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The Reliability and Validity of a Korean Translation of the ASAS Health Index and Environmental Factors in Korean Patients with Axial Spondyloarthritis

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The objective of this study was to develop a Korean version of the Assessment of Spondyloarthritis International Society-Health Index/Environmental Factor (ASAS HI/EF) and to evaluate its reliability and validity in Korean patients with axial spondyloarthritis (SpA). A total of 43 patients participated. Translation and cross-cultural adaptation of the ASAS HI/EF was performed according to international standardized guidelines. We also evaluated validity by calculating correlation coefficients between the ASAS-HI/EF score and the clinical parameters. Test-retest reliability was excellent. The correlations among the mean ASAS-HI score and all tools of assessment for SpA were significant. When it came to construct validity, the ASAS HI score was correlated with nocturnal back pain, spinal pain, patients's global assessment score, the Bath ankylosing spondylitis disease activity index (BASDAI), Bath ankylosing spondylitis functional index (BASFI), Bath ankylosing spondylitis metrology index (BASMI) and EuroQoL visual analogue scale (EQ VAS) (r = 0.353, 0.585, 0.598, 0.637, 0.690, 0.430, and -0.534). The ASAS EF score was also correlated with the patient's global assessment's score, BASDAI, BASFI, BASMI, and EQ VAS score (r = 0.375, 0.490, 0.684, 0.485, and -0.554). The Korean version of the ASAS HI/EF can be used in the clinical field to assess and evaluate the state of health of Korean axial SpA patients.

Keywords: Spondylitis, Ankylosing; Spondylarthropathies; Validation Studies

INTRODUCTION

Ankylosing spondylitis (AS) is characterized by inflammation of the axial skeleton, sacroiliac joints, and, to a lesser degree, peripheral joints and certain extra-articular organs, including the eyes, skin, and cardiovascular system (1). The most unique feature in AS is subchondral eburnation and the presence of syndesmophytes, which possibly lead to ankylosis and spinal fusion. 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).

The Assessment of Spondyloarthritis International Society (ASAS) Health Index (HI) has been developed to measure health based on the International Classification of Functioning, Disability and Health (ICF) (4, 5). The ICF core set for AS served as the underlying concept to capture the whole range of functioning and disability in patients with axial spondyloarthritis (SpA) (4, 6). The methodology of the ASAS HI has been described (5).

In short, the ASAS HI is based on an item pool which has been developed by linking items to the ICF core set for AS. The origin of the items is either existing questionnaires already in use for patients with axial SpA (axSpA) or items from questionnaires which are linked to the ICF. Some of the items have been rephrased to obtain a consistent item structure (expressed in the first person and in the present tense). In parallel, patients with AS proposed during a patient meeting important items to be included in the final measure or proposed new items which are not adequately represented in existing questionnaires. The final item pool with 251 items in 44 categories has been tested

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in two international cross-sectional studies with the aim of reducing the item pool. The final ASAS HI measure contains 17 dichotomous items addressing the ICF categories of pain, emotional functions, sleep, sexual functions, mobility, self care, community life and employment. In addition, a set of 9 environmental factors (EF) has been proposed which addresses the categories of support/relationships, attitudes and health services. These EF items can act as a barrier or a facilitator and may influence the health of patients with axial SpA. The items of the ASAS HI can also be the starting point for developing a disease-specific utility instrument that will enable the calculation of disease specific Quality Adjusted Life Years (QALYs), that can further be used in economic evaluations.

This study is one of the global projects. The objective was the translation of the ASAS HI and the EF item set into the Korean language.

MATERIALS AND METHODS

Subjects and clinical assessment

A total of 43 patients (13 patients with non-radiographic axial SpA and 30 patients with AS) were enrolled. We recruited outpatients diagnosed as having non-radiographic axial SpA by the ASAS classification criteria (6) and diagnosed as having AS by the modified New York criteria (7). Patients were excluded from this study if they had an injury of the lumbar vertebrae or femur, had a previous history of fracture of the bones, or a condition which involved a bone disease. Demographics and disease-related characteristics including age, gender, and disease duration since the occurrence of disease specific symptoms were assessed. Clinical assessments were also performed. These included the Bath ankylosing spondylitis disease activity index (BASDAI) (8), Bath ankylosing spondylitis functional index (BASFI) (9), Bath ankylosing spondylitis metrology index (BASMI) (10), and the patient's global assessment (PGA), spinal pain, and night back pain score (11). We used the Korean version of the EuroQoL (EQ) visual analogue scale (VAS) to measure the patients' quality of life (12).

Translation steps of the Korean version of ASAS HI/EF

Translation and cross-cultural adaptation of the ASAS HI and EF were performed according to the published recommendations (13). The proposed steps contained 5 stages: translation, synthesis of translation, back translation, expert committee review and pre-testing in a field test. First, three persons who had a different background (e.g. medical and non-medical) independently performed a forward translation of the instrument from the source language to the Korean language. The translators synthesized their results. Back translation was then performed by three independent bilingual native English speakers, blinded to the English original version. The expert committee agreed upon the final wording of the Korean version. The initial (forward and back) translators and two persons very familiar with cross-cultural adaptation participated in this expert meeting. The final version (APPENDIX) was tested with axial SpA patients with respect to their sex, age, disease duration, and educational level. After completion of the questionnaire, each question was discussed with the patient to check whether all items had been fully understood and to assess whether the patients had problems with the formulation.

Reliability

The reliability of the ASAS HI and EF were assessed by the test-retest method at a one week interval. This was an estimate of the instrument's reproducibility over time, assuming that no change in conditions had taken place. It was measured using the intra-class correlation (ICC).

Statistical analyses

Descriptive statistics were performed. Using Spearman's correlation coefficient, the validity was assessed by comparing the correlation of the ASAS HI/EF and clinical parameters in all patients. All statistical tests were two-sided and P values less than 0.05 were considered to indicate statistical significance. Statistical analysis was performed using SPSS for Windows (version 18.0; SPSS, Chicago, IL, USA).

Ethics statement

Information about the study and confidentiality was given to each patient, and informed consent was obtained. The study received approval by the institutional review board of Chonnam National University Hospital (IRB No. CNUH-2013- 068).

RESULTS

The clinical characteristics of the subjects are presented in Table 1. All the patients fulfilled the questionnaires by themselves. Because the final wording needs to be understood by people with a lower level of education, education levels were stratified as elementary school (two patients, 4.6%), middle school (six patients, 13.9%), high school (thirteen patients, 30.2%), college (nine patients, 20.9%), and university (thirteen patients, 30.2%). The mean age (SD) of the patients was 36.7 (11.3) yr. Most were males (83.7%). Duration of disease was 51.4 (50.7) months. Mean scores (SD) of BASDAI, BASFI, BASMI, and EQ VAS were 3.1 (1.9), 1.2 (1.9), 2.0 (1.7), and 66.1 (19.0), respectively. Mean time consumption (SD) of ASAS HI and EF were only 75.4 (31.7) and 64.5 (19.2) sec.

Test-retest reliability was assessed using the ICCs recorded from the first and second interview of the ASAS HI and EF. The ICCs were 0.97 (95% confidence interval [CI], 0.95-0.98; $P < 0.001$) for the ASAS HI and 0.95 (95% CI, 0.91-0.97; $P < 0.001$) for the

Table 1. Baseline demographics and clinical characteristics of subjects

Clinical features	Non-radiographic axial SpA (n = 13)	AS (n = 30)	All (n = 43)
Age (yr) (mean ± SD)	35.8 ± 9.7	37.1 ± 12.1	36.7 ± 11.3
Male, No. (total, %)	9 (69.2)	27 (90)	36 (83.7)
Disease duration (months) (mean ± SD)	32.6 ± 22.2	59.5 ± 57.4	51.4 ± 50.7
Nocturnal back pain (0-10 NRS) (mean ± SD)	1.6 ± 1.6	2.3 ± 2.2	2.1 ± 2.0
Spinal pain (0-10 NRS) (mean ± SD)	1.9 ± 1.7	2.3 ± 2.2	2.2 ± 2.0
PGA (0-10 NRS) (mean ± SD)	3.6 ± 1.4	3.4 ± 2.7	3.5 ± 2.4
BASDAI (mean ± SD)	2.9 ± 1.4	3.2 ± 2.0	3.1 ± 1.9
BASFI (mean ± SD)	0.3 ± 0.3	1.5 ± 2.1	1.2 ± 1.9
BASMI (mean ± SD)	0.8 ± 0.3	2.5 ± 1.9	2.0 ± 1.7
EQ VAS (mean ± SD)	66.5 ± 14.7	65.9 ± 20.8	66.1 ± 19.0
ASAS HI (mean ± SD)	4.4 ± 2.9	5.7 ± 4.6	5.3 ± 4.2
ASAS EF (mean ± SD)	2.7 ± 1.2	3.6 ± 1.8	3.3 ± 1.7
ASAS HI assessment time (sec) (mean ± SD)	72.7 ± 38.2	76.6 ± 29.0	75.4 ± 31.7
ASAS EF assessment time (sec) (mean ± SD)	60.8 ± 14.9	66.1 ± 20.8	64.5 ± 19.2

SpA, spondyloarthritis; AS, ankylosing spondylitis; NRS, numerical rating scale; PGA, patient's global assessment; BASDAI, Bath ankylosing spondylitis disease activity index; BASFI, Bath ankylosing spondylitis functional index; BASMI, Bath ankylosing spondylitis metrology index; EQ VAS, EuroQoL visual analogue scale; ASAS HI, The Assessment of Spondyloarthritis International Society Health Index; EF, Environmental Factors.

Table 2. Test-retest reliability in 43 patients with axial spondyloarthritis

Reliability	ASAS-HI	ASAS-EF
Test-retest reliability		
Mean (SD) for the first measure	5.30 ± 4.19	3.34 ± 1.69
Mean (SD) for the second measure	4.93 ± 3.68	3.34 ± 1.59
ICC (95% CI)	0.97 (0.95-0.98)	0.95 (0.91-0.97)
P value	$P < 0.001$	$P < 0.001$

ASAS HI, The Assessment of Spondyloarthritis International Society Health Index; ASAS EF, The Assessment of Spondyloarthritis international Society Environmental factors; ICC, intra-class correlation; SD, standard deviation.

ASAS EF (Table 2).

To assess construct validity, the ASAS HI, and EF were compared with the disease specific clinical parameters and quality of life. The ASAS HI score was correlated with nocturnal back pain, spinal pain, PGA, BASDAI, BASFI, BASMI, and EQ VAS (r = 0.353, 0.585, 0.598, 0.637, 0.690, 0.430 and -0.534). The ASAS EF score was also correlated with PGA, BASDAI, BASFI, BASMI, and EQ VAS score (r = 0.375, 0.490, 0.684, 0.485, and -0.554). Nevertheless, there were no significant correlations between ASAS HI/EF and disease duration (Table 3).

Table 3. Correlation coefficient between ASAS-HI/EF score and other clinical factors

Factors	Pearson correlation coefficients (n = 43)	
	ASAS-HI (scores)	ASAS-EF (scores)
Disease duration (months)	-0.028	0.123
Age (yr)	0.355*	0.313*
Noctunal back pain (0-10 NRS)	0.353*	0.112
Spinal pain (0-10 NRS)	0.585†	0.314
PGA (0-10 NRS)	0.598†	0.375*
BASDAI (scores)	0.637†	0.490†
BASFI (scores)	0.690†	0.684†
BASMI (scores)	0.430*	0.485†
EQ VAS (mm)	-0.534†	-0.554†

*$P < 0.05$, †$P < 0.01$. ASAS HI, The Assessment of Spondyloarthritis International Society Health Index; ASAS EF, The Assessment of Spondyloarthritis International Society Environmental Factors; PGA, patient's global assessment; BASDAI, Bath ankylosing spondylitis disease activity index; BASFI, Bath ankylosing spondylitis functional index; BASMI, Bath ankylosing spondylitis metrology index; EQ VAS, EuroQol visual analogue scale; NRS, numerical rating scale.

DISCUSSION

The Comprehensive ICF Core Set for comprehensive classification and the Brief ICF Core Set for clinical studies in AS are now available. The core sets aim to present new references for defining the functioning in AS and facilitate clinicians' and researchers' efforts to incorporate a patient-oriented, multilevel and comprehensive view of functioning in AS (4). The purpose of this project was to assess the relevance, acceptability, comprehensiveness and understandability of questionnaire items for SpA patients in Korean. The ASAS HI and EF were translated into Korean, according to international standardized guidelines. After the expert committee's agreement upon the final wording of the Korean version, face validity was also performed by feedback from the patients in case the initial translators needed to go back to the translation and modify it. All final translations were done in such a way so that the wording would be understood by lay people including people with a lower level of education. There was one problematic item in the translation step. Regarding EF Item 1, it was decided to allow the inclusion of the term "children or other relatives" in the translation by the ASAS committee. The test–retest reliability of the ASAS HI and EF was high, with an excellent ICC. These results were interpreted as showing appropriate reliability.

To reflect the multidimensional domains of a disease's impact, there is a need to include both patient-assessed specific and generic health-related quality of the outcome measures and range of motion measures in the evaluation of patients with AS (11, 14). We found significant correlations between ASAS HI and spinal pain, global health score, BASDAI, BASFI, and BAS-

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MI. ASAS EF also has good correlation with the global health score, BASDAI, BASFI, and BASMI. The EQ VAS is a generic measure of health status that does not focus on regional disabilities (15). Both ASAS HI and EF have significant correlations with EQ VAS. The results of the study support the applications of the Korean version of ASAS HI and EF in studies of assessing and evaluating Korean SpA patients.

Patient-reported outcome has become popular as an evaluation tool and is increasingly being used. The most important advantages are that questionnaires do not require the time of a doctor and they can be completed by the patient and returned by mail without the patient attending the hospital. Surprisingly, we registered less than 2 min in filling out the each instrument. These instruments will be cost effective and suitable in Korean studies with large populations, such as in registry studies. The translated version was made available freely without copyright or payment for use. The translation of the ASAS HI and the EF items set can be used in clinical trials and clinical practice as a new measure in patients with axial SpA to assess and evaluate the state of health in Korean AS (or axial SpA) patients.

In summary, despite the linguistic differences, the Korean ASAS HI and EF represents a standardized patient-based instrument for assess¬ing the status of health in patients with axial SpA. Future clinical practice should include the ASAS HI and EF to improve the quality of medical care associated with axial SpA.

DISCLOSURE

The authors have no conflicts of interest to disclose.

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Appendix 1

날짜: _____

이름: _____

I. Korean version _ASAS Health Index (ASAS 건강지표)

다음 설문지의 항목에 대한 답변을 **현재** 당신의 류마티스 질병 상태에 근거하여 한 개만 체크하여 주시기 바랍니다. ("류마티스 질병"이란 강직성 척추염을 포함한 모든 종류의 척추관절염을 말합니다.)

1. 통증으로 인해 일상생활에 지장을 받을 때가 있다.
   □ 그렇다
   □ 아니다
2. 오랜 시간 서 있기가 힘들다.
   □ 그렇다
   □ 아니다
3. 달리기가 힘들다.
   □ 그렇다
   □ 아니다
4. 변기를 이용하는 데에 어려움이 있다.
   □ 그렇다
   □ 아니다
5. 나는 자주 심한 피로감을 느낀다.
   □ 그렇다
   □ 아니다
6. 육체적 활동은 되도록 하고 싶지 않다.
   □ 그렇다
   □ 아니다
7. 성욕을 잃었다.
   □ 그렇다
   □ 아니다
   □ 해당 사항 없음, 답변 원하지 않음
8. 자동차 운전 시, 페달 조작에 어려움이 있다.
   □ 그렇다
   □ 아니다
   □ 해당 사항 없음, 운전 못함
9. 사람들과의 만남이 꺼려진다.
   □ 그렇다
   □ 아니다
10. 실외의 평지를 걸을 수 없다.
    □ 그렇다
    □ 아니다
11. 집중하기가 힘들다.
    □ 그렇다
    □ 아니다
12. 움직이는데 제약이 있어 여행이 쉽지 않다.
    □ 그렇다
    □ 아니다
13. 나는 자주 좌절감을 느낀다.
    □ 그렇다
    □ 아니다
14. 머리감기가 힘들다.
    □ 그렇다
    □ 아니다
15. 류마티스 질병으로 인해 경제적 사정의 변화가 있다.
    □ 그렇다
    □ 아니다
16. 밤에 잠을 잘 못 잔다.
    □ 그렇다
    □ 아니다
17. 내가 겪고 있는 어려움을 극복할 수 없을 것 같다.
    □ 그렇다
    □ 아니다

설문에 응답해주셔서 감사합니다

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Appendix 2

날짜: _____

이름: _____

I. Korean version_Environmental Factors related to ASAS Health Index (ASAS 건강지표관련 환경요인)

다음 설문지의 항목에 대한 답변을 **현재** 당신의 류마티스 질병 상태에 근거하여 한 개만 체크하여 주시기 바랍니다. ("류마티스 질병"이란 강직성 척추염을 포함한 모든 종류의 척추관절염을 말합니다.)

1. 내 류마티스 질병으로 인해, 가족 또는 친척들이 집안일을 더 많이 한다.
   □ 그렇다
   □ 아니다
2. 친구들이 나에게 행동하는 방식이 마음에 들지 않는다.
   □ 그렇다
   □ 아니다
3. 내 문제를 해결하는데 있어서 친척들의 도움을 기대할 수 없다.
   □ 그렇다
   □ 아니다
4. 나는 (류마티스 질병으로 인해) 가정과 직장 환경을 바꾸게 되었다.
   □ 그렇다
   □ 아니다
5. 의료진은 내 증상이 악화됐다고 잘 인정해 주지 않는다.
   □ 그렇다
   □ 아니다
6. 질병 치료에 시간이 많이 든다.
   □ 그렇다
   □ 아니다
7. 친구들이 내게 너무 많은 기대를 한다.
   □ 그렇다
   □ 아니다
8. 집안에서 누구도 나에게 크게 신경 써주지 않는다.
   □ 그렇다
   □ 아니다
9. 친구들은 나를 이해해준다.
   □ 그렇다
   □ 아니다

설문에 응답해주셔서 감사합니다

Appendix 3

사용자 매뉴얼

ASAS 건강지표에 대한 설명

ASAS 건강지표는 Assessment of SpondyloArthritis Inernational Society (ASAS)에 의해, 축성 척추관절염 환자들의 건강을 평가하기 위해 만들어졌습니다. 설문지는 International Classification of Functioning, Disbaility and Health (ICF)에서 개념화한 '기능, 장애, 건강'의 정도를 평가하는 17개의 항목들로 이루어져 있습니다. ASAS는 강직성척추염(AS) 환자들에게 있어 전형적이면서 관련되어 있는 핵심 항목들에 대해 정의하는 기초 자료로 인류의 기능, 장애, 건강을 조직적으로 체계화하고 기술화한 모델인 ICF를 사용해 왔습니다. 이러한 강직성 척추염환자들의 ICF의 핵심 항목들을 기초하여, 특정한 ICF 카테고리들과 연결된 다양한 항목들이 만들어졌습니다. 이 항목들의 영향력은 Rasch Analysis에 의해 평가되고 분석되었습니다. 가장 영향력 있는 항목들은 최종 안에 포함되었습니다. 이것은 임상시험에서 환자의 건강 상태에 대한 관련 정보를 얻는데 새로운 종합지표로 사용될 수 있습니다.

ASAS 건강 지표의 종합 점수

ASAS의 건강지표의 각각의 대답에 대해 '나는 동의한다'에는 1점을, '나는 동의하지 않는다'에는 0점을 주십시오. 모든 항목 점수들의 총점은 0점(기능이 좋음)부터 17점(기능이 좋지 않음)사이에 있을 것입니다.
항목 8번("나는 자동차 페달 조작에 어려움을 겪는다.")는 항목은 모든 환자에게 적용하지 않도록 명시해 주십시오. 운전하지 않는 환자들은 "해당되지 않음"에 표시하고 총점은 16점에 근거하여 분석되어야 합니다.

무응답 자료

총점은 자료의 20%미만이 무응답 되었을 때만 분석될 수 있습니다. 총점은 한 개에서 최대 세 개의 답변이 되어있지 않은 답변자들에 한해 다음과 같이 계산될 수 있습니다.

$$\text{총점} = \frac{\chi}{17-m} \times 17$$

χ = 항목 점수들의 합
m = 무응답 항목의 개수

3개 이상 답변이 없을 경우들에는 총점을 배정할 수 없습니다.

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