

*Brief communication*

## 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<sub>index</sub> and EQ-5D<sub>VAS</sub> 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 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-36 (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/

**Table 1.** General characteristics of the study subjects for validation

| Characteristic (unit)             | Disease group <sup>a</sup> |                    |                   |                   |                   | Total              |
|-----------------------------------|----------------------------|--------------------|-------------------|-------------------|-------------------|--------------------|
|                                   | AS                         | FMS                | OA                | RA                | SLE               |                    |
| Number of subjects                | 90                         | 104                | 103               | 100               | 111               | 508                |
| Gender, female n (%)              | 12 (13.3)                  | 99 (95.2)          | 99 (96.1)         | 93 (93.0)         | 106 (95.5)        | 409 (80.5)         |
| Age, years mean ( $\pm$ SD)       | 28.4 ( $\pm$ 7.9)          | 49.3 ( $\pm$ 11.1) | 61.2 ( $\pm$ 6.7) | 51.7 ( $\pm$ 9.9) | 33.2 ( $\pm$ 9.9) | 45.0 ( $\pm$ 15.2) |
| Education, years mean ( $\pm$ SD) | 13.8 ( $\pm$ 2.2)          | 10.1 ( $\pm$ 3.9)  | 6.1 ( $\pm$ 3.5)  | 9.1 ( $\pm$ 3.9)  | 13.1 ( $\pm$ 2.5) | 10.4 ( $\pm$ 4.3)  |
| Co-morbidity, yes n (%)           | 27 (30.0)                  | 21 (20.2)          | 42 (40.8)         | 28 (28.0)         | 60 (54.1)         | 178 (35.0)         |

<sup>a</sup> AS – ankylosing spondylitis; FMS – fibromyalgia syndrome; OA – osteoarthritis; RA – rheumatoid arthritis; SLE – systemic lupus erythematosus.

**Table 2.** Descriptive statistics of EQ-5D and SF-1

| Measure  | Disease group <sup>a</sup> |                     |                     |                     |                     | <i>p</i> <sup>b</sup> | Total               |
|--|----------------------------|---------------------|---------------------|---------------------|---------------------|-----------------------|---------------------|
|  | AS                         | FMS                 | OA                  | RA                  | SLE                 |                       |                     |
| <i>Dimension of EQ-5D (% of patients with any problem)</i>       |                            |                     |                     |                     |                     |                       |                     |
| Mobility   | 47.8                       | 54.8                | 72.8                | 64.0                | 33.3                | <0.001                | 54.3                |
| Self-care  | 27.8                       | 30.8                | 28.2                | 33.0                | 16.2                | 0.056                 | 27.0                |
| Usual activity   | 61.1                       | 76.0                | 77.7                | 70.0                | 37.8                | <0.001                | 64.2                |
| Pain/discomfort  | 87.8                       | 93.3                | 92.2                | 80.0                | 65.8                | <0.001                | 83.5                |
| Anxiety/depression   | 50.0                       | 72.1                | 60.2                | 54.0                | 49.6                | 0.005                 | 56.3                |
| <i>EQ-5D<sub>index</sub> [median, interquartile range (IQR)]</i> |                            |                     |                     |                     |                     |                       |                     |
|  | 0.69<br>(0.59–0.80)        | 0.62<br>(0.52–0.73) | 0.62<br>(0.52–0.69) | 0.63<br>(0.52–0.76) | 0.73<br>(0.66–0.85) | <0.001                | 0.69<br>(0.52–0.76) |
| <i>EQ-5D<sub>VAS</sub> (median, IQR)</i>                         |                            |                     |                     |                     |                     |                       |                     |
|  | 60 (40–70)                 | 60 (40–70)          | 60 (50–70)          | 70 (50–80)          | 70 (50–80)          | <0.001                | 60 (50–79)          |
| <i>SF-1<sup>c</sup> (median, IQR)</i>                            |                            |                     |                     |                     |                     |                       |                     |
|  | 42 (3–4)                   | 4 (4–5)             | 4 (3–4)             | 4 (3–4)             | 3 (3–4)             | <0.001                | 4 (3–4)             |

<sup>a</sup> AS – ankylosing spondylitis; FMS – fibromyalgia syndrome; OA – osteoarthritis; RA – rheumatoid arthritis; SLE – systemic lupus erythematosus.

<sup>b</sup> By chi-square test or Kruskal–Wallis test.

<sup>c</sup> The first question of the SF-36, which measures overall health status.

discomfort (83.5%). OA patients mainly reported physical problems, while FMS patients chiefly reported pain and emotional ones. Differences among disease groups were statistically significant ( $p < 0.001$  for all). Overall, SLE patients showed the highest status, while FMS and OA patients showed the lowest ones (Table 2).

As for reliability and responsiveness, 87.7% and 94.1% of the patients were women, and their mean ages were 52.2 ( $\pm$ 10.8, SD) and 40.1 ( $\pm$ 9.8) years, respectively (data not shown).

For hypothesis 1, Table 3 shows the negative correlations between the EQ-5D and condition-specific measures except for SLE. Meanwhile, it

was positively correlated with the SF-1, as assumed by hypothesis 2 (Table 3).

Comparing the EQ-5D scores across functional classes for hypothesis 3, those with more limited function exhibited lower scores (Table 4).

Table 5 indicates that hypothesis 4 was proved; the subjects with any problem in the physical dimensions of the EQ-5D exhibited significantly higher scores of physical scales among condition-specific measures (Table 5).

The ICCs of the EQ-5D<sub>index</sub> and EQ-5D<sub>VAS</sub> at 1-week interval were 0.751 and 0.767, respectively. Agreement by kappa was the highest for anxiety/depression (Table 6).

**Table 3.** Spearman correlation coefficients of the EQ-5D with condition-specific measures and the SF-1 (hypotheses 1 and 2)

| Disease <sup>a</sup> | Measure <sup>b</sup> | EQ-5D                  |                       |
|----------------------|----------------------|------------------------|-----------------------|
|                      |                      | EQ-5D <sub>index</sub> | EQ-5D <sub>VAS</sub>  |
| AS                   | BASFI                | -0.634**               | -0.511**              |
| FMS                  | FIQ                  | -0.662**               | -0.550**              |
| OA                   | WOMAC – pain         | -0.419**               | -0.469**              |
|                      | WOMAC – stiffness    | -0.324**               | -0.410**              |
|                      | WOMAC – function     | -0.477**               | -0.462**              |
| RA                   | HAQ                  | -0.608**               | -0.389**              |
| SLE                  | SLEDAI-2K            | -0.026 <sup>n.s.</sup> | 0.014 <sup>n.s.</sup> |
|                      | SDI                  | -0.068 <sup>n.s.</sup> | -0.288*               |
| Total                | SF-1                 | -0.510**               | -0.518**              |

Note: \* $p < 0.01$ , \*\* $p < 0.001$ , n.s. – not significant.

<sup>a</sup> AS – ankylosing spondylitis; FMS – fibromyalgia syndrome; OA – osteoarthritis; RA – rheumatoid arthritis; SLE – systemic lupus erythematosus.

<sup>b</sup> BASFI – the Bath Ankylosing Spondylitis Functional Index; FIQ – the Fibromyalgia Impact Questionnaire; WOMAC – Western Ontario and McMaster Universities, HAQ, the Health Assessment Questionnaire; SLEDAI-2K – the Systemic Lupus Erythematosus Disease Activity Index; SDI – the Systemic Lupus International Collaborating Clinics/ACR Damage Index; SF-1 – the first question of the SF-36.

For responsiveness, the paired  $t$  statistic between pre- and post-treatment was statistically significant. The effect size and SRM of the EQ-5D<sub>index</sub> were higher than those of the EQ-5D<sub>VAS</sub> (Table 7).

**Table 4.** The EQ-5D scores across the functional classes (hypothesis 3)

| Disease <sup>a</sup> | Functional class | EQ-5D                  |                      |
|----------------------|------------------|------------------------|----------------------|
|                      |                  | EQ-5D <sub>index</sub> | EQ-5D <sub>VAS</sub> |
| OA                   | I (n = 15)       | 0.73 (0.62–1.00)       | 70.0 (50.0–80.0)     |
|                      | II (n = 22)      | 0.62 (0.62–0.69)       | 60.0 (50.0–70.0)     |
|                      | III (n = 43)     | 0.62 (0.59–0.69)       | 60.0 (50.0–70.0)     |
|                      | IV (n = 23)      | 0.52 (0.12–0.66)       | 50.0 (40.0–70.0)     |
|                      | $p^b$            | 0.0002                 | 0.0894               |
| RA                   | I (n = 14)       | 0.73 (0.73–0.85)       | 75.0 (70.0–80.0)     |
|                      | II (n = 25)      | 0.69 (0.62–0.73)       | 70.0 (50.0–80.0)     |
|                      | III (n = 32)     | 0.63 (0.55–0.75)       | 65.0 (45.0–70.0)     |
|                      | IV (n = 28)      | 0.52 (-0.01–0.62)      | 55.0 (50.0–70.0)     |
|                      | $p^b$            | 0.0001                 | 0.0513               |

Unit – median (IQR).

<sup>a</sup> OA – osteoarthritis; RA – rheumatoid arthritis.

<sup>b</sup> By Kruskal–Wallis test.

**Table 5.** Association between physical dimensions of the EQ-5D and physical scales among condition-specific measures (hypothesis 4)

| Dimension of EQ-5D |             | AS <sup>a</sup><br>[BASFI] <sup>b</sup> | OA <sup>a</sup><br>[WOMAC –<br>function] <sup>b</sup> | RA <sup>a</sup><br>[HAQ] <sup>b</sup> |
|--------------------|-------------|---|---|---------------------------------------|
| Mobility           | No problem  | 0.85<br>(0.23–1.96)                     | 9.5<br>(4.0–16.0)                                     | 0.50<br>(0.06–1.00)                   |
|                    | Any problem | 3.77<br>(1.91–5.38)                     | 23.0<br>(18.0–29.0)                                   | 0.88<br>(0.50–1.50)                   |
|                    | $p^c$       | < 0.0001                                | < 0.0001  | 0.0009                                |
| Self-care          | No problem  | 1.55<br>(0.33–2.43)                     | 18.0<br>(11.0–27.0)                                   | 0.50<br>(1.23–0.88)                   |
|                    | Any problem | 4.10<br>(2.59–5.74)                     | 23.0<br>(18.0–33.0)                                   | 1.50<br>(1.00–1.75)                   |
|                    | $p^c$       | < 0.0001                                | 0.0067  | < 0.0001                              |
| Usual activity     | No problem  | 0.56<br>(0.13–2.01)                     | 8.0<br>(4.0–14.0)                                     | 0.25<br>(0.00–0.75)                   |
|                    | Any problem | 2.76<br>(1.63–4.94)                     | 22.0<br>(17.0–29.0)                                   | 0.94<br>(0.63–1.50)                   |
|                    | $p^c$       | < 0.0001                                | < 0.0001  | < 0.0001                              |

Unit – median (IQR).

<sup>a</sup> AS – ankylosing spondylitis; OA – osteoarthritis; RA – rheumatoid arthritis.

<sup>b</sup> BASFI – the Bath Ankylosing Spondylitis Functional Index; WOMAC – Western Ontario and McMaster Universities, HAQ, the Health Assessment Questionnaire.

<sup>c</sup> By Mann–Whitney test.

## Discussion

The samples appeared as adequate for the study since not only the size was large, but also their sociodemographic profile was diverse and major rheumatic conditions were covered (Table 1).

Table 2 shows that the descriptive system could reveal different attributes of the conditions, and that the valuing scores differed clearly across disease groups. Also, a-priori hypotheses testing indicated that it had sufficient construct validity and sensitivity (Tables 3 and 4). Exceptionally, the condition-specific measures for SLE showed low correlations, which might be attributable to them being physician-rated indexes based on physical examination and laboratory findings [11, 12] rather than patients' own perception. However, it is not clear whether this is due to the property of the measures or the patients' characteristics. Actually, SLE patients reported the best status while those with FMS, which is considered as a milder condition, showed the worst one (Table 2). Therefore,

**Table 6.** Reliability of the EQ-5D between repeated measures at 1-week interval

| EQ-5D scores                       | First measure median (IQR) | Second measure median (IQR) | ICC (95% CI)          |
|------------------------------------|----------------------------|-----------------------------|-----------------------|
| <i>(1) Test-retest reliability</i> |                            |                             |                       |
| EQ-5D <sub>index</sub>             | 0.62 (0.34–0.73)           | 0.62 (0.39–0.69)            | 0.751 (0.590–0.855)   |
| EQ-5D <sub>VAS</sub>               | 60.0 (50.0–75.0)           | 70.0 (50.0–77.5)            | 0.767 (0.615–0.865)   |
| Dimensions of EQ-5D                | Kappa statistics (95% CI)  |                             | <i>p</i> <sup>a</sup> |
| <i>(2) Agreement</i>               |                            |                             |                       |
| Mobility                           | 0.665 (0.439–0.892)        |                             | 0.706                 |
| Self-care                          | 0.527 (0.271–0.784)        |                             | 1.000                 |
| Usual activity                     | 0.690 (0.461–0.918)        |                             | 0.414                 |
| Pain/discomfort                    | 0.455 (0.010–0.900)        |                             | 0.317                 |
| Anxiety/depression                 | 0.772 (0.585–0.959)        |                             | 0.180                 |

<sup>a</sup> By McNemar test.

**Table 7.** Responsiveness of the EQ-5D<sub>index</sub> and EQ-5D<sub>VAS</sub> between pre- and post-treatment

| Attribute                              | EQ-5D <sub>index</sub> | EQ-5D <sub>VAS</sub> |
|--|------------------------|----------------------|
| Pretreatment, mean ( $\pm$ SD)         | 0.38 ( $\pm$ 0.33)     | 54.8 ( $\pm$ 19.9)   |
| Post-treatment, mean ( $\pm$ SD)       | 0.59 ( $\pm$ 0.19)     | 65.8 ( $\pm$ 19.0)   |
| Difference, mean ( $\pm$ SD)           | 0.22 ( $\pm$ 0.33)     | 10.9 ( $\pm$ 26.6)   |
| Paired <i>t</i> statistic ( <i>p</i> ) | 4.94 (< 0.0001)        | 3.09 (0.0031)        |
| Effect size                            | 0.658                  | 0.548                |
| Standardized response mean             | 0.649                  | 0.410                |

determinants other than clinical characteristics should be investigated further. Moreover, the scores of the condition-specific measures with physical attributes clearly differed across the levels of physical dimensions, indicating that descriptive system could discriminate the degree of disease activity (Table 5).

Hurst et al. reported that among RA patients, the EQ-5D showed significant correlations with the condition-specific measure and had good sensitivity [16]. Others also have reported good validity in AS [17], SLE [18] and various rheumatic diseases [19].

ICCs of the EQ-5D<sub>index</sub> and EQ-5D<sub>VAS</sub> were relatively low for individual-level interpretation, but sufficient for group comparison. Our reliability seems reasonable compared with the previous results; among the patients with AS, OA or RA, the ICC of the EQ-5D<sub>index</sub> was reported to range from 0.70 to 0.83, and that of the EQ-5D<sub>VAS</sub> was 0.73 to 0.85 [16, 17, 20]. Additionally, agreement of each dimension was fair to good, or even excellent [14]. One study among rheumatic patients reported smaller kappa, ranging from 0.29 to 0.61 [19].

Responsiveness by effect size and SRM was moderate [15]. One study among RA patients reported relatively high responsiveness (i.e., 0.70 for the EQ-5D<sub>index</sub> and 0.71 for the EQ-5D<sub>VAS</sub>), even higher than condition-specific measures [16]. However, others argued that it had limited responsiveness in chronic moderate conditions [20], and recommended the EQ-5D for a surgical but not a rheumatology-clinic group [21]. Considering that the EQ-5D was originally developed as a simple and easy ‘add-on’ instrument [22], the responsiveness of the Korean version seems acceptable.

There are some limitations in this study. We used the UK tariff scores to calculate EQ-5D<sub>index</sub>. Previous studies reported that the preference structure differs between countries, and that a country’s own social value set is required [23, 24]. Actually, to determine whether the value set is appropriate for Koreans, we performed a pilot test, using Time Trade-Off and Standard Gamble. However, even young and highly educated subjects failed to understand the concept properly, and consequently the scores obtained from them did not show any significant correlations with other measures. This was attributable to the concept of ‘trade’ being unfamiliar to Koreans. However, further studies on the preference valuations among Koreans are required since the results of cost-effectiveness analyses vary depending on the valuation method [25].

In conclusion, our findings suggest that the Korean version of the EQ-5D had good validity and sensitivity in several rheumatic conditions. Also, its reliability and responsiveness were moderate to good. If it is used simultaneously with

other condition-specific measures, it can give more satisfactory results.

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