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OROFARENGEAL MUKOZİTLİ HASTALARDA YAŞAM KALİTESİ ÖLÇEĞİ'NİN TÜRKÇE GEÇERLİLİK VE GÜVENİRLİĞİ ¹

TURKISH VALIDITY AND RELIABILITY OF THE LIFE QUALITY SCALE IN PATIENTS WITH OROPHARYNGEAL MUCOSITIS

Türkan ÖZBAYIR¹, Selda KARAVELİ ÇAKIR², Kevser KARACABAY³

¹ Ege Üniversitesi Hemşirelik Fakültesi Cerrahi Hastalıkları Hemşireliği Anabilim Dalı, İzmir / Türkiye ² Kastamonu Üniversitesi Sağlık Bilimleri Fakültesi Hemşirelik Bölümü, Kastamonu / Türkiye ³ Dumlupınar Üniversitesi Kütahya Sağlık Yüksekokulu Hemşirelik Bölümü, Kütahya / Türkiye

Öz: Amaç: Bu araştırma, "Orafarengeal Mukozitli Hastalarda Yaşam Kalitesi Ölçeği"nin Türkiye'deki hastalar için geçerli ve güvenilir bir araç olup olmadığını incelemek amacıyla yapılmıştır. Yöntem: Araştırma metodolojik bir çalışma olarak planlandı, veriler İzmir ili içerisinde yer alan bir üniversite hastanesinin onkoloji kliniğinde toplandı. Araştırmanın örneklemini oral mukoziti olan iletişim kurulabilen ve araştırmaya katılmayı kabul eden155 hasta oluşturdu. Araştırmanın verileri Birey Tanıtım Formu ve Orafarengeal Mukozitli Hastalarda Yaşam Kalitesi Ölçeği kullanılarak toplandı. Bulgular: Bu araştırmanın ön hazırlık aşamalarında ölçek ile ilgili uzman görüşü önerileri ve yapı dil geçerliliği çalışmaları sonucunda ölçeğin maddelerinde herhangi bir değişiklik yapılmadı. Orarengeal Mukozitli Hastalarda Yaşam Kalitesi Ölçeği'nin ve alt boyutlarının iç tutarlılık güvenilirlik katsayısı tüm ölçek için μ =0.98, semptomlar boyutunda μ =0.90, diyet boyutunda µ=0.94, sosyal fonksiyon boyutunda µ=0.95, yutma boyutunda µ=0.95 olarak bulundu. Sonuç: Bu çalışmada, Orafarengeal Mukozitli Hastalarda Yaşam Kalitesi Ölçeği" nin Türkçe formunun, Türk toplumunda kullanılabilecek geçerli ve güvenilir bir araç olduğu sonucuna varıldı.

Anahtar Kelimeler: Oral Mukozit, Yaşam Kalitesi, Geçerlilik, Güvenilirlik Abstract: Aim: The aim of the study is to examine the validity and reliability of the New Measure of Health-Related Quality of Life for Patients with Oropharyngeal Mucositis (OMQoL) for Turkish population. Method: The study was designed as a methodological research, and the data were conducted by researchers at a university hospital's oncology clinic, located in Izmir, Turkey. Outpatient or hospitalized patients receiving treatment in the oncology clinic of the research hospital made up the population of the research. The study sample consisted of 155 patients had oropharyngeal mucositis, can communicate and agreed to participate in the study. The data were collected in the study using a demographic data collection form and the OMQoL. Results: In the preliminary stages of this research, as a result of expert suggestions and language structure validity of the scale, there were no changes made to the scale items. Cronbach alpha reliability constant was found as µ=0.98 for all scale. Cronbach alpha reliability constants of OMQoL sub dimensions were found respectively as; symptoms μ =0.90, diet μ =0.94, social function μ =0.95, swallowing µ=0.95. Conclusions: The Turkish version of the OMQoL is a reliable and valid instrument to measure quality of life with oral mucositis patients.

Key Words: Oral Mucositis, Quality of Life, Reliability, Validity

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⁽¹⁾ Sorumlu Yazar: Selda KARAVELİ ÇAKIR, Kastamonu Üniversitesi Sağlık Bilimleri Fakültesi Hemşirelik Bölümü, Kastamonu / Türkiye seldakaraveli@gmail.com Geliş Tarihi / Received: 19.01.2017 Düzeltme Tarihi / Revised:14.04.2016 Kabul Tarihi / Accepted: 27.02.2017 Makalenin Türü: Type of Article (Araştırma – Uygulama / Research - Application) Çıkar Çatışması / Conflict of Interest: Yok / None "Etik Kurul Raporu Var- Yes Ethics Committe (Ege Üniversitesi Hemşirelik Yüksekokulu Etik kurulu: 31.03.2010 tarih, 447 sayılı).



INTRODUCTION

Oral mucositis, which is caused by the onset of mucosal injury with the administration of chemotherapeutic agents and radiotherapy, is an ulcerative and inflammatory process (Sonis et al., 2004a: 1995; Sonis, 2004b: 277; Scully et al., 2006: 229; Cheng et al., 2007a: 2590; Sonis, 2009: 1015; Karadakovan et al., 2010: 57; Georgiou et al., 2012: 215). Since oral mucosal epithelial cells are more rapidly divide than other cells, they are more affected by cytotoxic effects of chemotherapy (Raber et al., 2004: 219; Cheng, 2006: 2114; Yilmaz, 2007: 241). Oral mucositis is seen as a complication of chemotherapy, radiotherapy, bone marrow and stem cell transplantation in cancer cases (Cavusoglu, 2007: 398; Georgiou et al., 2012: 215).

Background

The degree of developing mucositis in patients receiving radiotherapy combined with chemotherapy is more than those who are only receiving chemotherapy. Oral mucositis, dry mouth and change of taste have detected as the most common side effects in research on cancer patients receiving chemotherapy (Scully et al., 2006:229; Cavusoglu, 2007: 398; Koroglu, 2007:5). Lack of proper oral and dental care during cancer treatment, is the most important factor triggering the development of oral mucositis (Cavusoglu, 2007: 399; Koroglu, 2007: 6). The incidence of oral mucositis varies according to the patient's diagnosis, age, status of oral health, chemotherapy received, dose of radiotherapy and frequency. This problem is prevalent in 75% of patients receiving chemotherapy (Koroglu, 2007: 6), 75-100% of stem cell transplant patients, 80% of radiotherapy receiving head and neck tumor patients and about 90% of pediatric oncology patients (Sonis, 2004b: 277; Scully et al., 2006: 230; Cavusoglu, 2007: 398).

Mucositis related pain is the most frequently reported problem by patients. Patients have difficulties in chewing, swallowing and speech together with mucositis. Mucositis which is related with acute and chronic symptoms causes anorexia, cachexia, dehydration and malnutrition (Cawley and Benson, 2005: 584; Scully et al., 2006: 230; Eren et al., 2007: 70; Cheng et al., 2007: 2591; Cavusoglu, 2007: 399; Cheng and Leung, 2009: 389). Pain, infection, nutritional changes, impairment of oral function, negative effect of treatment as well as economic difficulties, negatively affect the patient's quality of life (Cheng, 2007b: 36; Cheng and Leung, 2010: 1478). It can risk the patient's ability to tolerate the planned treatment, causes skipping of doses or reduction of dose. In additional to these, it increases mortality due to the risk of developing opportunistic infections and sepsis and leads to longer duration of hospitalization and



increase of the cost of treatment (Elting et al., 2003: 1531; Cawley and Benson, 2005: 586; Cavusoglu, 2007: 399; Sonis, 2013: 237). Because oral mucositis may lead to many clinical and economic problems, nurses have important responsibilities for its prevention, treatment and care (Cawley and Benson, 2005: 584; Fanning et al., 2006: 374; Cheng, 2007b: 37; Cheng and Leung, 2009: 390; Farrington et al., 2013: 6).

Aim

The aim of the study is to examine the validity and reliability of the New Measure of Health-Related Quality of Life for Patients with Oropharyngeal Mucositis (OMQoL) for Turkish population, which was developed by Karis K. F. Cheng, S. F. Leung et al (2007a).

METHODS

Design, sample and setting

Written permission was obtained from Karis K. F. Cheng to adapt the OMQoL into Turkish. Ege University Nursing School Ethical Committee (447) reviewed and approved this study for the protection of human subjects.

Instrument

Data were collected in the study using a demographic data collection form and the OM-QoL. OMQoL is a 31 items tool developed by Cheng et al in 2007 in Hong Kong in order to determine the quality of life of the patients with oral mucositis (Cheng et al., 2007a: 2590). The scale consists of four sub dimensions. The symptoms part consists of 9 questions (1-9 items), diet part consists of 10 (10-19 items), social function part consists of 7 (20-26 items) and swallowing part consists of 5 questions (27-31 items). It is a Likert type scale (1 none - 4 many). Scale score is calculated by calculating and grading all items oppositely. Average scores were used for scale scores. An average score is approximately 100 in the whole scale or its sub dimensions indicate that the patients have better life standards.

Procedures

Language validity study for the OMQoL

In order to test the validity of OMQoL for Turkish population; language validity studies of the scale were conducted in the first phase of the study. Primarily, the scale was translated into Turkish by the researchers. Then the scale is separately translated into Turkish by 5 experts with excellent English whose native language is Turkish. The final version of the scale which is created by selecting the most appropriate expressions as a result of these translations was translated from Turkish into English again by two English language



experts who are blind to the English version of scale and knows both languages. English expressions of the scale that are translated from Turkish into English are compared with the expressions of the original scale and necessary adjustments were made (Sireci and Berberoglu, 2000:230; Aksayan and Gozum, 2002b:10; Ercan and Kan, 2004:212; Erefe, 2004: 170; Eser and Baydur, 2007: 4; Ozgur, 2009: 31; Karayagız et al., 2015:4).

Content Validity

Turkish form of OMQoL was presented to 5 faculty members and 2 research assistants from Ege University School of Nursing, and total of 10 experts from Oncology Hospital; 2 doctors and 1 nurse and their opinions about the content were received. Content Validity Index (CVI) developed by (Waltz and Bausel, 1981:32) was used for the expert opinion evaluation. In this index, a score of 1–4 is given for each item (1=inappropriate, 2=item needs)modifications to make it appropriate, 3=appropriate but needs minor changes, 4=very appropriate) (Aksayan et al., 2002a:169). The Scale was finalized with more understandable expressions as a result of the suggestions received. In the preliminary stages of this research, as a result of expert suggestions and language structure validity of the scale, there were no changes made to the scale items.

Pilot testing

The draft scale, revised according to expert opinion, was administered to 20 patients who had similar characteristics to the research population.

Data collection

Data collection was conducted by researchers at a university hospital's oncology clinic, located in İzmir, Turkey. When a possible participant was interested in the study, the researchers provided the information on the study including the purpose, time to complete questionnaires and informed consent. If she/ he wanted to participate in the study, the researchers reviewed and signed the informed consent sheet with the participant. The participant filled out the questionnaires by themselves.

Participants

Outpatient or hospitalized patients receiving treatment in the oncology clinic of the research hospital made up the population of the research. Of these patients, 155 patients had oropharyngeal mucositis, can communicate and agreed to participate in the study consisted of the samples of the study.

After four weeks, later the first interview, the second interview for data collection from the 30 participants who participated in the first



interview was conducted to determine the test-retest reliability of the OMQoL.

Data Analysis

The analysis was conducted using descriptive statistics and reliability and validity statistical tests using the Statistical Package for Social Services SPSS 16.0. Content validity was assessed using an expert panel. Concordance of expert opinions was tested using the Kendal W statistic. Internal consistency was determined using Cronbach's alpha and item-to-total, sub dimensional scores of the sub dimensional items and total score correlations of the sum of sub dimension scores analysis was determined by using Pearson Correlation. Test-retest measurement was assessed using Pearson correlations and a dependent t-test with a four-week interval. Construct validity was assessed by confirmatory factor analysis (CFA). Indices to assess the degree to which the data fit the model were: the x^2 statistics, the ratio of chi-square to degree of freedom (x^2 /df), the root mean square error of approximation (RMSEA), the comparative fit index (CFI), the standardized root-mean square residual (SRMR) and the non-normed fit index (NNFI) (Simsek, 2007:158; Harrington, 2009: 50).

RESULTS

General characteristics of the participants

Table 1 summarizes the demographic data. The mean age of the participants was 47.57 years (SD=15.14) and about 53.5% of the participants were women. 66.5% of the participants had grade 2 mucositis.



Table 1. The Distribution of Participants Characteristics (n:155)

Characteristics	n	%			
Gender					
Female	83	53.5			
Male	72	46.5			
Educational level					
Illiterate	8	5.2			
Primary school	57	36.8			
High school	68	43.9			
University	20	12.9			
Post-graduate	2	1.3			
Marital status					
Single	30	19.4			
Married	113	72.9			
Divorced or widowed	12	7.7			
Treatment plan					
Chemotherapy	124	80.0			
<u>C</u> hemoradiotherapy	31	20.0			

*Descriptive test

Descriptive statistics of the OMQoL

Descriptive data for each item of OMQoL are shown in Table 2. The mean value of the items ranged from 1.90 (SD=0.94)–3.57 (SD=0.86) (Table 2).



Table 2. Descriptive Statistics of OMQoL and Pearson Correlation Coefficient Betweenthe Items and the Total Scale (n= 155)

Item Content	Μ	SD	R	Р
1. I have swelling inside my mouth.	3.28	0.90	0.68	0.000
2. I have mouth ulcer.	2.37	0.76	0.62	0.000
3. Mouth pain makes me distressed.	2.17	1.02	0.51	0.000
4. I have oozing/bleeding on my lips. or inside my mouth.	3.44	0.77	0.73	0.000
5. I feel discomfort while tooth brushing/mouth rinsing.	2.10	0.94	0.47	0.000
6. Mouth pain makes me have trouble sleep.	3.07	0.97	0.76	0.000
7. I have mouth pain.	2.40	0.87	0.74	0.000
8. I have burning sensation inside my mouth.	2.57	0.91	0.70	0.000
9. I have difficulty in opening my mouth.	2.72	1.06	0.79	0.000
10. I am unable to enjoy food.	1.95	0.90	0.66	0.000
11. I reduce outside social dining due to mucosal discomfort.	2.91	1.29	0.73	0.000
12. My saliva becomes thick/sticky and need to spit out frequently.	2.98	1.05	0.74	0.000
13. I have taste changes.	1.90	0.94	0.66	0.000
14. Eating difficulty makes me distressed.	2.15	0.99	0.81	0.000
15. I use longer time to drink/eat.		0.99	0.84	0.000
16. I have weight loss.		1.06	0.70	0.000
17. I modify my diet (e.g. food type. texture and size).	2.34	0.95	0.78	0.000
18. I reduce my soft/solid food intake.	2.42	1.02	0.82	0.000
19. I worry my inadequate nutritional intake.	2.64	1.04	0.78	0.000
20. I speak with lower quality/voice.	2.70	1.07	0.89	0.000
21. I have difficulty in talking.		0.99	0.90	0.000
22. I need to use other means (e.g. paper/pen. body language) to communicate with others.		0.86	0.76	0.000
23. I feel embarrassed at mealtimes with my family/friends.	3.43	0.85	0.73	0.000
24. Speaking difficulty makes me distressed.	2.96	1.06	0.88	0.000



25. I do not want to talk to others (including talking on phone) due to mouth discomfort.	3.09	0.99	0.83	0.000
26. I have my expression (including smiling to others) and communication affected.	3.01	0.85	0.85	0.000
27. I have throat discomfort.	2.72	1.15	0.85	0.000
28. I have difficulty in swallowing liquids (e.g. water. juice. soup).	3.22	.91	0.85	0.000
29. I have difficulty in swallowing soft/solid food.	2.62	1.05	0.84	0.000
30. I feel easily choked while swallowing.		1.14	0.80	0.000
31. I have difficulty in swallowing saliva.	2.90	1.06	0.85	0.000

M: Mean, SD: Standart Deviation, R: Range, p<0.05

*Descriptive test

Validity analysis

Construct validity

CFA was performed in order to confirm the sub dimensions/factors compatibility for the

structural validity of OMQoL. Factor burdens (way coefficients) of all the factors with their own dimensions have been found between 39 and 69 (Figure 1).

The model concordance indicators were found to be: x^2 368.93 (p >0.05), $x^2/p=$.86, RMSEA 0.000, CFI 1.00, SRMR



0.051 and NNFI 1.00.

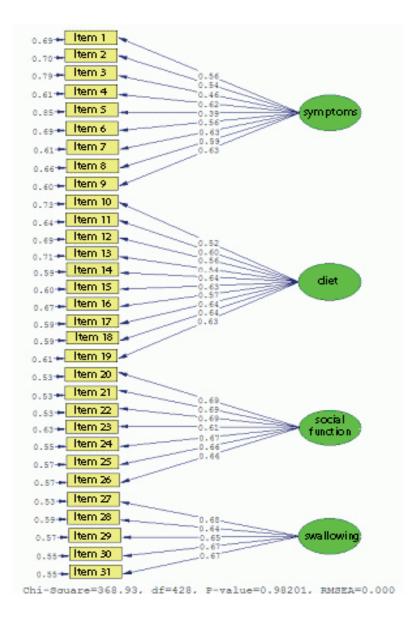


Figure 1. Health-Related Quality of Life for Patients with Oropharyngeal Mucositis Scale's Confirmatory Factor Analysis Model



Reliability

In the analysis performed to test internal consistency which is one of the reliability indicators of OMQoL and its sub dimensions, Cronbach alpha reliability constant was found as μ =0.98 for all scale. Cronbach alpha reliability constants of OMQoL sub dimensions were found respectively as; symptoms μ =0.90, diet μ =0.94, social function μ =0.95, swallowing μ =0.95.

Total item score correlations of all items of OMQoL were found between 0.47- 0.90 and was found to be statistically significant (p<0.001) (Table 2).

When the sub dimension items of OMQoL with sub-dimension total scores were examined with Pearson correlation analysis, reliability coefficients were; in symptoms dimension r=0.61 and 0.86, in diet dimension r=0.70 and 0.90 social function dimension r=0.80 and 0.93 in swallowing dimension were between r=0.84 and 0.94 and statistically significant (p<0.001).

When the sub dimension scores of OMQoL with total scale scores were evaluated with Pearson correlation analysis, reliability coefficients were found for symptoms dimension as r=0.89, for diet dimension r=0.94, for social functions dimension r=0.95, for swallowing dimension as r=0.92 and were found highly significant statistically (p<0.001).

Test -retest reliability

In order to evaluate the invariance with respect to time of OMQoL and sub dimensions, when mean scores obtained from test and retest reliability analysis were compared in dependent groups with t test; there was no significant difference detected between the mean scores of the two measurements performed with four weeks' interval (p>0.05).

When the relationship between the scores obtained from the first and second applications for the reliability analysis of OMQoL were evaluated with pearson correlation analysis; a very strong positive and statistically significant relationship was detected between measurement scores (p<0.001, Table 3).



Table 3. Comparison of OMQoL and Its Subscale Test-Retest Score Means and Correlations (n=30)

OMQoL - Subscales		First Administration	Second Administration	t*	р	r	р
		$\bar{\mathbf{x}}_{\pm \mathrm{SS}}$	x ±SS				
OM	IQoL Total Scale	64.44 ± 25.84	65.66 ± 23.71	1.925	0.064	0.99	0.000
Subscales	1. Symptoms	63.95 ± 24.76	65.93 ± 21.16	1.915	0.065	0.98	0.000
	2. Diet	56.67 ± 26.84	58.11 ± 25.05	1.941	00.062	0.99	0.000
	3. Social function	73.97 ± 30.01	74.13 ± 29.64	1.000	0.326	1.00	0.000
	4. Swallowing	67.56 ± 31.40	68.44 ± 29.81	1.278	0.211	0.99	0.000

* t-test in dependent groups: df =29

DISCUSSION

In order to be able to use a scale which is developed for certain cultures. its psycholinguistic and psychometric properties defined as validity and reliability should be evaluated (Sireci and Berberoglu. 2000: 229; Aksayan and Gozum. 2002b: 9; Ercan and Kan. 2004: 212).

Validity

Validity is the ability of a measurement tool to accurately measure the feature that it aims to measure without confounding with any other feature (Karasar. 2000: 137; Ercan and Kan. 2004: 212; Eser and Baydur. 2007: 5; Ozgur. 2009: 32). CFA is utilized in the study of scale validity. CFA is used to evaluate how

the factors created based on a theoretical foundation are compatible with actual data. Goodness of Fit statistics is needed to be at required level in CFA. The values described as consistency statistics values are;

Chi-square consistency statistics: When the value is two or below that is obtained by the division of chi-square value to degree of freedom indicates that the model is good and the value of five or below five indicates that it has an acceptable goodness of consistency (Simsek. 2007:158; Harrington. 2009: 51). In this study, the value obtained by division of chi-square value to degree of freedom according to CFA results has found to be 0.86. this value demonstrates that the scale has an acceptable goodness of consistency.



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Other goodness of compatibility tests frequently used are; Root Mean Square Error of Approximation (RMSEA). Standardized Root Mean Square Residual (SRMR). Comparative Fit Index (CFI). Non-Normed Fit Index (NNFI). Goodness of Fit Index. (GFI). Adjusted Goodness of Fit Index (AGFI). When the value of RMSEA is equal to 0.080 or less and p value is less than 0.05. it shows that consistency is good. when it is equal to 0.10 or less consistency is weak (Simsek. 2007:159; Harrington. 2009:51). In the CFA performed in this study RMSEA value is significant and found to be equal to .000 demonstrates that consistency is good.

Also. SRMR is less than .10 (Simsek. 2007: 159). CFI. NNFI values equal or above 0.90 (Simsek. 2007: 159; Harrington. 2009: 51). AGFI equal or above 0.80. GFI value equal or above 0.85 also demonstrates consistency (Harrington. 2009:51). In this study. according to SRMR. CFI. NNFI. GFI. AGFI values obtained from CFA. consistency was observed as good. These results support the construct validity of the Turkish version of the OMQoL.

Reliability

Reliability is related with the concepts of consistency. accuracy. uniformity and equivalence (LoBiondo-Wood et al., 2005: 328). Reliability of a measurement tool is providing

the opportunity to consistently obtain similar values in repetitive measurements under the same circumstances (Karasar. 2000: 137; Aksayan and Gozum. 2002b: 10; Ercan and Kan. 2004: 213; Eser and Baydur. 2007: 6; Ozgur. 2009: 32).

In scale development studies. it is necessary to test the internal consistency of the scale items (Akgul. 2005:7). Although there are various internal consistency methods. the most commonly used is Cronbach's alpha analysis particularly in Likert type scales. When this coefficient is below 0.40 it shows that the scale is "not reliable". between 0.40-0.59 shows that the scale has "low reliability". if between 0.60-0.79 shows that the scale is "reliable" and when between 0.80 and 0.100 shows that the scale is "highly reliable" (Akgul, 2005: 9). Cronbach alpha reliability coefficient was found as μ =0.98 for whole scale in the analysis performed to test internal consistency one of the reliability indicator of OMQoL and its sub dimensions. In the symptoms dimension of the OMQoL was μ =0.90. for diet dimension $\mu=0.94$. for social function dimension μ =0.95 and for swallowing dimension it was found as μ =0.95. This result shows high internal consistency and high reliability of the scale items with each other.

Higher correlation coefficient is considered to be the indicator of appropriate theoretical



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structure of that item. Lower limits of correlation coefficients are given as 0.20; 0.25; 0.30 in various sources (Aksayan et al., 2002a: 114; Aksayan and Gozum. 2002b: 12). For the reliability study of OMQoL. when 31 item-total score correlations were evaluated (Pearson correlation/Pearson Moments Multiplying Correlation). reliability coefficients were detected between 0.47 and 0.90 in positive direction and statistically significant (p<0.001) (Table 2). When the sub dimension items with sub dimension scores of the scale were evaluated with Pearson correlation analysis; reliability coefficient for symptoms dimension was determined between r=0.61 and 0.86. for diet dimension between r=0.70 and 0.90. for social function dimension between r=0.80 and 0.93 and for swallowing dimension determined between r=0.84 and 0.94. These results were found in the positive direction and highly statistically significant (p < 0.001). When the sub-scale total scores and total score of the scale were evaluated with Pearson correlation analysis. reliability coefficients were found between r= 0.89 and 0.95. The relationship between them was determined in the positive direction. strong and highly statistically significant (p<0.001).

In the literature test-retest is recommended to test and evaluate the scale for 15 days-1 month intervals with the same group of the analysis of the scale for time-invariance Aksayan et al., 2002a: 175; Aksayan and Gozum. 2002b: 12). Scores obtained from both measurements are calculated with 'Pearson Moments Multiplying Correlation Analysis'. The obtained coefficient is considered to be the indicator of invariance of the scale and this score must be at least 0.70 (Aksayan et al., 2002a: 180). In this current study. testretest application was performed with four weeks' interval and test-and retest reliability coefficient was found to be 0.99 for whole scale. and determined for the sub dimensions respectively as; for symptoms r=0.98. diet r=0.99. social functions r=1.00. swallowing r=0.99.

When the mean test and retest scores obtained from the reliability analysis in order to evaluate the invariance of OMQoL and its sub dimensions for time were compared with t test in dependent groups. there was no difference statistically detected between the mean scores of the two measurements performed with four weeks' interval (p>0.05. Table 3). When the relationship between the scores obtained from the first and second applications for the reliability analysis of OMQoL was evaluated with pearson correlation analysis; there was a significant strong relationship in the positive direction between the two measurement scores obtained with four weeks' interval. and statistically significant (p<0.001. Table 3).



CONCLUSION

The Turkish version of the OMQoL is a reliable and valid instrument to measure the quality of life of oral mucositis patients. The psychometric properties of the original version of the OMQoL were preserved. Psychometric analysis of the Turkish version of OM-QoL indicates high reliability (internal consistency) and good content and construction validity.

Relevance to clinical practice

This study provides evidence that Turkish version of the OMQoL is a reliable and valid instrument for assessing oral mucositis in patients. OMQoL allows evaluation of the quality of life of patients with oral mucositis within a short period of time.

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Conflict of interest

There is no conflict of interest.

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