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Kronik Kulak Anketi'nin Türkçe Geçerlik ve Güvenirliği

Turkish Validity and Reliability of the Chronic Ear Survey

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ÖZ

Amaç: Bu çalışmanın amacı Kronik Kulak Anketi' nin Türkçe versiyonunu sunmak ve unilateral veya bilateral kronik süpüratif otitis mediadan etkilenen Türk hastalardan oluşan bir örneklemde bu anketin geçerliliğini değerlendirmektir.

Materyal ve Metot: Kronik Kulak Anketi'nin İngilizce' den Türkçe'ye çevirisi uluslararası kılavuzlar izlenerek yapıldı. Daha sonra istatistiksel analizler için Kronik Kulak Anketi'nin Türkçe versiyonu ve Kısa Form-36 anketi toplam 150 katılımcıya uygulandı.

Bulgular: Korelasyon analizi, Kısa Form-36 ve Kronik Kulak Anketi'nin alt başlıklarının karşılaştırılmasında ve Cronbach alfa değerleri arasında istatistiksel olarak anlamlı bir ilişki olduğunu ortaya koydu.

Sonuç: Bu çalışma sonucunda Kronik Kulak Anketi'nin Türkçe versiyonunun İngilizce versiyonu ile benzer performans oranlarına sahip olduğu gösterildi. Bu nedenle anketin orijinal dili Türkçe olan hastalar için spesifik ve duyarlı bir yaşam kalitesi ölçüm yöntemi olarak kullanılabileceği şeklinde yorumlanabilir.

Anahtar Kelimeler: Irk, işitme bozuklukları, otitis media, sağlık durumu

ABSTRACT

Objective: It was aimed to present the Turkish version of the chronic ear survey and to evaluate the validity of this questionnaire in a sample of Turkish patients affected by unilateral or bilateral chronic suppurative otitis media. **Materials and Methods:** Translation of the chronic ear survey from English to Turkish was made following international guidelines. Then Turkish version of the chronic

national guidelines. Then Turkish version of the chronic ear survey and short form-36 questionnaires were applied to a total of 150 participants for statistical analyses.

Results: Correlation analysis revealed a statistically significant correlation between Cronbach's alpha values and in the comparison of short form-36 sub-headings and chronic ear survey sub-headings.

Conclusion: As a result of this study, the Turkish version of the chronic ear survey was shown to have similar performance rates as the English version. Therefore, it can be interpreted that the survey can be used as a specific and sensitive quality of life measurement method for patients whose original language is Turkish.

Keywords: Health status, hearing disorders, otitis media, race

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INTRODUCTION

Chronic suppurative otitis media (CSOM) is an inflammatory disease of the middle ear characterized by recurrent otorrhea with tympanic membrane perforation. More than 300 million people worldwide are affected by this disease. In addition to symptoms of otorrhea and hearing loss, some patients may complain of less common problems, such as earache, headache, fever, vertigo, ear fullness, odor, etc.¹ Upper respiratory tract infections and exposure to water in the external auditory canal may cause the activation of the disease, which poses a risk of severe complications in addition to recurrent symptoms that may be a reason for social avoidance for patients.^{2,3}

Quality of life (QoL) is an indicator of a person's emotional, social and physical well-being, and assessment of it can provide very important information in developing of treatment modalities for patients.⁴ The only way to determine the effects of a disease on daily life from the patient's point of view is to use quality of life questionnaires.

Short form 36 quality of life scale (SF-36) is the most widely used health and general quality of life scale. SF-36 consists of 8 subscales with a total of 36 items that evaluate physical and mental health. These subscales are physical function, physical role limitation, pain, general health, vitality, social function, emotional role limitation, and mental health.⁵ The total score is evaluated between 0-100.

Unlike the SF-36, the chronic ear questionnaire (CES) is a disease-specific health measure for patients with CSOM and it was developed by Nadol et al.⁶ The questionnaire consists of 13 items and 3 subscales, which are titled the activity restrictionbased subscale, symptom subscale and medical resource utilization subscale and is scored between 0-100 points, like the SF-36. The 3 questions in the activity restriction-based subscale are about the effect of the disease on daily activities and the social environment, the 7 questions in the symptom subscale are about disease-related symptoms, such as hearing loss, otorrhea, odor and otalgia, and the remaining 3 questions are related to medical resource necessity, which is entitled the medical resource utilization subscale.

In this study, it was aimed to present the Turkish version of the CES (CES-T) and to conduct a methodological study evaluating the validity of this questionnaire in a group of Turkish patients affected by unilateral or bilateral CSOM.

MATERIALS AND METHODS

Ethics Committee Approval: The research protocol was approved by the Sakarya University non-invasive Clinical Research Ethics Committee (Date: 23/11/2018, decision no: 266) and performed in accordance with the ethical regulations of the Declaration of Helsinki as well as Turkish laws and regulations. All patients signed an informed consent form.

Activity Restriction-Based Subscale					
A1. Because of your ear problem, you don't swim or shower without protecting your ear.					
□ definitely true □ true □ don't know □ false □ definitely false					
A2. At the present time, how severe a limitation is the necessity to keep water out of your ears?					
□ very severe □ severe □ moderate □ mild □ very mild □ none					
A3. In the past 4 weeks, has your ear problem interfered with your social activities with friends, family, or groups?					
□ all of the time □ most of the time □ a good bit of the time □ some of the time □ a little of the time □ none					
Symptom Subscale					
S1. Your hearing loss is:					
□ very severe ‰ severe □ moderate □ mild □ very mild □ none					
S2. Drainage from your ear is:					
□ very severe □ severe □ moderate □ mild □ very mild □ none					
S3. Pain from your ear is:					
□ very severe □ severe □ moderate □ mild □ very mild □none					
S4. Odor from your ear is very bothersome to you and/or others:					
Definitely true true don't know false definitely false					
S5:The hearing loss in your affected ear bothers you:					
all of the time most of the time a good bit of the time some of the time a little of the time none					
S6:In the past 6 months, please estimate the frequency that your affected ear has drained:					
\Box constantly \Box >5 times, but not constantly \Box 3-4 times \Box 1-2 times \Box not at all					
S7:The odor from your affected ear bothers you and/or others:					
□ all of the time □ most of the time □ a good bit of the time □ some of the time □ a little of the time □ none					
Medical Resource Utilisation Subscale					
M1: In the past 6 months, how many separate times have you visited your physician, specifically about your ear problem?					
□ >6 times □ >5 times, but not constantly □ 3-4 times □ 1-2 times □ not at all					
M2: In the past 6 months, how many separate times have you used oral antibiotics to treat your ear infection?					
\square >6 times \square >5 times, but not constantly \square 3-4 times \square 1-2 times \square not at all					
M3: In the past 6 months, how many separate times have ear drops been necessary to treat your ear condition?					
$\square > 6$ times $\square > 5$ times but not constantly $\square 3-4$ times $\square 1-2$ times \square not at all					

Table 1. Chronic Ear Survey (CES).

Translation and Adaptation: We obtained permission from the original owner of the CES^7 (Table 1) before the study plan was created.

Firstly, the translation and adaptation process was completed. All of this process was performed in accordance with international guidelines. In the first step of translation, two bilingual otolaryngologists made forward translations until the two versions were aforethought fully exchangeable (first consensus version). In the second step, two other specialists checked the clarity/readability of the first version of the survey and commented on the translation for improvement. In the third phase, two native speakers did backward translations from the first consensus version and provided comments regarding translation problems. Finally, the translations were com-

 Table 2. Turkish version of Chronic Ear Survey (CES-T).

Aktivite Kısıtlama-Temelli Alt ölçeği							
A1. Kulak sorununuz nedeniyle, kulağınızı korumadan yüzmez ve yıkanmazsınız.							
🗆 kesinlikle doğru 🛛 doğru 🔅 bilmiyorum 🖓 yanlış 🔅 kesinlikle yanlış							
A2. Şu anda, kulağınızı sudan korumak için ne kadar şiddetli bir su kısıtlaması gerekli?							
□ çok şiddetli □ şiddetli □ orta □ hafif □ çok hafif □ hiç							
A3. Son 4 hafta içinde, kulak probleminiz arkadaşlarınız, aileniz veya diğer gruplarla olan sosyal aktivitelerinizi etkiledi mi?							
□ her zaman □ çoğu zamanı □ zamanın büyük bir kısmı □ bazen □ çok az bir zaman □ hiç							
Belirti Alt ölçeği							
S1. İşitme kaybınız:							
□ çok şiddetli □ şiddetli □ orta □ hafif □ çok hafif □ hiç							
S2. Kulak akınıtmız:							
\Box çok şiddetli \Box şiddetli \Box orta \Box hafif \Box çok hafif \Box hiç							
S3. Kulak ağrınız:							
□ çok şiddetli □ şiddetli □ orta □ hafif □ çok hafif □ hiç							
S4. Kulağınızdan gelen koku sizi ve/veya çevrenizdeki diğer kişileri çok fazla rahatsız edicidir:							
□ kesinlikle doğru □ doğru □ bilmiyorum □ yanlış □ kesinlikle yanlış							
S5. Etkilenen kulağınızdaki işitme kaybı sizi rahatsız eder:							
□ her zaman □ çoğu zaman □ zamanın büyük bir kısmı □ bazen □ çok az bir zaman □ hiç							
S6. Lütfen son 6 aylık sürede, etkilenen kulağınızın akma sıklığını tahmin edin:							
□Sürekli □>5 kez, ancak sürekli değil □ 3-4 kez □ 1-2 kez □hiç							
S7. Etkilenen kulağınızdan gelen koku sizi ve/veya diğerlerini rahatsız eder:							
□ her zaman □ çoğu zaman □ zamanın büyük bir kısmı □ bazen □ çok az bir zaman □ hiç							
Tıbbi Kaynak Kullanım Alt ölçeği							
T1. Son 6 ay içinde, özellikle kulak sorununuz ile ilgili olarak farklı zamanlarda kaç kez doktorunuzu ziyaret ettiniz?							
□ >6 kez □ >5 kez, ancak sürekli değil □ 3-4 kez □ 1-2 kez □ hiç							
T2. Son 6 ay içinde, kulak enfeksiyonunuzu tedavi etmek için farklı zamanlarda kaç kez ağızdan antibiyotik kullandınız?							
$\square >6 \text{ kez}$ $\square >5 \text{ kez}$, ancak sürekli değil $\square 3-4 \text{ kez}$ $\square 1-2 \text{ kez}$ $\square hiç$							
T3. Son 6 ay içinde, kulak hastalığınızı tedavi etmek için farklı zamanlarda kaç kez kulak damlaları gerekli oldu?							
$\square >6 \text{ kez}$ $\square >5 \text{ kez}$, ancak sürekli değil $\square 3-4 \text{ kez}$ $\square 1-2 \text{ kez}$ $\square \text{ hiç}$							

pared with the original version and a final consensus Turkish version (CES-T) (Table 2) was created.

After this process, we implemented the survey with 15 patients in our otorhinolaryngology clinic for preliminary evaluation under the supervision of an otolaryngologist. In this preliminary application, there was no incomprehensible question in the survey.

Study Validation: We recorded 150 patients affected by CSOM presenting to the clinic to evaluate the validity of the CES-T survey. Diagnosis of CSOM was made by medical history and otomicroscopic findings. Demographic data of the patients was recorded. After written informed consents were obtained, all patients completed the CES-T and SF-36. For the test-retest analysis of the survey, the CES-T surveys were re-applied to the patients after three weeks from the first application, and the test-retest analysis was performed with all of the patients.

Statistical Analysis: Statistical analyses were performed using commercial software (IBM SPSS Statistics 20, SPSS inc., An IBM Co., Somers, NY). Continuous variables are presented as mean \pm standard deviation and as median minimum-maximum) value. Spearman rank order correlation coefficients were used to determine the test-retest reliability for individual items, subscales and total survey scores. Cronbach alpha correlation coefficients were used to calculate the internal consistency of the CES-T.

Pearson correlation coefficient between the total score and single subscales of the CES and the 8 scales of the SF-36 was used to examine the correlation between the CES-T and SF36. Physical composite score (PCS) and mental composite score (MCS) were also examined. A p value < 0.05 was accepted as statistically significant.

RESULTS

The mean age for the 150 patients was 37.2 years (SD, 13.8 years; range, 18 to 80 years); 61.3% were male and 38.7% were female.

The mean CES-T sub-scores for activity restriction, symptoms and medical resources subscales and total survey scores were 34.6, 50.8, 69.7, and 51.7 respectively. The mean SF-36 score of the total survey was 63.9 and the mean subscores of SF-36 for physical and mental composite scores

	Ι	A2	A3		22	23	42	çç	20	
AR	r=0.609	r=0.680	r=0.687	r=0.314	r=0.107	r=0.321	r=0.211	r=0.333	r=0.108	r=0.181
	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.191	p=0.000*	p=0.001*	p=0.000*	p=0.186	p=0.027*
ST	r=0.125	r=0.107	r=0.345	r=0.500	r=0.742	r=0.581	r=0.763	r=0.567	r=0.687	r=0.808
	p=0.127	p=0.193	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*
MR	r=0.110	r=0.171	r=0.235	r=0.149	r=0.342	r=0.238	r=0.224	r=0.229	r=0.418	r=0.326
	p=0.179	p=0.036*	p=0.004*	p=0.070	p=0.000*	p=0.003*	p=0.006*	p=0.005*	p=0.000*	p=0.000*
Total	r=0.355	r=0.393	r=0.583	r=0.451	r=0.538	r=0.525	r=0.545	r=0.512	r=0.557	r=0.605
	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*
	1	1								

Table 3. Spearman correlations for intrasurvey reliability

S2, S3, S4, S5, S6, S7; MR (medical resource subscale)-MI, M2, M3; Total (total survey) - Al-AR (activity restriction subscale) – A1, A2, A3; ST (symptom subscale) - SI, A3, SI-S7, and MI-M3; *: p<0.05.

Table 3. Continue.

	MI	M2	M3	AR	LS	MR
AR	r=0.171	r=0.277	r=0.261			
	p=0.037*	p=0.001*	p=0.001*			
L	r=0.291	r=0.220	r=0.439	r=0.289		
	p=0.000*	p=0.007*	p=0.000*	p=0.000*		
MR	r=0.777	r=0.639	r=0.639	r=0.274	r=0.426	
	p=0.000*	p=0.000*	p=0.000*	p=0.001*	p=0.000*	
[otal	r=0.517	r=0.473	r=0.672	r=0.681	r=0.785	r=0.723
	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*	p=0.000*
R (activit	v restriction subs	scale) – A1, A2,	A3: ST (sympto	m subscale) - S	l. S2. S3. S4. S5	, S6, S7; MR

AR (activity restriction subscale) – A1, A2, A3; ST (symptom subscale) - SI, S2, S3, S4, S5, S6, S (medical resource subscale)-M1, M2, M3; Total (total survey) - AI-A3, SI-S7, and MI-M3; *: p <0.05.

The item-subscale, item-total score and subscaletotal score correlation coefficients are shown in Table 4. Overall, the individual items correlated well with their corresponding subscales and the total survey. The AR (r = 0.680, p=0.000), ST (r= 0.780, p=0.000) and MR (r = 0.720, p=0.000) subscale scores all correlated well with the total survey score (Table 3). Cronbach alpha correlation coefficients for internal consistency were calculated as 0.34 for the AR subscale, 0.79 for the ST subscale, 0.68 for the MR subscale and 0.80 for the total survey.

The test-retest reliability of the individual items varied from 0.78 to 0.92. The test-retest reliabilities of the subscores and total score were high; the correlation coefficients for the AR, ST and MR subscores and the total score were 0.80, 0.91, 0.88, and 0.86, respectively (Table 4).

Correlation analysis between CES-T and SF-36 scores showed significant correlations with the majority of SF-36 subscale scores, except for only a few subscales. In addition, total CES-T scores and total SF-36 scores showed statistically significant correlations (Table 5).

 Table 4. Comparison of spearman correlation coefficients for test-retest reliability of English and Turkish versions of Chronic Ear Survey.

	Test-Retest (CES-T)	Test-Retest (CES)
Activity restriction sum	r=0.802	r= 0.810
	p=0.000*	p=0.000*
Symptoms sum	r= 0.911	r= 0.910
	p=0.000*	p=0.000*
Medical resources sum	r=0.888	r=0.810
	p=0.000*	p=0.000*
Total CES sum	r=0.862	r= 0.910
	p=0.000*	p=0.000*

CES: Chronic Ear Survey; CES-T: Turkish Versions of Chronic Ear Survey; *: p < 0.05.

1	l'able 5.	Corr	elation	analysis	between	the	CES-T	and SF	-36 scores.	

	Activity re- striction sum	Symptoms sum	Medical re- sources sum	Total CES sum
Physical composite	r=0.341	r= 0.306	r=0.202	r=0.382
score	p=0.000*	p=0.000*	p= 0.013*	p=0.000*
Mental composite	r=0.220	r= 0.127	r=0.141	r= 0.220
score	p=0.007*	p=0.121*	p= 0.084	p=0.007*
Total SF-36 sum	r= 0.325	r= 0.257	r= 0.199	r=0.354
	p=0.000*	p=0.002*	p=0.015*	p=0.000*

CES: Chronic Ear Survey; SF-36: Short form 36 quality of life scale; *: p < 0.05.

DISCUSSION AND CONCLUSION

Quality of life is an entity whose importance is increasing day by day, especially in the field of health and medicine. While the effects of diseases and treatments on the patient's physical, biological, and psychological characteristics are essential in traditional approaches, the effects on quality of life have become more critical in recent years⁷. The patients' self-reported QOL is of greater social importance as it includes personal comments about their health status. Therefore, the data from QOL questionnaires can improve their treatment and enable us to create different methods for the treatment and follow-up of new patients. With this information, today, we all accept the importance of quality-of-life questionnaires to detect the severity of diseases and their effects on patients' routine life. Nevertheless, since the investigated scientific questions in these questionnaires are evaluated from the patient's perspective, understandable plain language should be used. In this sense, the translation of the presented questionnaire, which was originally created in English (Table 4), was done following international guide-

lines.8

In the present study, the reliability of the survey was demonstrated by test-retest analysis and Cronbach's alpha value, and the validity by convergent validity analysis.9 According to the results, the test-retest reliability analysis results were close to the results of Nadol's study.¹⁰ Although the AR subscale was lower than the others, overall, higher values were found for all of them. The AR subscale was also lower for the Chinese and English versions than other subscales.10,11 Therefore, it can be interpreted that patients diagnosed with CSOM easily adapt to their daily activities. Another criterion used in reliability determination was Cronbach's alpha value. In our study, Cronbach's alpha value was found to be 0.801. This value is 0.83 for the English questionnaire, 0.73 for Italian, and 0.80 for Chinese.¹⁰⁻¹² With the CES-T (Table 5) questionnaire SF-36 convergent validity test; significant correlations were found for many parameters, as in studies conducted with other versions.¹⁰⁻¹² This result shows that the CES-T, shorter and easier to apply than the SF-36 questionnaire, can be easily used in clinical practice.

In conclusion, the statistical results obtained in our study show that the CES-T can be used effectively in CSOM patients. Through this first and only study on the translation into the Turkish language and efficiency analysis for the Turkish race of the chronic ear survey, we conclude that it can be used to compare Turkish CSOM patients in many different aspects with people of different cultures and races. The survey was previously translated into many languages and has proved its effectiveness. It can be beneficial in new studies that investigate the effects of medical or surgical treatment on patients' quality of life.

Ethics Committee Approval: The research protocol was submitted to and approved by the Sakarya University Ethics Committee. (Date: 23/11/2018, decision no: 266)

Conflict of Interest: No conflict of interest was declared by the authors.

Author Contributions: Concept – AK; Supervision – MSY, MG; Ingredients – SGE, BGŞ, HE; Data collection and/or processing – SGE, BGŞ, HE; Analysis and/or interpretation – AK; Posted by – AK, SGE.

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