Construction and psychometric properties of the Belgian Rheumatoid Arthritis Disability Assessment (BRADA) questionnaire: a new tool for the evaluation of activity limitations in patients with rheumatoid arthritis

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Abstract

Objectives
To describe the construction and psychometric properties of the Belgian Rheumatoid Arthritis Disability Assessment (BRADA) questionnaire, a self-report tool to evaluate chronic activity limitations in patients with rheumatoid arthritis (RA). The BRADA was developed to assess the eligibility of patients with RA for financial and social support measures.

Methods
The BRADA questionnaire evaluates functioning in 6 functional domains (mobility, nutrition, self care, household tasks, awareness of danger and communication) over the past week and the past 3 months. To assess the psychometric properties of the BRADA, patients with moderate to severe RA filled out the BRADA, HAQ-DI and SF-36 questionnaires twice, with a four-week interval. At each visit, the total number of swollen and tender joints, and global disease activity were recorded. DAS 28 was measured at the first visit. Internal consistency of items per domain was evaluated with Cronbach’s alpha method. Intraclass correlation coefficient (ICC) analysis was used to assess test-retest reliability. BRADA scores were compared to HAQ, SF-36 scores and disease activity parameters with Spearman’s Rho correlation coefficients to assess construct validity.

Results
Experts considered the content and face validity of BRADA to be adequate. Internal consistency was satisfactory for all functional domains (alpha >0.75), as was the test-retest reliability (ICC 0.78). BRADA scores showed excellent correlation with other validated questionnaires in RA (HAQ-DI, SF-36) and with measures of disease activity (VAS, DAS28)(p<0.001).

Conclusions
Its psychometric properties indicate that the BRADA questionnaire is a suitable instrument to evaluate disease-specific activity limitations in patients with RA.

Key words
rheumatoid arthritis, patient-reported outcomes, activity limitations, psychometrics, HAQ-DI, ICF core set for RA, SF-36, support measures
Introduction

Rheumatoid arthritis (RA) can have a major impact on human functioning and health-related quality of life. Therefore, support measures addressing activity limitations and participation issues are an important complement to the medical treatment. In order to assure equitable allocation of supporting measures, adequate instruments to objectively assess the level and area of activity limitations in patients with RA and to determine the level and type of supporting measures needed are essential.

Most existing instruments to assess functioning are either not disease-specific (e.g., Health Assessment Questionnaire [HAQ], Medical Outcome Study Short Form 36 [SF-36]), are aimed at measuring current impact of disease activity (e.g., visual analogue scale [VAS]) or assess a very limited set of activities (e.g., grip strength, walking time) (1, 2).

The Belgian RA Disability Assessment (BRADA) questionnaire, an instrument to measure the ability to perform daily activities in patients with RA in order to assess the need for access to support measures, was developed to fill this gap. This study describes the construction and psychometric properties of the BRADA questionnaire.

The BRADA questionnaire incorporates all domains covered by the HAQ, a validated generic self-report instrument that has proven useful in the context of RA (3, 4), and broadens the scope with additional activities from the likewise validated International Classification of Functioning, Disability and Health (ICF) core set for RA (5–10). Activities assessed in the BRADA questionnaire are grouped into 6 functional domains, corresponding to those used in the medical-social scale of the Belgian Federal Public Service Social Security, a generic not validated scale currently used in Belgium to determine the need for access to a number of supporting measures available for patients with chronic daily activity limitations and loss of autonomy.

The BRADA questionnaire was developed in a translational manner using the ICF core set for RA. As such, the BRADA questionnaire represents one of the first endeavours to implement the ICF framework and classification of the WHO. By assessing functioning over both the last week and the last 3 months, the BRADA questionnaire allows assessment of chronic baseline level of functioning in patients with RA, thus decreasing the influence of the disease course variability.

Patients and methods

Construction of the BRADA questionnaire

To construct the BRADA questionnaire, the Health Assessment Questionnaire Disability Index (HAQ-DI) was extended with elements of the ICF core set for RA. In the BRADA questionnaire, all validated questions of the HAQ are present. Elements from the ICF core set for RA were added for activities not represented in the HAQ.

The BRADA questionnaire (Supplementary file 1) assesses physical functioning and activity limitations in 6 functional domains (mobility, nutrition, self-care, household tasks, awareness of danger, communication) by scoring 6 items per functional domain. The BRADA takes into account functioning over A) the last week and B) the last 3 months. Each item is scored on a 0–3 scale, going from score 0 when the patient is able to perform the activity without any difficulty, over score 1 (some difficulty) and score 2 (much difficulty) to score 3, when the patient is unable to perform the activity.

Because social security is a federal matter in Belgium, the BRADA questionnaire must be available in Dutch as well as in French. The questionnaire was originally developed in Dutch. To create the French version, the Dutch version of the BRADA was translated into French; then the French version was translated back into Dutch. Subsequently, the translations were reviewed by an expert group to confirm the equivalence of both versions. The same procedure was followed to create the English translation of the BRADA questionnaire for the purpose of this paper (Supplementary file 1).

The content validity of the BRADA questionnaire was evaluated by experts. To assess its face validity, three patients were asked for feedback on its...
content after filling out the BRADA questionnaire.

To determine the optimal computation, overall BRADA scores were computed using the sum, average or maximum of the items scores per functional domain, which were then averaged to achieve an overall score of functioning. BRADA scores were calculated separately for the last week and the last three months.

The Health Assessment Questionnaire Disability Index (HAQ-DI)
The HAQ was one of the first instruments available for measuring patient-reported outcomes and has become one of the most important outcome measures in RA clinical trials. The HAQ was developed three decades ago by Fries and colleagues at Stanford University (11-13). Typically one of the two HAQ versions is used: the Full HAQ or the short 2-page HAQ. The Full HAQ contains five sections which address generic health dimensions: disability, discomfort, drug toxicity, dollar costs of health care utilisation and death. It also includes supplemental items on demographics, lifestyle and health behaviors. The Short HAQ, the most frequently used version, compromises the HAQ disability index (HAQ-DI) and the HAQ’s patient global and pain visual analog scales (12). The Short HAQ-DI has proven validity and reliability in patients with RA (3, 4) also as a tool to determine access to benefits and financial support (14, 15) and has been used in this study for the development of the BRADA questionnaire.

The ICF core sets for RA
The World Health Organisation (WHO) defines functioning as an umbrella term encompassing body function and structure, as well as activity and participation, in the context of personal and environmental factors (16). The ICF is the WHO’s framework for measuring health and disability (17). ICF additionally comprises a global language and classification consensus to describe functioning. Nowadays the challenge consists of implementing this classification into multiple sectors besides health including education, insurance, labour, disability policy and statistics. In the clinical context, the main challenge is the length of the classification (over 1400 categories). Therefore ICF core sets have been developed for a range of chronic health conditions, including RA (18-20). The brief ICF core set can be used as a minimal standard for the reporting of functioning and health in clinical studies and clinical encounters. The Comprehensive ICF core set serves as standard for multiprofessional, comprehensive assessment. Currently the ICF core set for RA has been validated from different perspectives (5-10).

The Belgian Social Security System medical-social scale
Supporting measures for patients with activity limitations available in the Belgian Social Security System include financial benefits (integration allowance, allowance for help to the aged), disease cost reduction measures (premium for people with chronic diseases), tax benefits (tax deductions, road tax and VAT exemption for motor vehicles), reduced rates for utilities (gas, electricity, telephone), and measures promoting mobility (parking card, free coach transport card).

The access to these support measures is currently evaluated by a medical-social scale of the Belgian Federal Public Service Social Security. This scale assesses activity limitations in daily life by scoring 6 functional domains: mobility, nutrition (eat and prepare food independently), self care (hygiene and...
distribution was tested with the Kolmogorov-Smirnov test. For not normally distributed variables, parameters, and as median and range are represented as mean ± standard deviation for normally distributed parameters, and as median and range for not normally distributed variables. Frequencies of categorical variables are represented as percentages. Normal distribution was tested with the Kolmogorov-Smirnov test. A paired t-test was used to compare VAS values between both visits.

The internal consistency of questionnaire items per functional domain was evaluated with Cronbach’s alpha method. Alpha is an estimate of and the lower bound to the proportion of test variance attributable to common factors among the items (21). Alpha values above 0.70 indicate good internal consistency (22). The Cronbach’s alpha statistic “if item deleted” was computed to assess the contribution of individual items to the overall alpha for the functional domain in order to assess redundancy in the items composing a functional domain.

The test-retest reliability of the BRADA questionnaire was assessed by calculating intraclass correlation coefficients (ICC) between both assessments (screening vs. baseline visit) for the different BRADA overall score computations.

To assess convergent construct validity, BRADA scores were compared with the validated HAQ-DI and Medical Outcome Study Short Form 36 (SF-36) scores assessed at the same time points and with VAS of global disease activity, ESR and DAS28 using Spearman’s Rho correlation analysis.

Statistical analyses were performed using SPSS for Windows (ver. 14.0). Statistical significance was presumed at p-values <0.05.

Results
Construction of the BRADA questionnaire
Table I maps the elements of the BRADA questionnaire to their counterparts in the HAQ and/or ICF core set for RA. A number of daily activities, mainly about communication and social interaction but also about mobility, preparing or eating food, personal hygiene, housekeeping and living without supervision, missing in the HAQ-DI were incorporated from the ICF core set for RA, namely: writing (code d170), hand and arm use (d445), using communication devices and techniques (code d360), maintaining a body position (code d415), changing basic position (code d410), moving around in different locations (code d460), walking (code d450), driving (code d475), using transportation (code d470), looking after one’s health (code d570), caring for body parts (code d520), preparing meals (code d630) and recreation and leisure (code d920). As the BRADA questionnaire is intended to be used as a medico-social scale to evaluate the activity limitations and loss of autonomy some items from the comprehensive and brief core set for RA were not withheld: assisting others (code d660), family relationships (code d760), intimate relationships (code d770), remunerative employment (code d850), work and employment, other specified and unspecified (code d859), community life (code d910) and moving around using equipment (code d465). BRADA assesses functioning over the past week as well as over the past 3 months as the main goal for developing the BRADA questionnaire was to provide an instrument able to assess the chronic activity limitations of patients with RA.

Study population
The study population is described in Table II. The BRADA questionnaire was filled out at two time points by 67 patients with moderate to severe RA (DAS28 5.7±1.0). The patient population consisted of 72.7% females, with age 55.7±11.6 years and median disease duration of 7.5 years (range 1–42 years). VAS values did not differ significantly between both time points (VAS was 72.1 and 70.5 for screening and baseline visits, respectively, with a mean difference 1.607, 95% CI: -1.1 to 4.3, p=0.236), indicating that disease activity in the study population did not undergo a significant change in the four-week interval between both evaluations.

Psychometric properties of the BRADA questionnaire
Content and face validity
The BRADA questionnaire was developed by extending the HAQ-DI with items of the ICF core set for RA. The researchers consider the questionnaire therefore as sufficiently representative.

Patients and study set-up
To assess the psychometric properties of the BRADA questionnaire, data collected at the screening and baseline visits from patients with RA included in a multicentre interventional study (ML22613, NCT00938444) were used. Inclusion criteria for this study were: moderate to severe RA with documented inadequate response to minimally two DMARDs, including oral or intramuscular methotrexate for a minimum duration of 3 months at a dose of 15 mg/week or higher. Screening and baseline visits used to evaluate the BRADA questionnaire occurred prior to the study intervention and a four-week interval existed between both visits. At each visit, patients were asked to fill out the BRADA, HAQ-DI and SF-36 questionnaires. All questionnaires were available in Dutch and French; participants filled out the questionnaire in their native language. At each visit, the total number of swollen and tender joints was evaluated and VAS of global disease activity was recorded. Additionally, erythrocyte sedimentation rate (ESR) and DAS28 were measured at screening.

All patients gave written informed consent and the study was approved by the ethical committees of the participating clinical centres.

Statistical analyses
Patient characteristics and demographics are represented as mean ± standard deviation for normally distributed parameters, and as median and range for not normally distributed variables. Frequencies of categorical variables are represented as percentages.
Table I. Mapping of BRADA questionnaire items to the HAQ-DI (24) and ICF core set for RA (16). HAQ-DI items are numbered as specified in the official HAQ instructions guide (24).

<table>
<thead>
<tr>
<th>HAQ Item</th>
<th>ICF Core Set for RA</th>
<th>BRADA Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Walk outdoors on flat ground</td>
<td>d450 Walking</td>
<td>d460 Moving around in different locations</td>
</tr>
<tr>
<td>9. Climb up five steps</td>
<td>d455 Moving around</td>
<td>d470 Using transportation</td>
</tr>
<tr>
<td>19. Get in and out of a car</td>
<td>d470 Using transportation</td>
<td>d475 Driving</td>
</tr>
<tr>
<td>15. Open car doors</td>
<td>d470 Using Transportation</td>
<td>Use public transportation (train, streetcar/tram or bus)</td>
</tr>
</tbody>
</table>

Function 1: Abilities with regard to mobility (Mobility)

8. Walk outdoors on flat ground
9. Climb up five steps
19. Get in and out of a car
15. Open car doors

Function 2: Abilities with regard to preparing or eating food (Nutrition)

5. Cut your own meat
6. Lift a full cup or glass to your mouth
7. Open a new milk carton
18. Run errands and shop
16. Open previously opened jars

Function 3: Abilities with regard to personal hygiene and to (un)dressing (Self-care)

1. Dress yourself, including shoelaces and buttons
2. Shampoo your hair
11. Take a tub bath
10. Wash and dry your body?
12. Get on and off the toilet

Function 4: Abilities with regard to doing chores around the house and housekeeping (Household tasks)

14. Bend down to pick up clothing from the floor
13. Reach and get down a 5 pound object (such as a bag of sugar) from above your head
20. Do chores such as vacuuming or yardwork
17. Turn faucets on and off

Function 5: Abilities with regard to living without supervision, being conscious of danger and being able to consciously avoid danger (Awareness of danger)

4. Get in and out of bed
3. Stand up from a straight chair

Function 6: Abilities with regard to communication and social interaction (Communication)

- d360 Using communication devices and techniques
- d360 Using communication devices and techniques
- d170 Writing
- d460 Moving around in different locations
- d920 Recreation and leisure
- d475 Driving
and complete to evaluate activity limitations in patients with RA. Three RA patients were asked to fill out the BRADA questionnaire and when interviewed about the experience, they did not report any problems or difficulties with the questionnaire.

Reliability

Internal consistency. Cronbach’s alpha test statistic for the six items composing every functional domain of the BRADA questionnaire shows that internal consistency is satisfactory for all domains (alpha > 0.70). However, the domains one, three and six contained one or more items that did not contribute to the overall alpha (Table III).

Test-retest reliability. The repeatability of the BRADA questionnaire was evaluated with ICC analysis for different computations of the overall BRADA score. Functional domain scores were computed with the sum, average or maximum of the item scores per functional domain. These functional domain scores were then averaged to compute the overall BRADA score (Table IV).

ICC values for overall score computations using sum or average of functional domain items yielded good test-retest reliability (ICC > 0.75), whereas scores using the maximum score per functional domain yielded considerably lower ICC values. Taking into account the ICC values and the usability of the questionnaire, the average of the summed item scores per functional domain was selected as the method of choice to compute BRADA scores in future studies. The BRADA questionnaire thus yields a score from 0 to 18 for both the one week and 3 month assessments.

Convergent construct validity: correlation with validated instruments and disease activity parameters

Table V shows Spearman Rho values testing the correlation of the BRADA questionnaire scores with validated questionnaires assessing functioning
(HAQ-DI and SF-36) and with measures of disease activity (VAS, DAS28). All correlations were significant with p<0.001. As expected the closest correlation was observed with the HAQ, which provided the basis for the construction of the BRADA questionnaire. Correlations with the SF-36 are negative as functional limitations give rise to lower SF-36 scores but higher BRA-DA scores.

**Discussion**

Rheumatoid arthritis-related impairments in joint structure and function, may cause limitations of physical activities and restrictions in familial, social and professional participation. To minimise the impact of RA on the patients’ health-related quality of life, support measures (e.g. income replacement, financial and tax benefits) are an important supplement to the medical treatment of RA.

As the disease course is heterogeneous and activity limitations in patients with RA tend to be progressive, it is essential to have adequate instruments to accurately measure the degree of disability or activity limitation, in order to ensure equitable access to financial and social support measures. Most existing instruments to assess functioning either lack disease specificity, are designed to measure current impact of disease activity or assess a very narrow scope of activities or functions. The BRADA questionnaire was developed precisely to overcome the limitations of the existing instruments for assessing functional impairment in patients with RA.

To ensure a sufficiently broad scope, BRADA was based on the HAQ-DI, an extensively validated questionnaire that can be considered the gold standard for the evaluation of functional limitations in RA patients (3, 4). The BRADA questionnaire consists of 36 items. Since a number of functions or activities are not covered by the HAQ-DI, a number of elements taken from the ICF core set for RA were also incorporated into the BRADA questionnaire to increase its comprehensiveness and disease-specificity. The ICF core set for RA has been validated with patients and clinicians, occupational and physical therapists (5–10). Using the ICF core set for RA to develop, on a translational manner, a new questionnaire, such as the BRADA questionnaire is one of the first endeavours to implement the ICF framework and classification of the WHO to assess activity limitations in daily life.

In the BRADA questionnaire, patients are asked to assess their level of functioning over the last week as well as over the last 3 months in order to assess the basal level of functioning over a longer period of time, to minimise the influence of the variable course of the RA, characterised by intermittent inflammatory flares on the evaluation. Adding ICF elements to build a more comprehensive instrument have made the BRADA questionnaire longer than the HAQ, which may raise the bar for its use in daily practice. However, structuring the questionnaire into functional domains covering a set of related activities may allow more focused use of the BRADA questionnaire, e.g. just for the functional domains in which patients show function limitations. Assessment of chronic, stable function limitations in patients with RA is the main application for which the BRADA questionnaire was designed. To assess current RA disease activity a variety of self-report tools are already available, and their responsiveness was recently found to be comparable to traditional composite indices of disease activity such as DAS28 (23). Experts found the face and content validity of the BRADA to be satisfactory. Reliability testing revealed good internal consistency of the composing elements for all functional domains, although the ability to ride a bicycle, drive a car, take a bath or use a telephone did not significantly contribute to alpha. The test-retest reliability of the BRADA questionnaire also proved to be adequate. Unsurprisingly, BRA-DA scores correlated significantly with the HAQ-DI results. They additionally showed a significant inverse correlation with SF-36 scores.

In the current study, the BRADA questionnaire was tested in patients with moderate to severe RA. Subsequent studies will also evaluate the psychometric properties of the BRADA questionnaire in the general population of patients with RA and investigate the responsiveness of BRADA scores to treatment changes.

Additional studies are planned to investigate whether the BRADA questionnaire can predict the need for access to social and financial supporting measures, and whether its predictive value is superior compared to that of the HAQ for this purpose.

**Acknowledgements**

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**The BRADA I study group**

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Supplementary file 1

BRADA questionnaire
Belgian Rheumatoid Arthritis Disability Assessment

Instructions:
With this questionnaire, we hope to learn how illness affects your ability to function independently in your daily life. You should not take into account any assistance that you may receive from third parties or through aids. We wish to learn what you can do, without assistance from third parties or through aids.

Tick the option that best describes what you were generally able to perform

A / in the past week
B / in the past three months

Function 1: Abilities with regard to mobility

<table>
<thead>
<tr>
<th>Can you:</th>
<th>Without any difficulty</th>
<th>With some difficulty</th>
<th>Very difficult</th>
<th>Impossible</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Walk outside on a flat terrain?</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>1.2 Walk outside on undulating terrain?</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>1.3 Walk up five steps?</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>1.4 Get in and out of a car, including opening and closing the door of a car?</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>1.5 Riding a bicycle?</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>1.6 Use public transportation? (train, streetcar/tram or bus)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

Function 2: Abilities with regard to preparing or eating food

Can you:

2.1 Cut meat? | □ | □ | □ | □ |
2.2 Take a full cup of coffee or a full glass to your lips? | □ | □ | □ | □ |
2.3 Open a carton of milk or fruit juice? | □ | □ | □ | □ |
2.4 Prepare meals? | □ | □ | □ | □ |
2.5 Do groceries and go shopping? | □ | □ | □ | □ |
2.6 Unscrew the lid of a jar, if it has been opened before? | □ | □ | □ | □ |

Function 3: Abilities with regard to personal hygiene and to (un)dressing

Can you:

3.1 Get dressed, including tying shoelaces and buttoning clothes? | □ | □ | □ | □ |
3.2 Wash your own hair? | □ | □ | □ | □ |
3.3 Get in and out of a bath tub? | □ | □ | □ | □ |
3.4 Wash and dry your own body? | □ | □ | □ | □ |
3.5 Shave or apply makeup at a washbasin? | □ | □ | □ | □ |
3.6 Get on and off the toilet seat? | □ | □ | □ | □ |
Function 4: Abilities with regard to doing chores around the house and housekeeping

Tick the option that best describes what you were generally able to perform

<table>
<thead>
<tr>
<th>Function 4</th>
<th>A / in the past week</th>
<th>B / in the past three months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Without any difficulty</td>
<td>With some difficulty</td>
</tr>
<tr>
<td>4.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2</td>
<td></td>
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<td>4.3</td>
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<tr>
<td>4.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Can you:

- Bend over to pick up clothes from the floor?
- Reach for and bring down an item weighing 1 kg, such as a pack of sugar, situated just above your head?
- Do homekeeping chores such as vacuuming or gardening?
- Open and close a tap?
- Participate in a one-day outing?
- Go to public buildings?
- Write a letter?
- Use a computer?
- Drive a car?
- Go to public buildings?

Function 5: Abilities with regard to living without supervision, being conscious of danger and being able to consciously avoid danger

Can you:

- Get in and out of bed?
- Get up from a straight chair?
- Stand-up for 15 minutes?
- Move about your own house?
- Get your medication out of the package and take it?
- Get up after a fall?

Function 6: Abilities with regard to communication and social interaction

Can you:

- Use a telephone?
- Use a computer?
- Write a letter?
- Go to public buildings?
- Participate in a one-day outing?
- Drive a car?


