

Performance of the ASAS Health Index for the Evaluation of Spondyloarthritis in Daily Practice

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ABSTRACT. *Objective.* The Assessment of SpondyloArthritis international Society Health Index (ASAS HI) is a tool designed to assess disease impact in spondyloarthritis (SpA), but its clinical performance is barely known. We aimed to test the clinimetric properties of ASAS HI in a real clinical setting.

Methods. This cross-sectional study included 111 consecutive patients with SpA. The measurement properties of ASAS HI were tested against conventional assessment measures. Convergent validity was assessed by Spearman rho correlations, while discriminative validity was analyzed through receiver-operating characteristic (ROC) curves. A multivariate regression analysis was designed to identify ASAS HI items associated with active disease.

Results. The average ASAS HI was 5.4 ± 3.8 (interquartile range 3–8). ASAS HI showed high convergent validity against other SpA measures ($\rho \geq 0.70$, $p < 0.0005$). The optimal criteria for detecting high/very high disease activity Ankylosing Spondylitis Disease Activity Score (ASDAS) categories was an ASAS HI score > 6 , area under the ROC curve 0.86 (95% CI 0.78–0.92), positive likelihood ratio 7.3 (95% CI 3.1–17.1), $p < 0.0001$. The ASAS HI items significantly associated with Bath Ankylosing Spondylitis Disease Activity Index active disease were “I often get frustrated” (OR 9.2, 95% CI 1.2–69.4, $p = 0.032$), and “I sleep badly at night” (OR 7.7, 95% CI 1.4–41.6, $p = 0.018$). As for ASDAS, it was “pain sometimes disrupts my normal activities” (OR 8.7, 95% CI 1.7–45.2, $p = 0.010$).

Conclusion. The ASAS HI is a useful and simple instrument for its application in daily practice. Given its good clinimetric properties, it could be used as an additional instrument to evaluate SpA.

Key Indexing Terms: ASAS HI, measurement properties, patient-reported outcome measures, spondyloarthritis

The spondyloarthritis (SpA) conditions are a group of related conditions that share a common genetic basis through HLA-B27, but also clinical and radiographic features¹. Axial spondyloarthritis (axSpA) includes diseases with predominantly axial involvement, such as ankylosing spondylitis (AS) and nonradiographic axial SpA, which share as key symptoms both inflammatory back pain and morning axial stiffness^{1,2}. On the other hand, psoriatic arthritis (PsA) is mostly a peripheral SpA with less axial component^{1,2}. In addition, in both peripheral and axial SpA, enthesitis or dactylitis may occur with some frequency, which makes the general clinical picture of these entities very heterogeneous¹.

For decades, different tools have been available to assess the activity [Bath Ankylosing Spondylitis Disease Activity Index/Ankylosing Spondylitis Disease Activity Score (BASDAI/ASDAS)], physical function [Bath Ankylosing Spondylitis Functional Index (BASFI)], movement metrics [Bath Ankylosing

Spondylitis Metrology Index (BASMI)], and structural damage [Bath AS Radiological Index/modified Stoke Ankylosing Spondylitis Spine Score (BASRI/mSASSS)] of SpA^{1,3}. Most of these indices are important for clinical and therapeutic decision making; however, these tools were designed based on the experience of clinicians who were very familiar with these entities. Therefore, although most of these instruments also contain patient-reported outcome measures (PROM), the information they provide is mainly oriented toward decision making based on the doctor’s vision. In different rheumatic diseases, including SpA, it is recognized that patients’ perceptions about what their disease means in their daily lives (disease effect) do not always coincide with the results derived from the different disease assessment instruments⁴. As a consequence, discrepancy between a patient’s and a physician’s ratings of general health status is not unusual in these diseases⁵. The consequence of such a discordant viewpoint is that often, patients and physicians do not make decisions together. The patients’ own perspectives of their health status should be important additional measures used to assess disease activity as well as its effect, and therefore used in clinical and therapeutic decision making.

Currently there is a growing tendency to use instruments that characterize, in the best possible way, the effect that SpA generate on patients’ lives. For that purpose, tools such as the

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Psoriatic Arthritis Impact of Disease (PsAID), for PsA, and the Assessment of SpondyloArthritis international Society Health Index (ASAS HI), for SpA, have been developed and validated^{6,7}. ASAS HI was developed to assess health in patients with AS according to the International Classification of Functioning, Disability and Health (ICF) categories. The 17 statements of ASAS HI were obtained from a pool of 251 items originating from questionnaires already in use for patients with axSpA or from questionnaires linked to the ICF⁷. The ASAS HI contains items addressing categories of pain, emotional functions, sleep, sexual function, mobility, self-care, and community life⁷. Therefore, ASAS HI could provide information on the full range of difficulties that patients with SpA face in their daily lives.

To date, very few studies have been published assessing the applicability of ASAS HI under conditions of routine clinical practice^{8,9,10,11}. It would be interesting to find out whether the ASAS HI correlates well with other standard measuring instruments used in SpA, and above all, whether it can discriminate between states of disease activity and inactive ones. This information would give a great boost to this tool for its dissemination in the clinical routine of rheumatologists attending patients with SpA. We have carried out the present study for this purpose.

MATERIALS AND METHODS

This cross-sectional study included 111 consecutive patients with axSpA who were classified according to ASAS criteria². The study population was recruited from an SpA monographic unit from a university hospital in northern Spain. The study period extended from May to October 2019. Patients were informed about the objectives of the study and their written informed consent was obtained. The clinical research ethics committee of our hospital approved the study (HUCA ref EO 12/19).

For this study, sociodemographic, clinical, analytical, and imaging variables were collected. All patients were adults of both sexes. Data were collected on educational level, disease duration, family history of SpA and other rheumatic diseases, as well as the presence of comorbidities, especially of the cardiometabolic type. Within the analytical limits, erythrocyte sedimentation rate (ESR, mm/h), C-reactive protein (CRP, mg/dl), rheumatoid factor, antinuclear antibodies, and HLA-B27 were included, among others. The presence of psoriasis (or personal/family history), enthesitis, dactylitis, uveitis, and inflammatory bowel disease was also included in the study protocol. In all patients, pelvis radiographs were performed in anteroposterior projection, as well as anteroposterior and lateral views of the cervical and lumbar spine. No specific reading method was used for the radiographic study, but the degree of involvement of the sacroiliac joints was assessed by the New York criteria¹². In patients with suspected SpA, but with normal radiographs, a magnetic resonance imaging (MRI) study was ordered to detect the presence of sacroiliitis (SI) following the definition for this purpose included in the ASAS criteria for axSpA².

As for assessment measures, ASDAS-CRP and BASDAI for disease activity, and BASFI for physical function, were included as standard. Although some metrics of axial skeleton movement were collected (Schober test, tragus to wall distance, chest expansion, finger to floor distance), the BASMI was not determined in this study.

For the assessment of disease effect on patients' lives, we used the ASAS HI questionnaire⁷. This instrument is composed of 17 items, expressed in the first person and in present tense, with a dichotomous response option: "I

agree" or "I do not agree." Each positive answer is scored 1 while a negative answer is scored 0. The final result is the sum of individual items⁷. Higher values reflect a major degree of impairment, limitations, and restrictions. All patients filled out the questionnaire only once; a test-retest study was not done. However, coefficients of agreement between ASAS HI scores on first and second administrations tended to be excellent^{8,10}.

Statistical methodology. A descriptive statistical analysis of all the variables was performed, including central tendency and dispersion measures for continuous variables, and absolute and relative frequencies for categorical variables. Student t test, Mann-Whitney U test, or Kruskal-Wallis test were used to compare quantitative variables and Pearson's chi-square or Fisher's exact tests for qualitative variables. We examined construct convergent validity by correlating the scores of the ASAS HI with ASDAS, BASDAI, and BASFI. Spearman rho correlation coefficients were obtained to quantify these relationships. Correlations were interpreted as follows: very high (> 0.90), high (0.70–0.89), moderate (0.50–0.69), low (0.26–0.49), and poor or almost nil (≤ 0.25). We also calculated the coefficient of variation (CV) as a measure of the extent of variability of ASAS HI in relation to the mean of it. If the CV is less than or equal to 80%, it means that the arithmetic mean is representative of the dataset; therefore the dataset is homogeneous. To distinguish patients with active and non-active disease (discriminant validity) and to assess their respective cutoff point values, the receiver-operating characteristic (ROC) curve analysis was used. A logistic regression was made to determine the ASAS HI items with greater capability to discriminate active versus inactive disease. Data were analyzed using SPSS V19.0 statistical software (IBM Corp.).

RESULTS

Seventy-four men and 37 women were included, mean age 43.3 ± 10.6 years [interquartile range (IQR) 36–50], average disease duration of 7.6 ± 6.8 years (IQR 4–10). Out of 111 patients, 74 (66.7%) had AS (male/female ratio 2.5:1), while the rest met axSpA criteria (Table 1). Eighteen out of 111 patients (16.2%) had peripheral arthritis (mostly asymmetric arthritis of the lower limbs). As for other manifestations of SpA, 8 (7.2%), 14 (12.6%), and 6 (5.4%) patients presented with enthesitis, anterior uveitis, and inflammatory bowel disease, respectively. Sixteen patients (14.4%) showed a family history of SpA. Of the study population, 43 (38.7%) patients had primary education, 34 (30.6%) secondary education, and another 34 (30.6%) had a university degree.

The average value of ESR was 7.2 ± 8.2 mm/h (IQR 2–8), CRP was 0.4 ± 0.5 mg/dl (IQR 0.10–0.40), while HLA-B27 testing was positive in 88 patients (79.3%). Women had significantly higher ESR values (9.6 ± 11.2 mm/h) than men (6.03 ± 5.9 mm/h, $p = 0.03$).

Regarding cardiometabolic risk factors, 44 (39.6%) patients were smokers, 18 (16.2%) were obese, 14 (12.6%) were hypertensive, 6 (5.4%) had diabetes, 26 (23.4%) had high lipid levels, and 1 patient (0.9%) had had a myocardial infarction. Table 1 summarizes the main sociodemographic and clinical features of the study population.

Regarding radiographic manifestations, the majority of patients presented bilateral SI (the most frequent grade being grade III). In the patients undergoing MRI study ($n = 25$), in most of them (18/25), the bone marrow edema

Table 1. Main disease features of the study population.

Features	N = 111
Age, yrs, mean ± SD	43.3 ± 10.6
Disease duration, yrs, mean ± SD	7.6 ± 6.8
Men, n (%)	74 (66.7)
Women, n (%)	37 (33.3)
AS, n (%)	74 (66.7)
Peripheral involvement, n (%)	18 (16.2)
Family history, n (%)	16 (14.4)
Educational level, n (%)	
Primary	43 (38.7)
Secondary	34 (30.6)
University	34 (30.6)
Cardiovascular risk factors, n (%)	
Tobacco	44 (39.6)
Obesity	18 (16.2)
Hypertension	14 (12.6)
Diabetes	6 (5.4)
Dyslipidemia	26 (23.4)
Cardiovascular adverse events, n (%)	1 (0.9)
SpA-related conditions, n (%)	
Enthesitis	8 (7.2)
Anterior uveitis	14 (12.6)
Inflammatory bowel disease	6 (5.4)
Analytical variables	
ESR, mm/h	7.2 ± 8.2
CRP, mg/dl	0.4 ± 0.5
HLA-B27, n (%)	88 (79.3)
Other comorbidities, n (%)	
Fibromyalgia	3 (2.7)
Depression	8 (7.2)
Pneumonia	1 (0.9)
Neoplasms	1 (0.9)
Celiac disease	4 (3.6)
Obstructive sleep apnea	1 (0.9)

AS: ankylosing spondylitis; SpA: spondyloarthritis; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein.

indicative of active SI was bilateral. Other classic signs of spondylitis found in our study were squaring and syndesmophytes, in 19.8% and 18.9%, respectively. More men (87.8%) than women (59.5%) presented with bilateral SI ($p = 0.002$). Also, more men (24.3%) than women (8.1%) showed syndesmophytes ($p = 0.040$).

Regarding the treatments received by the patients at the study visit, only 6 patients were taking conventional disease-modifying antirheumatic drugs; the majority (80.2%) took nonsteroidal antiinflammatory drugs on demand, and 67/111 were under biological treatment (mostly anti-tumor necrosis factor- α). Of the patients under biological therapy, 44 (65.7%) had received only 1 biological, 15 (22.4%) had received two, 5 (7.5%) three, 2 (3%) four, and 1 had received 5 of these therapies. The median number of biological therapies received by men was 1 (IQR 0–1) against 0 (IQR 0–1) in women ($p = 0.02$).

The average value of BASDAI was 3.4 ± 2.3 , for ASDAS-CRP it was 2.1 ± 0.84 , while for BASFI it was 2.95 ± 2.32 . Thirty-five

(31.5%) of the 111 patients were in BASDAI remission, while 17/111 (15.3%) were in the ASDAS inactive disease category. The average score for ASAS HI was 5.4 ± 3.8 (IQR 3–8). The CV of the ASAS HI was 70.2%. Mean ASAS HI score in men was 5.12 ± 3.94 , while for women it was 6.08 ± 3.54 ($p = 0.21$). HLA-B27–negative patients had a significantly higher average ASAS HI value (7.65 ± 4.47) than did HLA-B27–positive patients (4.86 ± 3.43 , $p = 0.002$). The only ASAS HI item with a significantly higher affirmative statement among women (89.2%) compared to men (70.3%) was item 1 (“pain sometimes disrupts my normal activities,” $p = 0.027$). There were no significant differences between men and women in relation to the affirmative answers given to the other ASAS HI items. Figure 1 illustrates the distribution of the different affirmative items of ASAS HI in the total population as well as in men and women.

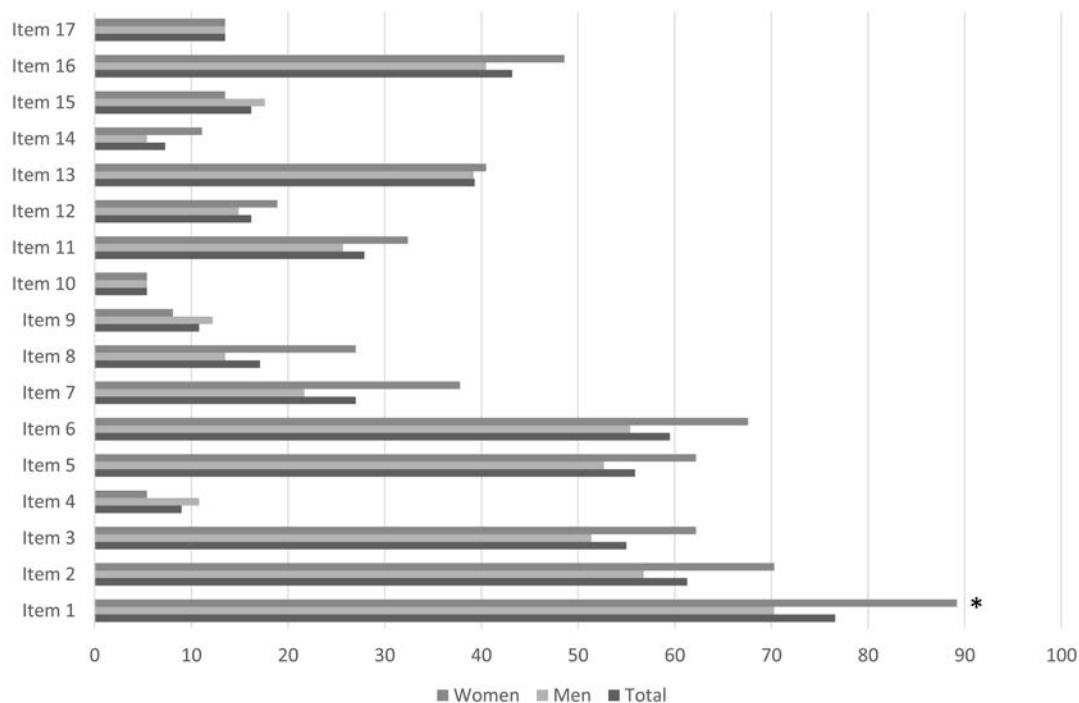
The correlations (Spearman rho) were high between BASDAI, BASFI, and ASDAS-CRP (Table 2, $p < 0.0005$). Construct convergent validity was high for ASAS HI, both against BASDAI (rho 0.77, $p < 0.0005$) and ASDAS (rho 0.70, $p < 0.0005$; Figure 2).

The ASAS HI also showed a high discriminative capacity, both for BASDAI remission [optimal criterion ≤ 2 , area under the ROC curve (AUC) 0.88 (95% CI 0.81–0.94), sensitivity 66%, specificity 96%, $p < 0.0001$], and for ASDAS-CRP inactive disease [optimal criterion ≤ 0 , AUC 0.87 (95% CI 0.80–0.93), sensitivity 59%, specificity 95%, $p < 0.0001$]. The ASAS HI also demonstrated a high discriminative capacity between the remission/low activity categories versus the high/very high activity categories of the ASDAS-CRP. Thus, the optimal criterion for detecting the high/very high disease activity ASDAS-CRP categories was an ASASHI score > 6 , with AUC 0.86 (95% CI 0.78–0.92), +LR 7.3 (95% CI 3.1–17.1, $p < 0.0001$; Figure 3).

In the multivariate regression model developed to weight ASAS HI items associated with active disease according to both BASDAI and ASDAS-CRP, the only 2 ASAS HI items significantly associated with BASDAI active disease were “I often get frustrated” (OR 9.2, 95% CI 1.2–69.4, $p = 0.032$), and “I sleep badly at night” (OR 7.7, 95% CI 1.4–41.6, $p = 0.018$). As for ASDAS-CRP, the only item significantly associated with active disease was “pain sometimes disrupts my normal activities” (OR 8.7, 95% CI 1.7–45.2, $p = 0.010$).

DISCUSSION

In our study we were able to verify that the ASAS HI, a disease impact measurement instrument, has a good convergent and discriminative validity, compared to the main evaluation instruments used in SpA. Thus, we found high correlations between ASAS HI, BASDAI, BASFI, and ASDAS-CRP, while an ASAS HI cutoff point of 6 marked an adequate boundary to discriminate between the states of high/very high disease activity, as opposed to the low activity and remission categories. On the other hand, ASDAS-CRP and BASDAI had a high correlation,



* p = 0.027 ♀ vs. ♂

Figure 1. Distribution of ASAS HI affirmative items. Item 1: Pain sometimes disrupts my normal activities; Item 2: I find it hard to stand for long; Item 3: I have problems running; Item 4: I have problems using toilet facilities; Item 5: I am often exhausted; Item 6: I am less motivated to do anything that requires physical effort; Item 7: I have lost interest in sex; Item 8: I have difficulty operating the pedals in my car; Item 9: I am finding it hard to make contact with people; Item 10: I am not able to walk outdoors on flat ground; Item 11: I find it hard to concentrate; Item 12: I am restricted in traveling because of my mobility; Item 13: I often get frustrated; Item 14: I find it difficult to wash my hair; Item 15: I have experienced financial changes because of my rheumatic disease; Item 16: I sleep badly at night; Item 17: I cannot overcome my difficulties. ASAS HI: Assessment of SpondyloArthritis international Society Health Index.

Table 2. Correlations between main disease outcomes.

Measure	BASDAI	BASFI	ASDAS	ASAS HI
BASDAI		0.86	0.89	0.77
BASFI	0.86		0.79	0.80
ASDAS	0.89	0.79		0.70
ASAS HI	0.77	0.80	0.70	

Correlations are expressed as Spearman rho. BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; ASDAS: Ankylosing Spondylitis Disease Activity Score; ASAS HI: Assessment of SpondyloArthritis international Society Health Index.

which supports the use of any of these instruments in the daily evaluation of disease activity in these patients.

We are witnessing an intense search for instruments that adequately, simply, and reliably identify the limitations and restrictions that patients with rheumatic diseases face in their

daily lives^{6,7}. This need has arisen from the finding that in many cases there is a notable disagreement or discrepancy between the results of conventional activity measures and PROM^{4,13,14}. For example, in the field of PsA, there is a certain mismatch between the results of activity measures (Disease Activity Index for Psoriatic Arthritis) or that of treatment targets [minimal disease activity (MDA)], and the results of disease effect tools such as the PsAID¹⁵. The factors that seem to explain this misalignment seem more psychological than physical¹⁴. On the other hand, the doctors' own perceptions of the states of remission or low activity of the disease do not usually coincide with the perceptions of the patients themselves⁵. In short, these mismatches between the visions of doctors and patients are not a minor issue, insofar as they can also lead to mismatches in therapeutic orientation. In a PsA study, it was found that one-third of patients in a clinically acceptable condition according to the evaluating physician did not reach the MDA response, so that if a treat-to-target strategy had been applied, these patients should

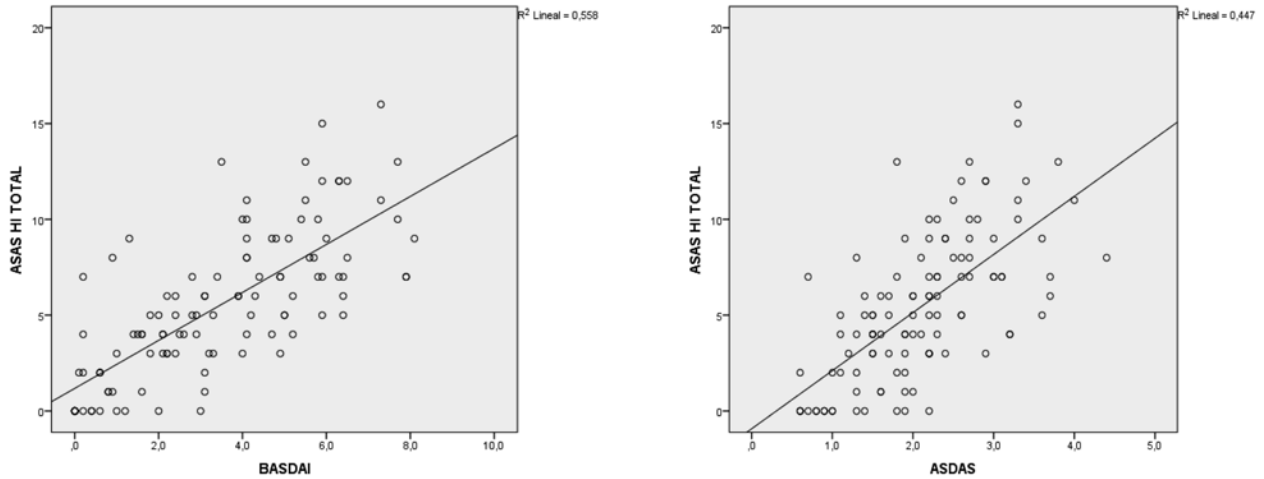


Figure 2. Correlations between ASAS HI and BASDAI ($\rho = 0.77$, $p < 0.0005$), and between ASAS HI and ASDAS ($\rho = 0.70$, $p < 0.0005$). ASAS HI: Assessment of SpondyloArthritis international Society Health Index; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; ASDAS: Ankylosing Spondylitis Disease Activity Score.

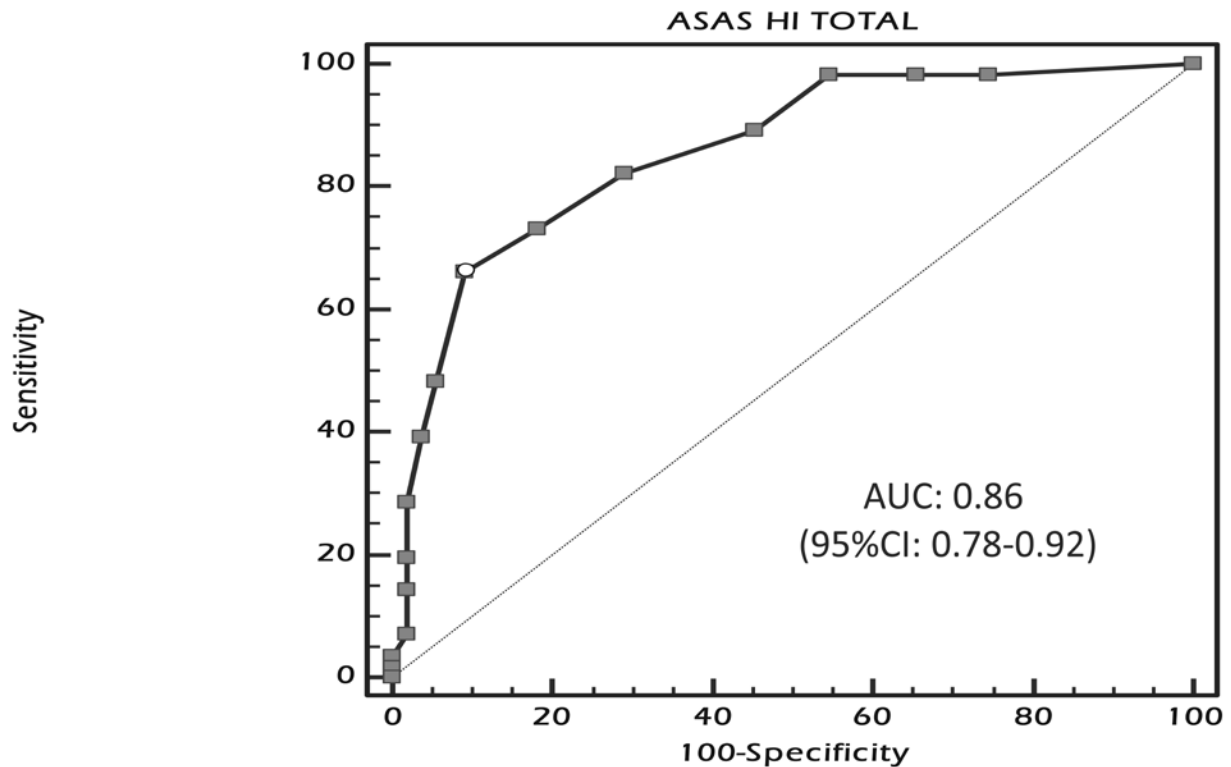


Figure 3. Area under the ROC curve (AUC) for discriminating between high/very high disease activity against remission/low disease activity categories of the ASDAS. Optimal criterion ASAS HI > 6 (95% CI 3–6), sensitivity 66.1, specificity 90.9. ASAS HI: Assessment of SpondyloArthritis international Society Health Index; ROC: receiver-operating characteristic; ASDAS: Ankylosing Spondylitis Disease Activity Score.

have received a therapeutic intensification¹⁶. Therefore, we need to balance the information from conventional activity measures against each patient's perceptions, to make clinical

and therapeutic decisions that conform to current disease management recommendations^{17,18}. In our study, however, the results of the ASDAS-CRP or BASDAI correlated well

with those of the ASAS HI, which gives great value to this latter instrument in the general assessment of this entity.

In the most important validation study carried out to date to define the measurement properties of ASAS HI, values ≤ 5 had balanced specificity to distinguish good health as opposed to moderate health, and values ≥ 12 were specific to represent poor health as opposed to moderate health¹⁰. In our study we verified that a value ≤ 6 aligned well with the states of remission/low activity of ASDAS, and therefore this cutoff point would represent the limit to define a good health state in our SpA population. However, other researchers, such as Di Carlo, *et al*, using ASDAS-CRP as the gold standard, have defined cutpoints slightly different from ours, so our results require other corroborative studies^{8,19}. These data are extremely interesting because they would have a place both in therapeutic and clinical decision making, and when planning treatment goals in these populations. In addition, several studies show that ASAS HI is a simple instrument for patients, with good test-retest ability, adequate convergent and discriminant validity, as well as good sensitivity to change^{8,9,10,11,19}. In sum, it has all the properties needed for its use in clinical routine; it could be the only instrument for SpA assessment in clinics with too-busy agendas.

In our study, ASAS HI score tended to be higher in women than in men, although these differences were statistically significant only for item 1. The latter is not particularly striking because item 1 refers to pain, a PROM that women tend to score higher than men in SpA as well as in other rheumatic conditions^{20,21}.

When the ASAS HI items associated with active disease were analyzed, by both BASDAI and ASDAS-CRP, these items were different in the 2 contexts of active disease definition. Therefore, despite the good correlation between ASDAS-CRP and BASDAI, the differences we found could imply the existence of subtle discriminative capacities between the tools regarding detecting a good state of health. However, deciding which of the 2 instruments would be better to determine the health status of patients with SpA is beyond the scope of our study. In any case, this issue should be addressed in future studies.

Our study has limitations. For example, not all SpA phenotypes were included. Also, the weight of structural damage measured by validated indices such as BASRI or mSASSS has not been assessed. However, in our study men had more SI and syndesmophytes than women, but they did not score higher in ASAS HI. Nor did our study include other outcome measures such as BASMI. Further, because of the cross-sectional nature of the study, it was also not possible to provide information on the sensitivity to change of this questionnaire. However, our results seem to align well, in convergent and discriminant validity, with other recently published studies, which ultimately gives consistency to the results drawn from our study.

We have verified a good clinimetric alignment between ASAS HI and other standard outcome measures in SpA. A cutoff point ≤ 6 seems to set the limit for a good state of health in our population with SpA. ASAS HI is a simple instrument that could be used as a single measure for the evaluation of these

patients in busy practices. Regardless, we must keep in mind that the ASAS HI and the BASDAI/ASDAS are instruments that were designed for different tasks; therefore these measures are not interchangeable, and both should be incorporated into the routine evaluation of these patients.

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