Patient-physician discordance in assessment of disease activity in Rheumatoid Arthritis patients

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ABSTRACT

Background. In rheumatoid arthritis (RA), global disease activity is commonly evaluated, from the patient's and the physician's perspective, through a 100mm visual analogue scale (VAS) and plays an important role in the assessment of diseases activity and treatment decisions. Our aim was to determine patient-physician discordance in the assessment of disease activity and to explore its determinants.

Methods. Cross sectional study including RA patients (ACR/EULAR 2010 classification criteria). The discrepancy between patients-physicians (ΔPPhGA) was defined as PGA minus PhGA, and a difference > |20mm| was considered as "discordant". Correlation between ΔPPhGA and other variables was assessed through Pearson's correlation and comparison between groups through t-test. Variables with p<0.05 or considered clinically relevant were included in multivariable linear regression analysis to identify determinants for ΔPPhGA. A p≤0.05 was considered statistically significant.

Results. In total, 467 patients with RA were included (81.2% female; mean age 63.9% ± 12.2 years). PGA and PhGA were discordant in 61.7% of the cases. The proportion of concordance increased ($p < 0.01$) when considering only patients in remission (DAS 28 3V <2.6). In multivariable analysis ($R^2_{adjusted}$=0.27), VAS-pain-patient (β 0.74, 95% CI 0.62-0.88, p=0.00) and tender joint count (β 0.16, 95% CI 0.45-0.48, p=0.02) remained associated with a higher ΔPPhGA.

Conclusion. Our study confirmed that a significant discrepancy between patients and physicians in the assessment of global disease activity is frequent in clinical practice, and is probably due to valorization of different parameters by the two groups.

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Keywords: Rheumatoid arthritis; Patient reported outcome measures; Outcome measures; Disease activity scores.

INTRODUCTION

According to current treatment paradigms, RA should be managed through regular quantitative assessment of disease activity and adjustments of medication aiming at achieving clinical remission, as early and consistently as possible, in a shared decision process between patient and rheumatologist[1]. Besides tender and swollen joint counts and acute phase reactants, physicians and patients' perspectives about disease activity status should be considered. Patient global assessment (PGA) and physician global assessment (PhGA) of disease activity are tipically scored using a 100-mm visual analogue scale (VAS) with 0 (best possible) and 100 (worst possible) as extremes. PGA is part of all the definitions of remission endorsed by the ACR/EULAR[2] and PhGA is included in two of them. Among the many issues raised regarding the use of PGA, it has been recognised that patients have difficulties in disassociating inflammatory activity of RA from confounding factors, such as unrelated pain, comorbidities or depression[3–7]. Physicians seem to base their score in more objective measurements, including tender and swollen joint count, erythrocyte sedimentation rate and C-reactive protein[3–6]. Unsurprisingly, disagreement between patients and physicians has been previously reported, among patients with RA, with patients rating disease activity higher than physicians[3–6,8]. The same is described for other pathologies such as psoriatic arthritis or spondyloarthritis[9,10], or more recently, for Behçet disease and systemic lupus erythematosus[11,12]. It is very important to understand the reasons underlying these differences, given the impact they have in shared decision making and on patients' satisfaction with healthcare and ad-

herence to treatment[9]. Our primary aim was to evaluate the discrepancy between patients and physicians in the assessment of disease activity in a cohort of patients with established RA. As secondary outcome, we aimed to identify clinical and socio-demographic determinants of patient-physician discordance.

METHODS

STUDY DESIGN AND POPULATION

This was a cross-sectional study in a single Portuguese center. Individuals were considered eligible if they fulfilled the following inclusion criteria: (1) age ≥ 18 years, (2) RA diagnosis according to the ACR/EULAR 2010 classification criteria, and (3) complete available data on PGA, PhGA, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP).

All patients were registered in the national rheumatology registry (Reuma.pt) and all signed an informed consent form. This study was approved by the Ethics Committee of our institution (CHUC 033-18).

DATA COLLECTION

Patient and Physician Global Assessments

PGA was assessed through the question, "Considering all of the ways your arthritis has affected you, how do you feel your arthritis is today?"[2] whereas PhGA was assessed by the question, "How do you assess your patient's current arthritis disease activity?", with 0 (best possible) and 100 mm (worst possible) as extremes in a VAS. PhGA was scored by the rheumatologist, who performed the joint count in knowledge of the laboratory results.

Other variables

Socio-demographic and clinical data,collected from the last visit to the rheumatology department, included age, gender, years of formal education, disease duration (years since diagnosis), tender and swollen 28-joint count (TJC and SJC, respectively), ESR (mm/h), CRP (mg/L), VAS-pain-patient (0 to 100 mm), the validated Portuguese versions of the Health Assessment Questionnaire – Disability Index (HAQ-DI)[10] and of the EuroQol five-dimension scale (EQ5D)[11]. The disease activity was calculated according to DAS with 28 joint count, CRP without PGA (DAS28CRP-3V) and the values were categorized as follows: ≤ 2.6: remission, >2.6, ≤3.2: low disease activity, >3.2. ≤5.1: moderate, and >5.1 high disease activity[12,13].

STATISTICAL ANALYSIS

Descriptive analysis of demographic and clinical data was performed, with categorical variables described as proportions and continuous data using means and standard deviations. Discrepancy between PGA e PhGA (ΔPPhGA) was calculated as PGA minus PhGA and classified as discordant when > |20mm|[5,14]. The agreement between patient and physician was expressed as intraclass correlation coefficient (ICC). Values <0.5 were considered poor agreement, 0.5-0.75 moderate, 0.75-0.9 good, and values >0.90 excellent agreement[14]. Correlations between PGA, PhGA and ΔPPhGA with other variables was assessed through Pearson correlation coefficient (*r*) and comparison between groups through t-test. *r* values 0.40 were considered poor, 0.40-0.59 moderate and ≥ 0.60 very good[15]. Patient-physician discordance according to the different disease activity states was assessed using Chi-square tests. The variables with statistical significance in the bivariable analysis, or clinically relevant in the researchers' perspective, were included in multivariable linear regression analysis to identify determinants for PGA, PhGA and ΔPPhGA. Prior to this analysis, the assumptions of normality and multicollinearity were confirmed. Variance and inflation factor values were below 5 for all variables included in the models, excluding multicollinearity as an issue. As recommended, R^2_{adjusted} was used to estimate the model fit. R^2_{adjusted} can range between 0-1 and values > 0.5 were considered as a good adjustment of the model[16]. A secondary analysis was made to assess the correlation between the modified Clinical Disease Activity Index, (mCDAI) - CDAI without PGA and ΔPPhGA.

Statistical analysis was performed with SPSS Statistics, V.23 and $p<0.05$ was considered statistically significant.

RESULTS

PATIENT CHARACTERISTICS

In total, 467 patients with RA [81.2% female; mean age: 63.9(12.2) years, mean duration of disease was 13.2(0.5) years] were included. The patient socio-demographic and clinical characteristics are presented in Table I.

Discrepancy between PGA e PhGA

Patients had, on average, a worse perception of disease

activity than physicians (mean PGA of 47.1±1.2 Vs mean PhGA 16.8±1.0). Agreement between PGA and PhGA was poor (ICC, 0.29; p <0.001). PGA and PhGA were discordant by more than 20mm in 61.7% of the cases, with the patient scoring higher than the physician in 95% of these cases. The proportion of concordance increased ($p < 0.01$) when considering only patients in remission (DAS28CRP--3V <2.6) (Figure 1).

TABLE I. SOCIO-DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE STUDY PARTICIPANTS (N =467). ALL VALUES ARE MEAN (SD) EXCEPT STATED OTHERWISE

Variables	Values
Socio-demographic characteristics	
Age, years	63.9 (12.2)
Caucasian patients, n (%)	467 (100)
Female, n (%)	379 (81.2)
Clinical characteristics	
Disease duration, years*	13.2 (0.5)
CRP, mg/L	7.5 (10.8)
ESR, mm/hour	15.2 (14.1)
Tender joint count (0-28)	1.1 (0.1)
Swollen joint count (0-28)	1.0 (0.5)
Disease activity states	223 (47.7)
Remission, n (%)	
LDA, n (%)	98 (21.0)
MDA, n (%)	133 (28.5)
HDA, n (%)	13 (2.8)
Disease activity scores	
DAS28CRP-3V (global)	2.5 (1.0)
SDAI	9.4 (0.3)
CDAI	8.6 (0.3)
Patient Reported Outcomes	
VAS-pain-patient (0-100), mm	48.4 (1.4)
HAQ-DI score (0-3) *	1.2 (0.7)
EQ5D score *	0.5 (0.3)
Patient and Physician Global Assessments	
PGA (0-100), mm	47.1 (1.2)
PhGA (0-100), mm	16.8 (1.0)
ΔPPhGA, mm	30.3 (1.3)

CDAI: Clinical Disease Activity Index; CRP: C-reactive protein; DAS28: Disease Activity Score in 28 joints; ESR: erythrocyte sedimentation rate; EQ5D: EuroQol five-dimension scale; HAQ-DI:Health Assessment Questionnaire-Disability Index; HAD: High disease activity; LDA: Low disease activity; MDA: Moderate disease activity; PhGA: physician's global assessment; PGA: patient's global assessment; SDAI: Simplified Disease Activity Index; VAS: visual analog scale (0–100 mm)
*Missing data: 8 patients had no information on disease duration, 29 on HAQ-DI score, and 53 on EQ5D

Determinants of PGA and PhGA

Correlation between PGA and VAS pain was very good (r = 0.82) and moderate between PGA and HAQ-DI (r = 0.52) and EQ5d (r = -0.52). It also showed weaker correlations (r <0.30) with all other measures (Table II). PhGA was moderately correlated with SJC28 (r=0.45) and showed lower values (r < 0.40) with all other variables (Table II). Female patients reported a higher mean PGA [49.0 (26.0) Vs 39.0(30.3) mm, p=0.002] and tended to have a higher mean PhGA [17.7(20.5) Vs 13.1(21.4) mm, p=0.06].

In the multivariable analysis ($R^2_{adjusted}$=0.65), only VAS-pain and age remained independently associated with PGA (Table III). SJC28, HAQ-DI scores, DAS 28 3V-PCR and VAS-pain remained significantly associated with PhGA ($R^2_{adjusted}$=0.38) (Table III).

Determinants of ΔPPhGA

Bivariable analyses showed that VAS-pain-patient had a moderate, but significant, positive association with the discrepancy between PGA and PhGA. The correlations were also significant (p<0.05) although weak, between ΔPPhGA and SJC28 (r = -0.12), HAQ-DI (r= 0.27), EQ5D (r = -0.28) and age (r = 0.21) (Table II). In multivariable analysis ($R^2_{adjusted}$=0.27), VAS-pain (β 0.74, 95% CI 0.62-0.88, p=<0.001) and TJC28 (β 0.16, 95% CI 0.45-0.48, p=0.02) were the only variables that remained independently associated with a higher ΔPPhGA (Table III).

In a secondary analysis, using mCDAI instead of DAS 28 3V-PCR, we found a poor significant correlation between mCDAI and ΔPPhGA (r = -0.12). Also, in multivariable analysis ($R^2_{adjusted}$=0.71), VAS-pain (β 0.66, 95% CI 0.60-0.73, p=<0.001), mCDAI (β -1.60, 95% CI -10.40- (-8.70), p=<0.001), TJC28 (β 0.67, 95% CI 8.73-11.54, p=<0.001), SJC28 (β 0.60, 95% CI 7.43-10.66, p=<0.001) and age (β 0.06, 95% CI 0.02-0.29, p=0.03) were determinants of ΔPPhGA.

DISCUSSION

In this study we confirmed that a significant discrepancy between patients and physicians in the assessment of global disease activity is frequently observed in clinical practice. Patients rate higher than physicians across all disease activity states, although the discordance is lower in the remission group. Pain was the strongest

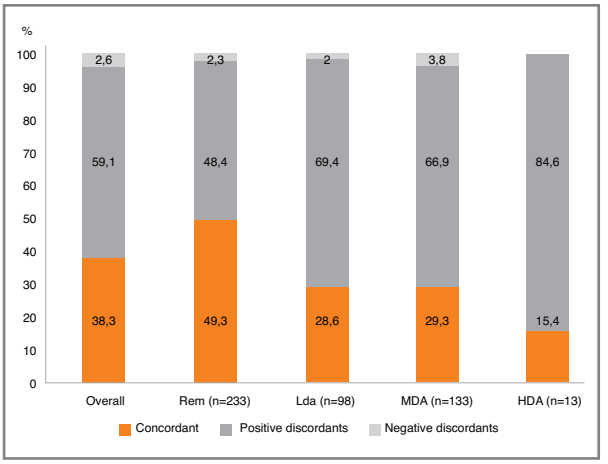

FIGURE 1. Concordance level (%) between patient and physician global assessment of disease activity according to the disease activity states

correlate of patient's perception of disease activity, while for the physician SJC28 seems paramount, which is consistent with the available literature[4–6,17].

During the past recent years, patient reported outcome measures have assumed an important position in the assessment of health status and management of health care[18]. PGA is an essential component of all validated disease activity scores and all endorsed definitions of remission, commonly used as targets of therapy. However, it has been claimed that it may lead to relevant bias due to its subjectivity and poor associations with objective measures of inflammation[7]. Many studies have demonstrated that VAS-pain is the strongest determinant of PGA[4–7,17]. Pain is itself a subjective experience and therefore, difficult to quantify and to summarize in a single number for the most of the patients. However, in the absence of an objective assessment, the patient reported outcomes are the most used tools to assess it[19].

There is also evidence that it is significantly affected by other subjective domains (such as HAQ-DI score, fatigue, function and psychological domains) and comorbidities, such as fibromyalgia[3,6,7,19–21]. One study compared PGA between RA patients with and without comorbidities[22]. Patients with comorbidities had higher PGA values than patients with RA only and the greater the number of morbidities, the greater the PGA value. In this study, fatigue, pain and HAQ were independent determinants of the PGA variation between the two groups[22]. Coinversely, the correlations with more objective measures of inflammation, such as CRP and SJC is poor[20,22], which are more influential on PhGA[4–6,17]. Recently, Ferreira *et al* highlighted the practical difficulties of patients with RA in completing PGA, thought qualitative approach using panels for patients[7]. Besides difficulties in understanding the true meaning of PGA, these authors also found that patients had difficulties related to the measurement of PGA itself and in understanding its purpose[7]. Furthermore, younger people feels like some patient reported outcomes are outdated or don't include some issues that are relevant for them, such as the impact on their appearance or sex life[24]. These findings contribute to the discrepancy be-

TABLE II. CORRELATION OF DEMOGRAPHIC AND CLINICAL VARIABLES WITH THE PGA, PHGA, AND DISCREPANCY BETWEEN PATIENTS AND PHYSICIANS (BIVARIABLE ANALYSIS)

	PGA	PhGA	ΔPPhGA
VAS-pain-patient	0.82*	0.30*	0.56*
DAS28CRP-3V	0.23*	0.39*	-0.07, N.S.
TJC	0.29*	0.36*	0.02, N.S.
SJC	0.17*	0.45*	-0.17*
HAQ-DI	0.52*	0.34*	0.24*
EQ5D	-0.52*	-0.28*	-0.28*
Age	0.24*	0.15*	0.12 *
Education level	-0.16*	NA	-0.15*
Disease duration	0.14*	0.16*	0.02, N.S.

*p<0.05; NA: Not applicable; N.S.: Non significant
DAS28CRP-3V: disease activity 28 joint count 3 variables; EQ5D: EuroQol five-dimension scale; HAQ-DI:Health Assessment Questionnaire--Disability Index; VAS: visual analog scale (0–100 mm); ΔPPhGA: discrepancy of global assessment of disease activity between patients and physicians > |20mm|

TABLE III. MULTIVARIABLE LINEAR REGRESSION MODELS FOR PGA, PHGA AND ΔPPHGA

	PGA (R2 adjusted=0.65)		PhGA (R2 adjusted =0.27)		ΔPPhGA (R2 adjusted =0.38)	
	β (95%CI)	p	β (95%CI)	p	β (95%CI)	p
VAS-pain-patient	0.72 (0.60-0.73)	<0.001	0.11 (0.001-0.16)	0.047	0.74 (0.62-0.88)	<0.001
DAS28CRP-3V	-0.008 (-2.41-1.96)	0.84	0.14 (0.52-5.54)	0.02	0.09 (-0.52-6.51)	0.09
TJC	0.05 (-0.55-1.96)	0.27	-0.06 (-2.10 – 0.76)	0.35	0.16 (0.45-0.48)	0.02
SJC	-0.011 (-1.29-0.97)	0.78	0.34 (2.50-5.10)	<0.001	-0.09 (-3.52-0.85)	0.23
HAQ-DI	0.07 (-0.65-6.02)	0.11	0.16 (0.77-8.44)	0.02	-0.06 (-7.13-2.54)	0.35
EQ5D	-0.04 (-13.10-4.44)	0.33	-0.008 (-10.70-9.46)	0.90	-0.07(-20.16-5.67)	0.27
Age	0.07 (0.01-0.28)	0.03	0.056 (-0.06-0.25)	0.22	0.008 (-0.18-0.22)	0.85
Gender	-0.02 (-5.60-2.50)	0.45	-0.02 (-5.70-3.62)	0.66	-0.07 (-6.48-5.44)	0.87
Disease duration	-0.03 (-0.24-0.08)	0.34	0.04 (-0.11-0.26)	0.43	-0.05 (-0.40-0.09)	0.20

DAS28CRP-3V: disease activity 28 joint count 3 variables; EQ5D: EuroQol five-dimension scale; HAQ-DI:Health Assessment Questionnaire-disability Index; VAS: visual analog scale (0–100 mm); ΔPPhGA: discrepancy of global assessment of disease activity between patients and physicians > |20mm|.

tween patients and physicians' scores, in addition to the different correlates/predictors of each assessment.

In a recent systematic literature review, values of this discrepancy can range between 25-76% of the cases, which is in agreement with our findings[9]. The rate of discrepancy varies significantly across the different studies depending on the cut-off used to define discrepancy. As expected, such discrepancy increases with more stringent cut-offs and decreases with cut-offs ≥|4|[9]. In our study, we considered a cut-off of 2, which is one of the most commonly used and which we considered to be the minimum value with clinical relevance.

Contrary to our study, Studenic *et al* found SJC was independently associated with ΔPPhGA, in addition to pain score[5]. Longstanding disease was also identified as a predictor of patient-physician discrepancy in one study[9], which was not verified in our study. Higher levels of depressive symptoms[23] and poor literacy[24] were also identified as independent predictors of discordance. Unfortunately, we were not able to analyse this relationship in our cohort because those variables were not available in our database.

Our study includes a considerable number of patients with complete clinical, laboratory, and functional data. Regarding limitations, we recognise that some potentially relevant factors have not been assessed. We were not able to include cultural factors, fatigue, psychological features and underlying comorbidities. Also, we did not include some variables related to the physician, such as gender, age, years of experience, number of patients seen with RA per week. This could justify why our model explained 65% of PGA and only 27% and 38% of PhGA and ΔPPhGA, respectively, that is, other variables not included in the model have influence on PGA, PhGA or ΔPPhGA. On the other hand, when using mCDAI instead of DAS 28 3V-PCR, we found that the greater the activity disease, the smaller the patient-physician discordance. This reinforce the fact that, in patients with less activity disease, some factors influence PGA but are not valued by PhGA. Despite that, our results are similar to others[5,17,19]. Physicians were not blinded to the patients' assessment, but this reflects normal clinical practice. Also, this was a cross-sectional study, so we cannot formally establish a causal relationship between the variables.

Future research in this field is still needed for a better understanding of the determinants of patient-physician discordance, especially in portuguese population. A multinational study including factors related to personality, social and familiar aspects could add some valuable information. Also, analysing different appointments (instead of just one) could help us understanding the perception of the patient of their own disease progression and therapy response.

CONCLUSION

In conclusion, different factors underlie patients and physicians' assessments of disease activity in RA. Patients base their perception and assessments on sub-

jective experiences while physicians tend to give more relevance to more objective measures, although our model explained only a small percentage of the variance in PhGA. We believe that these differences may affect significantly treatment decisions and adherence to therapy. A better understanding of both patient and physician's global assessment of disease activity may contribute to improve the shared decision process and , thus, foster better global outcomes, especially from the pespective of patients.

COMPLIANCE WITH ETHICAL STANDARDS

The authors report no conflicts of interest; this project was approved by the Ethics Committee of Centro Hospitalar e Universitário de Coimbra (CHUC 033-18); All included patients signed an informed consent form.

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