

## THE RELIABILITY AND CONSTRUCT VALIDITY OF THE RAQoL: A RHEUMATOID ARTHRITIS-SPECIFIC QUALITY OF LIFE INSTRUMENT

Z. DE JONG, D. VAN DER HEIJDE, S. P. MCKENNA\* and D. WHALLEY†

Department of Rheumatology, University Hospital, Maastricht, The Netherlands, \*Care Outcomes Group, Rheumatology and Rehabilitation Research Unit, School of Medicine, University of Leeds, Leeds and †Galen Research, Manchester

### SUMMARY

The present study was designed to test the psychometric properties of the RAQoL, a rheumatoid arthritis (RA)-specific quality of life (QoL) instrument. All stages of the development were conducted simultaneously in The Netherlands and the UK. The content of the draft measure was derived from qualitative interviews with RA patients in both countries. The final version of the RAQoL has 30 items with a 'yes'/'no' response format and takes ~6 min to complete. Both language versions have high internal consistency and test–retest reliability (>0.9), and good sensitivity to discriminate between groups with various disease activity and severity. Given the excellent psychometric properties of the new instrument, it will prove to be a valuable tool for assessing quality of life in clinical trials and for monitoring patients in routine clinical practice.

**KEY WORDS:** Rheumatoid arthritis, Quality of life, Validation, Outcome measurement.

THE aim of therapeutic interventions in rheumatoid arthritis (RA) is not only to improve symptoms and functional status, but also to improve quality of life. Quality of life (QoL) can be thought of as the overall impact of the illness and its treatment on patients, and their response to these impacts [1].

In order to assess QoL in RA adequately, it is necessary to use an instrument that is derived from the experiences of RA patients, specific to the illness, reliable, valid, responsive to change in QoL following interventions and practical for inclusion in clinical trials. Given the increasing number of multinational clinical trials, the measure should be available for (or capable of adaptation into) several languages. At present, such an instrument is not available.

Wherever possible, QoL should be assessed using questionnaires rather than interviews [2–4]. The use of interviewers is expensive and introduces an additional source of experimental error. However, it also requires the availability of questionnaires that are simple to administer and complete, and that are acceptable to respondents.

This study was designed to develop an instrument that satisfied these requirements and that followed the needs-based model of QoL described by Hunt and McKenna [5]. The theoretical basis for this model is that 'life gains its quality from the ability and the capacity of the individual to satisfy his or her needs'.

The content of the instrument was derived from qualitative interviews with RA patients, the results of which have been reported elsewhere [6]. This paper describes a pilot study designed to test two alternative response formats, and reports on further studies assessing the reliability and construct validity of the new instrument, the RAQoL. Each stage of the study

was conducted in parallel in The Netherlands and the UK.

### PATIENTS AND METHODS

The development and testing of the RAQoL is summarized in Table I and described below. Approval for all stages of the research was obtained from the relevant ethics committees in The Netherlands and the UK. A written consent form was obtained from each patient who participated in the studies. All participating patients fulfilled the ACR criteria [7].

Different patient samples were employed at each stage of the project. All samples included patients with a wide range of disease severity, ranging from non-active disease without destruction to severe RA with and without active disease. However, the samples were biased towards short or moderate disease duration.

#### *Development of the draft questionnaire*

Qualitative interviews were conducted with 25 patients in The Netherlands and 25 in the UK. The issues raised in each country were found to correspond closely. Transcripts of the interviews were produced and content analyses conducted to identify potential items. A draft questionnaire was constructed using items common to both sets of interviews using, as far as possible, the original words of the interviewees. The demographic characteristics of the interviewees, the methods used and the results are described in detail elsewhere [6]. Interviews were conducted with 50 patients (18% male), aged between 33 and 75 yr. Disease duration ranged between 7 months and 35 yr, and the patients represented a wide spectrum of disease severity. The selection of items for inclusion in the instrument reflected the frequency with which issues were raised by the interviewees. Therefore, an implicit weighting of needs is produced.

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Correspondence to: D. van der Heijde, Department of Rheumatology, University Hospital, PO Box 5800, 6202 AZ Maastricht, The Netherlands.

### Two- vs four-response format pilot study

The draft questionnaire contained 44 items. Two alternative response formats were developed: 'yes/no' responses and four-point Likert scales. While the original wording of the interviewees was used for the two-response format, slight changes in wording were necessary to allow use of a Likert response scale. A pilot study was conducted to identify the most suitable format, with particular attention being paid to their discriminatory power. Fifty RA patients in each country took part in the pilot study. In The Netherlands, the patients were recruited from a regular out-patient clinic at the University Hospital, Maastricht. The UK sample was made up of patients from out-patient clinics at St Albans City Hospital and Nottingham City Hospital (both district hospitals) and members of Young Arthritis Care and Arthritis Care (patient support groups). Patients were randomly allocated to the two- or four-response format. In The Netherlands, the patients completed the questionnaire in a private room at the out-patient department. The UK study took the form of a postal survey.

In addition to the QoL instrument, patients were asked to complete the Nottingham Health Profile (NHP) [8, 9], to state the duration of their condition and to rate its severity as mild, moderate or severe. They were also asked whether they were experiencing a flare-up and whether their RA was in remission.

### Validation study

In both The Netherlands (University Hospital, Maastricht) and the UK (St Albans City Hospital), RA patients attending out-patient clinics were recruited to the study.

*Field test.* A field test was conducted to assess the face and content validity and the practicality of the questionnaire (Table I). The 30-item questionnaire was completed by 15 respondents in each country in the presence of an interviewer.

The time taken to complete the instrument was recorded and note taken of any items considered inappropriate, difficult to answer or not fully understood. Respondents were also asked if they felt that any important issues had been omitted.

*Test-retest reliability, internal consistency and construct validity.* Following the field test interviews, formal assessments of test-retest reliability, internal consistency and construct validity [5, 10, 11] of the adapted questionnaire were undertaken by means of a postal survey in both countries. Patients completed the questionnaire twice, with a period of 14 days between administrations. They were also asked to rate the severity of their condition as mild, moderate or severe. In The Netherlands, respondents were asked how active they perceived their RA to be at the time of completing the questionnaire (not at all active, not very active, quite active or very active). In the UK, they were asked if they were having a very good day, a quite good day, a quite bad day or a very bad day. This difference in wording was due to patients in the UK expressing disease activity in terms of 'good days' and 'bad days'. Patients in the UK were also asked to complete the NHP at the first administration. All patients included in the study had been using the same RA medication (non-steroidal anti-inflammatory drug, disease-modifying anti-rheumatic drug) for at least 3 months.

Test-retest reliability estimates how stable responses to an instrument are over time, given that there is no change in condition. A correlation of 0.85 between scores at two administrations is the minimum acceptable value for an instrument to be suitable for inclusion in a clinical trial [12]. Reliability below this level indicates that the measure has too high a level of random measurement error.

Until recently, internal consistency was believed to indicate the unidimensionality of an instrument. However, it is now generally accepted that it is only indicative of the extent to which the constituent items are inter-related [13]. Cronbach's alpha values above 0.85 indicate adequate inter-relationship of items [12].

Construct validity addresses the issue of whether or not the instrument assesses the construct as defined in the measurement model. It was hypothesized that QoL would be related to perceived condition severity and perceived disease activity. The NHP was also selected as a comparator instrument in the UK, as it has been shown to be a useful measure of health status in RA [14, 15]. Moderate to strong correlations were expected between QoL scores and NHP section scores (particularly physical mobility, energy level and pain).

### Statistical analysis

Items on the four-response format questionnaire used in the pilot study were scored from zero to three (with zero the most desirable state). Items on the two-response format questionnaire were scored one for a 'yes' response and zero for a 'no' response. The overall score was the sum of the individual item scores, with a high score indicating poor QoL in both formats. Both versions of the instrument produced ordinal level scores and, consequently, non-parametric statistics were applied throughout. The data were analysed using the Statistical Package for the Social Sciences.

Cronbach's alpha [16] is used to estimate the internal consistency. Corrected item total correlations (CITC)

TABLE I  
Summary of the development stages of the RAQoL

Objectives	Methods
Development of items and production of draft instrument	Qualitative interviews Content analysis of interview transcripts
Selection of response format	Postal survey/interviews
Assessment of face and content validity	Field test interviews
Assessment of test-retest reliability, internal consistency and construct validity	Postal survey
Assessment of responsiveness	Current international clinical trial

were also produced to assess the relationship between the individual item scores and the total score.

Spearman rank correlation coefficients were employed to estimate the correlation between the QoL instrument and NHP section scores. This statistic was also used to evaluate test-retest reliability.

The Mann-Whitney *U*-test (or Kruskal-Wallis one-way ANOVA where three independent groups were compared) was used to estimate the difference in QoL scores between perceived disease activity and severity groups.

## RESULTS

### *Two- vs four-response format pilot study*

Each format was found to have good internal consistency, with Cronbach's alpha values above 0.9 in both countries. Both formats were able to distinguish perceived severity groups in each country (data not shown). The two-response format was judged to be preferable for three main reasons. First, the two-response format was better able to distinguish patients with active disease from those with non-active disease. Secondly, the two-response format version was found to have fewer items with a low correlation with other items (CITC < 0.2), demonstrating poor inter-relatedness or a high correlation with other items (CITC > 0.8), indicating redundancy. Thirdly, the original wording of the patients was maintained in the two-response format.

Following the pilot study, 14 items were removed from the 44-item draft questionnaire according to the following criteria; removal of items would increase internal consistency, CITC > 0.8 or < 0.2, or a skewed distribution of responses. The resulting draft measure had 30 items.

### *Validation study*

*Field test.* Of the 15 respondents in both countries, two of the patients were male. In The Netherlands, they were aged between 31 and 77 yr (mean 61.8, median 68 yr) and the duration of their RA ranged from 0.2 to 38 yr (mean 10.7, median 6 yr). In the UK, the respondents were between 34 and 79 yr of age (mean 57.8, median 63 yr), with duration of their RA ranging from 4 to 61 yr (mean 18.6, median 9.5 yr).

The mean time taken to complete the 30-item QoL instrument was 6 min (with a range of 2-8 min) in The Netherlands and 5 min (range 2-15 min) in the UK. The measure was well received by patients in both countries. It was considered easy to understand and complete, and respondents felt that most of the items were highly relevant to them.

Some changes were made to the questionnaire as a result of the comments made. One item (My condition affects my interest in sex) was removed because elderly female respondents in The Netherlands considered it to be irrelevant to them. Another item (I have problems turning taps on and off) was removed because responses were distorted by whether or not adaptations were available to the individual. Some respondents reported that they were uncertain whether two of the

items were related to their RA or to other factors. The phrase 'because of my condition' was added to these items.

Some interviewees identified the area of dressing as missing from the instrument. The interview transcripts were re-analysed and two items covering this area were added to the instrument ('I am limited in the clothes I can wear' and 'I have difficulty dressing'). The new instrument, which was named the RAQoL, had 30 items and went forward for further testing.

*Reliability, internal consistency and construct validity of the RAQoL.* In The Netherlands, 50 patients completed the questionnaire on both occasions (100% response rate). The sample was aged between 28 and 82 yr (mean 59.2, median 63 yr). Seventeen (34%) of the patients were male, 32 (64%) were married and the duration of illness was between 0.5 and 31 yr (mean 6.6, median 5.4 yr). In the UK, 82 patients completed the questionnaire on both occasions, an effective response rate of 85%. They were aged between 25 and 74 yr (mean 53.8, median 52 yr). Twenty-two (27%) were male, 69 (85%) were married, and the duration of illness was between 2 and 35 yr (mean 10.8, median 8 yr).

Only the data of those patients without missing responses were used in the analyses. In The Netherlands, 3.1% at time 1 and 2.1% at time 2 of all possible responses on the RAQoL were missing. In the UK, these percentages were 0.2 and 0.4%, respectively. The distribution of missing answers appeared to be random in both countries, showing that no individual items were problematic. Most of the missing answers resulted from respondents turning over two pages of the questionnaire together. The data were re-analysed, accounting for the missing data by multiplying the total score by the number of items in the scale (30) and dividing by the number of items answered. Patients with up to 20% missing data per questionnaire were included in the new analyses. The results from this exercise did not differ from the original, suggesting that the instrument can tolerate a reasonable proportion of missing responses.

TABLE II  
Mean and median values, standard deviations and range of scores on the RAQoL in The Netherlands and in the UK

	UK		The Netherlands	
	Time 1 (n = 77)	Time 2 (n = 73)	Time 1 (n = 37)	Time 2 (n = 37)
Mean	14.0	14.0	13.9	13.5
Median	15.0	14.0	14.0	14.0
s.d.	8.5	8.7	7.6	8.7
Range	0-30	0-30	1-27	0-30
Interquartile range	7.0-21.0	6.5-21.5	8.5-20.5	5.5-21.5
Percentage scoring minimum (0)	4	1	0	2
Percentage scoring maximum (30)	1	1	0	2

TABLE III

Ability of the RAQoL (range 0–30) to distinguish different disease severity groups, patients in perceived remission and different activity levels of RA in The Netherlands

	Number of patients	Median RAQoL score	Interquartile range	<i>P</i>
Disease severity				
Mild/moderate	26	12.5	7.0–18.5	< 0.05
Severe	11	20.0	14.0–25.0	
Remission				
Yes	23	13.0	3.0–15.0	< 0.05
No	14	20.0	14.25–22.0	
RA activity				
Not very/not at all active	23	13.0	4.0–15.0	< 0.05
Very/quite active	14	20.0	12.75–22.0	

Table II shows the mean, median, standard deviation, range and interquartile range of scores on the RAQoL in The Netherlands and in the UK. It shows that the instrument produced minimal floor and ceiling effects in this population.

Three patients in each country were excluded from the test–retest reliability analyses as their medication had changed between administrations of the questionnaire. Spearman rank correlation coefficients between the first and second administration were 0.90 in The Netherlands ( $n = 29$ ) and 0.94 in the UK ( $n = 67$ ), indicating that the RAQoL produces little random measurement error. The medians on both occasions were comparable (15.0 and 14.0 in the UK, and 14.0 and 14.0 in The Netherlands, respectively). Cronbach's alpha coefficient (internal consistency) was 0.92 in The Netherlands and 0.94 in the UK.

Tables III and IV show that the RAQoL was able to distinguish between groups of patients with different perceived severity of the condition, and between patients who perceived their RA to be in remission and those who did not. It was also able to distinguish between patients having a 'very/quite bad day' and those having a 'very good' or a 'quite good' day in the

TABLE IV

Ability of the RAQoL (range 0–30) to distinguish different disease severity groups, perceived remission and patients having a good or bad day in the UK

	Number of patients	Median RAQoL score	Interquartile range	<i>P</i>
Disease severity				
Mild	22	4.0	1.0–8.75	< 0.0001
Moderate	36	16.0	12.0–21.0	
Severe	17	25.0	19.5–27.0	
Remission				
Yes	36	10.0	2.25–16.0	< 0.005
No	35	18.0	12.0–22.0	
Good day/bad day				
Very good	10	2.0	1.0–3.75	< 0.0001
Quite good	44	13.0	8.0–19.5	
Quite/very bad	21	20.0	16.0–25.5	

TABLE V

Correlations between RAQoL and NHP section scores in the UK

NHP section	Number of cases	Correlation with QoL
Physical mobility	76	0.87
Energy level	76	0.80
Pain	76	0.77
Emotional reactions	76	0.66
Social isolation	76	0.62
Sleep	75	0.59

UK, and between those whose RA was 'very/quite active' and those whose RA was 'not very/not at all active' in The Netherlands. For statistical analysis of RA activity, patients in The Netherlands were divided into two groups. This was to ensure adequate sample sizes in each comparison group. The results indicate that both language versions of the RAQoL have good sensitivity, i.e. that they are able to detect differences between different patient groups.

Further evidence of the construct validity of the UK version was gained from the correlations with the NHP shown in Table V. As expected, the closest associations were between QoL and the physical mobility, energy level and pain sections.

## DISCUSSION

Clinicians and policy makers are growing increasingly aware of the importance of measuring QoL. In the past decade, patient-completed questionnaires have been introduced to clinical trials in RA. The most frequently used instruments are the Arthritis Impact Measurement Scales (AIMS) [17], NHP [8], EuroQoL [18, 19] and MOS 36-Item Short-Form Health Survey (SF-36) [20], and the limitations of these have been reviewed elsewhere [6]. Although such instruments were developed for different purposes, they are all commonly referred to as measures of QoL. However, they actually assess health status (or health state preferences in the EuroQoL), as they cover impairments, disabilities and to a limited extent handicap, as defined by the World Health Organization [21]. Tennant and McKenna [22] and Heinemann and Whiteneck [23] have recently shown that QoL measurement goes beyond such constructs by assessing the impact of health status on the individuals, and the interactions between health status and other influences on their lives. In the development of the RAQoL, Hunt and McKenna's model was adopted [5], in which QoL is defined as the extent to which RA interferes with the patient's ability to fulfil his or her needs.

A disadvantage of some of the currently used health status measures is that they are comprised of subscales or sections that cannot validly be combined into an index. A profile makes the assessment of change following an intervention more difficult to interpret. Furthermore, an index is essential for incorporation into certain types of economic analyses.

The commonly used generic health status measures were designed for use in population studies. In the

absence of an RA-specific QoL instrument, these generic measures have been employed as outcome measures in clinical trials. However, as such instruments were intended to be applicable to a wide range of diseases, they include irrelevant items and omit important areas for RA patients, reducing their responsiveness [24–27]. This, together with their relatively poor reliability [28], limits their value in clinical trials.

The only arthritis-specific health status instrument commonly used in clinical trials is the AIMS. Its content was derived from existing measures and represents the opinion of experts rather than patients. The instrument is limited in terms of its sensitivity to change and its practicality for clinical practice [6]. The AIMS is arthritis specific rather than RA specific and, consequently, omits certain issues of importance to RA patients.

The RAQoL is the first patient-completed instrument specifically developed for use with RA patients. It consists of 30 items derived directly from relevant patients, using, as far as possible, their own words. Respondents are required to indicate whether or not each of the items applies to them. Scores can range from 0 to 30, with a high score representing poor QoL. It was developed simultaneously in The Netherlands and the UK, with items that could only be expressed in one of the languages or that were not applicable to both cultures omitted from the questionnaire. Consequently, adaptation of the RAQoL into additional languages will be facilitated.

The instrument has good face and content validity, and is well accepted by patients, who commonly commented on the appropriateness of the items. The instrument has excellent test–retest reliability, indicating that it produces little random measurement error, and it was also shown to have good internal consistency.

Higher QoL scores were observed in patients who rated their RA as severe, compared with patients who perceived their condition to be either moderate or mild. Both the UK and the Dutch version were able to distinguish between patients who perceived themselves to be in remission and those who did not, and also between patients with or without active disease. Correlations with the NHP sections in the UK were as predicted, with strong relationships observed between the RAQoL and the physical mobility, energy level and pain sections. These results provide evidence of the construct validity of the RAQoL. The responsiveness of the instrument has yet to be established, but is presently under investigation in an international clinical trial.

The RAQoL is a practical instrument, taking only 5–6 min to complete. It is easy to administer and score, with the total score being the number of items affirmed. As such, the instrument is suitable for use both in clinical practice to follow individual patients and in clinical trials to determine the effectiveness of treatment. Other potential applications of the RAQoL are in cost-effectiveness studies and in

the determination of burden of illness, as well as in cohort studies on prognosis and outcome. The RAQoL could be used in conjunction with the WHO/ILAR/ACR core set of disease activity [29].

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## APPENDIX

Final 30 items of the RAQoL:

1. I have to go to bed earlier than I would like to
2. I'm afraid of people touching me
3. It's difficult to find comfortable shoes that I like
4. I avoid crowds because of my condition
5. I have difficulty dressing
6. I find it difficult to walk to the shops
7. Jobs about the house take me a long time
8. I sometimes have problems using the toilet
9. I often get frustrated
10. I have to keep stopping what I am doing to rest
11. I have difficulty using a knife and fork
12. I find it hard to concentrate
13. Sometimes I just want to be left alone
14. I find it difficult to walk very far
15. I try to avoid shaking hands with people
16. I often get depressed
17. I'm unable to join in activities with my family or friends
18. I have problems taking a bath/shower
19. I sometimes have a good cry because of my condition
20. My condition limits the places I can go
21. I feel tired whatever I do
22. I feel dependent on others
23. My condition is always on my mind
24. I often get angry with myself
25. It's too much effort to go out and see people
26. I sleep badly at night
27. I find it difficult to take care of the people I am close to
28. I feel that I'm unable to control my condition
29. I avoid physical contact
30. I'm limited in the clothes I can wear

Researchers wishing to use the RAQoL are requested to contact Diane Whalley at Galen Research, Enterprise House, Manchester Science Park, Lloyd Street North, Manchester M15 6SE (Fax number +44 161 226 4478).