Elaboration of the preliminary Rheumatoid Arthritis Impact of Disease (RAID) score: a EULAR initiative

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ABSTRACT

Background: Current response criteria in rheumatoid arthritis (RA) usually assess only three patient-reported outcomes (PROs): pain, functional disability and patient global assessment. Other important PROs such as fatigue are not included.

Objective: To elaborate a patient-derived composite response index for use in clinical trials in RA, the RA Impact of Disease (RAID) score.

Methods: Ten patients identified 17 domains or areas of health relevant for inclusion in the score, then 96 patients (10 per country in 10 European countries) ranked these domains in order of decreasing importance. The seven most important domains were selected. Instruments were chosen for each domain after extensive literature research of psychometric properties and expert opinion. The relative weight of each of the domains was obtained from 505 patients who were asked to "distribute 100 points" among the seven domains. The average ranks of importance of these domains were then computed.

Results: The RAID score includes seven domains with the following relative weights: pain (21%), functional disability (16%), fatigue (15%), emotional well-being (12%), sleep (12%), coping (12%) and physical well-being (12%). Weights were similar across countries and across patient and disease characteristics. Proposed instruments include the Health Assessment Questionnaire and numerical ratings scales.

Conclusion: The preliminary RAID score is a patient-derived weighted score to assess the impact of RA. An ongoing study will allow the final choice of questionnaires and assessment of validity. This score can be used in clinical trials as a new composite index that captures information relevant to patients.

Rheumatoid arthritis (RA) is traditionally assessed by physical examination by a physician, by laboratory tests and radiographs, in keeping with a "biomedical model," the dominant paradigm of 20th century medicine. However, since the start of the new millennium there has been growing interest in assessment of RA from the patient's perspective. Patient-reported outcomes (PROs) have been found to be as informative as joint counts, radiographic and laboratory data for the assessment of baseline status, change during interventions, and are predictive of long-term outcomes.[1–8] Current assessment of RA takes into account some PROs—namely, patient assessment of pain, functional disability and/or patient global assessment. These elements are recognised both by the American College of Rheumatology (ACR)[9 10] and the European League Against Rheumatism (EULAR),[11] and are assessed in the ACR criteria,[12] the Disease Activity Score (DAS)[13] as well as more recent measures such as the Simplified Disease Activity Index (SDAI), the Clinical Disease Activity Index (CDAI)[14 15] and the mean overall index of RA (MOI-RA)[16] and two PRO composite measures, the patient activity scale (PAS)[17] and the Routine Assessment of Patient Index Data 3 (RAPID3).[18] Formal quantitative joint counts, an integral part of the DAS, SDAI and CDAI, are frequently not performed in routine clinical practice.[19] The RAPID3 has been shown to be as efficient as the DAS and CDAI to detect changes in clinical trials,[18 20] and to be correlated with DAS and CDAI in usual clinical settings.[21] Current PRO composite scores therefore appear very useful. However, these scores only include three PROs, while other dimensions of health may be important from the patient's perspective and are included in clinical questionnaires such as the multidimensional Health Assessment Questionnaire (HAQ).[21] More complex generic quality of life instruments such as the Short Form (SF)-36[22] and the Arthritis Impact Measurement Scale (AIMS2)[23] capture information regarding several other domains including mental health and social functioning.

Over the last few years, expert panels and focus groups have indicated that the patient's perspective is not adequately reflected by only the three PROs: pain, function and patient's global. The Outcome Measures in Rheumatology Clinical Trials (OMERACT) international research meetings in 2002[24] and several focus group studies have indicated that other PROs are important for people with RA, such as fatigue, well-being and sleep pattern.[25–30]

The objective of the present work, under the aegis of EULAR, is to elaborate and validate a composite response score for clinical trials in RA based on patients' perception of the impact of the disease on domains of health: the patient-derived preliminary RA Impact of Disease (RAID) score. This paper addresses the elaboration of the score.

Table 1 Seventeen domains of health ranked for importance by 96 patients with RA

Domain*	Mean (SD) rank	Median rank	Order of domains by median	Patients giving rank 1–7 to the domain (%)	Patients giving rank 1–3 to the domain (%)
Pain	4.3 (4.2)	2	1	78.1	59.4
Functional disability	6.3 (3.9)	5.5	2	64.6	30.2
Fatigue	6.7 (4.2)	6	3	61.4	26.0
Physical well-being	8.3 (4.9)	9	5	44.8	24.0
Coping	8.8 (4.4)	9	5	41.7	16.7
Sleep	8.9 (4.8)	8	4	45.8	13.5
Emotional well-being	8.9 (4.0)	9	5	33.3	8.3
Being a burden to others	9.0 (4.6)	9.5	9	40.6	15.6
Family life	9.3 (5.3)	10	11	38.5	20.8
Satisfaction with health care	9.5 (5.1)	9	5	37.5	18.7
Anxiety	9.5 (4.5)	9.5	9	37.5	12.5
Ability to fulfil social role	9.5 (4.6)	10	11	35.4	11.5
Depression	10.0 (4.5)	10	11	32.3	9.4
Drug side effects	10.1 (4.8)	11	15	33.3	8.3
Professional life	10.2 (4.8)	10	11	33.3	12.5
Sexuality	11.2 (5.2)	12	16	23.9	10.4
Socioeconomic issues	11.5 (4.6)	13	17	27.1	5.2

*Domains are ordered by mean rank.

METHODS

Step 1: Identification and selection of candidate domains for the RAID score

Initial choice of domains

Ten patients with RA, one from each of 10 European countries, met in Zurich in March 2007. All had definite RA according to the ACR criteria,[31] spoke English and were selected by the principal investigators in each country. They had varying experience in research partnership; three are also part of the OMERACT patient group.

The patients were presented with an extensive literature review on domains of health in RA. During a ''focus group'' type meeting and in three successive sessions, the participants identified domains of health important for the patient based on their personal experience.

Ranking of domains

The steering committee had arbitrarily decided, on the basis of feasibility, to include in the composite score a maximum of seven domains. After the first step the resulting number of domains was too large so, to reduce the number of domains and to obtain better representativeness, a ''ranking'' strategy was designed.

One hundred patients with RA (10 in each country) were contacted by the principal investigator and/or by the patient representative. These people all had definite RA; there were no other selection criteria.

The names of the domains obtained in the previous step were translated into 12 languages with a brief explanation and presented as a list in random order. The participants were asked to rank the domains in order of decreasing importance by giving a number between 1 (most important) and 17 (least important) to the 17 domains. No other data were collected at this stage (May–June 2007). The seven highest-ranked domains were retained in the RAID score.

Step 2: Identification of instruments to measure the candidate domains

The participants were the steering committee, the principal investigators and two external experts (GAW and JPD). This was a data-driven process. One or several items, instruments or whole questionnaires were selected for each domain by consensus after an extensive literature review of published questionnaires, their psychometric properties[32] and their frequency of use.[33] When there were no available validated instruments, a numerical rating scale (NRS) was formulated by the group and validated with the 10 patients with arthritis who participated in the first step. Validated translations of the instruments were then collated; if these translations were not available, a translation/validation process was performed into 12 languages (Estonian, Dutch, Finnish, French, German, Greek, Italian, Norwegian, Romanian, Russian, Spanish, Turkish). The process included two separate translations, simple consensus, back-translation and cross-cultural validation by a multidisciplinary consensus committee, followed by pretesting on five patients.[34 35]

Step 3: Relative weight of the candidate domains to be included in the score

To allow aggregation of results into a single composite criterion, it was necessary to determine the relative importance of the different domains of health. It was decided that the relative importance should be based on patients' opinion,[36] so a weighting strategy was designed.

It was planned to include 500 patients (50 from each country). Selection criteria were definite RA,[31] ability to fill in a questionnaire and signed informed consent. Between June and November 2007, eligible patients filled in a questionnaire and were asked to ''distribute 100 points'' among the seven domains according to a method described by Ruta *et al*[37] and modified for our purposes. The question was: ''We want you to indicate how much your RA impacts your health in the following selected domains or dimensions; please distribute 100 points between the domains according to their impact''. In one country the arithmetic appeared too complicated and the process was performed with the same question but by asking patients to distribute 100 matches between the seven domains, materialised by papers.

The following other variables were also collected by the questionnaire: demographic data (age, sex, symptom duration, work status), Health Assessment Questionnaire (HAQ),[38] pain,

Table 2 The seven domains included in the preliminary RAID score, corresponding instruments and the weight attributed to each domain by 505 patients

Domain	Questionnaire	Mean (SD) weight/100	Median (IQR) weight/100	Ranked weight/100
Pain	NRS	21 (23)	12 (12–24)	21
	Pain questions of SF36			
Function	NRS	19 (16)	15 (7–24)	16
	HAQ			
	Modified HAQ			
Fatigue	NRS	17 (15)	12 (6–24)	15
Emotional well-being	NRS	12 (14)	12 (0–17)	12
Sleep	NRS	11 (12)	12 (0–18)	12
	MOS sleep disturbance subscale			
Coping	NRS	11 (12)	12 (0–18)	12
	Coping questionnaire			
Physical well-being	NRS	9 (12)	7 (0–12)	12

IQR, interquartile range; SD, standard deviation; HAQ, Health Assessment Questionnaire; MOS, Medical Outcome Study subscale (4 questions); NRS, numerical rating scale; Coping questionnaire: 20 questions derived from a validated coping questionnaire.[42] Weights are expressed as linearly transformed to a 0–100 range. The ranked weight was obtained by analysing the relative ranks of importance, then linearly transforming the result to a 0–100 scale.

patient global assessment and fatigue on visual analogue scales (VAS) and SF-36.[22]

Mean and median weights for each domain were computed and linearly transformed to a 0–100 range. Ranks of importance of domains (based on these points) were identified in each participating patient; for example, if a domain received 20 points and was the second most important domain it was given rank 2, whereas it was given rank 4 if the points were similar but it was the fourth domain. Mean and median ranks were then also computed for the whole group of 500 patients and linearly transformed to a 0–100 range. It was decided to use these ranks as the basis for the final weights.

Step 4: Assessment of the generalisability of the preliminary RAID

Using the data obtained from the elaboration of the RAID (both ranking and weighting), the extrinsic applicability of the relative importance attributed to the domains was assessed.

Data from the ranking process were used to compare ranks of importance of domains across countries.

- Groups of domains: domains were analysed in groups according to the original categorisation performed by the 10 initial patients with some modifications: fatigue was considered as a domain in itself as its importance is high in the published qualitative literature.[24 25 27] For each patient, a group of domains was attributed "high priority" if at least one of the domains in the group was given rank 1, 2 or 3 (out of a possible 17).
- Countries: the percentage of patients attributing high priority to each group of domains was compared between countries using the Fisher exact test.
- Groups of countries: countries were classified as high or low gross domestic product (above or below the median) according to 2005 data. High priority groups of domains were compared between these groups of countries using the Fisher exact test.

Data from the weighting process were used to analyse weights across demographic and disease characteristics. Weights were analysed as binary measures (dichotomised by median). By multiple component analysis, demographic (age, sex, disease duration) and activity/severity data (pain VAS, HAQ, fatigue VAS, global assessment VAS, SF36) were projected on the axes created based on dichotomised weights to assess potential relationships.

RESULTS

Step 1: Identification and selection of candidate domains for the RAID score

Initial choice of domains

The 10 patients with RA held three sessions to identify 17 domains. In the first session 80 different areas/words were reported; in the second session these areas were categorised into physical, psychological, social and general dimensions and simultaneously reduced to 32 areas (see Appendix 1 in the online supplement); and in the third session the patients with arthritis and the professionals together performed a regrouping of similar concepts which led to 17 domains.

Ranking of domains

The results of the ranking of the 17 domains by 96 patients are shown in table 1, including the mean and median ranks. The percentage of patients attributing high ranks to each domain is shown in the last two columns.

The following seven highest ranked domains were selected for the RAID score: pain, functional assessment, fatigue, sleep disturbance, physical well-being, emotional well-being and coping (table 2). Although slightly less prioritised, emotional well-being was selected because it potentially "covers" several concepts rated highly (ie, being a burden to others and anxiety).

Step 2: Identification of instruments to measure the candidate domains

A simple question (assessed by NRS) and often a more complete validated instrument/questionnaire were selected for each domain (see Appendix 2 in online supplement). The final choice of instruments will be performed based on the ongoing validation study. For each domain a simple carefully worded question[39] scored by NRS is proposed. For pain, the NRS is compared with the two pain questions issued from the SF-36.[22] For functional assessment, the NRS is compared with the 20-question HAQ[38] and with the modified HAQ (8 questions).[40] Sleep NRS is assessed against the four questions of the Medical Outcome Study (MOS) sleep disturbance subscale,[41] and coping is assessed by NRS and a 20-question coping questionnaire modified from a validated coping questionnaire.[42]

Table 3 Description of the 505 patients participating in the weighting process

Characteristic	Mean (SD), (range) or N (%)*	Range across countries of mean (SD) or %†
Female, N (%)	411 (82.5%)	72.0–97.3%
Age (years)	55.9 (13.2), (20.3–86.9)	48.5 (15.1)–60.4 (15.3)
Symptom duration (years)	14.5 (10.3), (1.3–57.0)	12.3 (10.6)–16.8 (11.0)
Formal education (years)	11.5 (4.5), (0–20)	7.4 (3.7)–14.5 (3.4)
Employed full-time or part-time when symptoms started, N (%)	293 (58.9%)	48.0–72.0%
Currently employed full-time or part-time, N (%)	149 (28.6%)	14.0–54.0%
Work disabled, N (%)	190 (41.0%)	30.4–68.1%
HAQ	1.23 (0.78), (0–3)	1.00 (0.74)–1.56 (0.80)
Pain VAS over 1 week (0–100)	44 (29), (0–100)	30 (22)–55 (25)
Patient global assessment VAS (0–100)	43 (25), (0–100)	32 (22)–50 (27)
Disease activity assessment over 6 months VAS (0–100)	45 (27), (0–100)	36 (24)–60 (24)
Fatigue VAS over 1 week (0–100)	46 (28), (0–100)	38 (27)–51 (32)
Morning stiffness duration (min)	70 (130), (0–360)	28 (31)–87 (75)
SF36 aggregated physical score	34.4 (10.4), (10.3–62.0)	28.1 (10.1)–37.4 (11.0)
SF36 aggregated emotional score	46.5 (12.2), (13.4–71.4)	41.6 (12.4)–51.6 (11.6)

*Results are presented as mean (SD) unless otherwise stated. Percentages are % of available data.
†Range of means or percentages: minimum and maximum values for means or percentages observed in participating countries.
HAQ, Health Assessment Questionnaire; SF36, Short Form 36 generic quality of life scale; VAS, visual analogue scale.

Step 3: Relative weight of the candidate domains to be included in the score

In total, 505 patients participated in the weighting process (table 3). Their mean (SD) age was 55.9 (13.2) years, mean (SD) disease duration was 14.5 (10.3) years, mean (SD) HAQ score was 1.23 (0.78) and 82% were women. The relative ranked weights for aggregation into a composite score were as follows (table 2): pain 21%, functional disability 16%, fatigue 15%, and emotional well-being, sleep, coping and physical well-being 12% each.

Step 4: Assessment of the generalisability of the preliminary RAID

Data from the ranking process

The 17 domains were analysed in five groups (table 4). At least one domain in each group was attributed high priority ranking with the following percentages: physical group, 81% (range across countries 40–100%); psychological group, 47% (range 30–70%); socioeconomic group, 40% (range 10–83%); fatigue, 26% (range 10–40%); and general group, 30% (range 10–60%). There were no significant differences across countries or groups of countries except for the physical group of domains, which was more often highly rated in countries with lower gross domestic product (92% vs 70%, p = 0.007, table 4).

Data from the weighting process

The first three axes contributed 68.6% to the total inertia. The domains that most contributed to the construction of axis 1 and which were best and similarly represented by that axis were pain and emotional well-being. A high score allocated to emotional well-being appeared to be associated with a higher score for pain. The variables that most contributed to the construction of axis 2 were functional disability, sleep and fatigue, the first two domains being best represented by axis 2. It appeared that higher scores for function were related to lower scores for the other two domains and vice versa. Physical well-being and sleep contributed most to the construction of axis 3.

Demographic and disease variables were projected on the axes: these variables were on the centre (data not shown), indicating that the demographic and disease variables did not explain the weights attributed to the different domains.

DISCUSSION

In this report a preliminary patient-derived score to assess the impact of RA from the patients' perspective is proposed. The score includes seven domains prioritised by patients. The domains of highest importance were pain, functional disability and fatigue; the four other domains were emotional and physical well-being, sleep disturbance and coping. The similarity of patient-perceived impact across different countries and different patient and disease characteristics strengthens the relevance and generalisability of the preliminary RAID score.

No single variable is considered sufficient to assess RA disease activity and composite indices are well adapted to this situation. Composite indices such as the DAS, the SDAI, the CDAI, MOI-RA, PAS and RAPID3 have been validated.[13–18] However, concerns have been raised that these indices may not adequately capture all patient-relevant data, which was the basis for the development of this new tool. However, patient-reported data are strongly colinear, so adding more variables may not add to information over the existing indices on a group level, which will need to be further explored.

The impact of RA is perceived by patients in different domains of health. Relevant domains were selected through a

Table 4 Attribution of high priority ranking to groups of domains by 96 patients: comparisons across countries

Group of domains	Domains included	Percentage with high priority	Range of percentages	Percentage in 5 countries with higher GDP	Percentage in 5 countries with lower GDP	p Value
Physical	Pain, functional disability, physical well-being, sleep disturbance	81	40–100	70	92	0.007
Psychological	Depression, anxiety, emotional well-being, feeling a burden to others, coping	47	30–70	50	44	0.7
Socioeconomic	Professional life, social role, family life, socioeconomic issues	40	10–83	39	40	0.9
General	Sexuality, drug side effects, satisfaction with health care	30	10–60	30	30	0.9
Fatigue	Fatigue	26	10–40	28	24	0.6

GDP, gross domestic product/capita in 2005.

patient-derived process, first by a focus group type meeting with 10 patients followed by a ranking process including 96 patients. The final selection of domains is in keeping with the published qualitative literature as pain, functional disability and fatigue appear to be of utmost importance to many patients[24–30] and were the first three domains in the ranking process. Only these three domains obtained consistently high ranks for impact. Pain and functional disability are part of the RA Core Set[9] and are regularly cited as important by patients with RA.[25 27–29] Fatigue is a frequent aspect of RA, as initially reported by the OMERACT patient group.[24 25] Other domains reported in the literature as important include well-being, sleep disturbance, coping, social life, professional status (ability to work) and satisfaction with health care.[24–30] In the present study, sleep, physical and emotional well-being and coping were also selected. Based on the ranking results, however, it can be seen that these domains did not stand out among the other domains. The International Classification of Functioning, Disability and Health (ICF) is a generally accepted framework to assess the biopsychosocial model of disease.[29] It is interesting to note that the domains selected in the RAID were also selected in ICF-based focus groups,[29] except for well-being. Patient global assessment was not selected by the patients with RA in the present study; it is possible that the notions of emotional and physical well-being translate ''patient global'' into terms more understandable for patients.

In the ranking process the physical group of domains was most often ranked highly, followed by the psychological group. Patient perception of the impact of RA on the physical group of domains was ranked higher in countries with lower gross domestic product, possibly because many patients in these countries still experience remarkable functional disability.[43] Interestingly, other impacts including psychological dimensions and fatigue were similar across countries. The domains selected for entry into the RAID score therefore appear relevant for patients across countries.

Not all domains selected and prioritised by patients can easily be measured. For example, well-being—though recognised as an important concept[24 25]—is not currently assessable. In such cases specific questions were elaborated by the authors. In other cases such as functional disability, it was impossible to select only one questionnaire based on the available literature. Coping was also a challenge as many coping questionnaires are available but there is no consensus on which is the most appropriate to use in RA.[44] Thus, in all, 12 instruments were selected for the seven domains. The final choice of one instrument per domain will be made after the ongoing validation study.

The weights attributed to each domain were based on the patients' scoring of the importance of the domains by name or description. When analysing weights according to baseline patient and disease characteristics, it appeared that patients rated the domains independently of their demographic characteristics. Thus, gender did not significantly influence the results, nor did age or disease duration. The weights attributed to the domains were also independent of the patients' personal status. For example, it seems that patients are able to distinguish their current level of pain from the impact they attribute to pain in RA, even if previous studies have indicated a statistical association between perceived pain intensity and pain as a prioritised area for improvement.[45 46] However, the overall independence between health status and perceived impact on RA support the notion that the selected seven domains are relevant for patients across demographic and disease activity/severity characteristics. We recognise that other approaches could have been applied to weigh the domains, such as a statistical evaluation of the relative importance of the actual scores of patient responses to questionnaires concerning function, pain, fatigue and other domains.

The ongoing next step is the validation of the preliminary RAID score in a large European study. Objectives of the ongoing study include assessment of psychometric properties of the RAID score, including its face, construct and external validity (and correlation with other validated scores) and discrimination, according to the OMERACT filter.[47] A final choice of domains will be performed based on these results. Coping or other domains will be excluded if psychometric properties are insufficient. A final choice of instruments will also be performed. Secondary objectives will be the elaboration of cut-off points to provide a patient-acceptable symptom state and minimal clinically important improvement for the RAID.[48] The RAID is viewed as an additional instrument for the assessment of RA in clinical trials, giving supplementary information on patient-relevant domains.

This study has strengths and weaknesses. Weaknesses include the necessary selection of some patients to elaborate the score, as they may not be representative; however, it should be noted that the characteristics of the patients participating in the weighting study (including their education level) were very similar to those of patients participating in an unselected cross-sectional study, the QUEST-RA.[43] Another limitation was the decision, for feasibility reasons, to limit the number of domains to seven. Strengths include the central involvement of patients for elaboration of the RAID and the inclusion of patients with RA from 10 countries with different cultures and socioeconomic backgrounds. Furthermore, the methodology used to obtain patient-derived weights is innovative and could be applied to other conditions.

In conclusion, this study enabled us to propose a preliminary patient-derived weighted score to assess the impact of RA. We consider that this RAID score will be of value in clinical trials as a new composite index that captures information which is relevant for patients, although its value still needs to be established in comparison with existing PRO indices. The process is in itself important, by involving patients and rheumatologists from 10 different countries.

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