

Physical Function and Health-Related Quality of Life of Spanish Patients With Ankylosing Spondylitis

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Objective. To determine the physical function and the quality of life (QOL) of Spanish patients with ankylosing spondylitis (AS), and to study the reliability of the Spanish version of the Bath Ankylosing Spondylitis Functional Index (BASFI).

Methods. Clinimetric variables, including Spanish BASFI (test-retest), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), QOL instruments (Short Form 36 [SF-36] and European Quality of Life Questionnaire [EuroQol]), Bath Ankylosing Spondylitis Metrology Index (BASMI), and chest expansion, were assessed.

Results. A total of 92 patients were included: 69 males (75%), age (mean \pm SD) 40.7 ± 9.1 years, and disease duration 11 ± 7.8 years. The scores (mean \pm SD) were (from 0 the best to 10 the worst): BASFI 4.3 ± 2.4 ; BASDAI 4.5 ± 2.2 ; global SF-36 5.5 ± 2.1 ; SF-36 physical function 3.8 ± 2.5 ; SF-36 physical scale 4.9 ± 2.7 ; SF-36 mental scale 3.7 ± 2.7 ; SF-36 physical role limitations 5.6 ± 4.4 ; SF-36 general health 5.5 ± 2.1 ; SF-36 pain 5.4 ± 2.8 ; SF-36 vitality 5.1 ± 2 ; EuroQol rating scale 3.9 ± 2.1 ; EuroQol health profile (from 0 the best to 2 the worst) 0.6 ± 0.4 ; and BASMI 4.7 ± 1.6 . Significant association was found between BASFI and SF-36 physical function domain ($r = 0.75$, $R^2 = 0.56$, $P < 0.0001$). BASFI Cronbach's alpha was 0.92, Spearman's rho = 0.91, $P < 0.0001$.

Conclusions. Physical function and QOL are deteriorated in AS. The physical domain is more impaired than the mental one. The SF-36 and the health profile of the EuroQol may be used as generic instruments to measure health-related QOL. Spanish BASFI index is a reliable instrument.

KEY WORDS. Quality of life; BASFI; Physical function; Ankylosing spondylitis.

INTRODUCTION

Physical function is among the recommended core set of endpoints in ankylosing spondylitis (AS) for all settings defined by the Assessments in AS Working Group (1). Two instruments are recommended to be used for assessing physical function (2): the Bath Ankylosing Spondylitis Functional Index (BASFI) (3) and the Dougados Functional Index (4). There are no Spanish versions of these instruments. The BASFI is considered a valid, reliable, and feasible instrument and it has been used in many

studies to measure the physical function of patients with AS (5–12).

Quality of life (QOL) is a very important domain in AS (13) and other rheumatic diseases. There are few studies focused on the health-related quality of life (HRQOL) of patients with AS (5,14,15). The Short Form 36 (SF-36), a generic HRQOL instrument, is the most used measurement technique.

The aim of this study was to assess the physical function and the HRQOL of AS Spanish patients. Secondary aims were to know the performance of 2 HRQOL generic instruments, the SF-36 and the European Quality of Life Questionnaire (EuroQol), and to evaluate the validity, reliability, and feasibility of a Spanish version of the BASFI.

PATIENTS AND METHODS

Design. This was a cross-sectional, test-retest study. A letter was sent to all 130 members of the Ankylosing Spondylitis Association of Seville (ASAS) inviting them to participate in a study about physical function and HRQOL in

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AS. All patients fulfilled the modified New York criteria for AS (16) and gave their consent to participate in the study.

The same rheumatologist evaluated all patients. Demographics and disease-related variables were collected. Patient and physician global assessments were done on a visual analog scale (VAS) from 0 (very well) to 10 (very bad). Patient pain assessment was done on VAS from 0 (no pain) to 10 (maximum pain). Disease activity was assessed by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI; from 0 = no activity to 10 = maximum activity) (17). A metrology index, the Bath Ankylosing Spondylitis Metrology Index (BASMI; from 0 = the best metrology to 10 = the worst) (18,19) was also applied. Chest expansion in centimeters was assessed.

Two generic HRQOL instruments were administered: the Spanish version of the SF-36 questionnaire (20) and the Spanish version of the EuroQol (21). The SF-36 was scored from 0 (the best QOL) to 10 (the worst). Physical and mental global scores were calculated as the mean of the physical and mental domains, respectively. The SF-36 global score was obtained as the mean of all the domains.

The EuroQol includes a health profile (from 0 = the best QOL to 2 = the worst) and a health state rating scale (from 0 = the best health state to 10 = the worst).

The Spanish BASFI (see Appendix) was validated. The original English version of the BASFI was translated and adapted to a Spanish version by 2 bilingual rheumatologists. The time spent by the patients to complete the questionnaire was recorded. The investigator evaluated the comprehension of the questionnaire. The validity of the Spanish BASFI was assessed using several constructs, mainly physical function measured by the SF-36. Test-retest evaluation was done in 26 randomly selected patients. The interval between each measurement was 1 hour. Internal consistency was also assessed.

Statistical analysis. Descriptive statistics were performed. Pearson's product moment correlation coefficient and simple regression analysis were used when appropriated. Regression models were constructed. Spearman's rank correlation coefficient was used for studying reproducibility (test-retest). Internal consistency was assessed by Cronbach's alpha. A 2-tailed *P* value of <0.05 was considered significant.

The study reached a power of 80% for detecting a significant Pearson's correlation coefficient >0.3 between BASFI and SF-36 physical function domain. The study also had a power of 80% for estimating HRQOL assessed by the SF-36 with 9% tolerance.

RESULTS

Ninety-two patients responded to the invitation to participate and were included in the study. There were 69 males (75%), age (mean \pm SD) 40.7 \pm 9.1 years, and disease duration 11 \pm 7.8 years. Fifty-three patients (58%) were taking nonsteroidal antiinflammatory drugs at the time of the study and 9 patients (10%) used second-line agents. Fifty-one patients (55%) usually performed exercise pro-

Table 1. Results of disease-related variables*

Variable	Mean	SD	Median	Range
Patient global assessment	4.4	2.7	4.7	0–10
Physician global assessment	4.1	2.4	4.1	0.1–9.2
Pain	4.9	2.8	4.9	0–10
BASDAI	4.5	2.2	4.5	0.1–9.7
BASMI	4.7	1.6	4.6	1.6–8.2
Tragus to wall	2.1	2	1	0–10
Cervical rotation	4.5	2.2	4	0–10
Lumbar flexion	7.1	1.8	7	0–10
Lumbar side flexion	5.1	2.7	5	0–10
Intermalleolar	4.8	1.5	5	0–8
Chest expansion, cm	3.4	1.6	3	0.5–7

* Patient global assessment and physician global assessment rated on a visual analog scale from 0 (very well) to 10 (very bad). Pain rated from 0 (no pain) to 10 (maximum pain). BASDAI = Bath Ankylosing Spondylitis Disease Activity Index, from 0 (no activity) to 10 (maximum activity). BASMI = Bath Ankylosing Spondylitis Metrology Index, from 0 (the best metrology) to 10 (the worst).

grams. The scores of disease-related variables are shown in Table 1.

The BASFI score (mean \pm SD) was 4.3 \pm 2.4, with a range of 0–8.9. Items 2 (“bending forward from the waist to pick up a pen from the floor without an aid”) and 10 (“doing a full days’ activities whether it be at home or at work”) showed the worst scores (5.5 \pm 3.7 and 5.5 \pm 3.2, respectively).

Table 2 shows the scores of the HRQOL instruments. The global physical scale of the SF-36 was significantly more impaired than the global mental scale (4.9 \pm 2.7 versus 3.7 \pm 2.3; *P* = 0.001) and than the social function scale (4.9 \pm 2.7 versus 2.9 \pm 2.7; *P* < 0.001). The health profile of the EuroQol had good correlation with the SF-36 global score (*r* = 0.77, *P* < 0.0001). The rating scale of the EuroQol had a lower correlation with the SF-36 global score (*r* = 0.43, *P* < 0.0001) and with the health profile of the EuroQoL (*r* = 0.46, *P* < 0.0001).

BASFI had a good correlation (Pearson's product moment correlation coefficient > 0.6) with SF-36 physical function (*r* = 0.75, *R*² = 0.56, *P* < 0.0001), patient and physician global assessments, pain measurements, BASDAI, and most of the HRQOL scores (data not shown). BASFI had a moderate correlation (Pearson's correlation coefficient between 0.4 and 0.6) with BASMI score (*r* = 0.57, *P* < 0.0001) and age (*r* = 0.41, *P* < 0.0001). The Cronbach's alpha of the BASFI Spanish version was 0.92. BASFI test-retest Spearman's rank correlation coefficient was 0.91 (*P* < 0.0001) for the global BASFI score. Eight items had a Spearman's rho > 0.87. Items 5 and 10 had lower correlations (rho = 0.74, *P* < 0.0001; and rho = 0.58, *P* = 0.001, respectively). Patients spent 2–3 minutes to complete the questionnaire and they understood it in well enough.

Regression models were constructed to identify variables associated with physical function and HRQOL. In the first model, the dependent variable was BASFI and the independent variables were age, patient and physician global assessments, patient pain assessment, BASDAI, BASMI, chest expansion, SF-36 physical function domain, SF-36 global physical scale, and SF-36 global score. This

Table 2. HRQOL: SF-36 and EuroQoL results*

Instrument	Mean (95% CI)	SD	Median	Range
SF-36				
General health	5.5 (5.1–5.9)	2.1	5.5	0–10
Physical function	3.8 (3.3–4.3)	2.5	3.5	0–9.5
Physical role limitations	5.6 (4.7–6.5)	4.4	7.5	0–10
Emotional role limitations	2.3 (1.5–3.1)	3.8	0	0–10
Social function	2.9 (2.3–3.5)	2.8	2.5	0–10
Pain	5.4 (4.8–6)	2.8	5.5	0–10
Mental health	3.7 (3.2–4.1)	2.2	3.6	0–10
Vitality	5.1 (4.6–5.6)	2.5	5	0–10
Global physical scale	4.9 (4.3–5.4)	2.7	5.4	0–9.8
Global mental scale	3.7 (3.2–4.2)	2.3	3.3	0–9.5
Global	4.3 (3.9–4.7)	2.1	4.4	0.2–9.1
EuroQoL				
Health profile	0.6 (0.5–0.7)	0.4	0.6	0–1.6
Rating scale	3.9 (3.5–4.3)	2.1	3.5	0–9

* SF-36 global physical scale = mean of the domains physical function, physical role limitations, and pain. SF-36 global mental scale = mean of the domains of emotional role limitations, mental health, and vitality. SF-36 global score = mean of the eight SF-36 domains. SF-36 scores from 0 (the best quality of life) to 10 (the worst). EuroQoL health profile score from 0 (the best quality of life) to 2 (the worst). EuroQoL rating scale score from 0 (the best health state) to 10 (the worst). HRQOL = health-related quality of life; SF-36 = Short Form 36; EuroQoL = European Quality of Life questionnaire; 95% CI = 95% confidence interval.

model explained 79% of the variance of the BASFI score ($P < 0.0001$). SF-36 physical function domain ($P = 0.017$), BASDAI score ($P = 0.003$), and BASMI score ($P = 0.046$) were independently associated with the BASFI score. In a second model, BASFI was the dependent variable and patient pain assessment, BASDAI, BASMI, and chest expansion were the independent variables. This model explained 72% of the variance of the BASFI score ($P < 0.0001$). Again, BASDAI ($P < 0.0001$) and BASMI ($P < 0.0001$) were independently associated with BASFI score.

Regression models were also constructed for the HRQOL scores. SF-36 global score, EuroQoL health profile, and EuroQoL rating scale were the dependent variables. In the SF-36 model, the independent variables were patient and physician global assessments, patient pain assessment, BASDAI, and BASFI. This model explained 56% of the variance of the SF-36 score ($P < 0.0001$). Physician global assessment ($P = 0.043$), patient pain assessment ($P = 0.036$), and BASFI score ($P = 0.002$) were independently associated with the SF-36.

In the EuroQoL health profile model, the independent variables were age, physician and patient global assessments, patient pain assessment, BASDAI, BASFI, BASMI, and chest expansion. This model explained 58% of the variance of the EuroQoL health profile score ($P < 0.0001$). Only BASFI score showed an independent association with the EuroQoL health profile ($P = 0.002$).

In the EuroQoL rating scale model, the independent variables were patient and physician global assessments, BASDAI, and BASFI. This model explained 19% of the variance of the rating scale ($P < 0.01$). BASDAI score was independently associated with the rating scale ($P = 0.05$).

DISCUSSION

In this study, we have developed and used a Spanish version of the BASFI for assessing the physical function of

Spanish AS patients. The BASFI scores were to similar those of other studies (2,7,22). Interestingly, the items with the highest scores were those related to the patient's ability to perform lumbar flexion (item 2) and to cope with everyday life (item 10), which indicate the pattern of physical impairment and limitations in daily life activities.

The wide ranges of the scores of the disease-related variables reflect the broad spectrum of our population with AS. BASFI scores reflected the types of patients included. Thus, these scores also had a wide range. It suggests that the BASFI scores be related to the global state of the patients. The good correlation with patient and physician global assessments and the high scores of the items related to the patients' ability to cope with everyday life support this idea. The regression models suggest that activity of the disease (BASDAI score) and metrology (BASMI score) are the main factors associated with physical function in AS. It must be said with caution, however, considering the cross-sectional design of this study.

There is no standard recommended HRQOL instrument for AS. We have used 2 Spanish versions of generic instruments: the SF-36 (20) and the EuroQoL (21). The results suggest that the SF-36 and the health profile of the EuroQoL have a similar performance for assessing HRQOL. However, longitudinal studies are needed to validate this.

In the case of the rating scale of the EuroQoL, it had a moderate correlation with the health profile of this instrument and with the SF-36. Besides, the disease-related variables included in the regression model explained only 19% of the variance of the scores of the EuroQoL rating scale. These data suggest that this scale is not an appropriate instrument to assess the HRQOL of AS patients.

According to our results, HRQOL of AS patients is impaired in a significant way. The physical area is more impaired than mental and social areas and the patients perceive their general health as fairly damaged. Physical

function assessed by the BASFI was the main associated factor with HRQOL in our patients, but longitudinal studies are needed to identify determinants of HRQOL.

In this work we have studied the validity, reliability, and feasibility of a Spanish version of the BASFI. The validity of the original English version of the BASFI was demonstrated being compared with the Dougados Functional Index (3) but there is no Spanish version of this instrument. Thus, we chose a validated Spanish version of the SF-36 (20) as the instrument being compared. The Spanish BASFI had a good correlation with the physical function domain of the SF-36 questionnaire ($r = 0.75$), with the global physical scale of the SF-36 ($r = 0.67$), and with several disease-related variables (constructs). The regression models support the validity of the Spanish BASFI. The Spanish BASFI has internal consistency and its reliability is similar to those reported for the original version (3,23). Spanish patients had no problems understanding the questionnaire and spent a short time completing it. Thus, the Spanish BASFI is a reliable and feasible instrument.

Responsiveness of the Spanish BASFI has not been assessed in this study. The metric properties of the Spanish BASFI are similar to those of the original version, but its responsiveness must be tested.

This work has some limitations. First, a selection bias must be considered because we studied members of the ASAS who responded to an invitation to participate. Patients who are not members of the ASAS and patients who did not respond can be different from the included patients. However, the broad spectrum of our patients supports the idea that they represent the entire population with AS. Second, the cross-sectional design limits the conclusions about the associated factors with physical function and HRQOL. However, it does not affect the main purposes of the study.

In conclusion, physical function and HRQOL of Spanish patients with AS are damaged in a significant way, and physical domain is more impaired than mental and social ones. The SF-36 and the health profile of the EuroQol may be used as generic instruments to measure HRQOL; they have similar performance assessing HRQOL of AS patients. The Spanish BASFI is a valid, reliable, and feasible instrument. Longitudinal studies are required to identify factors associated with physical function and HRQOL.

REFERENCES

1. Van der Heijde D, van der Linden S, Bellamy N, Calin C, Dougados M, Khan MA. Which domains should be included in a core set for endpoints in ankylosing spondylitis: introduction to the ankylosing spondylitis module of OMERACT IV. *J Rheumatol* 1999;26:945-7.
2. Van der Heijde D, Calin A, Dougados M, Khan MA, van der Linden S, Bellamy N on behalf of the ASAS Working Group. Selection of instruments in the core set for DC-ART, SMARD, physical therapy, and clinical record keeping in ankylosing spondylitis: progress report of the ASAS Working Group. *J Rheumatol* 1999;26:951-4.
3. Calin A, Garrett S, Whitelock H, Kennedy LG, O'Hea J, Mallorie P, et al. A new approach to defining functional ability in ankylosing spondylitis: the development of the Bath Ankylosing Spondylitis Functional Index. *J Rheumatol* 1994;21:2281-5.
4. Dougados M, Gueguen A, Nakache JP, Nguyen M, Mery C, Amor B. Evaluation of a functional index and an articular index in ankylosing spondylitis. *J Rheumatol* 1988;15:302-7.
5. Brandt J, Haibel H, Cornely D, Golder W, Gonzalez J, Reddig J, et al. Successful treatment of active ankylosing spondylitis with the anti tumor necrosis factor alpha monoclonal antibody infliximab. *Arthritis Rheum* 2000;43:1346-52.
6. Maksymowych WP, Jhangry GS, Leclercq S, Skeith K, Yan A, Russell A. An open study of pamidronate in the treatment of refractory ankylosing spondylitis. *J Rheumatol* 1998;25:714-7.
7. Jones SD, Koh WH, Steiner A, Garrett SL, Calin A. Fatigue in ankylosing spondylitis: its prevalence and relationships with activity, sleep, and other factors. *J Rheumatol* 1996;23:487-90.
8. Koh WH, Paude I, Samuels A, Jones SD, Calin A. Low dose amitriptyline in ankylosing spondylitis: a short term, double blind, placebo controlled study. *J Rheumatol* 1997;24:2158-61.
9. Moncur C, Cannon GW, Shaw M, Willardson D, Clegg DO. Inter-observer reliability of the Spondylitis Functional Index instruments for assessing spondylarthropathies. *Arthritis Care Res* 1996;9:182-8.
10. Calin A, Nakache J-P, Gueguer A, Zeidler H, Mielants H, Dougados M. Outcome variables in ankylosing spondylitis: evaluation of their relevance and discriminant capacity. *J Rheumatol* 1999;26:975-9.
11. Jones SD, Steiner A, Garrett SL, Calin A. The Bath Ankylosing Spondylitis Patient Global Score. *Br J Rheumatol* 1996;35:66-71.
12. Averns HL, Oxtoby J, Taylor HG, Jones PW, Dziedzic K, Dawes PT. Smoking and outcome in ankylosing spondylitis. *Scand J Rheumatol* 1996;25:138-42.
13. Van der Heijde D, Bellamy N, Calin A, Dougados M, Khan MA, van der Linden S on behalf of the Assessment in Ankylosing Spondylitis Working Group. Preliminary core set for endpoints in ankylosing spondylitis. *J Rheumatol* 1997;24:2225-9.
14. Ward MM. Health-related quality of life in ankylosing spondylitis: a survey of 175 patients. *Arthritis Care Res* 1999;12:247-55.
15. Ringsdal VS, Helin P. Ankylosing spondylitis-education, employment and invalidity. *Dan Med Bull* 1991;38:282-4.
16. Van der Linden SM, Valkenburg HA, Cats A. Evaluation of diagnostic criteria for ankylosing spondylitis: a proposal for modification of the New York criteria. *Arthritis Rheum* 1984;27:361-8.
17. Garrett S, Jenkinson T, Kennedy LG, Whitelock H, Gaisford P, Calin A. A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Spondylitis Disease Activity Index. *J Rheumatol* 1994;21:2286-91.
18. Jenkinson TR, Mallorie PA, Whitelock HC, Kennedy LG, Garrett SL, Calin A. Defining spinal mobility in ankylosing spondylitis (AS): the Bath AS Metrology Index. *J Rheumatol* 1994;21:1694-8.
19. Jones SD, Porter J, Garrett SL, Kennedy LG, Whitelock H, Calin A. A new scoring system for the Bath Ankylosing Spondylitis Metrology Index (BASMI) [letter]. *J Rheumatol* 1995;22:1609.
20. Alonso J, Prieto L, Antó JM. La versión española del SF-36 Health Survey (cuestionario de salud SF-36): un instrumento para la medida de los resultados clínicos. *Med Clin (Barc)* 1995;104:771-6.
21. Badía X, Roset M, Montserrat S, Herdman M, Segura A. The Spanish version of EuroQol: a description and its applications: European Quality of Life scales. *Med Clin (Barc)* 1999;112 Suppl 1:79-85.
22. Band DA, Jones SD, Kennedy LG, Garrett SL, Porter J, Gay L, et al. Which patients with ankylosing spondylitis derive most benefit from an inpatient management program? *J Rheumatol* 1997;24:2381-4.
23. Jones SD, Calin A, Steiner A. An update of the Bath Ankylos-

ing Spondylitis Activity and Functional indices (BASDAI, BASFI): excellent Cronbach's alpha scores [letter]. *J Rheumatol* 1996;23:407.

APPENDIX A: SPANISH VERSION OF THE BATH ANKYLOSING SPONDYLITIS FUNCTION INDEX

VERSION ESPANOLA DEL CUESTIONARIO BASFI PARA ESPONDILITIS ANQUILOSANTE.

A continuación se le indican una serie de actividades. Por favor, marque una raya vertical en la línea situada debajo de cada actividad, de acuerdo con su situación EN LA ULTIMA SEMANA. Tenga en cuenta que mientras más a la izquierda significa que se ha sentido MEJOR y que le ha sido más FACIL realizar esa actividad; mientras más a la derecha quiere decir que se ha encontrado PEOR y que le ha resultado más DIFICIL o, incluso, IMPOSIBLE realizar dicha actividad.

1. Ponerse los calcetines o medias sin ayuda.
FACIL _____ IMPOSIBLE
2. Recoger un bolígrafo del suelo sin ayuda, inclinándose hacia adelante (doblando la cintura).
FACIL _____ IMPOSIBLE
3. Coger de una estantería un objeto situado por encima de su cabeza, sin ayuda.
FACIL _____ IMPOSIBLE
4. Levantarse de una silla sin apoyar las manos ni utilizar ninguna otra ayuda.
FACIL _____ IMPOSIBLE
5. Estando acostado sobre la espalda, levantarse del suelo sin ayuda.
FACIL _____ IMPOSIBLE
6. Estar a pie firme sin apoyarse en nada durante 10 minutos y no tener molestias.
FACIL _____ IMPOSIBLE
7. Subir 12 ó 15 escalones sin agarrarse al pasamanos ni usar bastón o muletas (poniendo un pie en cada escalón).
FACIL _____ IMPOSIBLE
8. Mirarse un hombro girando sólo el cuello (sin girar el cuerpo).
FACIL _____ IMPOSIBLE
9. Realizar actividades que supongan un esfuerzo físico como ejercicios de rehabilitación, trabajos de jardinería o deportes.
FACIL _____ IMPOSIBLE
10. Realizar actividades que requieran dedicación plena durante todo el día (en casa o en el trabajo).
FACIL _____ IMPOSIBLE