Development of a functional disability measurement tool to assess early arthritis: the Recent-Onset Arthritis Disability (ROAD) questionnaire

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Abstract Objective

To develop a self-administered questionnaire, the ROAD (Recent-Onset Arthritis Disability), to probe physical disability in Italian patients with early arthritis (EA) of less than one year's duration.

Methods

The development of the ROAD follows a series of major steps: (1) identification of a specific patient population, (2) item pool development, (3) item reduction, (4) internal consistency, (5) pre-testing of the prototype instrument, and (6) a validation study which results in determination, reliability, validity and responsiveness. In this study we have verified the first five steps. Pre-defined areas of disability were culled from eight existing Italian version arthritis-specific questionnaires, and three generic global health measurement tools. Semi-structured interviews helped to derive a 76-item pool from an initial group of 122 items. This questionnaire was administered to 78 EA patients.

Results

For scale generation, a combination of frequency importance product (FIP= frequency x mean relevance score) and factor analysis was applied. The top 20 items based on the FIP were then subjected to further analysis. Each question was correlated with every other question. This allowed us to eliminate 8 questions that were therefore highly correlated and were measuring the same concept. The final instrument has 12 items, representing a combination of symptoms that are common, frequently recurring and of general importance to EA patients. Factor analysis provides a 3-factor health status model explaining 70.1% of the variance. The upper extremity function (5 items) is loaded on the first factor, which explains 45.4% of the total measured variance. The lower extremity function (4 items) formed the second factor (14.2% of the total variance). The third factor was determined by activities of daily living/work (3 items) and explain 10.5% of the total variance. The score of the different subscales can be presented graphically as a ROAD profile.

Conclusion

Using a traditional development strategy, we have constructed a self-administered instrument for measuring physical functioning in patients with EA. The next stage includes reliability, validity and responsiveness testing of the 12-item questionnaire.

Key words

Recent-onset arthritis disability index, early arthritis, disability, questionnaire, outcome assessment.

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Introduction

It is increasingly recognized that a key outcome measure for any health care intervention for early rheumatoid arthritis (RA), as for many other conditions, is a change in functional status (1-4). This reflects a growing appreciation of the importance of how patients feel and how satisfied they are with treatment and with disease outcomes. The Outcome Measure in Rheumatoid Arthritis Clinical Trials (OMERACT) committee has played a large role in these efforts, including specific recommendations of outcome measures for use in clinical trials of RA (5). These instruments used to test functional disability are useful only if they provide valid, reliable information and are sensitive to changes over the course of observation. While numerous health status questionnaires have been developed and are available for use, they tend to fall into 2 basic types: disease specific measure and generic health status measures (6-8). The Health Assessment Questionnaire (HAQ) is one of the most widely used comprehensive, validated, patient-oriented instrument for the measurement of functional status (9, 10) that has been widely used in observational studies of and clinical trials in RA(9-11). Because the HAQ emanated from the rheumatology field, it sometimes has been characterized as a "disease-specific" instrument, rather than having been adjudicated on the basis of its structure, content, and history of use. The HAQ has been and continues to be administered across different disciplines and in different clinical settings. It should be considered a "generic" rather than a "diseasespecific" instrument, since it assess the dimensions of death, disability, drug side effects, discomfort, and economic costs, none of which are "disease-specific". In patients with RA, self-report HAQ score are as effective as any available clinical measure, including laboratory tests and radiographs, to predict functional disability (12-14). The US Food and Drug Administration accepts it as a measure for evaluation of the prevention of disability.

One of the limitations of this instrument is that it is strongly influenced by factors such as socioeconomic status, gender and mental state, indicating that the trait phenomena have a large effect on self-reported disability scores (2, 9). Secondly, the scores also progress slowly, which 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 (15). This is especially true in early arthritis (EA). The psychometric properties of the HAQ, that is in use were initially developed over 20 years ago, limiting the extent to which they may completely address current vernacular and patterns of functional status for individual patients with early RA. This is especially pertinent given the new realities of a more aggressive and early management of RA (16,17). To avoid increasing the number of outcome measures and to promote normalization of disability assessment in recent-onset arthritis, it would be of interest to have a single instrument to assess disability. Thus, the purpose of this study was therefore to develop a measurement tool that was reliable, valid, responsive and user friendly for the assessment of physical disability for EApatients in Italy. It has been suggested that for an disability measure to be useful in the clinic it should require fewer than 10 minutes to complete and take fewer than 30 seconds to score. Here, we present data on its development.

Materials and methods

The development of a self-administered questionnaire usually follows a series of major steps (18-21): (i) identification of a specific patient population, (ii) item pool development, (iii) item reduction, (iv) internal consistency (v) pre-testing the prototype instrument, and (vi) validation study which results in determination, reliability, validity, and responsiveness. Thus, the process begins with the development of an item pool and ends with one or more validation studies establishing testretest reliability, internal consistency, construct validity and responsiveness, and relevant parameters for future sample size calculation. We followed this order, and the reliability, validity and responsiveness of the scale are currently under investigation.

Population identification

The purpose of this instrument is to evaluate the disease specific functional disability of patients with EA. Thus, the target population was patients with EA of less than one year's duration. Subjects who were considered to have a diagnosis other than inflammatory polyarthritis were excluded. Additional exclusion criteria were as follows: medical comorbidity that would render the patient unable to fully partecipate in the study procedures (e.g. terminal conditions such as end-stage renal disease, heart failure, or malignancy), alcohol abuse or major cognitive deficits or psychiatric symptoms that would preclude questionnaire completion. Either centre had approval from their respective ethics committees. All patients provided informed consent.

Item pool development

Item generation is considered the most important step in the development of disease specific functional disability measurement tool. This step must be comprehensive since the final measurement tool can only consist of the specific items identified in this stage. The item generation was carried out in three steps (22).

In the first step, a review of the literature was conducted to identify items that would be appropriate from the description of early arthritis. The method adopted for item generation capitalized on the experience of both clinical investigators and patients with RA. Predefined areas of disability were culled from eight existing Italian version arthritis-specific questionnaires, namely Arthritis Impact Measurement Scales (AIMS) (23); and the revised and expanded version of AIMS (AIMS2) (24); Health Assessment Questionnaire (HAQ) (25); Western Ontario and Mc-Master University Osteoarthritis (WO-MAC) index (26); Dreiser Functional Index (Dreiser) (27); Disabilities of Arm, Shoulder, and Hand (DASH) questionnaire (28); Lequesne algo-functional

index (26, 27), and Lee index (27), and five generic global health measurement tools (Sickness Impact Profile, General health Questionnaire, Nottingham Health Profile, European Quality of Life Questionnaire, and Medical Outcomes Study SF-36 Health Survey) (27, 29). In the second step, 14 rheumatology health professionals (8 doctors, 2 nurses, 2 physioterapists and 2 occupational therapists) were interviewed. The professionals were asked to identify the most important patient symptoms for each domain (hand and finger function, arm function, hygiene, mobility level, walking and bending, self-care tasks and household tasks, domestic care, self-care, professional activities, leisure activities, sports and recreation, sexuality, social interaction, and roles). In the final and most important step, patients with EAwere interviewed. The patients selected had a wide spectrum of patient characteristics, disease severity, and treatments to ensure that the entire spectrum of symptomatology would be elicited. Patients then underwent a semi-structured interview by a research assistant with expertise in the development in disability/quality of life measurement tools. During the interview, the patients were asked to identify any items that contributed to their functioning less than perfectly. A total of 34 patients were interviewed. Twenty-six patients (74.3%) had RA, and 9 patients (25.7%) had undifferentiated inflammatory arthritis (UIA). There were 23 females and 11 males and the patients' ages ranged from 19 to 78 (mean 48.9 years). The predominance of female subjects in the item generation sample was comparable to the approximate 2-3:1 ratio in reported clinical trials. Patients with UIA were defined as those with characteristics, a history, or examination or laboratory data suggesting the presence of an inflammatory disorder but in whom a specific rheumatic disease has not been diagnosed (30). By the end of this step 122 items were identified.

Item reduction

The necessity for item reduction was driven by the feasibility of carrying a large number of redundant items through the subsequent validation study. Obviously, a questionnaire with approximately 122 items would be clinically impractical. Therefore, the goal is to retain 10-20 items that are the most important to the patient and are representative of the functional disability. In order to reduce the number of items, the following exclusion rules were applied: (a) gender based items, (b) questions requiring special equipment, (c) incomprehensible or ambiguous items, (d) composite items, (e) elimination of alternatives (e.g., do/undo or fasten/ unfasten), (f) elimination of duplicates or similarities, and (g) missing responses greater than 5% (31). Any items which could not change following treatment were also discarded.

The end result of the process of item reduction was to be a pool of 76 items. This questionnaire was then administered to 78 new patients (not previously involved in item generation), attending the care facilities of the Rheumatology Units of Ancona and Pisa, who again represented the full spectrum of patients. Fifty-four patients (69.3%) had RA, 15 patients (19.2%) had UIA, and 8 patients (11.5%) had psoriatic arthritis. For each item, the subjects were asked to assess whether they experienced the item or not. If the item was experienced, they were further asked to rate the importance of the item to their overall functioning.

The importance was ranked on a Likert scale from one to three: 1 = irrelevant, unimportant; 2 = somewhat relevant, somewhat important; 3 = very relevant, very important. The mean relevance scores for each item were calculated. It was considered that the mean score of an item should be at least 2.0 (possible range, 1.0 to 3.0) to justify inclusion into the questionnaire. Additionally, the frequency with which each of the 78 interviews experienced the individual items were then ranked in order of their prevalence. For this process, questions that met the prevalence criteria of 50% were retained. The frequency importance product (FIP = frequency x mean relevance score) was then generated for each item. The top 20 items based on the FIP were then subjected to further analysis. Each question was correlated

Early arthritis-specific disability index /F. Salaffi et al.

with every other question. This allowed us to eliminate 8 questions that were therefore highly correlated and were measuring the same concept. The final instrument has 12 items, representing a combination of symptoms that are common, frequently recurring and of general importance to EApatients. The patient's reported difficulty in performing each activity during the past week is scored from 4 (unable to do) to 0 (without any difficulty). Exploratory principal components analysis with varimax rotation was used to develop the factor model.

Internal consistency

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. Chronbach's alpha values above 0.80 indicate adequate inter-relationship of items (32).

Testing the provisional questionnaire

Pre-testing the prototype questionnaire is conducted to ensure that the wording is clear and the patient interpreted the items as they are intended. The questionnaire was administered to a group of 35 subjects (25 females and 10 males) aged from 21 to 76 (mean 46.3 years) not previously involved in the development of the tool. To examine participants' level of comprehension of the instruments' content, a proxy question was asked; did you have any difficulty understanding the questionnaire items? (to be answered on a five-point Likert scale). Thirty-three participants (94.3%) affirmed they had 'no difficulty'. Three participants found 'some difficulty'and only one respondent seemed to have 'moderate difficulty' in understanding and responding to the items. No modifications to the questionnaire were necessary after this step.

Results

The mean age was 50.7 ± 8.3 years (range 23-80). Forty-eight of the respondents were female (61.5%), 30 were male (38.5%). The mean disease duration (i.e. symptomatic) was 6.5 \pm

2.9 months. Their school education level was generally low: 62.8% had received only a primary school education, and only 19.2% had received a high school education. The majority of patients (78.2%) were married and lived with the family; up to 32% of the patients were house-wives. Of the 78 subjects enrolled, 41 (52.6%) reported 1 or more medical co-morbidities, mostly cardiovascular (29.2%), respiratory (14.1%), and metabolic (10.5%) disorders.

All 12 items were reported with a prevalence 53%. The mean importance (MI) scores varied from 2.1 to 2.6. The FIPs, for the questionnaire of the 12 items ranged from 127.2 to 218.4 (Table I).

Principal component factor analysis with varimax rotation (Kaiser normalization) (SPSS package for Windows, version 11.0), provides a 3-factor health status model explaining 70.1% of the variance (Table II). An eigenvalue criterion of 1.0 was used to select the factors. The upper extremity function (5 items) is loaded on the first factor, which explains 45.4% of the total measured variance. The lower extremity function (4 items) formed the second factor (14.2% of the total variance), and the third factor, determined by activities of daily living/work (3 items), explains 10.5% of the total variance. Variables within factors with loadings of 0.60 or above were considered to be significantly related to the factor and retained. Table III shows the loading of each question after varimax rotation on the three factors.

Once the raw responses have been recorded (0 = without any difficulty, 1 = with a little of difficulty, 2 = with some difficulty, 3 = with much difficulty, 4 = unable to do), the scores of each item within the scale are simply added (Appendix). The range of scores depends upon the number of items in the scale. In order to express these scores in a clinically more meaningful format, a simple mathematical normalization procedure is then performed so that all the scores can be expressed in the range

Table I. Item rank ordered by frequency importance product (FIP).*.

	Frequency	Mean importance (MI)	Frequency importance product (FIP)
Item 1. Close your hand completely?	84	2.6	218.4
Item 2. Accept a hand shake?	74	2.4	177.6
Item 3. Do up buttons?	67	2.6	174.2
Item 4. Open jars which have previously been opened?	70	2.4	168.0
Item 5. Reach up for and take down a 2 Kg object from just above your head?	66	2.5	165.0
Item 6. Stand up?	74	2.1	155.4
Item 7. Walk on flat ground?	63	2.4	151.2
Item 8. Climb up five steps?	60	2.4	144.0
Item 9. Get in and out of a car?	56	2.5	140.0
Item 10. Wash and dry your body?	60	2.3	138.0
Item 11. Run errands and shop?	62	2.2	136.4
Item 12. Do a paid job or housework?	53	2.4	127.2
*FIP: frequency x mean relevance score.			

Table II. Factors in factor analysis.

Factor	Eigenvalue	% of variance	Cumulative %
Factor 1	5.444	45.366	45.366
Factor 2	1.707	14.223	59.589
Factor 3	1.259	10.489	70.078

Early arthritis-specific disability index / F. Salaffi et al.

Table III. Varimax rotated factor matrix. The highest loading of each item is in bold.

		Factor	
	1	2	3
Item 1. Close your hand completely ?	.761	056	.112
Item 2. Accept a hand shake ?	.812	217	.110
Item 3. Do up buttons ?	.722	450	.134
Item 4. Open jars which have previously been opened?	.826	267	.232
Item 5. Reach up for and take down a 2 kg object from just above your head ?	.795	112	.211
Item 6. Stand up ?	255	.778	326
Item 7. Walk on flat ground ?	282	.714	381
Item 8. Climb up five steps ?	368	.772	113
Item 9. Get in and out of a car?	.298	.770	.184
Item 10. Wash and dry your body ?	.455	176	.711
Item 11. Run errands and shop ?	248	251	.789
Item 12. Do a paid job or housework ?	.170	015	.772

Extraction method: principal component analysis; rotation method: Varimax with Kaiser normalization.

0-10, with 0 representing good health status and 10 representing poor status. In this way, 3 physical function subscores ranging from 0-10 can be presented graphically as a ROAD disability profile. The total score results from the mean of the three sub-scores. The scoring of this index is also included in the appendix. It is important to note, however, that the scalability, reliability, and validity of the scales are based upon the assumption that all the items within the scale have been answered. If any items within a given scale are omitted, then the score for the scale cannot accurately be calculated using these normalization procedures. If one item is missing, the average score of the other scale items may be substituted prior to normalization. If more than one item were omitted, the response for this dimension was considered invalid. Questions and answer options are given in the appendix. It can be selfadministered in 3-4 minutes and scored in less than one minute.

The distribution of the scores in the ROAD (upper extremity function, lower extremity function, and activities of daily living/work) are presented in Figure 1. The bar on the left of each graph represents the number 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). The ROAD had negligible floor and ceiling effects in patients with EA.

The inter-item correlation matrix showed that at an individual question level, some items gives poor or negative inter-item correlation, indicating that ROAD may not be a unidimensional concept (Table IV).

All ROAD subscale factors were internally consistent, with Cronbach's coefficient alpha of 0.882 for the upper extremity function subscale, of 0.838

Table IV	. Inter-item	correlation	(n =	78 patients.))
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		Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12
Correlation	Item 1	1.000	.566	.573	.605	.450	333	265	374	077	.420	.081	.213
	Item 2	.566	1.000	.654	.726	.538	341	415	465	152	.446	.110	.193
	Item 3	.573	.654	1.000	.725	.528	542	501	553	346	.515	.228	.195
	Item 4	.605	.726	.725	1.000	.611	463	537	514	162	.579	.197	.285
	Item 5	.450	.538	.528	.611	1.000	273	278	282	010	.339	053	.252
	Item 6	333	341	542	463	273	1.000	.740	.727	.432	447	419	293
	Item 7	265	415	501	537	278	.740	1.000	.663	.403	489	397	347
	Item 8	374	465	553	514	282	.727	.663	1.000	.421	368	236	205
	Item 9	077	152	346	162	010	.432	.403	.421	1.000	169	120	159
	Item 10	.420	.446	.515	.579	.339	447	489	368	169	1.000	.482	.528
	Item 11	.081	.110	.228	.197	053	419	397	236	120	.482	1.000	.372
	Item 12	.213	.193	.195	.285	.252	293	347	205	159	.528	.372	1.000
Sig. (1-tailed)	Item 1		.000	.000	.000	.000	.002	.011	.000	.255	.000	.246	.033
	Item 2	.000		.000	.000	.000	.001	.000	.000	.097	.000	.175	.049
	Item 3	.000	.000		.000	.000	.000	.000	.000	.001	.000	.025	.047
	Item 4	.000	.000	.000		.000	.000	.000	.000	.083	.000	.045	.007
	Item 5	.000	.000	.000	.000		.009	.008	.007	.466	.001	.327	.015
	Item 6	.002	.001	.000	.000	.009		.000	.000	.000	.000	.000	.005
	Item 7	.011	.000	.000	.000	.008	.000		.000	.000	.000	.000	.001
	Item 8	.000	.000	.000	.000	.007	.000	.000		.000	.001	.021	.039
	Item 9	.255	.097	.001	.083	.466	.000	.000	.000		.073	.153	.086
	Item 10	.000	.000	.000	.000	.001	.000	.000	.001	.073		.000	.000
	Item 11	.246	.175	.025	.045	.327	.000	.000	.021	.153	.000		.001
	Item 12	.033	.049	.047	.007	.015	.005	.001	.039	.086	.000	.001	



RCAD2 Fig. 1. Distribution of the score in the ROAD questionnaire: upper extremity function (ROAD 1), lower extremity function (ROAD 2), and

for the lower extremity function subscale, and of 0.811 for the activity of daily living/work subscale.

Discussion

One of the biggest challenges in managing RA is how to accurately identify (before joint damage has occurred) patients who have either persistent RA or risk factors for severe RA, particularly as more immediate and aggressive disease modifying antirheumatic drug (DMARD) intervention could be particularly rewarding for this population (16, 33, 34).

Several clinical, radiological and laboratory variables have been reported as prognostic factors in patients with early RA; the number of swollen joints (13, 35), the number of tender joints (13, 36), functional indices (12-14, 17, 37-41), erosions on radiology (13, 36), a positive rheumatoid factor test and the anti-citrullinated peptide antibody positivity (13, 30, 36, 42). Physical disability is the most powerful determinant of all long-term outcomes in RA (13, 33, 37, 43, 44), and is recommended as one of the core measures both in controlled clinical trials (45, 46) and in longitudinal observational studies (5). Assessment of functional disability should be regarded as an essential medical test along with blood pressure

measurement, magnetic resonance imaging or electrocardiogram (1). Wherever possible, functional disability should be assessed using questionnaires rather than interviews (6,7,47). The use of interviewers is expensive and introduces an additional source of experimental error (47). However, it also requires the availability of questionnaires that are simple to administer and complete, and are acceptable to respondents (6,7,47). Short questionnaires minimize a patient's time and effort, and thus increase the patient's willingness to complete the questionnaire.

Several instruments are available for measuring disability (11). These instruments used to test functional disability are useful only if they provide valid measurements (measure precisely what they set out to measure), acceptable to both patients and clinicians, providing the specific information needed in a form which is easily incorporated into a busy clinic setting (48). Sensitivity of the chosen measure to clinically important changes in health status over time is also important in rheumatology as therapeutic effects tend to be modest in the majority of patients (6, 7).

Most of the studies on predictive factors of functional capacity used either the HAQ (10) or Steinbroker's functional grades as outcome parameters.

The HAQ is the best predictor of functional disability (12, 13, 44), work disability (37, 44, 49-53), costs (38, 41, 54), joint replacement surgery (44, 55), and premature mortality (55-58). Although the HAQ is a validated instrument for the measurement of functional status that has been widely used in observational studies (15) of and clinical trials in RA, such an instrument may not be sufficiently sensitive or responsive to detect relatively small changes in disability associated with newly developed clinical interventions. These have been the subjects of a number of papers (15, 59-61) and is especially true in early disease (3). Further, Wiles et al. (62) found considerable within-patient variation when HAQ was assessed annually in patients with early inflammatory polyarthritis and concluded that it is not possible in the early years to track disability using centile reference charts (62). The eightitem modified HAQ (MHAQ) (9, 63) has, also, lower sensitivity to change than full HAQ and the scoring instructions differ. The phenomenon by which a patient may have a normal score on the HAQ or MHAQ, but nonetheless experience functional limitations not detected on the questionnaire, is known as a "floor effect" (64) ("ceiling effect" if a higher score indicates better function). The presence of a floor or ceiling effect means that items capture only a limited response range. Consequently, the measure's ability to detect changes resulting from treatment is greatly reduced. Although many measures might suffer from floor and/or ceiling effects, attention has been focused on identifying and resolving these issues.

Our goal was to develop a measurement tool that was reliable, valid, responsive and user friendly for the assessment of physical disability for EA patients in Italy. Developing an instrument is a time consuming process. According to Kirshner and Guyatt (18) the development of a scale should include a series of major steps: (a) identification of a specific patient population, (b) item pool development, (c) item reduction, (d) internal consistency, (e) pretesting of the prototype instrument, and (f) validation study which results in determination, reliability, validity and responsiveness. We followed this order, and the reliability, validity and responsiveness of the scale are currently under investigation.

The ROAD is a self-administered instrument that consists of 12 items assessing a patient's level of functional ability and includes questions of fine movements of the upper extremity, locomotor activities of the lower extremity, and activities that involve both upper and lower extremities. The item contents of the ROAD offer four potential advantages. Firstly, the ROAD was developed for early arthritis studies and contain items specifically chosen by patients. Secondly, there is the advantage of length, the ROAD contain only 12 questions. The HAQ disability index, for example, contains 20 questions and a list of 20 aids and devices. The length of an instrument is important in a postal survey to enhance response rates. Thirdly, eleven of the 12 ROAD items assess functional limitations; only one ("do a paid job or housework ?") is a measure of disability. There has been increasing recognition of the conceptual importance of separating functional limitations and disability (65). Finally, the ROAD items are reported separately in three subscales. This contrasts with the HAQ which reports a single score. 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 scale.

In conclusion, the practical advantages of this scale are clarity, comprehensiveness, simplicity, and a minimum requirement of professional time and money. It takes about 3-4 minutes to answer, and the four levels of answers result in a more sensitive grading of functional disability. The questionnaire may also be reviewed with a nurse when the weight or blood pressure are checked, or when the patient is placed in an examination room. 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 (a low percentage of ceiling effects indicates that this index has the potential for measuring improvement over time). Other potential applications of the ROAD are the determination of the burden of illness, as well as in cohort studies on prognosis and outcome. We are currently conducting further studies on the validity and responsiveness of ROAD against several other health status instruments.

References

- GUILLEMIN F: Functional disability and quality-of-life assessment in clinical practice. *Rheumatology* 2000; 39 (Suppl. 1): 17-23.
- SOKKA T, KRISHNAN E, HAKKINEN A, HANNONEN P: Functional disability in rheumatoid arthritis patient compared with a community population in Finland. *Arthritis Rheum* 2003; 48: 59-63.
- SCOTT DL, SMITH C, KINGSLEY G: Joint damage and disability in rheumatoid arthritis: an updated systematic review. *Clin Exp Rheumatol* 2003; 21 (Suppl. 31): S20-S27.
- PINCUS T, CALLAHAN LF, BROOKS RH, FUCHS HA, OLSEN NJ, KAYE JJ: Self-report questionnaire scores in rheumatoid arthritis compared with traditional physical, radiographic, and laboratory measures. *Ann Intern Med* 1989; 110: 259-66.
- WOLFE F, LASSERE M, VAN DER HEIJDE D et al.: Preliminary core set of domains and reporting requirements for longitudinal observational studies in rheumatology. J Rheu matol 1999; 26: 484-9.
- GUYATT GH, VAN ZANTEN SJOV, FEENY DH, PATRICK DI: Measurement quality of life in clinical trials: a taxonomy and review. *Can Med Assoc* 1989; 140: 1441-8.
- GUYATT GH, FEENY DH, PATRICK DL: Measuring health-related quality of life. Ann Intern Med 1993; 118: 622-9.
- OXMAN AD, GUYATT GH: Validation of an index of the quality of review articles. *J Clin Epidemiol* 1991; 44: 1271-8.
- BRUCE B, FRIES J: The Stanford Health Assessment Questionnaire: a review of its history, issues, progress, and documentation. *J Rheumatol* 2003; 30: 167-78.
- FRIES JF, SPITZ PW, KRAINES RG, HOLMAN HR: Measurement of patient outcome in arthritis. *Arthritis Rheum* 1980; 23: 137-45.
- 11. SWINKELS RAHM, OOSTENDORP RAB, BOUTER LM: Which are the best instruments for measuring disabilities in gait and gaitrelated activities in patients with rheumatic disorders. *ClinExpRheumatol* 2004;22:25-33.
- 12. WILES NJ, DUNN G, BARRETT EM, HARRI-SON BJ, SILMAN AJ, SYMMONS DPM: One year followup variables predict disability 5 years after presentation with inflammatory polyarthritis with greater accuracy than a baseline. *J Rheumatol* 2000; 27: 2360-6.
- 13. DROSSAERS-BAKKER KW, ZZWINDERMAN AH, VLIELAND TPMV et al.: Long-term outcome in rheumatoid arthritis: a simple algorithm of baseline parameters can predict radiographic damage, disability, and disease

course at 12-year followup. Arthritis Care Res 2002; 47: 383-90.

- EBERHARDT KB, RYDGREN LC, PETTER-SON H, WOLLEHEIM FA: Early rheumatoid arthritis – onset, course, and outcome over 2 years. *Rheumatol Int* 1990; 10: 135-42.
- WOLFE F: A reappraisal of HAQ disability in rheumatoid arthritis. *Arthritis Rheum* 2000; 43: 2751-61.
- FERRACCIOLI GF, VALENTINI G, VALESINI G, BOMBARDIERI S: Reconstructing the pyramid in rheumatoid arthritis. An urgent need. *Clin Exp Rheumatol* 2001; 19: 621-4.
- QUINN MA, EMERY P: Window of opportunity in early rheumatoid arthritis: possibility of altering the disease process with early intervention. *Clin Exp Rheumatol* 2003; 21 (Suppl. 31): S154-S157.
- KIRSHNER B, GUYATT GH: Methodological framework for assessing health indices. J Chron Dis 1985; 1: 27-36.
- BELLAMY N, CAMPBELL J, HARAOUI B et al.: Dimensionality and clinical importance of pain and disability in hand osteoarthritis: development of the Australian/Canadian (AUSCAN) Osteoarthritis hand index. Osteoarthritis Cart 2002; 10: 855-62.
- LYDICK E, ITKIN S, ZIMMERMAN I et al.: Development and validation of a discriminative quality of life questionnaire for osteoporosis (the OPTQoL). J Bone Miner Res 1997; 12: 456-63.
- 21. LO IKI, GRIFFIN S, KIRKLEY A: The development of a disease-specific quality of life measurement tool for osteoarthritis of the shoulder: the Western Ontario Osteoarthritis of the Shoulder (WOOS) index. Osteoarthri tis Cart 2001; 9: 771-8.
- 22. KIRKLEYA, GRIFFIN S, MCCLINTOCK J, NG L: The development of a disease specific quality of life measurement tool for shoulder instability. *Am J Sports Med* 1998; 26: 764-72.
- 23. SALAFFI F, FERRACCIOLI GF, TROISE RIODA W, CAROTTI M, SACCHINI G, CERVI-NI C: Validità ed affidabilità della versione italiana dell'Arthritis Impact Measurement Scales in pazienti con artrite reumatoide. *Rec Prog Med* 1992; 83: 7-11.
- 24. SALAFFI F, PIVA S, BARRECA C, CACACE E, CIANCIO G, LEARDINI G, on behalf of the GONARTHROSISAND QUALITYOF LIFE (GOQUO-LA) STUDY GROUP. Validation of an Italian version of the arthritis impact measurement scales 2 (ITALIAN-AIMS2) for patients with osteoarthritis of the knee. *Rheumatology* 2000; 39: 720-6.
- 25. RANZA R, MARCHESONI A, CALORI G et al.: The Italian version of the functional disability index of the Health Assessment Questionnaire. A reliable instrument for multicenter studies on rheumatoid arthritis. *Clin Exp Rheumatol* 1993; 11: 123-8.
- 26. SALAFFI F, LEARDINI G, CANESI B et al.: Reliability and validity of the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index in Italian patients with osteoarthritis of the knee. Osteoarthritis Car tilage 2003; 11: 551-60.
- 27. SALAFFI F, STANCATI A: Valutazione della qualità della vita nelle malattie reumatiche:

Early arthritis-specific disability index /F. Salaffi et al.

strumenti e metodi. *In: Scale di valutazione e malattie reumatiche*. Edizioni Mattioli 1885, pag. 3-20, 2001.

- PADUA R, PADUA L, CECCARELLI E et al.: Italian version of the Disability of the Arm, Shoulder and Hand (DASH) questionnaire. Cross-cultural adaptation and validation. J Hand Surg [Br] 2003; 28:179-86.
- APOLONE G, MOSCONI P: The Italian SF-36 Health Survey: translation, validation and norming. *J Clin Epidemiol* 1998; 51: 1025-36.
- 30. QUINN MA, GREEN MJ, MARZO-ORTEGA H et al.: Prognostic factors in a large cohort of patients with early undifferentiated inflammatory arthritis after application of a structured management protocol. Arthritis Rheum 2003: 48: 3039-45.
- 31. STREINER DL, NORMAN GR: Health Measurement Scales: a Practical Guide to their development and use. 2nd ed. New York: Oxford University Press; 1996.
- BELLAMY N: Musculoskeletal Clinical Metrology, Dordrecht, Kluwer Academic Publisher Group; 1993.
- SCOTT DL: Prognostic factors in early rheumatoid arthritis. *Rheumatology* 2000; 39 (Suppl 1.): 24-9.
- 34. EMERY P: Evidence supporting the benefit of early intervention in rheumatoid arthritis. *J Rheumatol* 2002; 29 (Suppl. 66): 3-8.
- 35. BOERS M, KOSTENSE PJ, VERHOEVEN AC, VAN DER LINDEN S, FOR THE COBRA TRIAL GROUP: Inflammation and damage in an individual joint predict further damage in that joint in patients with early rheumatoid arthritis. Arthritis Rheum 2001; 44: 2242-6.
- 36. VISSER H, LE CESSIE S, VOS K, BREED-VELD FC, HAZES JMW: How to diagnose rheumatoid arthritis early. A prediction model for persistent (erosive) arthritis. *Arthritis Rheum* 2002; 46: 357-65.
- 37. YOUNG A, DIXEY J, KULINSKAYA E et al.: Which patients stop working because of rheumatoid arthritis? Results of five years' follow up in 732 patients from the early RA study (ERAS). Ann Rheum Dis 2002; 61: 335-40.
- MICHAUD K, MESSER J, CHOI HK, WOLFE F: Direct medical costs and their predictors in patients with rheumatoid arthritis. *Arthritis Rheum* 2003; 48: 2750-62.
- 39. KAZIS LE, ANDERSON JJ, MEENAN R: Health status as a predictor of mortality in rheumatoid arthritis: a five-year study. J Rheumatol 1990; 17: 609-13.
- 40. WOLFE F, MICHAUD K, GEFELLER O, CHOI HK: Predicting mortality in patients with rheumatoid arthritis. *Arthritis Rheum* 2003; 48: 1530-42.
- 41. LEARDINI G, SALAFFI F, MONTANELLI M, GERTZELI S, CANESI B: A multicenter costof-illness study on rheumatoid arthritis in

Italy. Clin Exp Rheumatol 2002; 20: 505-15.

- 42. GOUGH A, FAINT J, SALMON M *et al.*: Genetic typing of patients with inflammatory arthritis at presentation can be used to predict outcome. *Arthritis Rheum* 1994; 37: 1166-70.
- WONG JB, RAMEY DR, SINGH G: Long-term morbidity, mortality, and economics of rheumatoid arthritis. *Arthritis Rheum* 2001; 44: 2746-9.
- 44. YOUNG A, DIXEYJ, COX N et al.: How does functional disability in early rheumatoid arthritis (RA) affect patients and their lives? Results of 5 years of follow-up in 732 patients from the Early RA Study (ERAS). *Rheumatology* (Oxford). 2000; 39: 603-11.
- 45. FELSON DT, ANDERSON JJ, BOERS A et al.: The American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. Arthritis Rheum 1993; 36: 729-40.
- 46. STRAND V, TUGWELL P, BOMBARDIER C et al.: Function and health-related quality of life. Results from a randomized controlled trial of leflunomide versus methotrexate or placebo in patients with active rheumatoid arthritis. Arthritis Rheum 1999; 42: 1870-8.
- 47. COOK DJ, GUYATT GH, JUNIPER E et al.: Interviewer versus self-administered questionnaires in developing a disease-specific, health-related quality of life instrument for asthma. J Clin Epidemiol 1993; 46: 529-34.
- 48. PINCUS T, SOKLA T, KAVAMAUGH A: Quantitative documentation of benefit/risk of new therapies for rheumatoid arthritis: patient questionnaires as an optimal measure in standard care. *Clin Exp Rheumatol* 2004; 22 (Suppl. 35): S26-S33.
- 49. BORG G, ALLANDER E, BERG E, BRODIN U, FROM A, TRANG L: Auranofin treatment in early rheumatoid arthritis may postpone early retirement. Results from a 2-year double blind trial. *J Rheumatol* 1991; 18: 1015-20.
- 50. FEX E, LARSSON BM, NIVED K, EBER-HARDT K: Effect of rheumatoid arthritis on work status and social and leisure time activities in patients followed 8 years from onset. *J Rheumatol* 1998; 25: 44-50.
- 51. JÄNTTI J, AHO K, KAARELA K, KAUTI-AINEN H: Work disability in an inception cohort of patients with seropositive rheumatoid arthritis: a 20 year study. *Rheumatology* (Oxford). 1999; 38: 1138-41.
- 52. BARRETT EM, SCOTT DG, WILES NJ, SYM-MONS DP: The impact of rheumatoid arthritis on employment status in the early years of disease: a UK community-based study. *Rheu matology* (Oxford). 2000; 39: 1403-9.
- 53. CHORUS AMJ, MIEDEMAHS, WEVERS CWJ, VAN DER LINDEN: Work factors and behavioural coping in relation to withdrawal from the labour force in patients with rheumatoid arthritis. Ann Rheum Dis 2001; 60: 1025-32.

- 54. ETHGEN O, KAHLER KH, KONG SX, REGIN-STER J-Y, WOLFE F: The effect of health related quality of life on reported use of health care resources in patients with osteoarthritis and rheumatoid arthritis: a longitudinal analysis. J Rheumatol 2002; 29: 1147-55.
- 55. WOLFE F, ZWILLICH SH: The long-term outcomes of rheumatoid arthritis: a 23-year prospective, longitudinal study of total joint replacement and its predictors in 1,600 patients with rheumatoid arthritis. *Arthritis Rheum* 1998; 41: 1072-82.
- 56. PINCUS T, CALLAHAN LF, SALE WG, BROOKS AL, PAYNE LE, VAUGHN WK: Severe functional declines, work disability, and increased mortality in seventy-five rheumatoid arthritis patients studied over nine years. *Arthritis Rheum* 1984; 27: 864-72.
- LEIGH JP, FRIE JF: Mortality predictor among 263 patient with rheumatoid arthritis. *J Rheumatol* 1991; 18: 1307-12.
- 58. SOKKA T, HAKKINEN A, KRISHNAN E, HANNONEN P: Similar prediction of mortality by the health assessment questionnaire in patients with rheumatoid arthritis and the general population. *Ann Rheum Dis* 2004; 63: 494-7.
- 59. GREENWOOD MC, DOYLE DV, ENSOR M: Does the Stanford Health Assessment Questionnaire have potential as a monitoring tool for subjects with rheumatoid arthritis? *Ann Rheum Dis* 2001; 60: 344-8.
- 60. GARDINER PV, SYKE HR, HASSEY GA, WALKER DJ: An evaluation of the health assessment questionnaire in long-term longitudinal follow-up of disability in rheumatoid arthritis. *Br J Rheumatol* 1993; 32: 724-8.
- 61. UHLIG T, SMEDSTATD LM, VAGLUM P, MOUM T, GERARD N, KVIEN TK: The course of rheumatoid arthritis and predictors of psychological, physical and radiographic outcome after 5 years of follow-up. *Rheuma* tology 2000; 39: 732-41.
- 62. WILES N, BARRETT J, BARRETT E, SILMAN A, SYMMONS D: Disability in patients with early inflammatory polyarthritis cannot be "tracked" from year to year: an examination of the hypothesis underlying percentile reference charts. *J Rheumatol* 1999; 26: 800-4.
- 63. PINCUS T, SUMMEY JA, SORACI SA JR, WALLSTON KA, HUMMON NP: Assessment of patient satisfaction in activities of daily living using a modified Stanford Health Assessment Questionnaire. *Arthritis Rheum* 1983; 26: 1436-53.
- 64. BLINDMAN AB, KEANE D, LURIE N: Measuring health changes among severely ill patients: the floor phenomenon. *Med Care* 1990; 28: 1142-52.
- 65. WORLD HEALTH ORGANIZATION. INTERNATION-AL CLASSIFICATION OF FUNCTIONING, DISABILI-TYAND HEALTH (ICF). Geneva: World Health Organization; 2001.

Appendix: Italian and English versions of the ROAD questionnaire

Le risposte alle domande - Answers to questions

- 0 = Sì, senza difficoltà Without any difficulty
- 1 = Possibile, con lieve difficultà With slight difficulty
- 2 = Possibile, con qualche difficoltà *With some difficulty*
- 3 = Possibile, con molta difficultà With great difficulty
- 4 = Impossibile *Unable to do*

Vorremmo che Lei rispondesse alle seguenti domande relative alle Sue normali attività volte nel corso dell'ultima settimana. - Please, answer the following questions regarding your usual activities over the past week

F1 - Funzionalità arti superiori - Upper Extremity Function

E'in grado di: - Are you able to:

- 1. Chiudere completamente la mano a pugno? Close your hand completely?
- 2. Accettare una stretta di mano? Accept a hand shake?
- 3. Abbottonarsi gli abiti? *Do up buttons?*
- 4. Svitare un coperchio di un barattolo già aperto in precedenza? Open jars which have been previously opened?
- 5. Raggiungere e afferrare un oggetto del peso di circa due chili posto sopra la Sua testa? *Reach up and take down a 2 Kg object from above your head?*

F2 - Funzionalità arti inferiori - Lower Extremity Function

- 6. Stare in piedi in posizione eretta? *Stand up*?
- 7. Camminare su un terreno piano? *Walk on flat ground?*
- 8. Salire un piano di scale (esempio 5 gradini)? *Climb up five steps or stairs?*
- 9. Salire e scendere dalla macchina? Get into and out of a car?

 $F3-Attivit{\`a}\ della\ vita\ quotidiana\ /lavorativa\ -\ Activit{\'a}\ of\ daily\ living/work$

- 10. Lavare ed asciugare tutto il corpo? Wash and dry your body?
- 11. Fare attività vigorose quali trasportare oggetti o borse pesanti? Run errands and shop?
- 12. Svolgere un lavoro retribuito o attività domestiche? Are you still able to do housework or/and your paid job?

ROAD SCALE CONTENTS AND SCORING.

Scale	Number of items	Raw score range	Normalization
1. Upper extremity function	5	0-20	*S x 0.5
2. Lower extremity function	4	0-16	S x 0.625
3. Activity of daily living/work	3	0-12	S x 0.833

*S=Added raw score values.