

# PSYCHOMETRIC PROPERTIES OF THE ORAL MUCOSITIS DAILY QUESTIONNAIRE IN TURKISH CHILDREN WITH CANCER

# Büşra Güliz Yıldırım<sup>1</sup>, Gülçin Özalp Gerçeker<sup>2</sup>

<sup>1</sup> Dokuz Eylul University Child Hospital, Izmir, Turkey

<sup>2</sup> Pediatric Nursing Department, Dokuz Eylul University Faculty of Nursing, Izmir, Turkey

ORCID: B.G.Y. 0000-0001-6995-1515; G.Ö.G. 0000-0002-2229-616X

Corresponding author: Gülçin Özalp Gerçeker, E-mail: gulcinozalp@gmail.com Received: 02.06.2022; Accepted: 14.11.2023; Available Online Date: 31.01.2024 ©Copyright 2021 by Dokuz Eylül University, Institute of Health Sciences - Available online at https://dergipark.org.tr/en/pub/jbachs

**Cite this article as:** Yıldırım BG, Özalp-Gerçeker G. Psychometric Properties of the Oral Mucositis Daily Questionnaire in Turkish Children with Cancer. J Basic Clin Health Sci 2024; 8: 30-38.

# ABSTRACT

**Purpose:** The Oral Mucositis Daily Questionnaire (OMDQ) can be used in pediatric cancer patients. This study aimed to investigate the Turkish validity and reliability of the OMDQ in children aged 8 - 18 years diagnosed with cancer at two university hospital pediatric hematology/oncology clinics.

**Material and Methods:** Children's International Mucositis Evaluation Scale (ChIMES) and the World Health Organization (WHO) Oral Mucositis Grading Scale were used in parallel form reliability. Thirty children with oral mucositis were included in the study at the inter-rater and test-retest reliability on the 14th and 15th days of chemotherapy treatment. Ninety-two children were included for the construct validity. Kappa Compliance Analysis, Spearman's correlation coefficient, and Cronbach's alpha were evaluated.

**Results:** The content validity index was calculated for the scores given by the experts and the items were changed between .90 and 1.00. On the 14th and 15th days of chemotherapy treatment, the correlation values for each item of OMDQ were found to be over .64. In the construct validity, the patient's mean age was  $11.7\pm3.3$ , and 46.7% diagnosed with Acute Lymphoblastic Leukemia. Cronbach Alpha value of OMDQ was .92. The OMDQ items showed a positive correlation with each other except for diarrhea questions. According to the WHO Oral Mucositis Grading Scale, 55.4% of the patients had grade 1 mucositis. The similar items of OMDQ and ChIMES had a positive significant relationship (p < .001).

**Conclusion:** The Turkish version of the OMDQ was a valid and reliable instrument in children aged 8 - 18 years diagnosed with cancer.

Keywords: Cancer, children, mucositis, reliability, validity

# INTRODUCTION

Most childhood cancers can be treated with combined forms of treatment, including various cytotoxic drugs, surgery, and radiotherapy (1). Mucositis, which is a common complication of chemotherapy, radiotherapy, bone marrow, and stem cell transplantation, is defined as inflammatory and/or ulcerative lesions of the oral and/or gastrointestinal tract [2). Oral mucositis (OM) is the most common oral complication of cancer therapy and affects more than 75% of pediatric patients (3). OM is associated with acute and chronic symptoms that negatively affect the patient's quality of life. Pain associated with mucositis and mucositis causes difficulties with swallowing and speech, problems with communication, problems with sleep, and oral intake (2). Mucositis is associated with poor nutritional status, and nutrition problems such as anorexia, cachexia, dehydration, and malnutrition can develop in many cancer patients. Most children require enteral or parenteral nutrition. It is seen that patients with mucositis have difficulties in eating, swallowing, and speaking because of pain. Fluid/food intake may be painful and inadequate in patients with OM (4-6). Depending on this, dehydration and malnutrition are observed. Mucositis creates a basis for the development of infection and decreases the quality of life of the patient and his family (4-8).

Before starting and during chemotherapy or radiotherapy, the oral mucosa should be evaluated for signs and symptoms of OM. The findings begin with erythema, and the pain may reach a level that affects the patient's chewing and swallowing with burning. There are many methods to determine the nature of changes in the oral cavity such as the National Cancer Institute Common Toxicity Criteria, and the WHO mucositis grading scale (6,8). The World Health Organization (WHO) Oral Mucositis Grading Scale mostly uses and includes subjective and objective criteria (8). It is very important to evaluate mucositis in children with cancer. There are observational scales to determine the change and quality of the oral mucosa (9-15). The Children's International Mucositis Evaluation Scale (ChIMES) evaluates the pain/soreness in the mouth and throat and related swallowing, drinking, eating, and medication (12-14). The Oral Mucositis Daily Questionnaire (OMDQ) evaluates the overall health, the amount of mouth and throat pain, the effect of mouth and throat soreness on swallowing, drinking, eating, talking, sleeping, and also the amount of diarrhea (10,14). The ChIMES had already been translated into Turkish and validated in children with cancer (16). The OMDQ includes the amount of diarrhea, although it is not correlated with other items (10). An important and debilitating symptom of intestinal mucositis is diarrhea, chemotherapyassociated mucositis can manifest as diarrhea, pain, and rectal bleeding (5,10). The OMDQ also evaluates the effect of mouth and throat soreness on sleeping and talking (10), ChIMES and OMDQ have differences. Mucositis assessment scales can be preferred according to healthcare professionals.

Symptoms of discomfort and pain often appear in the mouth and throat, preceding tissue changes (4). They can often be ignored in clinics, or the subjective and objective symptoms can be identified after the findings increase. In this regard, introducing existing scales into other languages, and making daily diagnoses in children receiving chemotherapy treatment through valid and reliable scales can prevent the exacerbation of mucositis (1,4,5,11-16). This study aimed to investigate the Turkish validity and reliability of the "Oral Mucositis Daily

Questionnaire" in children aged 8-18 years diagnosed with cancer.

# MATERIAL AND METHODS

This descriptive, cross-sectional, and methodological study was conducted to adapt the original version of OMDQ into Turkish. This study included pediatric cancer patients aged 8 - 18 years who had undergone chemotherapy for at least one month at the two university hospital's pediatric hematology/oncology clinics in Izmir, Turkey. Patients were recruited from February 2019 to May 2019. The sampling in methodological studies is stated to be at least fivefold the number of the items in the scale (17). OMDQ consisted of 6 items, and the sample size was determined as 30 pediatric cancer patients with OM for the test-retest reliability. Ninety-two pediatric cancer patients were taken at the construct validity to increase the power of the study using the purposeful sampling method. Inclusion criteria were; able to read and understand Turkish, had provided their written consent. Patients in the terminal stage, with neurologic or psychiatric disorders and who refused to participate in the study, were not included. Patients were recruited at their inpatient wards and outpatient clinics. Interviews were performed in patients' rooms and private rooms for outpatients.

# **Translation and Cultural Adaptation**

OMDQ was translated into Turkish for language equivalence. The scale was translated from English into Turkish by six translators who are fluent in English. These translators were 2 Ph.D. nurses, 2 MDs, and 2 RN at the pediatric hematology/oncology department. The resulting version of OMDQ was back-translated into English by two native English speakers who are fluent in Turkish. The authors assessed the back translation to establish the meanings of items. No important differences in meaning were found. Ten experts analyzed the semantic/idiomatic, conceptual, and cultural equivalence of the prefinal version of the scale. Scores changed from 1 (nonrepresentative) to 4 (representative) for each item. The content validity index (CVI) was calculated (17).

# **Data Collection Instruments**

These instruments were rated by the researcher based on child reports in this study. The Oral Mucositis Daily Questionnaire was administered to 30 children who were included in inter-rater and test-

	n (%)
Age Group	
8-12 years	56 (60.9)
13-18 years	36 (39.1)
Gender	
Girl	38 (41.3)
Воу	54 (58.7)
Stage of the disease	
New Diagnosis	19 (20.7)
Remission	47 (51.1)
Relapse	26 (28.3)
Diagnosis	
Acute Lymphoblastic Leukemia	43 (46.7)
Acute Myeloid Leukemia	14 (15.2)
Lymphoma	9 (9.8)
Central Nervous System Tumors	10 (10.9)
Other Solid Tumors	16 (17.4)
Treatment Period (months)	
1-4 months	21 (22.8)
5-9 months	16 (17.4)
10 months and more	55 (59.8)
Presence of Previous Mucositis	
Yes	89 (96.7)
No	3 (3.3)

retest reliability by the nurse as well as the researcher. All participants included in the construct validity completed the following questionnaires: The Oral Mucositis Daily Questionnaire, the WHO Oral Mucositis Grading Scale, and the Children's International Mucositis Evaluation Scale.

#### **Oral Mucositis Daily Questionnaire (OMDQ)**

In this study, we used the original version of OMDQ (10). This questionnaire is used for the assessment of mucositis in patients. A final 6-item version measured the overall health (Q1) (0 = Worst possible, 10 = Perfect health), the amount of mouth and throat pain (Q2) (0 = No soreness, 1 = A little soreness, 2 = Moderate soreness, 3 = Quite a lot of soreness, 4 = Extreme soreness), the effect of mouth and throat soreness (MTS) on swallowing (Q3a), drinking (Q3b), eating (Q3c), talking (Q3d), sleeping (Q3e), (0 = Not

limited, 1 = Limited A Little, 2 = Limited Some, 3 = Limited A Lot, 4 = Unable To Do), overall MTS (Q4), (0 = No soreness, 10 = Worst possible), amount of diarrhea (Q5), (0 = No diarrhea, 1 = little diarrhea, 2 = Moderate diarrhea, 3 = Quite a lot of diarrhea, 4 = Severe diarrhea) and overall diarrhea (Q6), (0 = No diarrhea, 10 = Worst possible) (10).

# WHO Oral Mucositis Grading Scale

The presence of oral mucositis is assessed based on clinical manifestations and ranges from 0 (the absence of symptoms) to 4 (oral feeding is impossible) (8).

# Children's International Mucositis Evaluation Scale (ChIMES)

The ChIMES is a self-reported scale that consists of six items assessing oral mucositis in children aged 8-18 years. Items 1-4 are scored from 0 (best) to 5 (worst). The remainder of items 5-6 are answered with a yes/no and assigned scores of 1 and 0, respectively. The maximum total score is 23 (12,13). Turkish version of ChIMES is valid and reliable (16).

#### **Psychometric Properties**

Pretest: In this period, ten children aged 8 - 18 years diagnosed with cancer were included, and they confirmed that the OMDQ items were clear and precise. All of the items were well understood by the respondents, who did not suggest any changes. These children were not included in the study.

# Inter-rater and test-retest reliability

The OMDQ was administered to thirty children by a researcher and nurse in the hematology/oncology clinic separately. The nurse in this study was a registered nurse who had worked in the hematology/oncology units for at least 5 years and had an oncology nursing certification. The researchers trained the nurse who collected data with OMDQ, and the researcher and the nurse administered OMDQ to 5 patients. Both of them rated the same score in these practices based on child reports.

For the test-retest reliability, children had to have oral mucositis. The OMDQ was administered to thirty children aged 8 - 18 years with OM on the 14th and 15th days of chemotherapy by the researcher and nurse separately. OMDQ was measured 24 hours apart with two separate evaluations on days 14 - 15th of chemotherapy by the researcher and nurse based

						Min- Max Score	M ± SD
Q1 – Overall health during the past 24 hours						0-10	1.2±1.6
Q2 – MTS during the past 24 hours	No soreness	A little soreness	Moderate soreness	Quite a lot of soreness	Extreme soreness	0-4	1.3±0.8
-	n (%)	n (%)	n (%)	n (%)	n (%)	-	
	11(12.0)	48 (52.2)	24 (26.1)	8 (8.7)	1 (1.1)		
During the past 24 hours, MTS limited at	Not limited	Limited a little	Limited some	Limited a lot	Unable to do		
-	n (%)	n (%)	n (%)	n (%)	n (%)	-	
Q3a – Swallowing Q3b – Drinking Q3c – Eating Q3d – Talking Q3e – Sleeping	58 (63.0) 41 (44.6) 28 (30.4) 46 (50.0) 68 (73.9)	28 (30.4) 38 (41.3) 45 (48.9) 34 (37.0) 17 (18.5)	3 (3.3) 9 (9.8) 14 (15.2) 8 (8.7) 4 (4.3 )	3 (3.3) 4 (4.3) 5 (5.4) 4 (4.3) 3 (3.3)	- - - -	0-4 0-4 0-4 0-4	0.4±0.7 0.7±0.8 0.9±0.8 0.6±0.8 0.4±0.8
Q4 – Overall MTS						0-10	1.4±1.0
Q5 – Diarrhea during past 24 hours	No diarrhea	A little diarrhea	Moderate diarrhea	Quite a lot diarrhea	Severe diarrhea	_	
	n (%) 71 (77.2)	n (%) 21 (22.8)	n (%) -	n (%) -	n (%) -	0-4	0.2±0.4
Q6 – Overall diarrhea						0-10	0.2±0.5

#### Table 2. Oral Mucositis Daily Questionnaire Items (n=92)

MTS= Mouth and throat soreness

on the child report. Inter-observer agreement was evaluated with Kappa Compliance Analysis. The relationship between the two measurements was evaluated by the Spearman correlation coefficient.

#### **Construct validity**

In this period, we included 92 children (Table 1), and they answered the OMDQ and ChIMES. The researcher filled out the WHO Oral Mucositis Grading Scale. Cronbach's alpha assessed for internal consistency. Spearman's correlation coefficient was used for the assessment of convergent validity between similar items of OMDQ and ChIMES.

# **Statistical Analysis**

The data were subjected to descriptive and inferential analyses using SPSS, version 22.0, software (IBM,

Armonk, NY). The significance level was p < .05. For the OMDQ cultural adaptation, CVI was used. Kappa Compliance Analysis, Spearman's correlation coefficient, and Cronbach's alpha were evaluated for reliability and validity. Correlation coefficients were defined as 0 - 0.25 negligible or not correlated, 0.25- 0.50 fair correlation, 0.50 - 0.75 moderate to good correlation, and > 0.75 very good to excellent correlation (17).

# **Ethical Considerations**

Permission to use the scale in Turkey was obtained from the scale's writers. Ethical approval was received from the Non-Invasive Clinical Studies Ethics Committee of the university (Date: 13.02.2019, Decision no: 2019/03-55).). The researcher informed children and parents about the aim of the study and

	Q1	Q2	Q3a	Q3b	Q3c	Q3d	Q3e	Q4	Q5	Q6
(Q1) Overall Health	1.00									
(Q2) MTS	0.688**	1.00								
(Q3a) MTS-swallowing	0.654**	0.744**	1.00							
(Q3b) MTS-drinking	0.633**	0.728**	0.835**	1.00						
(Q3c) MTS-eating	0.636**	0.733**	0.703**	0.806**	1.00					
(Q3d) MTS-talking	0.643**	0.711**	0.810**	0.820**	0.782**	1.00				
(Q3e) MTS-sleeping	0.592**	0.620**	0.719**	0.715**	0.682**	0.737**	1.00			
(Q4) Overall MTS	0.792**	0.795**	0.726**	0.741**	0.729**	0.746**	0.655**	1.00		
(Q5) Diarrhea	0.119	0.176	0.333	0.176	0.155	0.251	0.202	0.182	1.00	
(Q6) Overall diarrhea	0.131	0.080	0.294	0.140	0.126	0.230	0.218	0.185	0.888**	1.00

 Table 3. Correlation of Oral Mucositis Daily Questionnaire Items (n=92)

\*\*p < .001, MTS= Mouth and throat soreness.

obtained written consent forms from children and parents.

#### RESULTS

#### Test-retest reliability results (n=30)

The average age of the patients who were included in the test-retest reliability was  $12.6 \pm 3.1$ , all of them were inpatients and received chemotherapy treatment, 53.3% were girls (n=16), 26.7% were diagnosed with Acute Lymphoblastic Leukemia (n=8), 16.7% were Acute Myeloid Leukemia (n=5), 13.3% were Lymphoma (n=4), 43.3% were oncological tumors (n=13), and 33.3% were relapsed patients (n=10). Of the patients, 66.7% had Grade 1 mucositis (n=20), 30.0% had Grade 2 mucositis (n=9), 3.3% had Grade 3 mucositis (n=1) to the WHO Oral Mucositis Grading Scale on the 14th day of chemotherapy.

For test-retest reliability, the Pearson correlation coefficient was calculated on the 14th and 15th days of chemotherapy treatment for each OMDQ item. The scale was applied to children by the researcher and a nurse working in the clinic. There was no total score for the OMDQ, inter-observer compliance between researcher and nurse was evaluated with the Kappa Compliance Analysis for each item (0.87-1.00). OMDQ was applied to 30 children on the 14th and 15th days of chemotherapy treatment, and the interrater agreement for OMDQ items was determined between 0.64 and 1.00. According to the OMDQ results rated by the researcher, the general health mean score during the last 24 hours was 1.8 ± 1.7 on the 14th day and  $2.1 \pm 1.8$  on the 15th day (r = 0.86, p = .000); the mouth and throat pain mean score was  $1.1 \pm 0.8$  on the 14th day and  $1.3 \pm 0.8$  on the 15th day (r = 0.64, p = .000). Mouth and throat pain during the last 24 hours were  $0.3 \pm 0.5$  on the 14th day, 0.4  $\pm$  0.6 on the 15th day while swallowing (r = 0.89, p = .000); 0.8 ± 0.7 on the 14th day, 1.0 ± 0.7 on the 15th day while drinking (r = 0.82, p = .000);  $1.0 \pm 0.7$  on the 14th day,  $1.2 \pm 0.7$  on the 15th day while eating (r = 0.73, p = .000); 0.6  $\pm$  0.8 on the 14th day, 0.7  $\pm$  0.9 on the 15th day while talking (r = 0.94, p = .000) and  $0.3 \pm 0.6$  on the 14th day,  $0.3 \pm 0.6$  on the 15th day while sleeping (r = 0.96, p = .000). During the last 24 hours, the mouth and throat pain mean score was 1.5  $\pm$  1.3 on the 14th day and 1.7  $\pm$  1.4 on the 15th day (r = 0.85, p = .000). The mean score for amount of diarrhea was  $0.2 \pm 0.6$  on the 14th day and  $0.2 \pm 0.6$ on the 15th day (r = 0.85, p = .000). The mean score for overall diarrhea was 0.2 ± 0.6 on the 14th day and  $0.2 \pm 0.6$  on the 15th day (r = 1.00, p = .000). Correlations were evaluated for each item of OMDQ on the 14th and 15th days of chemotherapy treatment. The correlation values of the OMDQ items applied to children by the researcher and nurse were above 0.64 (p < .001).

#### Construct validity and reliability results (n=92)

In the construct validity, 92 children were included. All scores were rated by the researcher. The average age of the patients was  $11.7 \pm 3.3$ , 60.9% of them were 8-12 years old, 58.7% were boys, 46.7% were diagnosed with Acute Lymphoblastic Leukemia and 51.1% were in the remission stage (Table 1). All of the patients were receiving chemotherapy treatment only, and 71.7% were inpatients (n=66), 4.3% were feeding with a nasogastric tube because of mucositis (n=4), and 51% were requiring IV hydration (n=47).

•			<b>e</b> ( )		
	M±SD	r	р		
OMDQ - Q2	1.34±0.84	0.809	.000		
ChIMES Item 1	1.35±0.90				
OMDQ - Q3a	0.46±0.71	0.879	.000		
ChIMES Item 2	0.59±0.77				
OMDQ - Q3c	0.95±0.82	0.876	.000		
ChIMES Item 3	1.01±0.88				
OMDQ - Q3b	0.73±0.81	0.900	.000		
ChIMES Item 4	0.81±0.83				
OMDQ - Q2	1.34±0.84	0.642	.000		
WHO Oral Mucositis Grading Scale	1.11±0.75				

 Table 4. Relationship between OMDQ and ChIMES, OMDQ, and WHO Oral Mucositis Grading Scale (n=92)

OMDQ= Oral Mucositis Daily Questionnaire, ChIMES= Children's International Mucositis Evaluation Scale, Q2= The amount of mouth and throat pain, Q3a = Swallowing, Q3b = Drinking, Q3c = Eating

According to the WHO Oral Mucositis Grading Scale, 55.4% of patients were evaluated as Grade 1, 21.7% as Grade 2, 4.3% as Grade 3, and 18.5% as Grade 0. None of the patients had Grade 4 mucositis.

The mean score received for overall health during the past 24 hours was  $1.2 \pm 1.6$  (min:0, max:7). It was observed that 12% of patients had no soreness, 52.2% had a little soreness, 26% had moderate soreness, 8.7% had quite a lot of soreness and 1.1% had extreme soreness for the past 24 hours. During the past 24 hours, 30.4% limited a little while swallowing, 41.3% limited a little while drinking, 48.9% limited a little while eating, 37% limited a little while talking and 18.5% limited a little while sleeping. Patients with no soreness (n=11) had been evaluated as 'Not limited' in the MTS questions for the past 24 hours. The average score for MTS during the past 24 hours was 1.4 ± 1.0 (min: 0, max: 6). During the past 24 hours, 77.2% of patients had no diarrhea. The average score received for overall diarrhea during the past 24 hours was 0.27 ± 0.53 (min: 0, max: 3) (Table 2). The Cronbach Alpha value of OMDQ was .923.

We also evaluated the correlation between the items of OMDQ. Item Q1, Q2, Q3a, Q3b, Q3c, Q3d, Q3e, and Q4 positively correlated with each other (p <.001). Item Q5 and Q6 were correlated with each other, while not correlated with other items (Table 3). The ChIMES and WHO Oral Mucositis Grading Scale were used for construct validity. The OMDQ, ChIMES, and WHO Oral Mucositis Grading Scale measured the same or similar constructs (i.e. OMDQ MTS-related items, ChIMES Items 1 - 4). The correlation analysis between similar items of OMDQ (Q2, Q3a-3b-3c) and ChIMES (1 - 4) was evaluated. The OMDQ- Q2 and WHO Oral Mucositis Grading Scale ranged from 0 to 4 and evaluated the amount of mouth and throat pain. The correlation analysis between OMDQ- Q2 and the WHO Oral Mucositis Grading Scale was also evaluated.

In ChIMES Item 1, patients described the pain in their mouth and throat, 50% rated a little pain and 13% rated no pain. In ChIMES Item 2, patients described swallowing because of the mouth and throat pain, 50.4% stated "not hard" and 34.8% "little hard". In ChIMES Item 3, patients described eating because of the mouth and throat pain, 31.5% stated "not hard" and 42.4% "little hard". In ChIMES Item 4, patients described drinking because of the mouth and throat pain, 41.3% stated "not hard" and 40.2% "little hard". Patients of 73.9% had no pain medication and 26.1% needed medicine for mouth and throat pain (ChIMES Item 5). In ChIMES Item 6, 63% of patients had a mouth sore. The total average score of ChIMES was  $4.6 \pm 4.0$  (0-16).

There was a positive significant relationship between the OMDQ-Q2 and ChIMES Item 1 (pain in their mouth and throat), OMDQ 3a and ChIMES Item 2 (swallowing), OMDQ 3c and ChIMES Item 3 (eating), OMDQ 3b and ChIMES Item 4 (drinking), and OMDQ-Q2 and WHO Oral Mucositis Grading Scale (p < .001) (Table 4).

# DISCUSSION

Tomlinson et al. (15) adapted the original OMDQ for the pediatric oncology/hematology population, they made minor changes, and the OMDQ is appropriate for use in pediatrics. Parent report of a modified version of OMDQ was reliable for children receiving intensive chemotherapy (13). Manji et al. (5) examined the psychometric properties of the selfreport OMDQ in children aged  $\geq$  12 years diagnosed with leukemia/lymphoma or undergoing stem cell transplantation. This study suggested that the OMDQ is valid and reliable and that MTS-related questions on swallowing, drinking, eating, and talking are valid assessments of mucositis in children aged 8 - 18 years. In this study, OMDQ was applied to 30 children with oral mucositis on the 14th and 15th days of chemotherapy treatment by the researcher and a nurse working in the clinic for the test-retest reliability analysis. Children had to have mucositis for testretest reliability. It was seen that the correlation values of the scale items evaluated by the researcher and nurse were above 0.64. The test-retest reliability measured for OMDQ items were above the acceptable level (18). The mouth and throat pain mean score correlation value was 0.64. It had been questioned for the last 24 hours, a change between the 14th and 15th days can be considered normal. Manji et al. (5) found the test-retest reliability of the OMDQ when measured 24h apart on days 14 and 15 had a moderate correlation. The test-retest method is one of the most preferred reliability analyses that examine the invariance of the scale. It is recommended to evaluate the means and standard deviations of the scores obtained as a result of two measurements. Both measurement results should be similar. The correlation coefficient between the testretest scores on the scales is to be at least 0.70 (18,19). The OMDQ was applied for two consecutive days, and there was no statistical difference between the two measurements. In this study, based on the study investigated by Manji et al. (5), the test-retest method was applied and found a high correlation for all OMDQ items.

The Cronbach Alpha value of OMDQ was .923, it was concluded that it was a highly reliable scale (18). Similarly, Cronbach's alpha coefficient of ChIMES was found to be 0.91 in the Turkish reliability study (16). Manji et al. (5) examined the psychometric properties of OMDQ. In their study, OMDQ revealed at least a moderate correlation with the WHO Oral Mucositis Grading Scale, Pain Visual Analog Scale, and Functional Assessment of Cancer Therapy Esophageal Cancer Subscale for questions regarding pain, swallowing, drinking, and eating in the construct validity. Sleeping and talking had lower correlations and the diarrhea question of the OMDQ did not correlate with other items. In our study, OMDQ items (Q1-2-3a-3b-3c-3d-3e-4) were correlated with each other, and OMDQ's diarrhea items (Q5-6) were correlated with each other but did not correlate with others. The questions related to diarrhea (Q5-6) were removed in the Turkish version. The Q1-2-6 questions can make no sense to have such low values on these items when the ratings of mucositis were quite low. The Q1-2 did not need to be removed as correlated with other items.

We also used the WHO Oral Mucositis Grading Scale and ChIMES for construct validity. There was a positive significant relationship between the OMDQ and ChIMES items that measured the same situation. OMDQ- Q2 and WHO Oral Mucositis Grading Scale had also a positive significant relationship. The WHO Oral Mucositis Grading Scale is based on the ability to eat and drink, which is the most commonly used one-dimensional scale, not provide an adequate evaluation (8). Similar to the WHO Oral Mucositis Grading Scale, the Oral Mucositis Assessment Scale (OMAS) evaluates the ulceration and erythema in the mouth and is a valid one-dimensional scale for pediatric cancers (11). The ChIMES focused on the pain/soreness in the mouth and throat and related the swallowing, drinking, eating, and medication (12,13). The OMDQ focused on the mouth and throat pain/soreness related the swallowing, drinking, eating, talking, sleeping, and also diarrhea (10,15). The OMDQ can be called a comprehensive scale. OMDQ was also validated in Chinese pediatric cancer patients aged 6 - 18 years (1). The OMDQ adds only the relationship of mucositis to talking and sleeping and data on diarrhea. These questions can not be beneficial for mucositis. Questions related to diarrhea were removed because they did not correlate with other questions in the Turkish version. The OMDQ provides only subjective data and does not provide data on the presence of ulcers.

The original OMDQ was used in this study. In the modified OMDQ for use with children by Tomlinson et al. (15), there were no questions about overall health and diarrhea, minor changes had been made, and stated that its use is suitable for the pediatric population. In ChIMES, speaking and sleeping because of mouth and throat pain was not questioned. Children with mucositis may have trouble speaking and may not be able to sleep due to mouth and throat pain. OMDQ can be used to determine the development of mucositis, not the presence of ulcers, and its effect on the daily life activities of mouth and throat pain, and it can also be used in studies aimed at reducing pain associated with mucositis.

This study included 92 children who had undergone chemotherapy for at least one month. Children were at different treatment stages, many of them were in remission, and more than half were receiving chemotherapy for more than 10 months. Many patients come to the clinic on the first day of the cycle at which point little to no mucositis is expected. The study could have been improved by assessing patients at a time when mucositis was most likely to occur or by following patients daily to capture a full range of OMDQ scores. In addition to the mucositis assessment, we could also use symptom screening scales and evaluate other accompanying symptoms. The OMDQ was applied to 30 children with OM on the 14th and 15th days of chemotherapy treatment for the test-retest assessments, this time is quite simple to have an agreement with a score of zero and those might be peak times of mucositis. This time cannot be generalized for every child with cancer. These are a limitation of this study.

The limited study focused on the development and evaluation of oral mucositis in pediatric cancer patients. Modified adult oral mucositis instruments were used in these patients (10,15). Oral mucositis in children with cancer should be evaluated mainly on observational self-reports. Our study described the psychometric properties of the OMDQ in pediatric cancer patients aged 8-18 years.

# CONCLUSION

The MTS-related questions of the OMDQ are valid and reliable and can be completed by pediatric cancer patients aged 8 - 18 years daily to obtain more observations of OM. The OMDQ provides a simple method for self-assessment of mouth and throat pain and is effective as a validated clinical assessment tool. The questions related to diarrhea were removed from the OMDQ Turkish version. This scale item may need to be re-evaluated in more samples. The daily use of the OMDQ in addition to clinical assessment tools may enable clinicians to identify and manage OM more rapidly.

**Acknowledgement:** The authors thank the pediatric hematology/oncology nurses for their support. They also thank all the children who have participated in this research.

Author contribution: Büşra Güliz Yıldırım: Data curation, Writing-Original draft preparation, Software, Visualization, Investigation. Gülçin Özalp Gerçeker: Conceptualization, Methodology, Software, Data curation, Writing- Original draft preparation.

**Conflict of interests:** The authors declare no conflict of interest. **Ethical approval**: The procedures complied with ethical guidelines and received Non-Invasive Clinical Studies Ethics Committee of the Dokuz Eylül University (Date: 13.02.2019, Decision no: 2019/03-55).

**Funding:** No funding applied for or received. **Peer-review:** Externally peer-reviewed.

#### REFERENCES

- Cheng KF, Ip W, Lee V, Li C, Yuen H, Epstein J. Measuring oral mucositis of pediatric patients with cancer. A psychometric evaluation of the Chinese version of the oral mucositis daily questionnaire. Asia-Pacific Journal of Oncology Nursing 2017;4(4):330.
- Epstein JB, Thariat J, Bensadoun RJ, et al. Oral complications of cancer and cancer therapy. CA: A Cancer Journal for Clinicians 2012;62(6):400– 422.
- International Agency for Research in Cancer [Internet]. Estimated Incidence, Mortality and Prevalence Worldwide in 2012. [Accessed date: 30 December 2019]. Available from http://globocan.iarc.fr/Pages/fact\_sheets\_cancer .aspx
- Jacobs S, Baggott C, Agarwal R, et al. Validation of the Children's International Mucositis Evaluation Scale (ChIMES) in pediatric cancer and SCT. British Journal of Cancer 2013; 109(10):2515–2522.
- Manji A, Tomlinson D, Ethier MC, Gassas A, Maloney AM, Sung L. Psychometric properties of the Oral Mucositis Daily Questionnaire for child self-report and importance of mucositis in children treated with chemotherapy. Supportive Care in Cancer 2012;20(6):1251–1258.
- Mazhari F, Shirazi AS, Shabzendehdar M. Management of oral mucositis in pediatric patients receiving cancer therapy: A systematic review and meta-analysis. Pediatric Blood and Cancer 2019;66(3):e27403.
- Peterson DE, Bensadoun RJ, Roila F, ESMO Guidelines Working Group. Management of oral and gastrointestinal mucositis: ESMO Clinical Practice Guidelines. Annals of Oncology 2011; 22(Supplement 6):vi78–vi84.
- World Health Organization [Internet]. WHO handbook for reporting results of cancer treatment. [Accessed date: 30 December 2019]. Available from http://www.who.int/iris/handle/10665/37200.20
- 9. Sonis ST. Mucositis: The impact, biology and therapeutic opportunities of oral mucositis. Oral Oncology 2009;45(12):1015–1020.
- Stiff PJ, Erder H, Bensinger WI, et al. Reliability and validity of a patient self-administered daily questionnaire to assess the impact of oral mucositis (OM) on pain and daily functioning in patients undergoing autologous hematopoietic

stem cell transplantation (HSCT). Bone Marrow Transplantation 2006;37(4):393–401.

- Sung L, Tomlinson GA, Greenberg ML, et al. Validation of the oral mucositis assessment scale in pediatric cancer. Pediatric Blood & Cancer 2007;49(2):149–153.
- Tomlinson D, Gibson F, Treister N, et al. Understandability, Content Validity, and Overall Acceptability of the Children's International Mucositis Evaluation Scale (ChIMES). Journal of Pediatric Hematology/Oncology 2009;31(6):416– 423.
- Tomlinson D, Gibson F, Treister N, et al. Refinement of the Children's International Mucositis Evaluation Scale (ChIMES): Child and parent perspectives on understandability, content validity, and acceptability. European Journal of Oncology Nursing 2010;14(1):29–41.
- 14. Tomlinson D, Isitt JJ, Barron RL, et al. Determining the understandability and acceptability of an oral mucositis daily questionnaire. Journal of Pediatric Oncology Nursing 2008;25(2):107-11.
- 15. Tomlinson D, Ethier MC, Judd P, et al. Reliability and construct validity of the oral mucositis daily questionnaire in children with cancer. European Journal of Cancer 2011;47(3),383–388.
- Yavuz B, Bal Yilmaz H, Karaman N. A study of reliability and validity for the Turkish version of children's international mucositis evaluation scale for children with cancer. Turkish Journal of Oncology 2011;26(4):157–162.
- 17. Mukaka MM. Statistics Corner: A guide to the appropriate use of correlation coefficient in medical research. Malawi Medical Journal 2012;24(3):69–71.
- Polit DF. Getting serious about test-retest reliability: A critique of retest research and some recommendations. Quality of Life Research 2014;23(6):1713–1720.
- Polit DF, Beck CT. Essentials of nursing research: appraising evidence for nursing practice. 8th Edition, Lippincott Williams & Wilkins, Philadelphia;2014.