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The Reliability and Validity of a Korean Translation of the BASDAI in Korean Patients with Ankylosing Spondylitis

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ABSTRACT

Objectives: The objective of this study was to develop a Korean version of the original English version of BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) and to evaluate its reliability and validity in Korean patients with Ankylosing Spondylitis (AS).

Methods: A total of 50 outpatients diagnosed as AS by the modified New York criteria participated. To develop a Korean version of the BASDAI, we followed rigorous international translation steps and evaluated reliability and validity by calculating Cronbach's alpha and correlation coefficients between BASDAI score and clinical parameters (e.g., ESR, CRP, modified Schober test index, finger-to-ground index, and Bath Ankylosing Spondylitis Radiologic Index Score, and bone mineral density).

Results: Cronbach's alpha (= 0.75) was acceptable. The distribution of item responses evaluated by the ceiling and floor effects showed appropriate proportions and a good discrimination with the Korean version of the BASDAI. The correlations among the mean BASDAI score and five scales for the convergent validity was significantly correlated with each other (all P-values < 0.01). The correlations between the BASDAI score and both erythrocyte sedimentation rate and C-reactive protein for the criterion validity were positively correlated (all P-values < 0.05). The results of this study showed that the Korean translation of the BASDAI is an efficient tool in terms of its reliability and validity for the measurement of the disease activity in patients with AS.

Conclusions: The Korean version of the BASDAI could be used in clinical research to assess and evaluate the course of disease activity in Korean AS patients.

Keywords: ankylosing spondylitis, BASDAI, disease activity, Korean validation.

Introduction

Ankylosing spondylitis (AS) is a chronic, progressive, and inflammatory disorder, primarily affecting the sacroiliac joints of the pelvis, the axial skeleton, and thoracic cage [1]. Pain, stiffness, and bony ankylosis cause variable degrees of restricted mobility of the spine with consequent loss of functional capacity [2], and impairment and disability are important components of the patient's perception of the disease [3]. Assessment of variations in disease activity and severity is essential to evaluate the course of disease and treatment effects in patients with AS [4]. In assessment of AS, many single-component measures have been used in terms of function [2,5], metrology [6], radiology [7], global status [8], and disease activity [9]. The patient-assessed instruments are becoming increasingly important in the measurement of health outcomes in rheumatology, and provide supplementary information to traditional biomedical assessments [10].

The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) is identified as a patient-assessed instrument that is reliable, valid, comprehensive, sensitive to change, and reflects the entire spectrum of disease, and therefore is the appropriate instrument for defining disease activity in AS [10,11]. Although the BASDAI has been translated into several languages [11–16], no specific questionnaire exists for measuring such disease activity for Korean AS patients. We focused on the validation process to ensure that a Korean version of BASDAI is equally clear, precise, and equivalent in all ways to the original English BASDAI to have the adequate validity and reliability [17]. The objective of this study was to develop a Korean version of BASDAI and to evaluate its reliability and validity for use in clinical research and application.

Methods

Subjects

This study was conducted at a rheumatology center in a tertiary referral university hospital in Korea. A total

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Table 1 Demographics and clinical characteristics of subjects (n = 50)

Parameters	n (%) or mean ± SD
Sex, Male:Female	46 (92.0):4 (8.0)
Age, years	30.0 ± 6.8
BMI (kg/m^2)	21.6 ± 2.9
Duration of ankylosing spondylitis (months)	79.7 ± 62.9
Steroid (unit dose)	4.5 ± 12.7
CRP (mg/dL)	2.4 ± 2.5
ESR (mm/h)	35.3 ± 31.3
Modified Schober (cm)	3.19 ± 2.1
Finger-to-ground (cm)	20.5 ± 14.9
BASRI-s (N = 47)	
0	14 (29.8)
1	6 (12.8)
2	8 (17.0)
3	5 (10.6)
4	14 (29.8)

BMI, body mass index (calculated as weight in kg divided by height in m^2); AS, ankylosing spondylitis; CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; BASRI-s, Bath Ankylosing Spondylitis Radiologic Index Score; unit dose, dose equivalent of prednisolone 5 mg × month.

number of patients with AS who were registered to this center were 102 (n = 102) at the initiation of the study. We consecutively recruited outpatients diagnosed as AS by the modified New York criteria [18,19]. Patients were excluded from this study if they were postmenopausal or pregnant women, had liver or kidney disease, had injury on lumbar vertebrae or femur, had previous fracture history of the bones, and those with a condition which have altered bone mineral contents and metabolism. A total of 50 patients (mean age, 30.0 ± 6.8) met the eligibility criteria. Information about the study and confidentiality was given to each patient, and the informed consent was obtained. Most were males (n = 46; 92%). The mean body mass index (BMI) was 21.6 ± 2.9 kg/m^2. Duration of disease was 79.7 ± 62.9 months. The mean administered steroid unit was 4.5 ± 12.7 (Table 1).

Translation Steps of the Korean Version of BASDAI

We followed rigorous international translation steps based on Fayers and Marchin's guideline [17]. We obtained a written approval for developing a Korean version of BASDAI from the original author. Two trained bilingual Koreans translated the original English BASDAI into Korean independently. Both translators rated each item and a visual analog scale (VAS) for its conceptual equivalence to the original English version of BASDAI using 0 (not at all equivalent) to 100 (exactly equivalent) scales. Translated items and VAS that were rated less than 75 on the 0 to 100 scale were retranslated by the original translators and a group of specialists, including two rheumatologists, one research nurse, and one biostatistician until an acceptable independent rating of equivalence is obtained. We then produced the first draft of forward translation. A pilot test was conducted for cognitive testing in 15 patients with AS. In this pilot test, we examined whether patients were confused or had difficulties in understanding any item, ambiguous or annoyed in the translation. The draft of forward translation was then refined and finalized after rewording some of the items and VAS based on patients' feedback. The final forward translation was translated back to English version (back translation) by two bilingual native English speakers. Two backward translated versions were compared against the original English BASDAI to check and compare the conceptual consistency. The final Korean version of BASDAI was completed. We performed a field test using this Korean version of BASDAI and assessed its reliability and the validity.

Assessments

Disease activity assessment. The BASDAI consists of a 10-cm horizontal VAS and is used to answer six questions pertaining to five major symptoms of AS: fatigue, back pain, peripheral pain/swelling, areas of localized tenderness, and morning stiffness. BASDAI score is converted to 0 for "none (best)" to 10 for "very severe (worst)" scale, with a lower score indicating less disease activity. The mean of the two scores of morning stiffness (quantity and quality) counted as one variable. The final BASDAI score is defined by calculating the mean of five items [9].

The modified Schober's test and finger-to-ground test [20] were performed by a rheumatologist. The modified Schober's test is the most useful index for detecting limitation of spinal mobility for measuring activity of AS [21]. A mean flexion measurement by modified Schober test was converted to 0 to 10. The higher score means the more severe the patients' limitation of movement for their AS is [6]. Finger-to-ground distance (trunk forward flexion) is a reliable, valid, and responsive measurement for AS patients. The smaller distance means the greater movement [20].

Demographic and clinical assessment. Demographics and disease-related characteristics including age, sex, weight, height, BMI (kg/m^2), and disease duration since occurrence of back pain, vertebral stiffness, peripheral involvement, and other manifestations were assessed. The steroid dose administered was recorded as a unit (the equivalent dose of prednisolone 5 mg × month).

Laboratory assessment. Both Westergren erythrocyte sedimentation rate (ESR) and serum C-reactive protein (CRP) were assessed. The ESR was measured with the Westergren method (mm/h) and the CRP was measured with the turbidmetric method (mg/l). Serum calcium and phosphorus levels, liver and renal function tests (blood urea nitrogen (BUN), creatinine, total

Table 2 Mean scale scores, variability (SD, floor and ceiling effects) and internal consistency reliability of the Korean BASDAI

Scales	Mean ± SD	Range	Floor %	Ceiling %	Cronbach's α
BASDAI	4.72 ± 1.79	1.0–8.0	2.0	2.0	0.751
Fatigue	5.73 ± 1.83	2.0–10.0	2.0	2.0	
Back pain	5.54 ± 2.35	0.0–10.0	6.0	2.0	
Peripheral pain	2.84 ± 2.63	0.0–9.5	24.0	2.0	
Tenderness	4.38 ± 2.89	0.0–10.0	4.0	4.0	
Morning stiffness	5.13 ± 2.78	0.0–10.0	4.0	2.0	

BASDAI: BASDAI score = [Score of fatigue + back pain + peripheral pain + tenderness + (morning stiffness quantity + quality/2)]/5.
BASDAI, Bath Ankylosing Spondylitis Disease Activity Index.

bilirubin, aspartate aminotransferase (AST) and alanine aminotransferase (ALT)) were also assessed. Two levels of disease activity groups according to ESR or CRP were defined as the following: disease activity group for ESR ≥ 15 mm/h versus normal group for ESR < 15 mm/h, and disease activity group for CRP ≥ 1.4 mg/dL versus normal group for CRP < 1.4 mg/dL) [22].

Radiological and bone mineral density assessments. Radiological assessment was performed according to the Bath Ankylosing Spondylitis Radiological Index Score (BASRI-s). Both anteroposterior and lateral lumbar spine radiographs were examined. The films were scored by a radiologist who had over 10 years of experience and read by picture archieving and communication system (PACS, Piviewstar, Infinitt Inc., Korea). The score ranged from 0 to 4: grade 0 = normal or no change, grade 1 = secuspicious or no definite change, grade 2 = mild or minimum abnormality, grade 3 = moderate, and grade 4 = secevere abnormality. For a lumbar spine, both anteroposterior and lateral radiographs were examined and scored together. If one view shows less change than the other, the overall score will be determined to the view showing the more significant change [23]. Bone mineral density (BMD) was measured at a lumbar spine and a proximal femur (neck, greater trochanter, intertrochater area, and Ward's triangle) by dual energy x-ray absorptiometry (DEXA) (QDR 4500A, Hologic, USA) to determine the relationship between the BMD and the disease activity parameters such as BASDAI score, modified Schober test, finger-to-ground test and BASRI-s.

Statistical analyses. Reliability was assessed by Cronbach's alpha. Convergent validity and criterion validity were examined by Pearson correlation coefficients between the BASDAI score and various clinical parameters (such as ESR, CRP, modified Schober's test index, finger-to-ground test index, BASRI-s, and BMD). The BASDAI score, modified Schober's test index, finger-to-ground test index, and BASRI-s between normal group and disease activity group classified by ESR or CRP level were examined by the independent two-sample *t*-test. Statistical significance was *P*-value less than 0.05. All statistical data analysis was carried out using the SAS (version 9.1, Cary, NC, USA).

Results

Internal consistency reliability by Cronbach's alpha of the Korean version of BASDAI was 0.75. The distribution of item responses of the Korean BASDAI was good. There were no high proportions of both ceiling and floor effects except the peripheral pain scale (floor effect = 24%) with a range of 0 to 9.5% (Table 2). For the convergent validity, Pearson correlation coefficients between the BASDAI score and fatigue, back pain, peripheral pain, tenderness and stiffness were moderate to high ($r = 0.45$, 0.75, 0.66, 0.80, 0.83; all *P*-values < 0.001). For the criterion validity, the Korean BASDAI score was positively correlated with both CRP and ESR (*P*-values < 0.05). Nevertheless, there were no significant correlations between the Korean BASDAI score and modified Schober test index, finger-to-ground test index and BASRI-s (Table 3). The ESR was positively correlated with the scales of tenderness ($r = 0.42$; $P < 0.05$) and morning stiffness ($r = 0.33$; $P < 0.05$). The CRP showed positive correlations with the scales of peripheral pain, tenderness, and morning stiffness ($r = 0.29$, 0.42, 0.27, all *P*-values < 0.05) (Table 4). The BASDAI score and tenderness between normal and disease activity group classified by the ESR or CRP were significantly lower in the normal group than those in the disease activity group ($P < 0.05$) (Table 5).

Discussion and Conclusion

We have cross-culturally developed a Korean version of BASDAI, and the results of the study showed good internal consistency reliability and both convergent and criterion validity. Both floor and ceiling effects were acceptable.

There were no problematic scales in the translation steps during the development of the Korean version of BASDAI. In cognitive testing with 15 AS patients, Cronbach's alpha was 0.85, and all the five scales and the mean BASDAI score were positively correlated with each other. Unlike the original English BASDAI scale,

Table 3 Pearson correlation coefficients among scales of the Korean BASDAI for convergent validity

	Pearson correlation coefficients (n = 50)				
	BASDAI	Fatigue	Back pain	Peripheral pain	Tenderness
Fatigue	0.45*	—			
Back pain	0.75*	0.33†	—		
Peripheral pain	0.66*	0.22	0.28†	—	
Tenderness	0.80*	0.16	0.48*	0.39‡	–
Morning stiffness	0.83*	0.15	0.59*	0.38‡	0.67*

*$P < 0.001$; †$P < 0.05$; ‡$P < 0.01$.
BASDAI: BASDAI score = (Score of fatigue + back pain + peripheral pain + tenderness + [morning stiffness quantity + quality/2])/5.
BASDAI, Bath Ankylosing Spondylitis Disease Activity Index.

the Korean translation of the BASDAI included the phrase of "during the past week" in each of the six questions, respectively, to make a linguistically proper Korean sentence. In the field study, Cronbach's alpha of the Korean BASDAI was acceptable (= 0.75). Haywood [10] and Biasi [24] reported also similar range of Cronbach's alphas (0.87 and 0.839, respectively). The Korean BASDAI did not show high proportions of both ceiling and floor effects (ranged 0–9.5%), except a high proportion of floor effect in the peripheral pain scale (24%). A high proportion of floor percentage effect in the peripheral pain scale might be explained by the study sample, which consisted mostly of men because diagnosis of AS is frequently missed in women unless a high degree of suspicion exists. Unlike in women, men tend to have more involvement in spine than peripheral joint [21,25].

The validity of this study was similar to the previous reports [8–10], and indicated that the Korean version of BASDAI have good discrimination. For the convergent validity, all the scales of the Korean BASDAI showed moderate to high correlations ($r = 0.45$–0.83). Nevertheless, the correlations between fatigue and other parameters showed negligible to weak correlations ($r = 0.15$–0.33). The fatigue scale was previously overlooked although this was an important and common symptom in AS [26]. Fatigue can be defined either as a progressive impairment of generating capacity of muscle (peripheral or muscle fatigue) or a lessened capacity for work and reduced efficiency of accomplishment, and is usually accompanied by a feeling of weariness, sleepiness, and irritability [27]. In healthy subjects, this phenomenon is of natural occurrence, but in patients it is considered a lack of energy

Table 4 Pearson correlation coefficients between the Korean BASDAI score and clinical parameters for criterion validity

	Pearson correlation coefficients (n = 50)					
	BASDAI	Fatigue	Back pain	Peripheral pain	Tenderness	Stiffness
ESR	0.36*	–0.04	0.20	0.26	0.42*	0.33†
CRP	0.38*	0.12	0.19	0.29†	0.42*	0.27†
Modified Schober	–0.01	–0.00	–0.12	–0.11	–0.13	–0.01
Finger-to-ground	–0.05	–0.14	0.07	–0.16	0.02	–0.01
BASRI-S	–0.06	0.11	0.10	–0.17	–0.06	–0.01
Lumbar BMD	–0.08	0.01	–0.15	–0.10	–0.00	–0.04
Femur BMD	0.11	–0.06	0.11	0.17	0.02	0.13

*$P < 0.01$, †$P < 0.05$.
BASDAI: BASDAI score = (Score of fatigue + back pain + peripheral pain + tenderness + [morning stiffness quantity + quality/2])/5.
BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; BASRI-s, Bath Ankylosing Spondylitis Radiologic Index Score; BMD (g/cm^2), bone mineral density; Femur BMD (neck, greater trochanter, intertrochanter, and Ward's triangle).

Table 5 Criterion validity of the Korean BASDAI score by the ESR or CRP

	By ESR		By CRP	
Parameters	No activity	Disease activity	No activity	Disease activity
BASDAI	4.05 ± 1.69	5.17 ± 5.82*	4.23 ± 1.87	5.26 ± 1.56*
Fatigue	5.83 ± 1.70	5.67 ± 1.93	5.69 ± 1.78	5.77 ± 1.92
Back pain	4.78 ± 2.55	6.05 ± 2.09	5.04 ± 2.58	6.08 ± 1.98
Peripheral pain	2.38 ± 2.61	3.15 ± 2.64	2.52 ± 2.39	3.19 ± 2.88
Tenderness	2.98 ± 2.30	5.32 ± 2.90*	3.35 ± 2.71	5.50 ± 2.70†
Morning stiffness	4.31 ± 2.92	5.68 ± 2.58	4.55 ± 2.99	5.77 ± 2.43

*$P < 0.05$, †$P < 0.01$.
Disease activity group by ESR: ESR ≥ 15 mm/h (n = 30); no activity: ESR < 15 mm/h (n = 20).
Disease activity group by CRP: CRP ≥ 1.4 mg/dL (n = 24); no activity: CRP < 1.4 mg/dL (n = 26).
BASDAI: BASDAI score = (Score of fatigue + back pain + peripheral pain + tenderness + [morning stiffness quantity + quality/2])/5.
ESR, erythrocy sedimentation rate (mm/h); CRP, C-reactive protein (mg/dL).

[28]. This issue of fatigue might be explained by the limitation of small sample size, and/or the Korean AS patients could not discriminate whether fatigue was caused by their disease process or a simple tiredness. Even disease status, in terms of disease activity, disease progression, and prognosis are difficult to define in AS [29]. Both ESR and CRP are frequently used parameters to evaluate patients with AS for acute phase reactants [30]. Although the previous research reported that results between the ESR and CRP and disease activity in AS were ambiguous, or the CRP was a better marker of disease than the ESR [22,31], there were significant weak correlations for the criterion validity between the Korean BASDAI score and both ESR and CRP ($r = 0.34$, $r = 0.39$) in this study. Furthermore, to explain weak correlations we found between the Korean BASDAI score and both ESR and CRP, we classified two disease activity groups (normal and active) by the proper cutoff levels of the ESR and CRP. Both mean BASDAI score and tenderness in the normal group were significantly lower than those in the disease activity group ($P < 0.05$). The results indicated that the Korean BASDAI score might be a good indicator to assess the acute disease activity. Nevertheless, because both CRP and ESR were assessed cross-sectionally in the study, longitudinal assessment of the ESR and CRP is required to identify disease activity process. To reflect the multidimensional domains of diseases' impact, there is a need to include both patient-assessed specific and generic health-related quality of outcome measures and range of motion (ROM) measures in the evaluation of patients with AS [32]. Unlike Haywood's results [20] that the modified Schober index and fingertip-to-ground distance had adequate relationships with the BASDAI score, the Korean BASDAI score of this study, however, did not show significant differences with either the modified Schober index or finger-to-ground distance. In addition, the Korean BASDAI also showed negligible correlations with BASRI-s, lumbar BMD, and femur BMD. On the other hand, we found significant correlations between BASRI-s and modified Scober index ($r = 0.72$; $P < 0.0001$), finger-to-ground distance ($r = 0.33$; $P < 0.05$) and femur BMD ($r = -0.35$; $P < 0.05$). These findings might be explained by spinal mobility, which was better identified by radiological findings. Averns et al. (1996) [33] reported that characteristics of radiological change is essential for the diagnosis of AS, and is considered the "gold standard" for disease status. Mackay et al. (1998) [7,23] also reported that BASRI-s is disease-specific, sensitive to change, valid, simple, and rapid to perform.

The results of the study support the applications of the Korean version of BASDAI in studies of assessing and evaluating the Korean AS patients. The reliability and validity of Korean translation of BASDAI was verified.

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