The European Portuguese version of the ASAS Health Index for Patients with Spondyloarthritis: measurement properties

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ABSTRACT

Objective: The Assessments of SpondyloArthritis international Society Health Index (ASAS HI), estimates the impact of Spondyloarthritis (SpA) on global functioning and health. This article assesses the construct validity, reliability and responsiveness of the Portuguese version of the ASAS HI.

Patients And Methods: Patients fulfilling ASAS classification criteria for axial (axSpA) or peripheral SpA (pSpA) were included. Construct validity was assessed through Spearman's correlation analysis with other health outcomes. Discriminant validity was tested comparing the ASAS HI across disease activity and functional states using the Kruskal–Wallis test. Internal consistency was assessed by Cronbach's α , and test-retest reliability by intraclass correlation coefficients (ICC). Responsiveness was evaluated by the standardized response mean (SRM) in patients with active disease who required therapy escalation.

Results: Among the 91 patients included, 67% were male, mean (SD) age 47.2 (12.9) years, 63 patients with axSpA and 28 patients with pSpA. The hypothesis defined *a priori* to test construct validity were confirmed. The ASAS HI showed ability to discriminate between patients with different disease activity and functional states (p<0.001). Internal consistency (Cronbach's α : 0.88) and test-retest reliability [ICC=0.76 (95%CI 0.09-0.91)] were good. Responsiveness was moderate (SRM=-0.53). The smallest detectable change was 3.0. **Conclusions:** The Portuguese version of the ASAS HI is a comprehensible questionnaire that is valid, reliable and responsive. It can be used to assess the impact of SpA and its treatment on functioning and health, in clinical practice and for research purposes.

Keywords: Patient reported outcomes; Spondyloarthritis; Patient-reported outcome measure; Quality of life.

INTRODUCTION

Patient reported outcomes (PROs) are outcomes reported directly from patients about how they feel or function regarding a health condition and its therapy, irrespective of the influence of their healthcare professionals or other third parties. These PROs must be reported in a standardized way with the appropriate instrument¹. Nowadays, there is a growing attention towards the patient-centered healthcare system², a philosophy that also influences Rheumatology. In observational studies, clinical trials, and routine clinical practice PROs are as important as other measures of efficacy and safety, since these rely on patient feedback about health outcomes and as such enhance shared decision-making, treatment adherence and potentiate better outcomes^{3,4}.

The development of PROs in spondyloarthritis (SpA)

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has been a longstanding challenge, due to several reasons, such as the heterogeneity and subjectivity of constructs to be assessed or the nonspecific nature of inflammatory laboratory markers to monitor disease activity, among other reasons⁴. From the vast repertoire of PROs, the Assessment of SpondyloArthritis international Society (ASAS) recommends the use of a handful in clinical practice, as described elsewhere⁵.

The ASAS Health Index (ASAS HI) has been recently developed to measure functioning and health in patients with SpA with the aim to better define the impact and severity of the disease in these patients6. The item pool was developed by linking items from existing questionnaires to the Comprehensive International Classification of Functioning, Disability and Health (ICF) Core Set for Ankylosing Spondylitis (AS). The category used in the ASAS HI is related to the components of body functions, activities and participation^{6,7}.

The ASAS HI is a unidimensional questionnaire, which includes 17 dichotomous items, addressing pain, emotional functions, sleep, sexual function, mobility, self-care and community life representing a wide spectrum of different levels of functioning and disability in patients with SpA8. The sum score of the ASAS HI ranges from 0 (best health status) to 17 (worse health status)6. The ASAS HI was originally developed in parallel in English speaking countries (Australia, Canada, Ireland, UK, USA), and it has later been translated and cross-culturally adapted into 18 languages worldwide, including European Portuguese9-11. After the review of the Portuguese version by an expert committee, content and face validity as well as feasibility (time of completion) have already been confirmed^{10, 11}. The aim of the present study was to assess the construct validity, reliability and responsiveness of the European Portuguese version of ASAS HI. This new questionnaire can be used to assess, the disease specific, impact of SpA and its treatment on functioning and health, in clinical practice and for research purposes."

PATIENTS AND METHODS

PATIENTS

A cross-sectional observational study with a longitudinal component for reliability and responsiveness was performed. SpA patients fulfilling the ASAS classification criteria for either axial (axSpA) or peripheral SpA (pSpA) were included between 2014 and 2017^{12, 13}. The recruitment, taking place in the rheumatology de-

partment of 3 Portuguese hospitals (2 regional, 1 academic), should include 80% of patients with axial SpA (40% non-radiographic axSpA (nr-axSpA) and 60% radiographic axSpA (r-axSpA) and 20% with peripheral SpA (pSpA) with no more than 10% of all patients having concomitant psoriasis. Patients had to be older than 18 years with a range of different disease severities and all types of treatment. Patients with severe concomitant diseases that may influence functioning were excluded as well as patients unable to understand the objectives of the study and the different questionnaires. The plan was to include at least 25% of the sample into the "reliability arm" and 25% into the "sensitivity to change arm". All data were collected by rheumatologists. All Portuguese patients who participated in the international validation of the ASAS HI, were included in the current manuscript.

ETHICS

This project received approval from the local ethics committees and written informed consent was obtained from all respondents prior to their participation, in accordance with the standards of the Helsinki Declaration of 1975/83.

DATA COLLECTION

Demographic and clinical information was collected including age, gender, predominant presentation (i.e. axial or peripheral), presence of extra-articular manifestations (i.e. anterior uveitis, psoriasis, inflammatory bowel disease, other), years of education, employment status, current medications and C reactive protein (CRP) levels. Physician's global assessment of the patient's condition was recorded (on numerical rating scale (NRS) 0-10 and 4-point Likert scale, very poor to very good) by answering the questions "How active was the spondyloarthritis of your patient during the last week?", "Please score the overall status of the subject's signs and symptoms and the functional capacity of the subject" and "How do you rate the health of your patient today?".

Patients completed a series of self-reported European Portuguese versions of questionnaires at baseline: ASAS HI⁶, Bath AS Disease Index (BASDAI)¹⁴, Bath AS Functioning Index (BASFI)¹⁴, EuroQol five dimensions questionnaire (EQ-5D-5L index and thermometer)¹⁵, Short Form Survey Instrument 36-Item (SF-36)^{16,17}, Hospital Anxiety and Depression Scale (HAD-S)¹⁸, work productivity and activity impairment questionnaire (WPAI)¹⁹, general pain and spinal pain

(on NRS 0-10), and patient global assessment (on NRS 0-10 and 4-point Likert scale, very poor to very good). Patient's global assessment about his/her current functioning and health status was recorded by answering the questions "How do you rate your health today?", "Which effect had the disease on your well-being over the last week?" and "Which effect had the disease on your well-being over the last six months?". The Patient acceptable symptom state (PASS) was recorded with the question "Considering all the different ways your disease is affecting you, if you were to stay in this state for the next few months, do you consider that your current state is satisfactory?" (yes/no). The ASDAS score was calculated as well as ASDAS disease activity states;^{20, 21} the EQ-5D index was based on national value norm¹⁵.

For test-retest reliability, patients who considered themselves in a stable disease state and with stable treatment (i.e. no change in non-steroidal anti-inflammatory drugs (NSAIDs) over the last week, no change in conventional synthetic disease-modifying antirheumatic drug (csDMARD) or tumor necrosis factor inhibitor (TNFi) therapy over the last 4 weeks) were invited to complete the same questionnaire at home 4-7 days later. This period of time was considered to be sufficiently short to assume that the variable being measured had not changed²². Responsiveness was assessed in a subgroup of patients that required a therapeutic change (the sensitivity to change arm) with the initiation of an NSAID, csDMARD or TNFi, because of high disease activity. Patients were reassessed in the clinic 2-24 weeks after the treatment change had been implemented for NSAIDs or 12-24 weeks for csDMARD or TNFi. Therapeutic changes for reasons other than clinical disease activity were excluded (i.e. adverse events, pregnancy wish, patient decision). At the second assessment, patients were inquired whether their condition was stable, had improved or had worsened compared with baseline.

STATISTICS

COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) recommendations were followed to test and report measurement properties²³. Psychometric properties were assessed according to the Outcome Measures in Rheumatology (OMERACT) filter²⁴.

Socio-demographic and clinical characteristics were descriptively analyzed using frequency distributions and mean values. Ceiling and floor effects of the ASAS HI were considered to be present if more than 15% of respondents achieved the lowest or highest possible total score²⁵.

Construct validity was evaluated by Spearman correlation coefficients. Based on the constructs of ASAS HI and the other PROs, *a priori* hypotheses were formulated. It was hypothesized that the summary scores of the ASAS HI would be strongly correlated (0.50 to 0.90) with the BASFI, BASDAI, ASDAS-CRP, and the SF-36 (physical), and low to moderately correlated with the HAD-S Anxiety/Depression, SF-36 (mental), absenteeism and presenteeism (0.3-0.49). The level of correlation was based on predefined thresholds: low \leq 0.3, moderate 0.3-0.49, good 0.5-0.79 and very good \geq 0.8, following the international methodology²⁶.

Discriminant validity of the ASAS HI was assessed by calculating ASAS HI mean scores for predefined groups, according to: (i) ASDAS disease activity states: (inactive disease, low, high and very high disease activity²⁷; and (ii) BASDAI and BASFI thresholds: <2.0, 2.0–3.99, 4.0–5.99, \geq 6.0; using the Kruskal–Wallis test. In addition, the discriminant validity of the ASAS HI was assessed by applying the international cutoffs²³ defining the three health status groups (Good \leq 5.0, Moderate, <5.0 to <12.0, and Poor \geq 12.0). It was hypothesized that participants with higher levels of disease activity or higher functional repercussion would have higher scores on the ASAS HI than participants with low levels of disease activity or low functional repercussion.

Reliability was analyzed by internal consistency and test-retest reliability. Internal consistency was evaluated with the Cronbach's α coefficient for the total score. Acceptable internal consistency was defined as $\alpha \ge 0.7^{22}$. Test–retest reliability was assessed using the intraclass correlation coefficient (ICC) for absolute agreement in a two-way ANOVA model. An ICC ≥ 0.80 was considered to be indicative of excellent reliability²⁸.

Responsiveness was assessed by calculating the standardized response mean (SRM)²⁶. The magnitude of the SRM was considered as follows: <0.4 low effect, 0.4-0.79 moderate effect, and \ge 0.8 large effect²⁶.

Statistical analysis was performed using Stata version 14.0.

RESULTS

COHORT CHARACTERISTICS

A total of 91 SpA patients were enrolled in this study,

66% were male, mean (SD) age 47.2 (12.9) years, mean symptom duration 15 (12) years. There were 63 (69%) with axSpA (49 (78%) r-axSpA and 14 (22%) nr-axSpA) and 28 (31%) pSpA patients. The mean ASDAS-CRP was 2.4 (1.1), BASDAI 3.3 (2.3), BASFI 2.6 (2.6) and ASAS HI 6.4 (3.6); 74% of patients were treated with NSAIDs, 44% with csDMARDs and 18% with TNFi (Table I). Fourteen patients could not be included, neither in the reliability nor in the sensitivity to change arm, because they did not meet all the requirements or due to incomplete data in the second visit.

PSYCHOMETRIC PROPERTIES OF THE ASAS HI

The average score of the ASAS HI was 6.4 (SD 3.6). Floor and ceiling effects the ASAS HI of this version were acceptable (0% and 1.1%, respectively) (Figure 1).

The assessment of the construct validity confirmed significant correlations, in the expected directions. As hypothesized, the ASAS HI had a good correlation with the BASDAI (r=0.77), BASFI (r=0.76), ASDAS-CRP (r=0.66), and SF-36 PCS (-0.82) and the correlations were moderate to low with HAD-S Anxiety (r=0.41), Depression (r=0.45), presenteeism (r=0.44), absenteeism (r=0.23). ASAS HI had a good correlation with SF-36 MCS (-0.62) (Table II). The ASAS HI discriminated well between patients with different disease activity states, measured by ASDAS and BASDAI (both p<0.01) and function, measured by BASFI (p<0.01) (Table III). The groups with greater disease activity and more impaired functioning had higher mean ASAS HI scores (than those with lower disease activity or lower functional repercussion). Applying the two cut-off values as proposed by the international ASAS HI validation study, (26) we were able to show that the three resulting groups could discriminate with respect to disease activity, functioning and health measures (Table IV).

RELIABILITY

The ASAS HI scores showed a good internal consistency (Cronbach's α =0.88). Regarding disease subgroups, internal consistency was very good for r-axSpA (0.90) and good for nr-axSpA (0.86) but only poor for pSpA (0.50)

A total of 70 patients had a second assessment for reliability assessment. Test-retest reliability was good with an overall ICC of 0.76 (95%CI 0.09-0.91) and ICC were comparable in all disease subtypes (r-axSpA 0.69 (95%CI -0.06 to 0.90); nr-axSpA 0.90 (95%CI 0.66 to 0.97; pSpA 0.79 (95%CI 0.02 to 0.94). The Smallest Detectable Change was 3.0, which corresponds to the minimum change beyond measurement error that can be detected in an individual patient over time²⁶.

RESPONSIVENESS

Sensitivity to change was tested in 7 patients considering themselves to be improved, after therapy introduction. One patient started NSAIDs, 1 patient a csD-MARD, and 5 patients TNFi. The overall SRM was moderate (-0.53).

DISCUSSION

Current medical practice relies on measurements and tests. However, at the base of measuring and testing lies the assumption of uncertainty²⁹. In this context, the patient perspective gained relevance and contributed to increase patient adherence and better outcomes.

We have shown that the European Portuguese (PT) version of the ASAS HI is a valid, reliable and responsive measure to assess functioning and health in PT patients with SpA. The use of the ASAS HI is feasible since it contains only 17 items with a yes/no response option addressing important and non-redundant aspects of patients' complaints. The calculation to obtain a single sum score is simple in order to be feasible for use in clinical practice. In a former analysis we showed that time of completion was 2.2 ± 0.4 (range 1.2 to 3.2) minutes¹⁰. The psychometric properties of the European PT version of the ASAS HI were consistent with the results found in the international study²⁶, and also with the validation studies for Colombian-Spanish³⁰, Italian³¹ and Korean languages³².

There were no floor and ceiling effects for the ASAS HI PT total scores, similar to the results obtained in the international study²⁶. The scores have good content validity¹⁰ and the European PT version of the ASAS HI, demonstrated excellent correlation with other measures covering similar constructs of health status (e.g. activity, functioning, quality of life). As predicted in terms of construct validity there was a strong correlation with the BASDAI and the physical domain of SF-36, meaning that the worse the overall function and health (higher ASAS HI score) the higher the disease activity (higher BASDAI score) and the worse the physical function (lower SF-36-physical score). In addition, the good correlation between the ASAS HI and patient global assessment as well as generic health measures (such as SF-36) suggests that patients do not make

TABLE I. SOCIO-DEMOGRAPHIC CHARACTERISTICS

	All patient	Reliability	Sensitivity
Patient characteristics	(n=91)	(n=70)	to change (n=7)
Age (years)	47.2 (12.9)	48.7 (12.7)	43.4 (12.3)
Male, n (%)	60 (66)	43 (61)	6 (86)
Symptom duration (years)	15.1 (12.0)	16.8 (12.1)	14.0 (12.5)
axSpA, n(%)	63 (69)	46 (66)	7 (100)
r-axSpA	49 (78)	36 (78)	6 (86)
Peripheral manifestations, current, n(%)			
Arthritis	15 (17)	9 (13)	1 (17)
Dactylitis	0 (0)	0 (0)	0 (0)
Enthesitis	7 (8)	3 (4)	1 (17)
Extra-articular manifestations, current, n(%)			
Uveitis	0 (0)	0 (0)	0 (0)
IBD	4 (5)	4 (6)	0 (0)
Skin psoriasis	18 (18)	14 (20)	0 (0)
HLA-B27 positive, n(%)	50 (75)	37 (41)	5 (100)
CRP (mg/L)	14.2 (16.8)	12.2 (14.7)	22.2 (22.7)
Elevated CPR (≥0.5mg/L), n(%)	49 (60)	37 (56)	5 (83)
Current NSAID treatment, n(%)	65 (74)	49 (71)	5 (71)
Current steroids, n(%)	13 (15)	11 (16)	0 (0)
Current csDMARD treatment, n(%)	36 (44)	27 (42)	1 (14)
Current TNFi treatment, n(%)	15 (18)	12 (17)	0 (0)
ASAS HI (0-17) BL	6.4 (3.6)	5.9 (3.5)	9.4 (3.0)
ASAS HI (0-17) T2	4.1 (4.1)	3.8 (4.0)	6.4 (4.7)
ASDAS	2.4 (1.1)	2.2 (0.9)	3.7 (1.0)
BASDAI (0-10)	3.3 (2.3)	2.9 (2.2)	5.1 (2.0)
BASFI (0-10)	2.6 (2.6)	2.3 (2.5)	4.5 (2.2)
Pain, NRS 0-10	3.7 (2.7)	3.3 (2.6)	6.1 (1.1)
Physician global, NRS 0-10	3.2 (2.1)	3.1 (2.1)	4.5 (2.3)
Patient global, NRS 0-10	3.6 (2.5)	3.1 82.3)	6.0 (1.5)
PASS (yes)	63 (70)	53 (77)	1 (14)
HADS anxiety (0-21)	6.7 (4.2)	6.5 (4.1)	7.0 (2.1)
HADS depression (0-21)	5.5 (3.6)	5.4 (3.3)	7.1 (4.1)
EQ-5D	0.4 (0.5)	0.5 (0.4)	0.2 (0.2)
SF-36 PSC (0-100)	54.5 (17.8)	56.4 (16.3)	38.3 (13.5)
SF-36 MCS (0-100)	59.8 (18.2)	62.0 (17.7)	48.6 (14.8)
Employed (yes), n(%) If age ≤ 65 (n=81)	64 (79)	11 (18)	5 (71)
WPAI-SHP if employed			
Absenteeism	11.2 (25.6) (n=50)	11.1 (25.2)	6.7 (14.9)
Presenteeism	27.3 (20.6) (n=48)	23.7 (19.7)	44.0 (15.2)

ASAS HI, ASAS Health Index; ASDAS, Ankylosing Spondylitis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; CRP, C reactive protein; csDMARD, conventional synthetic diseasemodifying antirheumatic drug; EQ-5D, Euro Quality of Life 5 Dimensions; HADS, Hospital Anxiety Depression Scale; HLA, human leucocyte antigen; IBD, inflammatory bowel disease; MSC, mental component summary score; NRS, numerical rating scale; NSAID, nonsteroidal antirheumatic drug; PASS, Patient Acceptable Symptom State; PSC, physical component summary score; SF-36, Short Form 36; TNFi, tumour necrosis factor inhibitor; VAS, Visual Analogue Scale; WPAI, Work Productivity and Impairment Scale. BL: Baseline; T2, second time of assessment. Values are presented as mean(SD) or absolute number (%). Percentages are % of available data. Fewer than 5% of the data were missing, except for HLAB27 (26%), physician global (11%) and csDMARD (11%). Unless otherwise stated all described data is relative to the baseline observation.



FIGURE 1. Score distribution (0–17) of the ASAS Health Index (ASAS HI) at baseline.

substantial distinctions between disease-specific and more generally worded questionnaires. The adapted European PT version showed good internal consistency (Cronbach's $\alpha > 0.88$) similar to the Colombian-Spanish version (Cronbach's $\alpha > 0.91$), and a good test-retest reliability (ICC > 0.76) similar to the Colombian-Spanish version (ICC > 0.8)²⁷ but lower than the Korean (ICC > 0.97)²⁹. Internal consistence was somewhat lower in pSpA vs axSpA patients, maybe due to

the lower sample size and higher chance of outlier effect on the pSpA group. In this study the lower ICC is probably related with the low variance of scores between participants³³.

Importantly, this version of ASAS HI is also applicable in all patients with SpA irrespective of the disease subgroup. The results in internal consistency were "very good" in nr-axSpA and "good" in r-axSpA and pSpA, providing support for the use of these questionnaires in the whole group of patients with SpA. However, as the ASAS HI was originally developed in a cohort of patients with AS/r-axSpA and using AS/r-axSpA disease-specific questionnaires, caution is advised for its use in SpA patients other than r-axSpA. This is reinforced in the Portuguese population as the number of pSpA involved was relatively low (n=28, 31%).

The ASAS HI was sensitive to detect changes after starting a new pharmacological treatment. The SRM was moderate (-0.53) similar to the results seen in the original description of the instrument for NSAIDs (-0.44) and csDMARDs (-0.69) but lower than for TNFi (-0.85)²⁶. Considering the low number of patients involved in the sensitivity to change arm (n=7), in the Portuguese study the analyses was performed independently of the therapy (only five of these patients received TNFi). This may, to some extent, explain the

Variables	Hypothesis	R	Confirmation
Patient global	Good	0.59	Yes
Physician global	Moderate	0.39	Yes
BASDAI	Good	0.77	Yes
BASFI	Good	0.76	Yes
ASDAS-CRP	Good	0.66	Yes
SF-36 PCS	Good	-0.82	Yes
SF-36 MCS	Moderate	-0.62	No
HAD-S Anxiety	Moderate	0.41	Yes
HAD-S Depression	Moderate	0.45	Yes
EQ5D	Good	-0.75	Yes
EQ5D-VAS (0-100)	Good	0.21	No
WPAI-SHP			
Absenteeism	Moderate	0.23	No
Presenteeism	Moderate	0.44	Yes

TABLE II. SPEARMAN CORRELATION BETWEEN ASAS HEALTH INDEX SCORES AND OTHER PRO

Column indicates whether hypothesis generated prior to analysis about magnitude and direction of correlation was confirmed in the specific variable. ASAS HI, ASAS Health Index; ASDAS, Ankylosing Spondylitis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; CRP, C reactive protein; EQ-5D, Euro Quality of Life 5 Dimensions; HADS, Hospital Anxiety Depression Scale; MSC, mental component summary score; PSC, physical component summary score; SF-36, Short Form 36; WPAI, Work Productivity and Impairment Scale.

TABLE III. DISCRIMINANT VALIDITY OF ASAS HI (AT BASELINE) STRATIFIED BY DISEASE ACTIVITY AND PHYSICAL FUNCTIONING

Disease activity					p-value	
	Inactive	Low	High	Very high		
ASDAS thresholds	(N=16)	(N=18)	(N=35)	(N=22)		
ASAS HI	3.3 (1.4)	4.5 (2.0)	6.9 (3.5)	9.4 (3.2)	< 0.01	
BASDAI thresholds	<2.0 (n=31)	2.0-3.9 (n=24)	4.0-5.9 (n=21)	≥6.0 (n=13)	.0.01	
ASAS HI	3.8 (1.7)	4.9 (1.9)	8.4 (3.1)	11.5 (2.8)	<0.01	
Functioning					p-value	
BASFI thresholds	<2.0 (n=45)	2.0-3.9 (n=19)	4.0-5.9 (n=14)	≥6.0 (n=11)	<0.01	
ASAS HI	4.0 (1.7)	6.6 (2.3)	9.9 (3.4)	11.0 (3.0)		

All values given as mean (SD), ASDAS: Ankylosing Spondylitis Disease Activity Score; BASDAI: Bath Ankylosing Spondylitis Disease Index; BASFI: Bath Ankylosing Spondylitis Functioning Index, ASAS HI: ASAS Health Index

TABLE IV. DISCRIMINANT VALIDITY OF THE HEALTH STATUS GROUPS

Health state					
(number (n),	Good	Moderate	Poor		
% patients)	≤5.0 (n=44,48%)	<5.0 to <12.0 (n=37,41%)	≥12.0 (n=10,11%)		
ASAS HI	3.5 (1.1)	7.8 (1.6)	13.7 (1.8)		
BASFI	0.9 (1.1)	3.6 (2.4)	6.4 (2.0)		
BASDAI	1.8 (1.4)	4.1 (1.8)	6.9 (1.8)		
ASDAS	1.8 (0.8)	2.7 (0.9)	3.8 (1.1)		
SF-36 PCS	67.1 (8.9)	47.4 (13.6)	25.1 (10.8)		
EQ-5D	0.7 (0.2)	0.3 (0.3)	-0.5 (1.0)		

Values given as mean (SD) otherwise indicated.

ASDAS: Ankylosing Spondylitis Disease Activity Score; BASDAI: Bath Ankylosing Spondylitis Disease Index; BASFI: Bath Ankylosing Spondylitis Functioning Index, ASAS HI: ASAS Health Index; SF36-PSC: Short Form Survey Instrument 36-Item; EQ-5D: EuroQol five dimensions questionnaire

overall result.

This study has some weaknesses and clear strengths. In this study test-retest reliability was measured assuming that the disease remains stable in a short period of time (4-7 days). An additional weakness is related with the reduced sample size especially in the sensitivity to change arm (n=7). Strengths include the involvement of patients with different socioeconomic backgrounds, disease activity, therapies and pSpA subtype, within the validation process. The total number of patients included is higher than in other published versions^{27,29}.

This version of the ASAS HI is validated for the Portuguese population and not for others PT-speaking populations, for which additional cross-cultural adaptation and validation should be performed due to linguistic variations and cultural differences. Another Portuguese version of the ASAS HI is available (Portuguese from Brazil) and was developed independently during the international validation project¹¹.

CONCLUSION

In conclusion, the PT version of the ASAS HI is a comprehensible questionnaire that is valid, reliable and responsive11. Therefore, it can be used to assess the impact of SpA and its treatment on functioning and health, in clinical practice and for research purposes.

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REFERENCES

- 1. Doward LC, McKenna SP. Defining patient-reported outcomes. Value Health. 2004;7 Suppl 1:S4-8.
- IAPO. What is Patient-centred Health Care? A Review of Definitions and Principles. 2nd ed. London: IAPO; 2007. International Alliance of Patients' Organizations; pp. 1–34 e. 2007.
- Gossec L, Dougados M, Dixon W. Patient-reported outcomes as end points in clinical trials in rheumatoid arthritis. RMD Open. 2015;1(1):e000019.
- Nhan DT, Caplan L. Patient-Reported Outcomes in Axial Spondyloarthritis. Rheum Dis Clin North Am. 2016;42(2):285--299.
- Png K, Kwan YH, Leung YY, Phang JK, Lau JQ, Lim KK, et al. Measurement properties of patient reported outcome measures for spondyloarthritis: A systematic review. Semin Arthritis Rheum. 2018.
- Kiltz U, van der Heijde D, Boonen A, Cieza A, Stucki G, Khan MA, et al. Development of a health index in patients with ankylosing spondylitis (ASAS HI): final result of a global initiative based on the ICF guided by ASAS. Ann Rheum Dis. 2015;74(5):830-835.
- Boonen A, Braun J, van der Horst Bruinsma IE, Huang F, Maksymowych W, Kostanjsek N, et al. ASAS/WHO ICF Core Sets for ankylosing spondylitis (AS): how to classify the impact of AS on functioning and health. Ann Rheum Dis. 2010;69(1):102-7.
- Kiltz U, Essers I, Hiligsmann M, Braun J, Maksymowych WP, Taylor WJ, et al. Which aspects of health are most important for patients with spondyloarthritis? A Best Worst Scaling based on the ASAS Health Index. Rheumatology (Oxford). 2016;55 (10):1771-1776.
- Kiltz U, van der Heijde D, Boonen A, Bautista-Molano W, Burgos-Vargas R, Chiowchanwisawakit P, et al. 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. RMD Open. 2016;2(2):e000311.
- Cruz EB, Ramiro S, Machado P, Sousa S, Aguiar R, Sepriano A, et al. Translation and cross-cultural adaptation of the ASAS Health Index and ASAS Environmental Factors Item Set into European Portuguese Language. Acta Reumatol Port. 2017;42 (3):256-262.
- 11. ASAS. Description of ASAS-HI. https://www.asasgroup.org/clinical-instruments/asas-health-index. Accessed the 2nd of November 2018. 2018.
- Rudwaleit M, van der Heijde D, Landewe R, Listing J, Akkoc N, Brandt J, et al. The development of Assessment of SpondyloArthritis international Society classification criteria for axial spondyloarthritis (part II): validation and final selection. Ann Rheum Dis. 2009;68(6):777-783.
- Rudwaleit M, van der Heijde D, Landewe R, Akkoc N, Brandt J, Chou CT, et al. The Assessment of SpondyloArthritis International Society classification criteria for peripheral spondyloarthritis and for spondyloarthritis in general. Ann Rheum Dis. 2011;70(1):25-31.
- Pimentel-Santos FM, Pinto T, Santos H, Barcelos A, Cunha I, Branco JC, et al. Portuguese version of the bath indexes for ankylosing spondylitis patients: a cross-cultural adaptation and validation. Clin Rheumatol. 2012;31(2):341-346.
- Ferreira PL, Ferreira LN, Pereira LN. [Contribution for the validation of the Portuguese version of EQ-5D]. Acta Med Port. 2013;26(6):664-675.

- Ferreira PL. [Development of the Portuguese version of MOS SF-36. Part I. Cultural and linguistic adaptation]. Acta Med Port. 2000;13(1-2):55-66.
- Ferreira PL. [Development of the Portuguese version of MOS SF-36. Part II -Validation tests]. Acta Med Port. 2000;13(3):119--127.
- Pais-Ribeiro J, Silva I, Ferreira T, Martins A, Meneses R, Baltar M. Validation study of a Portuguese version of the Hospital Anxiety and Depression Scale. Psychol Health Med. 2007;12(2): 225-35; quiz 35-7.
- Reilly MC, Gooch KL, Wong RL, Kupper H, van der Heijde D. Validity, reliability and responsiveness of the Work Productivity and Activity Impairment Questionnaire in ankylosing spondylitis. Rheumatology (Oxford). 2010;49(4):812-819.
- 20. van der Heijde D, Lie E, Kvien TK, Sieper J, Van den Bosch F, Listing J, et al. ASDAS, a highly discriminatory ASAS-endorsed disease activity score in patients with ankylosing spondylitis. Ann Rheum Dis. 2009;68(12):1811-1188.
- 21. Machado P, Landewe R, Lie E, Kvien TK, Braun J, Baker D, et al. Ankylosing Spondylitis Disease Activity Score (ASDAS): defining cut-off values for disease activity states and improvement scores. Ann Rheum Dis. 2011;70(1):47-53.
- 22. Steiner LS NG. Health Measurement Scales: A practical guide to their development and use. 3rd ed2003.
- 23. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol. 2010;63(7):737-745.
- Boers M, Brooks P, Strand CV, Tugwell P. The OMERACT filter for Outcome Measures in Rheumatology. J Rheumatol. 1998;25(2):198-199.
- McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res. 1995;4(4):293-307.
- 26. Kiltz U, van der Heijde D, Boonen A, Akkoc N, Bautista-Molano W, Burgos-Vargas R, et al. Measurement properties of the ASAS Health Index: results of a global study in patients with axial and peripheral spondyloarthritis. Ann Rheum Dis. 2018.
- Machado PM, Landewé R, Heijde DV, (ASAS) AoSiS. Ankylosing Spondylitis Disease Activity Score (ASDAS): 2018 update of the nomenclature for disease activity states. Ann Rheum Dis. 2018;77(10):1539-1540.
- Nunnally J, Bernstein I. Psychometric theory. 3rd ed. New York: McGraw-Hill. 1994.
- Landewé RB, van der Heijde DM. Principles of assessment from a clinical perspective. Best Pract Res Clin Rheumatol. 2003;17(3):365-379.
- 30. Bautista-Molano W, Landewé RBM, Kiltz U, Valle-Oñate R, van der Heijde D. Validation and reliability of translation of the ASAS Health Index in a Colombian Spanish-speaking population with spondyloarthritis. Clin Rheumatol. 2018;37(11):3063-3068.
- Di Carlo M, Lato V, Di Matteo A, Carotti M, Salaffi F. Defining functioning categories in axial Spondyloarthritis: the role of the ASAS Health Index. Rheumatol Int. 2017;37(5):713-718.
- 32. Choi JH, Kim TJ, Shin K, Choi CB, Kim JH, Kim SH, et al. The reliability and validity of a Korean translation of the ASAS Health Index and Environmental Factors in Korean patients with axial spondyloarthritis. J Korean Med Sci. 2014;29(3):334-337.
- Portney LG W, MP. Foundations of Clinical Research : Applications to Practice2008.