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ORIGINAL ARTICLE

Evaluation of the Iranian versions of the bath ankylosing spondylitis disease activity index (BASDAI), the bath ankylosing spondylitis functional index (BASFI) and the patient acceptable symptom state (PASS) in patients with ankylosing spondylitis

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Abstract The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and the Bath Ankylosing Spondylitis Functional Index (BASFI) are widely used instruments in assessment of patients suffering from ankylosing spondylitis (AS). The Patient Acceptable Symptom State (PASS) is regarded as a target for patients' well-being. The aim of this study was to translate and adapt BASDAI, BASFI and PASS into the Iranian official language, Farsi, and evaluate their reliability and validity. Ninety patients with AS were included in this study. The questionnaires were translated into Farsi and back translated into English, modified until the final versions were approved with minor adaptations and the VAS was changed to numerical rating scales from 0 to 10. Forty-eight-hour test–retest agreement showed good reliability: interclass correlation coefficient (ICC) for BASDAI was 0.93 (CI at 95%, 0.90–0.95), for BASFI was 0.96 (CI at 95%, 0.94–0.97) and for PASS was 0.87 (CI at 95%, 0.79–0.92). Chronbach's alpha was 0.95, 0.96 and 0.87 for BASDAI, BASFI and PASS, respectively. BASDAI showed a significant correlation with patient global disease activity index, nocturnal back pain, total back pain, number of swollen joints, number of enthesites, morning stiffness, Bath Ankylosing Spondylitis Global Score (BAS-G), BASFI and BASMI. A significant correlation was also found between BASFI and occiput-to-wall distance, mentum-to-sternum distance, chest expansion, finger-to-floor distance, number of swollen joints, number of enthesites, nocturnal back pain, total back pain, BAS-G, BASDAI and BASMI. Patients who answered "no" to PASS (found their condition unsatisfactory) reported significantly increased pain scores, patient global disease activity scores, BAS-G, BASDAI and BASFI scores. The results showed that the Iranian versions of BASDAI, BASFI and PASS are adequately reliable and valid in patients with AS.

Keywords Ankylosing spondylitis · BASDAI · BASFI · Iranian · PASS

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Introduction

Ankylosing spondylitis (AS) is an autoimmune spondyloarthropathy with a chronic disabling course that affects 0.2–1.1% of population [1]. The disease mainly affects the axial skeleton and sacroiliac joints and is characterized by pain, reduced spinal mobility and functional disability [2]. The impact of this disease on patients' quality of life is considerable, and most treatments aim to improve symptoms and reduce movement limitations and deformities. Clinical, laboratory and radiological findings do not reveal improvements or deteriorations between visits, quantitatively. So in order to assess the symptomatic outcomes in

patients, the Assessment of SpondyloArthritis international Society (ASAS) suggested core set domains for clinical practice. These domains include the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), the Bath Ankylosing Spondylitis Functional Index (BASFI), pain, patient global assessment, spinal mobility, number of swollen joints and acute phase reactants [3]. BASDAI and BASFI are specific to disease, sensitive to change and reproducible [4]. By using biological treatments in AS, the use of these instruments has become more common in clinical practice [5]. However, these outcome measures are continuous variables that show the group response to a treatment in clinical trials. In order to facilitate the assessment of the individual response of a patient, rheumatologists can measure well-being of patients by asking whether their condition is satisfactory. The Patient Acceptable Symptom State (PASS) includes a single question with a yes/no answer that evaluates patient's well-being.

Considering the differences in languages and cultures, it seems necessary to demonstrate the reliability and validity of these measures before their use in any country. To the knowledge of the authors, these instruments have not been translated and adapted to the official Iranian language, Farsi. This study was performed to develop and evaluate the Iranian versions of the BASDAI, BASFI and PASS.

Methods

Of 140 patients with approved AS diagnosis based on modified New York criteria [6], ninety patients who were willing to participate and sent the questionnaires back via mail were included in this cross-sectional study. The patients were referred from Iran Ankylosing Spondylitis Society between May and October 2010. Patients with serious infections or cardiac and respiratory diseases were excluded from the study.

The social demographical information, clinical and radiological data were collected by a questionnaire, and physical examination was performed by a single rheumatologist.

The following parameters were evaluated for patients: nocturnal back pain and total back pain (scored from 0–10 based on no pain to the most severe pain, numerical rating score [NRS]), patient global disease activity score (overall assessment of disease activity scored 0–10 for the last week, NRS), the Bath Ankylosing Spondylitis Global Score (BAS-G) for the effect of the disease on well-being of the patients for the last week or the last 6 months (ranged 0–10, NRS) [7] and the Bath Ankylosing Spondylitis Metrology Index (BASMI) to define disease status and spine and hip mobility in patients [8]. BASMI was calculated by assessing cervical rotation, forward flexion, lateral flexion, Schober's test, intermalleolar distance and chest expansion on a scale of 0 (the best)–10 (the worst). Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels were measured for patients. Sacroiliac joint changes were graded based on New York scales of 0 (normal) to 4 (total ankylosis) [6].

Questionnaires

Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) is used to measure severity of fatigue, spinal and peripheral joint pain, localized tenderness and morning stiffness with six questions, ranging 0–10 [9]. Bath Ankylosing Spondylitis Functional Index (BASFI) reflects the activity related to the functional ability of patients and patients' ability to cope with everyday life with ten questions, ranging 0–10 [10]. The first 8 questions relate to the activity and functional abilities of patients, while the last 2 items question about the ability of patients to manage everyday life. Patient Acceptable Symptom State (PASS) assesses the satisfactory health state in AS patients with a single question [11]. The question is the following: "Considering all the different ways your disease is affecting you, if you would stay in this state for the next months, do you consider that your current state is satisfactory?" All patients filled the questionnaires while a qualified nurse was present to help them. All patients were requested to fill the questionnaires again after 48 h and send them back via prepaid mail.

Patients who had at least 2 of the following criteria were defined to have active AS: a BASDAI score $\geq$4, a total back pain score $\geq$4 measured by NRS or morning stiffness duration of $\geq$1 h [12].

Translation and adaptation

All questionnaires were translated into Farsi by two Iranian physicians. Then, both translations were reviewed by two rheumatologists and merged into one. English back translation was made by a linguist, and finalized version was compared with the original English version which seemed to be identical (Appendix 1—ESM).

As it was previously shown that VAS and numerical scales do not differ [13], VAS in BAS-G, BASDAI and BASFI were transformed to NRS from 0 to 10 to improve the understanding of the patients [14]. Because sock aid and helping hand are not available in Iran, these items were removed from the related questions in Iranian BASFI. As gardening is not common for urban Iranian patients, it was replaced by "washing the car."

Statistical analysis

Data management and statistical analysis were performed by SPSS 17.0 software (Chicago, USA). Continuous variables were expressed as mean ± standard deviation (SD) and categorical variables as counts and percentages. External construct validity was determined by comparing BASFI, BASDAI and PASS with clinical variables by Spearman's correlation coefficient (r); the values of the coefficient were interpreted as follows: strong correlation for r higher than 0.60, moderate correlation for r being between 0.30 and 0.60 and weak correlation for r being lower than 0.30. Reliability was assessed by Chronbach's alpha (≥0.70 regarded as satisfactory) and Interclass Correlation Coefficient (ICC- ≥0.80 regarded as satisfactory). Wilcoxon's signed rank test was used to compare the agreement between the same variables on separate occasions. P values of less than 0.05 were considered statistically significant.

Ethical considerations

All study protocols were approved by the Ethical Board of Tehran University of Medical Sciences, and written informed consent was obtained from all patients after explaining the study. All visits were performed free of charge.

Results

Patients

Ninety Iranian patients diagnosed with AS were included in the study. Female to male ratio was 1/3. Mean Body Mass Index (BMI) was 22.04 ± 4.28 without significant difference between males and females. Demographical and disease-related data of patients are shown in Table 1. Total and nocturnal back pain score showed moderate significant correlation with BASMI ($r = 0.43$ and $r = 0.38$, respectively, both $P < 0.0001$). BMI was not correlated with BASMI. In patients with ankylosis of sacroiliac joints on radiographs, pain, functional and disease activity indices were not different, but they had significantly higher ESR and CRP compared to patients with lower grades of sacroilitis.

Questionnaires

The difference between individual items and total BASFI and BASDAI scores was not statistically significant on two occasions measured (Table 2). Total BASFI and BASDAI scores correlated closely with the individual BASFI and BASDAI items, respectively (coefficients between $r_s = 0.71$ and $r_s = 0.83$, P value < 0.0001 for BASDAI and between $r_s = 0.70$ and $r_s = 0.84$, P value < 0.0001 for BASFI). The correlation between single questions of BASDAI and BASFI varied between $r_s = 0.44$ and $r_s = 0.65$, P values ≤ 0.0001 for BASDAI and between $r_s = 0.35$ and $r_s = 0.60$, P values ≤ 0.001 for BASFI, respectively.

Table 1 Demographical and disease-related characteristics of patients

N of patients	90
Female (%)	22 (24.4%)
Male (%)	68 (75.6%)
Age (years)	37.24 ± 9.84 (21–61)
Age at diagnosis (years)	30.70 ± 8.86 (14–52)
BMI (kg/m^2)	22.04 ± 4.28 (13.89–40.06)
Total BASMI score	3.87 ± 1.91 (0.8–8.40)
Total back pain	4.27 ± 2.72 (0–10)
Nocturnal back pain	4.67 ± 3.06 (0–10)
CRP (mg/l)	9.98 ± 16.45
ESR (mm/h)	18.01 ± 15.32

Values are mean ± SD (range), unless otherwise stated

Internal consistency that was measured by Chronbach's alpha was 0.95 and 0.96 for BASDAI and BASFI, respectively. Interclass coefficient (ICC) for test–retest agreement showed quite good reliability for BASDAI (ICC = 0.93, CI at 95% = 0.90–0.95) and BASFI (ICC = 0.96, CI at 95% = 0.94–0.97).

There were statistically significant correlations between the BASDAI and Patient global disease activity index, nocturnal back pain, total back pain, number of swollen joints, number of enthesites, morning stiffness, BAS-G, BASFI, BASMI but not ESR and CRP. The correlation between BASFI and the following items was also statistically significant: Occiput-to-wall distance, mentum-to-sternum distance, chest expansion, finger-to-floor distance, number of enthesites, number of swollen joints, nocturnal back pain, total back pain, BAS-G, BASDAI and BASMI. BASFI was not significantly correlated with ESR and CRP. BASFI but not BASDAI showed significant weak correlation with the duration of disease and age. BASDAI and BASFI were significantly but weakly correlated with BMI ($r = 0.23$, P value = 0.03 and $r = 0.22$, P value = 0.04, respectively).

Of the patients studied, 3 patients did not answer to the PASS question. Of patients who responded, 37 patients (42%) answered "yes" to the question (found their condition satisfactory and were PASS positive) and 50 patients (57.5%) answered "no" to the question (did not think of their condition as satisfactory and were PASS negative). The characteristics of PASS-positive and PASS-negative

Table 2 Total patient global disease activity score, BAS-G, BASDAI and BASFI scores from answers of 90 patients with AS on 2 separate times within 48 h

	First time Mean ± SD (range)	After 48 h Mean ± SD (range)	*P* value (Wilcoxon's signed rank test)
Patient global disease activity score	4.47 ± 2.58 (0–10)	4.04 ± 2.50 (0–10)	0.06
Total BAS-G score	4.88 ± 2.53 (0–10)	4.70 ± 2.38 (0–9)	0.4
Total BASDAI score	4.68 ± 2.44 (0.17–10)	4.21 ± 2.42 (0–9.67)	0.2
Total BASFI score	4.25 ± 2.44 (0–9.2)	4.28 ± 2.66 (0–9.5)	0.1

Table 3 Characteristics of patients with AS based on their response to PASS question

Parameter	PASS + ($n = 37$)	PASS − ($n = 50$)	*P* value (independent sample *T* test)
Female to male ratio	11 (12.6%)/26(29.9%)	11 (12.6%)/39(44.8%)	NA
Age in years, mean ± SD	39.95 ± 10.76	35.72 ± 8.85	0.04
BMI in kg/m^2	22.43 ± 4.63	21.76 ± 4.5	0.4
Age at symptom onset in years, mean ± SD	24.69 ± 6.72	20.89 ± 5.48	0.01
Age at the time of diagnosis in years, mean ± SD	32.54 ± 29.61	29.61 ± 8.16	0.1
Disease duration in years, mean ± SD	15.51 ± 9.52	13.81 ± 8.55	0.4
Duration of morning stiffness in minutes, mean ± SD	37.50 ± 54.05	73.44 ± 85.70	0.03
Total enthesites count	2.73 ± 2.89	7.76 ± 6.78	<0.0001
Number of swollen joints	1.28 ± 0.21	6.85 ± 0.96	0.01
Total BASMI score	3.54 ± 1.90	4.15 ± 1.90	0.1
Nocturnal back pain	3.11 ± 2.50	5.84 ± 2.97	<0.0001
Total back pain	3.14 ± 1.87	5.96 ± 2.62	<0.0001
Patient global disease activity score	3.12 ± 2.01	5.90 ± 2.56	<0.0001
BAS-G score	3.16 ± 1.94	6.20 ± 2.34	<0.0001
BASDAI score	3.16 ± 1.96	5.85 ± 2.15	<0.0001
BASFI score	2.95 ± 2.01	5.24 ± 2.30	<0.0001
CRP	8.14 ± 15.89	12.41 ± 17.54	0.3
ESR	16.28 ± 16.44	20.50 ± 14.55	0.2

NA not applicable

patients are shown in Table 3. Chronbach's alpha and ICC for PASS were 0.87, CI at 95% = 0.79–0.92.

Patients who answered "no" to PASS were significantly younger at symptom onset. Duration of morning stiffness at the time of the survey was higher in patients with a "no" answer to PASS compared to patients with a "yes" answer. Total enthesites count and number of swollen joints were significantly higher in patients who replied "no" to PASS. Meterology indices and clinical findings of physical examination related to AS (such as occiput-to-wall distance, mentum-to-sternum distance, finger-to-floor distance, cervical and lumbar rotations, chest expansion and intermalleolar distance) were not significantly different between the patients who answered "yes" or "no" to PASS. On the other hand, pain score, patient global disease activity score, BAS-G, BASDAI and BASFI were significantly higher in patients who answered "no" to PASS. ESR and CRP were also shown to be higher in patients who answered "no" to PASS, but the difference was not statistically significant. PASS response was not related to age, sex or BMI.

Patients with active disease

Of the patients studied, 54 patients (60%) were defined to have active form of AS. Patients who were defined to have active AS had significantly ($P < 0.0001$) higher scores for pain, patient global disease activity score, BAS-G and BASMI. Age and BMI were not significantly different in patients with active or inactive disease. Patients who had active disease more significantly answered "no" to PASS ($P < 0.0001$).

Discussion

The impact of AS on different aspects of life necessitates comprehensive and comparable evaluations of patients.

Self-reported measures constitute valuable tools for assessing disease progression and also deciding for treatment options. Moreover, patients were found to be suitable reporters of their clinical status [15]. As recommended by the ASAS working group, BASDAI and BASFI are useful tools in clinical trials and daily practice [16]. They have been translated and adapted to various languages such as French [17], German [18–20], Swedish [21, 22], Finnish [23], Mexican-Spanish [24], Tunisian [25], Arabic [14, 26] and Turkish [4, 27]. In this study, the BASDAI and BASFI were translated and adapted to Farsi, official Iranian language, and were compared with other assessment tools such as PASS.

BASFI and BASDAI showed strong reliability in this study and our results were comparable to the results obtained in other countries, such as Finland [23], Denmark [2], and Turkey [27] and relatively stronger compared to the results obtained in Spain [24]. In our study, ICC for BASDAI and BASFI ranged between 0.90 and 0.97, and Chronbach's alpha was satisfactory (alpha = 0.95 and 0.96, respectively). So, the Iranian versions of BASDAI and BASFI were revealed to be reliable and consistent.

To assess the validity of the questionnaires, responses were compared to multiple external measures. BASDAI was found to correlate with pain scores, number of swollen joints, enthesites, morning stiffness, BAS-G, BASFI, BASMI but not ESR and CRP. BASFI correlated significantly with disease clinical parameters, BAS-G, BASDAI, BASMI but not ESR and CRP. As reported by Ruof et al. in a literature review, acute phase reactants do not represent completely the disease process in AS [28], but in the study by Rostom et al., ESR correlated significantly with BASDAI [26]; in the study by Yanik et al. [4] and Spoorenberg et al. [29], ESR and CRP levels were weakly correlated with BASFI and BASDAI, respectively. In our study, these inflammatory factors did not correlate or associate with studied parameters.

Total and nocturnal back pain showed significant correlations with BASDAI, BASFI and BASMI, but the correlation was stronger for BASDAI and BASFI. As suggested by Martindale et al., while BASDAI and BASFI are patient-reported measures, BASMI is evaluated by physician and thus provides a more independent index of clinical situation [30]. In the study by Baysal et al., it was also revealed that BASMI had weaker relationship with psychological status when compared to BASDAI and BASFI, and it was shown that chronic pain is an important difficulty in AS that has correlation with psychological status [31].

This study similar to the study by Dougados et al. [12] showed that reliability of PASS question in assessing patients with AS in terms of satisfaction from health status is good. In the study by Dougados et al., test–retest reliability was evaluated in stable patients between the two visits, but in the present study, test–retest reliability as suggested by Dougados et al. [12] was calculated after 48 h in order not to be affected by any change in patients' condition. In the previous studies, PASS was shown to be a valid measure of the alterations in signs and symptoms of AS [12] and also to be significantly related to disease flares and number of rheumatology consults needed [11]. In our study, similar to the study of Maksymowych et al. [11], PASS-positive patients were significantly older, reported less total and nocturnal back pain, lower patient global disease activity index, BAS-G, BASDAI and BASFI scores. Compared to the study of Maksymowych et al. [11], disease duration was not significantly longer in PASS-positive patients in our study, and PASS-positive patients reported their symptom onset at a significantly older age. Morning stiffness duration, enthesites count and swollen joints were also lower in PASS-positive patients. In the current study, PASS question was capable of discriminating between patients with active vs inactive disease. However, physical examination and laboratory findings were not related to the response to PASS. Thus, PASS constitutes a simple, rapid and patient-reported measure of overall well-being in AS that can be readily understood by physicians and can be easily used in clinical practice and clinical trials [11, 32].

Limitations of our study included its selection bias because of choosing patients who accepted to participate. However, the clinical characteristics of patients were similar to other studies performed and suggested that the patient group was a representative of patients with AS in Iran.

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Conflict of interest None.

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