ARTICLE ORIGINAL

VALIDATION OF THE TUNISIAN VERSIONS OF BATH ANKYLOSING SPONDYLITIS FUNCTIONAL INDEX (BASFI) AND DISEASE ACTIVITY INDEX (BASDAI)

Mohamed Montacer Kchir*, Wafa Hamdi*, Samir Kochbati*, Dhouha Azzouz*, Lilia Daoud*, Kaouthar Saadellaoui*, Mohamed Mehdi Ghannouchi *, Dhia Kaffel*, Abdelmajid Ben Hamida**, Béchir Zouari**

*- UR04SP06 – Department of Rheumatology- Institute M. Kassab - Manouba -Tunisia
**- Department of Epidemiology- School of Medicine- Tunis, Tunisia

M. M. Kchir, W. Hamdi, S. Kochbati, D. Azzouz, L. Daoud, K. Saadellaoui, M. M. Ghannouchi, D. Kaffel, A. Ben Hamida, B. Zouari	M. M. Kchir, W. Hamdi, S. Kochbati, D. Azzouz, L. Daoud, K. Saadellaoui, M. M. Ghannouchi, D. Kaffel, A. Ben Hamida, B. Zouari
VALIDATION DES VERSIONS DIALECTALES TUNISIENNES DU BATH ANKYLOSING SPONDYLITIS FONCTIONAL INDEX (BASFI) ET DU BATH ANKYLOSING SPONDYLITIS DISEASE ACTIVITY (BASDAI)	VALIDATION OF THE TUNISIAN VERSIONS OF BATH ANKYLOSING SPONDYLITIS FUNCTIONAL INDEX (BASFI) AND DISEASE ACTIVITY INDEX (BASDAI)

RÉSUMÉ

Objectif : Traduire et adapter au contexte culturel Tunisien un indice fonctionnel (BASFI) et un indice d'activité (BASDAI) de la spondylarthrite ankylosante (SPA) et évaluer la validité et la fiabilité de ces versions.

Méthodes : Soixante huit patients répondant aux critères de New York modifiés pour la SPA ont été inclus dans cette étude. Il s'agit de 59 hommes et de 9 femmes, leur moyenne d'age est de 37 ans (18-76), la durée moyenne d'évolution de la SPA est de 13,6 ans (0,8-40). Les questionnaires du BASFI et du BASDAI ont été traduits et adaptés conformément aux recommandations internationales puis évalués pour leur reproductibilité, leur cohérence interne et leur validité de construction interne et externe

Résultats : La reproductibilité des deux indices était excellente, le coefficient de corrélation intra classe du BASFI était de 0.96 (IC à 95% :0.93-0.97) et celui du BASDAI était de 0.93 (IC à 95% :0.90-0.97). La consistance interne des deux questionnaires était bonne (coefficient alpha de Cronbach pour le BASFI: 0.91 et pour le BASDAI: 0.90). La validité de construction interne évaluée par la matrice de corrélation a montré une bonne corrélation entre les différents items des deux indices. Une corrélation statistiquement significative a été notée entre le BASFI et le BASDAI ainsi qu'entre chacun d'entre eux avec les autres indices spécifiques de la SPA (BASG-s, BASMI, MASES, BASRI, ASQoL) et avec les huit dimensions du SF-36.

Conclusion : Les versions traduites en arabe dialectal tunisien du BASFI et du BASDAI ont de bonnes propriétés psychométriques. Elles permettront le suivi des patients tunisiens atteints de SPA.

SUMMARY

Background: The Bath Ankylosing Spondylitis Functional Index (BASFI) and the Bath Ankylosing Spondylitis Disease Activity (BASDAI) are the most commonly used instruments to evaluate respectively functioning and disease activity in ankylosing spondylitis (AS).

Objective : The aim of this study was to translate, adapt and validate these instruments into the Tunisian language.

Methods. - The studied population consisted of 68 AS patients (59 males and 9 females). Their mean age was 37.9 years (range: 18-76). The mean disease duration was 13.6 years (range: 1-40).After translation and retranslation the BASFI and BASDAI questionnaires were administrated to the patients and tested for reliability, internal consistency and construct validity.

Results : The reproducibility of the indices BASFI and BASFAI was good, the intraclass correlation coefficient for reliability was 0.96 (CCI:0.93 – 0.97) for the BASFI and 0.93 (CCI:0.90 – 0.97) for the BASDAI, and the coefficient of internal consistency (Cronbach's alpha) was 0.91 for BASFI and 0.90 for BASDAI. Concerning construct validity, both questionnaires were significantly correlated to each other, to the disease-specific instruments (BASG-s, BASMI, BASRI, ASQoL) and to all domains of the SF-36.

Conclusion: the Tunisian versions of the BASFI and the BASDAI preserve the metrological properties of the original versions and were easy to use for the assessment of disease status in ankylosing spondylitis.

MOTS-CLÉS

Spondylarthrite ankylosante - Spondylarthropathie – Indice fonctionnel – BASFI - Indice d'activité - BASDAI

KEY-WORDS

Ankylosing spondylitis – Spondylarthropathy – Functional index – BASFI - Disease activity index - BASDAI

إعماد النسخة التونسية لإستمارة تقييم القدرة الوظيفية (BASFI) و إستمارة تقييم فاعلية المرض (BASDAI) في التهاب الفقار القسطي

يؤدي التهاب الفقار القسطي الفعال إلى قصور وظيفي عند المرضى.

الباحثون : كشيري ـ م.م - حمدي ـ و - كشباطي ـ س - عزوز ـ د - داود ـ ل - سعدالاوي ـ ك - قنوشي ـ م.م - قافل ـ د.

إثبات صحة النسخة التونسية لاستمارة تقييم القدرة الوظيفية (BASFI) و استمارة تقييم فاعلية المرض. (BASDAI)، استعملت طريقة الترجمة و الترجمة المعاكسة للاستمارتين طبق المناهج المعروفة. شملت هذه الدراسة 68 مريضا (59 رجل و 9 نساء)، معدل عمرهم 38 سنة قام جميعهم بالإجابة على الاستمارتين لمرتين يفصل بينهما أسبوع. تبدو كل من النسختين التونسيتين متماسكة وذات ارتباط متبادل مع المقاييس الخصوصية الأخرى للمرض ومؤشرات كيفية حياة المرضى. حافظت النسخة التونسية لاستمارتي (BASFI) و (BASDAI) على الصبغة الأصلية لكل منهما مما يمكن من استعمالهما عند المصابين بداء التهاب الفقار القسطي.

الكلمات الأساسية : التهاب الفقار القسطي، التقييم الوظيفي (قعبلشص، تقييم فاعلية المرض (BASDAI)

Ankylosing Spondylitis (AS) is a chronic inflammatory rheumatic disease that affects the axial squeleton and often peripheral joints. The consequences of the disease activity and the structural damage may result in physical limitations and disability (1). The international Ankylosing Spondylitis Assessment working group consensus statement (ASAS) (2,3) proposed the use of the Bath Ankylosing Spondylitis Functional Index (BASFI) (4) and the Bath Ankylosing Spondylitis Disease Activity (BASDAI) (5) to evaluate respectively functioning and disease activity in AS. Because of the worldwide distribution of the disease, these tools have to be cross-culturally adapted to different populations. The objective of this study is to translate, adapt and validate the BASFI and the BASDAI into the Tunisian dialectal language.

PATIENTS AND METHODS

Study population. Sixty eighth consecutive patients fulfilling the modified New York criteria of AS (6) were included in the study, between 2006 and 2007. Patients with comorbidity such as fibromyalgia, auditory or comprehension disorders were excluded. Socio-demographic characteristics of patients, duration of the disease and current treatment were collected. This validation did not include measurement of response to treatment, and therefore the sensitivity to change was not determined. The study was approved by the ethical committee for medical research.

Study instruments. At the first examination (Day 1), all participants were asked to fill out the Tunisian version of BASFI and BASDAI questionnaires (Appendix 1&2) and were tested for other disease-specific instruments. They were asked to complete the BASFI and the BASDAI a second time one week later (Day 8).

- Bath Ankylosing Spondylitis Functional Index (BASFI) (4): this measure includes ten items which ask the respondents about the perception of their functional ability and how well they are able to function in everyday life. Subjects rate their functional ability from 0-10 on a visual analog scale (VAS). The mean of the ten scales gives the BASFI score (range: 0-10).

- Bath Ankylosing Spondylitis Disease Activity (BASDAI) (5): this index consists of six visual analog scales dealing with fatigue, spinal and peripheral joint pain, localized tenderness, and morning stiffness (both qualitative and quantitative).Each VAS is scored from 0 to 10 (0=best, 10= worst score). The mean of the tow scores relating to morning stiffness is calculated, providing an aggregate score. The resulting score for the overall index (0-50) is converted to a 0-10 scale, providing the final BASDAI score.

- Bath Ankylosing Spondylitis Patient Global Score (BASG-s) (7) to evaluate the effect of AS on the well being over the last week and the last 6 months (score range: 0-10)

- Bath Ankylosing Spondylitis Metrology Index (BASMI) (8) for spinal mobility (score range: 0-10).

- Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) (9) to assess enthesitis
(range: 0-13)

- Bath Ankylosing Spondylitis Radiology Index (BASRI) (10)

for structural damage

- Health status was assessed by the Ankylosing Spondylitis Quality of Life (ASQoL) (11) and by the Arabic version of SF-36 (12).

Translation process. BASFI and BASDAI were translated into Tunisian dialectal by two persons, one of them a professional translator and the other, bilingual rheumatologist. The translation process was performed according to the standardized guidelines for the process of cross-cultural adaptation of self-report measures (13). Back translation into English was performed by two other bilingual persons.

Statistical analysis. The data are given as medians, ranges, means and standard deviations. For reproducibility analysis, the same questionnaires of BASFI and BASDAI were filled in again by the patients within one week (Day 8) after the first examination (Day1). Reliability was calculated by means of intra class correlation (ICC) coefficients. Internal consistency was assessed using Cronbach's alpha coefficient. For construct validity, correlation coefficients of both questionnaires with the other instruments (BASG-s, BASMI, ASQoL, BASRI and SF-36) were assessed by Spearman's rank correlation coefficient (r). Significance was set at $p<0.05$. Data were analysed using the Statistical Package for the Social Sciences (SPSS) 13.0 for Windows.

RESULTS

Characteristics of patients. The studied population consisted of 68 AS patients (59 males and 9 females). Their mean age was 37.9 years (range: 18-76). The mean disease duration was 13.6 years (range: 1-40). All of them were taking non steroidal anti inflammatory drugs at study time and 19 sulfasalazine.

Psychometric properties of the BASFI and the BASDAI. The mean time to complete each questionnaire was 4 minutes ± 30 s. The BASFI, BASDAI, BASG-s, BASMI, ASQoL, BASRI scores reported were shown in Table1.

Table 1 : Description of the disease-specific instrument scores reported by ankylosing spondylitis patients.

BASFI (score 0-10)	4.5 ± 2.7 (0.7-10)
BASDAI (score 0-10)	4.6 ± 2.3 (0.9-10)
BASG-s (score 0-10)	5.4 + 2.1 (0-10)
BASMI (score 0-10)	4.4 ± 2.2 (3 -10)
MASES (score 0-13)	3.6 ± 3.5 (0-13)
BASRI (score 2-16)	7.6 ± 3.5 (2-16)
ASQoL (score 0-18)	9.5 ± 5.5 (0-18)

- Comprehensibility: a mean score of 9.8 was reported for the both questionnaires (95% CI: 9.2-9.8 - range: 9.2 to 10).

- Reproducibility (Table 2): Interclass coefficient (ICC) consistency measures of BASFI and BASDAI demonstrated a good reliability of both questionnaires when repeated one week later. For the BASFI, reproducibility was 0.96 for the total score (p<0.001) and varied between 0.89 (doing a full day's activities, p<0.001) and 0.98 (reaching up, p<0.001). For the BASDAI,

reproducibility was 0.93 for the total score (p<0.001) and varied between 0.87 (local tenderness, p<0.001) and 0.96 (duration for morning stiffness, p<0.001)).

Table 2 : Intra class coefficient (ICC) reliability measures of BASFI and BASDAI

Items	ICC	95 % CI
BASFI	0.96	0.93 – 0.97
1 Putting on socks	0.97	0.94 – 0.98
2 Bending forward	0.95	0.93 – 0.96
3 Reaching up	0.98	0.97 – 0.98
4 Getting out of an arm-less	0.97	0.96 – 0.98
5 Getting up of the floor	0.96	0.94 – 0.96
6 Standing unsupported	0.94	0.89 – 0.95
7 Climbing 12 to 15 steps	0.96	0.93 – 0.97
8 Looking over your shoulder	0.96	0.94 – 0.96
9 Doing physically demanding activities	0.97	0.94 – 0.98
10 Doing a full day's activities	0.89	0.83 – 0.93
BASDAI	0.93	0.90 – 0.97
1 Tiredness	0.93	0.89 – 0.95
2 Spinal pain	0.95	0.93 – 0.96
3 Peripheral joint pain	0.91	0.89 – 0.93
4 Local tenderness	0.87	0.85 – 0.93
5 Intensity of morning stiffness	0.95	0.91 – 0.97
6 Duration of morning stiffness	0.96	0.93 – 0.97

- Internal consistency (Table 3):

Table 3 : Internal consistency of the BATH ANKYLOSING SPONDYLITIS FUNCTIONAL INDEX (BASFI)

	Item1	Item2	Item3	Item4	Item5	Item6	Item7	Item8	Item9	Item10
Item 1	1.00									
Item 2	0.86	1.00								
Item 3	0.40	0.37	1.00							
Item 4	0.69	0.65	0.45	1.00						
Item 5	0.61	0.58	0.46	0.59	1.00					
Item 6	0.39	0.32	0.32	0.41	0.65	1.00				
Item 7	0.56	0.58	0.45	0.69	0.63	0.49	1.00			
Item 8	0.43	0.69	0.47	0.31	0.37	0.35	0.37	1.00		
Item 9	0.54	0.57	0.37	0.37	0.55	0.47	0.45	0.41	1.00	
Item 10	0.36	0.45	0.35	0.31	0.51	0.53	0.51	0.30	0.71	1.00

Cronbach's alpha coefficient was 0.91 for the BASFI and 0.90 for the BASDAI. The values obtained demonstrate that the items in the individual scales are adequately interrelated.
For the BASFI, the correlation was high between the items 1 and 2 (r = 0.86) but was low between the items 8 and 10 (r = 0.30). For the BASDAI, a high correlation was found between the items 5 and 6 (r = 0.74) and a low correlation between the items 2 and 3 (r = 0.37).

- Construct validity (Table4):
All questionnaires were significantly correlated to each other, to the other disease-specific instruments and to all dimensions of SF-36. Although, for the BASDAI, significant correlation with BASMI and BASRI was relatively low compared with BASG-s, ASQoL, and MASES.

Table 4 : Internal consistency of the BATH ANKYLOSING SPONDYLITIS DISEASE ACTIVITY (BASDAI)

	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6
Item 1	1.00					
Item 2	0.66	1.00				
Item 3	0.50	0.37	1.00			
Item 4	0.51	0.49	0.57	1.00		
Item 5	0.63	0.58	0.51	O.61	1.00	
Item 6	0.60	0.54	0.61	0.55	0.74	1.00

DISCUSSION

The adapted and translated questionnaires demonstrated acceptable comprehensibility scores with a mean of 9.8. They were quick and easy to complete.
- BASFI was developed to assess functional ability in patients with AS. Results of this study revealed that the reproducibility of the Tunisian version was good; the intra class correlation coefficient (ICC) for reliability was 0.96 for the total score (p<0.001) and varied between 0.89 and 0.98 for the items. It was found comparable to that of the other versions (14-20). The coefficient of internal consistency (Cronbach's alpha) was 0.91, showed good correlations between all pairs of items and was found comparable to that of the other versions (15-20). However, Cronbach's score of the English original BASFI index (4) and that of the Swedish version (14) has not been reported, so they could not be compared. Concerning the construct validity, the Tunisian version of the BASFI demonstrated significant correlation with BASDAI (r=0.56), BASG-s (r =0.44), MASES (r=0.47), BASMI (r= 0.46), BASRI (r= 0.37), ASQoL (r= 0.53) and with each one of the eight dimensions of the SF-36. These results were comparable with the data of the literature. Besides, a comparison between BASFI and the Dougados functional index (DFI) showed that the discriminative capacity of BASFI was better than that of DFI (18,20).
- BASDAI was developed to assess the disease activity. Reliability of the Tunisian version showed an acceptable one week test-retest ICC (BASDAI ICC=0.93, 95% CI: 0.90– 0.97). The six questions of the BASDAI represent different aspects of disease but correlated also well with each other. There was a good internal consistency for all six questions (Cronbach's alpha = 0.90), good correlations with BASG-s (r=0.59), BASFI (r=0.56), MASES (r=046), ASQoL (r=0.48), and with the eight domains of SF-36. Thus, the psychometric properties of the Tunisian version were similar to the original version (5) and to the other versions (16, 20, 22-25). For the German BASDAI

(24), concordant validity showed substantial correlation with the scale bodily pain and acceptable correlation with the other domains of the SF-36. However, our study showed a low but significant correlation to BASMI (p=0.042) and to BASRI (p=0.023).

In fact, most of the included AS patients had considerable affection in their thoracic spine, witch is not assessed by the BASRI. Besides, the MRI had ability to detect inflammation of the whole spine, correlated significantly with clinical assessments and questionnaires scores (26).

In conclusion, the psychometric properties of the Tunisian versions of BASFI and BASDAI were comparable to the original English version and to versions in other languages. They were easy to use and they showed an adequate reliability, reproducibility, and validity confirming their utility for the assessment of disease status in AS Tunisian patients.

R É F É R E N C E S

1. Khan MA . Ankylosing spondylitis- the history of medical therapies. Clin Exp Rheumatol 2002; 20 [Suppl 6]:3-5
2. Van der Heijde D, Calin A, Dougados M, et al. Selection of instruments in the core set for DC-ART, SMARD, physical therapyand clinical record keeping in ankylosing spondylitis: progress report of the ASAS working group. J Rheumatol 1999; 26:951-4
3. Van der Heijde D, Dougados M, Davis J, et al. Assessment in ankylosing spondylitis international working group/spondylitis association of America recommandationfor conducting clinical trials in ankylosing spondylitis. Arthritis Rheum 2005; 52(2):386-94
4. Calin A, Garrett S, Whitelock H, 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.
5. 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
6. Moll JM. New criteria for the diagnosis of ankylosing spondylitis. Scand J Rheumatol 1987; 65 [Suppl]:12–24.
7. Jones SD, Steiner A, Garrett SL, Calin A. The Bath Ankylosing Spondylitis Patient Global Score (BASG-s). Br J Rheumatol 1996; 35:66–71.
8. Jenkinson TR, Mallorie PA, Whitelock HC, et al. Defining spine mobility in ankylosing spondylitis: The Bath Ankylosing Spondylitis Metrology Index (BASMI). J Rheumatol 1994; 21:1694-8.
9. Heuft-Dorenbosch L, Spoorenberg A, van Tubergen A at al.. Assessment of enthesitis in ankylosing spondylitis. Ann Rheum Dis 2003; 62:127-32
10. MacKay K, Mack C, Brophy S et al. The Bath Ankylosing Spondylitis Radiology Index: a new, validated approach to disease assessment. Arthritis Rheum 1998;41:2263-70.
11. Doward LC, Spoorenberg A, Cook SA, et al. Development of the ASQoL: a quality of life instrument specific to ankylosing spondylitis. Ann Rheum Dis 2003; 62: 20-6.
12. Coons SJ, Abdulmohsin SA, Draugalis JR, Hays RD. Reliability of an Arabic version of the Rand-36 Health Survey and Its Equivalence to the US-English Version. Medical Care 1998; 36 : 428-32
13. Guillemin F, Bombardier C, Beaton D. Cross cultural adaptation of health related quality of life measures:literature review and proposed guidelines.J Clin Epidemiol 1993;46:1417- 32
14. Cronstedt H, Waldner A, Stenström C.H. The Swedish version of the Bath ankylosing spondylitis functional index. Scand J of Rheumatol 1999; 28: 1-9
15. Heikkilä S,Viitanen J.V, Kautianen H, Kauppi M. Evaluation of the Finnish version of the Functional Indices BASFI and DFI in Spondylarthropathy. Clin Rheumatol 2000;19: 464-9
16. 16- Carduel MH, Londono JD, Gutiérrez E, Pächeco-Tena C, Vazquz-Mellado J, Burgos-VargasR. 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 :451-8
17. Huseyin T, E. Ozer, Tunay Sarpel, Bozkurt Gulek, Z. Nazan Alparslan, Eren Erken. The Turkish version of the Bath Ankylosing Spondylitis. Function Index : reliability and validity. Clin Rheumatol 2005; 24: 123-8
18. Salaffi F, Stancati A, Silvestri A, Carotti M, Grassi W. alidation of the Italian versions of the Bath Ankylosing Spondylitis Functional Index (BASFI) and the Dougados Functional Index (DFI) in patients with ankylosing spondylitis. Reumatismo 2005; 57 : 161-73
19. Chatzitheodorou D, Kabitsis C, Papadopoulos NG, Galanopoulou V. Evaluation of the Greek version of the Bath Ankylosing Spondylitis Functional Index : reliability, validity, and factor analysis. Clin Exp Rheumatol 2007; 25 :571-6
20. Pedersen OB, Hansen GO, Svendsen AJ, Ejstrup L, Junker P. Adaptation of the Bath measures on disease activity and function in ankylosing spondylitis into Danish. Scand J Rheumatol 2007; 36: 22-7
21. Calin A, Nakache J, Gueguen A, Zeidler H, Mielans H, Dougados M. Outcome variables in ankylosing spondylitis: Evaluation of their relevance and discriminant capacity. J Rheumatol 1999; 26: 975-9
22. Claudepierre H, Sibilia J, Goupille P, Flipo RM, Wendling D, Eulry F. Evaluation of a French version of the Bath Ankylosing Spondylitis Disease Activity Index in patients with spondylarthropathy. J Rheumatol 1997; 24: 1957-9
23. Waldner A, Cronstedt H, Stenström C.H. The Swedish version of the Bath ankylosing spondylitis disease activity index.Reliability and validity. Scand J of Rheumatol 1999;28:10-6
24. Brand J, Westhoff G, Rudwaleit M, et al. Adaptation and validation of the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) for use in Germany. Z Rheumatol 2003; 62 : 264-73
25. Park HJ, Kim S, Lee JE, Jun JB, Bae SC. The reliability and validity of a Korean translation of the BASDAI in Korean patients with ankylosing spondylitis. Value Heath 2008; 11 (Suppl) 1: S99 - 104
26. Spoorenberg A, de Vlam K, Van der Heijde D, de Klerk E, Dougados M, Mielants H. Radiologic scoring mrthods in ankylosing spondylitis: reliability and sensitivity to change over one year. J Rheumatol 1999;26: 997-1002.