Psychometric properties of sleep and coping numeric rating scales in rheumatoid arthritis: a subanalysis of an etanercept trial

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Abstract

Objective

In rheumatoid arthritis, quality of sleep and ability to cope are important for patients; however their usefulness as outcome measures is not well established.

Methods

Post-hoc analysis of an open-label 12-week trial of etanercept in biologic-naïve rheumatoid arthritis patients with visits at screening, baseline and over 12 weeks. Outcomes measured included Disease Activity Score 28 erythrocyte sedimentation rate (DAS28), numeric rating scales for sleep, coping, patient and physician-global assessment, pain and fatigue, and modified-HAQ. Reliability between screening and baseline visits by intra-class correlation, and responsiveness between baseline and 12 weeks by standardised response means were assessed for each outcome.

Results

In 108 patients, mean age 54 (standard deviation (SD) 13) years, mean disease duration 8 (SD 7) years, 75% women; disease activity was high at baseline: mean DAS28 5.5 (SD 0.8). Reliability intra-class correlation was 0.83[95% confidence interval: 0.77;0.88] for sleep, 0.81[0.74;0.87] for modified-HAQ, 0.80[0.71;0.86] for fatigue, 0.72[0.62;0.80] for physician-global assessment, 0.66[0.54;076] for coping, 0.65[0.53;0.75] for pain and 0.63[0.50;0.73] for patient-global assessment. Responsiveness standardised response means was 1.65[1.32;2.10] for physician-global assessment, 1.37[1.09;1.73] for pain, 1.36[1.08;1.73] for patient-global assessment, 1.15[0.95;1.41] for fatigue, 0.96[0.70;1.28] for coping, 0.92[0.73;1.15] for sleep and 0.86[0.69;1.07] for modified-HAQ.

Conclusion

Numeric rating scales assessing sleep and coping were found to be generally as reliable as 'usual' outcomes in rheumatoid arthritis. Responsiveness was less high, indicating these domains of health may be less accessible to biologic treatment. When assessing the patient's perspective on treatment, it is feasible and valid to measure sleep and coping by numeric rating scales.

Key words

rheumatoid arthritis, patient-reported outcomes, coping, sleep, psychometric properties

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Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory disease with a heavy burden on patients' overall health and quality of life, both directly - as a consequence of joint inflammation and damage – and indirectly – because of fatigue, sleep disturbances, psychological and social consequences. Objective measures of disease activity, such as acute phase reactants, and physician reported outcomes, such as joint counts, are insufficient to capture the whole impact of disease on patient's lives. Patient-reported outcomes (PROs) allow a better understanding of how RA patients perceive their disease and the effect of treatment. Current recommendations are to assess four PROs in trials - pain, patient global assessment of disease activity (PGA), functional capacity and fatigue (1–5). However, several other domains of health are recognised by RA patients as important though they are rarely assessed in clinical trials (6–9). These include quality of sleep and ability to cope (10).

Sleep disturbances are reported by a majority of RA patients and may be explained by disease activity as well as other important health domains, such as fatigue, or co-morbidities such as depression or obesity (11, 12). Evidence suggests that sleep correlates with disease activity in RA, although it is not as responsive to treatment as other outcomes (13–15).

Coping has been defined as "a response to a stressful or negative incident" (16), and in RA patients it refers to the way in which patients deal with their disease (17). It has long been shown that passive pain coping strategies result in greater pain and depression (18). Although both of these domains of health are important for patients with RA, there is little information on the potential usefulness of sleep and coping as outcome measures in trials (5). Some studies in RA have assessed sleep using the Sleep Problems Index II of the Medical Outcomes Study (MOS) sleep scale, a validated, 12-item questionnaire that assesses sleep problems in chronically ill populations (19, 20). However, no individual psychometric properties have been published for simple numeric rating scales (NRS) assessing sleep or coping specifically in RA patients, to our knowledge. NRS are useful because they are simple and feasible. Sleep and coping were included in the RA Impact of Disease - RAID score, a composite measure of RA impact which includes 7 questions (NRS), assessing pain, functional capacity, fatigue, physical and emotional well-being, sleep and coping (10). In our study we use individual NRS questions from the RAID score to assess sleep and coping.

New outcome measures in rheumatology need to show good psychometric properties according to the OMERACT filter (21). They must prove themselves reliable, *i.e.* stable when repeated in situations of no change, and responsive, *i.e.* able to detect change in situations of change. Anti-tumour necrosis factor (TNF) and in particular etanercept has demonstrated substantial efficacy in RA, thus we would expect outcome measures of RA disease activity to improve with etanercept treatment, at the group level.

The objectives of this study were to assess the reliability and responsiveness after introduction of etanercept of sleep and coping, evaluated by NRS, and to compare their reliability and responsiveness to that of other well-validated outcome measures.

Methods

Study design

This was a post hoc analysis of a French multicentre, open-label, single-arm trial with a screening visit, baseline visit (assuming patient disease activity was stable across the two visits) and visits after 4 and 12 weeks of etanercept therapy (clinicaltrials.gov allocated number NCT 00768053: Evaluation of EULAR-RAID Score in Rheumatoid Arthritis Patients (Rainbow) (22)). Etanercept was administered sub-cutaneously at 50 mg/week, generally with methotrexate as comedication (22). For each patient, written informed consent was obtained and the study was approved by the Institutional Review Board of Cochin Hospital, Paris, France.

Inclusion criteria

Briefly, patients had definite RA fulfill-

ing the 1987 criteria of the American College of Rheumatology (23). The disease had to be active according to the following definition: Disease Activity Score 28-erythrocyte sedimentation rate (DAS28-ESR) >3.2 and at least one of the following: ≥4 swollen joints or C-reactive protein (CRP) ≥10 mg/l or ESR ≥28 mm/1st H, and the patient had to be biologic naïve and eligible for TNF blocker therapy as defined by the French Society of Rheumatology (24).

PROs of interest

RAID questions on sleep and coping are formulated as follows (10):

- Sleep: circle the number that best describes the sleep difficulties (*i.e.* resting at night) you felt due to your rheumatoid arthritis during the last week: *No difficulty to extreme difficulty;*
- Coping, self-management: considering your arthritis overall, how well did you cope (manage, deal, make do) with your disease during the last week? *Very well to very poorly.*

The single-question NRS scales for sleep and coping included in the final version of the RAID score were compared to longer questionnaires – namely, an 18-question coping questionnaire (25) and the MOS sleep questionnaire (26) – in the initial development of the RAID and the single questions had similar psychometric properties (10). Moreover, longer questionnaires were associated with more missing data.

Comparison outcomes

'Standard' PROs were individually assessed for comparison purposes: pain NRS, PGA, mHAQ and fatigue NRS. The DAS28 (27), modified health assessment questionnaire (mHAQ) (28), RAID questionnaire (7 NRS questions (scored 0–10) then summed with variable coefficients, final result is 0–10) (10), tender and swollen joint counts, patient and physician global assessment (NRS) were collected at screening, baseline and after 4 and 12 weeks of etanercept therapy (22).

Demographic data

Patients' age, gender and disease characteristics (duration, anti-citrullinated protein antibody (ACPA) status) were collected at screening.

Statistical analyses

Reliability and responsiveness were assessed both for the PROs of interest and comparison PROs, but also for DAS28 and for physician global assessment (NRS), and tender and swollen joint counts.

Reliability was assessed between screening and baseline visits by intra-class correlation (ICC). Reliability is considered high when >0.80 Responsiveness was assessed between baseline and 12 week visits, by standardised response means (SRM), *i.e.* change divided by standard error of change. Responsiveness is considered high when >1 (21). Confidence intervals were calculated by bootstrapping.

Only patients with at least 1 etanercept injection were analysed. Patients who withdrew before week 12 were analysed for determining reliability but were not analysed for responsiveness. There was no imputation of missing data.

The Statistical Analysis System v. 9.0 was used.

Table I. Characteristics at baseline of RA patients in the etanercept trial.

Characteristic	Responsiveness population - patients who completed week 12, n=97	Reliability population - patients who received at least 1 etanercept injection, n=108
Age, years, mean (SD)	53.5 (12.8)	53.6 (12.9)
Women, n (%)	73 (75.3)	81 (75.0)
RA duration, years, mean (SD)	8.1 (7.0)	8.0 (6.8)
RF or ACPA positive, n (%)	64 (72.7)	69 (71.1)
DAS28-ESR, mean (SD)	5.5 (0.8)	5.5 (0.8)
Swollen joint count, n (SD)	8.8 (4.2)	8.6 (4.1)
Tender joint count, n (SD)	10.7 (5.9)	10.7 (5.8)

SD: standard deviation; RA: rheumatoid arthritis; RF: rheumatoid factor; ACPA: anti-citrullinated peptide antibody; DAS28-ESR: Disease Activity Score 28 - erythrocyte sedimentation rate.

Results

In all, 120 patients were screened in 18 centres; 108 patients were analysed for reliability and 97 for responsiveness (22). Patient characteristics are presented in Table I. Mean age was 54 years, disease duration 8 years, 73 (75%) were women. At baseline, patients had high disease activity: DAS28-ESR was 5.5±0.8.

Etanercept reduced disease activity at 12 weeks: mean DAS28 was 3.4±1.2; patient-reported outcomes improved: mean pain and PGA were 6.5±1.8 and 6.5±1.9 at baseline *versus* 3.1±2.3 and 3.3±2.3 at 12 weeks, respectively (Table II). Sleep also showed substantial improvement during follow-up (5.5±2.8 at baseline, 2.9±2.8 after 12 weeks) as did coping (4.8±2.0 at baseline, 2.6±2.3 after 12 weeks).

Reliability of PROs (Table II) was highest for sleep: ICC 0.83 [95% confidence interval, [CI: 0.77;0.88], and lowest for PGA: 0.63, [CI: 0.50;0.73] and pain: 0.65 [CI: 0.53;0.75]. Coping showed intermediate reliability: 0.66 [CI: 0.54;0.76], higher than PGA and pain but lower than mHAQ: 0.81 [CI: 0.74;0.87] and fatigue: 0.80 [CI: 0.71;0.86].

Responsiveness among PROs (Table II) was highest for pain: SRM 1.37, [CI: 1.09; 1.73] and PGA: 1.36, [CI: 1.08; 1.73], and lowest for mHAQ: 0.86, [CI: 0.69; 1.07]. Responsiveness for coping: 0.96 [CI: 0.70–1.28] and for sleep: 0.92 [CI: 0.73–1.15] was higher than for mHAQ but lower than for the other Core Set PROs in RA – pain, PGA and fatigue: 1.15 [CI: 0.95–1.41].

Joint counts and PhGA were more responsive than PROs but not more reliable (Table II).

Discussion

In the present study individual NRS assessing sleep and coping showed good psychometric properties and were found to be generally as reliable as 'usual' PROs in RA, such as pain, PGA, fatigue and mHAQ. Sleep was found to be as reliable as more objective measures of disease activity. Coping showed similar reliability to other "usual" PROs such

Table II. Disease outcomes at screening, baseline and after 12 weeks of etanercept; reliability and responsiveness of each outcome measure.

Characteristic	At screening	At baseline	At 12-weeks	Reliability ICC [95% CI]	Responsiveness SRM [95% CI]
Swollen joint count	8.2 (3.8)	9 (4)	2.2 (2.5)	0.89 [0.85;0.92]	1.80 [1.59; 2.08]
Tender joint count	10.3 (5.9)	11 (6)	4.2 (4.8)	0.90 [0.85;0.93]	1.20 [0.97;1.47]
Physician global assessment	6.0 (1.3)	6.0 (1.4)	2.6 (2.0)	0.72 [0.62;0.80]	1.65 [1.32;2.10]
Pain	6.6 (1.7)	6.5 (1.8)	3.1 (2.3)	0.65 [0.53;0.75]	1.37 [1.09;1.73]
Patient global assessment	6.7 (1.6)	6.5 (1.9)	3.3 (2.3)	0.63 [0.50;0.73]	1.36 [1.08;1.73]
mHAQ	0.8 (0.5)	0.9 (0.5)	0.4 (0.5)	0.81 [0.74;0.87]	0.86 [0.69;1.07]
Fatigue NRS	6.4 (2.3)	6.3 (2.2)	3.4 (2.7)	0.80 [0.71;0.86]	1.15 [0.95;1.41]
Sleep NRS	5.4 (2.9)	5.5 (2.8)	2.9 (2.8)	0.83 [0.77;0.88]	0.92 [0.73;1.15]
Coping NRS	4.9 (2.1)	4.8 (2.0)	2.6 (2.3)	0.66 [0.54;0.76]	0.96 [0.70;1.28]

Results are presented as mean (SD) at each timepoint.
SD: standard deviation; CI: confidence interval; NRS: numeric rating scales; ICC: intra-class correlation; SRM: standardised response means.

as PGA and pain. Nevertheless, most PROs showed less responsiveness than joint counts or physician global assessment. Furthermore, sleep and coping were less responsive than other 'usual' PROs (with the exception of mHAQ), indicating these domains of health may be less accessible to biologic treatment, as indicated in other trials (29). When assessing the patient's perspective on treatment, it seems feasible and valid to measure these 'unusual' domains of health by NRS, as done in the RAID score.

This study has strengths and weaknesses. Since sleep and coping are important from the patient's point of view and often altered in RA patients, we consider the main strength of this study to validate a simple and feasible way to assess these domains individually by means of NRS scales. These can be used to evaluate the impact of pharmacologic and non-pharmacologic interventions on each of these domains individually, something which has not been done so far. Interestingly, during the development of the RAID score there were concerns that including coping in the variable set would lead to an overall worse sensitivity to change, but the opposite was actually found (10). This is consistent with our finding of a good individual responsiveness for coping NRS in a different patient sample. There are also some limitations. The sample size is moderate; however, it was sufficient to demonstrate responsiveness of the outcome measures. Reliability was assessed only by ICC whereas other statistics such as Bland and Altman or kappas might be applied. Of note, it is a limitation of the present study that no more complete multi-item scales were used to assess coping and sleep, than the single RAID questions (30). Finally, the possible redundancy of different PROs and effect of confounding factors other than etanercept treatment were not controlled in this study, such as depression/mood changes, physical activity or obesity/weight loss, that might influence sleep and other PROs (11, 31).

On the other hand, including further PROs in RA clinical trials, beyond the Core Set currently defined would be in the patients' interest but is not without disadvantages. It adds further burden to the participants and may increase missing data, thus feasibility should be carefully balanced considering the patient burden and cost of use. Yet, these two questions (NRS) assessing sleep and coping are simple and very little time-consuming, and have proven feasible as part of the RAID score in large, multicentre, multinational studies. The thresholds of meaning for individuals (Minimum important difference, Patient acceptable state) according to the OMERACT filter also still need to be determined for these individual scores of sleep and coping.

Although sleep and coping may be less accessible to biologic treatment, these domains have previously been shown to be important for patients and are important to consider since they have implications in the management of disease: there are non-pharmacological strategies available which showed significant improvement in the ability to cope with the disease and should therefore be proposed to patients (17, 32-34). For instance, RA patients who underwent specific self-management programs demonstrated improvements in exercise, general health, disability, pain, self-efficacy, and depression (17, 32-34) Intriguingly, mHAQ, a core set PRO measuring functional capacity, showed the poorest responsiveness, possibly due to floor effects (35). Also, it is more affected by established damage instead of current disease activity, unlike pain or other PROs more weighted towards short-term symptoms.

Further studies should explore the additional value of sleep and coping in the decision making process in RA.

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Key messages

- Sleep and coping are important outcomes for patients with RA.
- Single questions (numeric rating scales, NRS) assessing sleep and coping are as reliable and generally as responsive as 'usual' patient-reported outcomes in RA.
- Sleep and coping assessed by a single-question NRS appear to be valid outcomes for RA clinical trials.

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