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ORIGINAL ARTICLE

Transcultural adaptation and psychometric properties of the Korean version of the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41)

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Abstract

Summary We translated and adapted transculturally the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41) for Korean patients. The translated Korean version of QUALEFFO-41 showed satisfactory reliability and validity.

Purpose The aim of this study was to translate the QUALEFFO-41 for Korean patients and then validate the Korean version of QUALEFFO-41.

Methods Translation and transcultural adaptation of the QUALEFFO-41 was conducted according to the international recommendations. Ninety-seven patients (mean age, 73.6 years) with osteoporosis were participated in validating the Korean version of QUALEFFO-41. To test reliability, internal consistency was evaluated using Cronbach's alpha coefficient. To test validity, convergent validity was assessed using correlation with the SF-12 and EQ-5D and discriminant validity was assessed using ROC curve analysis.

Results The English version of QUALEFFO-41 was translated and adapted to Korean without notable discrepancies. The Korean QUALEFFO-41 had good reliability with Cronbach's alpha ranging from 0.733 to 0.942. QUALEFFO-41 had good correlations to SF-12 and EQ-5D. Compared with subjects without history of vertebral fracture (VF), those with history of VF showed significantly worse scores according to QUALEFFO-41, but not according to SF-12 or EQ-5D. ROC curve analysis revealed that the physical function domain of QUALEFFO-41 had significant ability to discriminate between subjects with and without history of VF, while SF-12 or EQ-5D did not.

Conclusions The Korean version of QUALEFFO-41 demonstrated relevant internal consistency, convergent validity, and discriminant validity, which can be recommended to evaluate quality of life in Koreans.

Keywords Osteoporosis · Quality of life · Validation · QUALEFFO-41 · Korean

Introduction

Osteoporosis is a major health concern around the world [1]. It increases socioeconomic burden in the health care system worldwide [2, 3], and a large portion among the global burden of disease is composed of osteoporotic fracture [4, 5]. Moreover, osteoporotic fracture is an important cause of morbidity and mortality, particularly in the developed countries [6, 7]. Therefore, osteoporosis and osteoporotic fracture result in deterioration of physical and psychological function and in decrease in a patient's health-related quality of life (HRQoL) [8, 9].

Quality of life is an important parameter in evaluating the social burden and determining economic burden [10], and the quantitative measurement of QoL is also important in

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determining cost-effectiveness of some intervention for chronic disease such as osteoporosis [11, 12]. Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41) was developed in 1997 to evaluate HRQoL for patients with osteoporosis [13]. The questionnaire assesses quality of life in the aspect of pain, physical function, social function, general health, and mental health [13]. Nowadays, the QUALEFFO-41 is one of the most broadly used scoring systems to evaluate the HRQoL in patients with osteoporosis [14, 15] and has been shown to be reliable and valid [16].

The QUALEFFO-41 developed in European countries should be adapted cross-culturally to maintain the essential contents of the original version. In a recent study, quality of life assessed using QUALEFFO-41 differed between continents, countries, and ethnicities [17]. Although the QUALEFFO-41 is being used worldwide and has been translated into some languages, there is no Korean version of the QUALEFFO-41. Furthermore, no study has evaluated the QUALEFFO-41 in a Korean population.

The aim of this study was to translate and validate the QUALEFFO-41 questionnaire for Korean patients with osteoporosis to evaluate their functionality and quality of life.

Methods

Translation and transcultural adaptation of QUALEFFO-41 from English to Korean was done according to the standardized international recommendations [18]. Permission was obtained from the developer (IOF, International Osteoporosis Foundation) to use and translate the QUALEFFO-41 into Korean (https://www.iofbonehealth.org/quality-life-questionnaires-qualeffo-41). Then, testing of the psychometric properties of the questionnaire was conducted in patients with osteoporosis.

Translation and transcultural adaptation

Forward translation and reconciliation were done by two individuals (native Korean speakers fluent in English; one orthopedic surgeon and one non-orthopedic translator; professional interpreter). They independently translated the English version of QUALLEFO-41 into Korean. Then, at a consensus meeting with 3 orthopedic surgeons (YKL, YCH, and KHK), a single Korean version was made by reconciling these two Korean versions.

The reconciled Korean version was then back-translated into English by two bilingual native English speakers. They were Korean-Americans who were fluent in Korean (one medical personnel and the other a non-medical personnel) and were blinded to the original English version. To assess for harmonization, a consensus committee, consisted of the two translators, three orthopedic surgeons, one medical personnel, and a research assistant specialized in orthopedic scoring systems, reviewed the back-translated version and the original version of the QUALLEFO-41. Each committee member independently compared the two versions on an item-by-item basis and scored the equivalence with the originals semantically, idiomatically, experientially, and conceptually [18], as follows: "not equivalent at all" (0), "mildly equivalent" (1), "moderately equivalent" (2), "nearly equivalent" (3), and "totally equivalent" (4) [19–21]. After averaging the individual item scores, the translated Korean expressions for the items with an average equivalence score of less than 3 (nearly equivalent) were discussed and revised to establish the final Korean version of the QUALLEFO-41.

The final Korean version was pretested on 20 Korean outpatients visiting the orthopedic clinic at our institute. The patients completed the questionnaire and were then interviewed so that any possible difficulties in completing the questionnaire could be identified. When necessary, ambiguous expressions were modified after discussion.

Patients and data collection

The final draft of the Korean version was administered to patients diagnosed as osteoporosis at the orthopedic clinic of our institute (Seoul National University Bundang Hospital) between 2016 and 2017. Osteoporosis was confirmed using dual-energy X-ray absorptiometry (DXA) of the lumbar spine and/or the hip based on the World Health Organization criteria. The DXA results were expressed as bone mineral density (T-scores), and patients were diagnosed as osteoporosis if their T-scores were less than − 2.5. By review of electrical medical record, demographic and clinical data of the patients were collected. They included the following: age, age at menopause, body mass index (BMI), and presence of past history of vertebral fractures (VF). VF was confirmed by spine lateral radiograph.

Patients who fulfill all the inclusion criteria were invited by the clinical assistant to complete the questionnaires (Korean QUALEFFO-41, SF-12, and EQ-5D).

QUALEFFO-41 possesses five domains (41 items in total): pain (5 items), physical function (17 items), social function (7 items), general health perception (3 items), and mental function (9 items) (https://www.iofbonehealth.org/quality-life-questionnaires-qualeffo-41). The score of each domain is calculated as an average value of all the answered items linearly transformed on a scale 0–100. The total QUALEFFO score is calculated as a sum of all answers to items and then linearly transformed on the scale 0–100. The scoring algorithm is made in a way to calculate the total score proportionally to the answered items (when a missing value is present, the calculations are corrected according to the number of missing values). According to the scoring algorithm, the missing value should not have exceeded 30%; otherwise, the domain or the

Table 1 Characteristics of the study population

Number of subjects	97
Age (years)	73.6 ± 6.1 (62–83)
Age at menopause (years)	49.3 ± 5.5 (45–55)
BMI (kg/m^2)	22.6 ± 4.2 (12.6–34.4)
Number of vertebral fractures	0.6 ± 0.6 (0–2)

mean ± SD (range)

total score becomes inaccurate (https://www.iofbonehealth.org/quality-life-questionnaires-qualeffo-41) [22].

In addition to the Korean version of QUALEFFO-41, the patients simultaneously completed the Korean version of SF-12 and EQ-5D. The adaptation studies of SF-12 and EQ-5D for use in Korean patients were previously reported [23, 24]. They are self-assessment instruments and the score is calculated according to the user manual [25, 26]. The SF-12 ranges from 0 to 100, with higher scores indicating better conditions. The EQ-5D consists of two parts: a five-item questionnaire which has three answer options and a visual analogue scale (VAS) [25]. Through the answers from the questionnaire, EQ-5D health state value (HSV) was calculated according to the user manual and it ranges from 0 (the worst possible condition) to 1 (the best possible condition). The EQ-VAS score is the value that the patients mark the place that best reflects their current health status on a scale of 0 (the worst possible condition) to 100 (the best possible condition).

Statistical analysis

Demographics and clinical data of the patients were collected during the inclusion. According to the presence of past history of VF, patients were divided into two groups. For descriptive analysis, calculation of mean and standard deviation was done for each group.

After testing for normal distribution with the Kolmogorov-Smirnov test, the independent samples *t* test or Mann–Whitney *U* test was used for continuous variables.

To test the psychometric properties, internal consistency, convergent validity, and discriminant validity were evaluated.

The internal consistency is the degree of homogeneity of the items within each subscale. It was evaluated using Cronbach's alpha coefficient. Cronbach's alpha coefficient of 0.70 was considered satisfactory [27].

The convergent validity, which is a type of construct validity, suggests that the value of one parameter would have a quantitative relationship with another similar value of a different parameter. For the measurement of convergent validity, correlations between the results of QUALEFFO-41 subscales and the subscales of the SF-12 questionnaire and EQ-5D scores were evaluated using Spearman's rank correlation. Spearman's rho of > 0.50, 0.35~0.50, and < 0.35 was considered strong, moderate, and weak correlations, respectively [19, 28].

Discriminant validity was evaluated to find out if the questionnaire discriminates between two groups of patients who differed according to past history of VF. Area under curve (AUC) in receiver operating characteristic (ROC) curve analysis was obtained to compare the ability of QUALEFFO, SF- 12, and EQ5-D to discriminate between VF and non-VF groups.

Floor and ceiling effects, which can influence the reliability and validity, were calculated. When more than 15% of the respondents reached the highest or lowest possible score, floor and ceiling effects were considered present [29].

Statistical analysis was performed using SPSS version 15.0 (SPSS, Chicago, IL, USA), and *p* values of < 0.05 were considered significant.

Table 2 Comparison of the mean QUALEFFO-41, SF-12, and EQ-5D scores between the fracture group and the non-fracture group

	All patients ($n = 97$)	Fracture group ($n = 51$)	Non-fracture group ($n = 46$)	*p* value
QUALEFFO-41				
Pain (0~100)	20.8 ± 16.7	17.6 ± 16.4	24.3 ± 16.6	0.976
Physical function (0~100)	25.2 ± 19.0	32.3 ± 21.2	17.3 ± 12.1	< 0.001
Social function (0~100)	29.8 ± 24.2	33.0 ± 23.9	26.3 ± 24.3	0.291
Health function (0~100)	33.1 ± 20.9	35.8 ± 19.9	30.1 ± 21.2	0.429
Mental function (0~100)	40.1 ± 14.0	42.5 ± 13.9	37.4 ± 13.8	0.505
Overall (0~100)	36.0 ± 15.0	40.5 ± 15.8	30.9 ± 12.3	0.017
SF-12				
Physical (0~100)	44.3 ± 7.2	42.9 ± 7.2	45.9 ± 6.9	0.527
Mental (0~100)	48.5 ± 8.6	46.5 ± 8.0	50.6 ± 8.0	0.276
EQ-5D	0.81 ± 0.10	0.77 ± 0.08	0.85 ± 0.09	0.825
EQ-HSV (0~1)	0.81 ± 0.10	0.77 ± 0.08	0.85 ± 0.09	0.825
EQ-VAS (0~100)	62.8 ± 25.1	60.6 ± 25.5	63.9 ± 25.8	0.181

mean ± SD

Results

During the harmonization process for transcultural adaptation, the average of the transcultural equivalence scores was less than 3 (nearly equivalent) in two items ("How would you rate your overall quality of life compared with 10 years ago?" and "Do you feel full of energy?"). During the discussion for these items, the committee checked that the translation was comprehensive and verified the transcultural equivalence of the original English and final Korean versions.

Ninety-seven women who had osteoporosis (T-score ≤ − 2.5) were recruited for this study and completed the questionnaire. All women were independent outdoor ambulator without any assistance (Koval 1). The mean age of patients was 73.6 ± 6.1 years (range, 62–83) years, and the mean BMI was 22.6 ± 4.2 kg/m^2 (range, 12.6–34.4) (Table 1). Among the 97, 51 women with a history of previous VF were included in the fracture group (mean age 74.6 ± 5.3 years, range 62–82), and the remaining 46 women without a history of previous VF were included in the non-fracture group (mean age 72.4 ± 6.7 years, range 63–83). There was no significant difference of mean age between the two groups ($p = 0.085$).

Comparison of the mean QUALEFFO-41, SF-12, and EQ-5D scores between the fracture group and the control group is shown in Table 1. Patients with history of previous VF showed significantly lower scores in the physical function domain of QUALEFFO-41 ($p < 0.001$) and in the overall score ($p = 0.017$) compared with the non-fracture group, while SF-12 and EQ-5D resulted in no significant difference between the scores in the two groups (Table 2). Cronbach's alpha coefficient ranged from 0.733 to 0.942, which indicated the satisfactory internal consistency of each item (Table 3).

Strong correlations were observed between the physical function domain of QUALEFFO-41 and the physical domain of SF-12 ($r = -0.649$) and between the mental function domain of QUALEFFO-41 and the mental domain of SF-12 ($r = -0.527$), respectively. The correlation coefficients between other domains were moderate ($r = -0.328$~-0.538). Correlations with EQ-5D HSV showed strong correlations in the physical function domain ($r = -0.765$) and moderate or week correlations in other domains ($r = -0.267$~-0.525) (Table 4).

Table 4 shows the discriminate capacity of QUALEFFO-41, SF-12, and EQ-5D using a ROC curve analysis. While the pain domain showed a poor discriminative capacity (AUC = 0.360), the physical domain and the overall score of QUALEFFO-41 showed moderate level of capacity (AUC = 0.743 and 0.658, respectively). On the other hand, SF-12 and EQ-5D failed to discriminate for any domain (AUC range 0.296~0.374) (Table 5).

Any respondents did not present the lowest score and highest score, which means no floor or ceiling effect.

Table 3 Internal consistency of the QUALEFFO-41 questionnaire

QUALEFFO-41 subscales	Number of items	Cronbach's alpha coefficient[a]
Pain	5	0.798
Physical function	17	0.942
Social function	7	0.829
Health function	3	0.733
Mental function	9	0.789
Overall	41	0.931

[a] A value of 0.70 or above indicates adequate internal consistency

Table 4 Spearman's correlation coefficients between scores of domains of the QUALEFFO-41, SF-12, and EQ-5D

Domain of QUALEFFO-41	SF-12		EQ-5D	
	Physical	Mental	HSV	VAS
Pain	− 0.328**	− 0.133	− 0.267**	− 0.063
Physical function	− 0.649**	− 0.538**	− 0.765**	− 0.303**
Social function	− 0.363**	− 0.332**	− 0.525**	− 0.315**
Health function	− 0.418**	− 0.468**	− 0.429**	− 0.398**
Mental function	− 0.339**	− 0.527**	− 0.483**	− 0.568**
Total	− 0.647**	− 0.593**	− 0.763**	− 0.480**

*p value < 0.05

**p value< 0.01

Table 5 Area under curve (AUC) in receiver operating characteristic (ROC) curve for QUALEFFO, SF-12, and EQ-5D

	Area under curve	p value
QUALEFFO-41		
Pain	0.360 ± 0.059	0.019
Physical function	0.743 ± 0.050	< 0.001
Social function	0.595 ± 0.060	0.112
Health function	0.556 ± 0.060	0.352
Mental function	0.577 ± 0.060	0.196
Overall	0.658 ± 0.057	0.008
SF-12		
Physical	0.374 ± 0.058	0.035
Mental	0.359 ± 0.058	0.018
EQ-5D		
EQ-HSV	0.296 ± 0.054	0.001
EQ-VAS	0.458 ± 0.059	0.474

Discussion

The QUALEFFO-41 was translated into Korean language and a transcultural adaptation was performed in accordance with

Table 6 Internal consistency of several language versions of QUALEFFO-41

	Language	Pain	Physical function	Social function	Health function	Mental function
Nagammai et al. [27]	Malay	0.863	0.925	0.692	0.796	0.752
Kocyigit et al. [28]	Turkish	0.90	0.96	0.80	0.79	0.70
Azimi et al. [29]	Persian	0.78	0.81	0.79	0.71	0.78
De Oliveira et al. [31]	Portuguese	0.77	0.74	0.84	0.79	0.78
Rostom et al. [32]	Arabic	0.89	0.86	0.74	0.83	0.80
Current study	Korean	0.790	0.938	0.839	0.730	0.787

internationally published guidelines. Then, validity of the final Korean version was assessed. On the basis of our results, the Korean version of QUALEFFO-41 was found to be a reliable and a valid questionnaire for Korean patients, similar to other language versions of the QUALEFFO-41 [22, 30–35].

The internal consistency of the Korean version of QUALEFFO-41 was comparable with those observed in other language versions of the QUALEFFO-41 (Table 6) [30–34]. Cronbach's alpha coefficient was highest for the physical function subscale (0.942), which concurs with validation studies that were previously reported (0.96 in Turkish version and 0.925 in Malay version) [30, 31]. Although Cronbach's alpha coefficient of ≥ 0.7 indicates satisfactory internal consistency [36], a value that is excessively high implies that the items are redundant for a single subscale. Taking into account the high values of Cronbach's alpha coefficients (0.925~0.96) [30, 31], 17 items of the physical function subscale might have some redundant questions. Further studies on this issue will be necessary.

Regarding the convergent validity, the physical function domain of QUALEFFO-41 and the physical domain of SF-12 showed a satisfactory correlation, and the mental function domain of QUALEFFO-41 and the mental domain of SF-12 also showed a satisfactory correlation. These results were also observed in previous studies for other language versions [32, 34, 35].

Significant differences between the groups with and without history of VF were identified within the domains for physical function of QUALEFFO-41. This demonstrates the discriminative property of the tool considering that the generic SF-12 and EQ-5D tool could not discriminate the two groups. This discriminative property was also well reflected in the results of ROC analysis, which showed that the physical domain of QUALEFFO-41 was significantly predictive of previous history of VF, while the other domains of QUALEFFO-41, SF-12, and EQ-5D were not. The AUC values of 0.743 and 0.658 for the physical domain and the overall score of QUALEFFO-41, respectively, were comparable with those of other language versions [22, 32, 34, 35] (Table 7).

This study has limitations. First, we included a small number of patients. However, this number could be enough to determine reliability and validity of the Korean version of QUALEFFO-41. Second, we did not assess test-retest reliability showing reproducibility of measurement and sensitivity to change in this study. But other language versions of QUALEFFO-41 showed a satisfactory reproducibility [22, 30, 33, 37]. Third, we did not have a priori hypothesis for convergent/divergent validity. But our results on correlation between QUALEFFO-41 and SF-12/EQ-5D showed a satisfactory convergent validity.

Conclusion

In the present study, QUALEFFO-41 was translated and transculturally adapted to the Korean language according to international guidelines. Furthermore, the Korean version of the QUALEFFO-41 demonstrated relevant internal

Table 7 Discriminant validity of several language versions of QUALEFFO-41 using AUC

	Language	Pain	Physical function	Social function	Health function	Mental function	Overall
Azimi et al. [29]	Persian	0.674	0.785	0.741	0.685	0.685	0.72
Tadic et al. [30]	Serbian	0.62	0.75	0.69	0.65	0.67	0.74
Rostom et al. [32]	Arabic	0.785	0.829	0.696	0.764	0.706	NA
Perez et al. [22]	Spanish	0.585	0.729	0.720	0.516	0.606	NA
Current study	Korean	0.360	0.743	0.595	0.556	0.577	0.658

consistency, convergent validity, and discriminant validity, which was comparable with other languages.

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Compliance with ethical standards

Conflict of interest None.

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