



Validation of the Korean Ankylosing Spondylitis Quality of Life Questionnaire

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Background: Measuring accurate and reliable scores of quality of life in patients with ankylosing spondylitis (AS) is important in both decision-making and treatment planning for the disease. Questionnaire, The ankylosing spondylitis quality of life (ASQoL), is one of the representative tools for assessing how seriously AS patients view their disease severity, activity, as well as their overall health. To make these types of questionnaires readable and understandable, local language translation of surveys should be required. A Korean version of the ASQoL questionnaire has accordingly been developed. This study assessed the Korean version of the ASQoL survey to evaluate the reliability and validity of it.

Methods: Translation and reverse translation of the English ASQoL survey were conducted. A total of 120 consecutive AS patients received a mail including the Korean-translated 36-Item Short Form Survey (SF-36), the ASQoL survey, and the visual analog scale (pain). The coefficient of intraclass correlation and Cronbach's alpha were computed, and factor analysis, as well as reliability assessments utilizing the kappa agreement statistics for each item, was undertaken. By analyzing the responses to SF-36 and ASQoL questionnaire utilizing Pearson's correlation coefficient, construct validity was calculated.

Results: Factor analysis was performed regarding pain, physical function, and mental function. The kappa statistic of agreement was larger than 0.6 for all items. The ASQoL questionnaire had adequate test and re-test reliability (0.814). Furthermore, Cronbach's α , the internal consistency, was very good (0.877). The Korean-translated ASQoL questionnaire demonstrated a significantly strong correlation between the single domain and total SF-36 scores.

Conclusions: The Korean version of the ASQoL questionnaire showed acceptable properties of measurement and successful translation. Thus, it can be said that the questionnaire is appropriate for evaluating the outcomes of Korean patients with AS.

Keywords: Ankylosing spondylitis, Ankylosing spondylitis quality of life, Korean version

A chronic inflammatory rheumatic disease called ankylosing spondylitis (AS) has a major negative impact on the patient's health and quality of life (QoL).^{1,2)} AS is thought to be the major type of spondyloarthropathy,³⁾ and in AS

patients, the entire spine gradually stiffens in advanced stages.⁴⁾ The sagittal spinal balance is disturbed as the condition grows more severe, resulting in stiff thoracolumbar kyphosis. The head and face are tipped downward in aggravated thoracolumbar kyphosis. As the kyphosis develops, the patient will lose the ability to look beyond the horizontal gaze level.^{4,5)} Moreover, the gravity center shifts to the anterior direction, resulting in a bent posture downward-looking, which contributes to many impairments, including restraint of social activities. This change in posture deteriorates the QoL of the patient.

The measurement of QoL is increasingly used in research assessing the effect of new pharmacological sub-

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stances or comparing various treatment plans.⁶⁾ In the treatment of AS, medications are changed according to the worsening of symptoms. In addition, it is necessary to determine how effective the changed treatment agent is in clinically changing symptoms. For these reasons, an accurate and reliable QoL measurement method is important for planning, making decisions, and treating AS. The importance of these QoL measurements is recognized as being an integral part of the patient-reported outcomes in chronic conditions. These measurement methods aim to capture current QoL to detect changes over time, such as natural disease progression, or after medical or surgical interventions, thereby predicting further changes. The questionnaire of ankylosing spondylitis quality of life (ASQoL), measuring 18 items reported by divided groups of patients and calculating total scores ranging from 0 to 18, is the most commonly used tool for evaluating the QoL of patients with AS. This system was created to evaluate how AS therapies will affect QoL.⁶⁾ The ASQoL questionnaire offers details on the overall effect of the condition and treatment for AS patients. The foundation of the ASQoL questionnaire is a concise model that has been effectively applied in creating several other disease-specific tools for assessing QoL.^{7,8)} The usefulness of the ASQoL was proven in measuring general health, disease activity, and self-perceived disease severity for AS patients in the Netherlands and the United Kingdom ($p < 0.001$).⁶⁾ The ASQoL questionnaire has shown outstanding test/retest reliability and internal consistency, as well as the convergence of validity in AS patients.^{7,8)} The ASQoL questionnaire was established in the United Kingdom and has been translated and evaluated in American English, Canadian French and English, French, Italian, German, Turkish, Spanish, Greek, Swedish, and Chinese.^{6,9-13)} To widen the application of the ASQoL questionnaire, it should be translated into local languages in a readable and understandable manner, and a Korean version is also needed. To date, there is no Korean version that has been translated, validated, and published internationally. Translation of the Korean-adapted ASQoL questionnaire and validation of it with Korean AS patients were our goal in this article.

METHODS

The Clinical Research and Ethical Committee of Pusan National University Hospital (No. D-2109-003-184) approved this investigation. Written informed consent was acquired from all participants. In the case of two minors, written informed consent was acquired from their parents as legal guardians.

Translation with an adaptation procedure was performed with a self-reporting system using the guidelines of cross-cultural adaptation.^{14,15)} In the study, the translation process comprised three steps: initial translation, reverse translation, and discussion by an expert committee. A pilot study was further performed to determine the capability of understanding draft questionnaires in Korean AS patients. An expert committee discussed the final version, which was proven to be valid and reliable as the Korean version of the 36-Item Short Form Survey (SF-36).^{15,16)}

Initial Translation

Two native Korean translators initially translated the ASQoL questionnaire. One of the author (DSK) of this paper, who is also the first translator, has a medical background in orthopedic surgery. However, the other, who is a professional translator, has no medical background and is firstly unaware of the goal of the translation. The goal of translation was to produce a questionnaire that would be easy for readers to read and understand. For example, in item 8 “I have to keep stopping what I am doing to rest” was translated as “I have to take frequent breaks from work.” In addition, “I am unable to do jobs around the house” was translated as “I cannot do housework” in item 11, as these expressions used in the original version were unfamiliar to Koreans. The original untranslated version was compared with the translations, and until a single translation was drafted, it was scrutinized by the translator and the orthopedic surgeon.

Reverse Translation

Two bilingual interpreters, native English speakers with no medical background, independently conducted the reverse translation. Both of them could not provide information or make judgments regarding the previous translations.

Expert Committee Discussion for the Final Draft

An expert committee, comprising a Korean translation expert, 3 bilingual experts, and orthopedic surgeons, discussed all versions of the original documents and translations with 4 translators until a consensus regarding all discrepancies was reached. A final draft of the ASQoL questionnaire was created using the synthetic forward translation.

Final Korean Version

A pilot study was conducted to perform cognitive testing in 20 Korean-speaking patients with AS (7 women and 13 men; mean age, 37.3 years; age range, 19–55 years) in the outpatient orthopedic department. In this pilot study,

we examined whether patients were confused or had difficulties understanding any item, thought any aspect was ambiguous, or were annoyed with the translation. Our team asked interviewers to record any difficulties that arose during questionnaire management. At the end of the interview, all patients were asked to comment on the questionnaire and identify any difficult-to-understand words. All items were probed for correct understanding. There was no ambiguity or misunderstanding, and the questionnaire was found to be easy to fill in overall. The final Korean version of the ASQoL questionnaire was composed, in total agreement, of a committee of experts that included all the participating translators (Supplementary Material 1).

Patients

In the outpatient orthopedic clinic, 120 individuals were diagnosed with AS. Patients were diagnosed using the modified New York criteria for AS.¹⁷⁾ Exclusion criteria included severe physical disabilities, metabolic bone diseases, and/or malignant tumors.

The Korean version of the visual analog scale (VAS) for measuring pain, the ASQoL questionnaire, and SF-36 were mailed to 120 individuals (36 women and 84 men) diagnosed with AS. The initial correspondence included an informed consent form, a study description, the Korean version of the VAS pain scale, the ASQoL questionnaire, the SF-36, and a stamped and addressed return envelope. The first set of surveys was done by 102 patients (31 women and 71 men). There were 5 women and 13 men among 18 patients who did not respond. With an average age of 35.2 years, 8 of them refused to cooperate because they did not agree with the purpose of the study, 8 others refused to respond to the questionnaire for privacy reasons, and the remaining 2 were not contacted. The second questionnaire had 98 respondents (30 women and 68 men). The average age of the 98 patients at the time of the survey was 35.8 years (range, 21–53 years). Among them, 4 patients (1 woman and 3 men) with an average age of 36.2 years did not respond: 2 refused to respond due to the inconvenience of the overlapping questionnaire, 1 did not answer due to transfer to another hospital, and 1 could not be contacted. Between the first and second surveys, the average time was 2 weeks.

Statistical Analysis

The ASQoL questionnaire's test/retest reliability has been validated by comparing the primary and secondary evaluations. To evaluate reliability, the intraclass correlation coefficient (ICC, 1) and statistics of agreement for each item were used. To evaluate intrinsic consistency, Cronbach's

α was used. The dimensionality of the ASQoL items was determined using factor analysis. Factor rotation was not performed. The percentages of participants with the lowest and highest prospective domain scores were utilized to compute the floor and ceiling effects. Pearson's correlation coefficients were used to assess concurrent and construct validity. The distribution of the floor and ceiling effects of the Korean version of the ASQoL survey has been obtained using the proportion of participants who received the lowest and highest scores. IBM SPSS ver. 16.0 (IBM Corp., Armonk, NY, USA) was used for all statistical analyses.

Table 1. Demographic Characteristics of the Study Population

| Variable | First survey | Second survey |
|--|--------------|---------------|
| Sex | | |
| Female | 31 (30.4) | 30 (30.6) |
| Male | 71 (69.6) | 68 (69.4) |
| Age (yr) | 35.3 ± 13.7 | 35.8 ± 14.5 |
| Body mass index (kg/m ²) | 22.9 ± 3.2 | 23.0 ± 3.1 |
| Disease duration (yr) | 11.4 ± 6.8 | 11.8 ± 6.2 |
| Family history of AS | 13 (12.7) | 12 (12.2) |
| Educational level | | |
| Middle school | 6 (5.9) | 4 (4.1) |
| High school | 65 (63.7) | 64 (65.3) |
| University | 31 (30.4) | 30 (30.6) |
| Profession | | |
| White collar | 26 (25.5) | 25 (25.5) |
| Blue collar | 34 (33.3) | 33 (33.7) |
| Intermediate level | 16 (15.7) | 15 (15.3) |
| Retired | 2 (2.0) | 2 (2.1) |
| Housewife | 20 (19.6) | 19 (19.4) |
| Unemployed | 4 (3.9) | 4 (4.0) |
| ASQoL questionnaire | 9.6 ± 4.3 | 9.7 ± 4.4 |
| SF-36 | 43.8 ± 19.6 | 43.3 ± 20.1 |
| VAS | 54 ± 26 | 55 ± 25 |
| Duration between the first and second survey (day) | 14.0 (9–21) | |

Values are presented as number (%), mean ± standard deviation, or median (range).

AS: ankylosing spondylitis, ASQoL: ankylosing spondylitis quality of life, SF-36: 36-Item Short Form Survey, VAS: visual analog scale.

RESULTS

This study includes a total of 120 Korean participants with AS, with 98 patients completing the secondary evaluation. The demographic features of the research groups are summarized in Table 1. The average scores for the ASQoL questionnaire, VAS, and SF-36 are shown in Table 2. The Korean version of the ASQoL's factor analysis found three major factors: pain, physical function, and mental function which explained 63.9% of the variance and had eigenvalues > 1 (Table 3). The first factor (pain) represents the limitations of daily life due to pain (items 5, 9, and 14). The second factor (physical function) assesses the restriction of physical activity due to morning stiffness, joint construction, or spinal deformity due to AS (items 1, 3, 4, 6, 8, 10, 11, and 16). The third factor (mental function) represents items related to subjective emotional states such as fatigue and depression due to AS (items 2, 7, 12, 13, 15, 17, and 18).

All the items of the Korean version of the ASQoL survey had statistics of agreement > 0.6 (range, 0.63–0.82).

Table 2. Average Scores on the ASQoL Questionnaire and SF-36 Domains

| Domain (no. of questions) | Mean ± SD |
|--------------------------------|-------------|
| ASQoL questionnaire | |
| Pain (3) | 1.5 ± 0.7 |
| Physical function (8) | 4.3 ± 2.1 |
| Mental function (7) | 3.7 ± 1.6 |
| ASQoL–total (18) | 9.7 ± 4.4 |
| SF-36 | |
| Physical functioning (10) | 42.9 ± 19.7 |
| Role–physical (4) | 50.2 ± 28.6 |
| Bodily pain (2) | 49.1 ± 13.9 |
| General health perceptions (5) | 48.4 ± 16.0 |
| Vitality (4) | 43.0 ± 19.6 |
| Social functioning (2) | 41.5 ± 20.3 |
| Role–emotional (3) | 36.0 ± 21.7 |
| Mental health index (5) | 37.6 ± 18.3 |
| Mental component score | 42.4 ± 20.1 |
| Physical component score | 45.9 ± 22.7 |

ASQoL: ankylosing spondylitis quality of life, SF-36: 36-Item Short Form Survey, SD: standard deviation.

Among the 18 items of the Korean version of the ASQoL questionnaire, the ICC of test/retest reliability was 0.814, with specific values of 0.844 for the domain of pain, 0.788 for the domain of physical function, and 0.737 for the domain of mental function (Table 4). Cronbach's α revealed very good internal consistency (Table 5).

Table 3. Factor Analysis

| | Pain | Physical function | Mental function |
|---|-------|-------------------|-----------------|
| My condition limits the places I can go to. | | 0.578 | |
| I sometimes feel like crying. | | | 0.655 |
| I have difficulty dressing. | | 0.743 | |
| I struggle to do jobs around the house. | | 0.663 | |
| It is impossible to sleep. | 0.654 | | |
| I am unable to join in activities with my friends/family. | | 0.698 | |
| I am tired all the time. | | | 0.498 |
| I have to keep stopping what I am doing to rest. | | 0.615 | |
| I have unbearable pain. | 0.849 | | |
| It takes long time to get going in the morning. | | 0.654 | |
| I am unable to do jobs around the house. | | 0.733 | |
| I get tired easily. | | | 0.516 |
| I often get frustrated. | | | 0.545 |
| The pain is always there. | 0.811 | | |
| I feel I miss out a lot. | | | 0.511 |
| I find it difficult to wash my hair. | | 0.712 | |
| My condition gets me down. | | | 0.605 |
| I worry about letting people down. | | | 0.599 |

Table 4. Test/Retest Reproducibility as Determined by the ICC (n = 98)

| Questionnaire | ICC (95% CI) |
|-------------------------|---------------------|
| ASQoL–total | 0.814 (0.787–0.845) |
| ASQoL–pain | 0.844 (0.811–0.883) |
| ASQoL–physical function | 0.788 (0.755–0.850) |
| ASQoL–mental function | 0.737 (0.710–0.814) |

ICC: intraclass correlation coefficient, CI: confidence interval, ASQoL: ankylosing spondylitis quality of life.

Table 5. Internal Consistency by Cronbach's α (n = 98)

| | |
|-------------------------|-------|
| ASQoL-total | 0.877 |
| ASQoL-pain | 0.895 |
| ASQoL-physical function | 0.876 |
| ASQoL-mental function | 0.731 |

ASQoL: ankylosing spondylitis quality of life.

By comparing Pearson's correlation coefficients to compare responses to the Korean version of the ASQoL questionnaire with VAS data, concurrent validity was determined. A positive correlation was found between the Korean version of the ASQoL questionnaire and VAS ($r = 0.691$, $p < 0.001$ for the 18 items of the Korean version of the ASQoL questionnaire; $r = 0.701$, $p < 0.001$ for pain domain; $r = 0.603$, $p < 0.001$ for the physical function domain; and $r = 0.556$, $p < 0.001$ for the mental function domain). Based on a comparison with the SF-36 questionnaire, Table 6 displays the construct validity. The correlation coefficient between the Korean version of the ASQoL questionnaire and SF-36 scores was -0.713 . A moderate to high negative correlation ($r = 0.5-0.8$) was obtained using convergent validity for the Korean version of the ASQoL questionnaire. Furthermore, a strong negative correlation was found between the pain score of the Korean version of the ASQoL questionnaire and the SF-36 body pain score ($r = -0.636$), the physical function score of the ASQoL questionnaire, the physical function score of SF-36 ($r = -0.699$), the mental function score of the ASQoL questionnaire, and the mental health score of SF-36 ($r = -0.533$). The correlation coefficients between the domain scores of the Korean version of the ASQoL questionnaire and other domain scores of SF-36 had relatively weak correlations ($r < 0.5$), demonstrating an adequate divergent validity. There was no ceiling or floor effect identified for the Korean version of the ASQoL questionnaire. Scores ranged from 2 to 15. Two patients had the best score (2), and one patient had the worst score (15).

DISCUSSION

In this study, through rigorous translation and adaptation, we developed a Korean-translated version of the ASQoL questionnaire. The final version of the Korean ASQoL survey was easily applicable to the patients and understandable by the patients. Based on the outcomes of the research, we suggest that the Korean version of ASQoL, with comparable reliability as other AS tools,⁸⁻¹³ shows decent

Table 6. Pearson's Correlation Coefficient of the ASQoL Questionnaire with the SF-36

| | ASQoL | Pain | Physical function | Mental function |
|----------------------|--------|--------|-------------------|-----------------|
| SF-36 | -0.713 | -0.617 | -0.699 | -0.548 |
| Physical functioning | -0.472 | -0.541 | -0.693 | -0.312 |
| Role physical | -0.418 | -0.508 | -0.557 | -0.298 |
| Bodily pain | -0.493 | -0.636 | -0.639 | -0.447 |
| General health | -0.391 | -0.406 | -0.445 | -0.375 |
| Vitality | -0.353 | -0.401 | -0.413 | -0.384 |
| Mental health | -0.287 | -0.412 | -0.378 | -0.533 |
| Role emotional | -0.418 | -0.443 | -0.451 | -0.401 |
| Social functioning | -0.464 | -0.414 | -0.448 | -0.436 |

All correlations are significant at the 0.001 level.
ASQoL: ankylosing spondylitis quality of life, SF-36: 36-Item Short Form Survey.

validity and reliability to estimate AS patient outcomes.

In terms of reproducibility, in this study, the kappa statistic values of each 18 items were larger than 0.6. The mean reproducibility of the other items would have been lower, if the first and second questionnaires had been directly achieved in a consultation time by the patient. The waiting period of several patients for consultation may have been longer than others, and to prevent this bias, a Korean version of the VAS was sent to AS patients with pain, along with the ASQoL questionnaire and SF-36. In this study, the overall consensus was favorable. As a measurement of the reliability of the Korean ASQoL questionnaire, we obtained an ICC value of 0.814, which is good. Because the clinical status of patients with chronic pain is unlikely to change without specific interventions in 1 or 2 weeks, the reliability of the survey related to functional status can be evaluated at intervals of 1 to 2 weeks. Patients with acute spinal fractures were therefore excluded.

A positive correlation between VAS and the Korean-translated ASQoL questionnaire was identified in the evaluation of concurrent validity. During the study for construct validity, we expected the ASQoL questionnaire could show correlations with QoL scales related to health. Thus, by evaluating the total score of SF-36 and the Korean version ASQoL survey, we determined construct validity. The total scores of the ASQoL questionnaire and three measures of each SF-36 domain were calculated. By the subscales, several domains of ASQoL and SF-36 showed stronger correlations than other functional domains,

which were the pain domain of the ASQoL questionnaire and the bodily pain domain of SF-36 ($r = -0.636$), the physical function domain of the ASQoL questionnaire and the physical function domain of SF-36 ($r = -0.693$), as well as the mental function domain of the ASQoL questionnaire and the mental health domain of SF-36 ($r = -0.533$).

The limitations of the research are the short duration time between the test and retest, and the small number of patients, which may have resulted in a positive bias to the reliability results. Although patients in the AS group were given medical treatment for at least a year, the group might be heterogeneous in terms of disease activity (Bath Ankylosing Spondylitis Disease Activity Index [BASDAI], and Ankylosing Spondylitis Disease Activity Score [ASDAS]), disease progression (modified Stoke Ankylosing Spondylitis Spinal Score [mSASSS]), severity of their deformities, and the ability to compensate for the deformities. Furthermore, we did not include interactions with BASDAI, ASDAS, mSASSS, and hematologic factors such as erythrocyte sedimentation rates or C-reactive protein levels in the analysis and did not conduct subgroup analysis according to the treatment methods (nonsteroidal anti-inflammatory drugs or biologic agent), which are important considerations in AS. In addition, the construct validity evaluated by comparison of SF-36 and ASQoL was not very convincing. Therefore, further well-organized multidisciplinary studies should be needed.

The Korean ASQoL version would be a valuable instrument to assess the impact of AS in Korean-speaking patients, with the cultural equivalence with the original

version permitting its use in the same fields. The establishment and verification of multilingual adaptations of existing surveys standardize outcome measurements and play a key role in improving clinical research regarding statistical capabilities.

The ASQoL questionnaire, in this study, can be properly interpreted into Korean without losing the psychological characteristics of the survey. As a result, we showed that the Korean-translated ASQoL questionnaire can be a reliable and effective measure of the functional status of patients with AS. Therefore, the Korean version of the ASQoL survey is recommended for utilization in future domestic clinical research.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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SUPPLEMENTARY MATERIAL

Supplementary material is available in the electronic version of this paper at the CiOS website, www.ecios.org

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