a dermatologist. For these reasons we believe that our cohort of patients accurately represents the general population of patients with PsA.

Further analysis of the assessment of joint disease by the patients of this cohort showed that statistically significantly higher values of VAS scores correlated with the number of joints involved, supporting the validity of the VAS instrument for the domain of interest (patient self-report assessment). Nevertheless it was not uncommon to observe a severe perception of disease even when a single joint or very few joints were involved, depending on the sites involved. Further, there was no relationship to a particular subset of clinical type of PsA.

It is noteworthy that the occurrence of dactylitis in our cohort was perceived as severe by the patients. Dactylitis, a hallmark clinical feature of PsA occurring in an average 16%–48% of cases, as reported in the literature, may therefore be considered a clinical indicator of disease severity[21]. On the other hand, the presence of enthesitis, duration of arthritis, sex, age, and patient's occupation did not influence the perception of joint disease.

A similar approach was followed to analyze patient assessment of the influence of skin disease in relation to the degree of skin psoriasis by means of PASI, involvement of face, genitals, hands, buttocks and/or intergluteal and feet, psoriasis duration, sex, age, and occupation. A significant association was found only for PASI score and involvement of the hands ($R^2 = 0.35$), indicating that these variables accounted only for 35% of the total variation in PSA. Two major reasons explain this finding. First, it has been demonstrated that the PASI score performs better in active severe psoriasis than in mild psoriasis, as it is generally found in PsA patients, as well as in our cohort. Second, PASI scores do not differentiate on the basis of the involved area, but the personal perception of discomfort clearly is also dependent on the involvement of precise areas, not simply on the "amount" of involved skin. In this study, the site of major effect on patient perception was the hands, probably because of their role in working, life activities, and also in social interaction.

We further investigated the effects of arthritis compared to skin psoriasis. Analysis revealed that joint and skin disease did not correlate in terms of disease activity, a finding consistent with other studies[22,23]. Some drugs work better for one manifestation but not the other, such as cyclosporine for the skin and leflunomide for the joints[24,25]. Also, genetic factors may differ, as well as tissue-specific T cells that infiltrate the skin in psoriasis but not the synovium in PsA[26], and differences may apply to antigen-presenting cells[27]. Several lines of evidence may suggest that different mechanisms drive the 2 processes, but lack of knowledge of the causative agent(s) is the limiting factor in testing this hypothesis. The lack of correlation between the joint and skin disease scores (objective, but also perceived by the patients) raises the point that although the PGA performed well overall in our study as a single measure, a more complete assessment may be derived from also measuring PJA and PSA, for example, in the circumstance that drug therapy may adequately improve one of these domains but not the other.

Patient global self-assessment, as well as patient joint and skin self-assessment separately, are reliable in PsA. Although the PGA as a single measure was demonstrated to perform well in assessing the patient in totality, it was also observed that self-assessment of joint and skin disease activities may be divergent. Therefore, although PGA is an acceptable single measure for clinical trials and clinical practice, it should be kept in mind that there may be certain circumstances, such as study of a drug that improves the joints but not the skin, in which it would be important to assess the PJA and PSA as well.

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