ASAS Health Index in patients with spondyloarthritis and its association with disease activity and disease burden including fibromyalgia

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ABSTRACT

Objective. *To evaluate the association of the Assessment of Spondyloarthritis international Society Health Index (ASAS-HI) with disease activity and disease burden in patients with spondyloarthritis (SpA).*

Methods. *Observational, cross-sectional and single-centre study from the Córdoba AxSpA Task force, Registry and Outcomes (CASTRO). Scores related to disease activity (BASDAI and ASDAS), functionality (BASFI), structural damage, mobility, health and the presence of concomitant fibromyalgia (FM) were obtained from all patients. ASAS-HI score was considered the main outcome. Pearson's r statistic, Student's t test, and univariate and multivariate linear regressions were performed to assess the association between the ASAS-HI score and the studied covariates.*

Results. *A total of 126 SpA patients were included. The mean ASAS-HI score was 4.6±3.9, showing a "strong" positive linear correlation (r>0.60) with the BASDAI and BASFI and a "moderate" positive linear correlation (r=0.40 to 0.60) with the global VAS and ASDAS. Patients with FM showed a significantly higher ASAS-HI score than patients without FM (9.5±3.2 vs. 3.7±3.4, respectively, p<0.01).*

Multiple linear regression showed that 57.4% of the ASAS-HI variability (R^2=0.574) was explained by the presence of concomitant FM (β=2.23, 95% CI 0.73 to 3.80, p=0.004), higher scores on the BASDAI (β=0.62, 95% CI 0.25 to 0.97, p=0.001) and BASFI (β=0.57, 95% CI 0.26 to 0.88, p=0.001).

Conclusion. *The impairment of health in patients with SpA was mainly associated with high disease activity, worsening functionality and with the presence of a possible concomitant FM. Therefore, in patients with high ASAS-HI scores we must evaluate the presence of concomitant FM.*

Introduction

Spondyloarthritis (SpA) encompasses a group of interrelated chronic inflammatory diseases (1) that share common clinical, genetic and pathophysiological features, such as involvement of the axial skeleton, peripheral manifestations, extra-articular manifestations (uveitis, psoriasis and inflammatory bowel disease), and an association with the HLA-B27 antigen (2).

Patients with SpA can be classified according to their clinical presentation as patients with predominantly axial SpA (axSpA) or as predominantly peripheral SpA (pSpA) (3, 4). Patients with axSpA can also be classified as radiographic (r-axSpA) and non-radiographic axSpA (nr-axSpA) depending on the presence of sacroiliitis on X-ray. The main symptom of axSpA is inflammatory back pain (IBP) (5), caused by inflammation of enthesis on sacroiliac joints and spine, which leads to axial stiffness, predominantly in the morning. Inflammation of the spinal structures results in progressive spinal changes, such as the development of syndesmophytes or ankylosis, which are largely responsible for the decreased physical function and restricted mobility experienced by these patients (6). Thus, pain, stiffness, fatigue and limitations in spinal mobility are the main impairments and they result in a variety of limitations relevant to daily activities and participation in life situations (7).

In fact, several studies have shown that disease activity and functionality have an impact on the quality of life

in patients with SpA (8-10). Over the last decade, different tools have been validated to evaluate the impact of the disease and the general state of patients with SpA (11-13). The ASAS Health Index was developed under the auspices of the Assessment of SpondyloArthritis International Society (ASAS) to assess health status in patients within the whole spectrum of SpA (specifically r-axSpA, nr-axSpA and pSpA). This self-report questionnaire measures functioning and health across 17 items to assess aspects of health and 9 environmental factors (EF) in patients with SpA (14). The ASAS-HI index includes items addressing categories of pain, emotional functions, sleep, sexual function, mobility, self-care, and community life.

The ASAS-HI questionnaire has been recently validated and translated into Spanish (15) and good clinimetric properties have been demonstrated in a real clinical scenario (16).

However, there are still very few studies evaluating the utility of this questionnaire in daily clinical practice. The objective of this study was to evaluate the association of the ASAS-HI index with disease activity, disease burden (functionality and mobility) and structural damage in the daily clinical practice evaluation of in patients with SpA.

Patients and methods

This was an observational, cross-sectional and single-centre study in which consecutive patients with SpA were included from the Córdoba AxSpA Task force, Registry and Outcomes (CASTRO) maintained by the Department of Rheumatology at Reina Sofia University Hospital. All participants had a diagnosis of SpA and met the Assessments in Ankylosing Spondylitis (ASAS) working group criteria for SpA (either axial or peripheral) (3, 4).

The study was approved by the Ethics Committee at the Reina Sofia University Hospital, and each of the participants signed an informed consent form to be part of the study.

Collected variables

Sociodemographic data were obtained from all patients, including sex, age, and disease duration (years since first symptoms). Laboratory data such as c-reactive protein (CRP) levels and HLA-B27 antigen status were also obtained. All patients were submitted to a radiographic study to evaluate the presence of sacroiliitis on x-ray as well as the structural damage in the spine using the modified Stoke Ankylosing Spondylitis Spine Score (mSASSS) (17). These x-rays were evaluated by a single trained rheumatologist.

Spinal mobility was evaluated using a system named UCOTrack™ that captured kinematic measures from marker placed on the patient (18-19). This method provides an index of cervical and lumbar mobility (0-10 scale, with 10 being the worst mobility), named the University of Cordoba Ankylosing Spondylitis Metrology Index (UCOASMI), which has also been recently validated (20). The Bath Ankylosing Spondylitis Metrology Index (BASMI, 0–10 scale) (21) was also used to evaluate mobility. Mobility measures were performed by the same physician and at the same time of day in all participants to avoid variability in the measurements, especially those related to morning stiffness. The Bath Ankylosing Spondylitis Functional Index (BASFI, 0–10 scale) (22) questionnaire was used to evaluate functionality, while the global visual analogue scale (VAS) (0–10 scale) was used to evaluate the general condition of the patients. The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI, 0–10 scale) and the ASAS-endorsed Disease Activity Score based on CRP (ASDAS-CRP) (23) were used as variables related to disease activity. In this study, the ASDAS-CRP was considered as a quantitative and qualitative variable, using a cut-off of ≤2.1 and >2.1 (corresponding to moderate/low and high/very high disease activity, respectively) (24).

The Fibromyalgia Rapid Screening Tool (FiRST) was used to detect fibromyalgia (FM) syndrome (25). The FiRST self-questionnaire consists of six closed questions covering the different dimensions of fibromyalgia: widespread pain (item 1), fatigue (item 2), pain characteristics (item 3), non-painful abnormal sensations (item 4), functional somatic symptoms (item 5), sleep and cognitive problems (item 6). Patients with a score ≥5 were considered positive for FM. Finally, the ASAS Health Index questionnaire (13) measures functioning and health across 17 aspects of health and 9 environmental factors (EF) in patients with SpA. The ASAS-HI contains items addressing categories of pain, emotional functions, sleep, sexual function, mobility, self-care, and community life on a scale ranging from 0 to 17 (17 points the worst possible score). The ASAS-HI was used as the main outcome.

All the evaluators (including the x-ray reader) were blinded to laboratory and clinical data except sex and age.

Statistical analysis

Descriptive data are shown as the means ± standard deviation (SD) for continuous variables and as frequencies and percentages for qualitative variables.

First, linear correlations between the different quantitative variables (related to disease duration, disease activity, mobility, functionality, structural damage and health) were tested using the Pearson correlation coefficient (r) for each of the comparisons. Correlations were classified as moderate (r=0.40 to 0.69), strong (r=0.70 to 0.89), or very strong (r=0.90 to 0.99). Subsequently, considering ASAS-HI as the dependent variable, we calculated the coefficient of determination (R^2) using a univariate linear regression for each of the variables. In addition, a multiple linear regression was conducted to quantify the relationship of covariates with the ASAS-HI variability. Covariates included in the multiple linear regression were those with a r >0.30 obtained in the simple correlations. Collinearity, interactions and normality of residuals were tested. Finally, Student's t test was used to calculate the differences between means for the variables previously mentioned in different subgroups of patients according to sex, HLA-B27, FM, disease duration >10 years, the presence of radiographic sacroiliitis, ASDAS-CRP >2.1 and UCOASMI >3.7. For disease duration

and UCOASMI, medians were used as cut-offs when they were considered categorically. SPSS software v. 25.0 (SPSS, Inc., Chicago, IL) was used, and a p-value <0.05 was considered significant.

Results

A total of 126 patients were included in the study, of whom 83 (65.9%) were men; the mean age was 45.1±12.3 years and mean disease duration of was 18.7±13.5 years. Table I presents the population baseline characteristics.

Figure 1 shows the different correlations between the variables related to mobility (UCOASMI and BASMI), functionality (BASFI), disease activity (BASDAI and ASDAS-CRP), structural damage (mSASSS), and health status (ASAS-HI). The figure also includes the disease duration to evaluate its influence on the other variables. A moderate positive linear correlation (r=0.4–0.7) was identified (p<0.01) between ASAS-HI *vs*. BASDAI and between ASAS-HI *vs*. BASFI (r=0.64 and r=0.67, respectively). Additionally, a significant (p<0.01) moderate correlation was identified between ASAS-HI *vs*. ASDAS-CRP (r=0.48) and between ASAS-HI vs. global VAS (r=0.51).

Figure 2 shows six graphics that represent the goodness of fit of the simple linear regressions between the ASAS-HI and the different covariates. Overall, 48.1% (R^2=0.481) and 47.2% (R^2=0.472) of ASAS-HI variability was explained by the BASFI and BASDAI values, respectively (p<0.001).

A multiple linear regression (Table II) was performed to evaluate the ASAS-HI variability, including in the model BASDAI, BASFI, UCOASMI, ASDAS, mSASSS, disease duration, sex and FM. The final model showed that 57.4% of the ASAS-HI variability (R^2=0.574) was explained by the presence of FM (β=2.23, 95% CI 0.73 to 3.80, p=0.004), BASDAI (β=0.62, 95% CI 0.25 to 0.97, p=0.001) and BASFI (β=0.57, 95% CI 0.26 to 0.88, p=0.001) scores.

Table III represents the differences in the quantitative variable means between groups of patients stratified according to different characteristics. Pa-

Table I. Descriptive data of variables included in the study (n=126).

	n (%) or mean ± SD
Gender (male), n (%)	83/126 (65.9%)
Age (years)	45.1 ± 12.3
Disease duration (years)	18.7 ± 13.5
HLA-B27+, n (%)	99/123 (80.5%)
Fibromialgia (FIRST ≥5), n (%)	19/123 (15.4%)
UCOASMI (0-10)	4.2 ± 1.7
BASMI (0-10)	3.1 ± 1.7
BASDAI (0-10)	3.7 ± 2.1
ASDAS-CRP	2.3 ± 0.9
BASFI (0-10)	3.1 ± 2.4
Global VAS (0-10)	4.4 ± 2.5
ASAS-HI (0-17)	4.6 ± 3.9
CRP (mg/L)	6.3 ± 10.4
Bone marrow edema MRI positive, n (%)	55/107 (51.4%)
Radiographic sacroiliitis on x-ray, n (%)	96/120 (80%)
mSASSS total	14,77 ± 17,18
mSASSS cervical	7,05 ± 9,07
mSASSS lumbar	7,82 ± 9,36

All results are presented as mean and standard deviation (SD) and as percentages for continuous and categorical variables, respectively.
ASAS-HI: ASAS Health Index; ASDAS: ASAS-endorsed disease activity score-CRP; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; CRP: C-reactive protein; Global VAS: Global Visual Analogue Scale; FIRST: Fibromyalgia Rapid Screening Tool; mSASSS: modified Stoke Ankylosing Spondylitis Spine Score; UCOASMI: University of Cordoba Ankylosing Spondylitis Metrology Index.

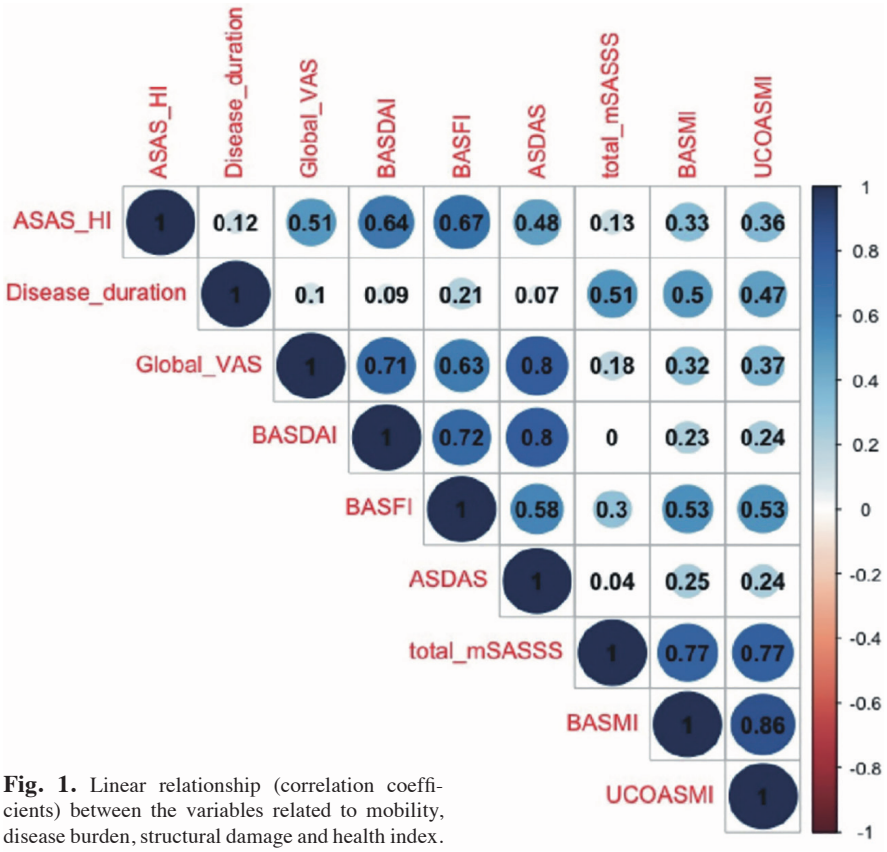

Fig. 1. Linear relationship (correlation coefficients) between the variables related to mobility, disease burden, structural damage and health index.
ASDAS: ASAS-endorsed disease activity score; ASAS-HI: ASAS Health Index; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI Bath Ankylosing Spondylitis Functional Index; BASMI Bath Ankylosing Spondylitis Metrology Index; Global VAS: Global Visual Analog Scale; Disease duration (years); mSASSS: modified Stoke Ankylosing Spondylitis Spine Score; UCOASMI: University of Cordoba Ankylosing Spondylitis Metrology Index.

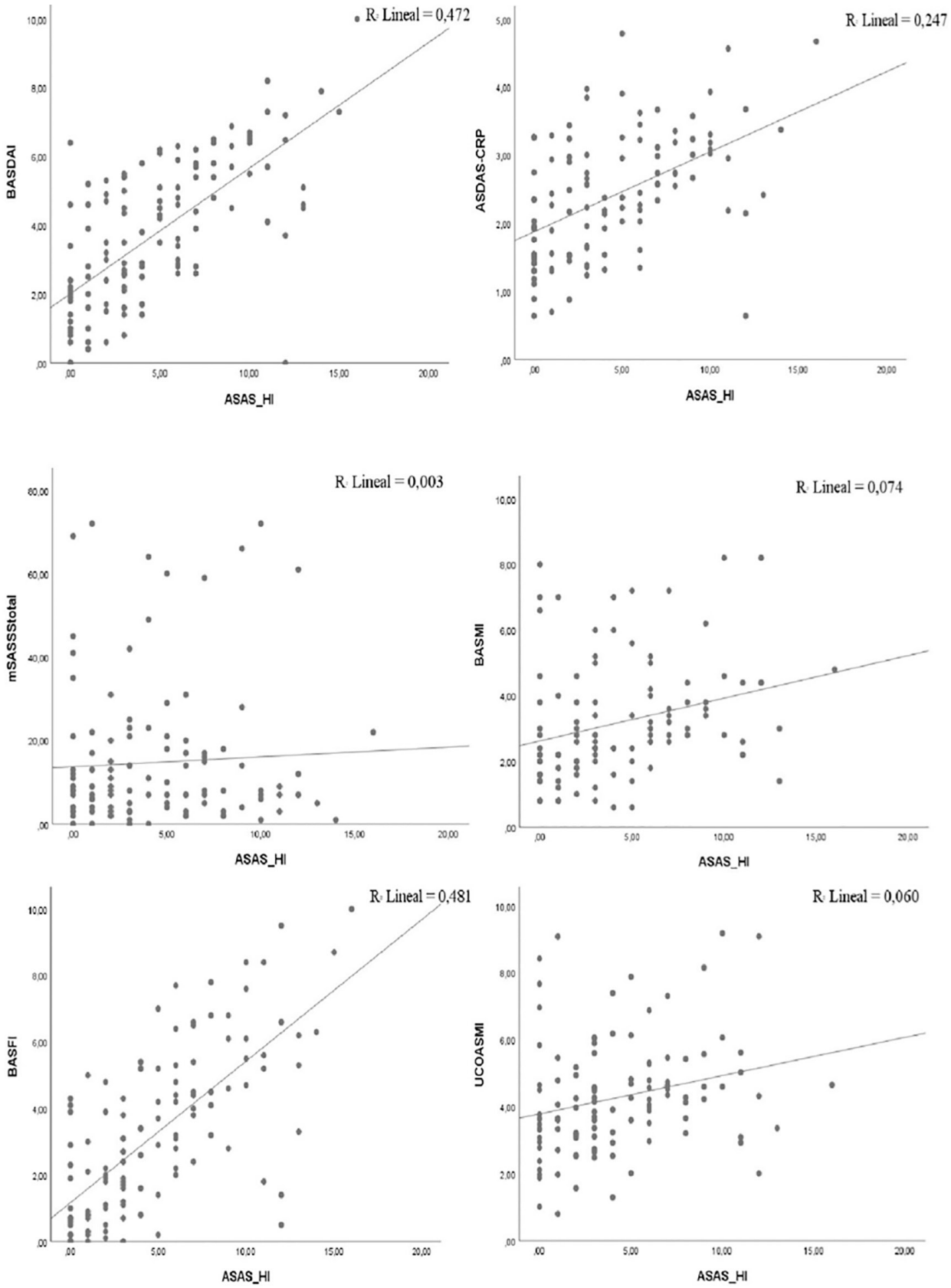

Fig. 2. Correlations between ASAS HI and the most important variables.
ASDAS: ASAS-endorsed disease activity score; ASAS HI: ASAS Health Index; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; mSASSS: modified Stoke Ankylosing Spondylitis Spine Score; UCOASMI: University of Cordoba Ankylosing Spondylitis Metrology Index.

Table II. Multiple linear regression to quantify ASASHI variability.

	Regression Coefficient β (CI 95%)	*p*-value
Fibromyalgia	2.2 (0.7 to 3.8)	0.004
BASDAI	0.6 (0.2 to 0.9)	0.001
BASFI	0.5 (0.2 to 0.8)	0.001

$R^2 = 0.574$.
Adjusted coefficient of determination (R2) = 57.4%.
ASAS-HI: ASAS Health Index; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; mSASSS modified Stoke Ankylosing Spondylitis Spine Score.

tients with a suspicion of concomitant FM showed higher scores ($p<0.05$) on the ASAS-HI (9.5±3.2 *vs*. 3.7±3.4), BASFI (5.9±2.4 *vs*. 2.6±2.1), ASDAS-CRP (3.0±0.7 *vs*. 2.2±0.8) and global VAS (6.5±1.6 *vs*. 3.9±2.4) than patients without a suspicion of FM. In addition, patients with high disease activity (ASDAS-CRP >2.1) showed higher scores ($p<0.01$) on the ASAS-HI (5.8±3.8 *vs*. 2.0±2.4), BASFI (3.9±2.3 *vs*. 1.3±1.3), and global VAS (5.5±2.1 *vs*. 2.1±1.9) than patients with low disease activity (ASDAS-CRP ≤2.1). Patients with greater spinal mobility limitation (UCOASMI >3.7) showed a statistically significant increase ($p<0.01$) in total mSASSS score (20.3±20.1 *vs*. 6.3±4.8) compared with those with less spinal mobility limitation.

Regarding other covariates, there were significant differences in mSASSS scores between males and females (18.1±19.5 *vs*. 7.6±6.5, respectively) and between patients with disease duration >10 years and patients with disease duration ≤10 years (18.5±19.8 *vs*. 7±6.4, respectively). Moreover, there were significant differences in total mSASSS score between radiographic and non-radiographic axSpA.

Finally, no significant differences were found between patients with differing HLA-B27 status.

Discussion

This study provides new information regarding the association between ASAS-HI questionnaire and disease activity, functionality, mobility and structural damage in the daily clinical practice in with SpA. Our results showed that the status of health measured by the ASAS-HI was independently associated with disease activity (BASDAI), functionality (BASFI) and with the presence of a possible concomitant FM (evaluated with the FiRST questionnaire). Disease activity has been previously reported as a factor strongly associated with the quality of life in these patients in a large registry of SpA patients (REGISPONSER) (26), while quality of life has been previously explained by the presence of pain, nocturnal awakenings and stiffness. Similar to previous studies, we found a direct relationship between the ASAS-HI score and loss of functionality (assed by BASFI) (9). Functionality has been reported as one of the most important factors that negatively influences the health and quality of life of these patients due to the related loss of autonomy and the impact on daily living activities, household maintenance and social function.

Interestingly, we found an independent association between the presence of a possible concomitant FM and high scores on the ASAS-HI index. FM is a common chronic pain condition that exerts a considerable impact on patients' daily activities and quality of life (27, 28). Patients with axSpA and FM usually report significantly worse disease activity, functionality, global severity scores and poor quality of life (29). Regarding the patients with suspicion of FM in this study, their ASAS-HI scores were significantly higher than those without suspicion of FM, which means that patients with a possible concomitant FM showed a poorer health status than those without a possible FM. This means that in SpA patients with high scores on the ASAS-HI index, the presence of concomitant FM should be ruled out. A previously published study confirmed that FM is a frequent comorbidity in patients with axSpA (with a prevalence ranging from 16.1% to 37.8% depending on the definition

Table III. Comparison of the variables related to quality of life, functionality, mobility, and structural damage, stratified according to different patient characteristics.

		ASAS-HI	ASDAS-CRP	BASFI	Global VAS	UCOASMI	Total mSASSS
Sex	Male, n=83	4.0 ± 3.8	2.2 ± 0.9	2.9 ± 2.5	4.1 ± 2.5	4.5 ± 1.9	**18.1 ± 19.5**
	Female, n=43	5.8 ± 3.9	2.6 ± 0.8	3.5 ± 2.2	4.8 ± 2.5	3.8 ± 1.0	**7.6 ± 6.5***
HLA-B27	Positive, n=24	5.4 ± 4.4	2.6 ± 0.9	3.4 ± 2.4	4.9 ± 2.1	3.8 ± 1.2	9.2 ± 8.9
	Negative, n=99	4.3 ± 3.7	2.3 ± 0.9	2.9 ± 2.4	4.2 ± 2.5	4.3 ± 1.7	16.1 ± 18.3
Radiographic	Positive, n=96	4.0 ± 3.6	2.3 ± 0.9	3.0 ± 2.4	4.1 ± 2.5	4.4 ± 1.7	**17.1 ± 18.2**
Sacroiliitis	Negative, n=24	6.2 ± 4.2	2.3 ± 0.8	3.5 ± 2.4	4.6 ± 2.3	3.7 ± 1.3	**4.9 ± 3.5***
ASDAS	>2.1, n=68	**5.8 ± 3.8**	-	**3.9 ± 2.3**	**5.5 ± 2.1**	4.5 ± 1.6	14.2 ± 17.9
	≤2.1, n=41	**2.0 ± 2.4****	-	**1.3 ± 1.3****	**2.1 ± 1.9****	3.8 ± 1.5	12.7 ± 13.4
UCOASMI	>3.7, n=68	5.1 ± 3.5	2.5 ± 0.8	3.8 ± 2.4	4.8 ± 2.4	-	**20.3 ± 20.1**
	≤3.7, n=44	2.9 ± 3.4	2.0 ± 0.8	1.6 ± 1.6	3.3 ± 2.4	-	**6.3 ± 4.8****

ASDAS: ASAS-endorsed disease activity score; ASAS HI: ASAS Health Index; BASFI: Bath Ankylosing Spondylitis Functional Index; Global VAS: Global Visual Analogue Scale; mSASSS: modified Stoke Ankylosing Spondylitis Spine Score; UCOASMI: University of Cordoba Ankylosing Spondylitis Metrology Index.
**p*-value <0.05, ***p*-value <0.01 for Student's t-test for each of the comparisons.

used) (30). Our prevalence of patients with suspicion of FM and SpA was 15.4%, which is in line with previous studies reporting a pooled prevalence of comorbid FM among populations with rheumatoid arthritis (RA), axSpA and psoriatic arthritis (PsA) of 18-24% in patients with RA, 14-16% in patients with axSpA and 18% in patients with PsA (31).

According to the results of our study, the subgroup of patients with a possible FM showed worse functional capacity as measured by the BASFI. Psychiatric comorbidity, especially symptoms of depression and anxiety, may also contribute to the impairment of physical function in patients with FM (32). In our study, the suspicion of FM was more common among women (18% women versus 9% men). FM has been considered to affect women more than men in the literature, with female-to-male ratios ranging from 2:1 to 30:1 depending on the criteria used (33). As axSpA patients with coexisting FM frequently present with a higher disease activity score (such as BASDAI and ASDAS scores), the evaluation of disease activity and treatment effect in these patients might be challenging (34, 35).

A previous study showed that the ASAS-HI score was higher in patients with axSpA than in those with nr-axSpA (36). However, we found no difference related to ASAS-HI between patients with and without radiographic sacroiliitis, although these results should be interpreted with caution since the group of patients with nr-axSpA was relatively small.

Patients with long-standing disease, *i.e.* more than 10 years of disease duration, presented with decreased mobility and greater structural damage compared with those with early forms of the disease; however, both groups showed similar ASAS-HI values. A possible explanation for this is that patients with an early diagnosis of SpA tend to limit their lives by pain. On the other hand, patients with a long evolution of the disease are used to performing fewer activities, and their normal life is not affected as much.

Neither the mSASSS nor the UCOASMI were associated with a change in the ASAS-HI, which means that, in our patients, neither structural damage nor mobility seemed to influence health status and physical limitation was not perceived as a problem in their daily lives. Previous studies have described the "habituation" phenomenon of functional deficits due to the loss of mobility among patients with long disease durations (37). These results also suggest that only subjective indexes (patient-reported outcomes (PROs)) and not objective markers (such as mSASSS and UCOASMI) seem to be associated with health in these patients.

This analysis has some weaknesses but also some strengths. One weakness concerns the evaluation of the mSASSS, which was performed by only one trained rheumatologist. However, this method was employed since our study resembled typical clinical practice, where x-rays are evaluated by only one reader. Other limitation was the cross-sectional design of the study that do not allow to determine long-term risk factors. One strength of this study was the use of the UCOASMI index, an objective measure of spinal mobility with high reliability and accuracy, which avoids subjectivity as well as intra- and interobserver variability of the conventional metrology.

In summary, our results suggest that the impairment indicated by the ASAS-HI index in patients with SpA was mainly associated with disease activity (BASDAI) and worsening of functionality (BASFI). Moreover, FM can coexist with SpA, worsening the quality of life of these patients and therefore impacting the scores on questionnaires used for evaluation of the patients and PROs. This could influence therapeutic decisions. In the same way, in clinical practice scenarios, for patients with SpA who score high on the different questionnaires, we must rule out the presence of concomitant FM, especially in women.

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