

Assessment of Functional Disability and Quality of Life in Patients with Ankylosing Spondylitis

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SUMMARY

Introduction Ankylosing spondylitis is a chronic progressive autoimmune inflammatory disorder involving mainly the axial skeleton and larger peripheral joints that progressively limits spinal mobility and may lead to irreversible structural changes and consequently to impaired physical function and reduced quality of life.

Objective The aim of this study was to assess functional disability and quality of life of patients with ankylosing spondylitis and determine the correlation between functional disability and quality of life.

Methods The study enrolled 74 patients with ankylosing spondylitis (16 females and 58 males). The demographic data of the patients were collected. Functional disability was assessed with the Bath Ankylosing Functional Index (BASFI). Quality of life was assessed by the Short-Form 36 (SF-36) and the European Quality of Life Questionnaire (EuroQoL/EQ-5D).

Results In our study, the mean age was 48.5±10.3 years. BASFI was negatively correlated with the SF-36 physical function subscale ($p<0.001$), physical role ($p=0.002$), bodily pain ($p=0.003$), general health ($p<0.001$), vitality ($p=0.012$) and mental health ($p=0.010$) subscale. There was a significantly inverse correlation between the BASFI score and the rating scale of EQ-5D ($p=0.001$). In the regression model, the BASFI score ($p=0.000$) showed an independent association with the physical function domain of SF-36.

Conclusion In conclusion, the BASFI index was associated with physical function, physical role, bodily pain, general health, vitality and mental health domains of SF-36 and also with the rating scale of EQ-5D.

Key words: ankylosing spondylitis; BASFI; quality of life; correlation

INTRODUCTION

Ankylosing spondylitis (AS) is a chronic progressive autoimmune inflammatory disorder involving mainly the axial skeleton and the larger peripheral joints that progressively limits spinal mobility and may lead to irreversible structural changes and consequently to impaired physical function and reduced quality of life (QoL) [1, 2, 3]. Functional disability is a very important component of the patient's perception of the disease and can be determined by patient-focused self-administered instruments that have been previously widely used [4, 5, 6].

Functional disability and overall health-related quality of life (HRQoL) measures have become an essential part of the overall assessment of patients with AS. QoL has been determined as the perception of the individual of his or her situation in the current culture and value system. While health situation and functional status are predominantly related to the physical condition, the term "quality of life" includes wishes, expectations and emotional responses of the individual related to his or her health [7]. The Medical Outcomes Short Form-36 questionnaire (SF-36) is a generic HRQoL instrument that has been a commonly used scale for different rheumatic diseases [8, 9, 10]. Another generic instrument, the European Quality of Life Questionnaire (EuroQoL/EQ-5D), has also been widely used in evaluative QoL studies [10, 11]. To our knowledge, there are only a few studies focused on the correlation between physical function and HRQoL of patients with AS [10, 12, 13].

OBJECTIVE

The aim of this study was to assess functional disability and the QoL of patients suffering from AS and determine the relationship between the physical function and measures of clinical condition including QoL.

METHODS

This study was carried out at the Institute of Physical Medicine, Rehabilitation and Rheumatology Igalo, Montenegro, between May 2005 and October 2007. Seventy-four adult patients diagnosed with AS were included in the study. The New York criteria for AS were applied and only patients with definite x-ray changes in the sacroiliac joints were accepted as definite AS [14]. Only patients who completed all questions in the scales, indices, questionnaires and mobility testing were included in this study. Patients with another inflammatory rheumatic disease including juvenile-onset AS were excluded. The Medical Ethics Committee of the University of Belgrade approved the study and written informed consent was obtained prior to testing from all patients.

The following data were collected: age, gender, duration of the disease, duration of symptoms, presence of HLA-B27 allele, education level, employment status, smoking status and duration of morning stiffness (min). The laboratory variable, erythrocyte sedimentation rate (ESR), was determined using the standard Westergren method (normal range 0-20).

Functional disability was assessed by Bath Ankylosing Spondylitis Functional Index (BASFI). After pain and stiffness, one of the most important complaints of patients with AS is functional disability [15]. The BASFI is a set of ten questions designed to determine the degree of functional limitation. The first eight questions consider activities related to functional anatomy. The final two questions reflect the patient's ability to cope with daily activities. A 10cm VAS is used to answer the questions. The mean score of the ten scales gives the BASFI score – a value between 0 and 10 (0 = the best, 10 = the worst score). The BASFI is also quick and easy to apply – it takes maximum 100 seconds to complete this index [4, 15, 16].

We also assessed global pain level, fatigue and global patient assessment was made on a separate VAS (range 0-10).

Health-related quality of life was estimated by two generic instruments: the Medical Outcomes Short-Form 36 questionnaire (SF-36) and the European Quality of Life Questionnaire (EuroQoL/EQ-5D).

The SF-36 is a generic instrument that is considered as a “golden standard” for quality of life of patients suffering from various conditions. The items of the SF-36 are grouped into eight subscales: physical functioning (10 items), role limitation due to physical problems (4 items), role limitation due to emotional problems (3 items), bodily pain (2 items), social functioning (2 items), mental health (5 items), vitality (4 items), and general health perception (5 items). The response choices in the role-functioning scales (physical and emotional) are dichotomous (yes/no). The other items have three to six response choices. The raw scores were coded and recalibrated following the standard guidelines, and the items were then summed up and transformed into the eight 0-100 scales (0 – the worst health, 100 – the best health). The SF-36 takes approximately 10 minutes to complete [17-20].

The EQ-5D is a generic measure of health-related QoL designed to be used in evaluative studies in all patients, and is a widely used scale for different rheumatic diseases [10, 11, 21]. It is considered the simplest form for use in clinical research. It assesses QoL in 5 dimensions: mobility, self-care, usual activity, pain/discomfort and anxiety/depression. These 5 dimensions produce one summary score: a health profile (range from 0 – the worst to 2 – the best QoL). The EQ-5D also includes overall assessment of patients' perception of their health state, named “rating scale”. Patients are asked to place a horizontal line across the point on a 100-point graphic rating scale that corresponds to their current health state and the score is read directly from the scale (range from 0 = the worst to 100 = the best QoL) [20, 22].

Statistical analysis

All data management and statistical analyses were performed using the Statistical Package for Social Sciences, version 15.0 (SPSS Inc, Chicago, IL, USA). Data are presented, for continuous variables, as means and standard deviations and for categorical variables, as frequencies and percentages. Student's t-test was used for comparison of contin-

Table 1. Summary of SF-36 and EuroQoL/EQ-5D questionnaires

Questionnaires		Mean	SD	Min-max	Median
SF-36	Physical function	64.39	16.65	10-95	65
	Physical role	34.46	28.28	0-100	25
	Bodily pain	38.30	15.11	0-74	41
	General health	42.73	18.15	0-87	45
	Vitality	40.40	17.90	0-80	40
	Social function	57.60	18.94	0-100	50
	Emotional role	56.76	36.91	0-100	66.7
	Mental health	66.22	15.17	16-92	70
EuroQoL/EQ-5D	Health profile	0.69	0.16	0.17-0.83	0.77
	Rating scale	54.81	17.13	10-90	51

uous variables. To assess correlations between continuous variables, Pearson's correlation coefficients were calculated. A multivariate linear regression analysis was performed to analyse the relationship between clinical variables and QoL. All statistical tests were two-sided, with $p=0.05$.

RESULTS

The study enrolled 74 patients with AS (16 females and 58 males). Demographic and clinical characteristics of the study population were collected. The mean age was 48.5 ± 10.3 years, 45% of patients were older than 50 years, and only 3% of patients were younger than 30 years. The mean disease duration was 15.2 ± 8.8 years, and the mean symptoms duration was 24.1 ± 9.3 years. Forty-nine (66%) patients were unemployed and twenty-one (28%) were with a tertiary education level. Twenty-four (32%) patients were active smokers. Ninety-four percent (66 patients) had a positive HLA-B27 allele. Mean erythrocyte sedimentation level was 22.3 ± 14.2 (range 2-57).

Mean value of the BASFI score was 3.9 ± 1.7 (range 0.7-9.8) indicating moderate functional impairment. Mean morning stiffness duration was 61.6 ± 53.0 minutes (range 0-360 minutes). Mean global pain level was 5.0 ± 1.9 (range 0.8-10), fatigue was 4.8 ± 2.1 (range 0.3-9) and global patient assessment 5.3 ± 1.9 (range 0.3-9.6).

Mean scores for the SF-36 and EuroQoL/EQ-5D domains are presented in Table 1. The most affected domains of the SF-36 in AS patients were physical role (34.46 ± 28.28) and bodily pain (38.30 ± 15.11).

Correlations between demographic/clinical parameters and physical function

The BASFI was most significantly correlated with fatigue ($p < 0.001$) and global patient assessment ($p < 0.001$). All other demographic and clinical data also correlated with the BASFI index (Table 2). No significant differences were

Table 2. Correlations between functional disability and demographic/clinical data

Parameter	BASFI	
	r	p
Age	0.291*	0.012
Disease duration	0.275*	0.006
Symptom duration	0.316*	0.006
ESR	0.230*	0.048
Morning stiffness	0.362*	0.001
Pain	0.323*	0.005
Fatigue	0.415*	<0.001
Global patient assessment	0.514*	<0.001

* statistically significant
r – Pearson's correlation coefficient

found between female and male patients with respect to physical function and all QoL scores in both questionnaires ($p>0.05$). The same was found between education level groups ($p>0.05$) (results not shown).

Correlations between Quality of Life and physical function

There were significantly inverse correlations between the BASFI and six domains of the SF-36: physical function ($p<0.001$), physical role ($p=0.002$), bodily pain ($p=0.003$), general health ($p<0.001$), vitality ($p=0.012$) and mental health ($p=0.010$) (Table 3). The BASFI was not significantly related to social function and emotional role.

There was a significantly inverse correlation between the BASFI score and the rating scale of the EuroQol/EQ-5D ($p=0.001$) (Table 4).

The first regression model was developed to identify variables associated with the PF domain of the SF-36. Only the BASFI score ($p=0.000$) showed an independent association with the physical function domain of the SF-36 (Table 5).

The second regression model was developed to identify variables associated with the Health profile dimension of the EuroQol/EQ-5D. Only global patient assessment score ($p=0.026$) showed an independent association with the Health profile dimension of the EuroQol/EQ-5D (Table 6).

Table 3. Correlations between SF-36 and functional disability

SF-36	BASFI	
	r	p
Physical function	-0.595*	<0.001
Physical role	-0.352*	0.002
Bodily pain	-0.345*	0.002
General health	-0.501*	<0.001
Vitality	-0.291*	0.012
Social function	-0.213	0.069
Emotional role	-0.158	0.178
Mental health	-0.300*	0.010

* statistically significant

Table 4. Correlations between EuroQoL and functional disability

EuroQol/EQ-5D	BASFI	
	r	p
Health profile	-0.218	0.061
Rating scale	-0.386*	0.001

* statistically significant

Table 5. Multivariate regression analysis with PF domain of SF-36 as dependent variable

Parameter	β	t	p
BASFI	-4.939	4.549	0.000
Global pain	-0.416	0.382	0.704
Global patient assessment	-1.086	0.918	0.362
ESR	0.007	0.064	0.949

Table 6. Multivariate regression analysis with Health profile dimension of EQ-5D as dependent variable

Parameter	β	t	p
BASFI	-0.002	0.150	0.882
Global pain	-0.008	0.634	0.528
Global patient assessment	-0.030	2.276	0.026
ESR	0.001	0.577	0.566

Table 7. Multivariate regression analysis with Rating scale dimension of EQ-5D as dependent variable

Parameter	β	t	p
BASFI	-2.640	2.256	0.027
Global pain	-3.352	2.856	0.006
Global patient assessment	-0.395	0.310	0.758
ESR	0.140	1.129	0.263

In the third regression model developed to identify variables associated with the Rating scale dimension of the EuroQol/EQ-5D, global pain level ($p=0.006$) and the BASFI ($p=0.027$) were the factors affecting the Rating scale dimension of the EuroQol/EQ-5D (Table 7).

DISCUSSION

Ankylosing spondylitis is a chronic inflammatory disease that predominantly affects the spine, generally worsens with age and longer disease duration and leads to serious functional impairment [23]. In this study, we are reporting the results of a descriptive analysis of patients suffering from AS from Montenegro. We explored correlations between functional disability and QoL. The BASFI index was used to assess functional disability because it is quick, easy to use, reliable and sensitive to change across the whole disease spectrum [4,15]. The BASFI has shown better comparative responsiveness than other functional indices widely used in AS: the Dougados Functional Index (DFI) and the ankylosing spondylitis-specific version of the Health Assessment Questionnaire (HAQ-S) [4].

There are different generic and disease specific instruments which are available in measuring health-related quality of life. Therefore, we assessed health-related quality of life using two generic instruments: the SF-36 and the EuroQol/EQ-5D. The EQ-5D has become an increasingly popular measure of health status. Its attractions include its simplicity and length, which makes it quick and easy to complete, and its potential for its use as a utility measure in economic analyses. For these reasons, it is widely used in clinical trials of treatment interventions. Its brevity means that, on its own, it would probably not provide adequate assessment of quality of life in a study where QoL is a major outcome, but it can be, and often is, used alongside more detailed QoL questionnaires like the SF-36 that we used

in this study. Although some users in rheumatic disease have found the EQ-5D valid and responsive, others have been critical of its inability to discriminate patients with moderate morbidity, the restricted distribution of scores and differences between patient and societal utility tariffs [20]. We also used the SF-36 questionnaire, which is the most widely used health status measure for musculoskeletal disorders worldwide. In some studies, responsiveness of the SF-36 was superior to other health status measures (e.g., the SF-36 identifies minor impacts on health status that cannot be identified using the Nottingham Health Profile). It provides a comprehensive measure of clinical outcome and is one of the few tools that takes into account both physical and psychological aspects of health [17-20].

Physical function has been identified as the main outcome domain in AS, and it deteriorates due to the disease activity and damage of axial and peripheral joints [3]. Functional disability generally worsens with age and longer disease duration [13, 24]. This study confirms the existence of such relationship between physical function and age, disease duration or symptom duration.

Our results show that the BASFI correlated with all four physical dimensions of the SF-36. Physical function and general health had the strongest correlations with the BASFI. In a lower degree of significance, the BASFI correlated with the vitality and mental health domain of the SF-36. Similarly, a significant relationship between physical function and QoL was reported previously [10, 13, 24]. Ariza-Ariza R et al. showed the regression model in which the BASFI, pain and physician global assessment were independently associated with the SF-36 [10]. Recent

studies indicate that AS affects mostly physical domains of QoL [10, 12].

The results of the multiple regression analysis confirm these findings; we found that the BASFI was the only significant independently associated factor with the physical function domain of the SF-36.

The results of the multiple regression analysis showed that the global assessment patient score (VAS) was the only one significantly associated factor with the Health profile EuroQol/EQ-5D dimension.

The results of the third multiple regression analysis showed that global pain score (VAS) and the BASFI score were the factors significantly associated with the Rating scale EuroQol/EQ-5D dimension.

Further prospective longitudinal studies are needed to establish the definitive relationship between functional disability and quality of life in ankylosing spondylitis.

CONCLUSION

In conclusion, this study showed that the BASFI index was associated with all four physical domains (physical function, physical role, bodily pain, general health) and with two mental domains (vitality and mental health) of the SF-36. The BASFI was also associated with the rating scale of EuroQol/EQ-5D. Recognizing complicated relationships between clinical measures and QoL in patients with AS can help us to develop further management strategies to reduce progressive loss of physical function and to improve their quality of life.

REFERENCES

- Ahn MS. Clinical features of ankylosing spondylitis. In: Hochberg MC, Silman AJ, Smolen J, Weinblatt ME, Weisman MH, editors. *Rheumatology*. Philadelphia: Elsevier; 2003. p.1161-1181.
- Dougados M. Diagnostic features of ankylosing spondylitis. *Br J Rheumatol*. 1995; 34:301-3.
- Van der Heijde DMFM, Bellamy N, Calin A, Dougados M, Khan MA, van der Linden S. On behalf of the assessment in ankylosing spondylitis working group. Preliminary core sets for end points in ankylosing spondylitis. *J Rheumatol*. 1997; 24:2225-9.
- Ruof J, Stucki G. Comparison of Dougados functional index and Bath ankylosing spondylitis functional index. A literature review. *J Rheumatol*. 1999; 26:955-60.
- 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.
- Hidding A, van Santen M, De Klerk E, Gielen X, Boers M, Geenen R, et al. Comparison between self-report measures and clinical observations of functional disability in ankylosing spondylitis, rheumatoid arthritis and fibromyalgia. *J Rheumatol*. 1994; 21(5):818-23.
- The WHOQOL Group. What quality of life? World Health Organization Quality of Life Assessment. *World Health Forum*. 1996; 17:354-5.
- Ozgul A, Peker F, Taskaynatan MA, Tan AK, Dincer K, Kalyon TA. Effect of ankylosing spondylitis on health-related quality of life and different aspects of social life in young patients. *Clin Rheumatol*. 2006; 25:168-74.
- Husted JA, Gladman DD, Farewell VT, Long JA, Cook RJ. Validating the SF-36 Health Survey Questionnaire in patients with psoriatic arthritis. *J Rheumatol*. 1997; 24(3):511-7.
- Ariza-Ariza R, Hernandez-Cruz B, Navarro-Sarabia F. Physical function and health-related quality of life of Spanish patients with ankylosing spondylitis. *Arthritis Care Res*. 2003; 49(4):483-7.
- Wolfe F, Hawley DJ. Measurement of the quality of life in rheumatic disorders using the EuroQol. *Br J Rheumatol*. 1997; 36:786-93.
- Turan Y, Duruoz MT, Cerrahoglu L. Quality of life in patients with ankylosing spondylitis: a pilot study. *Rheumatol Int*. 2007; 27:895-9.
- Bostan EE, Borman P, Bodur H, Barça N. Functional disability and quality of life in patients with ankylosing spondylitis. *Rheumatol Int*. 2003; 23:121-6.
- Van Der Linden S, 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.
- Calin A, Garrett SL, Whitelock HC, 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 (BASFI). *J Rheumatol*. 1994; 21:2281-5.
- Moncur C. Ankylosing spondylitis measures. *Art Rheum (Art Care Res)*. 2003; 49(5S):S197-209.
- Ware JR, Sherbourne C. The MOS-36 item short form health survey 1: conceptual framework and item selection. *Med Care*. 1992; 30:473-83.
- Medical Outcomes Trust editors. *How to Score the SF-36 Health Survey (SF-36)*. Boston: Medical Outcomes Trust; 1994.
- Gyatt GH, Feeney DH, Patric DL. Measuring health-related quality of life. *Ann Intern Med*. 1993; 118:622-9.
- Carr A. Adult measures of quality of life. *Art Rheum (Art Care Res)*. 2003; 49(5S):S113-33.
- Brazier JE, Harper R, Munro J, Walters SJ, Snaith ML. Generic and condition-specific outcome measures for people with osteoarthritis of the knee. *Rheumatology*. 1999; 38:870-7.
- EuroQol Group. EuroQol: a new facility for the measurement of health-related quality of life. *Health Policy*. 1990; 16:199-208.
- Khan MA. Ankylosing spondylitis: introductory comments on its diagnosis and treatment. *Ann Rheum Dis*. 2003; 61(Suppl III):3-7.
- Martindale J, Smith J, Sutton CJ, Greenan D, Goodacre L, Goodacre JA. Disease and psychological status in ankylosing spondylitis. *Rheumatology*. 2006; 45(10):1288-93.

Процена функционалне способности и квалитета живота особа оболелих од анкилозирајућег спондилитиса

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КРАТАК САДРЖАЈ

Увод Анкилозирајући спондилитис је хронично, прогресивно, аутоимуно, запаљењско обољење које захвата углавном аксијални скелет и велике периферне зглобове, доводећи временом до све већег губитка покретљивости кичменог стуба и иреверзibilних структурних промена, те последично до лошијег физичког функционисања и смањења квалитета живота у целини.

Циљ рада Циљ рада је био да се процене функционална способност и квалитет живота особа оболелих од анкилозирајућег спондилитиса, те испита повезаност између функционалне способности и квалитета живота ових болесника.

Методе рада Истраживање је обухватило 74 особе с анкилозирајућим спондилитисом (58 мушкараца и 16 жена). Функционална способност је испитивана помоћу специфичног индекса за процену функционалног стања особа оболелих од анкилозирајућег спондилитиса (*Bath Ankylosing Spondylitis Functional Index – BASFI*), а квалитет живота процењиван је помоћу општег кратког упитника америчких аутора (*Short-Form 36 Item Questionnaire – SF-36*) и европског упитника за процену квалитета жи-

вота (*European Quality of Life Questionnaire – EuroQoL/EQ-5D*).

Резултати Испитаници, од којих су прикупљени општи демографски подаци, у просеку су били стари 48,5 година. *BASFI* је негативно корелирао с упитником *SF-36* у областима физичког функционисања ($p < 0,001$), физичке улоге ($p = 0,002$), нивоа телесног бола ($p = 0,003$), општег здравственог стања ($p < 0,001$), виталности ($p = 0,012$) и у области менталног здравља ($p = 0,010$). Забележена је негативна корелација између вредности *BASFI* и скале процене упитника *EQ-5D* ($p = 0,001$). У регресионом моделу вредности *BASFI* су биле значајан независан предиктор физичког функционисања упитника *SF-36* ($p = 0,000$).

Закључак Истраживање је показало да су вредности *BASFI* повезане с квалитетом живота болесника у упитнику *SF-36* у областима физичког функционисања, физичке улоге, телесног бола, општег здравственог стања, виталности и менталног здравља, као и са квалитетом живота у упитнику *EQ-5D* у области скале процене.

Кључне речи: анкилозирајући спондилитис; *BASFI*; квалитет живота; корелације