Investigation of Validity, Reliability and Acceptability of the Turkish Version of the 15D Questionnaire Health-Related Quality of Life on the People with Visual Impairment

Görme Engelli Bireylerde 15D Sağlıkla İlgili Yaşam Kalitesi Anketi Türkçe Formunun Geçerlik, Güvenirlik ve Kabul Edilirliğinin Araştırılması

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ABSTRACT Objective: This study aims to establish the validity and reliability of the Turkish version of the 15D questionnaire in a population of visually-impaired subjects. **Material and Methods:** Fifty-seven people (mean age: 36.6 ± 12.3 years) who have a visual impairment and 63 sighted people (mean age: 54.4 ± 11.6 years) participated in this study. A background questionnaire, 15D questionnaire, the Family Affluence Scale (FAS), and the Beck Depression Inventory (BDI) were used. **Results:** Among socio-demographic variables studied, the age (r= -0.41; 95% CI:- 0.61 to-0.17; p< 0.05), having an additional chronic health problem (r= -0.46; 95% CI:- 0.64 to-0.23) and BDI score (r= -0.63; 95% CI: -0.61 to- 0.17; p< 0.05) were significantly correlated with 15 D index score. Reliability was assessed for subjects who participated both in the first and second interviews (N=52). Cronbach's alpha for the 15D questionnaire was 0.75 at Time 1 and 0.78 at Time 2, which was obtained after removal of two dimensions (dimensions # 6 and 7) from the index because of zero variance. ICC for the 15D index was 0.95. **Conclusion:** It was concluded that the Turkish version of the generic 15D questionnaire was an acceptable, valid and reliable measure of health related quality of life for people with visually-impairment.

Key Words: Quality of health care; vision disorders

ÖZET Amaç: Bu çalışma 15D sağlıkla ilgili yaşam kalitesi anketi Türkçe formunun görme engelliler için geçerlik, güvenirlik ve kabul edilirliğini araştırmak amacıyla planlandı. **Gereç ve Yöntemler:** Yaş ortalaması 36.3 ± 12.3 yıl olan 57 görme engelli ile yaş ortalaması 54.4 ± 11.6 yıl olan görme engeli olmayan 63 kişi çalışmaya dahil edildi. 15D anketi, Aile Refah Anketi (ARA) ve Beck Depresyon Envanteri (BDE) kullanıldı. **Bulgular:** Çalışmadaki sosyo-demografik değişkenlerden yaş (r= -0.41; 95% CI: -0.61 to -0.17; p< 0.05), ek kronik bir sağlık sorununun olması (r= -0.46; 95% CI -0.64 to-0.23) ve BDE puanı (r= -0.63; 95% CI:- 0.61 to-0.17; p< 0.05) ile 15D anketi puanı arasında anlamlı bir ilişki vardı. Güvenirlik ilk ve son görüşmeye katılan 52 olgu üzerinde değerlendirildi. 15 D'nin iki alt ölçeği sıfır varyans değeri aldığı için, bu iki alt ölçek kullanılmadan bakılan (bölüm 6 ve 7) güvenirlikte, ilk doldurulan anket için Cronbach alpha değeri 0.75 bulunurken ve ikincisi için 0.78 olarak bulundu. 15D anketi için ICC değeri 0.95 olarak tespit edildi. **Sonuç:** Görme engelli bireylerde 15D sağlıkla ilgili yaşam kalitesi anketi Türkçe formunun kabul edilir, geçerli ve güvenilir bir anket olduğu sonucuna varıldı.

Anahtar Kelimeler: Yaşam kalitesi; görme özürlü

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The World Health Organization estimated in 2002 that 37 million people around the world were blind and an additional 124 million had low vision.[1] Blindness and severe visual impairment have a significant impact on the socioeconomic development of individuals and societies. So, preventive, curative and rehabilitative programs should be available and accessible for all blind and visually-impaired people.

To facilitate the resource allocation decisions both at the level of clinical and health care policy, different health care programs and technologies should be assessed not only in terms of effectiveness, but also in terms of efficiency (cost-effectiveness/utility). Both direct and indirect or multi-attribute methods can be used to compare the efficiency of different health care programs.[2] One of the indirect methods for measuring the effectiveness of health care programs in their economic evaluation is 15D. The 15D is available in many languages and its use and qualities are described for a growing number of different populations and settings.

To our knowledge, the Turkish version of the 15D has not been used in studies in visually-impaired populations, therefore, little is known about its acceptability, validity and reliability in this population group. This study aims to establish the validity and reliability of the Turkish version of the 15D in a population of visually-impaired subjects.

MATERIAL AND METHODS

SUBJECTS

This prospective observational study investigated the psychometric properties of the Turkish version of the generic 15D instrument. The study was conducted in Ankara, Turkey between March and April 2008. Sample size was determined based on detecting a correlation coefficient of at least 0.40 between the null hypothesis correlation and alternative hypothesis correlation. A sample size of 46 achieves 80% power to detect a difference of - 0.40 between the null hypothesis correlation of '0' and the alternative hypothesis correlation of 0.40 using a 2-sided hypothesis test with a significance level of 0.05. To compensate for an assumed non-participation rate of approximately 20%, the sample size was increased to 57.

Fifty-seven visually-impaired subjects who have a visual acuity of less than 6/60 Snellen were randomly selected from the members of an association of blind people. Those who were less than 18 years of age and the ones with a chronic disease were not included in the study. Sighted people were selected consecutively from those who accompanied their relatives or friends for outpatient treatment in our department. Those who were suffering from a chronic disease were not included in the study. Each participant was informed about the study and they gave their written informed consent to participate. The ethical committee approval was obtained from Hacettepe University Ethical Committee.

INSTRUMENTS

This study was conducted by interview and consisted of four main elements: A background questionnaire, an individual material wealth assessment, a health-related quality of life (HRQoL) assessment, and a depression assessment. The background questionnaire collected information on the socio-demographic and clinical characteristics of the respondents. Respondents who completed the background questionnaire were then asked to complete the Family Affluence Scale (FAS), 15D questionnaire and the Beck Depression Inventory (BDI).

The HRQoL of the subjects were assessed using the 15D questionnaire. The 15D is a generic self-administered instrument of HRQoL that can be used both as a profile and as a single index score measure. It covers the physical, psychological and social aspects of health as defined by the World Health Organization. It describes the health status, assessing 15 dimensions, namely: mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. Each dimension comprises one question with five levels. For each dimension, the respondent must choose one of the five levels that best describes his/her state of health at the moment (best level= 1; worst level= 5). A single index score is obtained by population based preference weights to the dimensions. Index score ranges from 1 (no problems on any dimension) to zero (being dead). The original Finnish 15D instrument has shown good test–retest reliability, construct validity, and discriminatory power in general populations.[3-5] The Turkish version of the 15D has proved to be valid and reliable in patients with Type 2 diabetes.[6]

The depression level of subjects was described using the BDI. The BDI is a 21-item self-report instrument intended to assess the existence and severity of symptoms of depression.[7] Each of the 21-items of the BDI examines somatic, affective, and cognitive symptoms of depression. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression. Numerical values of zero, one, two, or three are assigned each statement to indicate degree of severity. Subjects select the item within each group that best describes how they felt during the past week. Inventory scores range from 0 to 63, with higher scores being a sign of more severe depression. The Turkish version of the BDI has been shown to be valid and reliable.[8] Individual material wealth of the respondents was measured using the FAS.[9] The FAS was composed of four items: does your family own a car (0, 1, 2 or more); do you have your own bedroom for yourself? (0, 1); how many times did you travel away on holiday with your family during the past 12 months? (0, 1, 2, 3 or more); and how many computers does your family own (0, 1, 2, 3 or more). The criteria were adjusted for general population because this scale was developed with adolescents. A reliability analysis showed that the second question (Do you have your own bedroom for yourself?) had a zero variance. The second item was therefore was removed from the scale. The remaining three items had a Cronbach's alpha coefficient of 0.70, which is within the conventional range of 0.70-0.90.[10,11] A principal component analysis revealed that these three items loaded significantly on a single factor with an Eigenvalue of 1.88. This factor accounted 62.7% of the variation. After this analysis, a composite FAS score was calculated by summing the responses to three items ranging from 0 to 8.

PROCEDURE

Study instruments were administered by the first (MKG) and third author (EHT) to the study subjects. Visually-impaired subjects who had participated in the first phase of the study (Time 1) were interviewed one week later (Time 2) by the same author (MKG). To derive the 15D score, there must be a response to each question. So, we defined missing data for each question of the 15D prior to further analysis. We dealt with missing data problem using regression analysis.[4] In order to do this, we first defined the dimension with missing data as a dependent variable in regression analysis. Then, we performed regression analysis with age, gender, education level, and composite FAS score as independent variables. Missing data was replaced with the predicted mean value of the dependent variable. In this procedure, we kept the coding of the variable original, i.e., 1-5.[12]

ANALYSIS

The Statistical Package for the Social Sciences (SPSS for Windows 13.0) was used to perform data analyses. Analysis of the data involved both descriptive and inferential statistics including means, standard deviations (SD), standard errors (SE), and correlation coefficients. To remove the effects of co-variants, which can modify the relationship of the categorical independents to the interval dependent ANCOVA test was used. The significance level for statistical analyses was set at $p< 0.05$ (2-tailed).

To evaluate the association between the 15D index score and the respondent characteristics, correlation coefficients were calculated. Pearson's correlation coefficients (r) were used to assess the linear association between scores on the index score of 15D and a number of continuous variables (age, highest year of education completed, composite FAS score). Point- bi-serial correlation coefficients (p_{bc}) were calculated manually to determine if there was a relationship between the index score of 15D and the dichotomous variables [gender (0= male, 1= female), marital status (0= married, 1= single), having an additional health problem (0= no, 1= yes)] Correlation coefficients were interpreted as follows: very weak= 0.00 to 0.19; weak= 0.20 to 0.39; moderate= 0.40 to 0.59; strong= 0.60 to 0.79; very strong= 0.80 to 1.00.[13] Acceptability was assessed in terms of refusal rate and rates of missing data.

Internal consistency reliability of the 15D instrument was assessed by Cronbach's alpha coefficient at Time 1 and Time 2. An alpha value of 0.70

or higher was considered as the acceptable reliability for group comparisons.[10,11] Test-retest reliability of the index scores was assessed by intraclass correlation coefficient (ICC). ICC was interpreted as follows: poor reproducibility= p< 04; fair to good reproducibility= 0.4 ≤ p< 0.75; excellent = p≥ 0.75.[14]

To determine the concurrent-criterion validity of the 15D instrument, we used "known group technique"[15] with the following hypotheses: 1) respondents who have a score above 17 on the BDI tend to have a lower mean 15D index score than those who have a score below of 17 on the BDI;[7] 2) respondents who have an additional chronic health problem tend to have a lower mean 15D index score than those without an additional chronic health problem; 3) visually-impaired subjects tend to have a lower mean 15D index score than the sighted subjects. Content validity was assessed by examining the floor and ceiling effects in the 15D index score.[16-19] We hypothesized that floor and ceiling effects were less than 20%.[20]

RESULTS

As shown in Table 1, the study groups were balanced in terms of gender. The mean age of visually-impaired subjects was 36.6 (± 12.3 SD), while that of sighted subjects was 54.4 (± 11.6 SD) (p< 0.05). Most of the visually-impaired subjects were single (64.9%), with a mean education level of 8.8 (± 4.6 SD) years and with a mean FAS score of 1.8 (± 1.4 SD). The study groups were significantly different from each other in terms of marital status, education level, individual material wealth, and the BDI score (all p's< 0.05).

As shown in Table 2, among socio-demographic variables studied, the age (r= -0.41; 95% CI:- 0.61 to - 0.17; p< 0.05), having an additional chronic health problem (r= -0.46; 95% CI:- 0.64 to - 0.23) and BDI score (r= -0.63; 95% CI:- 0.61 to - 0.17; p< 0.05) were significantly correlated with 15 D Score. Twelve (21.2%) of the visually-impaired subjects had an additional chronic health problem.

ACCEPTABILITY

Five (8.7%) visually-impaired subjects refused to take part in the second interview without giving a reason. There were no significant differences between refusers and participants in terms of age, gender, marital status, educational level, individual material wealth, and depression level (all p's< 0.05). In Time 1, the percentage of missing data across the 15 dimensions ranged from no missing data to a high of 5.3% (dimension #3).

RELIABILITY

Reliability was assessed for subjects who participated both in the first and second interview (N=52).

TABLE 1: Characteristics of study population.

	Groups		
Characteristics	**Visually-impaired (N= 57)**	**Sighted (N= 63)**	**p value**
Gender (male), n (%)	39 (68.4)	34 (54.0)	0.105†
Age, mean (SD), years	36.6 (12.3)	54.4 (11.6)	0.001‡
Marital status, n (%)			
Married	20 (35.1)	51 (81.0)	0.001†
Single	37 (64.9)	12 (19.0)	
Highest year of education completed, mean (SD)	8.8 (4.6)	11.2 (3.7)	0.005‡
Composite FAS score, mean (SD)	1.8 (1.4)	3.4 (1.9)	0.001‡
Having an additional chronic health problem, n (%)			
Yes	12 (21.2)	-	NA
No	45 (78.9)		
BDI score, mean (SD)	7.9 (8.5)	4.4 (5.5)	0.016‡

FAS: Family Affluence Scale; †: Chi-square test; ‡: Mann-Whitney test.
BDI: Beck depression ınventory.

TABLE 2: Correlation coefficients between the Turkish version of the 15D index score and the characteristics of participants in visually-impaired group (Time 1) (N=57)

	Correlation coefficients	P value
Age	r= -0.41	0.001
Highest year of education completed	r= 0.22	0.093
Composite FAS score	r= 0.16	0.250
Gender	p_{bc}= -0.18	0.092
Marital status	p_{bc}= 0.03	0.856
Having an additional chronic health problem	p_{bc}= -0.46	0.001
BDI score	r= - 0.63	0.001

Gender (0=male, 1=female), marital status (0=married, 1=single), having an additional chronic health problem (0=no, 1=yes)
r= Pearson's correlation coefficient; pbc= Point-biserial correlation coefficient.
FAS: Family affluence skale.
BID: Beck depression inventory.

Cronbach's alpha for the 15 D index was 0.75 at Time 1 and 0.78 at Time 2, which was obtained after removal of two dimensions (dimensions # 6 and 7) from the index because of zero variance. ICC for the 15 D index was 0.95.

CONCURRENT-CRITERION AND CONTENT VALIDITY

Table 3 shows the results of the concurrent-criterion validity analyses. As we hypothesized, after controlling for the influence of age, subjects who had a score above of 17 on the BDI had a lower mean 15D index score than those who had a score below of 17 ($p< 0.05$). Subjects who had an additional chronic health problem had a lower mean 15D index score than those without an additional chronic health problem ($p< 0.05$). Visually-impaired subjects' index score on the 15D was significantly lower than those of sighted subjects ($p< 0.05$). There were no ceiling or floor effects in the 15D index score.

DISCUSSION

In the present study we assessed the Turkish version of the generic 15D instrument's acceptability, validity and reliability in visually-impaired people. The response rate for Time 1 was 100%, for Time 2, 91.3 %. With regard to missing data, 5% to 10% missing data per variable are not considered large.[21] Our results indicated that the percentage of missing data was less than 10% for each of the dimensions. This result is consistent with a previous research that reported the completion rate by dimensions were 96-99%.[22] The lower completion rate for the dimension of hearing in the present study may indicate that this dimension is slightly less acceptable than the others in this population group. The high response and completion rates show that the Turkish version of the generic 15D instrument is acceptable for visually-impaired people.

Internal consistency reliability in the present study was lower than previously reported for the 15D instrument.[6] However, we found that Cronbach's alpha values for the Turkish version of the 15D instrument exceed the suggested cutoff value of 0.70, revealing an acceptable level of reliability for group comparisons.[10,11] Test-retest reliability in the present study was excellent. This finding is consistent with a previous study.[6] The results of reliability analyses of the 15D suggest that the Turkish version of the generic 15D instrument is a reliable instrument for assessing the health state of visually-impaired people.

TABLE 3: Concurrent-criterion validity of the Turkish version of the generic 15D instrument.

	Criteria	N	15D index score, mean (SE)	P values*
BDI score	≤ 17	43	0.9209 (0.006)†	0.005
	≥ 18	9	0.8754 (0.014)†	
Having an additional chronic health problem	No	41	0.9233 (0.007)‡	0.002
	Yes	11	0.8746 (0.013)‡	
Groups	Sighted	63	0.9383 (0.008)‡	0.017
	Visually-impaired	52	0.9069 (0.009)‡	

*: P values obtained from ANCOVA test
†: Estimated means after controlling of age and having an additional chronic illness
‡: Estimated means after controlling of age and the BDI score.
BDI: Beck depression Inventory.

Concurrent-criterion validity demonstrated that the Turkish version of the generic 15D was able to differentiate between groups with known differences in clinical problems. Floor effects are seen when subject scores are grouped at fair/poor state of health. Ceiling effects are seen when subject scores are grouped at excellent/very good state of health. In the present study, there were no ceiling or floor effects in the 15D index score. The absence of ceiling or floor effects indicates that the Turkish version of the generic 15D instrument is able to distinguish between subjects with different levels of health state.[23]

Several possible limitations should be considered when interpreting the results of this study. The results reported here do not provide evidence on responsiveness and feasibility of the 15D instrument. Further longitudinal studies evaluating the responsiveness and feasibility are needed. In addition, data were mainly collected from the members of an association of blind people in Ankara, and therefore cannot be generalized to all blind people in Turkey. However, in the light of the results presented in this study, we concluded that the Turkish version of the generic 15D instrument was an acceptable, valid and reliable measure of HRQoL for people with visual-impairment.

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