

Attainment of the Patient-acceptable Symptom State in 548 Patients with Rheumatoid Arthritis: Influence of Demographic Factors

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- 1 1 2 TITLE: Attainment of the Patient-acceptable Symptom State in 548 patients with 1 rheumatoid arthritis: influence of demographic factors 2 3 **AUTHORS:** 4 Catia Duarte^{a,b}, ORCID: 0000-0001-9327-6935 5 Eduardo Santos^{a,c,d}, ORCID: 0000-0003-0557-2377 6 Tore K Kvien^e, 7 Maxime Dougados^f, 8 Maarten de Wit⁹, 9 Laure Gossec^{h,i*}, ORCID: 0000-0002-4528-310X 10 11 J.A.P. da Silva^{a,b*} ORCID: 0000-0002-2782-6780 12 *LG and JAPS had equal contributions in this paper 13 14 Affiliations 15 16 a) Department of Rheumatology - Centro Hospitalar e Universitário de Coimbra, 17 18 Coimbra, Praceta, R. Prof. Mota Pinto, 3004-561 Coimbra, Portugal b) Coimbra Institute for Clinical and Biomedical Research, Faculty of Medicine, 19 20 University of Coimbra, Azinhaga Santa Comba Celas, 3000-548 Coimbra, 21 Portugal 22 c) Abel Salazar Institute of Biomedical Sciences, University of Porto, R. Jorge de 23 Viterbo Ferreira 228, 4050-313 Porto, Portugal 24 d) Health Sciences Research Unit: Nursing, Nursing School of Coimbra, Polo C, 25 Avenida Bissaya Barreto, 3046-851 Coimbra, Portugal e) Department of Rheumatology, Diakonhjemmet Hospital, Diakonveien 12, 0370 26 27 Oslo, NoruegaOslo, Norway 28 f) Rheumatology B, Cochin Hospital, Paris Descartes University, 12 Rue de 29 l'École de Médecine, 75006 Paris, France g) Patient Research Partner, Netherlands 30 h) Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé 31 Publique, 56 Boulevard Vincent Auriol, 75646 Paris, France 32 i) Pitié Salpêtrière Hospital, AP-HP, Rheumatology Department, 47-83 Boulevard 33 de l'Hôpital, 75013Paris, France. 34 3 1
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1 ABSTRACT

2 **Objectives:** To explore the clinical and socio-demographic factors associated with 3 Patient Acceptable Symptom Status (PASS) in Rheumatoid Arthritis (RA).

Methods: In a post-hoc analyses of a cross-sectional study, RA patients from 11 4 5 countries were included. PASS was assessed as acceptable/not acceptable status by the patient. Variables collected included socio-economic (gender, age and country 6 7 gross domestic product (GDP) per capita) and clinical variables: DAS28-3vESR (28 joint counts and Erythrocyte Sedimentation Rate), the patient-reported Rheumatoid 8 9 Arthritis Impact of Disease (RAID) score and its seven domains (scored 0 to 10). Patients in PASS or not were compared through univariable tests and factors 10 associated with PASS assessed by multivariable forward conditional logistic 11 regression. A similar analysis was performed in the subgroup patients in DAS28 12 13 remission (n=168).

Results: A total of 548 patients were included:80.5% female, mean (±SD) age 14 55.8±12.8 years, disease duration 13.6±10.6 years, DAS28 3.6±1.5. Overall, 360 15 (65.7%) considered themselves to be in PASS. Independent factors positively 16 17 associated with being in PASS were age>50 years (odds ratio, OR 1.67; [95% confidence Interval:1.04-2.67]), a lower DAS28 (OR:1.28 [1.08-1.52]), lower pain 18 (OR:1.45 [1.27-1.64]) and better emotional well-being (OR:1.28 [1.13-1.45]). Among 19 20 patients in remission, being in PASS was positively associated with less severe pain (OR:2.50 [1.79-3.84]), age>50 years (OR 3.30 [1.03 to10.87]) and living in a country of 21 22 the low GDP category (OR:5.08; [1.34-19.23]).

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24 **Conclusions:** Being in PASS is related to many factors besides disease activity, including age, perceived impact of the disease and national GDP. 25

26 27

28 **KEYWORDS:** Rheumatoid Arthritis, Patient Reported Outcomes, Patient Acceptable 29 Symptom State, Disease Activity, Socio-Demographic Aspects

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- 32
- 33 **CONFLICT OF INTEREST:** Authors declare no conflicts of interest.
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1. INTRODUCTION

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In a patient-centred care perspective, patients' satisfaction with their health condition becomes one of the most relevant objectives of medical practice, in parallel with physician-centred targets. Therefore, the evaluation of individual patient perceptions of disease impact, through Patient Reported Outcomes (PROs) should be encouraged, in addition to disease activity scores.

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8 Patient Acceptable Symptom State (PASS) is a strictly patient-centred outcome that 9 merits consideration as a treatment target [1]. It is assessed through a dichotomized 10 simple question about patient's global satisfaction with their current symptom status 11 and is recognized as facilitating the communication and decision sharing between 12 patients and health-care providers [1-3].

Understanding the factors associated with PASS is helpful to understand the 13 14 underlying message and to define the most adequate management strategy, 15 particularly in case of discordance between the perceptions of patient and the physician [4]. A patient considers himself as being in an acceptable status, despite 16 active arthritis, probably needs careful explanations to ensure adherence to additional 17 18 treatment. Conversely, in patients in inflammatory remission who continue to 19 experience a non-satisfactory status, underlying reasons should be evaluated and 20 addressed through adjunctive interventions, without intensification of 21 immunosuppressive therapy.

22 Previous studies have shown that PASS is related with disease activity, and with the 23 patient's perception of impact, with pain, function and physical well-being representing the most influential factors [5-7]. However, the role of non-disease-related factors, 24 which have been evaluated in different rheumatic conditions [3, 8-10], remains unclear 25 in RA. The effect of gender and age on acceptable status remains controversial [3, 6, 26 9-11]. Substantial differences in PASS thresholds have been reported between 27 English-speaking versus non-English-speaking countries, regarding spondylarthritis 28 29 [3]. However, these findings were not confirmed in other studies addressing different rheumatic conditions[12]. Moreover, the effect of the country's socio-economic welfare 30 in terms of gross domestic product (GDP) per capita has not been evaluated. 31

This study aimed at addressing these knowledge gaps by evaluating the sociodemographic factors associated with PASS in RA in a multinational cohort of patients.

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2. MATERIAL AND METHODS

3 2.1 Study design and patients:

4 This was a cross-sectional analysis of data from the RAID (RA Impact of Disease) 5 study, an international multicentric study performed in 2008-2009 involving adult RA patients from 10 European countries [13], with additional data from a Portuguese single 6 centre (2017-2018), a country not included in the RAID Study. All patients were adults 7 8 with the diagnosis of RA [14], able to fill in the guestionnaires and willing to provide informed consent. This study was conducted under approval of ethics committees from 9 10 the participating countries.

The present analysis only included patients without missing data regarding PASS, 11 12 DAS28-3vESR and individual items of the RAID questionnaire.

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2.2 Outcome of Interest 14

PASS was assessed in a binary way (PASS yes/no) through the question: "Think about 15 all the ways your RA has affected you during the last week. If you were to remain for 16 the next few months as you were during the last week, would this be: a) Acceptable or 17 18 b) Unacceptable". [7, 12]

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20 2.3 Data Collection

21 Socio-demographic data (age, gender and country) were collected. Information on 22 GDP per capita (adjusted for purchasing power parity, measured in international 23 dollars) for each country was extracted from the reports of the International Monetary 24 Fund for 2009 (for countries of RAID study) and for 2018 for Portugal [15]. GDP was dichotomised in low-GDP and high-GDP countries, with a cut-off at 35000 international 25 dollars per capita, which was the threshold that discriminated best between groups 26 after visual data inspection. 27

RA-related clinical characteristics were recorded, including tender 28-joint count (TJC), 28 29 swollen 28-joint count (SJC) and Erythrocyte Sedimentation Rate (ESR). Disease 30 activity was assessed using the 28-joint disease activity score (DAS28), calculated based on TJC, SJC and ESR (3v). In the absence of validated cut-offs for DAS28-31 3vESR, those validated for DAS28-4vESR were considered. Disease activity was, thus, 32 33 categorized as: High disease activity >5.1; Moderate Disease Activity [3.2 to 5.1]; Low 34 disease activity [2.6 to 3.2[and Remission < 2.6 [16]. The impact of RA was assessed using the RAID score. This is a composite measure specific for RA that reflects the 35

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patient's perception of the impact of disease on seven domains of health (pain, fatigue, 1 physical function, sleep disturbance, emotional well-being, physical well-being and 2 coping) [13]. Each domain is assessed through a single question answered on a 0 (the 3 4 best state) to 10 (the worst sate) numerical rating scale. Scores of the individual 5 domains were collected and the global RAID score was computed according to the 6 validated algorithm [13].

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8 2.4 Statistical Methods

9 Descriptive characteristics are presented as mean and standard deviation (±SD) for 10 continuous variables and as proportions (%) for categorical variables.

11 Differences in variables between patients in PASS and non-PASS were tested using the t-test for independent samples or Chi-square test, as adequate. Variables with 12 p<0.1 in univariate analysis, gender, age and GDP category were included in stepwise 13 multivariate logistic regression (Forward Conditional analysis), with PASS as 14 15 dependent variable. This analysis was repeated in the subgroup of patients in inflammatory remission, in order to explore factors independent of inflammation and 16 understand the reason of non-PASS in patients who have achieved the inflammatory 17 18 remission target.

Statistical Analysis was performed using the SPSS® software, version 24. Statistically 19 20 significant effects were assumed for p<0.05.

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22 2.5 Ethics

The RAID Study was conducted with approval of the ethics committees in the 23 24 participating countries. Portuguese study was approved by the Ethics Committee of the Centro Hospitalar Universitário de Coimbra (CHUC-160-17). All patients signed a 25 26 written informed consent before to participate.

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3. RESULTS 30

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32 3.1 Demographic and clinical characteristics

In total, 548 patients from 11 countries (number per country ranging from 34 (Greece to 33 34 96 (Portugal)) were included (supplementary table 1). Their demographic and clinical

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characteristics are presented in table 1. The majority were women (80.5%), with a
mean age of 55.8±13.0 years, and a mean disease duration of 13.6 ±10.5 years.

Disease activity, as measured by DAS28-3vESR, was reflected by a mean score of 3.6
±1.5 with 44.2% of patients being in remission or low disease activity. Impact of
disease assessed through RAID score was moderate to high (mean 4.2±2.2), with pain
(mean 4.6±2.6), fatigue (mean 4.5±2.7) and function (mean 4.4±2.6) being the most
severely affected domains.

8

9 **3.2 Prevalence and correlates of PASS status**

Of 548 patients, 360 (65.7%) rated their symptom status as acceptable. Disease activity (DAS 28 mean 3.1 ± 1.3 vs 4.4 ± 1.5), p<0.01), global impact (mean global RAID score 3.3 ± 1.8 vs 5.8 ± 1.8 , p<0.01) as well as in each of the seven domains of RAID were significantly lower in patients in PASS status (p<0.001). (Table1) Overall, the group of patients in PASS had a higher proportion of people aged > 50 years (72.5% vs 68.3%, p=0.019). No differences were observed in regarding gender, GDP category or disease duration.

In multivariable regression analysis, lower disease activity by DAS28-3vESR
(OR=1.28, 95%CI: 1.07 to 1.52), less intense pain (OR=1.45, 95%CI:1.27 to 1.65),
better emotional well-being (OR=1.28, 95%CI:1.19 to 1.45), and age>50 years
(OR=1.67, 95%CI:1.04 to 2.67) were associated with being in PASS. (Table 2)

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22 3.3 Subgroup analysis of patients in inflammatory remission

23 Considering only patients in inflammatory remission (n=168) according to DAS28-24 3vESR, living in a low GDP country (61.1% vs 54.2%) and being older than 50 years 25 (75.7% vs 50.0%) were associated with higher odds of being in PASS. Despite all being in remission, patients in non-PASS still perceived higher impact in all domains 26 27 than patients in PASS (p<0.01), scoring ≥ 5 in all domains of RAID, except for coping (mean 3.9±2.7) and for sleep disturbance (mean 4.5±3.2). Independent factors 28 associated with being in PASS status were lower levels of pain (OR=2.50, 95%CI=1.79 29 to 3.84), living in a country with a GDP/capita <35000 international dollars (OR=5.08, 30 95%CI=1.34 to 19.23) and age >50 years (OR=3.30, 95%CI=1.03 to 10.87). (Table 2) 31

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33 4. DISCUSSION

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This report shows that factors not related to the disease, such as age and GDP/capita,
have an important influence on PASS status of patients with RA, which is particularly
relevant in patients in inflammatory remission.

5 Two-thirds of all included patients were in PASS status. Coherently, patients who 6 considered themselves to be in a non-acceptable status reported worse scores for all 7 domains of health and had higher levels of disease activity. Among the factors related to the disease, pain was the most important factor preventing patients from reaching an 8 9 acceptable status, which is in agreement with previous studies [5, 6, 17]. As expected, and similarly to other studies, disease activity was independently associated with being 10 PASS. Emotional well-being had a significant impact on PASS status in our study, 11 similarly to other study where depression was independently associated with being in 12 Physical well-being, fatigue, function, sleep and coping were not 13 PASS.[17] associated with PASS/non-PASS in multivariable analysis in our study. Interestingly, 14 15 older age, in and of itself, was the strongest predictor of PASS status in multivariable analysis, i.e, after correction or potential confounders. 16

17 Among patients in inflammatory remission, 15% still considered their status as non-18 acceptable. These findings are aligned with observations that remission of 19 inflammation does not always result in symptom remission, [18] thus suggesting that 20 other factors besides disease activity need to be taken into consideration. Understand 21 the reasons underlying a non-acceptable status is particularly relevant in this subgroup 22 of patients to guide adjuvant interventions, as disease activity is already under control. 23 Our analyses indicate that that GDP/capita is the strongest independent factor of PASS 24 status, in these patients, followed by pain and age. Similar observations regarding age have been previously reported in SpA [3] and osteoarthritis [10], but not consistently in 25 RA [6] [7, 17, 19], with only one study showing that older age was independently 26 associated with being in PASS.[17] Similar correlates of GDP have been reported 27 28 regarding other PROs, such as PGA and fatigue [20, 21]. It is conceivable that higher expectations associated with higher GDP and younger age play a role in the observed 29 30 associations. Naturally, factors associated with ethnical and cultural backgrounds may also play a role, independently of the economy, as they have been shown to influence 31 32 the self-perceived impact of RA in several domains or ability to cope with disease [22] 33 as well with of anti-rheumatic drugs persistence in RA.[23] These could not be 34 addressed in the present study.

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Our study has some limitations. The cross-sectional design allowed assessment of patient's satisfaction in one single visit. However, patient satisfaction can be affected by previous experiences and vary according to whether there has been an improvement or worsening of health compared to the past [6]. The patients included in

3 4 improvement or worsening of health compared to the past [6]. The patients included in this analysis were enrolled in different decades, and significant development in RA 5 treatment occurred during this period of time, which can be considered a limitation of 6 7 our study. Education level, which was associated with other RA outcomes in previous 8 studies was not considered in our study. However, PASS wasn't associated with 9 education level in the recent study. [19] Despite the large sample size, the number of 10 patients per country is small and the influence of GDP should be interpreted with 11 caution and deserve confirmation in future studies including larger samples from the 12 different countries. Cultural and behavioural factors, strongly dependent of the country 13 residence and of the country of birth, were not considered in this study. However, GDP could be a surrogate marker for other objective and cultural factors. 14

In conclusion, reaching remission doesn't equate to being in a PASS status and sociodemographic characteristics, including as age or country of residence can have a relevant role in patients' perception of an (un)acceptable state. Dedicated research is warranted to understand the factors that drive patients' unsatisfaction with their health despite inflammatory remission and to design appropriate holistic interventions.

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1 AUTHOR CONTRIBUTIONS

- 2 All authors were involved in drafting the article or revising it critically for important
- 3 intellectual content, and all authors approved the final version to be published.

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- Table 1: Socio-demographic and clinical characteristics of 548 patients with RA

2	patients,	according to	PASS	status.
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	All	PASS	No PASS	p-value
	(n=548)	(n= 360)	(n=188)	
Female N (%)	441 (80.5)	283 (78.6)	158 (84.0)	0.13*
Age (mean /SD)	55.8 (13.0)	56.5 (13.3)	54.4 (12.2)	0.06*
Age				0.02#
>50 Yrs N (%)	379 (69.2)	261 (72.5)	118 (62.8)	
GDP				0.37*
Low GPD N (%)	318 (58.0)	204 (56.7)	114 (60.6)	
DAS28-3vESR	3.6 (1.5)	3.1 (1.3)	4.4 (1.5)	< 0.01*
Remission N (%)	168 (30.7)	144 (40.0)	24 (12.8)	n.a
Low N (%)	74 (13.5)	60 (16.7)	14 (7.4)	n.a
Moderate N (%)	208 (38.0)	129 (35.8)	79 (42.9)	n.a
High N (%)	98 (17.9)	27 (7.5)	71 (37.8)	n.a
RAID Score ((0 to 10))	4.2 (2.2)	3.3 (1.8)	5.8 (1.8)	< 0.01*
RAID Pain (0 to 10)	4.6 (2.6)	3.6 (2.2)	6.5 (2.3)	< 0.01*
RAID Function (0 to	4.4 (2.6)	3.4 (2.2)	6.2 (2.3)	< 0.01*
10)				
RAID Fatigue (0 to 10)	4.5 (2.7)	3.7 (2.5)	6.0 (2.3)	< 0.01*
RAID Sleep (0 to 10)	3.6 (2.8)	3.0 (2.6)	4.7 (2.9)	< 0.01*
RAID Emotional Well-	4.2 (2.5)	3.3 (2.1)	5.9 (2.2)	< 0.01*
being (0 to 10)				
RAID Physical Well-	3.9 (2.5)	3.1 (2.3)	5.3 (2.4)	< 0.01*
being (0 to 10)				
RAID Coping (0 to 10)	3.7 (2.5)	3.0 (2.2)	5.2 (2.3)	< 0.01*

Values are the mean ± SD unless indicated otherwise. PASS: Patient Acceptable Symptom State; Yo:

years old; GDP: Gross Domestic Product; DAS 28-ESR: Disease Activity Score, Erythrocyte

Sedimentation Rate; RAID: Rheumatoid Arthritis Impact of Disease. *Independent Samples T-Test, # Chi-2

Test. n.a: not analysed

Table 2: Adjusted Odds Ratio (OR) for being in PASS for all patients and for

patients in disease remission

	All Patients (n=548)	
	OR	95%CI
Age (>50 vs ≤50 years)	1.67	1.04-2.67
Pain (0-10, per reduction of 1 point)	1.45	1.27-1.64
RAID emotional Well-being (per reduction of 1 point)	1.28	1.13-1.45
DAS28-3vESR (per reduction of 1 point)	1.28	1.08-1.52
Patie	ents in disease Remission (n	=168)
	OR	95%Cl
Age (>50 vs ≤50 years)	3.30	1.03-10.87
GDP per capita of country (Lower vs Higher)	5.08	1.34-19.23
Pain (0-10, per reduction of 1 point)	2.50	1.79-3.84

GDP: Gross Domestic Product; OR: Odds Ratio; CI: confidence interval

	Country (n)	GDPpercapita, 1000	DAS28- 3vESR*	Remission (%)	PASS Total	PASS in Remission
		international dollars**			(%)	(%)
C*	Turkey (34)	15.64	4.1±1.6	23.5	64.7	75.0
	Romenia (51)	16.40	5.0±1.2	3.9	47.1	100.0
	Estonia (51)	20.97	3.8±1.4	19.6	52.9	70.0
	Greece (39)	30.35	4.3±1.2	7.7	43.6	100.0
	Spain (47)	32.00	3.5 ±1.4	34.0	72.3	100.0
۲	Portugal (96)	32.01	2.3±1.1	65.6	80.0	85.7
	France (42)	36.26	3.7±1.3	21.4	59.5	66.7
+-	Finland (48)	37.35	2.7±0.9	54.2	70.8	76.9
	Germany (50)	38.74	4.2±1.4	12.0	58.0	83.3
	TheNetherlands (45)	44.51	2.6±1.2	51.1	91.1	95.7
	Norway (45)	61.28	4.3±1.2	6.7	60.0	100.0

Supplementary table 1: Clinical Characterization per country

*Values are the mean ± SD. PASS: Patient Acceptable Symptom State; GDP: Gross Domestic Product;

DAS28-3vESR: Disease Activity Score 3 variables, Erythrocyte Sedimentation Rate, Countries are ordered by increasing GDP (international dollars). **International dollars are purchasing power parity adjusted

5 dollars, 2009 (all, except for Portugal) and 2018 (Portugal)