


Turkish Translation, Accreditation, and Validation of the Otitis Media-6 Questionnaire

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ABSTRACT

Objective: Otitis media is one of the most common ear disorders occurring in childhood, which causes alterations in communication between parents and children, thereby having a significant effect on the health-related quality of life. Otitis Media-6 questionnaire (OM-6) is a Likert-type scale used to assess the health-related quality of life in children with otitis media. In this study, our aim was to create a consistent, reliable, and valid Turkish version of the OM-6.

Methods: Children with otitis media presenting with effusion and healthy children were enrolled in this study between February 2019 and September 2019. The OM-6 test was administered to three different groups, including preoperative, postoperative, and control, among the children who had undergone ventilation tube insertion operation and among the healthy children.

Results: The overall scores of children with otitis media presenting with effusion exhibited a changing pattern, indicating a statistical significance in the evaluation of the health-related quality of life. The Turkish version of OM-6 includes the scores of construct validity (Spearman values between 0, 58-0, 89), internal consistency (Cronbach's alpha values between 0, 88-0, 96), and reliability (Pearson correlation value between 0, 67-0, 91). These scores exhibited a statistical significance.

Conclusion: The Turkish version of OM-6 is a stable, valid questionnaire with internal consistency.

Keywords: Otitis media, quality of life, surveys and questionnaires

INTRODUCTION

Otitis media is one of the most commonly diagnosed and antibiotic-prescribed diseases in the pediatric population worldwide (1). Long-term complications of otitis media include hearing loss and language development disorders (2). To define in a more specific manner, children with otitis media display lower levels of phonological awareness, semantic knowledge, narration, and reading ability (3). Thus, the presence of hearing loss and language development disorders in children with otitis media has a negative impact on their health-related quality of life (4).

Constructing a validated questionnaire is a typical method for assessing the health-related quality of life (5, 6). For this purpose, a six-item questionnaire termed the Otitis Media-6 questionnaire (OM-6) was developed by Rosenfeld. This questionnaire has been translated and validated in several different countries and languages (7-9). The primary aim of this study was to create a consistent, reliable, and validated Turkish version of the OM-6.

METHODS

This prospective study was conducted at the Otorhinolaryngology Department of Gaziantep University between February

2019 and September 2019. After the Turkish cultural adaptation and translation of OM-6, the test was applied to three groups of children. The preoperative group consisted of children with otitis media presenting with effusion (OME). In a 3-month follow-up period, the diagnosis of OME was made by physical examination and tympanometry tests. After obtaining informed consent for the surgical approach, a ventilation tube was inserted into children in the preoperative group. Three months after the ventilation tube insertion, the OM-6 test was reapplied to the OME group to evaluate the test-retest reliability. This retested group formed the postoperative group. The hospital staff's children aged between 4 and 12 years constituted the control group.

A consent response e-mail was received from the first author of the original version of OM-6 for the translation and application (Table 1: OM-6) (10). According to the Declaration of Helsinki, the Gaziantep University ethical committee approved this study.

Otitis Media-6 was applied to the caregivers or parents of children aged 4-12 years. OM-6 is a six-item Likert-type scale addressing the quality of life concerning hearing. These items are listed as follows: physical suffering, hearing loss, speech

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Table 1. Sample of Otitis Media Quality of Life Survey

	None (1)	Quite (2)	Somewhat (3)	Moderate (4)	Hardly (5)	Very Much (6)
Physical Suffering (Ear pain, ear discomfort, ear discharge, ruptured ear drum, high fever, or poor balance)						
HEARING LOSS Difficulty hearing, questions must be repeated, frequently says “what,” or television is excessively loud						
SPEECH IMPAIRMENT: Delayed speech, poor pronunciation, difficult to understand, or unable to repeat words clearly						
EMOTIONAL DISTRESS: Irritable, frustrated, sad, restless, or poor appetite						
ACTIVITY LIMITATIONS: Playing, sleeping, doing things with friends/family, attending school or day care.						
CAREGIVER CONCERNS: How often have you, as a caregiver, been worried, concerned, or inconvenienced because of your child’s ear infections or fluid over the past 4 weeks?						

impairment, emotional distress, activity limitation, and caregiver concerns. Verbal informed consent was obtained from all participants before applying OM-6. Each participant was kindly asked to fill the test by choosing points from 0 to 7 for each criterion separately. The mean point of these six criteria is the final score. A lower score correlates with a high quality of life.

Validation of the Turkish questionnaire was achieved in three steps. The first step included the translation of the original OM-6 from English to Turkish by two native Turkish translators. Then, OM-6 was retranslated from Turkish to English by two native English translators. The translators in both stages were

unaware of the other independent translators. In the final step, the translation and the adaptation of the final OM-6 form were reviewed. This final form was applied to the Turkish parents and caregivers.

The inclusion criteria were as follows: children aged between 4 and 12 years, children diagnosed with chronic OME, and parents or caregivers who can speak native Turkish speakers. The exclusion criteria were the presence of conductive, sensorineural, or mixed-type hearing loss that was not caused due to the OME. The other exclusion criterion was children with parents or caregivers who cannot read and/or understand the Turkish language. In addition, patients noticed with a ventilation tube on the physical examination were excluded. We assumed that these patients could not be available for assessing the test–retest reliability.

Otitis media presenting with effusion diagnosis was established by two independent specialists who performed monthly physical examinations for 3 months. In addition to physical examinations, monthly tympanometric tests were conducted for 3 months. After obtained the informed consent, patients diagnosed with OME underwent ventilation tube insertion under general anesthesia. Three months after the operation, OM-6 was reapplied for assessing the test–retest reliability.

Main Points:

- Hearing loss and language impairment in children with otitis media lower the health-related quality of life.
- The otitis media -6 is a constructed and validated questionnaire for the assessment of the health-related quality of life at the children with otitis media.
- Turkish version of OM-6 is a validated and the accredited form of the original OM-6 that could enable to evaluate the health-related quality of life in Turkish children with otitis media.

Table 2. Overall scores of the Turkish version of OM-6 and demographic variables

Group	Preoperative OME	Postoperative OME	Control	p
Age		6.29±2.14	6.11±1.72	0.821
Male		28	28	0.484
Female		40	27	
Q1*	4.26±1	1.91±0.93	1.62±0.68	<0.05
Q2	4.63±1.06	2.21±0.89	1.8±0.65	<0.05
Q3	4.5±1.14	2.18±0.93	1.71±0.68	<0.05
Q4	4.44±1.16	2.24±0.92	1.8±0.7	<0.05
Q5	4.46±1.11	2.25±0.76	1.67±0.66	<0.05
Q6	4.13±1.11	2.6±0.8	1.65±0.67	<0.05

* Question 1 of the OM-6 Turkish version

Table 3. The construct validity evaluation of the Turkish version of OM-6

Item description	Spearman correlation preoperative	Spearman correlation postoperative	Spearman correlation control	p
Q1*: Physical Suffering	0.643	0.691	0.789	<0.001
Q2: Hearing Loss	0.679	0.872	0.829	<0.001
Q3: Speech Impairment	0.679	0.898	0.817	<0.001
Q4: Emotional Distress	0.638	0.898	0.829	<0.001
Q5: Activity Limitations	0.597	0.872	0.852	<0.001
Q6: Caregiver Concerns	0.58	0.811	0.809	<0.001

Statistical Analysis

After the application of the Turkish version of OM-6 according to the abovementioned criteria, the consistency and the reliability were analyzed. The mean scores of the six items were compared between patients with OME and the control group to assess the construct validity of the test. The internal consistency of any association between the items was evaluated using the Cronbach’s alpha method. Pearson correlation test was applied to assess the test–retest reliability.

The mean OM-6 scores of the control group and the preoperative OME group were compared using an independent samples Student’s t-test. The comparison of OM-6 values between preoperative and postoperative time periods was accomplished using a paired sample Student’s t-test. All statistical analyses were performed using IBM Statistical Package for the Social Sciences (IBM SPSS Corp.; Armonk, NY, USA) version 18.0 software.

RESULTS

Over a period of 6 months, a total of three groups (two paired and one independent) were tested for the validation of the Turkish version of OM-6. The preoperative group consisted of 68 children diagnosed with OME who formed the initial group assessed using OM-6. After 3 months, this OME group, renamed as the postoperative group, was reevaluated using the same OM-6 form. The third group consisted of 55 healthy children. The overall scores and the demographic variables of all groups are shown

in Table 2. The Spearman correlation coefficient values to assess the construct validity identification of the OM-6 Turkish version are presented in Table 3. The Spearman correlation values were identified separately for each item of OM-6 among the three groups. The Spearman correlation values showed statistical significance among these groups.

The internal consistency of the Turkish version of OM-6 was evaluated by calculating Cronbach’s alpha values, which are shown in Table 4. After assessing the normality of the OM-6 scores of the preoperative and postoperative groups using the Kolmogorov–Smirnov test (p=0.283 for the preoperative group, p=0.426 for the postoperative group). Pearson correlation coefficient values were estimated to evaluate the test–retest reliability. These results are presented in Table 5.

DISCUSSION

An appropriate analysis of the effect of otitis media on the quality of life of children can achieve effective communication between patients and clinicians. For this purpose, numerous valuable health-related quality of life questionnaires have been developed (10, 11).

In the present study, a general method (translation, back-translation, and synthesis) was implemented for the cross-cultural adaptation of the Turkish OM-6 version (12). According to Spearman validity scores of 0, 89 points, the Turkish version of OM-6

Table 4. The internal consistency values of the Turkish version of OM-6

	Cronbach's alpha*			p
	preoperative	postoperative	control	
Q1*: Physical Suffering	0.901	0.962	0.953	<0.001
Q2: Hearing Loss	0.889	0.948	0.942	<0.001
Q3: Speech Impairment	0.889	0.940	0.945	<0.001
Q4: Emotional Distress	0.891	0.947	0.941	<0.001
Q5: Activity Limitations	0.900	0.942	0.944	<0.001
Q6: Caregiver Concerns	0.903	0.948	0.945	<0.001

*These Cronbach's alpha values represent the value when the item is removed

Table 5. Test-retest reliability of the Turkish version of OM-6

	Pearson correlation values		
	preoperative	postoperative	p
Q1: Physical Suffering	0.67	0.747	<0.001
Q2: Hearing Loss	0.757	0.893	<0.001
Q3: Speech Impairment	0.757	0.914	<0.001
Q4: Emotional Distress	0.704	0.914	<0.001
Q5: Activity Limitations	0.699	0.893	<0.001
Q6: Caregiver Concerns	0.683	0.851	<0.001

has been shown to be a valid tool for evaluating children with OME. Previous studies using different languages have reported similar construct validity scores (7-9).

Postoperative scores of each OM-6 items exhibited a decreasing pattern compared with preoperative scores. To determine whether there was a single item that has a major impact on the overall score, the internal consistency was assessed using Cronbach's alpha scores. When one item was removed respectively in OM-6, the scores exhibited good internal consistency. This finding was also consistent with previous reports (13).

In this study, the stability of the Turkish version of OM-6 was evaluated on children diagnosed with OME. Several reports have mentioned that ventilation tube insertion improves the health-related quality of life in children (14, 15). To analyze the reason, we preferred to evaluate the stabilization of the Turkish OM-6 version on children diagnosed with OME. The Pearson correlation values also confirmed that the Turkish version of OM-6 is a stable test that can be applied in different time periods.

The application of the Turkish version of OM-6 in only one center could be assumed as a limitation, and similar questionnaires for assessing the health-related quality of life in further multicentric studies could be considered. One of the limitations was that we did not use the overall analog scale of OM-6 in addition to the six-item. This analog scale is a clinician perspective regarding the extent of children's suffering. In our study, our aim was to reveal the patients' perspective. Another limitation could be that only the reliability of

OM-6 was assessed in children with a single subtype of otitis media. However, the literature has several reports indicating that OM-6 is a useful clinical tool for assessing other forms of otitis media in addition to OME (4, 16). We agree that after the validation of OM-6, it could be useful for evaluating other types of otitis media.

CONCLUSION

The Turkish translation of OM-6 is a stable, valid questionnaire that demonstrated an internal consistency. In addition, the clinical usage of this questionnaire may enable evaluating the clinical outcome for the treatment of otitis media in Turkish children. Finally, according to our opinion, the outcomes of the health-related quality of life could bring out a new path for evaluating the communication between the clinician and the patient.

Ethics Committee Approval: Ethics Committee approval was received for this study from the ethic committee of Gaziantep University of School of Medicine (Decision Date: 02.10.2019 Decision No: 2019/329).

Informed Consent: Verbal informed consent was obtained from all participants.

Peer-review: Externally peer-reviewed.

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