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Retesting the psychometric characteristics of the European cancer research and treatment organization's quality of life questionnaire palliative care 15 Turkish version (EQRTC QLQ C15-PAL) and evaluating the influencing factors

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ABSTRACT

Purpose: The study aimed to retest the reliability and validity of the European Organization for Research and Treatment of Cancer-Core Quality of Life-15 Items Questionnaire for Palliative Care (EQRTC QLQ-C15-PAL) for the Turkish society and examine the influencing factors.
Methods: The study was conducted in cancer patients who applied palliative treatment in the Dokuz Eylul University Oncology Institute Medical Oncology Division between May of 2014 and January of 2015. The demographic data collection form, performance status, and the EQRTC QLQ-C15-PAL scale were employed in order to gather data.
Results: A total of 164 patients completed the study. The total Cronbach's alpha value for the scale was 0.794. The mean scores including the overall questionnaire, and subscales, which were calculated after two measurements conducted at an interval of three weeks, presented a statistically significant difference ($p < 0.01$). Patients with higher and lower ECOG scores had significant differences in terms of total QLQ-C15-PAL questionnaire scores as well as its subscales of physical, emotional functioning (PF, EF), and fatigue (FA) ($p < 0.05$). The statistically significant differences between patients' ECOG scores and QLQ-C15-PAL total score, and PF, EF, FA, and pain (PA) scores were 0.375, 0.439, 0.245, and 0.221, respectively ($p < 0.001$). The QLQ-C15-PAL questionnaire is able to measure 94.0% of the factors measured by the QLQ-C30-PAL. The variables included in the model affected the patients' quality of life to the extent of 44.0%.
Conclusion: It has been shown that the scale is a valid/reliable instrument to detect the quality of life of Turkish cancer patients.

1. Introduction

Scientific and medical advances over the last century have ensured a longer and more comfortable life and deferred death.[1,2] The World Health Organization defines palliative care as "an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual,".[3] Palliative care was used in the early 1990s to provide patients dying of cancer with care in the United States and the majority of palliative care programs were launched for patients with cancer.[4] It is a family- and patient-centered approach that prioritizes patients' and their families' needs and seeks to improve the life quality of both patients and their families.[5] It is critical for patients with cancer to maintain their life quality as high as possible and continue their lives by assuming the responsibility of their own treatment and care. Therefore, it is important to evaluate the symptoms deteriorating the patients' quality of life and introduce them to the influential factors.[6]

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Health care professionals should assess the quality of life of palliative care patients on a daily basis. The European Organization for Research and Treatment of Cancer Core QoL Questionnaire 30 (EQRTC QLQ 30) was developed to assess the quality of life of patients with cancer. It is structured by the same organization. It is a comprehensive questionnaire developed to assess the palliative care patients' quality of life.[7] The questionnaire is used to evaluate the physical-psychosocial symptoms and functioning of the patients with cancer throughout the curative or palliative periods. However, the questionnaire is very long for the palliative care patients and it includes items that are not directly relevant to palliative care. Some questions are not specific to the palliative care.[7,8] The EQRTC QLQ 30 questionnaire includes 30 questions under three sub-topics: overall well-being, functional difficulties, and symptom control. Higher scores indicate a high quality of life and poor score imply reduced quality of life. The questionnaire was translated into Turkish by Guzelant et al. with demonstrated validity and reliability for Turkish people in patients with lung cancer.[9] The researchers shortened the questionnaire for purposes of specificity and because some items were irrelevant to the palliative care. Also, given the patients' present condition and prognosis, palliative care needs and condition of patients with cancer must be identified rapidly and without challenging them. For a quick identification of the patients' palliative care needs, the EQRTC QLQ C30 was shortened to obtain the EQRTC QLQ-C15-PAL questionnaire.[7] This questionnaire consists of a selection of items from the EQRTC QLQ 30 and was created in line with the interviews conducted with patients and health care professionals and based on prioritized criteria set for the care of palliative cancer patients. The symptoms include those frequently reported by the patients.[10] The 15 items selected from the EQRTC QLQ 30 questionnaire to create the EQRTC QLQ-C15-PAL are as follows: two items among those related to emotional functioning, two out of three items of fatigue, two items assessing the global health condition, one item from each related to pain, nausea, vomiting, dyspnea, insomnia, constipation and appetite loss, and one item assessing the quality of life.[11] The questionnaire's validity and reliability have been demonstrated for a variety of countries including Russia, China, Italy, Germany, Greece, Spain, Japanese, Brazil, Mexico, Korea, and Japan.[7,11–13] Ozcelik et al. demonstrated the reliability and validity of the questionnaire for Turkey.[14] The study reported a Cronbach's alpha value of 0.93–0.98. Subscales of the questionnaire exhibited the following correlations: negative and medium correlation between fatigue and physical functioning (−0.41) and insomnia and emotional functioning (−0.53); and a weak correlation between nausea/vomiting and appetite loss (0.31) and insomnia and pain (0.22). The same study found that patients experienced limited physical and emotional functioning as their performance capacity decreased and their global quality of life deteriorated due to the symptoms they suffered.[14] The study aimed to retest the reliability and validity of the EQRTC QLQ-C15-PAL questionnaire for the Turkish society and examine the influencing factors.

2. Methods

The present study was conducted methodologically in order to retest the validity and reliability of the EQRTC QLQ-C15-PAL questionnaire for Turkey and examine the influencing factors. It was conducted at the Medical Oncology Outpatient Clinic within Dokuz Eylul University from May 15, 2014 to January 15, 2015.

The literature on validity and reliability studies suggest 3 rules including the rules of five, ten, and a hundred while determining research samples. Experts stress that a factor analysis requires at least 5 people per item. If there is no difficulty of access to the sample, the number of people per item must be 10. The power analysis carried out based on a study by Shin et al. revealed a need for at least 154 people, with Type II error taken as 0.05 (95% power) and Type I error as 0.01.[13] As the EQRTC QLQ-C15-PAL questionnaire consists of 15 items, we calculated the required sample size as 150 (with 10 adults per item) for a reliability and validity study. This figure is 154 based on the study by Shin et al..[13] The following eligibility criteria were required for patient entry: volunteering to participate in the study; 18 years old or above; diagnosed with stage 4 cancer and receiving exclusive palliative anti-cancer treatments at the time of testing (chemotherapy, hormone therapy, targeted treatments, radiotherapy, etc.); With sufficient physical and mental capacity to be able to fill in the questionnaire. The research data were collected through “Patient Description Form”, Eastern Cooperative Oncology Group (ECOG), and the EQRTC QLQ-C15-PAL questionnaire. The demographic data collection form consists of questions related to the participants' socio-demographic characteristics. It includes various scoring systems and is used for determining the performance and functional status of cancer patients. The Eastern Cooperative Oncology Group (ECOG) scale of performance status is one of the most commonly used scales among them. The ECOG measures a patient's functional capacity on a scale of 0–4: (0) if the patient is fully active,[1] if the patient experiences problems but able to continue daily life,[2] if the patient experiences problems and rests up to 50% of the waking hours,[3] if the patient experiences problems and rests more than 50% of the waking hours, and[4] if the patient experiences problems and is totally confined to bed or chair.

EQRTC QLQ-C15-PAL questionnaire is a selection of 15 items from the 30-item questionnaire and was produced by Groenvold et al. to be administered to those patients receiving palliative care.[8] The total score correlation values of items varied within a range of 0.70–1.00, and alpha values of subscales changed between 0.40 and 0.83. The following subscales were reduced as follows (parenthetical figures indicate the number of items in the original questionnaire): physical function[5] to three items, emotional function[4] to two items, fatigue[3] to two items, global health condition/quality of life[2] to one item and nausea/vomiting[2] to one item. The pain[2] and dyspnea, insomnia, appetite loss and intestinal obstruction[1] subscales were unchanged. The questionnaire is a 4-point Likert scale ranging between 1 (not at all) and 4 (very much). Regarding the subscale scores, higher scores in physical subscale and lower scores in emotional subscale indicate better functional status.

As the 30-item form of the questionnaire had been adapted into Turkish, the items were not translated into Turkish or back-translated. The 15-item form relied on the 30-item questionnaire. It is recommended that at least three experts be consulted in order to determine that the items in the translated form are equivalent to those in the authentic form. Four experts will be consulted for the 15-item questionnaire. Experts were given the authentic and translated forms of the questionnaire and asked to rate the items' accuracy on a scale of 1–4 (1 = very accurate, 2 = accurate, 3 = minor changes required, 4 = major changes required). The compatibility of experts' opinions was determined with the Scope validity rate.

As part of the item editing efforts, it is an important step to administer the questionnaire to a sample of 10–20 individuals who bear the same characteristics with the individuals to whom the questionnaire would be administered, ask the participants whether the items are comprehensible, and correct the errors and shortcomings to give the questionnaire its final form. We administered the questionnaire to ten individuals following a compatibility analysis and expert evaluations.

The scope validity index was used to analyze the compatibility of expert opinions, Cronbach's alpha value to determine the questionnaire's internal consistency, Pearson's correlation analysis for

an item-total score analysis and to determine the levels of correlation among subscales, *t*-test for independent groups to compare the available groups, and confirmatory factor analysis to find out whether the items explained the authentic structure of the questionnaire or not. Also, the relationship between variables and factors was evaluated with a multiple regression analysis.

We obtained the permission of the European Cancer Research and Treatment Organization, which created the questionnaire, to conduct a validity and reliability study for the questionnaire. Then, we obtained the permission of the Non-Invasive Research Ethics Committee at Dokuz Eylul University and written and verbal consent of the participants.

3. Results

A total of 164 patients completed the study. Patients' mean age was 59.86 ± 11.68 (range: 22–82 years). Of them, 43.3% were female, 69.4% were primary school graduates, and 77.4% were married. 6.7% of the patients were diagnosed with colon, 6.1% with lung, 5.5% with ovary, and 4.9% with breast cancer. 97.6% of the patients were metastatic. Liver, bones and brain were the most common metastatic organs with the range of 22.6 to 15.9%. 82.3% of them received chemotherapy and 1.8% received radiotherapy. 94.5% of the patients lived together with their families. 20.1% of them had a co morbidity that accompanied cancer. Hypertension, diabetes, and both hypertension and diabetes were the most frequently observed co morbidities with rates of 8.5, 3.0, and 1.2%, respectively.

The explanatory factor analysis revealed the Kaiser-Meyer-Olkin coefficient (KMO) as 0.879 and the Barlett test result was X2 = 1022.502, p = 0.000. The variance explained for the Physical Functioning (PF), Emotional Functioning, Fatigue (FA), and Pain (PA) subscales were 39.71%, 10.0%, 7.29%, and 6.68%, respectively. The total variance explained was 63.68%. The explanatory factor analysis showed that items were divided into four factors, and the factor loads ranged 0.513–0.776, 0.740–0.772, 0.742–0.812, and 0.742–0.812 for subscales PF, EF, FA, and PA, respectively (Table 1). No factor analysis could be conducted for other subscales as they consisted of a single item.

The total Cronbach's alpha value for the scale was 0.794. The alpha values for PF, EF, FA, and PA subscales of the questionnaire were 0.792, 0.628, 0.857, and 0.767, respectively. The floor and ceiling effects of the questionnaire remained below 15% on the basis of the overall score and total subscale scores (Table 2). With the split-half method, the first and second halves had alpha values of 0.807 and 0.751, respectively. The correlation coefficient between the two halves was 0.820. Spearman-Brown and Guttman Split-half coefficients were 0.901 and 0.898, respectively. The questionnaire items' correlation with the total score ranged between 0.376 and 0.753. *Item-subscale total score correlations* varied as follows: *0.580-0.833* (PF), *0.31-0.878* (EF), *0.933-0.935* (FA), and *0.891-0.911* (PA).

The mean scores including the overall questionnaire, PF, FA and PA subscales, which were calculated after two measurements conducted at an interval of three weeks, presented a statistically significant difference (p < 0.01, Table 3). However, the mean scores in PF subscale, which were again calculated after two measurements conducted at an interval of three weeks, displayed no statistically significant difference (p > 0.01, Table 4). Test-retest scores for the questionnaire and its four subscales had a powerful, positive and statistically significant correlation (Total = 0.808; PF = 0.618; EF = 0.573; FA = 0.773; PA = 0.815, Table 4).

Patients with higher and lower ECOG scores had significant differences in terms of total QLQ-C15-PAL questionnaire scores as well as its subscales of PF, EF, and FA (p < 0.05). However, no significant difference was observed between those with higher and lower ECOG scores in terms of their mean PA scores (p > 0.05). The statistically significant differences between patients' ECOG scores and QLQ-C15-PAL total score, and PF, EF, FA, and PA scores were 0.375, 0.439, 0.245, and 0.221, respectively (p < 0.001, Table 4).

The QLQ-C15-PAL questionnaire is able to measure 94.0% of the factors measured by the QLQ-C30-PAL, and subscales of the former are able to measure 40.0–68,0% of those measured by the latter (Table 5). The variables included in the model affected the patients' quality of life to the extent of 44.0%. Of such variables, the educational background was the factor that significantly affected the quality of life (β = −0.402, Table 6).

Table 1
Explanatory factor analysis results.

ESS-C	KMO	Barlett test	Variance Explained	Factor Loads
PF			39.71	0.513–0.776
EF			10.0	0.740–0.772
FA			7.29	0.742–0.812
PA			6.68	0.752–0.898
Total	0.879	1022.502*	63.68	0.513–0.898

*p < 0.001 PF: Physical Functioning EF: Emotional Functioning FA: Fatigue PA: Pain.

4. Discussion

The present study aimed to retest the validity and reliability of the QLQ-C15-PAL questionnaire and determine the influencing factors. It consists of convenient and comprehensible items that are specific to the palliative care and focused on the symptoms experienced by patients.[7,8] The reliability and validity of the QLQC15-PAL questionnaire have been demonstrated for many languages.[7,11–14] As regards the QLQC15-PAL questionnaire's factor loads, the highest explained variance proportions belonged to pain, fatigue, and emotional functioning subscales, and they had a moderately significant correlation with the global quality of life score. This indicates that the subscales of the questionnaire effectively evaluate the symptoms in relation to the quality of life.[15] The results are similar to the findings reported by Ozcelik et al..[14]

"Time invariance," a criterion of reliability, refers to the relationship between the data groups subject to similar circumstances and measurements conducted at a certain time span.[16,18] Compared in terms of test-retest mean scores measured at a three-week interval, two measurements exhibited a powerful positive correlation (0.807, p < 0.01). This result is in line with the data reported in the relevant literature.[14,17] The reliability of questionnaires is assessed by calculating the Cronbach's alpha coefficient. The actual coefficient to indicate reliability depends on the questionnaire's purpose.

Acceptable levels are 0.90 + and 0.70 + for physiological measurements and involvement questionnaires, respectively. In addition, while 0.70 + is an acceptable value for a new questionnaire, a formerly created questionnaire requires 0.80+.[16,18] In the present study, the standardized Cronbach's alpha values of the subscales varied between 0.857 and 0.628. This indicated an acceptable level of reliability for physical functioning, fatigue and pain subscales. The emotional functioning subscale in the questionnaire had a Cronbach's alpha value of 0.628, which was lower than the acceptable threshold. It might be associated with the emotional condition of the sample group. However, not only the subscales but also the questionnaire's total Cronbach's alpha value must be taken into account while evaluating the reliability of a questionnaire. The Cronbach's alpha value of the questionnaire, the reliability and validity of which we tested for the Turkish society, is 0.794. This indicates a good level of reliability. Regarding the consistency of two halves of the questionnaire, Sperman-Brown coefficient was 0.901 and Gutmann Split-half coefficient was 0.898. These figures

Table 2
EORTC QLQ15 reliability analysis results.

EORTCQLQ 15	Cronbach α	M ± SD	Min-Max	Floor Effect %	Ceiling Effect %
PF	0.792	6.05 ± 2.52	3.-12	0.0	5.5
EF	0.628	2.89 ± 1.17	2–8	51.2	0.6
FA	0.857	4.04 ± 1.63	2–8	18.9	5.5
PA	0.767	3.15 ± 0.54	2.8	50.0	2.4
Total	0.794	27.33 ± 6.47	18–52	0.6	0.0

PF: Physical Functioning EF: Emotional Functioning FA: Fatigue PA: Pain.

Table 3
Test-Retest Mean Scores in the Questionnaire and its Subscales and their Comparison (n = 164).

Questionnaire		First Administration M±SD	Second Administration M±SD	t	p	r	p
Total		26.09 ± 7.83	28.57 ± 8.14	6.292	0.000	0.808	0.000
Subscales	PF	6.05 ± 2.52	5.50 ± 2.18	3.418	0.001	0.618	0.000
	EF	2.89 ± 1.17	2.90 ± 1.27	0.207	0.836	0.573	0.000
	FA	4.04 ± 1.63	4.57 ± 1.66	5.941	0.000	0.773	0.000
	PA	3.16 ± 1.54	3.44 ± 1.71	3.591	0.000	0.815	0.000

PF: Physical Functioning EF: Emotional Functioning FA: Fatigue PA: Pain.

Table 4
Comparison of the mean scores for the questionnaire and subscales by ECOG score.

Questionnaire		ECOG Low (n = 95)	ECOG High (n = 68)	t	p
Total		24.39 ± 7.06	28.54 ± 8.30	3.441	0.001
Subscales	PF	5.26 ± 2.03	7.17 ± 2.73	4.884	0.000
	EF	2.72 ± 0.97	3.13 ± 1.38	2.083	0.040
	FA	3.58 ± 1.48	4.69 ± 1.64	4.524	0.000
	PA	3.01 ± 1.46	3.38 ± 1.65	1.518	0.131

PF: Physical Functioning EF: Emotional Functioning FA: Fatigue PA: Pain.

Table 5
Explanatory (Predictive) power of QLQ-C15-PAL for QLQ-C30-PAL questionnaire.

	Number of Item	Proportion of Variance (R^2)	β	P value for β
QLQ-C15-PAL Total	15	0.94	0.969	0.000*
PF	3	0.580	0.763	0.000*
EF	2	0.525	0.725	0.000*
FA	2	0.681	0.825	0.000*
PA	2	0.523	0.723	0.000*
Overall Health	1	0.398	0.631	0.000*

*p < 0.001 PF: Physical Functioning EF: Emotional Functioning FA: Fatigue PA: Pain.

Table 6
Independent variables' predictive power for Q15.

	B	Standard Error	Standard Beta (β)	t	p
Constant	29.530	12.713		2.323	0.029
Age	0.241	0.133	0.337	1.811	0.082
Gender	3.201	2.665	0.234	1.201	0.241
Educational Background	-0.4.301	2.005	0.402	2.145	0.042
Marital Status	0.751	0.1749	0.086	0.429	0.671
Diagnosis	-0.402	0.262	-0.268	-0.532	0.138
Stage at Diagnosis	1.547	1.804	0.159	0.858	0.399
Co morbidity	0.122	0.310	0.063	0.394	0.697

R = 0.663 R^2 = 0.439 F = 2.796 p = 0.027 DW = 1.794 (1.5–2.5).

showed that the items were consistent with each other and included components that define a whole. Given the information provided above, the QLQC15-PAL questionnaire can be considered sufficient to allow for an identification of patients' palliative care needs. The findings are in line with those reported in the relevant literature.[14,15]

Item analyses are another approach to finding out whether items measure a certain characteristic, as part of which the correlation between a respondent's total score in the instrument of measurement and their scores in each item is calculated. If an item exhibits a poor correlation with the total score, it can be interpreted in such a way that the relevant item measures a characteristic other than the rest of the items. As a poor correlation between the item and total score decreases reliability, that item should be excluded

from the questionnaire.[16,18] There is no applicable standard concerning the criterion to indicate poor reliability when item-total score correlation coefficient is lower than the level envisaged for that criterion. In this context, Karasar suggests that one should suspect the reliability of those items with coefficients less than 0.50, while Oner advises that this coefficient remains above 0.30.[16,18]

The present study found that item-total score correlations of the questionnaire varied in a range of 0.376–0.753, while the items' test-retest correlations changed between 0.315 and 0.888. From this aspect, there is no item that should be excluded from the questionnaire. The questionnaire's subscale correlations varied between 0.656 and 0.935. This indicates good correlation figures between the item scale and pain, fatigue, emotional functioning, and physical functioning subscales. Those findings support and confirm the reliability of the QLQ C15-PAL Questionnaire. The findings are consistent with the literature data.[7,8,12–14,17,18]

As regards the relationship between the ECOG performance condition and the QLQC15-PAL Questionnaire's total and mean subscale scores, those patients with higher ECOG scores exhibited a significant correlation among the physical and emotional functioning and fatigue subscales when compared to those patients with lower ECOG scores. However, no significant relationship was observed with the pain subscale ($p > 0.05$). Nevertheless, there was a significant correlation between the total score and ECOG performance condition. Therefore, in line with the relevant literature, our findings confirm the interpretation that patients' quality of life improves with their performance and the questionnaire, as a whole, identifies the patients' palliative care needs according to their condition.[7,8,12–14,17,18]

We further examined the extent to which independent variables (age, gender, marital status, educational background, diagnosis, stage at diagnosis, and co morbidity) explained the QLQC15-PAL: Variables included in the model affected 44.0% of the quality of life, and educational background was the factor with the highest impact on patients' quality of life ($\beta = -0.402$). This indicates that patients tend to become more aware of their needs as their level of education rises. These findings are similar to the literature data.[12,15,19] In conclusion, the Turkish version of the QLQC15-PAL Questionnaire is demonstrated as a reliable and valid instrument for measurement. It can be relied on for cancer studies and to identify patients' palliative care needs.

Compliance with ethical standards

Institutional Ethics Committee approved the study protocol, and the study was in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. All persons gave their informed consent prior to their inclusion in the study.

Conflict of interest

The authors declare that they have no conflict of interest.

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