Comparison of the Recent-Onset Arthritis Disability questionnaire with the Health Assessment Questionnaire disability index in patients with rheumatoid arthritis

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Abstract

Background

Physical disability in patients with rheumatoid arthritis (RA) is often assessed by questionnaires. We compared the Recent-Onset Arthritis Disability (ROAD) questionnaire with the Health Assessment Questionnaire (HAQ) disability index (DI) in a cohort of RA patients. The aim of this study was to obtain information on several aspects of construct validity of these measures.

Methods

A cross-sectional multicentre study was carried out among patients with RA who were attending hospital outpatient clinics. The patient group included 196 patients partially or not responding to disease modifying anti-rheumatic drugs. For the evaluation of the psychometric properties of the ROAD in comparison with HAQ-DI this population has been compared to another cohort of 247 outpatients with RA who were participating in a long-term observational study. All patients completed the ROAD and HAQ-DI. Additional comparator composite indices of disease activity were analysed. The ROAD structural validity was first assessed using exploratory factor analysis. Concurrent validity was analysed by Spearman's correlations and cross-tabulations. Discriminant validity to distinguish patients with active and non-active disease was assessed with receiver operating characteristic (ROC) curve analysis. For agreement analysis Bland and Altman plots were calculated.

Results

Factor analysis yielded a two-factor ROAD score that accounted for 68.74% of the explained variance in the questionnaire. The first factor, namely upper extremity function/activity daily living and work (ROAD-upper) accounted for 55.6% of the explained variance. The second factor, namely lower extremity function (ROAD-lower) accounted for 13.1% of the explained variance. Significant correlations were found between the scores of the ROAD and the other clinical variables with a high ability to measure pain and disease activity, supporting the concept of convergent construct validity. The discriminatory power of both questionnaires to assess inactive and active RA patients was good, without significant difference.

Conclusion

ROAD is a good alternative to the HAQ-DI for the assessment of physical disability in RA. Use of the ROAD makes it easier and less costly to collect data and reduces the burden on RA patients and should be applied in both clinical trials and routine clinical care settings.

Key words

rheumatoid arthritis, ROAD, HAQ-DI, disability, patient-reported outcome, validity

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Background

Rheumatoid arthritis (RA) is a chronic disabling inflammatory joint disease affecting about 0.5% of the population (1) that can result in a significant morbidity or early mortality (mainly because of cardiovascular events) (2-4). Patients with RA report significant reduction of health-related quality of life (HRQL) in comparison with age- and gender-matched populations without RA (5-8). The decreased HRQL is attributed to the pain, impairment in physical function, and fatigue associated with this disease. Patient-reported functional disability is increasingly used to supplement objective (clinical and biological) measures of disease in assessments of the quality of services, health care needs, treatment effectiveness, and cost utility (7, 9-11). Moreover, demonstrating preserved physical function is a prerequisite for proving that a drug has disease-controlling capacity (9, 12-17). This is especially pertinent, given the new realities of more aggressive and early management of RA in the 1990s with costly interventions that could potentially have unique adverse effects (14, 15). Several self-report questionnaires have been constructed over the past decades for use in clinical practice and research, health policy evaluation, and general population surveys. The Health Assessment Questionnaire (HAQ) disability index (DI) (18) and its modifications – modified (M-HAQ) (19-22), multidimensional (MD HAQ) (22-24), and HAQ II (25) – or Arthritis Impact Measurement Scales 2 (AIMS2) (26, 27) have become the primary measure of physical function in RA, accompanied by use of generic measures such as Medical Outcomes Study 36 - Short Form (SF-36) (28, 29), or EuroQOL (EQ-5D) (30). Over its long history, the HAQ-DI has played an influential role in the paradigm shift to establishing patient-reported outcomes (PROs) as valid, reliable, and responsive hard data endpoints, and has enabled longitudinal studies to be performed (31-34). PROs, defined as outcomes that are completed by patients, have been increasingly recognised as important in RA performed (10, 11, 33, 34). The self-reported HAQ-DI assessing movements of the trunk and both upper and lower extremities. Each category contains at least two specific component questions. The HAQ-DI, although initially developed in patients with RA (18), has been broadly and extensively used and validated in widely diverse populations, including patients with osteoarthritis (35) juvenile RA (36), systemic lupus erythematosus (37, 38), scleroderma (39-41), ankylosing spondylitis (42, 43), psoriatic arthritis (44), fibromyalgia (45), polymialgia rheumatica (46), and in healthy populations (47, 48). The HAQ-DI is a predictive factor of future disability and joint damage in patients with RA (49, 50) and can be used to predict outcome of treatment (51). Because of its well documented sensitivity to change, the HAQ-DI was chosen by the Outcome Measures in Rheumatology Clinical Trials (OMERACT) (52, 53) and the American College of Rheumatology (ACR) (54), to be incorporated into the core set of outcome measures of RA disease activity. The psychometric properties of the HAQ-DI, which is in use, were initially developed almost 30 years ago limiting the extent to which they may completely address patterns of functional status for individual patients with early RA (47, 48). One of the limitations of this instrument of the HAQ-DI is that it is strongly influenced by factors such as socioeconomic status, gender and mental states. It means that the trait phenomena have a large effect on self-reported disability scores. Secondly, the fact that the scores also progress slowly may indicate that patients adapt to the instrument in some way. Thirdly, it is dominated by the effects of large joints such as the hips, knees and shoulders, and is relatively insensitive in detecting changes in, for example, hand function (47, 48). Finally, HAQ-DI has something of a "floor" problem, in that many persons with physical disability can have normal HAQ-DI scores (25, 47, 48). In order to facilitate the application of patient questionnaires beyond clinical research to standard clinical rheumatology care, we have recently developed and validated a simpler self-administered questionnaire, namely Recent-Onset Arthritis Disability (ROAD)

questionnaire (55, 56). The ROAD has 12 items assessing three reported patient-relevant dimensions: upper extremity function, lower extremity function, and activities of daily living/work. These items represent a combination of symptoms that are common, frequently recurring and of general importance to RA patients (55).

In this study, we address 3 questions: What are the similarities and differences in construct validity between the 2 instruments? How well do the ROAD and the HAQ-DI correlate with each other? Does the ROAD demonstrate better discriminative accuracy to distinguish patients with active and non-active disease, as compared with the HAQ-DI? The results of this analysis should be useful in guiding and clarifying interpretation procedures for ROAD domains from RA patients.

Patients and methods

Patients

One hundred and ninety-six patients with moderate to severe RA from 27 rheumatologic centres in Italy agreed to participate in a multicentre cross-sectional study of RA cohort, termed the NEW INDICES study (57). These subjects, partial- or non-responders to disease modifying anti-rheumatic drugs (DMARDs), were candidates to start a TNF-inhibitor. The patient selection criteria were as follows: fulfilment of the ACR 1987 revised criteria for RA (58), age 18-75 years, and active disease, with at least 3 of the following 4 features: either ESR ≥28mm/hour or a CRP level >19mg/dl, morning stiffness ≥30minutes, ≥5 swollen joints, and ≥10 tender joints (59). The involved rheumatologists were instructed to collect the data following standard definitions and procedures. The protocol was approved by the national health authorities and ethics committees in all 27 participating hospitals. All the patients gave informed written consent. For the evaluation of the psychometric properties of the ROAD, the above described population (Group A) has been compared to another cohort of 247 outpatients with RA (Group B), enrolled in a long-term observational study conducted by the Clinical Rheumatology of the Università Politecnica delle Marche, Ancona, Italy. This population included subjects that satisfied the minimal disease activity (MDA) or remission definitions, while taking conventional DMARDs or tumour necrosis factor-α blockers (*i.e.* infliximab, etanercept and adalimumab). MDA definitions included at least 5 of the following 7 World Health Organisation (WHO)/International League of Associations for Rheumatology (ILAR) core set measure thresholds, as proposed by the OMERACT (52): VAS pain ≤ 2 (0–10), swollen joint count (SJC) ≤1 (out of 28), tender joint count (TJC) ≤1 (out of 28), HAQ-DI ≤0.5 (0–3), patient's global assessment (PGA) ≤1.5 (0–10), evaluator global assessment (EGA) ≤2 (0–10), and erythrocyte sedimentation rate (ESR) ≤20mm/hour. Remission was evaluated according to modified ACR (mACR) (60). Fulfilment of the mACR remission criteria required 4 of the following 5 items to be met: morning stiffness ≤15 minutes, no joint pain by history, no joint tenderness, no swollen joints, and ESR<30 mm (female) or <20 mm (male). These thresholds were comparable to the original Pinals criteria (61), but with fatigue omitted. The other 4 criteria had to be fulfilled at one point in time. All of these 247 patients (Group B) were evaluated as controls for the NEW INDICES study.

Functional measures

All patients completed the HAQ-DI (18) and the ROAD (55, 56). The HAQ-DI assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas: dressing and grooming, arising, eating, walking, hygiene, reach, grip, activities. For each item, patients are asked to rate the level of difficulty over the past week on a 4-point scale, which ranges from 0 (no difficulty) to 3 (unable to perform). To calculate the disability dimension score, disability score ranges from 0 to 3, with a higher score indicating greater disability. The HAQ-DI, calculated for each of the subscales are summed, and then divided by 8. A version adapted for use among Italian patients was utilised in the present study (62). The HAQ-DI was scored without including aids or help from other people (18).

The ROAD questionnaire is a reliable, valid and responsive tool for measuring physical functioning in patients with RA, and it is suitable for use in clinical trials and daily clinical practice (55, 56). The ROAD consists of 12 items assessing a patient's level of functional ability and includes questions related to fine movements of the upper extremity, activities of the lower extremity, and activities that involve both upper and lower extremities. Eight of the 12 items overlaps with HAQ-DI. For each item, patients are asked to rate level of difficulty over the past week on a 5-point scale, which ranges from 0 (without any difficulty) to 4 (unable to do). The ROAD ranges from 0 to 48. In order to express these scores in a more clinically meaningful format, a simple mathematical normalisation procedure was then performed so that all the scores could be expressed in the range 0-10, with 0 representing better status and 10 representing poorer status. Unlike the HAQ-DI, the ROAD can be scored in 15 to 20 seconds.

Composite disease activity indices

Clinical assessments comprised the following single items of disease activity indices: 28 joint counts for swollen and tender joints (SJC and TJC, respectively), patient self-administered tender joint count (self-TJC), pain numerical rating scale (NRS-pain), evaluator and patient assessments of disease activity (EGA, PGA, respectively) by NRS, patient assessment of general status (GH), physical disability (by HAQ-DI and ROAD questionnaires) (55, 56), morning stiffness, ESR and CRP. These variables were used to calculate fulfilment of the Minimal Disease Activity (MDA) and mACR remission criteria and composite disease activity indices, such as the Disease Activity Score - 28 joints (DAS28) (63-65), the Simplified Disease Activity Index (SDAI) (66), the Clinical Disease Activity Index (CDAI) (67), and the Rheumatoid Arthritis Disease Activity Index (RADAI) (68).

The DAS28 includes 28-SJC and 28-TJC in addition to GH scale (0-100) and ESR values (63-65). The DAS28 was calculated by entering these four variables into the WEB calculator,

which was obtained from http://www.das-score.nl/www.das-score.nl/index.htm. The DAS28 range from 0 (totally inactive disease) to 9.4 (very active disease). The level of RA disease activity can be interpreted as low (DAS28 ≤3.2), moderate (3.2< DAS28 ≤5.1), or as high disease activity (DAS28 >5.1) (63-65). A DAS28 <2.6 corresponds to remission, according to the OMERACT criteria (65).

The SDAI (66) and the CDAI (67) are two new tools for the evaluation of disease activity in RA. They have been developed to provide physicians and patients with simple and more comprehensible instruments. Moreover, the CDAI is the only composite index that does not incorporate an acute phase response and can therefore be used to conduct a disease activity evaluation essentially anytime and anywhere. The SDAI employs a linear sum of five untransformed, unweighted variables, including 28-SJC and 28-TJC, PGA EGA on a 11–point NRS, and CRP. The SDAI score is computed as follow: SDAI = (SJC + TJC + PGA (in cm) + EGA (in cm) + CRP (in mg/dl)). The range of SDAI is 0-86. Predefined thresholds for remission, low and moderate levels of disease activity are 3.3, 11 and 26, respectively (66, 67). The CDAI is a modification of the SDAI without laboratory evaluation (CRP) to allow immediate clinical assessment. The CDAI score is computed as follow: CDAI = SJC + TJC + PGA (in cm) + EGA (in cm). The range of CDAI is 0-76. Thresholds for separating remission, low and moderate levels of disease activity are at 2.8, 10 and 22, respectively (67).

The RADAI contains five items on global disease activity during the past 6 months, current disease activity as measured by swollen and tender joints, current amount of arthritis pain, current duration of morning stiffness and current number of tender joints in a joint list. The first three items are scored on an 11-point NRS, with verbal anchors from ''no disease activity''/''no pain'' (score 0) to ''extreme disease activity''/''extreme pain'' (score 10) (68). The last two items are scored on a seven-point and four-point verbal rating scale. The scores on these two items range from 0 to 6 and from 0 to 48, and were transformed to a 0–10 scale, with higher scores indicating more disease activity. The total score of the RADAI was computed by summing the scores of the individual non-missing items and dividing this by five and ranges from 0 to 10 (68).

Statistical analysis

Continuous data were presented as means with standard deviations (SDs) or medians and interquartile ranges (IQR) depending on the distribution of the data (tested with the Kolmogorov-Smirnov test). Categorical data were presented as proportions. Demographic and clinical measures were compared using Mann-Whitney U-test or Kruskal-Wallis test for continuous variables, and chi-square analysis for discontinuous variables. *P*-values below 0.05 were regarded as statistically significant. Evidence for construct validity can only be accumulated by 'a priori' hypothesised patterns of associations with other validated instruments. In this study, the construct validity of the ROAD was examined in three ways. First, we used exploratory factor analysis to assess the degree to which items in the ROAD scale did address common themes. Using the patterns of inter-correlations among item responses, factor analysis group items that appear to measure discrete factors. We used the principal component analysis as an extraction method. The number of appropriate factors was determined by the eigenvalue above unity (69), and interpretability of the factors. We used the varimax method of rotation as an aid to the interpretability of the model. To judge whether the sample had a suitable factorial structure, (*i.e.* whether correlation between variables can be explained by other variables) we used measures of sampling adequacy. The Kaiser-Meyer-Olkin measure compares correlation and partial correlation coefficients; if values lie below 0.70, the factor analysis should be reconsidered or the item rejected. Secondly, we examined convergent validity by correlating the scores of the ROAD scale and subscales with HAQ-DI and other measures applied in the study. A particular subscale is expected to converge with the scores of those instruments targeting the same construct, and to deviate from the scores given by instruments or scales assessing a different one (divergent validity). To quantify these relationships, Spearman's rho correlation coefficients were obtained. Correlations >0.90 were interpreted as very high, 0.70–0.89 as high, 0.50–0.69 as moderate, 0.26–0.49 as low and ≤0.25 as little if any correlation (70). In addition to the presented correlation coefficients, we sought to determine the relationship between disability scales and different levels of activity scores in individual patients. We therefore created 4 patient groups based on the patients' DAS28 ranks within the cohort. Then, we grouped the patients in the same way based on their ROAD and adjusted HAQ-DI scores, and used non parametric Kruskal-Wallis test to assess the level of significance of different disease activity categories on individual patients. Furthermore, we created patient groups based on the patients' physical disability ranks within the cohort and used chi-square statistics to assess the level of overall agreement of different disability categories on individual patients. Although there is no official consensus as to what constitutes mild, moderate, or severe disability, HAQ-DI scores were categorised into 4 groups as follows: 0 to 0.49 (no disability), 0.50–0.99 (mild disability), 1.00–1.99 (moderate disability), and >2.00 (severe disability). Similarly, the ROAD scores were categorised into 4 groups according to the percentile distribution of the values reported in Table I: 0 to 1.49 (no disability), 1.50–2.99 (mild disability), 3.00–6.99 (moderate disability), and >7.00 (severe disability). In addition, differences between ROAD scores and adjusted HAQ-DI were plotted against the average of the two scores using Bland–Altman method (70). The HAQ-DI was recoded to a 0–10 scale multiplied by 3.33 (recoded HAQ-DI). The mean differences and limits of agreement between recoded HAQ-DI and ROAD were calculated and plotted as a line, using the mean difference ±1.96 SD. Finally, we used the receiver operating characteristic (ROC) curve analysis to explore the dis-

Table I. Demographic and clinical characteristics of the two cohort's of patients enrolled in the study. Values are mean (standard deviation) unless otherwise indicated.

	Group A (n=196)	Group B (n=247)	*p*-value
Patients			
Women (%)	83.1	80.1	NS
Age (years)	56.7 (12.1)	58.1 (11.2)	NS
Disease duration (years)	5.1 (5.9)	6.2 (6.6)	NS
Rheumatoid factor positive (%)	78%	76%	NS
Educational level, n (%)			NS
- primary school	110 (56.1)	129 (52.2)	
- secondary school	67 (34.2)	78 (31.6)	
- high school/university	19 (9.7)	40 (16.2)	
No of comorbid conditions, n (%)			NS
- none	53 (27.0)	74 (29.9)	
- 1	50 (25.5)	69 (27.9)	
- 2	46 (23.5)	60 (24.3)	
- 3	21 (10.7)	26 (10.5)	
- 4	11 (5.6)	10 (4.1)	
- 5 or more	15 (7.7)	8 (3.3)	
Disease activity characteristics			
Swollen joint count (0–28)	8.4 (4.1)	1 (1.1)	<0.0001
Tender joint count (0–28)	12.6 (5.5)	1.5 (3.2)	<0.0001
Self-administered tender joint count (0–10)	4.5 (1.8)	1.5 (1.4)	<0.0001
Patient global assessment of disease activity (0–10)	7.1 (1.7)	2.8 (2.3)	<0.0001
Physician global assessment of disease activity (0–10)	6.8 (1.5)	2.0 (2.2)	<0.0001
Patient global assessment of health status (0–100)	72.9 (16.2)	9.2 (9,8)	<0.0001
Patient assessment of pain (0–10)	7.1 (1.7)	2.5 (2.3)	<0.0001
Health Assessment Questionnaire (0–3)	1.35 (0,58)	0.44 (0.47)	<0.0001
Recent-Onset Arthritis Disability (ROAD index (0–10)	4.3 (1.9)	1.1 (1.1)	<0.0001
Erythrocyte sedimentation rate (mm/hour)	36.9 (23.7)	15.2 (13.1)	<0.0001
C-reactive protein (mg/dl)	4.9 (2.4)	2.9 (4.8)	<0.001
DAS28 (0.9.4)	5.7 (1.4)	2.5 (1.2)	<0.0001
SDAI (0–86)	38.7 (15.6)	10.3 (5.8)	<0.0001
CDAI (0–76)	33.9 (10.5)	8.2 (4.5)	<0.0001
RADAI (0–10)	5.8 (1.6)	1.8 (1.6)	<0.0001

DAS28: Disease Activity Score-28; SDAI: Simplified Disease Activity Index; CDAI: Clinical Disease Activity Index; MOI-RA: Mean Overall Index for RA; RADAI: Rheumatoid Arthritis Disease Activity Index.

criminative accuracy of the ROAD and HAQ-DI scores, to distinguish patients with active (Group A) and non-active disease (Group B). The OMERACT criteria for MDA and mACR criteria for remission were applied as external criterion. Since ROC analysis requires external criteria to be dichotomous, MDA and mACR remission were grouped together as "overall" low disease activity. ROC curves were created by plotting the true-positive proportion (sensitivity) versus the false-positive proportion (100-specificity) for the discrimination between inactive and active patients for multiple cut-off points. The area under the ROC curve (AUC), was calculated to quantify the discriminative accuracy. According to Sweets *et al*. (71). AUC from 0.50 to about 0.70 represent poor accuracy, those from 0.70 and 0.90 are "useful for some purposes", and higher values represent high accuracy. From the ROC curves, we computed the optimal cut off point corresponding to the maximum sum of sensitivity and specificity. The non-parametric Wilcoxon's signed ranks test is used for calculation and comparison of the areas under the ROC curves, as suggested by Hanley and McNeil (72). All data were entered into a Microsoft Access database, which had been developed for management of cross-sectional multicenter. The data were analysed using the SPSS version 11.0 (SPSS Inc, Chicago, IL), and the MedCalc® version 10.0 (MedCalc Software, Mariakerke, Belgium).

Results

Demographic and clinical data

There was no significant difference in the main demographic characteristics of the subjects of the two cohorts (Group A and B) (Table I). Group A is made of 196 patients (163 women and 33 men); the mean age was 56.7±12.1 years and the mean duration of disease was 5.1±5.9 years. Their school education level was generally low: 56.1% had received only a primary school education, and only 9.7% had received a high school education. Of the 196 subjects enrolled, 143 (73%) reported 1 or more medical comorbidities, mostly cardiovascular (28.5%), respiratory (13.7%), and metabolic (11.1%) disorders. All patients had active RA and the large majority was classified as having moderate or severe disability. Groups B was made of 247 independent subjects (198 female and 49 male); the mean age was 58.1±11.2 years and the mean duration of disease was 6.2±6.6 years. The proportion of patients achieving MDA, as defined by the OMERACT criteria, or remission as defined by a mACR criteria were similar: 51% (126 subjects) and 49% (121 subjects), respectively.

Comparison of ROAD and HAQ-DI

A comparison of the two physical function scales showed more similarities than differences in the behaviours measured. The majority of items of the HAQ-DI overlap with the ROAD physical function scale. Both scales contain items that assess only upper extremity function (8 items on the HAQ-DI and 5 on the ROAD), only lower extremity function (4 items on the HAQ-DI and 4 on the ROAD) as well as both upper and lower extremity function (8 items on the HAQ-DI). With this regard, the ROAD contains 3 items that specifically assess upper extremity function and Activities of Daily Living (ADL) and work.

Score distributions of ROAD and HAQ-DI

Table II summarises the descriptive statistics for ROAD and HAQ-DI scores. Figure 1 presents estimates of central tendency and distribution of score for ROAD (Fig. 1a) and HAQ-DI (Fig. 1b) in the entire RA patient cohort (Groups A and B). The bar on the left of each graph represents the number

Table II. Descriptive statistic and percentiles of ROAD, HAQ-DI and normalised values of HAQ-DI (adjusted HAQ-DI scores).

	ROAD	HAQ-DI	Adjusted HAQ-DI
Lowest value	0.0000	0.0000	0.0000
Highest value	10.0000	3.0000	9.3240
Arithmetic mean	2.7257	0.8534	2.7876
95% CI for the mean	2.5260 to 2.9254	0.7930 to 0.9137	2.5777 to 2.9974
Median	1.9000	0.6200	2.3310
95% CI for the median	1.5000 to 2.3000	0.5000 to 0.8518	2.0646 to 2.8971
Variance	5.5919	0.5109	5.0389
Standard deviation	2.3647	0.7148	2.2447
Relative standard deviation	0.8676 (86.76%)	0.8376 (83.76%)	0.8053 (80.53%)
Standard error of the mean	0.1017	0.03073	0.1068
Coefficient of Skewness	0.7878 (p<0.0001)	0.6797 (p<0.0001)	0.6657 (p<0.0001)
Coefficient of Kurtosis	-0.3639 (p=0.1084)	-0.5424 (p=0.0278)	-0.2389 (p=0.2924)
Kolmogorov-Smirnov test for Normal distribution	reject Normality (p<0.001)	reject Normality (p<0.001)	reject Normality (p<0.001)
Percentiles			
0.1	0.0000	0.0000	0.0000
0.25	0.0000	0.0000	0.0000
0.5	0.0000	0.0000	0.0000
1	0.0000	0.0000	0.0000
2.5	0.0000	0.0000	0.0000
5	0.0000	0.0000	0.0000
10	0.2000	0.0000	0.0000
20	0.6000	0.1200	0.3996
25	0.8000	0.3200	1.0656
40	1.5000	0.5000	1.6650
60	3.0000	1.0000	3.2501
75	4.4000	1.3200	4.3290
80	5.0000	1.5000	4.6620
90	7.0000	2.0000	5.9940
95	7.1900	2.2135	6.9930
97.5	7.5000	2.3200	7.6590
99	8.0300	2.5090	8.6846
99.5	9.1000	2.6795	8.9910
99.75	9.9980	2.9318	9.1225
99.9	10.0000	3.0000	9.7745

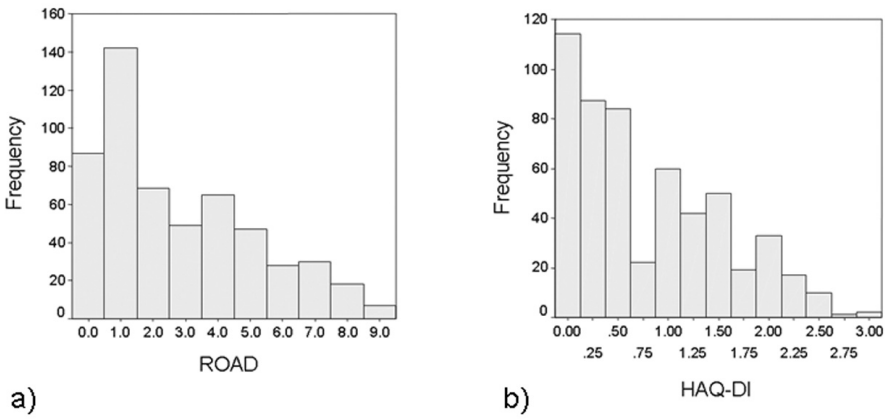

Fig. 1. Control tendency and distribution of scores of ROAD (**a**) and HAQ-DI (**b**) in the entire RA patient cohort. ROAD: Recent-Onset Arthritis Disability index; HAD-DI: Health Assessment Questionnaire-Disability Index.

of subjects with a score of 0 (floor effect); the bar on the right represents the number of subjects with a maximum possible score (ceiling effect). ROAD and HAQ-DI values were, such as the other instruments to evaluate disability or HRQL, non-normally distributed (Kolmogorov-Smirnov test). HAQ-DI values are considerably shifted to the left compared with ROAD. The median (IQR) of ROAD and of HAQ-DI were 1.90 (0.80 to 4.40) and 0.62 (0.32 to 1.32), respectively.

Construct validity of the ROAD

Factor analysis was carried out to examine the factorial structure of the ROAD questionnaire. The analysis revealed a two-factor solution (eigenvalues 6.67, and 1.57) (Table III). Factor 1 consisted of 8 items and factor 2 of 4 items. The first factor, namely upper extremity function/ ADL activities (ROAD-upper) accounted for 55.65% of the explained variance. The second factor, namely lower extremity function (ROAD-lower) accounted for 13.10% of the explained variance. Table IV shows the high loading (more than 0.70) of each item after varimax rotation with Kaiser normalisation on the two factors. Each factor loading represents the correlation between that item and the underlying factor. The inter-item correlation between the two factors was r=0.51.

In testing for convergent validity between instruments (Table V) we found that correlation coefficients for the subscales and total scores of the ROAD, and HAQ-DI ranged from 0.789 to 0.985. Both the two dimensions of ROAD correlated significantly with each other (rho=0.611; p<0.0001). Generally, higher significant correlations were seen when comparing ROAD-upper subscale to other clinical variables with a high ability to measure pain and disease activity, but correlation coefficients were somewhat lower when comparing CRP and ESR with ROAD scores. Of special interest are the correlations among ROAD total score and ROAD-upper subscale with all composite indices of disease activity (all at p-significance of <0.0001) (Table V). On categorising patients into those in remission, low, moderate and, severe activity, with respect to the ROAD and recoded HAQ-DI were highly significantly different between the four categories (all p<0.0001) (Fig. 2). In addition, stratification into four categories of both disability scales showed a significant overall agreement (defined as the percentage of observed exact agreements) (chi-square=967.95;

Table III. Factor structure of the ROAD in 443 patients with rheumatoid arthritis.

	Initial Eigenvalues			Extraction sums of squared loadings		
Component	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %
1	6.678	55.650	55.650	6.678	55.650	55.650
2	1.572	13.103	68.754	1.572	13.103	68.754
3	.687	5.722	74.475			
4	.547	4.559	79.034			
5	.455	3.793	82.827			
6	.398	3.319	86.146			
7	.366	3.051	89.197			
8	.338	2.816	92.013			
9	.298	2.480	94.493			
10	.258	2.153	96.646			
11	.211	1.759	98.405			
12	.191	1.595	100.000			

Extraction method: Principal Component Analysis.
When components are correlated, sums of squared loadings cannot be added to obtain a total variance.

Table IV. Factor loadings of the ROAD items in 443 rheumatoid patients.

	Component	
	ROAD-upper	ROAD-lower
Item 1: Close your hand completely	0.770	0.218
Item 2: Accept a hand shake	0.794	0.265
Item 3: Do up buttons	0.805	0.444
Item 4: Open jars which have been previously opened	0.787	0.448
Item 5: Reach and get down a 2 kg object from above your head	0.815	0.538
Item 6: Stand up	0.388	0.838
Item 7: Walk on flat ground	0.375	0.868
Item 8: Climb up five steps or stairs	0.463	0.901
Item 9: Get into and out of a car	0.590	0.848
Item 10: Wash and dry your body	0.751	0.440
Item 11: Run errands and shop	0.742	0.430
Item 12: Housework or/and your paid job	0.775	0.398

Extraction method: Principal Component Analysis; Rotation method: Oblimin with Kaiser Normalisation.

$p<0.0001$) (Table VI). In this respect, we also conducted a Bland and Altman type of agreement analysis by assessing the relationship between the mean of the recoded HAQ-DI and ROAD scores and the difference between the 2 scores. The Bland and Altman plot (Fig. 3) indicated a significant relationship between the mean of the scores and the difference between the scores. Figure 4 shows the ROC curve analysis for the ROAD total score and the HAQ-DI, which was carried out to assess the capacity for discriminating between inactive and active patients for multiple cut-off points. The AUC for ROAD was 0.905, with 95% C.I. from 0.874 to 0.931) whereas for the HAQ-DI was 0.887 (95% C.I. from 0.854 to 0.915). Instruments showed similar performance (difference between areas = 0.018; $p=0.124$). The optimal cut-off value for ROAD total score, obtained from the ROC analysis was 1.9. Based on this cut-off value, the sensitivity was 88.2% (95% CI for the mean, 82.8–92.4) and the specificity was 88.3% (95% CI for the mean: 83.6–92.0).

Discussion

Quantitative assessment of functional disability remains a very complex process in RA, even with help from the physician (10, 11, 19, 24, 33). Wherever possible, functional disability should be assessed using questionnaires rather than interviews. The use of interviewers is expensive and introduces an additional source of experimental error (10, 11, 33, 34). However, it also requires the availability of questionnaires that are simple to administer and complete, and are acceptable to respondents. The HAQ-DI is widely used and consequently this index is included in the ACR and the European League Against Rheumatism (EULAR) (33) functional status criteria for RA and in residual minimal disease activity recommendations (52, 74). The HAQ-DI has been successfully implemented in numerous diverse areas, such as prediction of successful aging, inversion of the therapeutic pyramid in RA, quantification of nonsteroidal anti-inflammatory drug gastropathy, development of risk factor models (14, 50, 75), and examination of mortality risks in RA (4). One barrier to more widespread use of such questionnaires is their length. Consequently, existing questionnaires have been shortened by omission of subscales, omission of items, or both. However, short forms have inherent weaknesses relative to the longer versions. The length of an instrument is also important in a postal survey to enhance response rates or to capture PRO data in patients with RA using an interactive touch-screen computer system (43, 76). Therefore, short questionnaires, such as the MDHAQ (22-24) and ROAD, minimise a patient's time and effort, and thus increase a patient's willingness to complete the questionnaire in clinical setting. The MDHAQ has scoring templates that allow a health professional to formerly depict a quantitative number for each scale within 15 seconds, directly on the questionnaire. The 10 activities of daily living can be quickly totalled without a calculator, computer or any other device (other than a human brain); the total is divided by 10 to reach a 0–3 score, with scores comparable to the HAQ. One can also divide the score by 3 to derive a 0–10 score, which will then be similar to scores for pain and global status.

Cost sparing associated with reduced time duration of patients' interview, as well as costs spared for evaluation of results obtained by ROAD or MDHAQ, can be considered especially for the long course of RA. Reduction in time, needed for patient evaluation, represents an important issue to save costs in clinical practice.

The construct/convergent validity, predictive validity, and sensitivity to change of the ROAD have been estab-

Table V. Spearman correlations between ROAD and clinical and laboratoristic variables for all RA participants.

	ROAD Total		ROAD Upper		ROAD Lower		HAQ-DI	
	Rho	*p*	Rho	*p*	Rho	*p*	Rho	*p*
ROAD Total	—		0.948	0.0000	0.816	0.0000	0.985	0.0000
ROAD Upper	0.948	0.0000	—		0.611	0.0000	0.926	0.0000
ROAD Lower	0.816	0.0000	0.611	0.0000	—		0.789	0.0000
HAQ DI	0.985	0.0000	0.926	0.0000	0.789	0.0000	—	
28-joint Disease Activity Score (DAS28)	0.771	0.0000	0.556	0.0000	0.291	0.0000	0.768	0.0000
Clinical Disease Activity Index (CDAI)	0.789	0.0000	0.540	0.0000	0.263	0.0000	0.787	0.0000
Simplified Disease Activity Index (SDAI)	0.766	0.0000	0.535	0.0000	0.259	0.0000	0.768	0.0000
Rheumatoid Arthritis Disease Activity Index (RADAI)	0.850	0.0000	0.668	0.0000	0.481	0.0000	0.844	0.0000
Swollen joint count (SJC 0–28)	0.694	0.0000	0.410	0.0000	0.135	0.0209	0.699	0.0000
Pain (NRS 0–10)	0.791	0.0000	0.601	0.0000	0.478	0.0000	0.785	0.0000
Tender joint count (TJC 0–28)	0.736	0.0000	0.461	0.0000	0.249	0.0000	0.740	0.0000
Evaluator global assessments of disease activity (EGA NRS 0–10)	0.724	0.0000	0.481	0.0000	0.256	0.0000	0.720	0.0000
Patient global assessments of disease activity (PGA NRS 0–10)	0.755	0.0000	0.580	0.0000	0.394	0.0000	0.746	0.0000
C-reactive protein (CRP)	0.216	0.0000	0.261	0.0000	0.129	0.0271	0.235	0.0000
Erythrocyte sedimentation rate (ESR mm/h)	0.319	0.0000	0.200	0.0005	0.127	0.0293	0.321	0.0000

Rho = Spearman rank correlation coefficient; *p* = statistical significance value.

lished in previous studies (55, 56). We have shown that ROAD subscales were internally consistent and have been significantly correlated with a wide variety of health status measures, including self-report measures, biochemical and clinical data (55, 56). Further, the ROAD subscale scores improved significantly due to intervention, indicating that the ROAD is a valid measure for change over time (56).

In the present study, we compared, the similarities and differences in construct validity of the ROAD and HAQ-DI scales in patients with RA. Analysis of comparability between instruments can be helpful for instrument selection, can permit comparisons of findings across disease conditions, and can provide insight into considerations regarding generic and disease specific instruments. Overall, we found that there was a great deal of commonality between the 2 physical function scales in the types of functional abilities assessed. These similarities, along with their respective histories, reaffirm their utility as measures of functional status. The 12-item ROAD scale is easier than the HAQ-DI to use and score in the clinic and in research studies. Because the scales are so closely allied and have mean scores that differ by only 0.2 units, it is relatively easy to substitute one scale for another. Differently from the previous study of validation of the ROAD (55), where the three-dimensional aspect of the instrument was revealed (upper and lower extremity functions and daily living/work activities), in the present report we demonstrate that the ROAD index consists mainly of two factors, which have moderate correlation and evaluate the upper and lower extremity functions. Putting together the first five items (regarding upper extremity function) and the last three items (regarding daily living/work activities) of the ROAD index allows a plain evaluation of the upper extremity. On the contrary, the first five items can be used for the evaluation of the fine movements of the hand. This contrasts with the HAQ-DI that reports a single score (40, 44). Single scores have the disadvantage of aggregation. This leads to the loss of information as the same score can be obtained from many different combinations of the sub-domains of the

Table VI. Overall agreement (defined as the percentage of observed exact agreements) of ROAD and HAQ-DI for different disability states.

	ROAD				
HAQ-DI	0	1	2	3	
0	198	3	0	0	201 (37.2%)
1	31	80	2	0	113 (20.9%)
2	0	11	153	2	166 (30.7%)
3	0	0	32	29	61 (11.3%)
	229 (42.3%)	94 (17.4%)	187 (34.6%)	31 (5.7%)	541

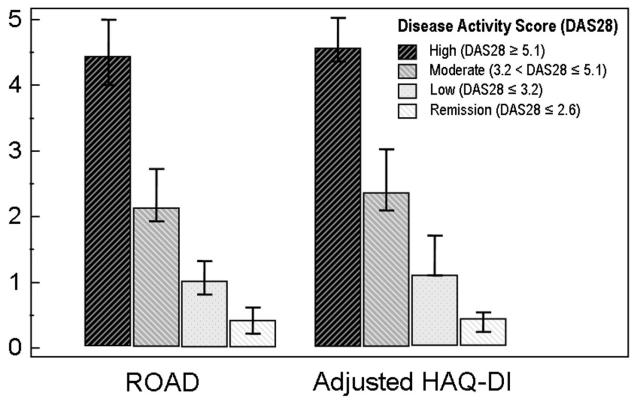

Fig. 2. Patient categorisation into those remissions, low, moderate and, high activity, with respect to the ROAD and recoded HAQ-DI. The error bars represent the 95% confidence interval – lines around median.

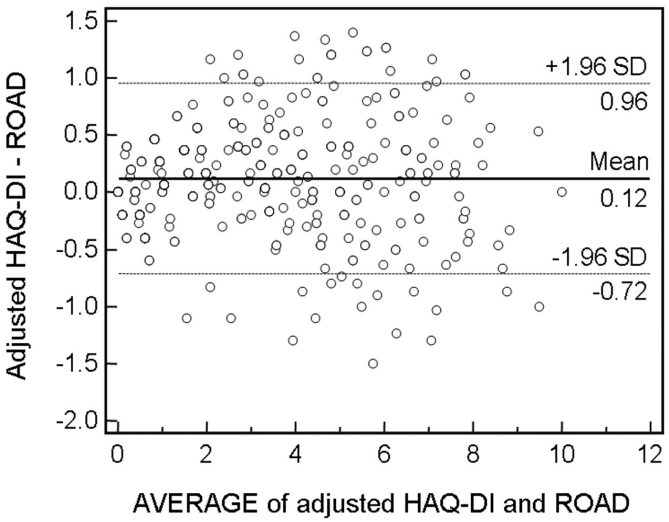

Fig. 3. The Bland and Altman plot shows a significant relationship between the mean of the scores and the difference between the scores.

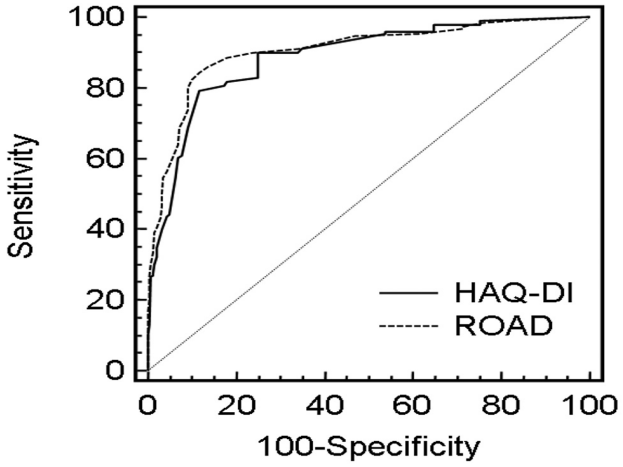

Fig. 4. ROC curve analysis for the ROAD total score and the HAQ-DI.

scale. However, findings in RA patients regarding the construct validity of the ROAD do not necessarily generalise to other diagnostic groups.

The second goal was to examine the association between the HAQ-DI and ROAD physical function to determine the extent of their relationship with each other and with other additional comparator composite indices of disease activity. Both scales were significantly and strongly correlated, indicating that the scales performed well and that patients interpreted them similarly. Clinical parameters are not the gold standard for the validation of physical functional status. However, because disease activity and physical ability are closely related, one could expect an association. Consistent with this expectation and the result of previous studies (77) we found a strong relationship between both the HAQ-DI and the ROAD and pain scales and composite disease activity indices in the cross sectional assessment.

The third goal was to demonstrate that ROAD has better discriminative accuracy to distinguish patients with active and non-active disease, as compared with the HAQ-DI. The validation results of this study suggest that the ROAD performs at least as well as the HAQ-DI. This should not be surprising, since 8 of the 12 ROAD items come directly from the HAQ-DI.

A strength of this study is that it was a national sample drawn from rheumatology practices. However, there are several limitations as well. First, because of the nature of the sample, the results are not generalisable beyond RA patients being treated in rheumatology practices. The second limitation was the cross-sectional study design. This does not allow test-retest reliability evaluation and does not provide information on the sensitivity to change after treatment. Larger multicenter studies over longer periods of time or after interventions are warranted to address these issues (32). Furthermore, assessments of patients were performed by different clinician teams. The involvement of different assessors in the patient should not, however, be a major concern because the analyses and results (with the exception of joint count examination) were based on PROs measures.

In conclusion, the ROAD is a valid 12-item questionnaire that performs at least as well as the HAQ-DI in RA patients and is simpler to administer and score. Both questionnaires may be useful when screening patients for physical function, and the choice of the appropriate instrument depends on the setting where it is used. Two key areas can be addressed in future research: the viability of the ROAD in other frequently assessed populations and comparison to other recent instruments, as the HAQ-II (25). Also, it will be important to evaluate how useful the ROAD is relative to instruments that are more specific to body regions (*i.e.* upper extremity, lower extremity, etc.).

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