

Translation and cross-cultural adaptation of the ASAS Health Index and ASAS environmental factors item set into European Portuguese language

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ABSTRACT

Objective: There is a lack of outcome measures to assess the impact of axial spondyloarthritis (axSpA) on health, function and quality of life. The Assessment of SpondyloArthritis International Society (ASAS) group developed the ASAS Health Index (ASAS-HI) and the ASAS Environmental Factors Item Set (ASAS-EF) to measure functioning and health across all aspects of health that are typically affected and relevant for patients with axSpA, based on the International Classification of Functioning, Disability and Health (ICF). The aim of this paper was to describe the translation and cross-cultural adaptation of both questionnaires into European Portuguese among patients with radiographic and non-radiographic axial SpA (nr-axSpA) and test the conceptual equivalence of the translated version in the Portuguese context.

Material and Methods: The ASAS-HI and ASAS-EF were firstly translated into European Portuguese and then back-translated into English, following forward-backward procedure. After the review of the Portuguese version by an expert committee, the field test with cognitive debriefing involved a sample of 10

axSpA patients with different gender, age, disease duration, and educational background.

Results: Minor difficulties arose from the translation process of the ASAS-HI. The EF Item Set offered more difficulties indicating that concepts underlying the contextual factors may be more culture-dependent. A total of 10 patients with axSpA [8 males, mean age of 41.4 (± 13.7)] participated in the field test. Cognitive debriefing showed that items of the ASAS-HI and EF Item Set of the Portuguese version are clear, relevant, understandable and easy to complete. As a result of cognitive debriefing, the wording of four items had to be changed to avoid misunderstandings or unintended interpretations, and a new response option “not applicable” was added to two items of the ASAS-HI to improve appropriateness.

Conclusions: The resulting Portuguese version of the ASAS-HI and ASAS-EF showed acceptable linguistic validity and has potential for use in both clinical practice and research settings. Nevertheless, before European Portuguese versions can be fully implemented, its psychometric properties (validity and reliability) need to be evaluated.

Keywords: Health quality of life; Outcome research; Axial spondyloarthritis.

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INTRODUCTION

The term spondyloarthritis (SpA) has been introduced to classify and diagnose patients who are characterized by axial and/or peripheral skeletal manifestations, as well as extra-articular manifestations such as psoriasis, anterior uveitis and colitis^{1,2}. Ankylosing spondylitis (AS) is the prototype of SpA, which forms, together with non-radiographic axial SpA (nr-axSpA), the subgroup

that is now called axial SpA (axSpA). The prevalence of SpA in the Portuguese population is 1.6% (95% CI: 1.2%-2.1%)³. Because axSpA usually starts in early adulthood the lifetime impact of the disease can be considerable, resulting in pain, stiffness, fatigue, limitation in activities and social participation and early retirement⁴⁻⁷. Therefore, it is essential to assess the impact of axSpA on functioning, health and quality of life (QoL) of these patients^{2,7} according to a patient perspective. It is also important to assess the benefits of any new therapeutic option being evaluated on the basis of the changes in the patients' functioning or well-being.

The International Classification of Functioning, Disability and Health (ICF) is a model to systematically classify and describe functioning, disability and health in human beings. Based on this framework, the ASAS group have established the aim of developing and validating a health index to assess health and global functioning in patients with SpA based on the ICF components.

Based on the categories of the Comprehensive and Brief ICF Core Set for axSpA an item pool was created containing various items describing the typical spectrum of problems related to the functioning of these patients in a multidisciplinary assessment^{1,8}. The performance of the item pool was tested and analysed with Rasch Analysis⁹ and the best performing items were included in two final questionnaires, ASAS Health Index (ASAS HI) and ASAS Environmental Factors Item Set (ASAS EF)⁷. The ASAS HI is a unidimensional questionnaire, which contains 17 dichotomous items addressing categories of pain, emotional functions, sleep, sexual function, mobility, self-care, and community life. Each statement on the ASAS HI is given a score of "1" (I agree) or "0" (I do not agree). All item scores are summed to give a total score that ranges from 0 (good functioning) to 17 (poor functioning).

In agreement with the biopsychosocial model of health, the ASAS HI is accompanied by a multidimensional item set, ASAS EF Item Set. This questionnaire contains 9 dichotomous items, addressing categories of support/relationships, attitudes and health services that can influence functioning either as a facilitator or as a barrier¹⁰. Both questionnaires can be used in clinical trials or in clinical practice as a new composite index that captures relevant information on the health status of axSpA patients.

In order to use these questionnaires and ensure that the concepts assessed are equivalent in several different countries, with both a different culture and language,

a translation and a cross-cultural adaptation of ASAS HI and ASAS EF needs to be carried out following a rigorous methodology ensuring conceptual equivalence across languages¹¹⁻¹⁴. Consequently, the ASAS group established the objective of translating and adapting the ASAS HI and the ASAS EF cross-culturally into 15 languages with 17 versions and to field test the new versions in patients with axSpA^{9,15}.

This study reports the translation and cross-cultural adaptation of the ASAS HI and the ASAS EF into the European Portuguese language among patients with radiographic and nr-axSpA.

MATERIAL AND METHODS

The cross-cultural adaptation study of the ASAS HI and ASAS EF into European Portuguese language followed the international standardized protocol used by the ASAS group^{9,15}, developed on the basis of the current international recommendations¹¹⁻¹⁴. Translation and cross-cultural adaptation of the English version was done using the forward-backward procedure, which consists of 5 steps¹³.

A national principal investigator (FPS) was appointed and provided with a description of the methodology including literature about cross-cultural adaptation and a standardized operating procedure describing the setting of the field test. The international study coordinator supervised all the procedures, in order to ensure consistency of the methods used. All the process was carried out between March and December 2013.

TRANSLATION

Three bi-lingual translators (native speakers for European Portuguese) produced independent forward translations of the item content, response options, and instructions of the ASAS HI and ASAS EF Item Set into European Portuguese. Two translators were informed of the medical background concepts of the questionnaires and the third translator was neither aware nor informed of the conceptual content (*i.e.*, an uninformed translator). The different profiles of the translators were chosen to assure good agreement and accuracy with the original English version in terms of both the clinical content and the appropriateness of the terminology to the typical patient that would ultimately be completing the questionnaires¹³. Each translator produced an independent written report of

its translation, identifying specific challenging phrases or uncertainties, as well as the rationale for the final choices.

SYNTHESIS OF TRANSLATION

Together with the members of the Portuguese research team, an online consensus meeting was scheduled and the translations were compared. After discussing the discrepancies that had arisen, minor adjustments were made and the three versions were harmonized in a single consensual version of the questionnaires. Following this meeting a written report was produced to document the synthesis of the three translations, specifying the issues addressed and the consensus achieved.

BACK TRANSLATION

Totally blind to the original version of the questionnaires, two other translators back translated the synthesized version of the ASAS HI and ASAS EF questionnaires into the original English language. Both translators were bilingual (native speakers for English). None of the back translators was aware or informed of the concepts used in the questionnaires. Two back translations based on the synthesized translation by translators blinded for the original version were made.

EXPERT COMMITTEE REVIEW

Finally, an expert committee consisted of the translators, back translators, the members of the research team, and one patient fluent in English reviewed all the translations and translations reports for semantic equivalence (*i.e.*, ensuring that the words had the same meaning), idiomatic equivalence (*i.e.*, formulation of equivalent expressions for colloquialisms), experiential equivalence (ensuring that each item properly captured the experience of daily life in the target culture), and conceptual equivalence (ensuring that items held the same conceptual meaning). The role of the committee was to reach consensus on discrepancies, consolidate all the versions of the questionnaires and develop a pre-final European Portuguese version of the ASAS HI and ASAS EF Item Set for field-test evaluation. Additionally, the original author was consulted for additional clarification of the conceptual meaning of any ambiguous item.

FIELD TEST WITH COGNITIVE DEBRIEFING

The final version was pre-tested in a representative sample of native Portuguese patients with axSpA. A convenience sample including patients across a broad

spectrum of socio-demographic background (age, gender, disease duration, education) was recruited from the Rheumatology outpatient clinic of the Centro Hospitalar de Lisboa Ocidental – Hospital de Egas Moniz (CHLO-HEM), Lisbon, according to the following inclusion criteria: 1) axSpA according to the ASAS classification criteria; 2) able to communicate verbally and in writing in European Portuguese. Participants were excluded in the presence of severe comorbidities (e.g. recent stroke), which could potentially influence results of the assessment.

Ten patients (6 AS and 4 nr-axSpA) participated in the field test. First, patients filled the ASAS HI and ASAS EF Item Set in a face-to-face interview (cognitive debriefing) with two members of the research team and a trained physician. During the interviews notes were taken about: 1) the time to complete the questionnaires; 2) whether patients read the instructions; 3) and whether patients had comments on specific items.

The cognitive debriefing interviews aimed to assess the cultural relevance, acceptability, comprehensiveness and understandability of the questionnaire items for patients and its applicability. During the interview, participants were reminded that the purpose of the exercise was for them to test the questionnaire, not for the clinicians to test them. In addition, information on age, gender, disease characteristics, including disease activity information (as measured with the Bath Ankylosing Spondylitis Disease Activity Index – BASDAI), educational level, and working status were collected in a pre-established form.

To create an audit trail of this translation and adaptation process, all the steps were documented through written reports by the different participants. The final translation, the socio-demographic and clinical data and the interview report were sent to the international study coordinator for proof reading and audit. This study received approval from the ethics committee of CHLO-HEM. Written informed consent was obtained from all respondents prior to the start of the study.

RESULTS

The ASAS HI and EF Item Set were successfully translated and culturally adapted into European Portuguese language. The final Portuguese version is shown in the Appendix and can be obtained from the ASAS website (<http://www.asas-group.org/clinical-instruments.php?id=00>).

TRANSLATION AND BACK TRANSLATION OF THE ASAS HI AND ASAS EF

ASAS Health Index: No major differences arose in the majority of the ASAS HI items when the three independent translations were compared. Given the similitude of the items 1, 10 and 16 with the previously validated questions of the *Nottingham Health Profile*, all the participants in the first consensus meeting agreed to adopt and incorporate those already translated items in the harmonized forward translated version. A minor discrepancy was found with the translation of the item 9 (“I am finding it hard to make contact with people”), where two alternatives were formulated to be further discussed in the expert committee meeting (“*Tem sido difícil manter o contacto com as pessoas*” and “*Tem sido difícil dar-me com as pessoas*”). Discrepancies were solved by discussions in the translation teams with support by ASAS international study coordinator providing the background information for the item.

ASAS Environmental Factor Item Set: A few noteworthy discrepancies in meaning arose in items 2 (“friends act around me”), 4 (“modify environment”), 5 (“getting relapses acknowledged by”) and 6 (“treatment is taking up time”) indicating that these concepts may be more culture-dependent. These items were challenging because of misunderstanding of the underlying concepts. In addition, 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”. Alternatives were formulated to be further discussed in the expert committee meeting and in field test evaluation and, a specific request to clarify the conceptual meaning of these items was sent to the ASAS international study coordinator:

- In item 2, “I don’t like the way my friends act around me”, two alternatives to the expression “friends act around me” were formulated (“*Não gosto da forma como os meus amigos agem à minha volta*” and “*Não gosto da forma como os meus amigos se comportam comigo*”).
- 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 item 5, “I have difficulties getting relapses acknowledged by a health care professional”, although a direct equivalent was available for the word “acknowledged”, three alternatives were formulated

and discussed (“*reconheça*”, “*valorize*” or “*altere a sua atuação*”).

- In item 6, “Treatment of my rheumatic disease is taking up time”, the expression of “treatment is taking up time” was considered ambiguous and two translation alternatives were formulated for further discussion (“*O tratamento da minha doença reumática está a demorar*” and “*O tratamento da minha doença reumática rouba-me tempo*”).

All these discrepancies were further discussed in the expert committee meeting with support by ASAS international study coordinator providing the background information for the item and a final consensus was achieved. The committee agreed that the synthesized forward translated version fulfils semantic, idiomatic, experiential and conceptual equivalence and the backward translation showed good accordance with the original English version.

FIELD TEST AND COGNITIVE DEBRIEFING

In the Field test, 10 patients with axSpA (6 with AS and 4 with nr-axSpA, 8 men and 2 women, mean age of 41.4 (± 13.7) years, underwent a cognitive debriefing interview. Tables I and II, summarize the demographic and clinical characteristics of the participants, respectively.

The mean total score of the ASAS HI was 5.1 ± 4.0 (range 0-17, with a lower score indicating a better health status) and ranged from 1 (two participants) to 13 (1 participant); there is no sum score for the EF Item Set (because it is a multidimensional questionnaire). Completion times for ASAS HI and for ASAS EF were respectively, 2.2 ± 0.4 (range 1.2 to 3.2), and 1.2 ± 0.3 minutes (range 0.5 to 1.5).

COGNITIVE DEBRIEFING

In general, all the participants found both questionnaires and respective response scales, clear and easy to complete. They reported that the included items were understandable and appropriate to assess their present condition. Besides that, minor suggestions were made concerning the particular needs of each patient. For example, it was proposed to introduce questions related with up and down stairs and/or sit or get off the sofa without help (ID#10), or “enter/exit the car” (ID#2; ID#8).

In the ASAS HI, two participants (ID#2; ID#3) have considered Item 4, “I have problems using the toilet” ambiguous. Two participants (ID#4; ID#5) found a

TABLE I. INDIVIDUAL PATIENTS' CHARACTERISTICS

Patient ID	Gender	Age	Diagnosis (AS/nr-axSpA)	Disease duration (yrs)	Working status*	Years of formal education	BASDAI (0-10)
P1	M	57	nr-axSpA	1.5	7	12	1.5
P2	M	52	AS	22	1	9	3.5
P3	M	31	nr-axSpA	1	1	12	8.2
P4	M	57	AS	33	1	12	3.5
P5	M	50	AS	4	1	9	5.8
P6	M	21	AS	1	6	15	2.9
P7	M	33	AS	2	1	12	1.7
P8	F	33	nr-axSpA	12	1	17	2.8
P9	F	53	AS	8	1	9	5.5
P10	M	27	nr-axSpA	5	6	16	0.8

*working status: 1= full-time, 2= part-time, 3= work disability due to health, 4= retired due to age, 5= homemaker, 6= student, 7= job-seeking
AS= ankylosing spondylitis; BASDAI= bath ankylosing spondylitis disease activity index; nr-axSpA= non-radiographic axial SpA

TABLE II. GROUP CHARACTERISTICS OF THE PARTICIPANTS TAKING PART IN THE FIELD TEST

Parameter	Value
Work status	Paid work 70%; Unpaid work 30%
Formal education (years); mean (SD), range	12.3 (\pm 2.9), 9-17 years
Disease subtype	AS, 60%; nr-axSpA, 40%
Disease duration (years); mean (SD), range	8.9 (\pm 10.7), 0-33 years
BASDAI (0-10); mean (SD)	3.6 (\pm 2.3), 0.8-8.2

contradiction between the introductory statement that focused on the participant's current situation/condition, "at this moment", and the use of word "often" in item 5, "I am often exhausted" and item 13 "I often get frustrated". Item 7 ("I lost interest in sex") and item 8 ("I have difficulty operating the pedals in my car") 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 these items.

In the ASAS EF, three of the participants (ID#4; ID#6; ID#10) did not fill in item 1 "As a result of my rheumatic disease, the children take more responsibility for household tasks", of the ASAS EF because it was not applicable to their situation. They suggested to change the word "children" in this item (item 1) to "family". The final sentence includes therefore both

words, "As a result of my rheumatic disease, the children/family take more responsibility for household tasks". In the item 4, three participants (ID#4; ID#6; ID#10) found the statement "I modify my living environments" too ambiguous, and made suggestions to improve its clarity by specifying the type of environment by adding "work or home environment". This change was made and the final sentence became "I modify my living (work or home) environments". Finally, two participants (ID#2; ID#5) considered the item 7, "My friends expect too much of me", one participant (ID#3) considered item 8 "I have difficulty operating the pedals in my car" and one participant (ID#2) considered item 9 "My friends understand me", irrelevant or less important.

In summary, the participants found the items of the Portuguese version of the ASAS HI and ASAS EF clear and understandable. The field test provided evidence for face validity without need to modify the final European Portuguese versions of the questionnaires.

DISCUSSION

The current study succeeded in providing a validated and culturally adapted European Portuguese version of the ASAS HI and the EF Item Set (see www.asas-group.org) following the current international recommendations for this process¹¹⁻¹⁴. In the ASAS HI only minor modifications to the initial translation were required and no major cultural differences were noted during the translation process suggesting that the con-

cepts covered are meaningful to the Portuguese culture¹⁵. Minor linguistic problems were solved and a new response option for two items was added to address the needs of the patients.

The ASAS EF Item Set offered more difficulties indicating that concepts underlying the contextual factors may be more culture-dependent¹⁵. The translation of item 2 “friends act around me” and item 6 “treatment is taking up time” were challenging because of the misunderstanding of the underlying concepts. However, these discrepancies were solved through discussion among the members of the expert committee and the international study coordinator.

The field test interviews show that the European Portuguese version of ASAS HI and the EF Item Set have high face and content validity. These Portuguese versions were found to be clear, comprehensive and acceptable to patients with different disease duration and educational backgrounds. The field test findings also indicated that the items covered by the ASAS HI and ASAS EF are meaningful for Portuguese patients with axSpA, with and without peripheral manifestations, which has contributed to validate this Items Set for the whole spectrum of patients with axSpA. The current study is an important step for the implementation of the ASAS-HI and the EF Item Set into clinical practice. However, before their use is widely recommended, it is important to confirm the validity, discriminative ability and responsiveness of the questionnaire when applied to a larger group of patients.

Patient-reported outcome (PRO) measures are increasingly being used to assess disease severity, disease impact and to capture the treatment benefit of health-care interventions from the patient perspective. A strength of this disease-specific questionnaire is that it provides a health index of the overall functioning and health in patients with axSpA based on the Comprehensive ICF Core Set identified for this condition. Both questionnaires showed good acceptability and feasibility to patients. The administrative burden of the questionnaires is low with approximately 2 min for filling out each questionnaire and no additional resources required for interviewer administration over self-administration. There is also no need for medical training to score the questionnaires.

CONCLUSION

The ASAS HI and the EF Item Set were successfully

translated into European Portuguese. These Portuguese versions provides a measure of functioning and health, reflecting what people with all forms of axSpA consider most important to address, with good content validity. Therefore, the ASAS HI and the EF Item Set have the potential to be both, a useful clinical tool and an outcome measure for research. Further research is underway to test the psychometric properties of this new disease-specific questionnaire.

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