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Reliability and validity of Family Caregiver Quality of Life Scale in heart failure

Kalp yetersizliğinde Aile Bakım Verici Yaşam Kalitesi Ölçeği'nin güvenirlik ve geçerliği

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ABSTRACT

Background: In this study, the Family Caregiver Quality of Life scale developed specifically for family caregivers of heart failure patients was translated into the Turkish language, and its reliability and validity was performed.

Methods: The scale was first translated into Turkish and back-translated, adapting it to the Turkish culture. The Turkish questionnaire of the scale was applied to 200 family caregivers. To evaluate the reliability of the scale and all subscales, test-retest was applied, and the Cronbach's alpha reliability coefficients were calculated. The structural validity of the scale was examined through the factor analysis.

Results: The internal consistency reliability (α=0.82) of the Turkish Questionnaire of the scale was proved. Two-week test-retest reliability was supported by an intraclass correlation coefficient of 0.91. The questionnaire's factor structure demonstrated acceptable fit, indicating that it could be applied to the Turkish population. The item loads found by the factor analysis ranged from 0.32 to 0.99, explaining %63 of the variance (eigenvalue=2.61-4.06). Criterion-related validity was supported by correlations with the Short Form-36 General (r=0.473, p<0.01) and Mental (r=0.406; p<0.01) Health subscales.

Conclusion: The Turkish version of this scale can measure the quality of life of family caregivers of heart failure patients with adequate reliability and validity.

Keywords: Family caregiver; health failure; quality of life scale.

ÖZ

Amaç: Bu çalışmada, kalp yetersizliği olan hastaların aile bakım vericilerine özgü geliştirilen Aile Bakım Verici Yaşam Kalitesi Ölçeği Türkçe diline çevrildi ve güvenirlik ve geçerliği yapıldı.

Çalışma planı: Ölçek önce Türkçeye çevrildi ve geri çevirisi yapılarak Türk kültürüne uyarlandı. Ölçeğin Türkçe soru formu 200 aile bakım vericiye uygulandı. Ölçeğin ve alt ölçeklerin güvenirliğini değerlendirmek için test-yeniden test yapıldı ve Cronbach alpha güvenirlik katsayıları hesaplandı. Ölçeğin yapı geçerliği faktör analizi ile incelendi.

Bulgular: Ölçeğin Türkçe soru formunun iç tutarlılık güvenirliği (α=0.82) kanıtlandı. İki haftalık test-yeniden test güvenirliği, 0.91'lik sınıf içi korelasyon katsayısı ile desteklendi. Soru formunun faktör yapısı Türk toplumuna uygulanabileceği anlamına gelen kabul edilebilir bir uyum sergiledi. Faktör analizi ile bulunan madde yükleri varyansın %63'ünü (özdeğer=2.61-4.06) açıklayarak, 0.32 ile 0.99 arasında değişiklik gösterdi. Kritere bağlı geçerlik, Kısa Form-36 Genel (r=0.473, p<0.01) ve Mental (r=0.406; p<0.01) Sağlık alt ölçekleri ile korelasyonlarla desteklendi.

Sonuç: Yeterli güvenirlik ve geçerliğe sahip bu ölçeğin Türkçe versiyonu, kalp yetersizliği olan hastaların aile bakım vericilerinin yaşam kalitesini ölçebilir.

Anahtar sözcükler: Aile bakım verici; kalp yetersizliği; yaşam kalitesi ölçeği.

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Heart failure (HF) is a global public health issue affecting about 26 million individuals worldwide. There are reported to be 15 million HF patients in Europe, 5.7 million in the USA,[1] and two million in Turkey,[2] and chronic diseases have been shown to increase with increased life spans.[1,3]

Heart failure is associated with frequent hospitalizations, morbidity and mortality, high cost of care, and low quality of life (QoL).[1,4] It seriously affects not only patients, but also their families.[5-7] These patients experience several physical and emotional complaints, such as dyspnea, fatigue, edema, sleep disorders, depression, and chest pain which limit their daily physical and social activities; therefore, they require the help of a family caregiver to combat the disease and to meet their self-care requirements.[4-6,8]

In addition to its negative emotional and physical effects,[6,7] the associated low QoL of being a caregiver of a HF patient has been demonstrated.[6,9-11] Moreover, it was reported that the mortality rate is about 63% higher in caregiver spouses than in non-caregivers,[12] and the risk of coronary heart disease increases by 82% in caregivers who care for a patient spouse.[13] In this case, the caregiver is the mostly affected individual by chronic diseases, besides the patient.[5,14]

As chronic diseases has increased need for care, a holistic approach by the healthcare professionals to the patient and the family caregiver, with an assessment of QoL of these individuals, may positively affect the well-being of both the caregiver and the patient.[5,14] Although many studies have been conducted to assess the QoL of HF family caregivers until now,[6,7,9] a systematic review that examined caregiver experience have shown that scales developed for other patient populations do not fully evaluate this population.[15] Moreover, studies on caregivers of cancer patients have demonstrated that population-specific scale is more responsive to mental health problems of caregivers than the Short Form-36 (SF-36), which is a generic QoL scale.[16,17] These results indicate the importance of a caregiver-specific assessment tool to correctly evaluate the QoL in HF family caregivers.

It is of utmost importance that healthcare professionals intervene to support caregivers in their difficult tasks. However, a reliable and valid assessment tool that is specific to this population is needed to measure the adequacy of such interventions. Unfortunately, since no such assessment tool has been developed or translated into Turkish, systematic evaluation of the QoL of HF family caregivers and functionality are still lacking. Although the psychometric properties of the Family Caregiver Quality of Life (FAMQOL) have been established,[3] scale validation has not been conducted in the Turkish population. In the present study, therefore, we aimed to adapt the FAMQOL scale developed to assess the QoL of family caregivers of HF patients into the Turkish language and test its reliability and validity.

PATIENTS AND METHODS

This methodological study was conducted on the family caregivers of patients who were being treated with the diagnosis of HF in the cardiovascular surgery wards of Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital between 01.06.2015 and 31.08.2015. While there is no established consensus for the sample size required for intercultural adaptation of a scale, it has been reported that the sample size should be 10 times the number of items of the scale and not less than 200.[18] Considering that the FAMQOL comprises 16 items, a sample size of 200 was deemed appropriate. Inclusion criteria were as follows: being age 18 or above, ability to communicate in Turkish, and being volunteer to participate in the study. The exclusion criterion was the presence of any cognitive/speech disorder.

Before the data collection, permission for use of the scale was taken from Nauser et al.[3] who developed the original scale. The Ethics Committee for Marmara University Institute of Medical Sciences approved the study with no. 26.01.2015/12. The study was also approved by the institution at which the study was conducted (13.02.2015/1387). A written informed consent was obtained from each participant. The study was conducted in accordance with the principles of Declaration of Helsinki.

The data were collected using the Demographic Characteristics Questionnaire, the FAMQOL Scale Turkish Questionnaire, and the General Health and Mental Health subscales of the SF-36 QoL Scale.

The Family Caregiver Quality of LifeScale

The scale assesses the physical, psychological, social and spiritual well-being of family caregivers affected by their caregiving responsibilities. The scale which contains 16 items in total can be used in part as physical (items 1, 5, 8 and 9), psychological (items 2, 3, 4 and 6), social (items 7, 10, 11 and 12) and spiritual (items 13, 14, 15 and 16) well-being subscales as well as general QoL. It is a five-point Likert-type scale with replies ranging from “strongly disagree” to “strongly agree”. After applying reverse scoring for the negative

items (items from 1 to 7), the scores of each item are summed. Total score of each subscale can be 4 at minimum and 20 at maximum, and total score can be 16 at minimum and 80 at maximum. Higher scores are indicative of better QoL. FAMQOL, which is a short and easily applicable scale, can be applied via phone or by the participants themselves. The internal consistency, test-retest reliability, and structure and measure validity of the scale are applicable to the general scale as well as the three subscales which contain physical, psychological and social well-being.[3]

The Short Form 36 Quality of Life Scale

Short Form-36 is a generic QoL scale for which the reliability and validity in Turkish community were tested by Kocyigit et al.[19] in 1999. In this study, the SF-36 General Health and Mental Health subscales were used to evaluate the criterion validity of the FAMQOL Turkish questionnaire.

The General Health subscale consists of four statements about General Health, with five-point response scales from definitely true to definitely false and one statement about their health rating from excellent to poor. The Mental Health subscale (5 items) is a five-point Likert-type scale that contains the frequency of various emotions from "all of the time" to "none of the time". Scores from each subscale can be 0 at minimum and 100 at maximum. Higher general health and mental health subscale scores indicate a better state.[19]

Translation into Turkish and Assessing the Forward Translation. In the first phase, the original of the scale was translated from English into Turkish by three bilingual academicians. In the second phase, another native Turkish-speaker fluent in English evaluated the three translated versions and consolidated them into a single version. In the third phase, this version was back-translated into English by another bilingual specialist who did not see the original form of the questionnaire. In the fourth phase, another specialist reviewed the assessment of the backward-translated version. This process focused on the conceptual equivalence to the original FAMQOL. Subsequently, to determine content validity of the FAMQOL Turkish questionnaire, it was submitted to 12 academicians having at least doctorate degree who are specialists in their fields for feedback. Items were scored as follows: "1= item is not appropriate," "2= item needs to be changed," "3= item is appropriate but need minor corrections," and "4= item is well suited." After obtaining their feedbacks, content validity index (CVI) was calculated using the Davis technique.[20] In this study, CVI was found to be 0.83 which transpates to suitable content validity.[20]

A pilot study was conducted on 50 HF family caregivers at cardiovascular surgery clinics using the FAMQOL Turkish pre-final questionnaire. No issues were faced in the application of the questionnaire, and none of the patients declined participation for the pilot study. To determine the test-retest reliability, the questionnaire was applied again to the same 50 caregivers after an interval of 15 days.

The Turkish version of the FAMQOL (final version) was administered to 200 HF family caregivers to evaluate its validity and reliability. The entire questionnaire (including the items) in the present study was read aloud by a single-researcher at face-to-face interviews to ensure consistency in data collection. All items were completed by the participants and took an about five minutes. During this process, none of the caregivers rejected to participate in the study.

Statistical analysis

Statistical analysis was performed using the Number Cruncher Statistical System 2008 Statistical Software (NCSS LLC, Kaysville, Utah, USA) (License No: 1675948377483; Serial Number: N7H5-J8E5-D4G2-H5L6-W2R7). The demographic characteristics were analyzed by descriptive statistics. Intraclass correlation coefficients (ICC) were used to measure reliability and the 95% confidence intervals were determined. The Cronbach's alpha was used to determine the internal consistency, and the Pearson's Correlation analysis was used to determine the correlation between the

Table 1. The FAMQOL Turkish Questionnaire test - retest values (n=50)

	Test	Retest	
	Mean±SD	Mean±SD	*p*
Social well-being	20.6±3.7	20.5±3.7	0.605
Spiritual well-being	18.6±1.9	18.5±1.9	0.569
Psychological well-being	19.4±3.6	19.5±3.8	0.754
Overall FAMQOL	58.7±6.5	58.6±6.7	0.796

SD: Standard deviation; Paired Samples Test. FAMQOL: Family Caregiver Quality of Life scale.

Table 2. Cronbach's alpha values and interclass correlation coefficient of the FAMQOL Turkish Questionnaire subscales and overall score

	Cronbach alpha	ICC (95% CI)	*p*
Social well-being	0.76	0.93 (0.88-0.96)	<0.001
Spiritual well-being	0.99	0.86 (0.78-0.92)	<0.001
Psychological well-being	0.78	0.88 (0.80-0.93)	<0.001
Overall FAMQOL	0.82	0.91 (0.85-0.95)	<0.001

ICC: Interclass Correlation Coefficient; CI: Confidence interval; FAMQOL: Family Caregiver Quality of Life scale.

general scale and the subscales. The structural validity of the FAMQOL was tested using factor analysis. The criterion validity was tested by Pearson's Correlation analysis. The Student's t-tests were performed to item analysis based on upper and lower group mean values (according to 27% rule) and the test-retest results. A *p* value of <0.05 was considered statistically significant.

RESULTS

Participants' characteristics

A total of 50 family caregivers who participated in the translation and cultural adaptation phase were included in final sample of 200 family caregivers. The mean age of the participants was 47.3 years (SD=12.1, range 18-82), most of them were females (75.5%), married (n=85.5), primary school graduates (43.5%), and daughters or wives of the patients (41% and 35%, respectively). The mean daily caregiving time was 4.0±1.5 hours (range 1-5 hours). Total caregiving duration was longer than seven months for 60.5% of the participants.

Reliability

There was no significant difference between the two applications performed with a 15-day interval in the mean scores of the overall FAMQOL Turkish questionnaire and the subscales in terms of reproducibility and temporal consistency (Table 1). For the reliability prediction, the Cronbach's alpha coefficient was 0.82 for the overall scale and ranged from 0.76 to 0.99 for the subscales, indicating a good internal consistency. The intraclass correlation coefficients between the overall scale and the subscales ranged from 0.86 to 0.93 (Table 2), indicating a good internal consistency.[18,21]

Validity

Before testing the structural validity of the scale for factor analysis, it was found whether the sample was adequate and whether the data had a multivariate normal distribution. The Kaiser-Meyer-Olkin measure of the sample (KMO value = 0.51) and Bartlett test of sphericity (χ^2= 60.884, p<0.001) were support the use of the data for factor analysis.[18,22]

To explore factors that use the correlations between variables based on a pre-determined structure, the confirmatory factor analysis (CFA) was used and the results of the scale were examined using goodness-of-fit indices. There is no clear consensus about which goodness-of-fit indices should be used to determine the structural validity. It is desirable that chi-square (χ^2), used to assess the fit index, should not be significant for the acceptability of the model; however, it is usually significant in large samples.[18] In the present study, the χ^2 value was found significant (χ^2= 295.80, p<0.001). The corrected χ^2 value (χ^2/df ratio) affected by the sample to a less extent is a measure that can be used as a substitute; a value of between 2 and 5 is acceptable.[18] In this study, the χ^2/df ratio was 2.93. According to additional indices, including the Root Mean Square Error of Approximation (RMSEA), Standardized Root-Mean-Square Residual (SRMR), and Relative Fix Index (RFI) values (Table 3), the fit of the Turkish

Table 3. Indices of model fit of the Family Caregiver Quality of Life Turkish Questionnaire (n=200, df=101)

Fit indexes	Good fit*	Acceptable fit*	The fit values of the FAMQOL Turkish version
χ^2 "*p*" value	>0.05	-	<0.001
χ^2 /df	<2	<5	2.93
RMSEA	0.00≤ RMSEA ≤0.05	0.05< RMSEA ≤0.10	0.098
SRMR	0.00≤ SRMR ≤0.05	0.05< SRMR ≤0.10	0.079
RFI	0.90< RFI <1	0.85< RFI <0.90	0.85

FAMQOL: Family Caregiver Quality of Life; RMSEA: Root Mean Square Error of Approximation; RFI: Relative Fix Index; SRMR: Standardized Root-Mean-Square Residual.

Table 4. Factor Analysis for 16-Item Family Caregiver Quality of Life Turkish Questionnaire

Item	Factor I	Factor II	Factor III
Social			
(7) Socially isolated			0.32
(10) Participate in enjoyable activities			0.71
(11) Personal relationship with others			0.66
(12) Religious activities			0.62
(8) Exercise if I want			0.71
(9) Able to go to my Dr. appointments			0.70
Spiritual			
(13) Purpose/mission	0.99		
(14) Inner strength	0.99		
(15) Inner peace	0.99		
(16) Adds meaning to life	0.98		
Phychological			
(2) Overwhelmed		0.80	
(3) Feel selfish		0.34	
(4) Tired		0.60	
(6) Strained emotionally		0.64	
(1) Sick more often		0.72	
(5) Physical health suffered		0.84	
Eigenvalue	4.06	3.38	2.61
Variance (%)	25.43	21.14	16.37

questionnaire was acceptable.[23] According to these values, the FAMQOL Turkish questionnaire was seen to be compatible with Turkish culture.

The exploratory factor analysis (EFA) was used to determine the subdimensions into which the items fall based on the factor loads and whether the subdimensions into which the items fall are conceptually suitable for these items. In this study, the EFA, that is supported by the eigenvalues, the explained variance rates and the graphical distribution of the eigenvalues, provided a three-factorial structure. The item loads, the eigenvalues and the explained variance rates found by the EFA are presented in Table 4. Sixteen items of the FAMQOL Turkish questionnaire had load values ranging from acceptable to excellent (0.32 to 0.99) in three factors.[18] The eigenvalues for these three factors that explain 63% of the variance of the scale items (from 16.37% to 25.43%) ranged from 2.61 to 4.06. The first factor was spiritual well-being. This factor had a cut-off point of 0.98, consisted of four items, and explained 25.43% of the total variance. The second factor, psychological well-being, consisted of six items and explained 21.14% of the total variance. The third factor, social well-being, consisted of six items and explained 16.37% of the total variance. The EFA results demonstrated that the scale has structural validity.[18]

When the correlations between the determined factors, the correlation coefficients between the general FAMQOL Turkish questionnaire and the spiritual ($r=0.379$, $p<0.01$), psychological ($r=0.860$, $p<0.01$), and social well-being ($r=0.802$, $p<0.01$) subscales also supported the structural validity. Although a significant correlation was found between the social well-being factor and the psychological well-being factor ($r=0.502$, $p<0.01$), the spiritual well-being factor did not show correlation with the psychological ($r=0.133$, $p=0.060$), and social ($r=0.049$, $p=0.492$) well-being factors.

Total scores were listed in an ascending order to determine discriminative and predictive power of the items in relation to total scores. The mean score of the participants who constitute the lowest 27% (n=54) of the sample was significantly lower than that of the participants who constitute the highest 27% (n=54) of the sample (48.3±4.6 vs 67.7±3.6, respectively; $t=-24.214$, $p<0.001$). This indicates that the scale items are able to predict the total score and have good distinctiveness.[22]

The correlation coefficients between the overall FAMQOL Turkish questionnaire and SF-36 General Health ($r=0.473$, $p<0.01$) and Mental Health ($r=0.406$, $p<0.01$) subscales demonstrated evidence of criterion validity. Similarly, the psychological and

social well-being subscales also showed correlation with the SF-36 General Health (r=0.526 and 0.308, respectively, p<0.01) and Mental Health (r=0.413 and 0.298, respectively, p<0.01) subscales. However, the spiritual well-being subscale did not show correlation with the SF-36 General Health (r=0.063, p=0.374) and Mental Health (r=0.073, p=0.305) subscales.

DISCUSSION

There is a strong evidence that HF family caregivers, as a result of their responsibilities, experience physical and mental problems which lead to low QoL.[6,9-11] While various QoL assessment tools are available, these are often too generic to examine the experiences specific to this population.[15] A caregiver-specific tool would be more responsive to assess the QoL of family caregivers of HF patients.[3,9] However, the lack of the Turkish QoL instruments specific to HF family caregivers limit studies in this area. Also, no studies were conducted relating to psychometric features of the FAMQOL in the Turkish population. We assessed the psychometric properties of the FAMQOL in Turkish, as this questionnaire specifically assesses the QoL of family caregivers of HF patients.

The results of the study demonstrated that the 16-item FAMQOL Turkish questionnaire had adequate reliability and validity to assess QoL of family caregivers of HF patients. In addition, the CVI value of the FAMQOL Turkish questionnaire in terms of content validity was quite good. The questionnaire was carefully evaluated by 12 specialists, and no difficulties were reported by the participants with respect to the completion of the questionnaire. Based on the present study, the FAMQOL Turkish questionnaire was considered easy-to-understand and simple.

The results of the study demonstrated strong evidences on the internal consistency and test-retest reliability of the FAMQOL Turkish questionnaire and each of the three subscales. In the two applications performed with 15-day interval showing the repeatability and temporal consistency of the questionnaire,[18,21] the difference between the total score and the subscale scores was found to be non-significant. Additionally, the ICC value for the general scale and the subscales ranged from 0.86 to 0.93 indicating excellent agreement.[18,21] These values were higher than those obtained by Nauser et al.,[3] (0.70-0.83). Moreover, the results of the study demonstrated that the three subscales had good internal consistency for reliability prediction. Similarly to the study conducted by Nauser et al.,[3] the spiritual well-being had the highest value (α= 0.99).

Although the χ^2 value was found significant in terms of goodness-of-fit in this study, in practice, it is very responsive to sample size and usually yielding significant values.[18] However, the corrected χ^2 value obtained by CFA was within the fit limits. Despite the limitations of goodness of fit indices,[18,23] the factor structure of the Turkish questionnaire demonstrated an acceptable fit. Additionally, the EFA provided evidence relating to the structural validity of the FAMQOL Turkish questionnaire. The questionnaire also showed a strong three-factorial structure reflecting spiritual, psychological and social well-being with suitable factor load and high variance which could be explained by each with respect to total variance for factor analysis.[22] This finding is different from that found in the study in which the four-factorial FAMQOL was developed.[3] The items "(Even though I am a caregiver) I am still able to exercise as I want" and "(Even though I am a caregiver) I am able to get to my own checkups with doctors, dentists, and other health care providers" that are in the physical factor in the study of Nauser et al.[3] were merged under the social factor in this study. In the present study, probably these items were considered as a social activity by the participants. In the study of Nauser et al.,[3] these items were loaded in both the physical and social factors, and it was decided to leave these in the physical domain, since the factor loads were higher. Similarly, the items "(As a caregiver) I seem to get sick more often" and "(Because of caregiving) my physical health has suffered" that were included in the physical factor in the study in which the scale was developed,[3] were merged under the psychological factor in this study. These items may have been perceived as emotional by the participants. In particular, the item "My physical health has suffered" was loaded in both the physical and psychological factors in the study in which the scale was developed, and it was decided to leave these in this area, since the factor loads were higher, and it was desired by the authors that the items fit in the physical area.[3]

The significant correlation of the general FAMQOL Turkish questionnaire with all three subscales supported the use of the total score of the scale as a measure of caregivers' overall QoL as well as the use of the subscales to assess the mental and social well-being. This finding also supports the results of a recent study (2016) which reported that Chinese HF patients' family caregivers experience more serious impairment in their mental health compared

to physical health.[24] Differently from our study, no significant correlation was found between the general scale and the spiritual well-being subscale in the study in which the scale was developed. The authors, therefore, reported that the structural validity of the FAMQOL was applicable to the general scale and the three subscales including physical, psychological, and social well-being.[3] However, while the previous study reported that each subscale showed correlation with each other, the spiritual well-being subscale did not show any correlation with the psychological and social well-being subscales in the present study. Similarly, in our study, the only subscale that did not show correlation with the SF-36 General and Mental Health subscales was the spiritual well-being subscale. Therefore, care should be taken in the interpretation of the results of the spiritual well-being subscale until the measure validity is supported.

In this study, the caregivers' education level was also lower (mean 7.9 years vs 13.8 years) and the daily caregiving time was longer than those in the study in which the scale was developed.[3] Although the FAMQOL is a self-report questionnaire, this issue in administering the questionnaire should be considered due to the prevalence of lower education levels in Turkey.[25]

The facts that the caregivers in this sample mainly consisted of women and spouses and adult children, and that the perception of the caregivers and the dependency level of the patients were not investigated can be deemed as the limitations of the study.

In conclusion, the findings of this study show that the FAMQOL Turkish questionnaire is a valid and reliable assessment tool to assess the overall quality of life of family caregivers of heart failure patients in the Turkish population. The findings of the study also demonstrate that the questionnaire is responsive to the mental and social health problems of family caregivers of heart failure patients. Therefore, using the subscales that contain the spiritual, psychological, and social well-being, healthcare professionals can direct their interventions to these areas mostly needed by caregivers. However, this questionnaire was unable to capture the physical well-being area of quality of life, which is an important element of caregiver experience. Therefore, until a questionnaire that reflects the multidimensional areas (including the physical area) of quality of life is developed, it is suggested that the scale be used to assess the overall quality of life as well as the mental and social health problems of family caregivers of heart failure patients in the Turkish population.

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