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Evaluating health and functional impairments in axial spondyloarthritis: A comprehensive analysis using the ASAS Health Index and Environmental Factors

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ABSTRACT

OBJECTIVE: To assess the health status and functional impairments in patients with axial spondyloarthritis (axSpA) using the Assessment of SpondyloArthritis International Society Health Index (ASAS-HI) and Environmental Factors (ASAS-EF) Index, and to evaluate the correlation of these indices with established clinical parameters.

METHODS: This cross-sectional study included 91 patients diagnosed with axSpA at the Rheumatology Department between November 2017 and July 2018. Participants were evaluated using ASAS-HI, ASAS-EF, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire, and Health Assessment Questionnaire (HAQ). Descriptive statistics and correlation analyses were performed to examine relationships between these indices and various clinical and demographic variables.

RESULTS: The study found that 49.5% of patients had a BASDAI score >4, indicating high disease activity. The mean ASAS-HI score was 6.8, reflecting moderate to severe functional impairment in the study population. Significant positive correlations were observed between ASAS-HI and BASFI, BASDAI, spinal pain, and HAQ scores ($p<0.05$). However, no significant correlations were found between ASAS-HI and ASQoL, disease duration, CRP, or ESR. ASAS-EF was also positively correlated with BASFI, BASDAI, spinal pain, and HAQ scores.

CONCLUSION: The ASAS-HI and ASAS-EF indices effectively evaluate health status and functional impairments in patients with axSpA. The significant correlations with established clinical parameters highlight the indices' utility in capturing the multifaceted impact of axSpA, emphasizing the importance of comprehensive disease assessment in guiding targeted interventions.

Keywords: Axial spondyloarthritis; ASAS Environmental Factors; ASAS Health Index; Bath Ankylosing Spondylitis Disease Activity Index; Bath Ankylosing Spondylitis Functional Index.

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Axial spondyloarthritis (axSpA) is a chronic inflammatory disorder that influences the spine and sacroiliac joints, manifesting in multiple forms and greatly affecting a patient's health-related quality of life (HRQoL). Axial spondyloarthritis (axSpA) is a persistent inflammatory condition that affects the spine and sacroiliac joints, presenting in various ways and significantly impacting a patient's health-related quality of life (HRQoL) [1]. Beyond the hallmark symptoms of back pain and stiffness, axSpA often leads to reduced functional abilities, fatigue, and diminished overall well-being [1, 2]. The diagnosis and treatment of axSpA have pri-

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marily focused on clinical characteristics, imaging tests, and assessments reported by patients, including the Bath Ankylosing Spondylitis Disease Activity Score (BASDAI) and the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire. Traditionally, diagnosis and management of axSpA have centered on clinical features, imaging studies, and patient-reported measures, such as the Bath Ankylosing Spondylitis Disease Activity Score (BASDAI) or the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire [3–5].

While these tools are valuable, the complex nature of axSpA necessitates a more comprehensive assessment approach. This approach should capture the interplay between the disease's clinical manifestations, functional impairments, and the influence of environmental factors on a patient's overall health status. Growing recognition of this need paved the way for developing the Assessment of SpondyloArthritis International Society Health Index (ASAS-HI) and Environmental Factors (ASAS-EF) Index [6, 7]. These indices offer a standardized framework for evaluating health and capturing how social support, healthcare access, and personal circumstances might shape an axSpA patient's experience.

Recent research underscores the significance of comprehensive disease assessment in axSpA. Studies have established the strong validity and reliability of the ASAS-HI across diverse patient populations [8]. Moreover, the ASAS-HI effectively captures the multifaceted impact of axSpA on crucial aspects of health, such as pain, sleep, fatigue, and physical functioning, as identified by patients [9]. Importantly, research indicates that higher disease activity correlates with diminished quality of life and function, making effective disease management paramount [10]. Together, these findings support the value of the ASAS-HI in providing a holistic understanding of axSpA patient experiences and guiding targeted interventions.

Although the ASAS-HI and ASAS-EF have shown promise in assessing health and functionality in axSpA patients, inconsistencies remain in understanding how these indices correlate with other widely used clinical and patient-reported tools, such as BASDAI and ASQoL, particularly in diverse populations. Additionally, the influence of cultural and socioeconomic factors on these correlations is not well-documented, leaving a gap in the literature. Our study aimed to address these gaps by evaluating the relationship between ASAS-HI, ASAS-EF, and established clinical parameters in a Turkish cohort of axSpA patients, providing a more comprehensive understanding of their health status and functional impairments. This correlation analysis further establishes the validity and reliability of these indices for clinical practice and highlights their potential utility in guiding targeted interventions.

Highlight key points

- ASAS-HI scores correlated strongly with clinical markers like BASFI, BASDAI, spinal pain, and HAQ, highlighting its relevance in assessing disease impact.
- Environmental factors, as measured by ASAS-EF, showed significant associations with functional indices, underscoring their role in disease management.
- A mean ASAS-HI score of 6.8 suggests a higher disease burden in this cohort, emphasizing the need for early, targeted interventions.
- ASAS-HI and ASAS-EF are practical tools for comprehensive health assessments in axSpA, with implications for improving patient outcomes.

MATERIALS AND METHODS

This cross-sectional study included 91 patients diagnosed with axSpA, according to the ASAS criteria, who were admitted to the Rheumatology Department of our hospital between November 2017 and July 2018. These patients met the requirements of having sacroiliitis detected by radiography or MR imaging and at least one SpA feature or being HLA-B27 positive with two SpA features. Patient examinations were performed by a single physician experienced in rheumatology examinations (M.C.). During their routine clinic visits, they completed a comprehensive questionnaire [health assessment questionnaire (HAQ), ASAS, ASAS HI, ASAS EF, Bath Ankylosing Spondylitis Functional Index (BASFI), BASDAI, ASQoL] with sociodemographic information and disease-related data such as disease duration, serum C-reactive protein levels (CRP, mg/L), erythrocyte sedimentation rate (ESR, mm/hour), HLA-B27, presence of axial involvement, presence of peripheral involvement, comorbidities and treatments received. A single person (O.K.) administered scales to the patients. Additional comorbid conditions like hypertension, myocardial infarction, peripheral arterial disease, major neurological problems, diabetes, gastrointestinal diseases, chronic respiratory disease, kidney disease, and visual impairment were also evaluated.

Istanbul Medipol University Ethics Committee assessed the study's compliance with ethical standards, and ethical approval was obtained (date: 04.10.2017, num-

ber: 349). Every patient consented to join the study and completed an informed consent document. This study was conducted in accordance with the principles of the Declaration of Helsinki.

Assessment Tools

The ASAS HI questionnaire includes 17 items that use the first-person singular and present tense. Participants are expected to respond with "I agree" or "I disagree." Each positive response is scored as 1, and each negative response as 0. The final score is the numerical sum of all items. The test evaluates disease-related quality of life, functional limitations, physical activity, disease activity, pain severity, and ability to participate in social settings. An ASAS HI score of ≤4 is considered normal function; >4 and ≤8 indicate moderate functional impairment, and >8 indicates severe functional impairment. The ASAS HI is a reliable test for determining functionality in patients with axial SpA. Patients were provided with the Turkish translation of the ASAS HI [7].

The BASFI consists of 10 questions and evaluates functional limitations in patients with AS. Each question is scored on a numbered 11-point scale, and patients are asked to rate their ability over the past week. The mean of the ten parameters gives the BASFI score. A value between 0 and 10 indicates lower functional limitation with a lower score. The previously validated Turkish version of the BASFI was used [11].

The ASQoL is an important parameter reflecting the health status of patients with ankylosing spondylitis. It measures the consequences and severity of the disease. It is significant for assessing the quality of life of AS patients from their perspective. It provides a rapid and simple assessment. The questionnaire evaluates how the disease affects various aspects, including sleep, mood, motivation, coping strategies, daily activities, independence, relationships, and social interactions. A dichotomous response option ("no"=0, "yes"=1) is provided for all items. The total score is the sum of all item scores and can range from 0 to 18, with higher scores indicating a more significant impairment in HRQoL. The previously validated Turkish version of the ASQoL was used [12].

The BASDAI uses a numeric rating scale to measure fatigue, spinal and peripheral joint pain, morning stiffness and localized tenderness in patients with AS. Every question is rated on a horizontal scale ranging from 0 to 10, where 0 represents the absence of symptoms and 10 signifies extreme symptoms. Question 6 (morning stiffness) is time-dependent (0-2 hours). The means of questions 5 and 6 are calculated separately. The BASDAI score is calculated as the mean of the first four questions and the separate means of the last two questions. Lower scores indicate lower disease activity, with a score of 4 or higher indicating active disease [4]. Patients were provided with the Turkish version of the BASDAI [13].

The HAQ was developed by Fries et al. [14] and is one of the earliest patient-reported outcome measures. It is widely used worldwide to determine the functional status of patients with various rheumatic diseases, both in drug studies and routine practice. The Turkish version has been validated [15].

Inclusion Criteria

Participants meeting the ASAS classification criteria for ankylosing spondylitis, aged over 18, who consented to participate in the study and provided informed consents were included.

Exclusion Criteria

The criteria for exclusion included having other current musculoskeletal disorders (like gout, calcium pyrophosphate dihydrate crystal deposition disease, or rheumatoid arthritis), a prior cancer diagnosis or a lymphoproliferative disorder, poorly controlled diabetes, unstable ischemic heart disease, congestive heart failure, ongoing inflammatory bowel disease, positive hepatitis B serology, active tuberculosis, and concurrently having fibromyalgia.

Statistical Analysis

Data were analyzed to evaluate the relationships between clinical variables and health outcomes in patients with axSpA. Descriptive statistics were employed to summarize the demographic and clinical traits of the study sample. Continuous variables were reported as means and standard deviations (SD) for data that followed a normal distribution and as medians and interquartile ranges for data that did not. Categorical variables were presented as frequencies and percentages.

The Shapiro-Wilk test was utilized to evaluate the normal distribution of continuous variables. According to the distribution of the data, comparisons between groups were performed using either the independent t-test or the Mann-Whitney U test for continuous variables, and the Chi-square test or Fisher's exact test for categorical variables.

Table 1. Baseline demographic and clinical characteristics of patients

Variable	%
Number of patients	91
Gender (male)	45 (49.5)
Mean age (years)	35.6±10.6
BASDAI score> 4	49.5
Normal function (ASAS-HI)	31.8
Moderate dysfunction (ASAS-HI)	35.1
Severe dysfunction (ASAS-HI)	29.7
HLA B27 positive	30.7
Axial involvement	87.9
Non-radiographic axial spondyloarthritis	7.6
Peripheral joint involvement	26.4
Uveitis	7.6
NSAID use	53.8
TNF-α blocker use	14.3
Salazopyrin use	31.9

BASDAI: Bath Ankylosing Spondylitis Activity Index; ASASI-HI: Assessment of SpondyloArthritis International Society Health Index; HLA-B27: Human leucoyte antigen B27; NSAID: Non-steroid anti-inflammatory drugs; TNF-α: Tumor necrosis factor alpha.

The relationships between the ASAS-HI and other clinical parameters, such as the BASDAI and the BASFI, were evaluated using Pearson's correlation coefficient for data that is normally distributed, or Spearman's rank correlation coefficient for data that is not normally distributed. A p-value of less than 0.05 was considered statistically significant in every analysis. The statistical analyses were performed using IBM SPSS Statistics for Windows (Version 25.0. Armonk, NY: IBM Corp.).

RESULTS

This study included 91 patients with axSpA, 45 (49.5%) were males. The mean age was 35.6 years (SD=10.6). Almost half of the patients (49.5%) had a BASDAI score > 4, indicating active disease. Based on ASAS-HI results, 29 patients (31.8%) had normal function, 32 (35.1%) had moderate dysfunction, and 27 (29.7%) had severe dysfunction. HLA B27 positivity was found in 28 patients (30.7%), and axial involvement was observed in 80 patients (87.9%). Peripheral joint involvement was seen in 24 patients (26.4%).

Regarding medication, 49 patients (53.8%) used NSAIDs, 13 (14.3%) used TNF-α blockers, and 29 (31.9%) used salazopyrin. Uveitis was present in 7 (7.6%) patients (Table 1).

Table 2. Summary of clinical scores and inflammatory markers

Clinical features	Patients (n=91)
Disease duration (months)	
Mean (±SD)	25.7±40.5
Median (min–max)	8 (0–180)
Spinal pain (0–10 NRS)	
Mean (±SD)	5.3±2.4
Median (min–max)	5 (0–10)
BASDAI (0–10 NRS)	
Mean (±SD)	4.08±2.1
Median (min–max)	3.9 (0–8)
BASFI (0–10 NRS)	
Mean (±SD)	2.5±2.3
Median (min–max)	1.9 (0–10)
ASQoL (0–18)	
Mean (±SD)	2.8±2.7
Median (min–max)	1 (0–9)
HAQ (0–3)	
Mean (±SD)	0.2±0.3
Median (min–max)	0.2 (0–1.5)
ASAS-HI	
Mean (±SD)	6.8±3.8
Median (min–max)	6.5 (0–16)
ASAS-EF	
Mean (±SD)	3.5±1.5
Median (min–max)	3 (1–8)
CRP (mg/L)	
Mean (±SD)	7.2±9.3
Median (min–max)	4 (0–54)
ESR (mm/hr)	
Mean (±SD)	16.1±1.6
Median (min–max)	10.5 (0–81)

SD: Standard deviation; Min: Minimum; Max: Maximum; NRS: Numeric Rating Scale; BASDAI: Bath Ankylosing Spondylitis Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; ASQoL: Ankylosing Spondylitis Quality of Life; HAQ: Health Assessment Questionnaire; ASASI-HI: Assessment of SpondyloArthritis International Society Health Index; ASASI-EF: Assessment of SpondyloArthritis International Society Environmental Factors; CRP: C-Reactive Protein; ESR: Erythrocyte sedimentation rate.

Clinical Parameter Scores and Inflammatory Markers

The mean disease duration was 25.7 months (±40.5). Patients reported a mean spinal pain score of 5.3 (±2.4). The mean BASDAI score, which indicates disease activity, was 4.08 (±2.1). The mean BASFI score, which assesses functional limitations, was 2.5 (±2.3). As measured by the ASQoL, quality of life had a mean score

of 2.8 (±2.7). Functional assessments revealed a mean HAQ score of 0.2 (±0.3), indicating low functional impairment. The ASAS HI and ASAS EF scores were also evaluated. The mean ASAS HI score was 6.8 (±3.8), reflecting the disease's overall health impact. The mean ASAS EF score was 3.5 (±1.5), indicating the influence of environmental factors on patients' health. The mean sedimentation rate was 16.1 mm/hr (±1.6), and the mean CRP level was 7.2 mg/L (±9.3). The mean patient-reported outcome scores were as follows: BASDAI 4.08, spinal pain 5.3, HAQ 0.2, ASQoL 2.8, BASFI 2.5, ASAS HI 6.8, and ASAS EF 3.5 (Table 2).

Further analysis revealed positive correlations between ASAS HI and several measures: BASFI, BASDAI, spinal pain, and HAQ score ($p<0.05$). However, ASAS HI and ASQoL did not show a correlation. Disease duration, CRP, and ESR also did not correlate with ASAS HI scores. Finally, the ASAS EF was positively correlated with BASFI, BASDAI, spinal pain, and HAQ score (Table 3).

Table 3. Correlation of ASAS-HI and ASAS-EF scores with clinical parameters

Clinical parameters	ASAS-HI		ASAS-EF	
	r	p	r	p
BASDAI	0.6	<0.01	0.3	<0.01
BASFI	0.5	<0.01	0.2	0.03
Spinal pain	0.5	<0.01	0.2	<0.01
ASQoL	-0.1	0.3	-0.1	0.2
HAQ	0.6	<0.01	0.2	<0.01
Disease duration	0.1	0.5	0.1	0.3
CRP	-0.05	0.6	0.01	0.8
ESR	0.09	0.4	0.01	0.9

ASASI-HI: Assessment of SpondyloArthritis International Society Health Index; ASASI-EF: Assessment of SpondyloArthritis International Society Environmental Factors; BASDAI: Bath Ankylosing Spondylitis Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; ASQoL: Ankylosing Spondylitis Quality of Life; HAQ: Health Assessment Questionnaire; CRP: C-Reactive protein; ESR: Erythrocyte sedimentation rate.

DISCUSSION

Our cross-sectional study involving 91 patients revealed significant correlations between the ASAS-HI and various clinical parameters, providing significant insights into the health status and functional impairment of patients with axSpA, utilizing the ASAS-HI and ASAS-EF. The mean disease duration of the patients included in the study was 25.7 months. The mean ASAS-HI score in our cohort was 6.8 (±3.8), which is higher than some previously reported values [16–18], indicating a potentially higher disease burden and worse functional outcomes in our patient population.

The strong correlations observed between ASAS-HI and clinical parameters such as BASFI, BASDAI, spinal pain, and HAQ underscore the sensitivity of the ASAS-HI in reflecting both disease activity and functional impairment. These findings are consistent with previous research, such as the study by Skokić et al. [19], which demonstrated significant correlations between ASAS-HI and ASDAS-CRP ($r=0.62$, $p<0.0009$) and BASFI ($r=0.75$, $p<0.001$) in a similar patient cohort. The lack of a significant correlation between ASAS-HI and disease duration in both studies suggests that the ASAS-HI reflects more current disease activity than the length of time a patient has had the disease. This reinforces the utility of ASAS-HI as a tool for capturing the immediate impact of axSpA on patients' health.

When comparing our results with the study by Qu et al. [20], who reported a mean ASAS-HI score of 6.28 (±5.23) in 484 Chinese AS patients, we observed a slightly higher mean score in our cohort. They also found that patients with an ASDAS≥3.5 had a 12.5-fold increased risk of poor health status (OR=12.53, 95% CI=8.1-19.3, $p<0.001$), emphasizing the critical role of disease activity in determining health outcomes. This comparison underscores the need for early and aggressive disease management in our patient population to prevent severe functional impairment and poor quality of life.

Our study found that 49.5% of patients had a BASDAI score above 4, indicating a high level of disease activity, aligning with the significant correlation we observed between BASDAI and ASAS-HI ($r=0.6$, $p<0.01$). In comparison, Redeker et al. [21] reported a mean BASDAI score of 3.4 (±2.1) and a mean ASAS-HI score of 5.8 (±4.0) in their cohort of 384 axSpA patients. In their study, a considerable proportion of patients had lower disease activity (BASDAI<4), which correlates with the overall lower ASAS-HI scores observed. Additionally, the correlation between disease activity and ASAS-HI was strong, with ASDAS showing a correlation coefficient of 0.64 with ASAS-HI, further emphasizing the impact of disease activity on overall health status.

Moreover, they found that female gender was associated with higher ASAS-HI scores ($\beta=0.67$, 95% CI=0.32 to 1.03, $p<0.01$), indicating poorer health status among fe-

male patients. This aligns with our findings, where female patients also had higher ASAS-HI scores, although the gender difference was not statistically significant in our cohort. Additionally, they reported that an increase in BASFI by 1 unit was associated with an increase in ASAS-HI by 1.25 units (95% CI=1.04 to 1.40, p<0.01), further corroborating the strong association between functional impairment and overall health status in axSpA [21].

Interestingly, our study did not find a significant correlation between ASAS-HI and ASQoL (r=-0.1, p=0.3), contrasting with other studies' findings [8, 22]. For example, Di Carlo et al. [8] found a significant correlation between ASAS-HI and ASQoL, suggesting that while ASAS-HI is a comprehensive tool for assessing health status, it may not fully capture certain quality-of-life dimensions that are better reflected by ASQoL. This indicates the potential need for multiple assessment tools for a more holistic view of patient well-being.

The ASAS-EF scores in our study were also positively correlated with BASFI (r=0.2, p=0.03), BASDAI (r=0.3, p<0.01), spinal pain (r=0.2, p<0.01), and HAQ (r=0.2, p<0.01), indicating that environmental factors significantly influence health outcomes in axSpA patients. This finding emphasizes the importance of considering social and environmental contexts in the management of axSpA to address the broader determinants of health.

In a recent international validation study involving 976 patients with axSpA, Fong et al. [23] examined the differences in health outcomes between patients with radiographic axSpA and non-radiographic axSpA. The research indicated that patients with radiographic axSpA had marginally higher ASAS HI scores in comparison to their non-radiographic counterparts (mean ASAS HI score: 6.8±4.4 vs. 6.0±4.0, p=0.02), suggesting a poorer overall health status in the radiographic axSpA population. However, multivariable regression analysis showed that the axSpA phenotype did not significantly correlate with ASAS HI scores (β=-0.19, 95% CI=-0.56 to 0.19, p=0.33). The study also found that female gender was linked to elevated ASAS HI scores (β=0.67, 95% CI=0.32 to 1.03, p<0.01), reflecting worse health status among female patients. Additionally, poorer physical function, assessed by the BASFI, was strongly associated with increased ASAS HI scores (β=0.59, 95% CI=0.50 to 0.67, p<0.01). Likewise, greater disease activity as measured by the ASDAS was found to correspond with higher ASAS HI scores (β=0.54, 95% CI=0.35 to 0.72, p<0.01). These results emphasize that overall health and functioning are similarly impacted in both radiographic and non-radiographic axSpA, with modifiable factors such as physical function and mental health being vital to patient well-being.

Our findings align closely with those reported by Akgul et al. [24], who also observed similar mean ASAS-HI scores in a large cohort of axSpA patients (mean ASAS-HI score=6.16± 4.37). The comparable ASAS-HI scores between our study and theirs suggest that the health impairment in our patient population is consistent with broader trends observed in axSpA patients across different regions. Additionally, the strong correlations we found between ASAS-HI and clinical parameters such as BASFI and BASDAI are supported by the significant correlations (BASFI: r=0.570, BASDAI: r=0.506, both p<0.001), reinforcing the validity of ASAS-HI as a reliable measure of disease impact. The proposed cut-off points (≤4 for good health and ≥12 for poor health) offer a valuable framework for interpreting ASAS-HI scores in clinical practice, suggesting that a substantial portion of our patients may fall within the moderate to poor health status categories [24].

Ozgul et al. [25] evaluated the quality of life in AS patients using the SF-36. The most affected subfunctions of the quality-of-life criteria were physical role power, general health assessment, and pain. Similarly, our study found a relationship between spinal pain and high disease activity, general health assessment, and functional impairment. The researchers emphasized that the general health and physical role power of those with an education level of 8 years or less and those with more than 8 years of education were significantly different. According to these results, education positively affected quality of life. Additionally, it was found that the quality-of-life criteria, other than pain, was higher in patients who continued working compared to patients who had to quit their jobs due to disease activity.

The patients were from an inception cohort included early in the disease course. Previous studies have evaluated quality of life and physical function in patients with advanced ankylosing spondylitis using the BASFI and ASQoL scales. Our study appears different from others because our cohort consisted of early-stage patients.

Interestingly, our study did not observe a significant correlation between ASAS-HI and ASQoL. This discrepancy may stem from the differing focuses of these tools; while ASAS-HI evaluates a broad range of health dimensions, including physical, social, and environmental factors, ASQoL predominantly captures subjective aspects of quality of life. Additionally, cultural and psychosocial factors unique to our Turkish cohort and better economic

status for our patients may have influenced patients' perceptions of quality of life, leading to this unexpected result.

This study has some limitations. Since we are a tertiary care center, half of the patients included in the study had high disease activity. Similarly, the functional impairment levels of the patients were also found to be high. The function and health relationship can be evaluated by increasing the number of patients and adding parameters such as the patient's education level and smoking status. Another limitation of our study is the lack of radiological evaluation.

This research is fundamental for advancing our understanding of functional impairment and overall health status in individuals with ankylosing spondylitis. It involves a new index, which allows for a more comprehensive evaluation and emphasizes its significant relationship with other established clinical parameters. Additionally, it demonstrates that functional impairment commences early in the disease course and that disease activity is high. These findings support the idea that the primary treatment goal for individuals with ankylosing spondylitis should be to promptly suppress the disease and minimize the potential for functional loss.

Conclusion

This study highlights significant functional impairments and high disease activity in patients with axial spondyloarthritis, as measured by the ASAS-HI and other clinical parameters. The strong correlations between ASAS HI and key clinical measures underscore its utility in capturing disease impact, even early in the disease course. These findings reinforce the importance of early intervention and disease control to prevent functional loss and improve quality of life in axSpA patients.

Ethics Committee Approval: The Istanbul Medipol University Non-interventional Clinical Research Ethics Committee granted approval for this study (date: 04.10.2017, number: 349).

Authorship Contributions: Concept – MC, OK; Design – MC, OK; Supervision – MC; Data collection and/or processing – MC, OK; Analysis and/or interpretation – MC, OK; Literature review – MC, OK; Writing – OK; Critical review – MC.

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