The ASAS Health Index (ASAS HI) – a new tool to assess the health status of patients with spondyloarthritis

U. Kiltz[1], D. van der Heijde[2], A. Boonen[3], J. Braun[1]

[1]Rheumazentrum Ruhrgebiet, Herne Germany;
[2]Department of Rheumatology, Leiden University Medical Center, Leiden, The Netherlands;
[3]Division of Rheumatology, Department of Internal Medicine, Maastricht University Medical Center, and Caphri Reseach Institute, Maastricht, The Netherlands.

Uta Kiltz, MD
Desiree van der Heijde, MD, PhD
Annelies Boonen, MD
Jurgen Braun, MD

Please address correspondence to:
Dr Uta Kiltz,
Rheumazentrum Ruhrgebiet,
Claudiusstr. 45, 44649 Herne, Germany.
E-mail: uta.kiltz@elisabethgruppe.de

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ABSTRACT

Within the variable course of ankylosing spondylitis (AS), peripheral arthritis, enthesitis, and involvement of other organs can add to the burden of the disease. The primary complaints of patients with spondyloarthritis (SpA) are pain, stiffness, fatigue, and limitation in activities and social participation. Instruments currently available for the assessment of patients with SpA focus predominantly on specific aspects of health such as pain, disease activity, and physical function and measure specific concepts like physical function and health-related quality of life (HR-QoL). However, the overall picture of impairments, limitations and restrictions in activities or social participation of patients with AS is not adequately assessed in SpA-specific questionnaires. Most of the existing questionnaires are not conceptualised with regard to their underlying construct. The International classification of functioning, disability and health (ICF) Core Set for AS may serve as an appropriate model and underlying construct to develop a health index, since the whole range of functioning and disability of patients with AS is captured. Based on these assumptions, ASAS developed for patients with SpA an instrument assessing health as operationalised by the ICF. The questionnaire was developed by preparing an item pool, linkage of the items to the comprehensive ICF core set for AS and test of the item pool in two cross-sectional studies. The analysis of the questionnaire and the response scale were done with Rasch analysis. Emphasis was on optimal targeting, the capacity of items to differentiate between different levels of health, and optimal coverage of items to the spectrum of ICF categories, so that the final questionnaire could represent as much of the entire range of difficulty levels as possible. The ASAS HI is a linear composite measure and includes 17 items which cover most of the ICF core set. Preliminary validity has been confirmed in a field test in 4 English-speaking countries. The ASAS HI should soon be used in clinical trials and in clinical practice to test its real life performance and to confirm that this new composite index captures relevant information on functioning and health of patients with AS.

Introduction to spondyloarthritis

The term spondyloarthritis (SpA) is now increasingly used to classify and diagnose patients who are characterised by axial and entheseal inflammation, potentially new bone formation, as well as extraarticular manifestations due to psoriasis, anterior uveitis and colitisresultingin part caused from chronic inflammatory bowel diseases. Ankylosing spondylitis (AS) is the prototype of SpA, which constitutes, together with non-radiographic axial SpA, the subgroup that is now termed axial SpA (axSpA), which is differentiated from peripheral SpA by the predominance of axial in contrast to peripheral symptoms.

Role of ASAS

The Assessment of SpondyloArthritis international Society (ASAS) was founded in 1995 with the aim to develop standardised tools for the assessment of AS – the goals were later broadened to the whole group of SpA. ASAS has now more than 100 international experts in the field of SpA. The plan to develop a general health index for AS arose about 7 years ago from discussions inside ASAS, which made it clear that it was impossible to find an international agreement on disease severity. A mere combination of the two concepts of activity and damage did not suffice to fulfill this aim. Because work on the ASAS HI started before the new terminology and classification was developed and published, the ini-

tial concentration was on AS. However, the aim clearly is to include the whole subset of axSpA, althoughthe initial data have been generated with the help of patients with AS.

Funtion and its impact on disease severity

Within the variable course of AS, peripheral arthritis, enthesitis, and involvement of other organs can add to the burden of the disease. The main complaints made by patients with SpA are pain, stiffness, fatigue, and limitation in activities and social participation (1-3). Next to making a correct diagnosis, the impact of disease on functioning is essential for clinicians when reporting on health problems of individuals. Functioning is increasingly been taken into account when assessing the impact of chronic diseases on the individual, and also when quantifying the efficacy of interventions in clinical studies. Functioning is often referred to as function.

However, it is important to realise that *function* is often limited to physical function ignoring the complexity of global functioning. The term 'severity' (see above) which contains different aspects of the disease (disease activity, damage, reduced mobility, reduced physical function, reduced social participation) comes close to *impact of the disease* which is related to *quality of life*, but in a sense that is even a bit broader than the subjective experience of health problems.

The ICF and its core sets

This broader concept is included in the International Classification of Functioning, Disability and Health (ICF) which has been published by the World Health Organisation (WHO) more than a decade ago. The ICF represents a universally accepted model that classifies and describes functioning, disability and health in individuals with a wide spectrum of diseases or conditions in a systematic way (4). The term "functioning" in the context of the ICF is equated more with "health" than "function" as the latter term is limited to physical function. ASAS has applied the ICF as a basis to define a core set of items relevant for patients with AS (5). Within the Comprehensive ICF Core Set for AS, 80 categories have been selected describing the typical spectrum of problems related to the functioning of AS patients in a multidisciplinary assessment.

Instruments currently available for the assessment of patients with SpA focus predominantly on specific aspects of health such as pain, disease activity, and physical function and measure specific concepts like physical function and health-related quality of life (HR-QoL) (6, 7). However, the overall picture of impairments, limitations and restrictions in activities or social participation of patients with AS are not adequately assessed in SpA-specific questionnaires (8). Most of the existing questionnaires are not conceptualised with regard to their underlying construct. The ICF Core Set for AS may serve as an appropriate model and underlying construct to develop a health index since the whole range of functioning and disability of patients with AS is captured (9). No ICF based self-reported measure has been published to date.

The ASAS Health Index

Based on these assumptions, ASAS developed for patients with SpA an instrument assessing health as operationalised by the ICF according to ICF categories of functioning (10). Such a measure must fulfill a requirement of unidimensionality which has already been confirmed for the ICF categories (9, 11). The disease-specific questionnaire reported here is based on the Comprehensive ICF Core Set for AS and is named the ASAS Health Index (ASAS HI) (12).

The ASAS HI is a linear composite measure and contains 17 items (dichotomous response option: "I agree" and "I do not agree") which cover most of the ICF core set (Table I). Five phases was used to develop the questionnaire and to achieve an index for functioning and health which is easy to administer, easy to fill in and applicable to patients worldwide (Table II).

The items incorporated into the final questionnaire originate from an item pool with 251 items, which had been developed by linking items from existing questionnaires (either disease-specific or generic instruments) to 44 categories of the the Comprehensive ICF Core Set for AS related to the components of body functions, activities and participation. Items included in the initial item pool or required to be short, comprehensible, and addressing a single concept. A total of 76 items covered the 23 ICF categories from the component *body functions*, 122 items the 24 categories from the component *activities and participation,* and 53 items covered 14 categories of environmental factors. The total item pool were weighted by patients (n=13) who ascertained which

Table I. Items of the ASAS HI.

Item	Categories	ICF number
Pain sometimes disrupts my normal activities.	Pain	b280
I find it hard to stand for long.	Maintaining a body position	d415
I have problems running.	Moving around	d455
I have problems using toilet facilities.	Toileting	d530
I am often exhausted.	Energy and drive	b130
I am less motivated to do anything that requires physical effort.	Motivation	b1301
I have lost interest in sex.	Sexual functions	b640
I have difficulty operating the pedals in my car	Driving	d475
I am finding it hard to make contact with people.	Community life	d910
I am not able to walk outdoors on flat ground.	Moving around	d455
I find it hard to concentrate.	Handling stress	d240
I am restricted in traveling because of my mobility.	Recreation and leisure	d920
I often get frustrated.	Emotional functions	b152
I find it difficult to wash my hair.	Washing oneself	d510
I have experienced financial changes because of my rheumatic disease.	Economic selfsufficiency	d870
I sleep badly at night.	Sleep	b134
I cannot overcome my difficulties.	Handling stress	d240

Table II. Phases of development for the ASAS Health Index.

	Phase	Aims	Methods
Ia	Preparatory	Development of a pool of items representing the categories of the Comprehensive ICF Core Set for AS	Linkage of various assessment tools for functioning and health to ICF categories
Ib	Patient meeting	Patient preference and weighting of the items per ICF category	Relative weight to each item, patients distributed 100 points per ICF category.
II	1st International cross-sectional survey	Item reduction (within and across ICF categories)	Rasch analysis, Spearman rank correlation coefficient
III	Expert consultation	Agreement on item reduction	Nominal Consensus Process
IV	2nd International cross-sectional survey	Validation of the draft version and further item reduction	Testing psychometric properties Rasch analysis
V	Consensus meeting	Agreement on a final version	Nominal Consensus Process

items were considered important and preferrable.

Two cross-sectional international web-based surveys (n=2441) followed by expert consultation were undertaken to test the item pool to identify the best candidate items regarding functioning and health within the ICF context. Rasch analysis was used as the preferred method to test the item pool and the response scale of the items. Rasch analyses were conducted in iteration cycles in which several items were removed because of misfit, because of differential item function (DIF) for age, gender and disease activity, because of high residual correlation and because of low chi-square probability values. Emphasis was put on optimal targeting, the capacity of items to differentiate between different levels of health, and optimal coverage of items to the spectrum of ICF categories of the Comprehensive ICF Core Set for AS so that the final questionnaire was able to represent the whole range of difficulty levels (Fig. 1). The final questionnaire consists of 17 items which fit the model without residual correlation and absence of constant DIF. A wide range of ICF categories are assessed including pain, emotional functions, sleep, sexual functions, mobility, self-care, and community life. Thus, the final 17 items represented all levels of functioning of SpA patients and covered 15 out of 66 categories of the ICF Core Set for AS (Table I). Preliminary validity has been confirmed in a field test in 4 English-speaking countries. The ASAS HI has been translated so far into 15 languages and the psychometric properties of the ASAS HI and its translations are tested in a large ongoing trial worldwide.

On initiation of the project in early 2008, the ASAS classification criteria for axial SpA (axSpA) and peripheral SpA had not been published (13), (14). Patients with AS were included in the early development phase of this study, whereas patients with the whole range of axial SpA manifestations were included in the field test. Both patient groups did not respond differently in the field tets to the ASAS HI.

The development of the ASAS HI, the first disease-specific patient-reported outcome (PRO) measure, aimed at the measurement of overall functioning and health based on the ICF in patients with SpA. As stated above, existing instruments for patients with AS have focused on specific symptoms like physical function and HR-QoL (6, 7). However, these tools cannot provide

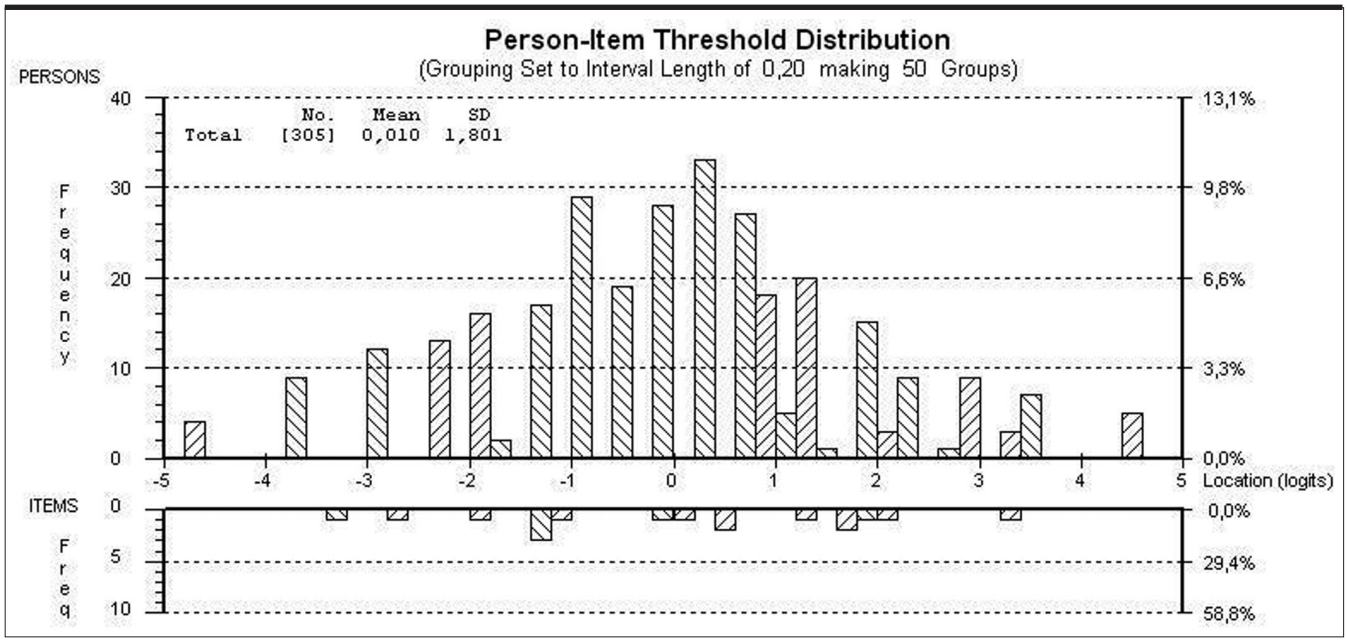

Fig. 1. Person-Item distribution of the sample with the final 17 items (see attached JPEG file).
Interpretation of the figure: The horizontal line represents the latent trait "functioning" according to the ICF. The value of -3 means that a patient with a score result on the left side of the continuum has no major limitation in functioning. The lower the score, the better the 'functioning'.

information about the whole range of common difficulties of patients with AS as defined by the ICF Core Set for AS, which was our conceptual basis and content validity standard during the whole process (5).

It is important to emphasise that the ASAS HI is a health index and not a HR-QoL instrument. Health is thereby operationalised through the ICF concept of functioning. With the ASAS HI we capture whether problems are present in different categories of functioning and not the subjective experience of those problems. This differentiation is frequently not clear because the functioning categories that are assessed, such as pain and moving around, are the same, but they are captured from a different perspective. The functioning perspective is based on an objective description while the HR-Qol perspective is based on a subjective appraisal. Furthermore, existing disease-specific questionnaires usually cover aspects of physical function or mobility, but seldom address aspects of self-care or leisure activities which are considered important from the patient perspective (1, 8, 15).

In conclusion, the ASAS HI is a health index based on the ICF Core Set developed for patients with AS. This index forms a unidimensional scale providing a sum score representing a wide spectrum of different levels of functioning. Furthermore, the use of the ASAS HI seems feasible since it includes only 17 dichotomous items addressing categories of pain, emotional functions, sleep, sexual functions, mobility, self-care, community life and employment. The ASAS HI should soon be used in clinical trials and in clinical practice to test its real life performance and to confirm that this new composite index captures relevant information on functioning and health of patients with AS. Further studies are needed to assess whether the ASAS HI can be used as a proxy to assess the global burden of disease in patients with SpA.

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