Incorporating patient reported outcome measures in clinical practice: development and validation of a questionnaire for inflammatory arthritis

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Abstract

Background

Rheumatology is embarking on a fundamental redesign of rheumatic disease care. It has become mandatory not only to recognise disease activity core set data, but also the risks for other co-morbidities associated with inflammatory arthritis. Measurement of patient reported outcomes have become critical in both standard clinical practice and long term observational studies.

Objectives

To assess validity, reliability and responsiveness to change of a patient self-reported questionnaire which can assess construct outcome measures of patients with inflammatory arthritis.

Methods

Four hundred and sixty-two patients with inflammatory arthritis were included in this work. The questionnaire was developed by integrating information obtained from patients suffering from inflammatory arthritis based on the Rasch model for ordered response options. The questionnaire includes assessment for functional disability, quality of life, VAS for joint pain, global status, fatigue, duration of morning stiffness, review of the systems, falls and cardiovascular risks, self-helplessness, as well as self reported joint pain.

Results

The questionnaire was reliable as demonstrated by a high-standardised alpha (0.891-0.992). The questionnaire items correlated significantly ($p<0.01$) with clinical parameters of disease activity. RA patient reported tender joints correlated significantly with the physician's scores (0.842). Changes in functional disability, quality of life as well as self-helplessness scores showed significant ($p<0.01$) variation with disease activity status. The PROMs questionnaire also showed a high degree of comprehensibility.(9.4).

Conclusion

Integrating patient reported outcome measures into standard clinical practice is feasible and applicable. This version of a multidimensional questionnaire was found to be valid and reliable. It provides informative quantitative measures for the disease activity core set data, and in the mean time, facilitates assessing the patients' health related quality of life measure, cardiovascular and falls risks on an individual basis.

Key words

Patient reported outcome measures, inflammatory arthritis, EROMIA, electronic data recording.

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Introduction

Rheumatoid arthritis (RA) is a chronic, progressive disease characterised by pain, physical impairment, fatigue, disability, psychiatric changes and increased co-morbidity (1). With the availability of the new biologic agents for treatment of RA and the introduction of the quality improvement movement into rheumatology, the development of a valid and feasible approach to handle RA patients in the outpatient setting has become an area of active research (2, 3). Because of the nature of the disease causing multi-systemic affection, the focus has been on the development of disease indices that can incorporate both objective (*e.g.* acute phase reactants and radiographic imaging results) and subjective (*e.g.* joint count and patient assessment of disease activity) measurements (4-6).

Patient reported outcome measures (PROMs) are an attractive option in a busy medical practice, as the time burden is transferred from the clinician to the patients (7). The importance and value of PROMs of health status and health related quality of life in RA has been emphasised in several reports (8, 9). A multidimensional health assessment questionnaire (MDHAQ) has been adapted from the health assessment questionnaire for usual care (10, 11). More recently, the comprehensive International Classification of Functioning, Disability and Health (ICF)-Core Set for RA was introduced (12). This is composed of 96 categories representing aspects in the functioning of patients with RA. The ICF-Core Set for RA has given an extra depth into functional disability and quality of life that has not been fully covered by the previous multidimensional health assessment questionnaires. The interest in rheumatoid arthritis has gone beyond joint affection to include systemic co-morbidities. In 2008, EULAR issued 10 recommendations for cardiovascular risk management in patients with rheumatoid arthritis (RA), ankylosing spondylitis, and psoriatic arthritis (13). Falls are another common co-morbidity among RA patients (14). Neither cardiovascular risk nor falls risk was included also in the earlier multidimensional health assessment questionnaires (10, 11). In a recent article, Pincus and Sokka (15) noted that further improvements in the patient questionnaires are anticipated over time. A deeper understanding of the disease impact as well as the recent trend of global assessment of the patients highlights the need to develop new tools that would widen the scope of the patients' care.

Earlier research studies have established the value of patient questionnaires. The questionnaire provides a better understanding of what is happening to patients and allows the treating health care physician to monitor the effectiveness of care provided better than information from laboratory tests, radiographs, and other traditional medical sources. One of the reasons that use of self-report questionnaires has not caught on among rheumatologists may be that clinicians are not familiar with them and may be concerned that use of patient questionnaires in their practices may impede rather than enhance the care of the patient (16, 17). While swollen and tender joint counts as well as levels of acute-phase reactants and global severity represent disease process measures as specified in the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR), guidelines for clinical trials (18, 19). Anxiety, depression, helplessness, fatigue, lack of self-efficacy and social support are measures that act as outcome modifiers. On the other hand, work disability, total joint replacement, and mortality are complete, or final, outcomes. Some factors may play dual role *e.g.* pain, sleep disturbance, functional disability or psychological status may be a process reflecting inflammation or pain, but more usually is considered as an outcome (17).

This study was carried out to assess validity, reliability and responsiveness to change of a patient self reported questionnaire which can assess construct outcome measures of patients with inflammatory arthritis.

Patients and methods

Patients

The patients' questionnaire has been incorporated into our routine clinical

practice for the last 4 years. Data from patients with inflammatory arthritis were consecutively gathered. This included 264 rheumatoid arthritis patients, 123 with psoriatic arthritis and 75 patients with inflammatory bowel disease associated arthritis. RA patients were diagnosed according to the approved ACR criteria for diagnosis of rheumatoid arthritis (20). Psoriatic arthritis patients were diagnosed according to the ESSG criteria (21). Patients with inflammatory arthritis were treated according to the NICE guidelines (22). TNF-alpha inhibitor therapy was considered should the patients fail 2 two disease modifying drugs, one of them being methotrexate.

All patients were asked to fill out the multidimensional patient reported outcome measures questionnaire, presented in a self-administered paper format whilst sitting in the waiting area prior to their assessment in the rheumatology clinic.

The Multidimensional Patient Reported Outcome Measures (PROMs) Questionnaire

– *The questionnaire (appendix 1) included*

1. Using Rasch analysis for ordered response options and item pools of questions for functional disability and quality of life, content analysis and semi structured group discussion, the combined inflammatory arthritis questionnaire (CIAQ) was developed including: 10-item scale to assess functional impairment (CIAQ-FI), and 10-item scale to assess quality of life (CIAQ-QoL). Prior to the study, the construct validity and reliability of the two questionnaires were assessed in 534 RA patients, 246 psoriatic arthritis and 241 patients with inflammatory bowel disease associated arthritis and results revealed that Cronbach's alpha for CIAQ-FI was 0.90 and had no misfitting items, whereas Cronbach's alpha for CIAQ-QoL was 0.92. The two questionnaires showed accepted validity as it correlated significantly with clinical parameters of disease activity, DAS-28 score, as well as CRP (p<0.01) (23). The patients should respond using one of the four standard response options: 0=without any difficulty, 1=with some difficulty, 2=with much difficulty and 3=unable to do. The mean score for each of the functional disability as well as quality of life indices is calculated and the total score ranged from 0–3.
2. Modified rheumatology attitude index including 10-item questions and using a numeric rating of "0-10 cm" Visual Analogue Scale to score each item. A mean score is calculated across all items. The total score ranged from 0–10. The modified self-helpless index, which is a modification of the original rheumatology attitude index (24), was derived from interviews with patients suffering from inflammatory arthritis and spondyloarthritis, content analysis and semi structured group discussion. The modified rheumatology attitude index (mRAI) includes: a 10-item scale and scored using the numeric VAS on 0-10. Prior to the study, the validity, reliability and sensitivity to change of the newly developed scale was studied in 241 RA patients, 211 psoriatic arthritis, and 134 patients with inflammatory bowel disease associated arthritis. Results showed accepted validity as it correlated significantly (p<0.01) with clinical parameters of disease activity, DAS-28 score, CRP as well as both CIAQ-FI and CIAQ-QoL. On the other hand, the Cronbach's alpha was 0.89-0.92. A significant correlation was observed in percentage change and effect size of the mRAI and changes in disease activity parameters as well as DAS-28 score (p<0.001).
3. Disease activity parameters, namely joint pain, patient global assessment, and fatigue score, assessed using numeric rating "0–10-cm" horizontal visual analogue scales (VAS) that contains half units, where a score of 0=no symptoms, and a score of 10=very severe symptoms. The range is 0–10.
4. Assessment of the duration of morning stiffness in minutes.
5. Self report joint tenderness: this was carried out on a joint diagram with the joint names written beside it as a guide, and the patients were asked to tick the box matching the painful joint(s) (25).
6. A checklist of 39 common symptoms, which are incorporated into a structured "review of systems". In addition to 5 questions to assess for the falls risk and 8 questions to assess for the cardiovascular risk (26). In addition, each patient completed a copy of the Stanford HAQ (27).

Clinical evaluation

Full history, including disease duration, assessment for articular as well as extra-articular manifestations, revision of the current medications and assessment for possible cardiovascular as well as falls risks were carried out for every patient. Each patient was then subjected to full clinical examination to assess for the parameters of the disease activity including number of tender and swollen joints, physician overall assessment score and the presence of extra-articular sings.

Each patient had a blood check for ESR and CRP levels, lipid profile, Rheumatoid factor, anti-CCP, ECG, carotid Doppler and haemoglobin A_1c. (The erythrocyte sedimentation rate (ESR) measured using Westergren's method and CRP using ELISA technique).

Validation

The routine clinic was used as a setting for the questionnaire evaluation. All patients were asked to complete the PROMs questionnaire while sitting in the waiting area before being examined by the treating physician. A supervising nurse was present to provide help, if needed. The PROMs questionnaire was validated by comparing its yield to a group of other instruments' results that explore different disease activity parameters:

Disease activity assessment

This was carried out by:

a. Assessment of the tender joint count: by scoring tenderness to pressure and joint manipulation on physical examination; the types of tenderness are collapsed into a single tender versus non-tender dichotomy for each point. The scores for each patient were summed over 28 joints.

b. Swollen joint count. Analogous to tender joint count, the scores of 28 joints for each patient were summed.
c. The patiens global health assessment (PGH) of disease activity measured on a continuous 0–10 cm visual analogue scale (VAS).
d. Grip-strength, which was measured using a grip strength tester (manufactured by Pharma design Inc, Warren NJ, USA). The tester is simply a gauge to measure a patient's grip strength and its scale is rated from 0 to 10, where 10 is the maximum strength.
e. Disease Activity Score (DAS-28) (28).

Cardiovascular risk was assessed by SCORE (29). Cardiovascular risk score was calculated by multiplying the derived CV risk estimate by 1.5 if at least two of the following criteria are present: disease duration of more than 10 years, RF and/or anti-CCP positivity, presence of severe extra-articular manifestations (13).

Reliability and comprehensibility

Test-retest reliability (reproducibility) was assessed by asking the patients to complete a second copy of the questionnaire one week after the initial visit to the rheumatology department, when they completed the first copy. If the patients were in need of one of the fast working therapies, *e.g.* local injections, this was scheduled to be carried out on the 7th day after completing their second copy of the questionnaire. "Analysis of properties of the questionnaire" was set as a justification for completing the questionnaire for the second time. After completing the questionnaire for the first time, every patient was asked to rate the questionnaire out of 10 to assess for the comprehensibility.

Responsiveness

Responsiveness has been described as the ability of an instrument to measure clinically important change over time with change at present (30). Sensitivity to change of the PROMs questionnaire was assessed in 146 patients who were treated with anti-TNF therapy. Patients completed the questionnaire before and 3 months after treatment. Changes in the questionnaire scores were compared to changes of other disease activity parameters including DAS-28.

Table I. Demographic and clinical characteristics of the studied patients.

Characteristic	Parameter
Age, mean (SD)	59.6 (9.6)
Female, n (%)	328 (71.9)
Disease, n (%)	
• Rheumatoid arthritis	264 (57.1)
• Psoriatic arthritis	123 (26.6)
• Inflammatory Bowel Disease	75 (16.2)
Disease duration in years, median (IQR) min-max	4 (0.8–7.0), 0.1–40.0
Tender joint count by Patient, mean (SD)	7.1 (7.3)
Tender joint count by Physician, mean (SD)	6.9 (7.7)
Swollen joint count by Physician, mean (SD)	1.2 (0.6)
HAQ, mean (SD)	2.13 (0.8)
Grip strength	
• Right, mean (SD)	6.9 (2.7)
• Left, mean (SD)	7.1 (2.7)
CIAQ-FI	2.20 (0.7)
CIAQ-QoL	2.13 (0.9)
Modified Rheumatology Attitude Index	6.8 (1.3)
ESR, mean (SD) mm/h	32.2 (18.4)
CRP, mean (SD) mg/dl	16.6 (25.4)

ESR: erythrocyte sedimentation rate, CRP: C-reactive protein.

Data recording

The patients reported outcome measures, medications taken and past DMARD/biologic therapy as well as details of tender and swollen joints were recorded electronically using the: Electronic Recording Outcome Measures for Inflammatory arthritis and Ankylosing spondylitis (EROMIA) software (31, 32) which was carried out as part of the patient assessment and management in the standard clinic. The disease activity score (DAS-28), cardiovascular risk, as well as falls risk were calculated electronically and the patients were made aware of the outcome. The course of the disease and response to therapy were also assessed on the spot and showed to the patients as charts, offering a visual feedback to the patients regarding his management.

Local ethical and methodological protocols for approval of the study were followed.

Statistical analysis

Statistical manipulation was performed using the 11th version of SPSS. Variables are summarised in the form of mean and standard deviation if continuous, and frequency distribution if categorical. Median and Inter-quartile range (IQR) were calculated for skewed data. The Pearson correlation coefficient was used to figure out the correlation between quantitative variables. Error bars and scatter diagram were used to illustrate deviations and correlation respectively of different variables. Changes in the PROMs questionnaire were calculated by subtracting the second record from the first record. The intra-class correlation coefficient for agreement (reliability) and consistency was calculated, and the alpha statistic was calculated as an additional measure of reliability. Validation was tested by calculation of the Spearman's correlation coefficient with the tested questionnaire and the selected confirmatory tests. *p*-value is significant if less than 0.05.

Results

Four hundred and sixty-two patients with inflammatory arthritis were included in this work to assess the validity and reliability of the PROMs questionnaire: 71.9% were females (n=328) and their mean age was 59.6 years old ranging between 25 and 84 years old. The median disease duration was 4 years. Table I shows clinical and laboratory characteristics of the studied groups of patients.

Applicability and feasibility of the PROMs

The mean time to complete the ques-

Table II. Patients with inflammatory arthritis**:** Correlation of the PROMs items with the disease activity parameters assessed by the physician as well as the inflammatory markers (ESR and CRP) as validating tools.

Items of the PROMsQ	TJC (Physician assessed)	SJC (Physician assessed)	Grip Strength		Physician global assessment	Original HAQ	ESR	CRP	DAS-28
			Right	Left					
CIAQ-FI	0.442**	0.168*	-0.461**	-0.583**	0.619**	0.933**	0.269**	0.369**	0.641**
CIAQ-QoL	0.793**	-0.679**	-0.560**	-0.564**	0.682**	0.552**	0.621	0.521**	0.782**
Pain score	0.256**	0.063	-0.169*	-0.261**	0.488**	0.113	0.604**	0.382*	0.645**
Patient global assessment	0.317**	0.121	-0.256**	-0.358**	0.546**	0.250**	0.121	0.421**	0.671**
Fatigue score	0.428**	0.425**	-0.128	-0.223*	0.364*	0.059	0.578**	0.478**	0.764**
Morning stiffness	0.313**	0.312**	-0.249*	-0.297*	0.397**	0.248**	0.079	0.379*	0.464**
Patient TJC assessment	0.822**	0.416**	-0.361**	-0.351**	0.533**	0.453**	0.302*	-0.402**	0.576**
mRAI	0.562**	0.635*	-0.472*	-0.410**	0.516**	0.684**	0.429**	0.429**	0.741**

**$p<0.01$, *$p<0.05$

TJC: tender joint count; SJC: swollen joint count; RAI: Rheumatology Attitude Index; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; CIAQ-FI: Combined Inflammatory Arthritis Questionnaire-Functional Impairment; CIAQ-QoL: Combined Inflammatory Arthritis Questionnaire-Quality of Life; mRAI: modified Rheumatology Attitude Index.

tionnaire was 8.25±0.25 minutes. The mean time to scan and score the patients' answers was 20.61±1.38 seconds, whereas the mean time to record the patient data was 31.43±2.61 seconds. Data entry into the proforma was performed during the assessment of each patient.

Four hundred and twenty-nine (92.8%) assigned the PROMs questionnaire as comprehensive giving scores higher than or equal to 8.5. Only two patients recorded a score of 7 out of 10. A mean score of 9.4 was reported by the interviewed patients (95% CI 9.2–9.6)

Validity

To assess the validity of the PROMs questionnaire items were compared to the parameters of disease activity, Table II shows the correlation of the PROMs items with the disease activity parameters assessed by the physician as well as the inflammatory markers (ESR and CRP) in the arthritic patients included in this work.

Variation in the "Functional impairment" showed a limited range for confidence interval. The "quality of life score" demonstrated more variations in psoriatic arthritis and RA.

Comparing the CIAQ-FI to the Stanford HAQ among patients with inflammatory arthritis (Fig. 1) revealed a significant correlation with r=0.933, p<0.001 among RA patients. Similar significant correlations were found in patients suffering from psoriatic arthritis (r=0.927).

There was also a significant correlation between tender joint count assessed by the patient, using the joint diagram for tender joint assessment, in relation to physician report joint tenderness (r=0.822, p<0.001). Table III shows the correlation of the patient self-reported tender joint count to the PROMs items in different arthritic conditions included in this study.

Reliability

Minimal changes ranging between -0.03 and 0.06 were noticed when repeating the CIAQ for functional impairment assessment while the quality of life score demonstrated changes ranging between 0.02 and 0.11 (Table IV).

The standardised alpha as well as the intra-class correlation coefficient (ICC) showed a relatively high value for the functional impairment, quality of life as well as modified rheumatology attitude index scores.

Assessment of falls risk revealed that 249/462 (53.9%) of the rheumatoid arthritis patients had a positive history of changing their gait or walking speed, whereas 189/462 (40.9%) gave a history of more than one fall during the past year. Increased falls risk among rheumatoid arthritis patients was significantly correlated (p<0.01) to DAS-28 score, HAQ score, CIAQ-FI, tender joint count, ESR and CRP titre. Similarly, there was an increased

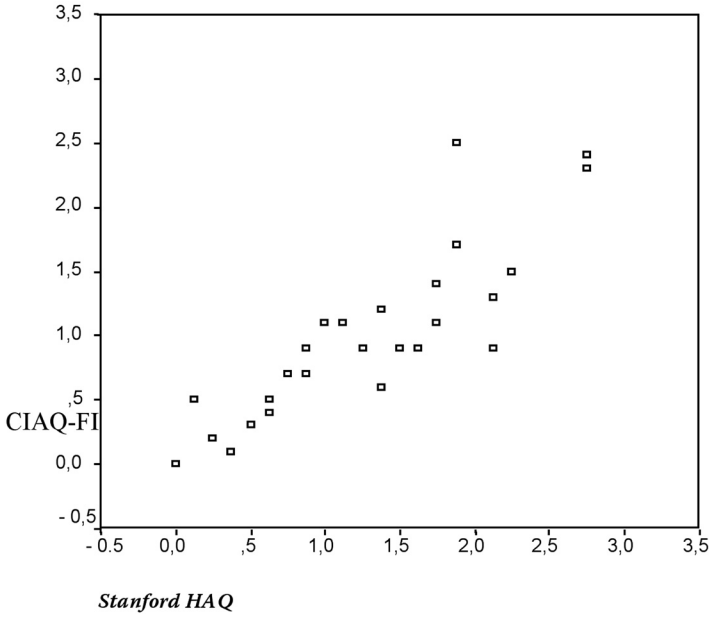

Fig. 1. Scatter diagram displaying correlation of the CIAQ-FI with the Stanford HAQ amongrheumatoid arthritis patients. r=0.933, p-value <0.001* HS.

prevalence of the cardiovascular risk factors among arthritic patients. The prevalence for CV risk factors among rheumatoid arthritis patients was 38% for hypertension (mean systolic 140.4 mmHg (±13.6), mean diastolic 89.3 mmHg (±14.0)), 20% for diabetes mellitus, 13% for hyperlipidemia, 12% for ischemic heart disease and 13% for hyperlipidemia. The 10-year CV risk among RA patients was 10.5% (±0.64); whereas the 10-year CV risk in psoriatic arthritis patients was 9.5% (±0.57).
57.7% of the patients (267/462) reported sexual difficulties with their partner (143/267 (53.6%) were males and 124 (46.4%) were females). Among the male patients, 46/143 patients (32.2%) put their difficulties down to their joint pain, whereas 67.8% (97/143 patients) attributed it to erectile dysfunction.

Table III. Correlation of the patient reported tender joint count to the PROMs items in different arthritic conditions included in this study.

Items of the PROMsQ	RA n=82	Psoriatic arthritis n=57	IBD n=57
CASQ-FI	0.585**	0.605**	0.780**
CASQ-QoL	0.490**	0.085	0.745**
Pain score	0.500**	0.484*	0.661**
Patient global assessment	0.488**	0.398	0.782**
Fatigue score	0.782**	0.447**	0.712**
Morning stiffness	0.446**	0.600**	0.447**
Physician global assessment	0.471**	0.458**	0.432**
Physician TJC assessment	0.842**	0.799**	0.839**
mRAI	0.768**	0.672*	0.757**

**$p<0.01$, *$p<0.05$
TJC: tender joint count; SJC: swollen joint count; RAI: rheumatology attitude index; CIAQ-FI: Combined Inflammatory Arthritis Questionnaire-Functional Impairment; CIAQ-QoL: Combined Inflammatory Arthritis Questionnaire-Quality of Life; mRAI: modified Rheumatology Attitude Index; RA: rheumatoid arthritis, IBD: inflammatory bowel disease.

Table IV. Reproducibility of PROMs Questionnaire.

	First measure mean (SD)	Change mean (95% CI)	Standardised alpha	ICC (95% CI)
CASQ-FI	1.1 (0.8)	0.01 (-0.03 – 0.06)	0.9928	0.912 (0.894-0.931)
CASQ-QoL	1.2 (0.9)	0.07 (0.02 – 0.11)	0.9645	0.931 (0.912 – 0.947)
Joint Pain	6.4 (1.2)	0.11	0.891	0.83 (0.81-0.85)
Fatigue Score	7.6 (1.1)	0.1	0.911	0.85 (0.83-0.87)
mRAI	7.6 (0.47)	0.07 (0.05-0.09)	0.942	0.944 (0.936 – 0.952)

CIAQ-FI: Combined Inflammatory Arthritis Questionnaire-Functional Impairment; CIAQ-QoL: Combined Inflammatory Arthritis Questionnaire-Quality of Life; mRAI: modified Rheumatology Attitude Index; ICC: Intraclass coefficient.

Discussion

Earlier data (15, 33), revealed that any 3 or 4 of the RA Core Data Set measures, including joint counts, inflammatory markers, patient self-report scores, or global estimates, can be compiled into a pooled index that functions equally well to one another and to the DAS, CDAI, RAPID3, and likely RADAI5. However, studies indicated that physicians may underestimate the severity of patients' pain and functional disability (34-35). Other studies revealed that patient self-report RA Core Data Set measures appear as sensitive, or even more sensitive than physician or assessor-reported data (36-42) and are more likely to be abnormal in patients with RA than an erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) in RA (43).

Results of this study revealed that the multidimensional PROMs questionnaire was valid, reliable and sensitive to change of the disease activity. Health related quality of life measures were assessed using the combined inflammatory arthritis questionnaire for functional disability and quality of life. The combined questionnaire items covered the main components identified by the ICF Core Set for RA (12). Results of this work agreed with the earlier findings (23, 44), which revealed that the combined inflammatory arthritis questionnaire was a valid and reliable tool for assessment of health related quality of life as well as functional disability measures in patients with inflammatory arthritis. In the study carried out by Uhlig *et al*. (45), the ICF Core Set for RA demonstrated moderate responsiveness in the real-life setting of patients where minor changes occurred during treatment. However, it has to be highlighted that the ICF was not designed as a measure of health status, and the main objective of the ICF was to describe important aspects of health and not to measure them. Results of this study showed that the PROMs questionnaire did manage to cover this gap, being comprehensible, valid, reliable and showed good response to therapy.

The patient reported outcome measures questionnaire evolved from experience in using the original HAQ in routine care (15), trials to assess disease activity and to meet the recent guidelines and recommendations (EULAR and NICE) (13, 22, 28) regarding monitoring of the disease as well as its comorbidities in the standard clinical practice. In contrast with the lengthy research questionnaires (such as SF-36 and ICF) (12), which are often the only types of questionnaires known to most clinicians from clinical trials and other research studies, the patient reported outcome measure questionnaire assessed in this work has been designed specifically for standard clinical practice, with attention paid not only to validity and reliability as primary criteria for any questionnaire, but also to feasibility and acceptability in busy clinical settings. The recent trend in assessment of patients suffering from inflammatory arthritis entails a comprehensive approach. Earlier questionnaires, such as RAPID 3 (46) and RADAI5 (47) focused mainly on the RA Core Data Set to assess the disease activity. Other parameters such as functional disability and self-reported joint count have been excluded from assessment of the RADAI5. A fact that contradicts with

the findings from other studies which found these parameters playing an important role and contributing significantly to the ongoing patients' care (15, 48).The multidimensional health assessment questionnaire (MDHAQ) (10) is an elegant and more comprehensive tool to assess RA patients. Being more than 10 years old, it lacks the assessment of the more recent comorbidities associated with inflammatory arthritis and its authors anticipate further improvements in the MDHAQ over time (15). The PROMs tool assessed in this study is a step forward toward comprehensive assessment of the patients. In addition to the well-documented disease activity parameters, it includes thorough assessment of the disease impact on the patient (quality of life, self-helplessness, ability to work, family relationships); systemic affections, cardiovascular and falls risk assessment, which are not included in other questionnaires. This comes in a patient-friendly format and excellent cost/time-benefit ratio.

Patient self-reported joint pain has been studied in earlier researches (49-51), which revealed no significant difference on comparing tender joints reported by the patients versus that reported by the treating physician. In a cross sectional study, RA patients' self-assessment showed significant correlation with trained assessors' joint count (49). In another study (50), it was found that intra-observer reliability for tender joint count was excellent for patients, physician and nurse (ICC 0.95, 0.98 and 1 respectively). Also, the patient-derived DAS-28 was at least as reliable as those assessed by the physician and the nurse (51). Scoring templates to facilitate scoring and recording of the main Core Set measures was included in the PROMs questionnaire studied in this work. The 10 activities of functional disability as well as quality of life can be quickly totalled and scored. The VAS used a numeric scale, rather than the traditional 10 cm line, to facilitate scoring without a ruler. A similar scoring template system was used earlier to facilitate calculating the total RAPID3 score (37) where it was reported that such templates added to the utility in the standard clinic setting and facilitated the disease activity scoring from the three core set data measures. In contrast to the multidimensional health assessment questionnaire (11), which used a flow sheet to record the scores on one page, a computer automated system was used to record and track patients' data in this work. The Electronic Recording of Outcome Measures of Inflammatory arthritis and Ankylosing spondylitis (EROMIA) (30) has had a positive impact on the patients' management. In a recent article (52), a Standard Protocol to Evaluate Rheumatoid Arthritis (SPERA) has been suggested to collect essential data from patients and health professionals to assess, monitor, and document changes in standard clinical care and clinical research. Three one-page forms are completed by a health professional assessor, which can be completed at baseline for use at all future visits and include data about: 1) clinical features of rheumatoid arthritis (RA); 2) medications taken; and 3) a 42-joint count. The authors concluded that the 15-20 minutes involved in completing the SPERA generally add efficiency to subsequent visits in standard clinical care. Collection of additional information for clinical care and/or clinical research is also possible. The SPERA was presented not as an optimal format but rather as an example of a possible approach to develop a common format for core clinical data to be collected in standard clinical care. In contrast, another study (31) found that electronic data recording facilitated documentation of the clinical measures, medications as well as scoring of the disease activity (DAS score) in a significantly shorter time than that recorded in the SPERA protocol (52). Also scoring of risk factors and highlighting tender and swollen joints in a colourful format made the "eyeball" review of the PROMs very easy and in a minimal time. This was carried out in the clinic setting both at baseline and in all the follow up visits without any extra effort from the treating physician or health care professional. Also, assessment of the patients' disease course in the clinic enabled the patients to see their response to therapy in graphs, which helped to improve the patients' adherence to therapy. A recent study (53), educating the RA patients about their disease showed a significant improvement in disease-specific knowledge and general health perception with no harmful effects on their psychosocial status noticed. The PROMs questionnaire used in this study was in a paper format. A recent study (54) investigated the acceptability, feasibility, reliability of collecting rheumatoid arthritis (RA) patient-reported outcome (PRO) data using an interactive touch-screen computer system. Results revealed that computer touch-screen questionnaires were well accepted by RA patients, with good data quality, reliability and score agreement.

Results of this study revealed that assessing the patients' health related quality of life as well as self helplessness showed the highest *r*-value in correlation with parameters of disease activity, which reflected the patients' perception of their disease activity status, benefits of the therapeutic intervention as well as the results of any potential adverse effects. In fact, the self-helplessness score was the most sensitive measure to reflect how patients perceive their overall response to therapy. In addition, the PROMs questionnaire allowed assessment of the patients' ability to work. In a recent study, linking together self-reported data about functioning and work load helped in early identification of the RA patients at risk for loss of working days (55).

By itself rheumatoid arthritis is an independent cardiovascular risk factor. The link between RA and cardiovascular events has been proven in both chronic active and severe forms as well as early forms of arthritis (56, 57). Results of this study revealed that hypertension, diabetes mellitus and hyperlipidemia were the most prevalent risk factors. In a recent study done to assess cardiac involvement in RA patients using a comprehensive cardiac magnetic resonance approach (58), myocardial involvement was frequent in RA patients without known cardiac disease. In systematic review (59), it has been reported that methotrexate reduces cardiovascular risk in RA pa-

tients. Recently, EULAR released its evidence-based recommendations for cardiovascular risk management in patients with inflammatory arthritis (13). It was highlighted that inflammatory arthritis should be regarded as a condition associated with higher risk for cardiovascular disease. The increased risk appears to be due to both an increased prevalence of traditional risk factors and the inflammatory burden.

Adequate control of disease activity is necessary to lower the CV risk has been advised. CV risk assessment has been recommended for all RA as well as psoriatic arthritis patients on an annual basis (22). Risk score models should be adapted for RA patients by introducing a 1.5 multiplication factor. Getting the patients involved with identifying their risk factors for cardiovascular disease and electronic assessment of the cardiovascular risk, not only help the treating rheumatologist, but also have a positive impact on the time-benefit ratio and quality of care given to the patients (31).

Patients with RA have an increased risk of fractures and falls compared to healthy controls (14). Assessment for falls risk in this study, using the PROMs questionnaire, revealed that its prevalence was 53.9%. In a study carried out to assess the incidence of falls in RA patients (60), there was significant correlation ($p<0.01$) between increased falls risk among rheumatoid arthritis patients and DAS-28 score, HAQ score, CIAQ-FI, tender joint count, ESR and CRP titre. In another study carried out to assess the risk factors for falls in RA patients, it was found that functional disability, tender joint counts, and impaired general health were significantly associated with falls in RA patients (61).

Intimate interpersonal relationship has been included in the comprehensive ICF Core set for RA. PROMs questionnaire has helped to identify this group of patients as the results of this study showed that 57.7% has difficulties in the sexual relationship with their partners. In a recent study, 57 RA male patients were assessed for erectile dysfunction. 68% of the patients were suffering from this problem. In comparison to patients suffering from other chronic diseases, it was found that erectile dysfunction was more common in patients with RA compared with other chronic conditions, and in particular in those with known cardiovascular disease. It has been recommended that assessment for erectile dysfunction should be included in the holistic approach of RA patients (62).

In conclusion, patient reported outcome measures are considered central for standard clinical practice as well clinical trials. Disease specific standardised clinical data sets will need to replace narrative documentation. Integrating patient reported outcome measures of disease activity and responsiveness into standard clinical practice is feasible and applicable. This new version of multidimensional questionnaire was found to be valid and reliable not only provide informative quantitative measure for the disease activity core set data, but also facilitate assessing the patient's cardiovascular and falls risk on individual basis. Electronic recording of the data gave an opportunity for documentation, rational monitoring as well as enhanced efficiency of the patients' care.

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Multi-Dimensional Questionnaire for Patient Reported Outcome Measures

This questionnaire includes information not available from blood tests, X-rays, or any source other than you. Please try to answer each question. There is **no right or wrong answer**. Please answer exactly as **YOU** think or feel.

1.We are interested in learning how your illness affects your ability to function in daily life. Please tick (√) the ONE best answer that describes your usual abilities OVER THE PAST WEEK:

RAQ-FI

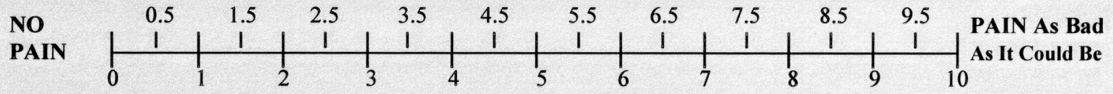
Over the LAST WEEK, were you able to	Without ANY Difficulty	With SOME Difficulty	With MUCH Difficulty	Unable TO DO
1. Get on and off the toilet?	.....	.....	.....	.....
2. Use your grip strength e.g. open previously opened Jars Or lift a saucepan during cooking?	.....	.....	.....	.....
3. Dress yourself, including tying shoelaces & doing buttons?	.....	.....	.....	.....
4. Stand up from a chair without arms?	.....	.....	.....	.....
5. Wait in a line for 15 minutes?	.....	.....	.....	.....
6. Reach and get down a 5-pounds-object (such as a bag of sugar) from just above your head?	.....	.....	.....	.....
7. Walk outdoors on a flat ground?	.....	.....	.....	.....
8. Go Up 2 or more flights of stairs?	.....	.....	.....	.....
9. Do house work / DIY jobs around the house?	.....	.....	.....	.....
10. Move heavy objects?	.....	.....	.....	.....

RAQ-Qol

					Not Applicable
1. Get a good night's sleep?	.....	.....	.....	.....	.....
2. Deal with the usual stresses of daily life?	.....	.....	.....	.....	.....
3. Cope with social/ family activities?	.....	.....	.....	.....	.....
4. Deal with feelings of anxiety or being nervous?	.....	.....	.....	.....	.....
5. Deal with feelings of low self esteem or feeling blue?	.....	.....	.....	.....	.....
6. Get going in the morning?	.....	.....	.....	.....	.....
7. Do your work as you used to do?	.....	.....	.....	.....	.....
8. Deal with any worries about your future?	.....	.....	.....	.....	.....
9. Continue doing things you used to do, despite tiredness?	.....	.....	.....	.....	.....
10. Continue your relationship with your partner (husband/wife)?	.....	.....	.....	.....	.....

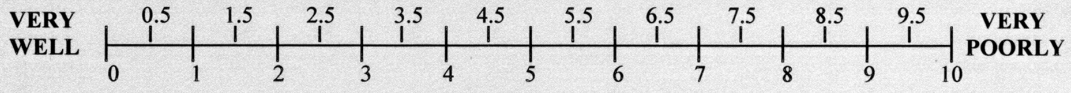
2. How much PAIN have you had because of your arthritis OVER THE PAST WEEK?
Please put a circle around the number that best indicates your level of pain:

Pain



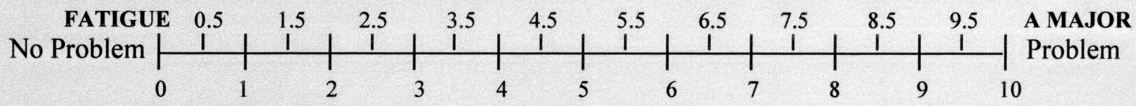
3. Considering all the ways your arthritis may be affecting you AT THIS TIME
Please put a circle around the number that best indicates how well you are doing:

PGA



4. How much of a problem has UNUSUAL FATIGUE or tiredness been for you OVER THE PAST WEEK? (please put a circle around the number that best indicates your fatigue)

Fatigue



5. OVER THE LAST WEEK when you awakened in the morning, did you feel stiff?

MS

YES: ☐ Please indicate the number of **minutes** ....., or **hours** ..... until you are as limber as you will be for the day.

No: ☐

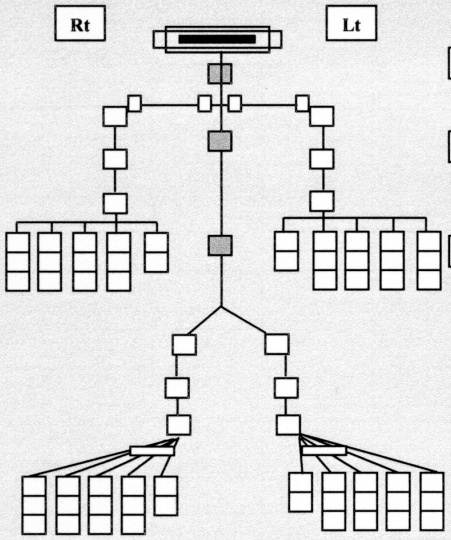
6. Please place a (X) in the appropriate box to indicate in which of your joints you feel painful TODAY.

Alternatively you can put a figure 1, 2 or 3 to describe the severity of the pain you feel in any joint as follows:

1 = mild pain,
2 = moderate pain,
3 = severe pain.

Tender Joint count

Shoulder	
Elbow	
Wrist	
Knuckles / Fingers	
Hip	
Knee	
Ankle	
Top Foot	
Toes	



7. Please tick (√) if you have experienced any of the following OVER THE LAST MONTH:

						Cardiovascular Risk Assessment	
Fever		Dry Eye		Gynecological problem		Age > 50 years old	
Weight gain (> 10 lbs)		Dry Mouth		Short plans for having a baby		High Blood pressure	
Weight Loss (> 10 lbs)		Other eye problems		Sexual Relationship Problems		High Cholesterol	
Loss of appetite		Problems with smell or taste		Problems with erection (for men)		Current Smoker	
Lump in the throat		Headache		Numbness or tingling		Ischemic Heart Disease	
Trouble swallowing		Wheezing		Muscle pain, ache or cramps		Stroke	
Soreness in the mouth		Cough		Weakness/ Paralysis of arms or legs		Overweight/under weight	
Skin Rash		Heartburn		Absent from work due to joint pain		Diabetes Mellitus	
Swollen Glands		Stomach pain or cramps		> 3 Alcoholic drinks per day		The section below is for official use. Please do not tick	
Unusual bruising or bleeding		Feeling Sickly / Nausea		Falls Risk Assessment			
Other skin problems		Constipation		Impaired balance			
Loss of hair		Diarrhea		Problems with your sight		Sex: Male / Female	
Problems with hearing		Dark or bloody stools		Weakness of your grip strength		BMI: ≥ 30 / < 20	
Ringing in the ears		Shortness of breath		>1 Fall in the last year		DAS:	
Problems with thinking/memory		Problems with urination		Change in Gait / Slow walking speed		Total Score:	

8. The statements below concern your personal beliefs. Please circle the number that best describes how do you feel about the statement. 0 = Not at all; 10 = Strongly Agree

RAI

	0 1 2 3 4 5 6 7 8 9 10
1. My condition is controlling my life.	
2. I would feel helpless if I could not rely on other people for help with my condition.	
3. I am concerned that medicines can not help me.	
4. I've concerns regarding side effects of medications used to treat my condition.	
5. I often do not take my medicines as directed.	
6. No matter what I do, or how hard I try, I just can not seem to get relief from my symptoms.	
7. I am not coping effectively with my condition.	
8. Sometimes I feel my condition is beyond both my and my doctor's control.	
9. Sometimes my condition makes me feel like giving up.	
10. Due to my condition, sometimes I feel I am a burden to those close to me.	

Date: / / 200

☐ I consent to my clinical data being used for research/audit.

Signature of the patient: .....

Patient:

D.O.B.: