



## Reliability and validity of the Turkish version of the ECOS 16 questionnaire in postmenopausal osteoporosis

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**Aim.** The purpose of this study was to develop a Turkish version of ECOS 16 Questionnaire and assess its reliability and validity.

**Methods.** Sixty four women with postmenopausal osteoporosis were included in the study. It was mandatory for all patients to be Turkish literate and without symptoms of dementia. Patients who were diagnosed as secondary osteoporosis by clinical and laboratory examinations were excluded from the study. After translation process, the Turkish version of the scale was applied to each participant twice with an interval of 2 weeks. For reliability study, internal consistency (Chronbach  $\alpha$ ) of ECOS 16 total score and test-retest intraclass correlation coefficient (ICC) were calculated. Validation study was assessed by correlating the scale with QUALEFFO 41.

**Results.** The mean age at menopause and age of patients were 45.61 $\pm$ 6.04 years and 59.91 $\pm$ 8.69 years respectively. Chronbach  $\alpha$  of the Turkish version of the ECOS 16 was 0.90. The test-retest reliability (ICC) of the Turkish version of the ECOS 16 was determined as 0.83 for the total score, and ranged between 0.72-0.88 for individual items. In terms of validity; the Turkish version of ECOS 16 correlated significantly with QUALEFFO 41 ( $r=0.844$   $P<0.0001$ ).

**Conclusion.** The Turkish version of the ECOS 16 is a reliable and valid questionnaire to be used in the evaluation of Turkish women with postmenopausal osteoporosis.

**KEY WORDS:** Osteoporosis - Quality of life - Questionnaires.

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In our era a marked increase in an average life span has occurred with the contribution of scientific, technological and socioeconomic advances and as a related consequence, the effects of many chronic diseases on quality of life have gained indisputable importance. Quality of life also includes environmental, educational and economical factors in addition to health status. Conventional therapeutic approaches of physicians aim at slowing down the progression of the disease, control of symptoms and prolonging survival. In recent years improvement in measures of patients' health status *i.e.* functional, psychological aspects and social welfare, in other words quality of life of the patient in chronic diseases owing to technological developments are being increasingly emphasized.

Osteoporosis is an important healthcare issue worldwide. Currently the most valid definition of osteoporosis is a systemic disease characterized with lower bone mass, deterioration in microarchitecture of the skeleton and related fragility of bones, and an increase in the risk of fracture mostly involving vertebrae, wrist and hip bones.<sup>1, 2</sup> However this definition is inadequate within the context of detailed information related to the impact of osteoporotic fractures on patient's quality of life. Osteoporosis should not be defined only as a loss of bone mass. In

fact this entity is an important clinical syndrome which causes many problems with respect to functional status and quality of life. In osteoporosis vertebra, hip and wrist fractures are common. Osteoporotic vertebral fractures represent the most common type of osteoporotic fracture. They can cause significant morbidity and mortality, including physical, functional, and psychosocial impairments.<sup>3, 4</sup> Vertebral fractures often can not be detected clinically, but lead to low back pain and functional restriction. Effect the quality of life substantially.<sup>5</sup> However some studies report lesser impact of osteoporosis on quality of life measures.<sup>6, 7</sup>

Various instruments have been used to evaluate quality of life. The instrument to be used for the monitorization of osteoporotic patients has not been precisely defined. In addition to instruments assessing quality of life in general, disease specific instruments have been also developed. Among measures specific to osteoporosis, Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO), Osteoporosis Quality of Life Questionnaire (OQLQ), mini-OQLQ, ECOS 16, Osteoporosis Assessment Questionnaire (OPAQ), Osteoporosis Functional Disability Questionnaire (OFDQ) can be exemplified.

ECOS 16 has been developed to evaluate quality of life in postmenopausal osteoporotic patients. This questionnaire has been formulated based on osteoporosis specific quality of life forms as QUALEFFO<sup>8</sup> and OQLQ.<sup>9</sup> In a study where these two questionnaires were compared, their reliability and convergent validity were found to be identical.<sup>10</sup> ECOS 16 questionnaire contains 12 items from QUALEFFO and 4 items from OQLQ. The 16 items in the ECOS 16 are divided in four dimensions including physical functioning, pain, fear of illness and psychosocial function. Each item comprises of 5 options of response. Scores vary between 1 and 5 points, 1 represent the best and 5 the worst QoL score.<sup>11</sup>

The aim of this study was to translate ECOS 16 into Turkish, to adapt it for Turkish population, and to determine its reliability and validity.

## Materials and methods

### Subjects

Sixty-four female patients with postmenopausal osteoporosis being followed at the outpatient clinic of

the physical and medicine rehabilitation (PMR) department of the hospital were enrolled in this study. Osteoporosis was diagnosed by using dual-energy X-ray absorptiometry (DXA), based on the criteria established by World Health Organization (WHO) (spine or hip t scores <-2.5).<sup>12</sup> The patients had at least one vertebral fracture (reduction of anterior, middle or posterior vertebral height of more than 20% on radiographs).<sup>13</sup> The participants without any evidence of dementia were required to be able to read and write in Turkish. Patients diagnosed with physical examination and laboratory tests as secondary osteoporosis, endstage renal failure, heart failure, and those having any malignancy were excluded. After completion of the translation procedure, the participants filled up the questionnaire two times at 2 week intervals. The second investigation was performed 2 weeks later to retest the participant.

To test reliability, internal consistency of ECOS total score (Cronbach  $\alpha$ ) and test-retest intraclass correlation coefficient (ICC) were calculated. Validity was evaluated with determination of essential similarity to QUALEFFO 41 whose reliability and validity of its English version have been established.

### PARAMETERS OF EVALUATION

On the first physical examination patient's age, menopausal age, level of education, profession, presence of nocturnal pains, pain on movement and /or during rest were interrogated and recorded. Likert scale was used for the assessment of pain (1=no pain, 2=mild, 3=moderate, 4=severe, 5=unbearable).

Patient's quality of life was evaluated using QUALEFFO questionnaire. This form is one of the osteoporosis specific QoL scales whose validation of the Turkish version has been fully investigated.<sup>11</sup> In the Turkish reliability study, internal consistency (Cronbach's alpha) was between 0.70 and 0.96 and the validity rates of domains were between 89% and 100%.<sup>14</sup> QUALEFFO questionnaire consists of totally 41 questions at subscales of pain (5 questions), physical function (17 questions), social function (7 questions), general assessment of general health state (3 questions) and mental function (9 questions). For total scores and subscale scores "0" represents "good" and 100 worst health condition.<sup>14</sup>

### TRANSLATION PROCEDURE

For translation and cross-cultural adaptation previously published recommendations of Guillemin

*et al.*,<sup>15</sup> Baeton *et al.*<sup>16</sup> and EORTC Quality of Life Group<sup>17</sup> were utilized.

At the first step for forward translation two Turkish native speaker specialists well versed in English, translated the scale independently from English into Turkish. The differences in-between was resolved during a session with the participation of a third translator.

At the second step back translation was realized. Turkish version of the scale was translated by two English-speaking linguists who were blinded to the original scale and the aim of the study. The differences were resolved and a satisfactory concordance with the original scale was achieved with a meeting session among five translators.

#### RELIABILITY AND VALIDATION STUDY

For the studies of reliability, internal consistency of ECOS 16 total score (Chronbach  $\alpha$ ) and test-retest ICC were estimated. To test reliability of the Turkish version of ECOS 16 final version was applied on 64 participants. For test-retest study the same procedure was repeated 2 weeks later and ICC was estimated.

For ECOS 16 total score Chronbach  $\alpha$  value, for test-retest ICC and Spearman correlation were estimated.

To estimate converging validity ECOS 16 was correlated with QUALEFFO. Since validation of the Turkish version of osteoporosis specific QoL scale *i.e.* QUALEFFO questionnaire was realized previously, the authors have used this form in their study. The converging validity of ECOS 16 using QUALEFFO questionnaire was determined.

In all statistical analyses, a value of correlation coefficient between 0 and 0.25 was regarded as "no or poor" correlation; 0.26-0.50 was regarded as "moderate" correlation; 0.51-0.75 was regarded as "good" correlation and 0.76-1.00 was regarded as "very good" correlation.

#### Statistical analysis

All statistical analyses were performed with the NCSS 2007 package program. Besides descriptive statistically methods (mean $\pm$ standard deviation), reliability studies were performed by internal consistency (Cronbach's  $\alpha$ ) and test-retest reliability. Cronbach's  $\alpha$  was used for total score and, if Cronbach's  $\alpha$  value was greater than 0.7, it was considered as an acceptable internal consistency. Test-

retest reliability was assessed by determining the intraclass correlation coefficient (ICC) and confidence interval (95%). The consistency of each item between two successive tests was measured by Spearman's correlation test. A validation study was performed with converging relationships between ECOS 16 and QUALEFFO. A level of  $P < 0.05$  was considered statistically significant.

## Results

Mean age ( $\pm$ SD) of 64 female participants was 59.91 $\pm$ 8.69 years (min 45-max 80 years) mean age of entering menopause was 45.61 $\pm$ 6.04 years (min 35-max 57 years). Initial BMD and t score for lumbar vertebra were 0.81 $\pm$ 0.09, -3.09 $\pm$ 0.7 respectively. Same measures for femur were 0.72 $\pm$ 0.11, -2.08 $\pm$ 0.87 respectively. Antiresorptive treatment and calcium (1 000 mg/day), vitamin D (880 IU) supplementation were given all patients. The study population included housewives (N=54), a worker (N=1), public officers (N=19 and veterans (N=8). Twenty participants were literate (31.25%), and 36 subjects were primary (56.25%), and 8 high school (12.5%) graduates. According to Likert scale the estimated scores for nocturnal pain, pain on movement and during rest were 2.41 $\pm$ 1.29, 2.59 $\pm$ 1.12 and 1.97 $\pm$ 1.02 points, respectively (Table I).

#### Reliability and validity study

Internal consistencies (Cronbach's  $\alpha$ ) of the ECOS 16 total score was 0.90 (Table II). Test-retest reliability results are shown in Table III. For test-retest reliability assessments, the ICC of ECOS 16 total score was 0.83, ranging between 0.72-0.88 points among items (Table III). For test-retest reliability evaluations, Spearman's

TABLE I.—Demographic data of patients.

	Mean $\pm$ SD
Age (year)	59.91 $\pm$ 8.69
Age of menopause (year)	45.61 $\pm$ 6.04
BMI	26.05 $\pm$ 4.06
Night pain (Likert)	2.41 $\pm$ 1.29
Motion pain (Likert)	2.59 $\pm$ 1.12
Rest pain (Likert)	1.97 $\pm$ 1.02

BMI: Body Mass Index

TABLE II.—Cronbach's  $\alpha$  coefficients of ECOS 16 and QUALEFFO total score.

	Cronbach's $\alpha$
ECOS-16 Total	0.900
QUALEFFO Total	0.862
Pain	0.889
Physical function	0.940
General health	0.844
Social function	0.859
Mentally health	0.861

BMI: Body Mass Index.

correlation coefficient of items varied between 0.34-0.70, and the total score was 0.71.

Psychometric measure results for Turkish, Italian and Spanish version of ECOS-16 are shown in Table III.

When assessed for converging validity, significant and positively strong correlations were detected between ECOS 16 total scores and QUALEFFO total and domains of pain, physical and social functions, general and mentally health scores ( $P < 0.0001$ ) (Table IV). Besides a strongly significant positive correlation between ECOS 16 total score and nocturnal pain, pain on movement and during rest as evaluated by Likert was found ( $P < 0.0001$ ) (Table IV).

## Discussion

Diseases involving musculoskeletal system incur changes on general health status and affect quality of life of the patient adversely. During the evaluation process of the patient, investigation of the degree of their impact on patient's quality of life, the magnitude of restriction of his/her daily activities, and alterations of patient's psychosocial state plays an important role in current medical practice. Thus generic and specific QoL measures have been developed for the evaluation of diseases. In a study by Picavet *et al.* where 12 different musculoskeletal conditions (discal hernia, gout, repetitive strain injury, epicondylitis, knee osteoarthritis, hip osteoarthritis, osteoporosis, whiplash injury, rheumatoid arthritis, other chronic arthritis, fibromyalgia, tendinitis and capsulitis) had been evaluated, the authors stated that primarily patients with musculoskeletal diseases have a worse QoL when compared with that of general population, and they also found that among musculoskeletal diseases, knee and hip osteoarthritis, rheumatoid arthritis, osteoporosis and fibromyalgia had the worst scores for pain and physical functioning.<sup>18</sup> In the aforementioned study generic QoL measures were used.

Osteoporosis should not be defined as loss of bone mass. In fact it is a clinical syndrome which leads to

TABLE III.—Test-retest reliability, and Spearman's correlation coefficients related to grand total scores of each ECOS-16 item.

	Test-retest reliability (intraclass correlation)	Spearman correlation	Mean $\pm$ SD
ECOS 1	0.72	0.72 (0.64-0.83)	3.27 $\pm$ 1.5
ECOS 2	0.81	0.81 (0.79-0.89)	2.63 $\pm$ 1.08
ECOS 3	0.77	0.77 (0.66-0.80)	2.92 $\pm$ 1.11
ECOS 4	0.88	0.88 (0.82-0.94)	2.53 $\pm$ 1.16
ECOS 5	0.81	0.81 (0.79-0.89)	2.52 $\pm$ 1.68
ECOS 6	0.74	0.74 (0.67-0.84)	2.67 $\pm$ 1.12
ECOS 7	0.81	0.81 (0.68-0.88)	1.96 $\pm$ 0.91
ECOS 8	0.88	0.88 (0.78-0.91)	1.77 $\pm$ 0.83
ECOS 9	0.83	0.83 (0.79-0.91)	2.37 $\pm$ 1.14
ECOS 10	0.86	0.86 (0.82-0.95)	2.28 $\pm$ 1.11
ECOS 11	0.87	0.87 (0.81-0.91)	2 $\pm$ 1.08
ECOS 12	0.81	0.81 (0.74-0.87)	2.78 $\pm$ 1.2
ECOS 13	0.80	0.80 (0.75-0.85)	2.77 $\pm$ 1.11
ECOS 14	0.86	0.86 (0.76-0.90)	2.54 $\pm$ 1.16
ECOS 15	0.81	0.81 (0.75-0.86)	2.58 $\pm$ 1.33
ECOS 16	0.88	0.88 (0.77-0.87)	2.65 $\pm$ 1.43
ECOS Total	0.83	0.83 (0.72-0.90)	2.52 $\pm$ 0.762

TABLE IV.—*Converging validity of ECOS 16 total scores with those of QUALEFFO 41 and Likert.*

		ECOS16 Total
Pain	r	0.83
	P	0.0001
Physical function	r	0.793
	P	0.0001
General health	r	0.307
	P	0.0001
Social function	r	0.494
	P	0.0001
Mentaly Health	r	0.488
	P	0.0001
QLF 41 total	r	0.844
	P	0.0001
Likert (night pain)	r	0.611
	P	0.0001
Likert (motion pain)	r	0.473
	P	0.0001
Likert (rest pain)	r	0.438
	P	0.0001

many problems regarding functional state and quality of life. Despite usage of various generic quality of life forms for the evaluation of QoLs of osteoporotic patients (*i.e.* SF-36, Nottingham Health Profile), clinicians tend to use specific QoL measures because of inadequacy of these general QoL scales to inquire patients' fear of fall from a height and occurrence of fractures, and inability to achieve domestic chores from which most of the osteoporotic patients suffer. In the authors' previous study four different types of musculoskeletal diseases were analyzed using SF-36, the authors found that the QoLs of osteoporotic patients were relatively less deteriorated when compared with those of patients with knee osteoarthritis and fibromyalgia.<sup>19</sup> This finding subsequently suggested that usage of generic QoL questionnaires might be effective. If perhaps disease specific QoL questionnaires were used for the evaluation of osteoporotic patients, their quality of life might demonstrate similar rates of deterioration. For this reason, specific quality of life questionnaires are thought to yield more detailed and specific information. Among specific quality of life inquiry forms, QUALEFFO and OQLQ have been used in osteoporosis. However longevity of these forms which take up much more time to complete, restricts their clinical usage. Therefore nowadays the need for

shorter, easily applicable, and more practical specific questionnaires have arisen.

ECOS 16 is a shorter QoL questionnaire which has been developed to evaluate quality of life in postmenopausal osteoporotic patients.<sup>11</sup> This form has been formulated based on 2 QoL forms specific to osteoporosis *i.e.* QUALEFFO<sup>8</sup> and OQLQ.<sup>9</sup> This inquiry form contains items from QUALEFFO (N=12) and OQLQ (N=4). Each item has 5 response options. For each item, scores change between 1 and 5. One point represent the best and 4 the worst QoL score.<sup>11</sup> Its beneficial role in both researches and routine clinical usage has been demonstrated in the evaluations of QoLs of postmenopausal osteoporotic patients.<sup>20</sup> ECOS 16 has a Cronbach  $\alpha$  coefficient of 0.92 with a relatively higher internal consistency. Its intraclass correlation coefficient was found to be 0.80.<sup>20</sup> The validity and reliability studies of its Italian version have been performed.<sup>21</sup> In the Italian study conducted by Salaffi *et al.* the internal consistency of ECOS 16 was generally good for all subscales with Cronbach  $\alpha$  values between 0.81 and 0.89. Test-retest reliability for total ECOS 16 score was 0.87.<sup>21</sup> Accordingly our aim was to translate ECOS 16 inquiry form which is easier to use in clinical practice into Turkish, and also perform its validity-reliability tests. In our study Turkish version of ECOS 16 was found to possess relatively higher internal consistency (Cronbach  $\alpha$  coefficient 0.90). For test-retest reliability assessments, the ICC of ECOS 16 total score was 0.83, ranging between 0.72-0.88 points among items. When assessed for converging validity, significant and positively strong correlations were detected between ECOS 16 total scores and QUALEFFO total scores ( $r=0.844$ ,  $P<0.0001$ ).

The results of this study indicate that the Turkish version of ECOS 16 is a reproducible, reliable and validated assessment tool for quality of life in postmenopausal osteoporosis.

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