

ORIGINAL ARTICLE

Measuring impairments of functioning and health in patients with axial spondyloarthritis by using the ASAS Health Index and the Environmental Item Set: translation and cross-cultural adaptation into 15 languages

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ABSTRACT

Introduction: The Assessments of SpondyloArthritis international society Health Index (ASAS HI) measures functioning and health in patients with spondyloarthritis (SpA) across 17 aspects of health and 9 environmental factors (EF). The objective was to translate and adapt the original English version of the ASAS HI, including the EF Item Set, cross-culturally into 15 languages.

Methods: Translation and cross-cultural adaptation has been carried out following the forward-backward procedure. In the cognitive debriefing, 10 patients/country across a broad spectrum of sociodemographic background, were included.

Results: The ASAS HI and the EF Item Set were translated into Arabic, Chinese, Croatian, Dutch, French, German, Greek, Hungarian, Italian, Korean, Portuguese, Russian, Spanish, Thai and Turkish. Some difficulties were experienced with translation of the contextual factors indicating that these concepts may be more culturally-dependent. A total of 215 patients with axial SpA across 23 countries (62.3% men, mean (SD) age 42.4 (13.9) years) participated in the field test. Cognitive debriefing showed that items of the ASAS HI and EF Item Set are clear, relevant and comprehensive. All versions were accepted with minor modifications with respect to item wording and response option. The wording of three items had to be adapted to improve clarity. As a result of cognitive debriefing, a new response option 'not applicable' was added to two items of the ASAS HI to improve appropriateness.

Discussion: This study showed that the items of the ASAS HI including the EFs were readily adaptable

Key messages

What is already known about this subject?

► The Assessments of SpondyloArthritis international society Health Index (ASAS HI) questionnaire has been developed in English-speaking countries worldwide to assess functioning and health in patients with ankylosing spondylitis.

What does this study add?

► Translation and cross-cultural adaptation of the ASAS HI into 15 languages in 23 countries showing good performance in different cultures in patients with axial and peripheral spondyloarthritis.

How might this impact on clinical practice?

► Functioning and health in patients with axial spondyloarthritis can be assessed in clinical trials and in daily routine by using one of the disease-specific ASAS HI versions covering most of the languages worldwide.

throughout all countries, indicating that the concepts covered were comprehensive, clear and meaningful in different cultures.

INTRODUCTION

The Assessments of SpondyloArthritis international society Health Index (ASAS HI), published in 2014, is a unidimensional

questionnaire measuring functioning and health in patients with ankylosing spondylitis (AS).¹ Consistent with the biopsychosocial model of health, the ASAS HI includes a multidimensional item set assessing the relevant contextual environmental factors (EF Item Set). AS is a chronic inflammatory rheumatic disease and is characterised by signs of sacroiliitis on plain radiograph.² Recently, patients with similar symptoms and signs as AS, with and without radiographical changes can be classified as axial spondyloarthritis (axSpA).³ Since axSpA usually starts in early adulthood, the lifetime impact of the disease on functioning and health can be substantial because of pain, stiffness, fatigue and limitations in activities and social participation.⁴⁻⁶ As no agreement on an objective clinical definition of the severity of AS was reached among expert members of ASAS it was chosen to assess severity using a patient-reported outcome.

The ASAS HI and the EF Item Set measure functioning and health across many aspects of health that are typical and relevant for patients with AS. It is based on the Core Set of AS which was derived from the International Classification of Functioning and Health endorsing the biopsychosocial framework of health.⁷ The ASAS HI contains items addressing categories of pain, emotional functions, sleep, sexual function, mobility, self-care and community. The items form a unidimensional scale providing a sum score representing different levels of functioning. The EF Item Set contains items addressing categories of support/relationships, attitudes and health services. These EF items can act as a barrier or a facilitator and they may influence the health of patients.⁸

The ASAS HI was originally developed in five English speaking countries (Australia, Canada, Ireland, UK and USA). To support the distribution and use in different countries, ASAS members were asked to participate in an international translation project to develop validated and reliable additional language versions.

The aim of this paper is to describe the translation and cultural adaptation of the ASAS HI and the EF Item Set into 15 languages across 23 countries among patients with radiographic and non-radiographic axSpA (nr-axSpA).

METHODS

The ASAS HI contains 17 items with a dichotomous response option indicating “I agree” and “I do not agree” (see online supplementary material 1). The total sum of the ASAS HI ranges from 0 to 17, with a lower score indicating a better health status. The EF Item Set contains nine dichotomous items with identical response option (see online supplementary material 2) but without a sum score because of its multidimensional nature. Translation and cross-cultural adaptation of the English version was carried out using the forward-backward procedure, which consists of five steps:⁹

1. Translation: Two independent translations into target language by an informed and an uninformed

- translator, both bi-lingual but native speaker of the target language

2. Synthesis: Synthesis of the two translations
3. Back translation: Create two back translations based on the first two translations by translators blinded for the original version
4. Expert committee review: Review all reports, reach consensus on discrepancies, produce a prefinal version
5. Field test with cognitive debriefing: Test complete questionnaire in the target language in a small group of relevant patients or lay people in order to test alternative wording and to check understandability, interpretation and cultural relevance of the translation.

The investigator were informed to use for item 2, 4, 9, 10, 11, 13 and 14 the validated country-specific translation because those items were derived from existing questionnaires (Ankylosing Spondylitis Quality of Life (ASQoL) (item 13 and 14), Health Assessment Questionnaire (HAQ) (item 10), Nottingham Health Profile (NHP) (item 2 and 9), Rheumatoid Arthritis Quality of Life (RAQoL) (item 4 and 11). Participating countries were selected based on their interest in research in axSpA. A national subinvestigator was appointed, who was provided with a description of the methodology including literature about cross-cultural adaptation and a standardised operating procedure describing the setting of the field test.^{9 10}

The different steps of the translation had to be documented in a written document to ensure transparency and comparability. Forward and backward translations were performed for 15 languages in 20 countries (Austria, Belgium, China, Colombia, Croatia, Egypt, France, Germany, Greece, Hungary, Italy, Korea, Mexico, Portugal, Russia, Spain, Switzerland, Thailand, the Netherlands, and Turkey). For languages spoken in more than one country (Dutch/Flemish, German and Spanish), the national subinvestigators worked together and were free to decide to harmonise one translation or to proceed with translational steps by using country-specific versions. Each reconciled translation was reviewed by UK and discussed with the steering committee (AB, JB and DvdH).

The cognitive debriefing was conducted in 4 English (Australia, Canada, UK and USA) and 18 non-English-speaking countries (all centres which participated in the translation except for Austria and Switzerland). Adult patients with axSpA were eligible for participation in the exercise. At least 10 patients (60% AS and 40% nr-axSpA) per country are needed to participate in the field test. Attention was paid to include in this convenient sample patients across a broad spectrum of sociodemographic background (age, gender and education) focusing on patients with lower education (as recorded by number of years of formal education). First, patients completed the ASAS HI and the EF Item Set in the presence of an interviewer and the completion time for the ASAS HI and EF Item Set was recorded. Afterwards patients underwent a structured interview focusing on skipped or missing items,

potential ambiguous and inappropriate items. Patients were asked by the interviewer to comment on the items of the questionnaires, the instructions and the response format by using open questions and documenting the response as direct quotations. The information of the cognitive debriefing was documented in a semistructured written report by responding to predefined questions and the possibility to document the thoughts of the patients. The cognitive debriefing interview aimed to test the relevance, acceptability and comprehensiveness of the translated ASAS HI and the EF Item Set and its applicability in patients representing the entire clinical spectrum of axSpA. All centres received approval from the responsible ethics committees. Written informed consent was obtained from all respondents prior to the start of the study. Each country provided the findings of the cognitive debriefing in a written report and the results were analysed descriptively.

RESULTS

The ASAS HI and EF Item Set were successfully translated into 15 languages: Arabic, Chinese, Croatian, Dutch/Flemish, French, German, Greek, Hungarian, Italian, Korean, Portuguese, Russian, Thai and Turkish as well as three different versions of the Spanish language (Colombia, Mexico and Spain). Since some items included in the ASAS HI had been derived from other validated questionnaires for which translation was already available (eg, ASQoL, HAQ, NHP, RAQoL), the items of the validated translations were used for items 2, 4, 9, 10, 11, 13 and 14.¹ Furthermore, emphasis was on conceptual rather than linguistic translations so that some of the translated items could take a different form compared to the original version.

ASAS Health Index: Most of the 17 items and the instructions of the ASAS HI were translated into all 15 languages without difficulties. The translation of the word “running” in item 3 and “exhausted” in item 5 of the ASAS HI caused linguistic problems because in some languages the word has different meanings (‘running’) (Dutch, German) or does not exist as such (‘exhausted’) (Korean, Thai). Discrepancies were solved by discussions in the translation teams with support by ASAS providing the background information for the item. Item 4 was cross-culturally adapted by emphasising that “problems using toilet facilities” is the main content of this item.

Environmental Factor Item Set: Difficulties were experienced with translation of the contextual factors indicating that these concepts may be more culture-dependent. The translation of item 2 “friends act around me” and item 6 “treatment is taking up time” was challenging because of misunderstanding of the underlying concepts. Discrepancies were solved by discussion and providing the background of these items to the translation team. Item 4 (“modify environment”) raised concerns because the relation to the specific setting was not clear enough and therefore the item was specified to “modify home and work environments” in all languages.

In the field test, 215 patients (mean age 42.4±13.9, range 18–86 years, 62.3% men) in 22 countries (~10 patients/country) with axSpA underwent a cognitive debriefing interview. A total of 140 patients (65.1%) were diagnosed with AS and 75 patients (34.8%) presented as nr-axSpA. Altogether, 71 patients (33.0%) suffered from peripheral involvement in this cohort with a disease duration of 11.2±11.0 (range 0–53) years. We noticed a moderate disease activity with a BASDAI of 3.8±2.3 (range 0–9.6). Altogether, 117 patients (56.6%) included in the cohort were employed, whereas unpaid work was due to disability (n=35), retirement (n=16), homemaker (n=15), student (n=12) and job seeking (n=10). Formal education varied between 4 and 22 years with a mean of 13.3±3.8. The country-specific details are listed in [table 1](#) and [table 2](#).

About 95% of interviews showed that the English questionnaire and the translations were clear, appropriate, relevant, comprehensive and easy to complete in the different cultures. However, we received comments on some items, especially item 7 (“I lost interest in sex”) and item 8 (“I have difficulty operating the pedals in my car”). These items of the ASAS HI were discussed frequently because some patients either could not or did not want to answer the questions. As a result of the discussion, a new response option ‘not applicable’ was added to the ASAS HI for items 7 and 8. In the EF Item Set, the phrasing of item 6 (“getting relapses acknowledged by a health professional”) was not clear enough for the patients so that the original version and the translations were changed to the wording “worsening of my disease”. All translations were accepted with minor modifications.

The total score of the ASAS HI was 7.1±4.4 (mean±SD, range 0–17). Completion times for ASAS HI and for EF Item Set were short with 2.6±1.6 and 2.1±1.5 (mean±SD) minutes, respectively. The country-specific details are listed in [table 1](#) and [table 2](#). All versions are available free for use and they can be downloaded from the ASAS homepage, section clinical instruments (<http://www.asas-group.org/clinical-instruments.php?id=03>).

The patients were asked to mention concepts which are important for them but are not represented by the 17 aspects of the ASAS HI. Ten percent of the patients expressed that they missed concepts which included the following themes: medication, being able to perform sports, impaired vision, shortness of breath, sitting for a long time, depression, pregnancy and psychological issues such as patients concealing their disease from colleagues and friends (each <5%).

DISCUSSION

The ASAS HI and the EF Item Set were successfully translated in parallel into 15 languages with 17 versions (see <http://www.asas-group.org>, English version see online supplementary 1 and 2). The field test interviews show that the ASAS HI and the EF Item set have high face and

Table 1 Characteristics of patients taking part in the field test in each of the European countries

	Belgium n=9	Croatia n=10	France n=7	Germany n=10	Greece n=10	Hungary n=10	Italy n=10	Nether lands n=11	Portugal n=10	Russia n=10	Spain n=7	Turkey n=10	UK n=11
Age (years), mean (SD)	35.0 (8.1)	46.0 (12.3)	45.0 (11.2)	43.7 (17.5)	37.9 (13.0)	59.8 (10.1)	44.1 (16.6)	49.2 (18.6)	41.4 (13.7)	32.8 (12.0)	49.0 (10.5)	38.4 (12.4)	40.4 (16.0)
Gender, male (%)	67	30	14	50	80	70	60	45	80	60	71	40	73
Disease subtype, AS (%)	56	60	50	70	80	60	60	64	60	60	67	60	70
Disease duration (years), mean (SD)	6.8 (3.8)	7.3 (7.1)	9.0 (6.0)	8.7 (9.4)	12.7 (12.4)	11.5 (11.7)	6.8 (8.0)	14.7 (15.0)	8.9 (10.7)	25.3 (9.7)	15.7 (13.8)	6.8 (7.3)	8.1 (8.9)
Working status, paid work (%)	78	70	43	50	70	20	60	27	70	50	57	30	55
Education (years), mean (SD)	14.3 (3.4)	13.7 (2.2)	10.0 (9.5)	15.9 (2.6)	16.0 (1.6)	10.9 (3.9)	14.7 (3.6)	9.0 (2.9)	12.3 (2.9)	13.6 (3.4)	16.3 (5.1)	10.2 (4.3)	13.5 (2.5)
ASAS HI, mean (SD)	3.6 (3.8)	12.1 (5.9)	8.0 (2.8)	4.9 (1.9)	5.3 (2.7)	9.5 (4.8)	6.7 (3.4)	5.1 (3.7)	5.1 (4.0)	7.9 (4.3)	4.7 (3.9)	6.4 (3.4)	6.0 (4.2)
ASAS HI, range (0–17)	0–10	2–17	3–11	2–8	2–10	0–15	0–13	0–11	1–13	1–16	0–12	1–11	0–14
BASDAI, mean (SD)	2.6 (2.0)	5.7 (1.7)	4.6 (1.6)	3.5 (1.9)	2.2 (1.8)	3.7 (3.0)	3.4 (1.4)	3.8 (1.8)	3.6 (2.3)	3.8 (3.0)	2.2 (1.6)	3.1 (2.0)	4.6 (2.8)
BASDAI, range (0–10)	0.5–6.7	3.1–8.0	2.9–7.5	1.0–6.5	0.3–4.8	0.4–9.6	2.0–5.8	1.3–6.5	0.8–8.2	0–8.4	0.2–4.8	0.6–6.1	2.1–9.4

AS, ankylosing spondylitis; ASAS HI, ASAS Health Index; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index.

Table 2 Characteristics of patients taking part in the field test in each of the non-European countries

	Australia n=10	Canada n=10	China n=10	Colombia n=10	Egypt n=10	Korea n=10	Mexico n=10	Thailand n=10	USA n=10
Age (years), mean (SD)	43.5 (19.8)	45.9 (13.4)	27.8 (12.2)	45.9 (8.8)	37.3 (14.7)	34.8 (11.0)	36.8 (9.4)	42.8 (12.6)	51.6 (12.5)
Gender, male (%)	80	60	100	50	60	90	60	50	70
Disease subtype, AS (%)	60	80	60	60	50	60	60	100	80
Disease duration (years), mean (SD)	21.9 (7.6)	11.9 (13.5)	2.7 (4.5)	5.7 (4.2)	9.3 (7.7)	3.0 (1.8)	12.9 (8.9)	9.5 (6.9)	18.3 (19.1)
Working status, paid work (%)	60	70	40	60	90	30	90	60	30
Education (years), mean (SD)	13.5 (3.7)	13.9 (1.7)	14.2 (8.5)	13.8 (2.1)	14.9 (4.0)	11.7 (3.6)	13.3 (5.5)	13.1 (4.5)	15.8 (3.7)
ASAS HI, mean (SD)	5.7 (2.7)	8.2 (4.3)	6.1 (5.0)	12.6 (2.7)	6.0 (3.6)	7.4 (5.1)	9.2 (3.9)	6.5 (4.7)	8.4 (4.2)
ASAS HI, range	2–10	0–16	0–15	7–16	0–11	0–14	3–15	1–14	2–15
BASDAI, mean (SD)	3.4 (2.3)	4.5 (2.8)	3.0 (2.4)	5.9 (2.0)	3.9 (2.3)	3.5 (2.0)	4.0 (1.9)	3.2 (1.9)	5.3 (2.2)
BASDAI, range	2–10	1.2–8.7	0.2–7.0	1.8–8.4	1.2–8.1	0.4–7.4	0.2–6.6	0.6–6.3	0.7–8.4

AS, ankylosing spondylitis; ASAS HI, ASAS Health Index; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index.

content validity, both with a short time to complete the questionnaire. The English and the translated versions were found to be clear, comprehensive and acceptable to patients in all countries. The simultaneous process of translation and cultural adaptation into several languages is beneficial in order to facilitate effective implementation of the ASAS HI into daily practice.

This study also showed that the items were readily adapted across countries, indicating that the concepts covered are meaningful for many different cultures. Minor linguistic problems were solved and a new response option for two items was added to address the needs of the patients.

The knowledge about other disease manifestations apart from AS was limited in the development process of the ASAS HI which started in 2009. As a result of the new classification criteria, the characteristics of this disorder have changed and the applicability of this new outcome measure was warranted for the whole SpA spectrum.³ We were able to show in the cognitive debriefing interviews that face and content validity was covered both for patients with AS and nr-axSpA, irrespective of peripheral involvement or not. The involvement of a broad spectrum of patients with axSpA has contributed to preliminarily validate the ASAS HI and the EF Item Set for the whole spectrum of patients with axSpA.

Further studies are needed to fully validate the questionnaires. An international validation study will help to confirm the discriminative ability and responsiveness in a larger patient group. This ongoing project will be an important step for the implementation of the ASAS-HI and the EF Item Set into clinical practice on an international level and more translations will be produced in the mean time.

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