Patient's Global Assessment as an Outcome Measure for Psoriatic Arthritis in Clinical Practice: A Surrogate for Measuring Low Disease Activity?

Ennio Lubrano, Fabio Massimo Perrotta, Wendy J. Parsons, and Antonio Marchesoni

ABSTRACT. ***Objective.*** To assess the low disease activity (LDA) in a group of patients with psoriatic arthritis (PsA) receiving antitumor necrosis factor-α (TNF-α) by using the patient's global assessment (PtGA) in clinical practice, and to compare PtGA with minimal disease activity (MDA) and other outcome measures.

Methods. Patients with PsA classified by the ClASsification for Psoriatic ARthritis (CASPAR) criteria and consecutively admitted to an outpatient clinic dedicated to biologic therapy were assessed during their routine followup. The primary outcome measure was the proportion of patients achieving a PtGA ≤ 20 at 4-, 8-, and 12-month followups. Secondary outcome measures included the proportion of patients achieving MDA and other outcome measures. Correlation of PtGA with MDA and other process and outcome measures were also performed.

Results. During the period of observation, 124 patients were evaluated. PtGA ≤ 20 was achieved in 25.7% at 4 months, 48.9% at 8 months, and 65.3% at 12 months of followup. The percentage of PtGA ≤ 20 statistically improved throughout the 3 timepoint assessments and it was statistically correlated to MDA. A significant correlation with the Disease Activity index for PSoriatic Arthritis (DAPSA), Bath Ankylosing Spondylitis Disease Activity Index, and Health Assessment Questionnaire was also observed. MDA, DAPSA, and Disease Activity Score at 28 joints with C-reactive protein remission were achieved at 12 months in 64%, 36%, and 71% of patients, respectively.

Conclusion. PtGA can estimate the LDA status and could be considered as a surrogate of outcome measures for the assessment of global disease activity in patients with PsA receiving anti-TNF therapy during routine clinical practice. These data suggest that PtGA might be used in outpatient settings, being a simple, reliable, and not time-consuming instrument. (J Rheumatol First Release November 1 2015; doi:10.3899/jrheum.150595)

Key Indexing Terms:
OUTCOME MEASURES PSORIATIC ARTHRITIS SPONDYLOARTHROPATHIES
MINIMAL DISEASE ACTIVITY REMISSION PATIENT'S GLOBAL ASSESSMENT

Psoriatic arthritis (PsA) is a chronic inflammatory disease characterized by the association of arthritis and psoriasis and by a variable clinical course[1]. In fact, some patients have mild disease that can be responsive to therapeutic intervention, while some others have an erosive arthritis that is often refractory to several treatments and potentially associated with functional disability and poor quality of life[2,3].

Comprehensive evaluation of patients with PsA involves the assessment of joints, entheses, dactylitis, skin, and nails[4]. In the context of this multifaceted disease, the global assessment of PsA is still considered an unmet need[5].

The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) identified 6 domains as the core set to be measured in all clinical trials. These include peripheral joint activity, skin activity, pain, patient's global assessment (PtGA), physical function, and health-related quality of life[6,7].

The goals of GRAPPA were the validation and standardization of outcome assessment tools in PsA and psoriasis, both for basic clinical and therapeutic studies and for routine clinics. Therefore, GRAPPA set up a working group of 18 centers in 10 countries to assess this issue. The main aim of that study was to assess the reliability of the PtGA, measured by means of 0–100 mm visual analog scale (VAS), in a group of patients with PsA[8]. This multicenter study showed that

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PtGA assessed by VAS was a reliable tool to measure joint and skin disease activity[8].

In routine outpatient clinics, PtGA could be an easy surrogate of many process measures, and possibly a reliable mirror of the global activity status of patients with PsA.

Minimal disease activity (MDA) has been proposed as an outcome measure of disease activity for patients with PsA. It is a composite index that encompasses the different aspects of disease domains[9]. These criteria were validated using interventional trial data[10,11]. Achieving sustained MDA (defined as MDA for over 12 mos at consecutive clinic visits) was found to reduce radiographic joint damage progression over a 3-year period, with an increase in damaged joint count of 0.9 units in patients persistently in MDA compared with an increase of 2.4 units in those not achieving sustained MDA[10,11]. However, the complexity of the disease led to the development of other disease activity measures and definitions of remission[12].

The purpose of our present study was to determine whether PtGA could be considered as a surrogate of process and outcome measures in the assessment of disease activity in a group of patients with PsA during the routine clinical practice using MDA as the gold standard. Moreover, PtGA was compared with other outcome measures such as the Disease Activity Score at 28 joints (DAS28) with C-reactive protein (CRP)[13], Disease Activity index for PSoriatic Arthritis (DAPSA)[14], and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)[15].

MATERIALS AND METHODS

Study design. Our study was designed as a single-center observational study involving patients with PsA, satisfying the ClASsification of Psoriatic ARthritis (CASPAR) classification criteria[16]. Patients with PsA were recruited consecutively during their followup visit regardless of clinical subsets, as defined according to Wright and Moll[17]. Our study was carried out at the outpatient clinic for patients with PsA treated with biologic agents. In particular, tumor necrosis factor-α (TNF-α) blockers were prescribed according to the recommendation of the Italian Society of Rheumatology[18].

During the observation period (May 1, 2012–April 30, 2015), all patients with PsA attending the outpatient clinic of the Academic Rheumatology Unit in Campobasso, Italy, were evaluated at baseline and then every 4 months for a 12-month period.

Our study was approved by the local ethics committee and all patients gave their written informed consent.

Clinical and functional assessment. In all patients, a detailed clinical and functional assessment was performed. The American College of Rheumatology joint count [68 tender joint count (TJC), 66 swollen joint count (SJC)] was used for peripheral joint evaluation, and the BASDAI for patients with axial involvement (n = 58)[15]. The definition of axial disease was the same as that used in a previous study on biological treatment in this subset of disease[19]. DAS28-CRP[13] was assessed and a value of ≤ 2.6 identified a remission state. Acute-phase reactants [CRP and erythrocyte sedimentation rate (ESR)] were also tested to monitor the disease activity; even if in PsA these are useful markers, they cannot always be judged as reliable monitors of the disease activity. The Psoriasis Area and Severity Index (PASI) was used for skin psoriasis[20]. Presence of dactylitis and enthesitis was clinically assessed. Enthesitis was measured using the Maastricht Ankylosing Spondylitis Enthesitis Score[21], while dactylitis was recorded as presence/absence in any digit at each visit. Drug treatment at time of recruitment was also recorded. Function was assessed by the Health Assessment Questionnaire (HAQ; the Italian-validated version)[22]. Patient's perception of disease was investigated following specific questions by means of a 0–100 mm VAS as a global score (PtGA), encompassing both joints and skin. The questionnaire was the same as that administered for the study supported by GRAPPA[8]. A concomitant global assessment of disease activity by the physicians was also performed in the same fashion as the study by GRAPPA[8].

MDA was defined as indicated by Coates, *et al*[9], while a condition of MDA by PtGA was defined as ≤ 20 on a VAS scale, which is the same cutoff value used by the MDA criteria[9]. Remission was also defined according to the composite index DAPSA[14] calculated as SJC of 66 joints + TJC of 68 joints + PtGA + pain VAS (cm) + CRP (mg/dl). A DAPSA score ≤ 3.3 defined remission according to Husic, *et al*[23].

PtGA was administered in the waiting room of the outpatient clinic by a research nurse trained in inflammatory arthritis.

Statistical analysis. Statistical analysis was carried out using the SPSS package (version 17.0). Descriptive analysis was performed, expressing variables as mean ± SD or median with 25th and 75th percentiles, according to data distribution.

The McNemar test was used to assess any statistical differences between the proportion of PtGA ≤ 20 at 4-, 8-, and 12-month followup visits. Comparisons between baseline and 4, 8, and 12 months were performed using the Wilcoxon signed-rank test for paired and Mann–Whitney U test for unpaired samples. Spearman correlation analysis was carried out to evaluate the strength of association between PtGA and MDA, PtGA and DAPSA, and PtGA and DAS28-CRP. Moreover, Spearman correlation coefficient was also carried out between PtGA and joint counts (TJC and SJC), PtGA and PASI score, PtGA and BASDAI, and PtGA and other outcome measures (CRP, ESR, HAQ). Concordance was assessed using Cohen κ coefficient and it was considered as follows: < 20 poor, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 good, and 0.81–1.00 very good.

Sensitivity, specificity, and likelihood ratio were evaluated to assess the accuracy of PtGA.

All statistical procedures were 2-sided; a significance level was accepted at $p < 0.05$.

RESULTS

During the period of observation, 124 patients were assessed and followed up for their treatment with anti-TNF-α. All patients were naive for treatment with TNF-α blockers. At baseline, no patients were in MDA or had a DAPSA score ≤ 3.3, and median DAS28-CRP score was 3.72 (range 2.7–4.8). PtGA ≤ 20 was recorded in 8 patients (6.4%). No differences were found among the different variables between sexes. Table 1 shows the demographic and clinical characteristics of the patients enrolled in our study.

After 4 months, the proportion of patients with a PtGA ≤ 20 was 25.7% (n = 27), at 8 months the proportion rose to 48.9% (n = 48), and at 12 months it was 65.3% (n = 49). When compared, these percentages at the various timepoints were significantly different ($p < 0.001$). Figure 1 shows the trend of PtGA ≤ 20 and of physician's global assessment ≤ 20 during the 4 followup observations. Patients' and physicians' evaluations were similar, but with a tendency to overestimate by the physicians compared with the patients. In particular, the concordance (expressed as Cohen κ) between the 2 assessments was 0.42 at baseline, increasing to 0.5 at 4 months, to 0.59 at 8 months, and finally to 0.75 at 12 months, which could be deemed a good level of concordance.

Table 1. The main demographic and clinical features of patients with PsA at baseline treated with TNF-α blockers (n = 124). Values are median (25th–75th percentile) unless otherwise specified.

Features	Values
Male/female, n	58/66
Age, yrs	52 (42.25–61)
Disease duration, mos	84 (48–159)
Articular manifestations, %	
Axial	45.9
Peripheral arthritis	91.9
Enthesitis	29.8
Dactylitis	33
Extraarticular manifestations, %	
Uveitis	5.6
Psoriasis	82.2
IBD	1.3
DAS28-CRP	3.72 (2.7–4.8)
DAPSA	20 (14.2–28.05)
TJC	4.5 (1–10)
SJC	1 (0–5)
ESR, mm/h	22 (12–29)
CRP, mg/dl	0.7 (0.36–1.2)
PtGA, mm	59 (45–70)
VAS pain, mm	56 (45–75)
VAS physician, mm	45 (39–55)
HAQ	1 (0.62–1.25)
PASI	0.9 (0–2.5)
MASES	1 (0–2.5)
Concomitant treatment at baseline, n (%)	
DMARD	49 (39.5)
Prednisone intake	39 (31.5)
NSAID intake	99 (79.8)
Anti–TNF-α therapy, n (%)	
ADA	39 (31.4)
ETN	62 (50)
GOL	23 (18.5)

PsA: psoriatic arthritis; TNF-α: tumor necrosis factor-α; IBD: inflammatory bowel diseases; DAS28: Disease Activity Score at 28 joints; CRP: C-reactive protein; DAPSA: Disease Activity index for Psoriatic Arthritis; TJC: tender joint count; SJC: swollen joint count; ESR: erythrocyte sedimentation rate; PtGA: patient's global assessment; VAS: visual analog scale; HAQ: Health Assessment Questionnaire; PASI: Psoriasis Area and Severity Index; MASES: Maastricht Ankylosing Spondylitis Enthesitis Score; DMARD: disease-modifying antirheumatic drugs; NSAID: nonsteroidal antiinflammatory drugs; ADA: adalimumab; ETN: etanercept; GOL: golimumab.

Table 2 summarizes all data regarding the proportion of patients who showed MDA, DAPSA remission, DAS28 remission, PtGA ≤ 20 mm, and VAS physician ≤ 20 mm at the different followup points. A good level of achievement of these outcomes was seen throughout the study period. At Month 12, the percentage was 64%, 36%, and 71% of patients for MDA, DAPSA remission, and DAS28 remission, respectively. When measured, the concordance between PtGA ≤ 20 mm and MDA was good at the 4, 8, and 12 months (κ 0.73, 0.72, and 0.73, respectively). This result was consistent with good validity of the PtGA as an instrument to assess low disease activity (LDA)/remission in patients with PsA taking anti-TNF-α agents in a clinical practice setting.

The correlation between PtGA values and the values of other measures of disease activity (Table 3) was also good for DAPSA, DAS28-CRP, and BASDAI, but not for the individual components of the DAPSA and for the skin involvement measured by the PASI. Figure 2 and Figure 3 show the correlation with DAPSA and BASDAI. In addition to confirming that PtGA might be a reliable instrument to assess LDA/remission in peripheral PsA, these findings seem to indicate that it might also have good validity in patients with PsA with axial involvement.

Finally, as additional data to test the accuracy of PtGA, we evaluated the sensitivity, specificity, and likelihood ratio for the MDA and found a high specificity during the followup observations (Table 4).

DISCUSSION

Clinical remission is an achievable goal in patients with PsA under treatment with biological agents and more in general in spondyloarthritis with either radiographic or nonradiographic axial disease[24,25]. MDA has been widely recognized as a good instrument to define LDA status in patients with PsA. Recently, a study showed that 64% of patients with this condition achieved a sustained MDA after 12 months of treatment with TNF-α blockers[26]. Our study showed similar data, with 64% of patients in MDA at 12 months.

PtGA is a simple instrument that has been shown to be a reliable tool in the assessment of patients with PsA[8]. PtGA is a very quick test that, if administered correctly, can reflect the global status of patients, simplifying some routine assessments. Therefore, we evaluated the validity of this instrument to assess disease activity in a group of patients with PsA receiving TNF-α blockers during their routine clinic evaluations. We found that at 12 months, PtGA ≤ 20 had a good concordance with the MDA criteria. On the other hand, and to a certain extent, it would not be a surprise to note a concordance this good with MDA because PtGA is 1 of the 7 components of this composite instrument. In keeping with this result, we also demonstrate a high specificity (> 80% during the followup observations) of PtGA ≤ 20 mm for MDA, making the PtGA a useful and simple surrogate to assess low disease state in patients with PsA.

Although PtGA identified many domains of disease activity and status of PsA, it is not considered so comprehensive as to replace all of the process and outcome measures, as well as the objective signs of inflammation (i.e., CRP or ESR). In fact, it is also a single-item measurement with limited face validity. Our results only suggest that PtGA can be deemed as a surrogate to assess the disease status by the patient's perspective.

The results of our study also showed a good concordance between PtGA and disease global evaluation by the physicians, although with a tendency toward lower values by the

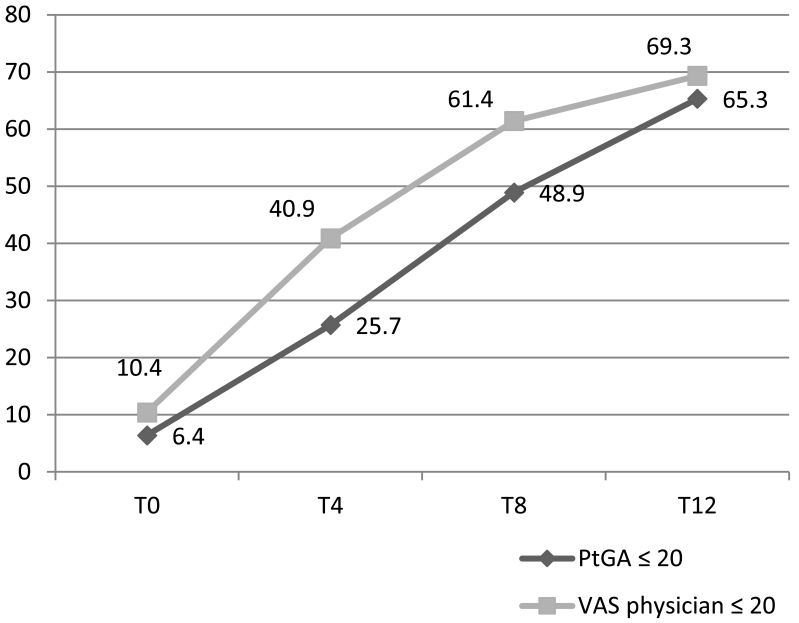

Figure 1. Percentage of PtGA ≤ 20 and VAS physician ≤ 20 during followup. PtGA: patient's global assessment; VAS: visual analog scale.

Table 2. Patients who achieved MDA, DAS28 remission, DAPSA remission, PtGA ≤ 20 mm, and VAS physician ≤ 20 mm at T0, T4, T8, and T12. Values are n (%).

Variables	T0, n = 124	T4, n = 105	T8, n = 96	T12, n = 75
MDA	0 (0)	30 (28.5)	53 (55.2)	48 (64)
DAS28 remission	25 (20.1)	46 (44.2)	51 (53.1)	53 (71)
DAPSA remission	0 (0)	14 (13.3)	18 (18.9)	27 (36)
PtGA ≤ 20 mm	8 (6.4)	27 (25.7)	48 (48.9)	49 (65.3)
VAS physician ≤ 20 mm	13 (10.4)	43 (40.9)	59 (61.4)	52 (69.3)

MDA: minimal disease activity; DAS28: Disease Activity Score at 28 joints; DAPSA: Disease Activity index for Psoriatic Arthritis; PtGA: patient's global assessment; VAS: visual analog scale.

Table 3. Main results on the correlation (Spearman ρ) between PtGA with outcome measures at the different observation timepoints.

Variables	T0	T4	T8	T12
No. TJC	0.05	0.32*	0.29*	0.14
No. SJC	0.12	0.22^	0.15	0.11
ESR	0.12	0.23^	0.19	0.18
CRP	0.02	0.02	0.15	0.48*
PASI	0.07	0.06	0.19	0.06
HAQ	0.41*	0.66*	0.67*	0.73*
DAS28	0.07	0.49*	0.55*	0.47*
DAPSA	0.25*	0.63*	0.85*	0.88*
BASDAI	057*	0.64*	0.69*	0.69*
MASES	0.30*	0.30*	0.40*	0.20
VAS physicians	0.49*	0.59*	0.76*	0.78*

^ $p < 0.05$. * $p < 0.01$. PtGA: patient's global assessment; TJC: tender joint count; SJC: swollen joint count; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; PASI: Psoriasis Area and Severity Index; HAQ: Health Assessment Questionnaire; DAS28: Disease Activity Score at 28 joints; DAPSA: Disease Activity index for Psoriatic Arthritis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; MASES: Maastricht Ankylosing Spondylitis Enthesitis Score; VAS: visual analog scale.

physicians. This finding seems to be in contrast with some data, in which a patient's self-report of joint and skin manifestations had a poor correlation with the physician's assessment[27]. Our study estimated the global disease status rather than defined which component (joint and/or) skin was more predominant. However, it has been reported that PtGA does not correlate with joint counts and does not differentiate skin versus joint function[28].

Another interesting result of our study was the good correlation of PtGA with some remission indices. This finding seems to confirm that a condition of LDA can be reliably measured by PtGA. In spite of the good correlation between PtGA and DAPSA, there was no significant association of the former with any of the single components of DAPSA. In other words, PtGA did not correlate with the TJC/SJC (only at some timepoints and with a weak correlation), or with CRP (except at 12-month followup). Further, there was no correlation between PtGA and PASI. This is in keeping, to a certain extent, with Cauli, *et al*[8] and it showed that PtGA

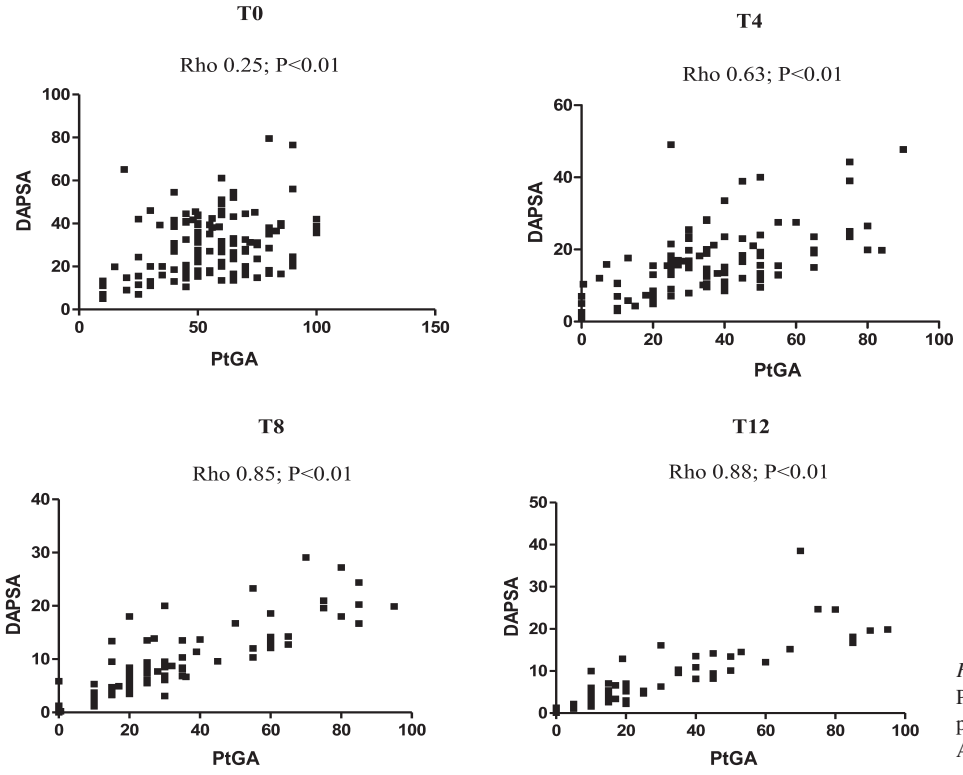

Figure 2. Correlation (Spearman rho) between PtGA and DAPSA during followup. PtGA: patient's global assessment; DAPSA: Disease Activity index for Psoriatic Arthritis.

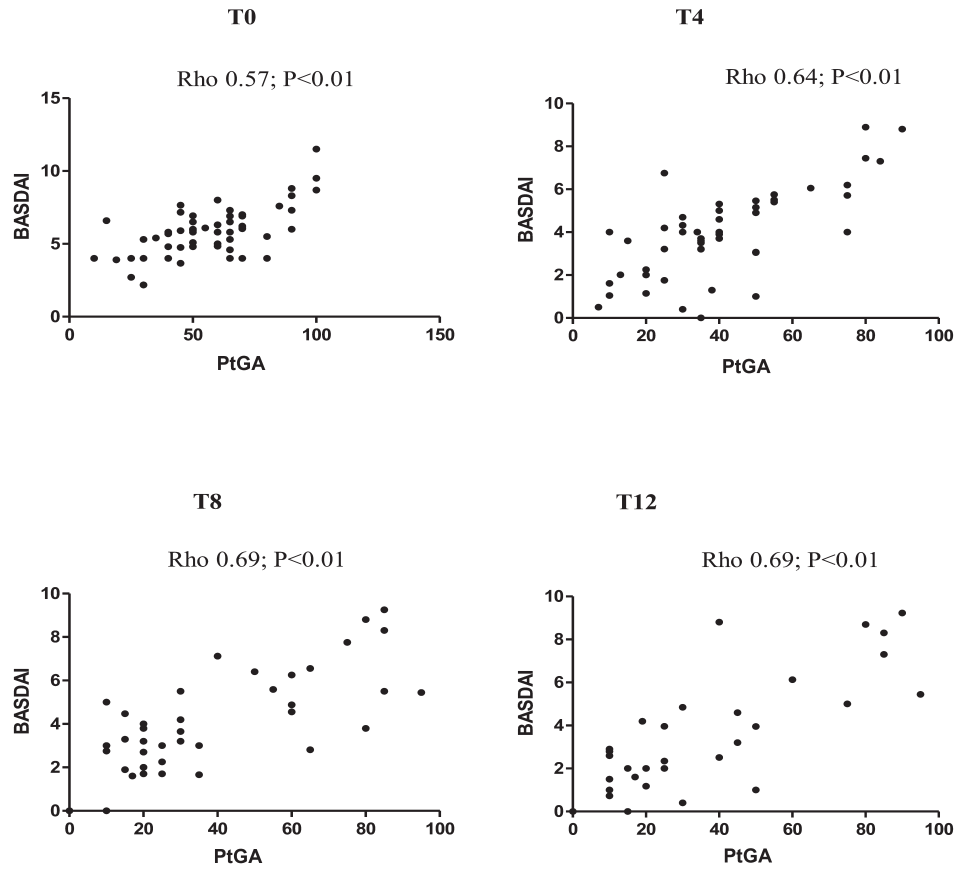

Figure 3. Correlation (Spearman rho) between PtGA and BASDAI during followup. PtGA: patient's global assessment; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index.

Table 4. Sensitivity, specificity, and likelihood ratios of the single components of the MDA criteria plus VAS physician regarding MDA during followup.

Variables	4 Mos			8 Mos			12 Mos		
	Sensitivity (95% CI)	Specificity (95% CI)	Likelihood Ratio	Sensitivity (95% CI)	Specificity (95% CI)	Likelihood Ratio	Sensitivity (95% CI)	Specificity (95% CI)	Likelihood Ratio
TJC ≤ 1	0.55 (0.41–0.69)	0.98 (0.89–0.99)	29.56	0.70 (0.57–0.81)	0.71 (0.53–0.85)	2.467	0.93 (0.82–0.98)	0.37 (0.085–0.75)	1.500
SJC ≤ 1	0.40 (0.28–0.52)	0.94 (0.80–0.99)	7.000	0.58 (0.48–0.69)	1.0 (0.54–1.0)	—	0.66 (0.54–0.77)	1.00 (0.29–1.00)	—
VAS pain ≤ 15 mm	1.0 (0.85–1.0)	0.91 (0.83–0.96)	11.57	0.93 (0.78–0.99)	0.64 (0.51–0.75)	2.603	0.92 (0.80–0.98)	0.75 (0.56–0.88)	3.714
HAQ ≤ 0.5	0.56 (0.41–0.70)	0.94 (0.85–0.98)	10.69	0.86 (0.74–0.93)	0.92 (0.78–0.98)	10.92	0.92 (0.80–0.97)	0.92 (0.74–0.99)	11.50
PtGA ≤ 20 mm	0.85 (0.66–0.95)	0.90 (0.82–0.96)	9.370	0.91 (0.79–0.97)	0.81 (0.67–0.91)	4.879	0.76 (0.57–0.90)	0.94 (0.87–0.98)	14.76
PASI ≤ 1 or BSA ≤ 3	0.30 (0.20–0.41)	0.78 (0.56–0.92)	1.380	0.58 (0.47–0.69)	0.56 (0.29–0.80)	1.348	0.70 (0.58–0.81)	0.77 (0.39–0.97)	3.185
Tender entheseal point ≤ 1	0.30 (0.20–0.42)	0.83 (0.62–0.95)	1.846	0.68 (0.56–0.78)	0.90 (0.69–0.98)	7.146	0.76 (0.60–0.87)	0.55 (0.35 -0.73)	1.697
VAS physician ≤ 20 mm	0.53 (0.37–0.68)	0.92 (0.81–0.97)	6.820	0.79 (0.67–0.89)	0.88 (0.73–0.96)	6.970	0.90 (0.78–0.96)	0.94 (0.72–0.99)	16.27

MDA: minimal disease activity; VAS: visual analog scale; TJC: tender joint count; SJC: swollen joint count; HAQ: Health Assessment Questionnaire; PtGA: patient's global assessment; PASI: Psoriasis Area and Severity Index; BSA: body surface area.

reflected the global health status, but did not identify specific domains of PsA. In contrast, PtGA correlated well with the HAQ score, which is a good indicator of function, as well as with the BASDAI, which is an index of disease activity designed for axial involvement.

There are some limitations in our present study, including the small sample size, the cross-sectional design, and the fact that the sensitivity of PtGA change was not evaluated. Indeed, our present study only indicates some degree of agreement with a composite endpoint, but is not substantiated with association with longterm good clinical outcomes (e.g., radiographic outcomes). Thus, further and larger studies may be required.

Our study showed only that PtGA might be used as a surrogate of disease activity and detection of LDA status in patients with PsA in real clinical practice.

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