Validation of Rheumatoid Arthritis Quality of Life (RAQoL) Questionnaire into Portuguese Language

Duarte C[1], Fernandes F[2], Madeira N[3], Pinto P[4], Furtado C[5], Ribeiro C[6], Couto M[7], Santos-Faria D[8], Martins-Rocha T[9], Freitas R[10], Cunha R[11], Heaney A[12], McKena S[13], Pereira da Silva JA[1]

ACTA REUMATOL PORT. 2019;44:65-70

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic systemic autoimmune inflammatory disease, characterised by pain, stiffness and swelling, leading to joint destruction, functional disability, reduced quality of life and increased mortality[1]. Therefore, RA has a major impact on several domains of patients' lives including pain, fatigue, sleep, emotional well-being and participation in social life, significantly reducing their quality of life (QoL). In Portugal, with an estimated prevalence of 0.7% in adult population, RA is the second inflammatory musculoskeletal disease with the greatest impact on patients' QoL and ability to function[2].

Over recent decades, the development of new drugs and treatment strategies has significantly improved the prognosis for RA patients[3]. As no curative treatment exists, the goal is to achieve consistent abrogation of inflammation as a means to halt disease progression, limit disability and achieve the ultimate aim of therapy: improving QoL[1]. The assessment of QoL of these patients is recommended by several scientific societies[4,5], as an outcome of utmost relevance in both research and clinical practice[6].

Both generic and specific instruments are available for measuring patient-reported outcomes in RA. Generic instruments such as the Nottingham Health Profile (NHP)[7], the Short Form Health Survey 36 (SF 36)[8] and the EuroQoL[9] are designed to compare health states across different disease populations. For this purpose, they must contain items that are applicable to a large variety of disease conditions, and, thus, pay less attention to issues that are of specific importance for patients with RA. Consequently, generic measures used in RA patients have reduced validity and sensitivity to clinically relevant changes[10].

The Rheumatoid Arthritis Quality of Life questionnaire (RAQoL) is a patient-centric assessment of QoL specific to RA[11]. It was developed by researchers in the UK and the Netherlands for use in clinical trials and for monitoring individual patients in clinical practice. The content of the RAQoL was derived from unstructured qualitative interviews conducted with relevant patients[11].

Since its development, the english version of RAQoL has been successfully adapted into 36 languages and fully validated in 24[12]: Canada (English and French)[13], Denmark[14], Estonia[15], Australia[16], Serbia[10], Sweden[17-19], among others[20], in addition to the original UK and Dutch[11] versions. RAQoL has been the most widely employed RA-specific patient-centric Patient Reported Outcome Measure (PROM). All language versions of the RAQoL exhibit high internal consistency, construct validity, internal validity, reliability and sensitivity to change[12].

An adapted Portuguese version of the RAQoL is available[21], but no formal evaluation of its psychometric properties and validation has been performed.

MATERIAL AND METHODS

SAMPLE

Adult patients with RA diagnosis according to the EULAR/ACR 2010 Rheumatoid Arthritis Criteria[22] were consecutively recruited from ten Portuguese Rheumatology Departments, including the mainland and the

1. Reumatologia, Centro Hospitalar Universitário de Coimbra; Coimbra Institute for Clinical and Biomedical Research (iCBR) - Faculty of Medicine, University of Coimbra, Portugal2. Faculdade de Medicina da Universidade de Coimbra
3. Instituto Português de Reumatologia
4. Reumatologia, Centro Hospitalar de Gaia
5. Reumatologia, Hospital do Divino Espírito Santo
6. Reumatologia, Centro Hospitalar Universitário do Algarve
7. Reumatologia, Centro Hospitalar Tondela-Viseu
8. Reumatologia, Unidade Local de Saúde do Alto Minho
9. Reumatologia, Centro Hospitalar São João
10. Reumatologia, Hospital Garcia d´Orta
11. Reumatologia, Centro Hospitalar Baixo Vouga
12. Galen Research
13. School of Health Sciences, University of Manchester

Azores archipelagos. Patients were contacted by telephone or during clinical visits. Those who were able to read and understand Portuguese and were willing to provide informed consent were included in the study.

VALIDATION SURVEY

Two hundred patients who agreed to participate received an envelope by post, consisting of a letter explaining the purpose of the study, an informed consent form, the Portuguese RAQoL, the NHP[23], HAQ[24] and a standardized questionnaire enquiring about socio-demographic information and clinical aspects. Patients were asked to rate their self-perception of 1) general health status *("How would you describe your general health at the moment? Excellent, Good, Fair and Poor"*); 2) RA severity *("In general how severe would you say your Rheumatoid Arthritis is? Mild, Moderate, Quite Severe, Very Severe"*) and 3) presence of flare symptoms *("Are you currently having a flare up of your illness? Yes, No")*.

A pre-paid and addressed envelope was also sent to allow the return of the documents to the respective center.

Patients who completed and returned the questionnaire in the first phase were sent a second envelope, containing the Portuguese RAQoL approximately 2 weeks later. They were asked to complete the RAQoL and return it as before.

STATISTICAL ANALYSIS

Statistical analysis was carried out with SPSS software for Windows, version 22. Continuous variables are presented as mean (±SD) or median (IQR), as appropriate. Categorical variables are presented as proportions.

Internal consistency was evaluated using Cronbach's α coefficient. A result of α greater than 0.7 was rated as "good"[25].

Test-retest reliability (reproducibility) was assessed by correlating RAQoL scores collected at the two administrations (time 1 and time 2), using Spearman's Rank correlation coefficient. A correlation above 0.85 indicated high instrument reproducibility[26]. Only patients whose rating of RA severity remained stable were included in this analysis.

Construct validity was assessed in terms of convergent and known group validity. Convergent validity was determined by correlating RAQoL scores with those on the HAQ and the six NHP sections, using Spearman's Rank correlation coefficient. Correlations of 0.3-0.5 were considered "weak", 0.5-0.7 "moderate", and greater than 0.8 as "strong". Known group validity was determined by comparing the RAQoL scores for different groups regarding self-perceived RA severity, general health status and flare of arthritis symptoms. For statistical analysis, Self-perceived RA severity was dichotomized in "Mild/Moderate" and "Severe/Quite Severe", and self-perceived general health status as "Good/Very good", "Fair" and "Poor". Non-parametric tests for independent samples were used (Mann-Whitney U test for two groups and Kruskal-Wallis One-Way Analysis of Variance for three or more groups). A $p<0.05$ was considered statistically significant in all analysis.

ETHICS

The RAQoL validation study complied with the principles of the Declaration of Helsinki[27]. Informed consent was obtained from all individual participants included in the study. The study was approved by the National Data Protection Commission (Proc. 9730/2017) and the Ethics Committee of Centro Hospitalar e Universitário de Coimbra (Proc. N. CHUC 124-17).

RESULTS

SAMPLE

From 200 RA patients contacted who were willing to participate in the study, 178 (85.4% female, mean age of 56.6 ±12.6 years and mean disease duration of 13.6 ±10.6) years) returned the questionnaire on the first occasion. Of these, 168 completed and returned the second questionnaire, thus being included in the test--retest reliability analysis. Sociodemographic and clinical characteristics are presented in Table I.

Most respondents (64.0%) assessed their overall health as fair and their RA severity as moderate (56.7%). When asked about the presence of a flare, 65.2% stated that they were not experiencing one at time 1.

Scores on the RAQoL ranged from 0 to 30, with a median of 11 at both time points. No significant floor or ceiling effects were observed - fewer than 5% of patients scoring the minimum or the maximum values. RAQoL was shown to be practical, with a low rate of missing data (3.9%).

INTERNAL CONSISTENCY

The Portuguese RAQoL had high internal consistency

TABLE I. SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE RA STUDY SAMPLE

Age (Years old), mean (SD)	56.6 (12.7)
Gender, n (%)	
Male	26 (14.6)
Female	152 (85.4)
Disease Duration (years), mean (SD)	13.6 (10.6)
Geographical Area n (%)	
North	31 (17.5)
Centre	66 (37.1)
South	61 (34.2)
Azores	20 (11.2)
Marital Status, n (%)	
Married	121 (68.0)
Divorced	17 (9.6)
Widowed	22 (12.4)
Single	16 (9.0)
Work Status, n (%)	
Full Time	65 (36.5)
Part-time	7 (3.9)
Retired	53 (29.8)
Homemaker	14 (7.9)
Retired due disease or Long-Term Sick Leave	27 (15.1)
Unemployed	10 (5.6)
Patient-Perceived General Health, n (%)	
Very Good	3 (1.7)
Good	27 (15.2)
Fair	114 (64.0)
Poor	31 (17.4)
Patient-Perceived RA Severity, n (%)	
Mild	29 (65.2)
Moderate	101 (56.7)
Severe	37 (20.8)
Very Severe	8 (4.5)
Patient-Perceived Symptoms Flare, n (%)	
Yes	53 (29.8)
No	116 (65.2)

(Cronbach's α = 0.95) indicating adequate interrelations between the items in the questionnaire.

TEST-RETEST RELIABILITY

Reproducibility was high (r = 0.92), indicating low levels of random measurement error.

CONVERGENT VALIDITY

RAQoL correlated moderately with each of the sections of the NHP: physical mobility (r = 0.77) emotional reactions (r = 0.69), pain (r = 0.68) and energy level (r = 0.65), demonstrating the association between these dimensions. Low association was found with the sleep section (r = 0.41). RAQoL scores correlated strongly with the HAQ (r = 0.8). (Table II)

The shared variance between these two measures was 64%, indicating that they measure different but interrelated types of outcomes.

KNOWN GROUP VALIDITY

No significant differences in RAQoL scores related to gender or marital status were found. Older patients had worse scores than younger patients ($p < 0.01$).

Patients who considered their RA "Quite Severe/Severe" had significantly higher RAQoL scores than those who considered their condition less severe ($p < 0.001$). Similarly, those with "Poor" general health had worse QoL ($p < 0.001$), as did those experiencing a flare of symptoms at the time of evaluation ($p < 0.001$). All these findings demonstrate discriminant validity (Figure 1).

DISCUSSION

The Portuguese version of the RAQoL showed excellent psychometric properties, with high levels of internal consistency, reproducibility and construct validity. There were moderate correlations between RAQoL scores and relevant NHP section scores, indicating they assess related, although different, constructs. These findings are similar to those reported from the validation of the original RAQoL[11] and are in accordance with results reported in several other RAQoL validations studies[12].

Test-retest reliability was high in our study. This is an important psychometric property of a scale and can be defined as "a measure of the reproducibility of the scale, that is, the ability to provide consistent scores over time in a stable population"[28]. The definition of an adequate between-assessment time gap for the retest is of the utmost importance. An insufficient period might allow respondents to recall their first answers, and a longer interval might allow for a true change in QoL[29, 30]. The appropriate time interval depends on the construct to be measured and the target population. Two weeks is generally considered most appropriate for patient-reported outcome measures such as the RAQoL[25].

Other PROMs, such as the MOS-36 (SF-36) and

TABLE II. DESCRIPTIVE STATISTICS AND CORRELATIONS BETWEEN THE RAQoL, NHP SECTIONS AND HAQ

	n	Median	IQR	Min-Max	Scoring Min (%)	Scoring Max. (%)	Correlation with RAQoL*
RAQoL (T1)	171	11.0	5.0-19.0	0-30	4.5	2.2	–
NHP (T1)							
Energy	150	33.3	0-66.7	0-100	34.6	17.3	0.65
Pain	148	62.5	25.0-87.5	0-100	10.6	15.1	0.68
Emotional Reactions	149	22.2	0-44.4	0-100	22.3	2.8	0.69
Sleep	150	40.0	0-60.0	0-100	27.4	4.5	0.41
Social	150	0	0-20.0	0-100	56.4	2.2	0.56
Physical-Mobility	148	37.5	12.5-62.5	0-100	15.6	0.6	0.77
HAQ (T1)	158	1	0.375-1.0	0-2.75	13.3	0.6	0.8
RAQoL (T2)	161	11.0	5.0-18.0	0-30	6.7	2.8	0.92

*All correlations are significant at the 0.01 level, (Spearman's Rank correlation coefficient)
RAQoL: Rheumatoid Arthritis Quality of Life; NHP: Nottingham Health Profile; HAQ: Health Assessment Questionnaire; IQR: Interquartile Range; Min: Minimum; Max: Maximum

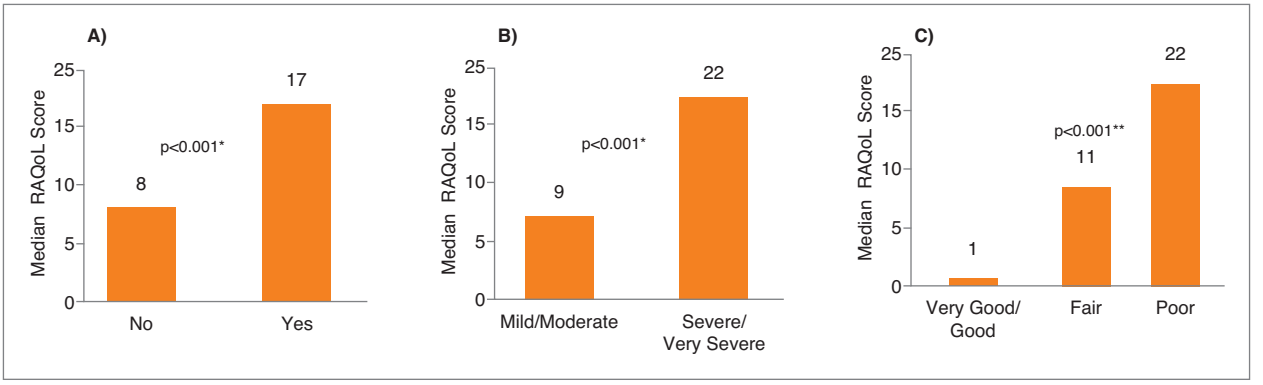

FIGURE 1. Median RAQoL Scores according to A) Perceived disease flare B) Perceived RA severity C) Perceived General Health
RAQoL: Rheumatoid Arthritis Quality of Life; *Mann-Whitney test; **Kruskal-Wallis Test

EQ-5D have been most widely used to assess outcome in Portuguese patients[31-33]. However, these measures have quite poor psychometric properties in RA due to their generic nature. In contrast, our results show that the Portuguese RA-specific RAQoL has excellent psychometric properties, maximising its ability to detect true change in QoL associated with effective treatment.

Some limitations of the study should be acknowledged. Disease activity was not assessed by clinicians. Comorbidities or psychological issues that could affect QoL were also not considered.

It was not possible to evaluate sensitivity to change in this study due to the need for an intervention study. However, the large sample size, the inclusion of patients from all over the country and the methodology applied are important strengths of this study.

In conclusion, the Portuguese RAQoL was successfully proved to be a valid and reliable measure of QoL in RA. It has the appropriate properties to become a valuable tool in future studies and clinical practice involving the RA population in Portugal.

COMPLIANCE WITH ETHICAL STANDARDS

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The

study was approved by the National Data Protection Commission (Proc. 9730/2017) and the Ethics Committee of Centro Hospitalar e Universitário de Coimbra (Proc. N. CHUC 124.17).

INFORMED CONSENT

Informed consent was obtained from all individual participants in the study.

CONFLICTS OF INTEREST

All authors declare they have no conflict of interest.

FUNDING

This study received a funding from the Portuguese Society of Rheumatology (Grant without number attributed)

CORRESPONDENCE TO

Cátia Cristina Marques Duarte
Serviço de Reumatologia, Centro Hospitalar Universitário de Coimbra
Praceta Mota Pinto – 3000 Coimbra, Portugal
E-mail: catiacmduarte@gmail.com

REFERENCES

1. Whalley D, McKenna SP, de Jong Z, van der Heijde D. Quality of life in rheumatoid arthritis. Br J Rheumatol 1997; 36: 884--888.
2. Branco JC, Rodrigues AM, Gouveia N et al. Prevalence of rheumatic and musculoskeletal diseases and their impact on health-related quality of life, physical function and mental health in Portugal: results from EpiReumaPt- a national health survey. RMD Open 2016; 2: e000166.
3. Owens GM. Optimizing Rheumatoid Arthritis Therapy: Using Objective Measures of Disease Activity to Guide Treatment. Am Health Drug Benefits 2015; 8: 354-360.
4. Smolen JS, Landewe R, Bijlsma J et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis 2017; 76: 960-977.
5. Duarte C, Sousa-Neves J, Agueda A et al. Portuguese Recommendations for the use of biological therapies in patients with rheumatoid arthritis- 2016 update. Acta Reumatol Port 2017; 42(2): 112-126.
6. Lillegraven S, Kvien TK. Measuring disability and quality of life in established rheumatoid arthritis. Best Pract Res Clin Rheumatol 2007; 21: 827-840.
7. Hunt SM, McKenna SP, McEwen J et al. The Nottingham Health Profile: subjective health status and medical consultations. Soc Sci Med A 1981; 15: 221-229.
8. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992; 30: 473-483.
9. Herdman M, Gudex C, Lloyd A et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res 2011; 20: 1727-1736.
10. Zlatkovic-Svenda M, Rouse M, Radak-Perovic M et al. Adaptation and validation of the Rheumatoid Arthritis Quality of Life (RAQoL) questionnaire for use in Serbia. Rheumatol Int 2017; 37: 641-646.
11. de Jong Z, van der Heijde D, McKenna SP, Whalley D. The reliability and construct validity of the RAQoL: a rheumatoid arthritis-specific quality of life instrument. Br J Rheumatol 1997; 36: 878-883.
12. Heaney A, Stepanous J, Rouse M, McKenna SP. A Review of the Psychometric Properties and Use of the Rheumatoid Arthritis Quality of Life Questionnaire (RAQoL) in Clinical Research. Curr Rheumatol Rev 2017; 13: 197-205.
13. Neville C, Whalley D, McKenna S et al. Adaptation and validation of the rheumatoid arthritis quality of life scale for use in Canada. J Rheumatol 2001; 28: 1505-1510.
14. Thorsen H, Hansen TM, McKenna SP et al. Adaptation into Danish of the Stanford Health Assessment Questionnaire (HAQ) and the Rheumatoid Arthritis Quality of Life Scale (RAQoL). Scand J Rheumatol 2001; 30: 103-109.
15. Tammaru M, McKenna SP, Meads DM et al. Adaptation of the rheumatoid arthritis quality of life scale for Estonia. Rheumatol Int 2006; 26: 655-662.
16. Cox SR, McWilliams L, Massy-Westropp N et al. Adaptation of the RAQoL for use in Australia. Rheumatol Int 2007; 27: 661-666.
17. Eberhardt K, Duckberg S, Larsson BM et al. Measuring health related quality of life in patients with rheumatoid arthritis--reliability, validity, and responsiveness of a Swedish version of RAQoL. Scand J Rheumatol 2002; 31: 6-12.
18. Hedin PJ, McKenna SP, Meads DM. The Rheumatoid Arthritis Quality of Life (RAQoL) for Sweden: adaptation and validation. Scand J Rheumatol 2006; 35: 117-123.
19. McKenna SP, Hedin PJ. Adapting the Rheumatoid Arthritis Quality of Life Instrument (RAQoL) for use in Sweden. Scand J Rheumatol 2003; 32: 320-322; author reply 323-324.
20. Wilburn J, McKenna SP, Twiss J et al. Further international adaptation and validation of the Rheumatoid Arthritis Quality of Life (RAQoL) questionnaire. Rheumatol Int 2015; 35: 669-675.
21. Duarte C, Barcelos A, Lagoas Gomes J et al. Cultural adaptation of the Rheumatoid Arthritis Quality of Life (RAQoL) for Portugal. Acta Reumatol Port 2018; 43: 132-136.
22. Aletaha D, Neogi T, Silman AJ et al. 2010 rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. Ann Rheum Dis 2010; 69: 1580-1588.
23. Ferreira PL. Percepção da Saude e qualidade de vida: validação intercultural do perfil e saude de Nottingham. . Nursing (Lond) 1999; 135: 23-29.
24. Andre RS; Reis P; Rebelo P ; Costa Dias F MRC, Viana de Queiroz M. "Health Assessment Questionnaire" adaptação para língua portuguesa e estudo da sua aplicabilidade. Acta Reumatologica Portuguesa 1996; 21: 15-20.
25. Streiner DL, Norman GR, Cairney J. Health measurement scales: a practical guide to their development and use. Oxford University Press, USA,2015.
26. Weiner EA, Stewart BJ. Assessing individuals: psychological and educational tests and measurements. Little Brown,1984.
27. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. J Am Coll Dent 2014; 81: 14-18.
28. Aaronson N, Alonso J, Burnam A et al. Assessing health status and quality-of-life instruments: attributes and review criteria. Qual Life Res 2002; 11: 193-205.
29. Frost MH, Reeve BB, Liepa AM et al. What is sufficient evidence

for the reliability and validity of patient-reported outcome measures? Value Health 2007; 10 Suppl 2: S94-s105.
30. Fayers PM, Machin D. Quality of life: the assessment, analysis and interpretation of patient-reported outcomes. John Wiley & Sons,2013.
31. Rosa-Goncalves D, Bernardes M, Costa L. Quality of life and functional capacity in patients with rheumatoid arthritis - Cross-sectional study. Reumatol Clin 2017.
32. Cunha-Miranda L, Santos H, Miguel C et al. Validation of Portuguese-translated computer touch-screen questionnaires in patients with rheumatoid arthritis and spondyloarthritis, compared with paper formats. Rheumatol Int 2015; 35: 2029-2035.
33. Canhao H, Faustino A, Martins F, Fonseca JE. Reuma.pt - the rheumatic diseases portuguese register. Acta Reumatol Port 2011; 36: 45-56.