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Psychometric Properties of Patient Global Assessment in Psoriatic Arthritis: A Systematic Literature Review

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ABSTRACT. *Objective.* Patient global assessment (PtGA) is a patient-reported outcome (PRO) that reflects a patient's judgment of their health/disease activity (DA). The objective of this systematic literature review was to assess the psychometric properties of PtGA in psoriatic arthritis (PsA).

Methods. Research articles reporting the assessment of psychometric properties of PtGA in PsA, listed in PubMed and extracted according to the Outcome Measures in Rheumatology (OMERACT) Filter 2.1 and the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) terminology, were selected. Validity was assessed for comprehensiveness (content), correlation with other DA instruments (construct), and with quality of life measurements (criterion). A metaanalysis regarding construct validity was performed. Correlations between PtGA variations and other indices' variations (external responsiveness) and PtGA variations after treatment (internal responsiveness) were collected. Data on the formulation of PtGA and its discordance with physician global assessment (PGA) were also collected.

Results. Of 60 articles analyzed (comprising 17,453 patients), 44 were observational studies and 16 were trials. PtGA was assessed through 27 different formulations. In all the retrieved studies, PtGA assessed DA, and in 3 studies, PtGA was assessed as a variable of global health status. The correlation between PtGA and PROs was strong ($\rho > 0.50$), whereas with other DA indices and PGA, it ranged from weak to moderate ($\rho 0.20-0.50$). Three studies described a positive discordance (PtGA > PGA). Responsiveness, assessed in 24 studies, showed a strong correlation with joint count index variations ($\rho 0.51-0.52$).

Conclusion. PtGA is a valid and responsive tool in PsA. Correlations were higher with PROs and weaker with DA composite indices and PGA. PGA was usually scored lower than PtGA. A standardized formulation of PtGA would be useful.

Key Indexing Terms: health status, patient outcome assessment, psoriatic arthritis, psychometric

Psoriatic arthritis (PsA) is a chronic inflammatory articular disease characterized by a diversity of clinical manifestations and a highly variable disease course.¹ In recent years, the importance of a tight control of disease activity (DA) has been put forward.²⁻⁴ Tight control rests on the correct assessment of DA; this is challenging due to the heterogeneity of PsA, which encompasses a combination of articular (such as axial disease,

peripheral arthritis, enthesitis, and dactylitis) and extraarticular involvement, and because of the lack of specific biomarkers that would help monitor changes over the course of the disease. Several outcome instruments to assess PsA DA have been developed, but due to their complexity, they are used almost exclusively in research.⁵⁻⁷ Moreover, treatment recommendations emphasize the need for the physician to work in partnership with the patient, and for a shared decision-making process based on shared treatment objectives, which is key to optimal management of PsA.⁸ To this end, an assessment of health and disease status by the patient is needed.

The simplest way to assess disease activity from the patient's perspective is through the use of a single global question, termed the *patient global assessment (PtGA)*, assessed using a visual analog scale (VAS) or a numerical rating scale (NRS).⁹

For the first time in 2007, the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA)–Outcome Measures in Rheumatology (OMERACT) working group proposed a core set of 6 domains for appropriately evaluating the impact of PsA and the efficacy of therapies in clinical trials; these domains include PtGA, together with peripheral joint activity, pain, physical function, health-related quality of life (HRQOL), and fatigue assessment.¹⁰ A high consensus

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(95%) was reached in identifying PtGA as the instrument that best reflected the patient perspective on PsA activity. Today, PtGA is included in several composite indices used in PsA,¹¹ including the Disease Activity Index for Psoriatic Arthritis (DAPSA), GRAPPA Composite Exercise (GRACE), Psoriatic Arthritis Disease Activity Score (PASDAS),^{4,12-14} and Psoriatic Arthritis Response Criteria (PsARC).¹⁵ Patient global DA is also integrated in the definition of a state of minimal DA (MDA), proposed as a target for treatment^{4,8,16} and subsequently validated.^{17,18}

However, there are several issues with PtGA. First, there is no consensus regarding its formulation (ie, the wording, as well as the use of a single comprehensive PtGA vs separate scales for skin and joint manifestations), and whether a VAS should be preferred over an NRS.^{10,11,19,20} Second, there is a need for a clear assessment of PtGA psychometric properties, as is the case for all outcome measures.²¹⁻²³

Discordance between PtGA and PGA is also an issue. In clinical practice, patient and physician perspectives regarding disease-related health status may differ, resulting in patient dissatisfaction that negatively affects compliance and disease outcomes.²⁴

The aim of this systematic review was to describe the different formulations used for PtGA in PsA, to assess its psychometric properties, and to quantify patient and physician discordance in global assessments.

METHODS

Literature search. A systematic review of the literature was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines,²⁵ searching for articles reporting data on the assessment of psychometric properties of PtGA in PsA.

The following search strategy was used through MEDLINE via PubMed to search for articles written in English regarding adult patients (19+ years), with no limitation on the year of publication up until April 30, 2022: (((("psoriatic arthritis"[MeSH Terms] OR ("psoriatic"[TIAB] AND "arthritis"[TIAB]) OR "psoriatic arthritis"[TIAB] OR "psa"[TIAB]) AND ("patient global assessment"[TIAB] OR "PtGA"[TIAB] OR "PGA"[TIAB])). Additional papers were obtained by checking the references from the selected studies. Articles reporting data of PtGA exclusively related to skin disease were excluded.

The PICO (Patient/Population - Intervention - Comparison/Comparator - Outcome) process included:

- Population: patients classified as having PsA, with peripheral or axial involvement
- Intervention: PtGA
- Comparison: other DA instruments (DAIs) or patient-reported outcomes (PROs)
- Outcome: assessment of psychometric properties of PtGA

Whenever papers reported duplicate data, the most recent article was selected. Two investigators (EC and AC) independently selected the articles, initially on the basis of titles and abstracts, and excluded studies that did not focus on the PsA population or did not mention the use of PtGA. Next, full-text articles were retrieved and reviewed independently by 2 authors (EC and AC).

Data were extracted in order to collect psychometric properties. Whenever available, data on the type of study, the number of patients involved, the formulation of the PtGA (including wording, acronym, score, length in millimeters, and the question used to assess it), and the discordance between PtGA and PGA were collected from the paper or its supple-

mentary material. Disagreements between investigators were solved by consensus.

Extraction of psychometric properties of PtGA. Each study was examined in order to extract data on the psychometric properties of PtGA according to OMERACT²³ and Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) terminology.²²

Content validity was assessed by 2 authors (EC and AF), evaluating whether the PtGA had the relevance, comprehensiveness, and comprehensibility according to COSMIN terminology.^{26,27}

Construct validity was collected as correlations between PtGA and other DAIs (PGA, DAPSA, Disease Activity Score in 28 joints [DAS28], Ankylosing Spondylitis Disease Activity Score [ASDAS], and Bath Ankylosing Spondylitis Disease Activity Index [BASDAI]), musculoskeletal (MSK) DA domain (tender joint count [TJC], swollen joint count [SJC], and enthesitis and dactylitis indices), and skin DA domain (Psoriasis Area and Severity Index [PASI], body surface area [BSA], and Nail Psoriasis Severity Index [NAPSI]).

Criterion validity was collected against characteristics or phenomena subsequently influenced by disease health status²⁸ (ie, HRQOL measurements, including the Health Assessment Questionnaire [HAQ], 36-item Short Form Health Survey [SF-36], and Psoriatic Arthritis Impact of Disease [PsAID]), damage assessments, comorbidities (fibromyalgia, osteoporosis, and depression), clinical characteristics (age, disease duration, and BMI [calculated as weight in kilograms and divided by height in meters squared]), and biomarker levels (vitamin D levels).

Reliability was assessed as how similar a given patient's scores were at 2 visits after a 1-week interval without any change in treatment.²⁹

Responsiveness, or sensitivity to change, was collected as "internal responsiveness," reflecting how PtGA score changed over time in response to treatment,³⁰ and "external responsiveness," reflecting how changes in PtGA score correlated with variations in other scores (eg, variations in TJC, SJC, DAS, and HAQ).³⁰

Extraction of discordance data. Data on the difference between PtGA and PGA, called discordance, were also collected.

Statistical analysis. Descriptive statistics were presented as mean (SD), percentage, or median (IQR). A *P* value ≤ 0.05 was considered significant.

For validity, correlations were collected and reported as ranges; they were considered weak if $\rho \leq 0.30$, moderate if $\rho > 0.30$ and ≤ 0.50 , strong if $\rho > 0.50$ and < 0.80 , and very strong if $\rho \geq 0.80$.²⁸ A metaanalysis was performed to estimate pooled correlation of PtGA with PGA, BASDAI, and DAS28, but not for other DAIs, as < 3 studies with comparable outcomes were available. In particular, using the MedCalc statistical software (Version 18.2-0, MedCalc Software), the Hedges-Olkin method was applied for calculating the weighted summary correlation coefficient under the fixed effects model, using a Fisher *Z* transformation of the correlation coefficients. As we expected heterogeneity across the selected publications, we implemented a random effects model metaanalysis. The result of every analysis was presented in forest plots. Heterogeneity was tested using *I*². The quantification of reliability was expressed by intraclass correlation coefficients (ICC) between VAS score at week 0 and at week 1. ICCs ≥ 0.8 were considered to indicate excellent reliability.³¹

Internal responsiveness was collected considering the achievement of a significant decrease in PtGA score ($P < 0.05$) as positive outcome of response. PtGA changes after the treatment interval were reported as least squares mean change (95% CI) or as a resultant score at the end of follow-up. Response was reported as a 20%, 50%, or 70% improvement of PtGA using a 0-5 Likert scale,³² or as the achievement of a sustained PtGA $< 20/100$ ³³ or a good/very good PtGA on a 5-point scale.³⁴ A minimal clinically important difference was defined as a decrease of at least 10 mm on a VAS³⁵ or 1-point decrease on an NRS.³⁶ External responsiveness was expressed with Spearman correlations between change scores (good when $\rho > 0.50$) or with the area under the receiver-operating characteristic curve (good when $\rho > 0.70$).

Discordance was reported in studies as PtGA score minus PGA score. A positive discordance consisted of a higher PtGA than PGA, and a negative discordance consisted of a lower PtGA than PGA. A significant difference between PtGA and PGA was defined as up to ± 20 mm on a VAS^{9,37,37} or up to 3 points on a 0-10 NRS.³⁸

RESULTS

Literature search. The literature search identified 1307 articles, and 16 additional articles were retrieved from their reference lists. Of the 16 references retrieved from hand-searched papers, 9 were not included in the analysis because “PGA” referred to cutaneous psoriasis (PsO) assessment or PGA and not to PtGA. The remaining 7 references were not captured by the search methods, although they were published in journals listed in the MEDLINE database, but they were all included in our study. A total of 60 articles were included in the study (Figure 1), accounting for 17,453 patients in 44 observational studies and 16 trials (of which 6 were randomized controlled trials [RCTs], 4 were open-label nonrandomized trials, and 6 were posthoc analyses [4 posthoc analyses of RCTs and 2 posthoc analyses of open-label nonrandomized trials]).

Formulations of PtGA. Fourteen different definitions of PtGA were retrieved, some referring to DA evaluation and others to global health status (Table 1). Eight question formulations and 4 acronyms were found (Table 1). When specified, the PtGA was scored on a VAS in 27 studies and on an NRS in 14 studies; for DAPSA, PtGA was assessed on a 0-10 or 0-100 VAS; for PsARC, on a 0-5 Likert scale; and for MDA, on a 0-100 VAS. The scale used was 0-100 in 28 studies, 0-10 in 17 studies, and 0-5 in 6 studies. The length of the scale was 100 mm in 25 studies and 10 mm in 1 study,⁴⁰ and DA referred to the last week^{9,38,40-43} or the current day.^{44,45} In 8 studies,^{9,44,46-51} PtGA was used to specifically assess joint DA separate from skin activity, as suggested for the first time in Cauli et al.²⁹

Psychometric properties of PtGA.

- **Content validity.** The PtGA was used as a variable of DA in PsA in all the retrieved studies.^{4,9,18,29,32-87} In particular, 1 study

defined the PtGA as the main outcome measure to assess DA.⁴¹ In a study focused on the patient’s perspective, PtGA was the unique instrument to assess DA.⁸³ In another study, the PtGA was used, together with PGA and treatment change, as the instrument of reference to assess the outcome.⁶⁹ In 3 studies,^{47,68,75} the PtGA was used as a variable of global health status.

PtGA was also integrated into other indices: it was part of DAPSA in 14 studies^{18,33,38,39,50,53,56,57,63,78-82} and part of PsARC in 3 studies.^{34,55,77} Alternatively, PtGA was integrated into the definition of DA status: it was part of MDA in 11 studies^{4,18,33,53,61,65,66,80-82,84}; in 3 studies of remission, it was part of the DAPSA score ≤ 4 , DAS28 based on C-reactive protein [CRP] < 2.6 , and PtGA ≤ 20 on VAS^{33,65,67}; it was represented by TJC = 0 and SJC = 0, with PtGA and PGA being low, normal acute-phase reactants⁶⁷; and it was part of Boolean remission (TJC ≤ 1 , SJC ≤ 1 , CRP ≤ 1 , PtGA ≤ 1) in 1 study.⁶⁵ In 1 study, a PtGA score ≤ 20 was used to define low DA,⁴¹ and in another, high DA state was defined as a PtGA score $\geq 6/10$.⁶⁹

- **Construct validity.** Construct validity was reported in 11 studies^{42,43,48,50,52,58,68,69,71,73,75} (Figure 2).

Correlation coefficients ranged from very weak to strong/excellent with BASDAI in 4 studies (ρ 0.54-0.84),^{48,50,69,71} with DAS28 in 3 studies (ρ 0.07-0.55; Figure 2),^{43,50,68} with ASDAS in 2 studies (ρ 0.47-0.81),^{69,71} and with DAPSA in 1 study (ρ 0.25-0.88).⁵⁰ Pooled data from 4 studies ($n = 799$) showed that the pooled correlation between BASDAI and PtGA was strong (ρ 0.68, 95% CI 0.56-0.77; I^2 85.69%, 95% CI 72.53-92.55; Figure 2A), whereas pooled data from 3 studies ($n = 748$) showed a weak to moderate correlation with DAS28 (ρ 0.43, 95% CI 0.30-0.55; I^2 78.28%, 95% CI 52.11-90.15; Figure 2B).

The correlation with PGA was determined in 6 studies^{48,50,52,58,68,75} and ranged from 0.29 to 0.78, with pooled data showing an acceptable pooled correlation (ρ 0.56, 95% CI 0.45-0.65; I^2 84.31%, 95% CI 72.78-90.96; Figure 2C). The weakest results were shown in a cross-sectional study⁶⁸ of patients from a tertiary rheumatology center using a 0-10 NRS (ρ 0.29), in which the patients were asked to give a score about the global status, and

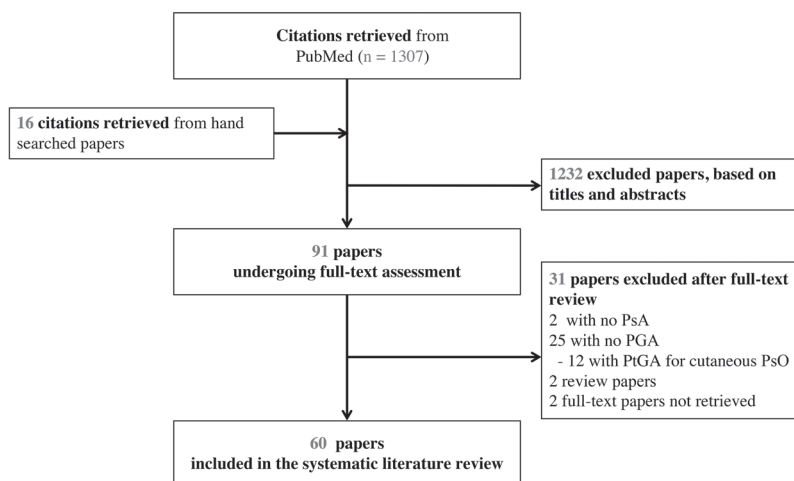


Figure 1. Flow chart of the systematic literature search on PtGA in PsA studies. PGA: physician global assessment; PsA: psoriatic arthritis; PsO: psoriasis; PtGA: patient global assessment.

Table 1. Different formulations used to assess PtGA in PsA studies.

	Type of Study (n studies if > 1)	Reference
Definitions/titles used for PtGA		
VAS patient global assessment	12 OBS, 3 T	4,33,34,38,49,54,56,59,61,64,67,69,70,73,87
Patient global disease activity	CSS	4,61
Patient global	CSS	42
Patient global (joints/neck, back, hip pain/psoriasis)	CSS	47
Patient global activity	LCS	56
Global disease activity	CSS	48
Patient's global evaluations	CSS	63
Patient global disease assessment	RCT	32
Patient VAS for pain and global assessment	LCS	54
Patient general disease assessment	LCS	39
Patient's opinion on the level of disease activity	CSS	42
Patient's perception of disease	LCS	50
Patient disease severity	CSS	49
Joint disease assessment	T	44
Acronyms used for PtGA		
PtGA	15 OBS, 3 T, 3 PH	18,35,37,46,50,52,53,55,57,58,60,62,65,77,79-85
PGA	12 OBS, 2 RCT, 1 PH	9,28,39-41,43,45,63,68,74-76,78,86,89
PaGA	CSS, LCS	66,72
PatGA	PH	51
Acronym not given	4 OBS, 2 T	32,42,44,47,48,71
Questions used to assess PtGA		
Assessment from "best status" to "worst status"	CSS	46,52,68
Assessment from "very well" to "very poor"	PH	51
"What's your assessment of your disease activity during the last week?"	LCS	9
"In all the ways in which your PSORIASIS and ARTHRITIS, as a whole, affect you, how would you rate the way you felt over the past week?"	RCT	41
"How active was your rheumatic disease on average during the last week?"	CSS	42
"Considering all the ways PsA has affected you during the last week, circle the number that best describes how you have been doing"	CSS	38,43
"How do you estimate your disease activity today?"	LCS	45
"How active do you feel your joint disease is today?"	RCT	44
In DAPSA definition: PtGA, 0-10 or 0-100 VAS	8 CSS, 6 LCS	18,33,38,39,43,50,53,56,57,63,78-82
In MDA definition: patient global disease activity, 0-100 VAS	7 CSS, 2 LCS, 2 T	4,18,33,53,61,65,66,80-82,84
In PsARC definition: patient global assessment of disease activity, 0-5 Likert scale	1 T, 1 CSS, 1 LCS	34,55,77

CSS: cross-sectional study; DAPSA: Disease Activity Index for Psoriatic Arthritis; LCS: longitudinal cohort study; MDA: minimal disease activity; OBS: observational study, including longitudinal and cross-sectional study; PH: posthoc analysis of RCT; PsA: psoriatic arthritis; PsARC: Psoriatic Arthritis Response Criteria; PtGA: patient global assessment; RCT: randomized controlled trial; T: includes randomized and nonrandomized trials; VAS: visual analog scale.

in a multicenter GRAPPA study⁵⁸ on 319 patients using a 0-10 VAS for DA (ρ 0.36) and specific musculoskeletal involvement (ρ 0.39). The highest correlation was found in a single-center longitudinal cohort study showing how, during the 1-year follow-up assessment, the correlation increased from 0.49 at baseline assessment to 0.78 at the 12-month visit.⁵⁰

A very weak correlation was seen with physical examination scores (ie, TJC of 68 joints [ρ 0.05-0.47, 4 studies],^{9,43,48,50} SJC of 66 joints [ρ 0.11-0.36, 4 studies],^{9,43,48,50} enthesitis by Leeds Enthesitis Index [LEI; ρ 0.25, 1 study],⁹ Maastricht Ankylosing Spondylitis Enthesitis Score [MASES; ρ 0.20-0.40, 2 studies],^{48,50} dactylitis count [ρ 0.17-0.29, 2 studies],^{9,52} cutaneous PsO [PASI; ρ 0.26-0.33, 3 studies],^{9,48,50} BSA [ρ 0.24, 1 study],⁴³ and NAPSI

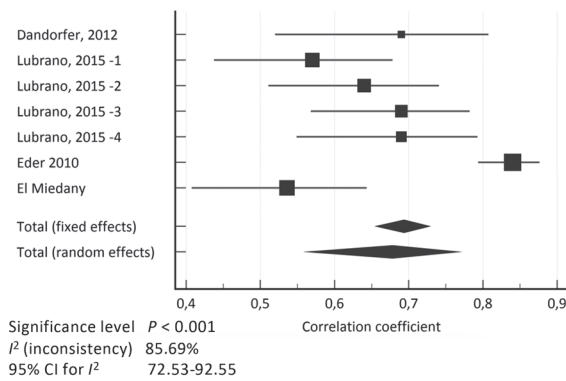
[ρ 0.13, 1 study]⁵⁵; Supplementary Table S1, available with the online version of this article).

- *Criterion validity.* Sixteen studies^{9,39,40,42,43,45,47-50,52,59,63,69,82,86} assessed criterion validity of PtGA (Supplementary Table S2, available with the online version of this article). A high correlation was found with other PROs such as the 12-item PsAID (PsAID-12; ρ 0.84, $P < 0.001$) and 9-item PsAID (PsAID-9; ρ 0.84, $P < 0.001$),⁴⁷ and a moderate to high correlation was found with HAQ (ρ 0.41-0.73)^{9,43,45,50} and VAS pain (ρ 0.71-0.75).^{9,45}

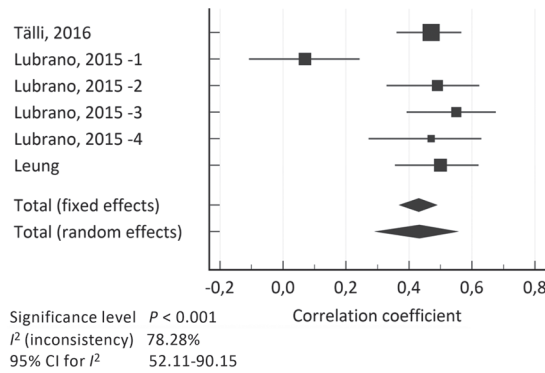
- *Reliability.* Reliability of PtGA was calculated in 1 study at a 1-week interval,²⁹ and the ICC was 0.87 (95% CI 0.83-0.90).

- *Responsiveness.* Changes in PtGA after treatment (internal

(A) PtGA vs BASDAI



(B) PtGA vs DAS28



(C) PtGA vs PGA

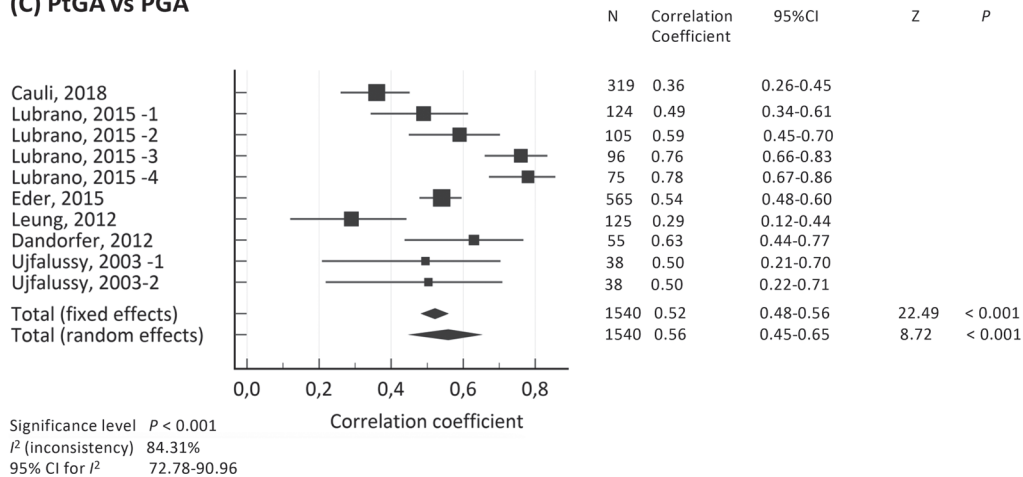


Figure 2. Metaanalysis of the studies reporting data concerning construct validity of PtGA with (A) BASDAI, (B) DAS28, and (C) PGA. Correlation is weak if $\rho \leq 0.30$, moderate if $0.30 < \rho \leq 0.50$, strong if $0.50 < \rho < 0.80$, and very strong if $\rho \geq 0.80$. The pooled correlation coefficient (95% CI) is given both for the fixed effects model and the random effects model. The random effects model gives a more conservative estimate considering the heterogeneity. BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; DAS28: Disease Activity Score in 28 joints; PGA: physician global assessment; PtGA: patient global assessment.

responsiveness) were reported in 25 studies.^{32-36,41,44,51,54-57,60,62,65,70,72-74,76,77,80,84,85,87} In 1 study,⁴¹ the reduction of the PtGA was the main outcome measure, and in 18 studies, it was the secondary outcome. PtGA changes in trials were collected up to

12 months of treatment and were significant in all the reported studies, with a median least square mean change of -29 (IQR -33.9 to -15.4 ; Table 2).

In 1 study, the PtGA together with PGA was the instrument

Table 2. Internal responsiveness of PtGA: Variations of PtGA after treatment.

Reference	Treatment	No. of Patients	Baseline PtGA ^a	Interval After Treatment	PtGA After Treatment ^a	Least Squares Mean Change (SE or 95% CI)	P
35	TOF 5 mg/BID	107	54.7 (22.1)	3 mos	–	–20.08 (2.28)	< 0.01
35	TOF 10 mg/BID	104	53.6 (22.9)	3 mos	–	–25.50 (2.29)	< 0.001
35	ADA 40 mg	106	50.6 (23.0)	3 mos	–	–21.47 (2.33)	< 0.001
35	PBO	105	53.9 (22.6)	3 mos	–	–11.40 (2.44)	NS
36	PBO	367	6.3 (2.0)	24 wks	–	–1.6 (–1.8 to –1.4)	NS
36	UPA 15 mg	390	6.6 (2.0)	24 wks	–	–3.4 (–3.6 to –3.2)	< 0.001
36	UPA 30 mg	376	6.4 (2.1)	24 wks	–	–3.6 (–3.9 to –3.4)	< 0.001
36	ADA 40 mg	391	6.3 (2.0)	24 wks	–	–2.9 (–3.1 to –2.6)	NS
44	ETN	1122	2.8 (1.1)	24 wks	1.4	1.5 (1.39 to 1.55)	< 0.05
51	IXE every 4 wks	122	62.7 (19.1)	24 wks	–	–33.8 (2.48)	< 0.001
51	IXE every 2 wks	123	62.5 (19.9)	24 wks	–	–35.6 (2.50)	< 0.001
51	PBO	118	61.1 (22.7)	24 wks	–	–14.8 (2.65)	NS
56	MTX	73	5.7 (2.5)	9 mos	1.7 (2.0)	–	< 0.05
57	CZP	12	57.4 (5.4)	24 wks	27.5 (4.5)	–	< 0.001
62	SEC 150 mg	202	55.2 (24.0)	24 wks	–	–20.6 (1.7)	< 0.001
62	SEC 75 mg	202	56.1 (22.6)	24 wks	–	–20.0 (1.7)	< 0.001
62	PBO	202	55.6 (21.7)	24 wks	–	–7.4 (2.5)	NS
70	TNFi	152	5.5 (0.2)	12 mos	2.2 (0.2)	–	–
73	MTX	330	51.5 (20.9)	6 mos	–10.7 (–13.1 to –8.3)	–	0.009
74	NSAIDs for 3 mos then MTX for 3 mos	19	3.5 (1.0)	6 mos	1 (2)	–	< 0.05
74	NSAIDs + MTX for 6 mos	16	4.0 (1.0)	6 mos	2 (1)	–	< 0.05
80	ADA	277	56.1 (24.1)	12 mos	29.1	–	0.001
80	DMARDs	148	45.1 (24.7)	12 mos	37.9	–	0.001
84	MTX	284	60.7 (1.3)	24 wks	–	–22.70	–
84	ETN	284	62.9 (1.3)	24 wks	–	–31.64	< 0.001
86	MTX + ETN	283	61.0 (1.2)	24 wks	–	–29.04	< 0.05
85	PBO	212	6.8 (2.0)	24 wks	–	–0.8 (–1.2 to –0.5)	NS
85	UPA 15 mg	211	6.8 (1.9)	24 wks	–	–2.6 (–2.9 to –2.3)	< 0.001
85	UPA 30 mg	218	6.7 (2.2)	24 wks	–	–3.1 (–3.5 to –2.8)	< 0.001
87	IFX	11	57 (27-100)	84 days	10 (1-73)	–	< 0.001

^aValues are mean (SD) or median (IQR). ADA: adalimumab; CZP: certolizumab pegol; DMARD: disease-modifying antirheumatic drug; ETN: etanercept; IFX: infliximab; IXE: ixekizumab; MTX: methotrexate; NS: not significant; NSAID: nonsteroidal antiinflammatory drug; PBO: placebo; PtGA: patient global assessment; SE: standard error; SEC: secukinumab; TNFi: tumor necrosis factor inhibitor; TOF: tofacitinib; UPA: upadacitinib.

of reference to identify the indices most sensitive in detecting clinical changes during therapy (Supplementary Table S3, available with the online version of this article). DAS28 (ρ 0.48, P = 0.003), TJC of 28 joints (ρ 0.52, P = 0.001), SJC of 28 joints (ρ 0.51, P = 0.002), and HAQ (ρ 0.48, P = 0.003) were the activity variables that correlated well with variations of the PtGA. In 1 study, variations in PtGA scores weakly correlated positively with changes in anxiety score (ρ 0.25, P = 0.001).⁷⁶

- *Discordance between PtGA and PGA.* Discordance was eval-

uated in 3 studies (Table 3). A positive discordance was found in 25% to 56.5% patients^{9,37,38} and a negative discordance in 4.1-20.4%.^{9,38} However, in a single-center Asian study, negative discordance was more frequent than positive (20.4% vs 17.6%).⁹ A multicenter European study on 460 patients showed that determinants of discordance were psychological rather than physical domains of health.³⁸ A higher difference between PtGA and PGA was related to higher fatigue, lower self-perceived coping, and impaired social participation,³⁸

Table 3. Discordance between PtGA and PGA in PsA.

Reference	Positive Discordance, PtGA > PGA, %	Negative Discordance, PtGA < PGA, %	No. of Patients	No. of Physicians	Type of Scale
9	17.6	20.4	142	3	0-100 VAS
37	56.5	NR	1458	90	0-100 VAS
38	25	4.1	460	NS	0-10 NRS

NR: not reported; NRS: numerical rating scale; NS: not significant; PGA: physician global assessment; PsA: psoriatic arthritis; PtGA: patient global assessment; VAS: visual analog scale.

whereas in the Asian cohort, age, fatigue, and pain were the associated factors.⁹

DISCUSSION

Our systematic literature review (SLR) showed that although PtGA is widely used in PsA, the formulations vary. PtGA was a valid and responsive tool with a strong correlation with other PROs, whereas weak correlations were found with DAIs based on objective items and with PGA. Finally, we found discordance between PtGA and PGA, with PtGA usually higher than PGA.

The most remarkable evidence from this SLR is that, despite the widespread use of PtGA as an isolated instrument or integrated in indices, a universal definition of PtGA does not exist. We found 14 different wordings for PtGA, 8 different ways of questioning the patient, 4 acronyms, and 2 different ranges of time; the term “patient global assessment” with the acronym “PGA” was also used in the evaluation of cutaneous activity, creating an overlap. Moreover, in about half of the studies, the authors chose a VAS, whereas in 14 studies, a 0-5 or 0-10 NRS was employed. In some cases, the authors used different scales to assess the same domain when PtGA was part of definite composite indices, such as MDA (0-100 VAS), DAPSA (0-10 or 0-100 VAS), or PsARC (0-5 Likert scale). Although this variety of terms and metrics can be considered a minor problem in clinical practice, the lack of homogenization in the use of the scale makes it difficult nevertheless to compare results between studies and should be standardized. In fact, the metaanalysis performed in our study also indicated a high heterogeneity of results. The selection of one formulation over another was not determined by factors such as the type of study, the year of publication, or the number of patients, implying that the choice was arbitrary and depended on the author of the study. The first study reporting the use of PtGA appeared in 2000,⁸⁷ but the majority of articles retrieved through this literature search were gathered in the last 10 years, outlining the growing importance of the patient’s point of view in the assessment of PsA. Our SLR showed that PtGA was used in all the retrieved studies as a tool capable of defining DA. Nevertheless, with only one exception in which PtGA was the unique instrument, the assessment of DA as a whole was generally not left to the patient judgment’s alone; it was always used together with other tools, separate or integrated in indices. This evidence suggests that PtGA provides a comprehensive assessment, supporting its content validity, but an evaluation of specific domains is still needed in order to manage the patient. In particular, in 46 studies, PtGA was associated with VAS pain assessment, probably with the aim to discriminate when higher PtGA scores were determined by the active disease itself or by pain due to other factors, such as damage or comorbidities. Due to the subjectivity of the instrument, our metaanalysis showed that a good construct validity was observed with the tools based mainly on self-reported assessment (BASDAI, pooled correlation coefficient 0.69, 95% CI 0.66-0.73; ASDAS, ρ 0.47-0.81), whereas we found lower correlation with scores that included objective items (DAS28, pooled correlation coefficient 0.43, 95% CI 0.29-0.55; DAPSA, ρ 0.25-0.88) and

a weak correlation with objective physician-driven scores, such as MSK DA domains (ρ 0.11-0.40) and skin DA domains (ρ 0.13-0.33). Further, an excellent/good correlation was found with other PROs such as PsAID-12 (ρ 0.84), PsAID-9 (ρ 0.84), and VAS (ρ 0.75). In addition, the lower correlation found with DAS28 that includes the objective data of the joint count and the inflammation index is conditioned by the evaluation of a small number of joints, having been developed for rheumatoid arthritis; this confirms it is not suitable for PsA assessment. Studies have evidenced that PtGA was explained not only by physical but also psychological aspects,⁴³ and among factors that contributed to achieving the status of MDA,⁵³ the “objective” or “physician-driven” domains were more easily reached, whereas the most frequently missed items were those “patient-driven,” such as the PtGA. Nevertheless, one study⁵⁰ showed that correlations increased during 1 year of follow-up assessment. These data were not discussed by the authors; however, since a better correlation could be achieved repeating the assessment, training on how to score the PtGA could be useful to obtain an “homogenization” of the score.

The metaanalysis of construct validity with the PGA showed a moderate pooled correlation coefficient (ρ 0.52, 95% CI 0.48-0.56), but a high heterogeneity (I^2 84.31%, 95% CI 72.78-90.96). Analyzing the single studies, we found that when the domain evaluated matched precisely between the 2 assessors (patient and physician), the correlation was higher. The lower correlation was found when the patient marked the global status while the physician assessed the DA (ρ 0.29), whereas a good correlation was retrieved for the evaluation of isolate joints (ρ 0.54). It is an important reminder that according to the updated 2016 PsA core domain set,²¹ the PtGA should reflect a global health status, as reported in 3 studies of this SLR, and not only DA. This divergence in the domain to be measured would necessarily cause a discrepancy between scores. Of note, the best correlation was achieved in the 12-month follow-up study, as the patient became more familiar with the scoring method.⁴⁸ In up to half of the evaluations of the discordance between patient and physician assessment, patients’ scores were higher than physicians’; this result is generally attributed to an overestimation by patients, identifying fatigue level, pain score, and other psychological aspects as determinants of positive discordance.^{9,37,38} Of note, the authors did not collect data for chronic widespread pain syndromes and fibromyalgia, which are reported to have a significant impact on PtGA in PsA.^{82,88} Moreover, a recent cross-sectional study highlighted that gender could influence PtGA, with higher results in female individuals (mean PtGA: female 5.0 [SD 2.5] vs male 4.0 [SD 2.4], $P < 0.001$). Further, the same study showed sex differences in the burden of the disease, with women having higher TJC and SJC, more fibromyalgia, but less cutaneous extension of PsO, and the authors suggested a potential different treatment strategy according to sex.⁸⁹ However, it is reasonable to question if the positive discordance could be due to a physician underestimation, considering that nonobjectifiable symptoms have less effect on PGA. More studies are necessary to investigate where the discordance truly lies.

Even if no study assessed its responsiveness against a gold standard, the PtGA was used to evaluate response to treatment in 25 studies and was able to discriminate between baseline status and response to treatment as well as between placebo and treatment groups. Moreover, it showed a good sensitivity to change correlating with objective items (DAS28, TJC, and SJC) and HAQ, thus indirectly demonstrating itself to be a responsive tool.

In a single study, reliability of PtGA was excellent²⁹; however, more data are needed on this subject.

A limitation of this SLR may be a potential incomplete retrieval of identified research studies. If not considered important, PtGA results may not have been always summarized in the abstract, resulting an outcome reporting bias. However, including more articles would have increased the variability of the PtGA formulations, supporting the thesis of the importance of instrument's homogenization. Another limitation concerns the construct validity. Higher correlations were reported with DAPSA, which includes PtGA among its items, and with BASDAI, which is relevant only for the minority of patients with axial disease. Another weakness of our study is that we did not formally perform a quality assessment of the papers, although they were all peer-reviewed studies and we excluded case reports or case series.

In conclusion, PtGA showed good content validity, strong to weak construct validity with the lowest correlations with DAIs based on objective items and PGA, and high criterion validity with HRQOL measurements. It showed to be a responsive tool, although more studies are necessary to confirm its reliability. Its weakness lies in the need to standardize the type of question and wording, interval of time, and length of the scale in order to homogenize the outcome results. Given the wide use of PtGA as an outcome measure in PsA, further studies are needed to ensure more homogeneity.

DATA AVAILABILITY

The authors will make the raw data supporting this article's conclusions available upon reasonable request.

ONLINE SUPPLEMENT

Supplementary material accompanies the online version of this article.

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