

Cross-cultural adaptation and validation of the Brazilian-Portuguese version of the Bath Ankylosing Spondylitis Functional Index (BASFI)

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ABSTRACT

Objective: To conduct a cross-cultural adaptation of the Bath Ankylosing Spondylitis Functional Index (BASFI) into Brazilian-Portuguese language and to assess its measurement properties. **Methods:** The BASFI was translated by four rheumatologists and three English teachers. The translated questionnaire was applied to ankylosing spondylitis patients by trained observers, and self-administered in three moments: days 1, 2, and 14. The validity was assessed analyzing the association of BASFI and functional capacity measures (cervical rotation, intermalleolar distance, Schober's test and occiput-to-wall distance). The internal consistence was tested by Cronbach's α coefficient and the reliability by test-retest (intraclass correlation coefficient – ICC). **Results:** A total of 60 patients with ankylosing spondylitis was included: 85% male, mean age 47 ± 12 years, and mean disease duration 20 ± 11 years. The intra-observer test-retest (two-week interval) reliability showed a high ICC (0.999, 95% CI: 0.997–0.999) and a high internal consistency (Cronbach's α coefficient: 0.86, CI 95%: 0.80–0.90). Considering the validity, the BASFI indices were correlated with cervical rotation (0.53, $P < 0.001$) and with intermalleolar distance (0.50, $P < 0.001$). **Conclusion:** The BASFI Brazilian-Portuguese version is reliable and valid for assessment of patients with ankylosing spondylitis.

Keywords: ankylosing spondylitis, translation, questionnaires, BASFI, health status.

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INTRODUCTION

Ankylosing spondylitis (AS) is a chronic rheumatic disease with a worldwide prevalence of up to 0.9%.¹ Men are more commonly affected than women, similar to other spondyloarthritis HLA-B27-positive related diseases.² The sacroiliac joints are affected and, to a varying degree, the spinal column, while peripheral joints may be involved, specially in the lower limbs. Patients commonly experience pain, morning stiffness and disability, generally increasing with long standing disease.³

There is no single “gold standard” management and prognostic factors for AS because of its heterogeneous nature,

long standing characteristic and, until recently, lack of appropriate, validated outcome measures.⁴ As consequence, the optimal quantitative measures to monitor status and to assess long-term prognosis are often derived from patient self-report questionnaires. This has resulted in significant increase in the availability of patient-assessed health instruments which aim to measure aspects of health from the perspective of the patient. These instruments usually contain multiple items or questions to reflect the broad nature of health status, disease, or injury.^{5,6}

In fact, an interesting systematic literature review (1988–2004) have been done to retrieve references related to the development and evaluation of multi-item

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patient-assessed health instruments (12 AS-specific and three arthritis-specific). Among the instruments evaluated, both The Bath Ankylosing Spondylitis Functional Index (BASFI) and Dougados Functional Index (DFI) demonstrated acceptable levels of reliability with good evidence for construct validity and similar levels of responsiveness following drug therapy evaluation. The BASFI is an AS specific functional index, worldwide accepted, has shown better content validity, and it is more responsive following physical therapy.⁷

Recently, the Assessment in Ankylosing Spondylitis Group (ASAS) have recommended several domains for the evaluation of patients with AS in both clinical research and routine practice, which include the analysis of functional disability, spinal stiffness, and pain.⁸ In this regard, patient-assessed instruments with measurement properties to support their role in evaluation should be identified to fulfill these domains.⁹

Therefore, with increasing numbers of multinational and multicultural research projects, the need to adapt health status measures for use in other than the source language has also grown rapidly. Because there was no Brazilian-Portuguese version of this instrument to assess AS functional ability, we decided to translate and culturally adapt the BASFI, based on its strong measurement properties, described in the literature. Thus, in order to develop a Brazilian-Portuguese version of the BASFI, the aim of the present study was to do a cross-cultural adaptation of the BASFI into Brazilian-Portuguese and to validate it in AS patients, following the international guidelines.¹⁰ The BASFI satisfies the criteria required for a functional index because it is quick and easy to complete, reliable, and sensitive to change across the whole spectrum of disease. The validity and reliability of the original BASFI English version, as well as other language's versions, has been demonstrated.^{11–15} In addition, the BASFI questionnaire has been approved by OMERACT IV filter for use as functional index in spondyloarthritis.¹⁶

PATIENTS AND METHODS

Sixty patients were consecutively selected from the Rheumatology Division of the Universidade de São Paulo during a period of six months. The inclusions are based on the diagnosis of AS accordingly to the New York criteria.¹⁷ All patients had to be able to answer the questionnaires and an informed consent was obtained from all participants. Patients who were attending any rehabilitation intervention/program were excluded.

BASFI

This self-assessment instrument was designed by a team of medical professionals and patients and consists of eight specific questions regarding physical function in AS and two questions reflecting the patient's ability to cope with everyday life.¹⁸ Each question is answered on a 10 cm horizontal Visual Analogue Scale, scoring from 0–10. The questionnaire is easily understood and can be self-administered or applied by an interviewer. All results are the arithmetic sum of the answers, considering that 0 is no disability and 10 is the maximum disability. The BASFI satisfies the criteria required for a functional index and it is brief and easy to be completed, reliable, and sensitive to change across the whole spectrum of disease.¹⁸

Translation process

The translation of the BASFI was done into three steps. First, four rheumatologists fluent in English and one English teacher translated the original BASFI (English version) into Brazilian-Portuguese (T1). Secondly, this version (T1) was back-translated into English by a second English teacher (blinded about the disease and from the objectives of the study) (BT1). Afterwards, a third English teacher translated the BT1 into Brazilian-Portuguese (T2). Finally, the committee, composed by the rheumatologists and English teachers involved in the translation process, consensually defined the final version (T12).

This study was approved by the Ethics Committee of the Hospital de Clínicas, Medical School, Universidade de São Paulo and the author of BASFI have formally allowed and authorized its translation into Brazilian-Portuguese language and to culturally adapt it.

BASFI application

On day 1 (D1) all patients who fulfilled the inclusion criteria had their physical parameters taken by a trained physical therapist (PT). The measures evaluated were: cervical rotation (CR) (goniometer), intermalleolar distance (IMD) (cm), Schober test (ST) and occiput-to-wall distance (OWD) (cm). Afterwards, all patients were interviewed by the first observer (O1) to fill out the questionnaire (BASFI). All patients were interviewed by a second observer (O2) in the same day (D1), to assess the inter-observer test-retest reliability. On day 2 (D2) all patients filled the BASFI at home (self-administered) and were instructed not to change their daily activities and to answer the questionnaires in the morning period. On the fourteenth day (D14) all patients were interviewed again by the same first observer (O1) to fill the BASFI questionnaire and were blinded from their previous answers (D1).

Statistical analysis

All data was given as measures of central tendency and dispersion. Reliability (intra-, inter-observer and observer X self-administered) were analyzed by the intraclass correlation coefficient (ICC) and the internal consistency was tested by the Cronbach's α coefficient. Multiple linear regressions were applied for evaluation of the construct validity between BASFI indices and physical measures (CR, IMD, ST, OWD). A $P < 0.05$ was considered statistically significant.

RESULTS

A total of 60 AS patients participated in the study. Eighty five percent were men, mean age of 47 ± 12 years and mean disease duration of 20 ± 11 years. Educational level was divided according to years at school and more than a half of the patients studied less than five years (56.7% < 5 years, 21.7% from 5–9 years, 13.3% from 9–12 years and only 8.3% > 12 years).

Mean total score of BASFI obtained in this group was 4.45 ± 2.43 . For validity, the BASFI indices were correlated to CR (mean 29.3 ± 20.6 grade, 0.53, $P < 0.001$ /exponential), IMD (mean 61.9 ± 25.3 cm, 0.50, $P < 0.001$ /cubic). The BASFI indices were not significantly correlated to the ST (mean 2.9 ± 2.97 cm, 0.85, $P = 0.51$) and OWD (mean 8.2 ± 6.93 cm, 0.22, $P = 0.09$).

Multiple regression was applied to assess the influence of the variables age, disease duration and education level in the BASFI indices. There was no statistical significant influence of those variables in the BASFI indices (data not shown).

The inter-observer reliability (ICC) was 0.95, 95% CI: 0.91–0.97. In the observer X self-administered reliability (ICC) the result was 0.96, 95% CI: 0.93–0.96 while in the intra-observer reliability (ICC) the figure was 0.999, 95% CI: 0.997–0.999. The internal consistency (Cronbach's α) was 0.86, 95% CI: 0.80–0.90.

DISCUSSION

At literature we have found some physical and cultural characteristics in AS patients around the world. Much of results differ between countries. Our results suggest that the self-administered Brazilian BASFI can be a useful alternative either in further studies or in clinical practice.

In our study, mean BASFI results were similar to a Spanish study (4.3 ± 2.4) and one from United Kingdom (5 ± 2.6).^{11,19} The clinical characteristics of our patients and disease

severity were similar. Our patients have longer disease than Spanish group (11 ± 7.8) and also the United Kingdom group (9.9 ± 9.8).

In contrast of two recent Turkish studies, our patients were older with more disease duration and worse BASFI results compared to their data.^{20,21} Furthermore, in our study the BASFI results had no correlation with age. This is in line with Turkish and Finnish studies. In the Finnish study only DFI showed correlation with age.^{13,15} However, the BASFI Chinese version showed weak correlations both with age and disease duration.²² In fact, it is possible that not only age but other variables combined result in disease severity and functional disability so that, as a consequence, a patient could be older but with less severe disease, while a younger patient could have more severe disease.

The reliability (ICC) of the present study was very good considering both the intra-observer (D1 X D14) and observer vs. self-administered approach (D1 X D2) (0.99 and 0.96, respectively). The inter-observer reliability (at the same day) also showed good results (0.95, 95% CI: 0.91–0.97). The same trend was found in one study whose BASFI test-retest Spearman's rank correlation coefficient was 0.91 ($P < 0.0001$) for the global BASFI score.¹¹ These results are also in line with another study that applied the BASFI (self-administered approach in D1 and D2) and their results showed also an excellent reliability (ICC = 0.99).¹⁵ In addition, the test-retest reliability of BASFI was good, with a high intraclass correlation coefficient between the two time points (24 hours interval, ICC = 0.93).¹³ In opposite direction, a Mexican-Spanish version found worse results than the studies described above. There was an acceptable 24-hour test-retest (ICC = 0.68).¹⁴ The internal consistency (Cronbach's $\alpha = 0.86$) in the present study was similar to other international studies.^{7,11,22,23}

Most cross-cultural studies showed good BASFI validity, comparing its indices with clinical measurements but with differences in correlation. In the literature two studies found that the BASFI showed a negative correlation with Schober's test of -0.444 ,^{21,24} one of them with significant correlation of -0.31 .²² In the present study we found no statistically significant correlation between the BASFI and the Schober's test (0.85, $P = 0.518$).

BASFI showed a positive correlation with OWD^{22,24} and no correlation in another²¹ (0.33, 0.535 respectively). We found no statistically significant correlation between the BASFI with the OWD (0.22, $P = 0.095$). The selection bias could explain the lack of correlation between BASFI scores, the Schober's test and OWD in our study. The majority of patients had long term disease duration and had no significant physical limitation.

One study showed negative but weak correlation between the BASFI with the measurements of lumbar flexion ($r = -0.38$, $P = 0.001$) and cervical rotation ($r = 0.28$, $P = 0.013$).¹³ We have found significant correlations between BASFI with intermal-leolar and cervical rotation.

Some studies describe patients' difficulty in fulfilling the BASFI in a self-administered approach.²⁵ That could be related to low socioeconomic level, because it was not observed in the developed countries.^{11,15} In Yanik's study (Turkish patients), 36% of the patients' educational level was primary school and the questionnaire was well performed by the patients.¹³ In addition, Spanish patients also had no problems in understanding the questionnaire and spent a short time completing it.¹¹ Although the BASFI is a self-administered questionnaire, we also applied it by face-to-face interviews, considering the low educational level of

our sample (57% < 5 years of schooling) and our patients had no difficulties in answer our Brazilian BASFI version in both formats.

Our study had some weaknesses, including selection bias, because only patients attending our University tertiary facility were enrolled. The small sample size probably precluded the validity, considering the narrow physical functional disability of the patients. Therefore, further studies should also enroll patients from the community, considering different disease durations and disability levels.

In conclusion, the Brazilian-Portuguese version of BASFI contributes to underscore the international findings, such as feasibility, good reliability, and internal consistency.^{11,13,15} Therefore, the Brazilian-Portuguese version of BASFI can be applied in AS patients. Further studies are necessary to corroborate its measurement properties.

REFERENCES

1. Sieper J, Braun J, Rudwaleit M, Boonen A, Zink A. Ankylosing spondylitis: an overview. *Ann Rheum Dis* 2002; 61(Suppl 3): iii8–18.
2. Zink A, Braun J, Listing J, Wollenhaupt J. Disability and handicap in rheumatoid arthritis and ankylosing spondylitis – results from the German rheumatological database. German Collaborative Arthritis Centers. *J Rheumatol* 2000; 27(3):613–22.
3. Braun J, Bollow M, Remlinger G, Eggens U, Rudwaleit M, Distler A *et al.* Prevalence of spondylarthropathies in HLA-B27 positive and negative blood donors. *Arthritis Rheum* 1998; 41(1):58–67.
4. Robertson LP, Davis MJ. A longitudinal study of disease activity and functional status in a hospital cohort of patients with ankylosing spondylitis. *Rheumatology (Oxford)* 2004; 43(12):1565–8.
5. Pincus T, Sokka T. Complexities in the quantitative assessment of patients with rheumatic diseases in clinical trials and clinical care. *Clin Exp Rheumatol* 2005; 23(5 Suppl 39):S1–9.
6. Van Der Heijde D. Assessment of SpondyloArthritis International Society (ASAS). Assessment of Ankylosing Spondylitis. Patient-reported instruments (BASFI). Available from: <http://www.asas-group.org>. [Accessed on February 2nd, 2011]
7. Haywood KL, Garratt AM, Dawes PT. Patient-assessed health in ankylosing spondylitis: a structured review. *Rheumatology (Oxford)* 2005; 44(5):577–86.
8. Braun J, Van der Berg R, Baraliakos X, Boehm H, Burgos-Vargas R, Collantes-Estevez E *et al.* Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis* 2011; 70(6):896–904.
9. van der Heijde D, Bellamy N, Calin A, Dougados M, Khan MA, van der Lindsen S. Preliminary core sets for endpoints in ankylosing spondylitis. Assessments in Ankylosing Spondylitis Working Group. *J Rheumatol* 1997; 24(11):2225–9.
10. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine (Phila Pa 1976)* 2000; 25(24):3186–91.
11. Ariza-Ariza R, Hernández-Cruz B, Navarro-Sarabia F. Physical function and health-related quality of life of Spanish patients with ankylosing spondylitis. *Arthritis Rheum* 2003; 49(4):483–7.

12. Akkoc Y, Karatepe AG, Akar S, Kirazli Y, Akkoc N. A Turkish version of the Bath Ankylosing Spondylitis Disease Activity Index: reliability and validity. *Rheumatol Int* 2005; 25(4):280–4.
13. Yanik B, Gursel YK, Kutlay S, Ay S, Elhan AH. Adaptation of the Bath Ankylosing Spondylitis Functional Index to the Turkish population, its reliability and validity: functional assessment in AS. *Clin Rheumatol* 2005; 24(1):41–7.
14. Cardiel MH, Londoño JD, Gutiérrez E, Pacheco-Tena C, Vázquez-Mellado J, Burgos-Vargas R. Translation, cross-cultural adaptation, and validation of the Bath Ankylosing Spondylitis Functional Index (BASFI), the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and the Dougados Functional Index (DFI) in a Spanish speaking population with spondyloarthropathies. *Clin Exp Rheumatol* 2003; 21(4):451–8.
15. Heikkila S, Viitanen JV, Kautianen H, Kauppi M. Evaluation of the Finnish versions of the functional indices BASFI and DFI in spondylarthropathy. *Clin Rheumatol* 2000; 19(6):464–9.
16. van der Heijde D, van der Linden A, Dougados M, Bellamy N, Russell AS, Edmonds J. Ankylosing spondylitis: plenary discussion and results of voting on selection of domains and some specific instruments. *J Rheumatol* 1999; 26(4):1003–5.
17. 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(4):361–8.
18. Calin A, Garrett S, Whitelock H, Kennedy LG, Mallorie P, O’Hea J *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(12):2281–5.
19. Roussou E, Sultana S. Spondyloarthritis in women: differences in disease onset, clinical presentation, and bath Ankylosing Spondylitis Disease activity and functional indices (BASDAI and BASFI) between men and women with spondyloarthritis. *Clin Rheumatol* 2011; 30(1):121–7.
20. Bodur H, Ataman S, Rezvani A, Buğdaycı DS, Cevik R, Birtane M *et al.* Quality of life and related variables in patients with ankylosing spondylitis. *Qual Life Res* 2010; 20(4):543–9.
21. Ozdemir O. Quality of life in patients with ankylosing spondylitis: relationships with spinal mobility, disease activity and functional status. *Rheumatol Int* 2011; 31(5):605–10.
22. Wei JC, Wong RH, Huang JH, Yu CT, Chou CT, Jan MS *et al.* Evaluation of internal consistency and re-test reliability of Bath ankylosing spondylitis indices in a large cohort of adult and juvenile spondylitis patients in Taiwan. *Clin Rheumatol* 2007; 26(10):1685–91.
23. Ruof J, Sangha O, Stucki G. Evaluation of a German version of the Bath Ankylosing Spondylitis Functional Index (BASFI) and Dougados Functional Index (DFI). *Z Rheumatol* 1999; 58(4):218–25.
24. Ozer HT, Sarpel T, Gulek B, Alparslan ZN, Erken E. Turkish version of the Bath Ankylosing Spondylitis Functional Index: reliability and validity. *Clin Rheumatol* 2005; 24(2):123–8.
25. Van Tubergen A, Debats I, Ryser L, Londoño J, Burgos-Vargas R, Cardiel MH *et al.* Use of a numerical rating scale as an answer modality in ankylosing spondylitis-specific questionnaires. *Arthritis Rheum* 2002; 47(3):242–8.