

Disease activity is the major determinant of quality of life and physical function in patients with early axial Spondyloarthritis: Results from the ESPERANZA Cohort.

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FUNDING: Dr Fernández-Carballido received a grant from the Spanish Society of Rheumatology, for an stay in HU La Paz during which the present study was conducted. The ESPERANZA programme: At first, Pfizer (previously Wyeth) financially supported the Spanish Foundation of Rheumatology to run the ESPERANZA Programme. Currently, the programme is supported by a restricted grant from the Institute Carlos III (FIS project PI13/02034) and Fondos FEDER. The sponsors had no role in the study design, the collection, analysis or interpretation of the data; in the writing of the report; or in the decision to submit the article for publication.

DISCLOSURE STATEMENT: The authors declare no conflicts of interest regarding the present study.

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word count: 1768

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process which may lead to differences between this version and the Version of Record. Please cite this article as an 'Accepted Article', doi: 10.1002/acr.22908

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Received: Dec 01, 2015; Revised: Mar 17, 2016; Accepted: Apr 05, 2016

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ABSTRACT

Objective: To describe health related quality of life (HRQoL) and physical function (PF) in patients with early axial Spondyloarthritis (axSpA) and to assess their associations with disease activity and radiographic damage.

Methods: Cross-sectional study drawing upon baseline data of axSpA patients (ASAS criteria) from the ESPERANZA cohort. Linear regression analyses were used to evaluate the associations between disease activity and radiographic damage (spine and sacroiliac joints) with HRQoL, PF and spinal mobility (SM).

Results: In total, 259 patients were included. Mean (SD) age was 32.2(6.9) years; disease duration 13.3(6.8) months; ASQoL, 5.9(4.8); BASFI, 2.4(2.3); BASMI, 1.4(1.3); BASDAI, 3.8(2.3); CRP, 9.7(13.2) mg/L and BASRI-spine, 1.7(1.6). HRQoL was mainly associated with disease activity on univariate analysis (β values for BASDAI 0.646, patient global VAS 0.641, night back pain VAS 0.598, physician VAS 0.560 and CRP 0.275; all $p < 0.01$) whereas the association with radiographic damage was weaker (Std β for BASRI-spine 0.142, $p < 0.05$). On multivariate models, HRQoL only remained significantly associated with disease activity (Std β for BASDAI 0.330; $p < 0.01$ and physician VAS 0.205 and night back pain VAS 0.210; $p = 0.01$). Similarly, PF was associated with disease activity and radiographic damage on univariate analysis, but only with disease activity (BASDAI β : 0.466; $p < 0.01$) on multivariate analysis. However, SM was associated with radiographic damage in both, univariate and multivariate analyses.

Conclusions: Patients with axSpA have already impaired, albeit mildly, quality of life and physical function at the beginning of their disease course. Both outcomes are mainly associated with disease activity in these patients.

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Significance and Innovations

- Health related-quality of life and physical function are already affected, yet mildly, in patients with early axial SpA.
- In this cohort of patients with early axial SpA, both outcomes (health related-quality of life and physical function) are associated with disease activity, while no association with radiographic damage has been identified.
- An association between spinal mobility and the spinal radiographic damage is detected, even in these early stages of the disease.

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Axial spondyloarthritis (axSpA) are chronic inflammatory diseases and include patients with established radiographic sacroiliitis (termed as Ankylosing Spondylitis -AS-) but also patients who have not radiographic sacroiliitis and, therefore, are referred to as non-radiographic axial SpA (nr-axSpA). Health-related quality of life (HRQoL) and physical function (PF) are considered to be major outcomes in axSpA (1). Both outcomes are significantly reduced among these patients and have been directly related to the socio-economic impact of the disease (2). At the same time, these outcomes have been associated with other variables. For example, HRQoL has been independently associated with disease activity and physical function (1,3). Physical function has also been independently associated with disease activity (1,3,4) and radiographic damage (4,5) or spinal mobility (1,3). However, all of the available studies evaluating HRQoL and PF, and their relationships, have included patients with longstanding AS, and data from patients with recent onset axSpA are scarce. Moreover, patients with early axSpA have either absent or lower radiographic damage than patients with advanced AS. Thus, it remains unclear whether the relationships among these outcomes are similar at the beginning of the disease. The hypothesis of the present study was that disease activity is the major determinant of HRQoL and PF in patients with early axSpA. Based on this theory, the objectives of this study were to describe the HRQoL and PF in patients with early axSpA and to assess their associations with disease activity and radiographic damage. Also, spinal mobility (SM) was included into the analyses as a secondary outcome.

METHODS

Population: The present study was a cross-sectional investigation drawing upon baseline data from the ESPERANZA Programme, a Spanish prospective national health initiative

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intended to facilitate the early diagnosis and follow-up of patients with SpA through the implementation of a referral strategy and the creation of early SpA clinics (ESC). Details of this programme have been previously published (6). In summary, the referral criteria were as follows: 1) age from 18 to 45 years; 2) symptoms duration between 3 and 24 months; and 3) experiencing one of the following: a. inflammatory back pain (IBP), b. asymmetrical arthritis or c. spinal or joint pain plus one SpA feature.

For the current study, data from 291 patients (37.5% of all patients referred to the ESPERANZA programme) fulfilling the ASAS axSpA criteria (7) were selected. Because 32 (11%) patients were excluded for lacking HRQoL or PF data, 259 patients were finally included. All patients signed an informed consent before their inclusion into the ESPERANZA programme. The programme was reviewed and approved by the Research Ethics Committee of Hospital Reina Sofía, Cordoba, Spain. The approval covers the analysis of the data described in this study.

Independent variables: The independent variables were disease activity and radiographic damage. Disease activity was measured through the Spanish validated version of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (8), the Ankylosing Spondylitis Disease Activity Score (ASDAS) (9), physician's visual analogue scale (VAS), patient's global and night back pain VAS, enthesitis (MASES index), CRP (mg/L) and ESR (mm/hour) levels. Radiographic damage was assessed at the level of the lumbar and cervical spine and sacroiliac joints. Radiographs were scored locally by the rheumatologists in charge of the ESC, according to the Bath Ankylosing Spondylitis Radiology Index for the spine (BASRI-s) (10) and as described in the AS modified NY criteria for the sacroiliac joints.

Outcomes: The main outcomes for this study were HRQoL and PF, as assessed by the

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Spanish validated versions of the Ankylosing Spondylitis Quality of Life scale (ASQoL) (11) and the Bath Ankylosing Spondylitis Functional Index (BASFI) (3), respectively. As a secondary outcome, spinal mobility was measured using the Bath Ankylosing Spondylitis Metrology Index (BASMI) linear definition (12) and was performed by the rheumatologists in charge of the ESC.

Statistical Analysis: First, descriptive analyses were performed for the demographic and clinical variables. The results are shown as means and standard deviation (SD) for continuous variables and relative frequencies for categorical variables. Later, the associations between the independent variables and the outcomes were investigated using univariate and multivariate linear regression models. Estimates for these associations are shown as standardized beta coefficients (Std β). All analyses were adjusted for age, gender and disease duration. Furthermore, sensitivity analyses were performed to evaluate whether or not the association between the independent variables and the outcomes were different in patients with AS versus patients with nr-axSpA. SPSS 21.0 software was employed for the analyses and p-values less than 0.05 were considered statistically significant.

RESULTS

A total of 259 axSpA patients (66.8% men) were included. Thirty-nine percent of patients had AS and 61% non-radiographic axSpA. The demographic and clinical characteristics are summarized in table 1. The mean (SD) baseline values were as follows: age 32.2(6.9) years, disease duration 13.3(6.8) months, BASDAI 3.8(2.3), ASDAS 2.3(1.0), CRP 9.7(13.2) mg/L, BASMI 1.4(1.3) and BASRI-s 1.7(1.6). There were no differences between the total sample and the selected patients for this analysis (table 1).

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Health related quality of life (HRQoL): The mean (SD) ASQoL was 5.9 (4.8). HRQoL was predominantly associated with the disease activity-related variables (table 2) on univariate analysis. The activity parameters more strongly associated were BASDAI, patient global VAS, night pain VAS, ASDAS and physician VAS (std β range from 0.646 to 0.560; all $p < 0.01$). Additionally, a significant but weaker association with spinal radiographic damage was identified. However, in the multivariate model (table 3), HRQoL remained associated with disease activity alone (std β for BASDAI 0.330; $p < 0.01$).

Physical function (PF): The mean (SD) BASFI was 2.4 (2.3). In the univariate analysis, statistically significant associations with all disease activity (std β from 0.691 for BASDAI to 0.303 for CRP; all $p < 0.01$) and radiographic damage variables (std β 0.155 for BASRI-s and 0.147 for radiographic sacroiliitis; both $p < 0.05$) were observed (table 2). Nonetheless, multivariate analysis only showed associations with disease activity-related variables (table 3).

Spinal mobility (SM): The mean (SD) BASMI was 1.4 (1.3). SM was associated with radiographic damage (std β 0.329 for BASRI-s and 0.287 for radiographic sacroiliitis; both $p < 0.01$) and, to a lesser extent, with disease activity variables (std β 0.280 for physician VAS and 0.183 for ASDAS; both $p < 0.01$) on univariate analysis (table 2). On multivariate analysis, a statistically significant association was found with physician VAS (std β 0.247; $p = 0.02$) and radiographic damage at the spine (std β 0.216; $p = 0.04$) (table 3).

For all three outcomes, HRQoL, PF and SM, the analysis was repeated to include ASDAS instead of CRP and BASDAI in the multivariate models. Despite the lower number of patients with available ASDAS ($n = 187$), the observed results were similar. Finally, all analyses were repeated stratified by the subtype of axSpA (AS vs nr-axSpA). Overall, no

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relevant differences were observed between both groups (data not shown).

DISCUSSION

This study shows that, even in the early stages of the disease, health-related quality of life and physical function are impaired in patients with axSpA. The degree of physical function impairment found in this study is similar to that observed in other early axSpA cohorts, including patients with almost the same disease duration (13-14). To the best of our knowledge, no ASQoL data in similar populations are available for comparison with our results. In patients with longstanding AS, disease activity has been found to be associated with quality of life (1,3) and physical function (1,4), although evidence has shown that structural (radiographic) damage also determines these outcomes (4-5). However, in our study quality of life and physical function are both independently associated with disease activity, though not with radiographic damage. A possible explanation for this result may be the early nature of our cohort, in which non-radiographic axSpA forms predominate, and so less radiographic damage is present than in cohorts with established disease. It is to note that when non-radiographic axial SpA and AS have been compared, more radiographic damage of the spine and worse physical function (which is partly explained by radiographic damage) and higher serum CRP levels have been reported in patients with AS than in patients with non-radiographic axial SpA (15). In our cohort, AS patients also had more radiographic damage and worse physical function than patients with non-radiographic axial SpA, but differences in CRP levels were not detected. Furthermore, no relevant differences in the associations with the outcomes between both groups were observed.

To our knowledge, this is the first study to evaluate the association between quality of life and physical function with disease activity or radiographic damage in patients with early

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axSpA. An important strength of the study is that a large cohort of such patients was analyzed. Furthermore, the Esperanza cohort reflects daily clinical practice. Additionally, multiple validated outcomes and disease activity assessments, commonly employed in clinical studies and recommended or endorsed by ASAS, were explored. Nevertheless, this study has some limitations. First, the local scoring of images might be regarded as a weakness. However, the reading was previously standardized, and a detailed explanation of the scoring system was provided. In addition, all of the readers were rheumatologists from GRESSER (GRupo de Estudio de ESpondiloartritis de la Sociedad Española de Reumatología), the Spanish working group with common interests in SpA; therefore, they were familiar with the scoring systems. Second, HRQoL generic instruments, such as SF-36, could have been employed, but as we did not intend to compare our patients with non-SpA populations, we used ASQoL, a validated, disease-specific HRQoL measure for patients with AS, the psychometrics of which support its use in clinical studies. Third, the possibility of a selection bias must be considered; however, no relevant differences were observed between the selected patients and the entire axSpA sample. Finally, other variables, such as psychological, social, cultural or educational factors, that can impact the outcomes, were not analyzed.

In summary, this study finds that patients with axSpA have already impaired, albeit mildly, quality of life and physical function at the beginning of their disease course. Furthermore, our data suggest that, in these early stages of the disease, both outcomes are primarily determined by disease activity. Considering that the primary goal of treating patients with SpA is to maximize long-term health related quality of life and social participation, and that patients with AS have been reported to lose most of their functionality within the first 10 years of disease (5), we found it relevant to devote careful attention to these outcomes

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from the early stages of the disease. Based on the results of our study, it is plausible that tightly controlling the disease activity from its onset may bestow a substantial benefit on the HRQoL and PF of patients with axSpA, although further research and longitudinal studies in this field are required to confirm this hypothesis.

ACKNOWLEDGMENT: We would like to thank the **UIFER members** (Unidad de Investigación de la Fundación Española de Reumatología) who were involved in the ESPERANZA Programme design and analyses and to all the **participant patients**.

AUTHOR CONTRIBUTIONS:

All authors made substantial contributions to acquisition of data, were involved in drafting the article or revising it critically for important intellectual content, and approved the final version to be submitted for publication. Dr Navarro-Compán had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Table 1. Demographic and clinical characteristics of the patients from the ESPeranza programme fulfilling ASAS axSpA criteria.

Characteristic	Patients fulfilling ASAS axSpA criteria n =291	Patients included in the analysis n (%)=259 (89%)
Age (years)	32.0 ± 7.0	32.2 ± 6.9
Male, n (%)	191 (65.6)	173 (66.8)
Symptoms duration (months)	13.0 ± 6.7	13.3 ± 6.8
IBP (ASAS definition), n (%)	112 (38.5)	97 (37.5)
Response to NSAIDs, n (%)	216 (74.2)	198 (76.4)
Enthesitis, n (%)	57 (19.6)	53 (20.5)
Psoriasis, n (%)	33 (11.3)	30 (11.6)
Dactylitis, n (%)	16 (5.5)	15 (5.8)
IBD, n (%)	9 (3.1)	9 (3.5)
Uveitis, n (%)	23 (7.9)	19 (7.3)
Arthritis, n (%)	53 (18.2)	51 (19.7)
Family history, n (%)	101 (34.7)	89 (34.4)
HLA-B27 positive, n (%)	219 (75.3)	192 (74.1)
CRP (mg/L)	10.8 ± 15.2	9.7 ± 13.2
ESR (mm/h)	13.6 ± 13.5	12.8 ± 12.9
VAS (0-10 cm) physician	2.9 ± 2.2	2.9 ± 2.2
VAS (0-10 cm) patient global	4.2 ± 2.7	4.2 ± 2.7
VAS (0-10 cm) night back pain	3.8 ± 2.9	3.8 ± 2.9
BASDAI (0-10)	3.8 ± 2.3	3.8 ± 2.3

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ASDAS	2.3 ± 1.0	2.3 ± 1.0
MASES (0-13)	0.5 ± 1.3	0.6 ± 1.4
BASMI linear (0-10)	1.4 ± 1.2	1.4 ± 1.3
BASRI spine (0-8)	1.7 ± 1.6	1.7 ± 1.6
Sacroiliitis on xRay (mNY), n (%)	109 (37.5)	101 (39.0)
BASFI (0-10)	2.4 ± 2.3	2.4 ± 2.3
ASQoL (0-18)	5.9 ± 4.8	5.9 ± 4.8
Work incapacity, n (%)	31 (10.6)	26 (10.0)

Results are reported as mean ± SD unless otherwise specified.

axSpA= Axial Spondyloarthritis, according to ASAS criteria,[12]; IBP= inflammatory back pain; IBD= inflammatory bowel disease; CRP= C Reactive Protein; ESR= erythrocyte sedimentation rate; VAS= visual analogue scale; BASDAI= Bath Ankylosing Spondylitis Disease Activity Index; ASDAS = Ankylosing Spondylitis Disease Activity Score, calculated with the CRP (in mg/L); MASES= Maastricht AS Enthesitis Score; BASMI= Bath Ankylosing Spondylitis Metrology Index; BASRI = Bath Ankylosing Spondylitis Radiographic Index; mNY = modified New York criteria; BASFI= Bath Ankylosing Spondylitis Functional Index; ASQoL= Ankylosing Spondylitis Quality of Life Questionnaire.

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Table 2. Univariate analysis. Association between ASQoL, BASFI and BASMI with disease activity and radiographic damage.

	ASQoL		BASFI		BASMI	
	Std Beta	p value	Std Beta	p value	Std Beta	p value
CRP (mg/L)	0.275	p<0.01	0.303	p<0.01	0.183	p<0.01
ESR (mm)	0.113	p<0.1	0.186	p<0.01	0.074	NS
VAS (0-10) physician	0.560	p<0.01	0.617	p<0.01	0.280	p<0.01
VAS (0-10) patient global	0.641	p<0.01	0.651	p<0.01	0.112	p<0.1
VAS (0-10) night back pain	0.598	p<0.01	0.594	p<0.01	0.100	p<0.1
BASDAI (0-10)	0.646	p<0.01	0.691	p<0.01	0.166	p<0.01
ASDAS-CRP	0.569	p<0.01	0.614	p<0.01	0.183	p<0.01
MASES (0-13)	0.244	p<0.01	0.241	p<0.01	0.048	NS
BASRI spine (0-8)	0.142	p<0.05	0.155	p<0.05	0.329	p<0.01
Sacroiliitis xRay (mNY)	0.096	NS	0.147	p<0.05	0.287	p<0.01

ASQoL= Ankylosing Spondylitis Quality of Life Questionnaire; BASFI= Bath Ankylosing Spondylitis Functional Index; BASMI= Bath Ankylosing Spondylitis Metrology Index; CRP= C Reactive Protein; ESR= erythrocyte sedimentation rate; VAS= visual analogue scale; BASDAI= Bath Ankylosing Spondylitis Disease Activity Index; ASDAS = Ankylosing Spondylitis Disease Activity Score, calculated with the CRP (in mg/L); MASES= Maastricht AS Enthesitis Score; BASRI = Bath Ankylosing Spondylitis Radiographic Index; mNY = modified New York criteria.

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Table 3. Multivariate analysis. Association between ASQoL, BASFI and BASMI with disease activity and radiographic damage.

	ASQoL		BASFI		BASMI	
	Std Beta	p value	Std Beta	p value	Std Beta	p value
CRP (mg/L)	0.117	0.05	0.138	0.01	0.015	0.8
VAS (0-10) physician	0.205	0.01	0.263	<0.01	0.247	0.02
VAS (0-10) night back pain	0.210	0.01	0.065	0.4	-0.096	0.4
BASDAI (0-10)	0.330	<0.01	0.466	<0.01	0.052	0.6
MASES (0-13)	0.105	0.1	0.088	0.1	-	-
BASRI spine (0-8)	-0.020	0.7	-0.074	0.3	0.216	0.04
Sacroiliitis xRay (mNY)	-	-	0.101	0.2	0.013	0.9

ASQoL= Ankylosing Spondylitis Quality of Life Questionnaire; BASFI= Bath Ankylosing Spondylitis Functional Index; BASMI= Bath Ankylosing Spondylitis Metrology Index; CRP= C Reactive Protein; VAS= visual analogue scale; BASDAI= Bath Ankylosing Spondylitis Disease Activity Index; MASES= Maastricht AS Enthesitis Score; BASRI = Bath Ankylosing Spondylitis Radiographic Index; mNY = modified New York criteria.