Cross-cultural adaptation and validation of the Korean version of the EQ-5D in patients with rheumatic diseases

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Abstract

Objectives: This study aimed to determine the cross-cultural adaptation and validation of the Korean version of the EQ-5D in rheumatic conditions. Methods: Translation, back-translation and cognitive debriefing were performed according to the EuroQol group’s guidelines. For validity, 508 patients were recruited and administered the EQ-5D, Short-Form 36 and condition-specific measures. Construct validity and sensitivity were evaluated by testing a-priori hypotheses. For reliability, another 57 patients repeated the EQ-5D at 1-week interval, and intra-class correlations (ICC) and kappa statistics were estimated. For responsiveness, another 60 patients repeated it at 12-week interval within the context of clinical trial, and standardized response mean (SRM) were calculated. Results: The cross-cultural adaptation produced no major modifications in the scale. The associations of the EQ-5D with the generic- and condition-specific measures were observed as expected in hypotheses: the higher EQ-5D index and EQ-5D VAS scores, the better health status by generic- or condition-specific measures, and the better functional class. The ICCs were 0.751 and 0.767, respectively, and kappa ranged from 0.455 to 0.772. The SRM were 0.649 and 0.410, respectively. Conclusion: The Korean EQ-5D exhibits good validity and sensitivity in various rheumatic conditions. Although its reliability and responsiveness were not excellent, it seems acceptable if condition-specific measures are applied together.

Key words: Quality of life, Reliability and validity, Rheumatic disease

Abbreviations: AS – ankylosing spondylitis; FMS – fibromyalgia syndrome; SF-36 – Health Survey Short-Form 36; OA – osteoarthritis; RA – rheumatoid arthritis; SRM – standardized response mean; SLE – systemic lupus erythematosus

The EQ-5D is one of the most widely used instruments for measuring utility, and now available in many major languages with cultural adaptations [1]. The Korean version is, however, not available yet. This study evaluated the cross-cultural adaptation and validation of the Korean version in rheumatic patients.

Methods

Translation and cross-cultural adaptation was done according to the EuroQol group’s guidelines. Two independent translators performed forward translation, followed by backward translation by another two translators. When the consensus
version was determined, cognitive debriefing was done by eight laypersons; three rheumatic patients and five healthy persons irrelevant to healthcare professions.

To assess validity, we consecutively recruited subjects at rheumatology clinics in Korea from December 2001 to April 2002. The American College of Rheumatology criteria were applied to diagnose fibromyalgia syndrome (FMS) [2], osteoarthritis (OA) [3], rheumatoid arthritis (RA) [4] and systemic lupus erythematosus (SLE) [5], while ankylosing spondylitis (AS) was diagnosed by the modified New York Criteria [6]. Finally, 508 patients participated; 90 AS, 104 FMS, 103 OA, 100 RA and 111 SLE patients.

For reliability, another 57 patients were re-recruited and repeated the questionnaires at 1-week interval. For responsiveness, another 60 RA patients repeated them at 12-week interval within the context of clinical trial.

The Health Survey Short-Form 36 (SF-36) as a generic measure, and condition-specific measures such as the Bath Ankylosing Spondylitis Functional Index [7], the Fibromyalgia Impact Questionnaire [8], Western Ontario and McMaster Universities OA index [9], and the Health Assessment Questionnaire for RA [10] were administered with the aid of research assistants. Among SLE patients, the SLE Disease Activity Index and the Systemic Lupus International Collaborating Clinics/ACR Damage Index were used [11, 12]. In all the condition-specific measures, a higher score indicates more severe status.

Validity was evaluated based on construct validity and sensitivity by testing a-priori hypotheses [13]. From the assumptions regarding relationship between the measures, we established the following hypotheses: (1) those with higher EQ-5D scores would have lower scores of condition-specific measures, indicating lower disease activity; (2) those with higher EQ-5D scores would also have a lower score of the first question of the SF-1, which means self-rated overall health; actually, we could not use other scales of the SF-36 as a reference, because the norm for Koreans is not available yet; (3) those in a better functional class would have higher EQ-5D scores; and (4) those reporting more problems in the physical dimensions of the EQ-5D would have higher scores of physical scales among condition-specific measures. These hypotheses were examined by Spearman correlations, Mann–Whitney or Kruskal–Wallis tests.

To evaluate reliability, it was assumed that the statuses between measurements did not change. For this, the data from the subjects whose scores of the SF-1 were the same at two measurements, 45 out of 57 patients, were analyzed. The test–retest reliabilities were evaluated by intra-class correlation (ICC), and interpreted as appropriate if they were greater than 0.7 or 0.9 for group and individual comparisons, respectively [13]. Additionally, the degree of agreement for its five dimension was evaluated by kappa statistics, which greater than 0.75 indicates excellent agreement, below 0.40 poor, and between 0.40 and 0.75 fair-to-good [14].

For responsiveness, the pre- and post-treatment scores were compared. We calculated internal responsiveness measures of the paired t statistic, effect size and standardized response mean (SRM). Values of effect size and SRM greater than 0.8 and less than 0.2 represent high and low responsiveness, respectively [15].

All analyses were performed using SAS version 8.1, and a probability of 0.05 was considered as statistically significance.

Results

The translation and adaptation produced only minor modifications to the original version. For instance, in the dimension of self-care, the first-level description ‘I have no problems with self-care’ was replaced with ‘I have no problems with washing or dressing myself’ as presented in the other two levels. The instruction box to be linked with the thermometer scale was changed to black-colored one at the suggestion of the EuroQol group.

Tables 1 and 2 show the general characteristics of the subjects for validity evaluation. Most of them were women except for AS group. Generally, AS and SLE patients were younger and more educated, while OA patients were older and less educated (Table 1). RA and OA patients exhibited relatively even distributions across four functional classes (see Table 4). Among five dimensions of the EQ-5D, the proportion of having any problem was the highest for pain/