

Turkish Validation and Reliability of the EORTC QLQ-CR29 Quality of Life Scale for Colorectal Cancer

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ABSTRACT

Background: This study aims to test the validity and reliability of the Turkish version of the European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire-Colorectal Cancer Scale, and to evaluate the relationship between the factors affecting the quality of life in patients with colorectal cancer (CRC).

Methods: 117 patients diagnosed with CRC and treated at the Training and Research Hospital were included. A Personal Information Form, questionnaires on the Quality of Life in Cancer Patients, Quality of Life in Patients with CRC, and the Adaptation Scale for Individuals with Ostomy were used.

Results: The validity and reliability of the KKHYYK scale were found significant ($P < .05$). From the demographic data of the patients, the differences between 3 sub-dimensions, grouping according to gender, and 2 sub-dimensions were statistically significant. In the characteristics related to the disease, the differences between the groups were significant; for one for the diagnosis time of the disease, 2 dimensions in the adaptation parameter ($P < .05$).

Conclusion: The Turkish version of the scale is a measurement tool with validity and reliability indicators to measure the quality of life of patients with CRC. It was concluded that patients did not have sufficient knowledge about their disease, and that this increased the burden of nursing care.

Keywords: Colorectal cancer, quality of life, nursing, adaptation to disease

INTRODUCTION

Despite the recent developments in the field of medicine, there is a significant increase in the prevalence and incidence of cancer. While some studies attribute the reason for this increase to the greater production and use of carcinogenic substances, some studies link the disease statistics to increased awareness and better follow-up.¹⁻⁵

Genetic factors, smoking, and other social and demographic factors have been evaluated and listed as risk factors for cancer.⁶⁻⁹ In-depth studies are currently being conducted by both the public authorities and non-governmental organizations to find ways to minimize the damage caused by these factors. Many current studies in the field of medicine list "psychogenic" factors as the leading factors affecting the cause of the disease or the success of the treatment, for many diseases including cancer.¹⁰⁻¹³ At this point, patient participation in treatment is a sine qua non condition. This can be attributed to 2 reasons. First, the effect of

psychological processes on body chemistry is related to the fact that the pathophysiology of the disease is not yet known. In addition, the positive role of the patient's psychological well-being in the treatment of a disease has always been known and accepted. Colon cancer is the third most common among cancers in the world, at 9.7%. It has been shown that more than half the cancer cases (56.8%) and cancer-related deaths (64.9%) are in underdeveloped countries. Over the last 20 years, the development of diagnostic and treatment methods and the introduction of screening programs has enabled CRC to be diagnosed at an early stage, and the mortality rates associated with this disease have decreased. Since more than 80% of colon cancers develop from colon polyps, colon cancer is now considered a preventable cancer, because screening tests allow patients with colon or early stage cancer to maintain their normal life with appropriate treatment.¹⁴⁻¹⁷ It was aimed to study the validity and reliability study of the Turkish version of the European Organization for Research and Treatment

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of Cancer, Quality of Life Questionnaire-Colorectal Cancer (EORTC QLQ-CR29) scale, and to evaluate the relationship between the factors affecting the quality of life in patients with CRC and their socio-demographic characteristics.

METHODS

A total of 117 patients diagnosed with CRC and treated at the Training and Research Hospital were included in the study. A Personal Information Form, the questionnaires on Quality of Life in Cancer Patients (KHYK) (EORTC QLQ-C30), Quality of Life in Patients with Colorectal Cancer (KKHYK) (EORTC QLQ-CR29), and the Adaptation Scale for Individuals with Ostomy (OUÖ-23) were used.

Personal Information Form

The Personal Information Form was prepared in line with the literature, considering the factors that may affect the quality of life and the compliance of the patients who were diagnosed and treated for CRC. This form consists of a total of 34 questions that question personal and disease-related features.

European Organisation for Research and Treatment of Cancer, Quality of Life Questionnaire-Cancer (EORTC QLQ-C30)

The European Cancer Research and Treatment Organization (EORTC) developed a cancer-specific quality of life scale, the EORTC QLQ-C30, and finally the EORTC QLQ-C30 version 3.0. The scale was adapted to Turkish by Beser and Öz (2003). The EORTC QLQ-C30 questionnaire is a questionnaire that has been widely used in clinical studies related to cancer all over the world, especially in European countries, with consistency, correlation, and validation. Version 3.0, filled by the patients themselves, is a multidimensional questionnaire that evaluates a global health status and quality of life scale, 5 functional scales, and 3 symptom scales with 30 questions. The functional scales evaluate physical, role, cognitive, emotional and social functions; the symptom scales evaluate weakness, pain, and nausea/vomiting. In addition, dyspnea, insomnia, loss of appetite, constipation, diarrhea and financial constraints are measured with each question.

European Organisation for Research and Treatment of Cancer, Quality of Life Questionnaire-Colorectal Cancer (EORTC QLQ-CR29)

The EORTC QLQ-CR29 is a quality of life questionnaire prepared specifically for CRC. It consists of 29 questions evaluating disease symptoms, treatment side effects, body image, sexual condition, and future expectation. Everybody answers the first 18 questions, and the next questions are divided into sections according to gender, sexual function, and colostomy status, and each patient fills the sections appropriate for their situation. The scores related to the function and global health status and symptoms are calculated in accordance with the EORTC QLQ-CR29 scoring manual. Each parameter has a score between 0 and 100. While a high score on the functional scale shows good health status, a high score on the symptom scale indicates excess symptoms, that is, a decreased quality of life. The EORTC QLQ-CR29 must always be used with the EORTC QLQ-C30 and must be completed.

For test-retest analysis, 32 patients filled the scale twice, 'in 7 to 14 days each.' Then, a correlation analysis was made between the relevant items of each scale. The research was approved by the T.C. İstanbul Bilim University Clinical Research Ethics Committee with the decision number 04.11.2014 / 25-170.

In the reliability analysis of the KKHYK scale, Cronbach Alpha values were examined for structural reliability. Next, the Principal Component Analysis, one of the factor analysis methods, was performed to ensure the structural validity of the scale. Rotational results of the scale items were obtained using Varimax rotation during the analysis. In factor analysis, the Kaiser-Meyer-Olkin test (KMO) and Barlett's test of sphericity were used for sample adequacy. In the definition of research data, parametric data were defined by mean and standard deviation values, and nonparametric data were defined by the Frequency Analysis method. In the difference analysis, Mann-Whitney *U* tests were used in the analysis of nonparametric data. In the difference analysis of more than 2 groups, the Kruskal-Wallis test was used for the analysis of nonparametric data.

RESULTS

Of the patients participating in the study, 0.9% were between the ages of 18 and 30, 5.1% between the ages of 31 and 40, 16.2% between the ages of 41 and 50, 29.9% between the ages of 51 and 60, and 47.9% of them were 61 years or older. Female patients comprised 41.9% of the study participants, while 58.1% were men. In general, it can be stated that men were the majority compared to

women. Most of the patients (82.1%) were married, and 12.0% stated that they were widows; 7.0% of the patients were single; 91.5% of the patients had children, and only 10 patients stated that they did not have children; 12.0% of the patients participating in the study stated that they were illiterate, while 12.8% stated that they were literate. Primary school graduates were the most ill, and the rates of illness among secondary and high school graduates were the same (8.5%). There were 3 patients with higher education. An analysis of the patients' monthly income distribution showed that, in general, the income of this group of patients was between 501 TL and 1500 TL. In general, it can be stated that the income levels of patients were below average. When the distribution by profession was examined, it was seen that the majority of the participants were retirees (42.7%), and this was followed by housewives (39.3%). This distribution was also in line with the monthly income of the patients.

The test-retest correlation coefficients of the items of the QLQ-C30 scale were above the 0.40 value accepted in the literature. In addition, correlations of all scale

items were found to be statistically significant ($P < .05$). Therefore, the QLQ-C30 scale appears to be reliable. The results of the Basic Components Analysis for EORTC QLQ-CR29 scale, the Kaiser-Meyer-Olkin test, and Bartlett's test of sphericity, conducted in this study, are given in the table below.

According to the results of the factor analysis, 6 factor groups emerged. There were 8 items in the first factor, 4 items in the second factor, 3 items in the third factor, and 2 items in the fourth factor. Since the item factor loads of the other 2 components were close to each other, the factors with the highest factor load were taken and reduced to 4 factors. The factor loads of all items were above 0.40, which is accepted in the literature. Accordingly, the items in factor groups have been renamed according to their sub-dimensions, as follows: General Health Complaints (GHC): 35, 41, 42, 43, 44, 45, 46, and 47 items; Urinary System Satisfaction (USS): 31, 32, 33, and 34 items; Urinary Tract Infection (UTI): 36, 38, and 39 items; Drug Side Effects: 37 and 40 items.

Table 1. Factor Analysis Results for EORTC QLQ-CR29

	Factors			
	1	2	3	4
C29_45	0.841			
C29_47	0.726			
C29_46	0.714			
C29_44	0.560			
C29_43	0.543			
C29_42	0.528			
C29_35	0.508			
C29_41	0.441			
C29_31		0.850		
C29_32		0.832		
C29_34		0.546		
C29_33		0.472		
C29_36			0.587	
C29_39			0.576	
C29_38			0.509	
C29_37				-0.525
C29_40				0.524

KMO = 0.688; chi-square = 680.873; variance explained = 68.97.

KMO, Kaiser-Meyer-Olkin Measure of Sampling Adequacy.

Table 2. Average Quality of Life Scale and Difference Results in Patients with Colorectal Cancer According to Demographic Features

	General Health			Urinary System			Excretory System			Drug Side Effects			Stoma Bag		
	Complaints			Satisfaction			Satisfaction			SS			x		
	x	SS	P	x	SS	P	x	SS	P	x	SS	P	x	SS	P
Age															
18-30	1.13	0.00	.607*	1.25	0.00		1.00	0.00	.115*	2.00	0.00	.284*	1.86	0.00	.708*
31-40	1.54	0.65		1.75	0.59		1.06	0.14		1.58	0.49		1.79	0.60	
41-50	1.62	0.54		1.64	0.45	.812*	1.37	0.37		2.08	0.75		1.88	0.31	
51-60	1.49	0.38		1.77	0.59		1.17	0.29		1.67	0.48		1.87	0.57	
61<	1.62	0.47		1.83	0.67		1.34			1.90			2.09		
Gender															
Female	1.73	0.51	.005**	1.86	0.62	.117**	1.36	0.53	.017**	1.94	0.68	.194**	2.20	0.59	.003*
Male	1.46	0.41		1.70	0.59		1.21	0.45		1.78	0.54		1.76	0.40	*
Marital Status															
Married	1.56	0.41	.796*	1.81	0.61	.184*	1.25	0.42	.839*	1.82	0.54	.859*	1.92	0.51	.449*
Single	1.60	0.81		1.39	0.38		1.62	1.11		1.71	0.39		2.29	0.52	
Divorced	1.66	0.64		1.71	0.63		1.23	0.37		2.07	1.00		2.10	0.79	
Child															
Have	1.55	0.45	.207**	1.80	0.61	.103**	1.27	0.50	.890**	1.81	0.58	.106**	1.94	0.54	.230*
Do not have	1.83	0.62		1.48	0.45		1.27	0.38		2.20	0.75		2.21	0.44	*
Education															
Illiterate	1.82	0.55	.245*	1.98	0.68	.414*	1.59	0.80	.053*	2.21	0.67		2.25	0.73	.088*
Literate	1.69	0.39		1.88	0.75		1.12	0.28		1.79	0.58		2.19	0.29	
Primary	1.55	0.47		1.78	0.59		1.29	0.49		1.76	0.58		1.86	0.54	
Secondary	1.43	0.46		1.55	0.44		1.07	0.14		1.70	0.26	.287*	1.74	0.36	
High school	1.50	0.49		1.58	0.64		1.27	0.26		2.15	0.85		1.90	0.50	
License	1.38	0.22		1.92	0.38		1.00	0.00		1.67	0.58				
Master's and Doctorate	1.29	0.40		1.50	0.25		1.33	0.58		1.83	0.29		1.50	0.51	
Monthly income															
500 TL and under	1.56	0.54	.836*	1.89	0.38	.265*	1.76	1.03	.048*	1.79	0.27	.929*	1.95	0.50	.859*
501-1000 TL	1.60	0.46		1.77	0.73		1.36	0.57		1.97	0.84		2.06	0.57	
1001-1500 TL	1.52	0.43		1.77	0.57		1.16	0.26		1.84	0.53		1.92	0.44	
1501-2000 TL	1.58	0.21		1.33	0.20		1.11	0.17		1.75	0.42		2.00	0.00	
2001 TL and over				1.83	0.62		1.12	0.25		1.68	0.42		1.93	0.78	

Occupation	1.58	0.52	.008*	1.45	0.33	.411*	1.07	0.15	.242*	1.80	0.45	.332*	1.50	0.51	.034*
Worker	1.58	0.52	.008*	1.45	0.33	.411*	1.07	0.15	.242*	1.80	0.45	.332*	1.50	0.51	.034*
Officer	1.38	0.22		1.75	0.25		1.33	0.58		1.67	0.58		1.86	.	
Retired	1.48	0.38		1.71	0.61		1.23	0.49		1.85	0.63		1.76	0.36	
Self-employed	1.10	0.50		1.63	0.63		1.11	0.53		1.33	0.62		1.50	0.59	
Housewife	1.75	0.60		1.86	0.53		1.36	0.42		1.91	0.55		2.22	0.61	
Other	1.58	0.52		2.04	0.33		1.33	0.15		2.00	0.45		2.00	0.51	
Health insurance															
Social system	1.56	0.45	.135*	1.76	0.61	.154*	1.27	0.49	.386*	1.84	0.61	.366*	1.96	0.53	.152*
Public aid	1.13	.		2.13	0.18		1.17	0.24		2.25	0.35		1.57	0.00	
None	2.75	0.00		2.75	0.00		1.67	0.00		2.00	0.00		2.86	0.00	
Residence															
City	1.64	0.44	.101*	1.67	0.49	.612*	1.18	0.44	.070*	1.79	0.58	.898*	1.96	0.54	.991*
Province	1.46	0.44		1.80	0.67		1.26	0.38		1.81	0.50		1.98	0.56	
Village	1.63	0.50		1.88	0.68		1.47	0.69		1.86	0.64		1.92	0.52	

*Kruskal-Wallis test $P < .05$ significance level; **Mann-Whitney U -test $P < .05$ significance level.

The highest mean General Health Complaints (GHC) was seen in patients aged 41-50 years and older than 61 years, the mean age of patients with USS was 61 years and above, the mean age of patients with UTI was between 41 and 50 years, and the ST mean was 61 years. It was also determined that all the sub-dimensions of the scale by age groups did not show a statistically significant difference ($P > .05$). It was seen that the average values of male patients in all quality of life dimensions were lower than for female patients. On the other hand, while the differences between groups according to the mean of GHC, Excretory System Satisfaction (ESS), and Stoma Bag (SB) were statistically significant ($P < .05$), the differences between the mean values of Urinary System Satisfaction (USS) and UTI were not statistically significant ($P > .05$).

The mean of GHC, UTI, and ST of patients with children was lower, and BSM averages were close in both those who had children and those who did not. Here too, it was found that all the scale averages did not show statistically significant difference according to marital status ($P > .05$). According to the educational level, the average of all the scales of illiterate people was higher than that of the other groups with different educational levels, and the average decreased with increased educational level. Here too, it was observed that the average of the scale dimensions according to the educational status did not have a statistically significant difference ($P > .05$). According to monthly income, the scale averages were close to each other and the average in the class with the highest and the lowest monthly income was observed to be higher than that for the other groups. Here, only BSM average showed statistically significant difference between groups ($P > .05$). With respect to the profession, the average scores of patients who were housewives or from other professions were higher than those of civil servants, retired, and self-employed patients. With regard to the groups based on profession, not all scale averages showed statistically significant difference ($P > .05$).

The scores of those without health insurance were much higher than those with health insurance. When grouped according to health insurance, not all scale averages show statistically significant difference ($P > .05$). According to the type of residence, it is seen that the average of the scale increases toward those who live in the village. On the other hand, it is seen that those who live in the province have a higher average with a small difference in General Health Complaints (GHC) average. All scale averages do

not show a statistically significant difference with respect to residence type groups ($P > .05$).

DISCUSSION

In this study, to measure the quality of life in patients with CRC, the validity and reliability of the KKHYK scale developed by EORTC was tested, and the quality of life and compatibility of patients with CRC were evaluated. In the literature, there are studies in which the scales developed by EORTC have been translated into different languages and studied for validity and reliability.¹⁸⁻²⁰

Benzten et al.¹⁸ examined the health-related quality of life impairment in patients with anal cancer after chemotherapy and conducted a cohort study with 128 cancer survivors. In the study, the long-term health-related quality of life of the sample was measured with QLQ-C30 and QLQ-CR29 scales published by the EORTC. A control study was carried out with 269 people whose age and gender distribution were similar and who did not receive pelvic cancer treatment. The results of the QLQ-C30 scale of the control group were also compared with the Norwegian and Dutch normal population data. According to the results of the study, it was reported that the cancer patients had statistically significant difficulty in performing their social and role functions compared to the control group.¹⁸ Nowak et al.¹⁹ conducted validation studies of the EORTC's QLQ-CR29 quality of life module on Polish patients with rectal cancer. Validity and reliability analyses were performed in the study. The data collected from 20 patients were analyzed according to the EORTC procedure, and the compatibility of the data with the theoretical and experimental structure was examined. The difference between patients with and without ostomy was examined. According to the results of the study, while the difference in the quality of life of scale by gender was not statistically significant, the difference in body image scale and stool leakage items was observed in individuals without ostomy.¹⁹ Similarly, Peng et al.²⁰ evaluated the results of the QLQ-CR29 scale in Chinese patients who were diagnosed with rectal cancer and treated. In the study, the QLQ-30 scale used for all cancer patients was applied to the 2 groups and to the experimental group with CRC, in addition to the QLQ-CR29 scale. In the study, the results of individuals with and without ostomy with different treatment modules were evaluated. According to the study results, having a stoma bag decreases the quality of life.²⁰ In their study, Thaysen et al.²¹ validated the Danish version of the QLQ-CR38 scale. The study was performed on 190 patients with CRC. In the study, the reliability of

the scale was evaluated with the Cronbach Alpha coefficient. If valid in the study, compliance was made with validity and discriminant validity, and internal validities were measured. While the Danish version of the scale was highly valid and reliable in the study, sufficient answers to the questions about sexuality were not obtained in the research.²¹

In another study, Tomaszewski et al.²² validated the Polish version of QLQ-OG25 esophageal gastric cancer patients. In the study, compatibility validity between the QLQ-30 and QLQ-OG25 scales was made with Pearson's moment method. The Cronbach Alpha coefficient was used for reliability.²² In this study, it was revealed that the Polish version of the scale is a highly valid and reliable scale, similar to our study. Fernandez et al.²³ reported in their study that delayed diagnosis was the most important factor affecting patients' quality of life.²³ When the information about the disease was examined in our study, we found that most of our patients did not have sufficient information about the stage of the disease and medical diagnosis. The extent of chemotherapy training was very low and training sessions were mostly conducted by nurses. The time of diagnosis was at 1 year or less, and most of the patients stated that they were able to adapt to the disease.

In their study, Conroy and Blazeby²³ reported that the quality of life in patients with CRC is closely related to their perception and compliance levels. Xu et al.²⁴ reported that there were significant changes in quality of life before and after cancer, and patients' adaptation to the disease increased their quality of life. Ribocco et al.²⁵ reported that there were no significant changes in patients' quality of life before and after treatment. In our study, the majority of patients considered their illness to be a disease that requires treatment for a long time, while those who adapted to drug treatment were the majority. Again, more than half of the patients (54.7%) went for regular health checks, and in the same proportion, our patients stated that they were stressed in their daily lives.

CONCLUSION

The results of the study showed that the Turkish version of the KKHYK Scale is a measurement tool with validity and reliability indicators in measuring the quality of life of patients with CRC. In addition, it was concluded that patients did not have sufficient knowledge about their disease, and this situation increased the burden of nursing care.

Ethics Committee Approval: This study was approved by the Turkish Republic Istanbul Bilim University Clinical Research Ethics Committee with the decision numbered 04.11.2014/25-170.

Informed Consent: In the recruitment process, all patients were given the "Minimum Informed Consent Form" on a voluntary basis, so they could read and sign the form. In this way, it was ensured that the patients voluntarily participated in the study.

Peer Review: Externally peer-reviewed.

Author Contributions: Funda AKDURAN: Study design, data collection, analysis, data collection, analysis.

Zehra DURNA: Concept, study design.

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