

Validity and reliability of the Quality of Life in Reflux and Dyspepsia (QoLRAD) questionnaire in patients with gastroesophageal reflux disease for the Turkish population

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ABSTRACT

Background/Aims: Gastroesophageal reflux disease negatively affects quality of life. The aim is to improve quality of life because of high recurrence rate. There is a strong need for patient-reported outcome measures. The present study aimed to evaluate the validity and reliability of the Quality of Life in Reflux and Dyspepsia Questionnaire (QoLRAD) to adopt it into Turkish.

Materials and Methods: A total of 142 patients with complaints of heartburn or regurgitation once a week or commonly diagnosed with 24-hour intraesophageal impedance-pH monitoring and/or upper gastrointestinal endoscopy were included in this study. Sociodemographic Data Collection Form, QoLRAD-TR, and Short Form-36 (SF-36) were applied to patients who were off proton pump inhibitors.

Results: The Cronbach's alpha coefficient value of the questionnaire was 0.97, and the intraclass correlation coefficient (ICC) value of the result of test-retest method was between 0.97 (Vitality) and 0.99 (Eating/Drinking Disorders). There was a positive correlation between all subdomains of QoLRAD-TR and SF-36 scales. The lowest correlation (0.10) was between Emotional Distress and Role-emotional Limitations, and the highest (0.34) was between Energy and Vitality.

Conclusion: The QoLRAD test measuring quality of life, except some subdomains in our study that we performed on patients diagnosed with GERD, was found to be valid and reliable.

Keywords: Quality of life in reflux and dyspepsia questionnaire, gastroesophageal reflux disease, validation

INTRODUCTION

Gastroesophageal reflux disease caused by the transmission of stomach contents into the esophagus is characterized by the symptoms or findings that interrupt the patients quality of life (1,2). GERD is developed through typical (heartburn-regurgitation) and/or atypical findings (such as pharyngolaryngeal, pulmonary, and chest pain) (1,3). Epidemiological studies conducted to determine the frequency of GERD are limited by the presence of symptoms in the patients (once a week or more heartburn or regurgitation). Therefore, the frequency of GERD in our country in Western societies (20%) was found to be similar to that worldwide (22.8%) (4-6). Typical symptoms affect quality of life in many ways, such as daily activities, human relationships, a good night sleep, and eating and nutrition patterns (7). Another significant point in terms of quality of life is the responses of patients to the proton pump inhibitors (PPI). The high number of patients with heartburn and especially those resistant to acid regurgitation reduces quality of life (6). Studies have shown that after 4 weeks of using the standard PPI dose once a day

revealed partial or complete disappearance of the symptoms in 60%-70% of the patients with GERD (8).

It is almost impossible to cure GERD with medication; therefore, the main purpose of medication therapy is to improve quality of life (9,10). There are several questionnaires for evaluating quality of life in patients with GERD. The Quality of Life in Reflux and Dyspepsia Questionnaire (QoLRAD) is one of the most common and effectively used questionnaire. The aim of our study was to evaluate the validity and reliability of QoLRAD questionnaire and to adopt it into Turkish.

MATERIALS AND METHODS

The sample of this study comprised 142 patients who were admitted to our institution, GERD study group outpatient department. Patients were included if all of the following criteria were met: heartburn and/or regurgitation once a week or more, upper gastrointestinal endoscopy and/or pathologic 24-hour intraesophageal impedance-pH monitoring, can read and speak Turkish,

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and aged more than 18 years. Sociodemographic Data Collection Form, QoLRAD, and Short Form-36 (SF-36) were used as data collection forms. All tests were performed when the patients did not receive PPI for at least 10 days considering that the PPIs induce considerable changes in the symptoms. Written permissions were obtained from the institution, and informed consents were obtained from the subjects of this study. All data were analyzed with the Statistical Package for Social Sciences 16.0 (SPSS Inc.; Chicago, IL, USA) program.

QoLRAD questionnaire

QoLRAD, a quality of life questionnaire for the gastroesophageal reflux disease, comprises 25 questions and 5 subdomains: Emotional Distress (questions 12, 14, 15, 17, 19, and 22), Sleeping Disorders (questions 8, 10, 11, 18, and 21), Eating/Drinking Disorders (questions 3, 5, 9, 13, 16, and 20), Physical/Social Function (questions 2, 6, 23, 24, and 25) and Vitality (questions 1, 4, and 7). The QoLRAD questionnaire was answered with a 7-point Likert-type scoring scale by the patients. A low score indicates low quality of life, whereas a high score indicates high quality of life (11, 12).

SF-36

SF-36, which the subjects fill themselves to be informed about the general health condition of the patients; is composed of 36 questions and 5 subdomains (Physical Function, Social Function, Physical Role Limitations, Role-emotional Limitations, and general perception of health, mental health, energy, and pain). Domains evaluate the health between 0 and 100 (0 indicates poor health conditions). It is reported that this questionnaire can be used to assess quality of life in individuals having physical health problems. The validity and reliability of SF-36 into Turkish have been performed (13).

Evaluation of psychometric properties of the questionnaire (validity-reliability)

Linguistic equivalence studies of the questionnaire

In the first phase of the study, experiments were conducted to evaluate the validity of the language to translate the QoLRAD into Turkish. The questionnaire was translated from English into Turkish for the first time by one of the author (SB). Subsequently, it was translated into English by an expert speaking two languages (Turkish and English) and five native Turkish academicians speaking good English. Following these translations, the most suitable expressions were determined, and the QoLRAD was translated again into English by linguistics. The trans-

lated questionnaire was compared with the original and corrected according to expert opinions.

Structure validity

Structure validity is the relation between the form (QoLRAD-TR) in which structure validity is not yet determined and the reference form (SF-36) in which the reliability of the validity is already determined. If the correlation between the two forms is greater than 0.60, it is evaluated as good. If it is between 60 and 30, it is evaluated as average. If it is less than 30, it is evaluated as poor/bad (7,14).

To evaluate the validity of the QoLRAD-TR questionnaire, Pearson product-moment correlation between the domains of the questionnaire and SF-36 were used.

Internal consistency

The Cronbach's alpha coefficient method was used to test the internal consistency of the QoLRAD-TR questionnaire. If the Cronbach's alpha coefficient value is greater than 0.70, it is considered as excellent (15).

Test-retest

Test-retest reliability is used to measure the power of a measurement tool to give consistent results for repeated applications. When the same measurement tool is applied to subjects at different times, the similarity or consistency of the answers given by the subjects to the measurement tool is the indicator of the invariance of that measurement tool (16). The test-retest method is used for measuring the time invariance of the QoLRAD-TR questionnaire. A total of 142 individuals were interviewed, and the questionnaires were applied. The QoLRAD-TR questionnaire was randomly reapplied to 31 individuals 2 weeks following the first interview. In both measurements, it was considered that all subjects were off PPIs.

RESULTS

A total of 142 patients were included in this study, and 31 of these individuals were tested twice. The average age of the subjects included in the study was 43.4 ± 11.8 , 54.2% were males, and 35.2% was literate (Table 1). The total number of questions in the QoLRAD-TR questionnaire was 25, Cronbach's alpha coefficient value was 0.97, and average score was 96.08 ± 34.76 . The Cronbach's alpha coefficient values of the domains of the questionnaire ranged from 0.76 to 0.94 (Table 2). The intraclass correlation coefficient (ICC) value of the subdomains of QoLRAD-TR questionnaire was found to be between 0.974 (Vitality) and 0.99 (Eating/Drinking Disorders) (Table 3).

A positive correlation was noted between all subdomains of the QoLRAD-TR and SF-36 questionnaires. According to this evaluation, it was observed that the lowest correlation (0.103) was between Emotional Distress and

Role-emotional Limitations and the highest (0.344) was between Energy and Vitality (Table 4).

DISCUSSION

Heartburn and regurgitation, the most common symptoms of GERD, affect patients in many ways, such as in daily activities, human relationships, sleeping at night, and eating and drinking patterns (7,17). Recently, we have showed that all of the GERD subgroups (erosive, non-erosive, and esophageal hypersensitivity) and functional heartburn were significantly more depressed than the control group (30%-65%). The prevalence of depressive disorders was significantly higher in the functional heartburn group than in the non-erosive and erosive reflux disease groups (18). This situation also leads to a decrease in quality of life of patients. Given that there is no single objective diagnostic method for GERD, it is necessary to use measurement tools based on patient

Table 1. Sociodemographic characteristics.

Introductory Information	S	%
Male	77	54.2
Female	65	45.8
Age years	Average 43.4±11.8	
University	35	24.6
High/secondary school	15	10.6
Elementary school	42	29.6
Literate	50	35.2

Table 2. Cronbach alpha coefficient, mean, standard deviation values of QoLRAD-TR questionnaire and its domains.

	$\bar{X}$	SS	Cronbach's Alpha coefficient	Number of Questions
Emotional Distress (Questions 12, 14, 15, 17, 19, and 22)	22.50	9.35	0.94	6
Sleeping Disorder (Questions 8, 10, 11, 18, and 21)	20.06	8.09	0.92	5
Eating/Drinking Disorders (Questions 3, 5, 9, 13, 16, and 20)	21.06	8.49	0.89	6
Physical/Social Function (Questions 2, 6, 23, 24, and 25)	21.61	7.63	0.89	5
Vitality (Questions 1, 4, and 7)	10.85	4.34	0.76	3
QoLRAD-TR Total	96.08	34.76	0.97	25

Table 3. Test-retest reliability (ICC) of the QoLRAD-TR questionnaire.

	ICC
Emotional Distress (Questions 12, 14, 15, 17, 19, and 22)	0.98 (0.97-0.99)
Sleeping Disorder (Questions 8, 10, 11, 18, and 21)	0.98 (0.97-0.99)
Eating/Drinking Disorders (Questions 3, 5, 9, 13, 16, and 20)	0.99 (0.98-0.99)
Physical/Social Function (Questions 2, 6, 23, 24, and 25)	0.97 (0.95-0.98)
Vitality (Questions 1, 4, and 7)	0.97 (0.93-0.98)
QoLRAD-TR Total	0.99 (0.99-0.99)

Table 4. Pearson product-moment correlation between QoLRAD-TR and SF 36 domains.

	Emotional Distress	Sleeping Disorder	Eating/Drinking Disorders	Physical/Social Function	Vitality
Physical Function	0.18	0.15	0.15	0.18	0.16
Social Function	0.18	0.16	0.19	0.27	0.18
Role-Physical Limitations	0.24	0.21	0.25	0.29	0.26
Role-emotional Limitations	0.10	0.12	0.10	0.11	0.12
Mental Health	0.28	0.14	0.13	0.24	0.21
Energy	0.28	0.22	0.26	0.23	0.34
Pain	0.22	0.27	0.26	0.30	0.29
General Perception of Health	0.20	0.14	0.22	0.23	0.24

reports to assess the effect of the disease and therapies on quality of life (19).

One of the most important tools for evaluating quality of life is QoLRAD that has very good psychometric properties when tested in clinical research. There is no validated questionnaire-based patient report to evaluate quality of life in GERD, such as QoLRAD in Turkey. The aim of our study was to evaluate the validity and reliability of the QoLRAD questionnaire and to translate it into Turkish.

We showed that the lowest Cronbach's alpha coefficient value of the QoLRAD-TR questionnaire was between 0.74 (Vitality) and 0.94 (Emotional Distress) and overall Cronbach's alpha coefficient value of the questionnaire was 0.97 (Table 2). These values are greater than 0.70 and are considered as excellent (15). The ICC value was determined to evaluate the time invariance of the QoLRAD-TR questionnaire in line with the test-retest results and was found to be between 0.97 (Vitality) and 0.99 (Eating/Drinking Disorders) (Table 3). These values are higher than that reported in other validity-reliability studies on the QoLRAD questionnaire (7,11,19-24).

The use of PPIs in patients during the study has been neglected in some studies. PPI responses cannot be predicted; therefore, patients should not use PPI over the course of tests, especially during test-retests. The use of PPI in some studies may have caused the test-retest results of the QoLRAD questionnaire to be higher than those of studies without PPIs. Another explanation would be that patients are assessed by advanced technological methods in terms of the presence of GERD, such as 24-hour intraesophageal impedance-pH monitoring that is a

new technology and is more sensitive than conventional pH monitoring. Additionally, it can be noted that patients with more severe complaints refer to our tertiary GERD outpatient department, and this also might be a biased population.

The Pearson product-moment correlation was used to evaluate the Construct Validity of the QoLRAD-TR questionnaire (Table 4). According to this evaluation, it has been observed that the lowest correlation (0.10) was between Emotional Distress and Role-emotional Limitations and the highest (0.34) was between Energy and Vitality. Although these values were lower than those of previous studies, it is observed that they have a positive correlation.

The Pearson product-moment correlation was between 0.44 and 0.71 in the original study by Wiklund et al. (11) and 0.37 and 0.71 in the German version by Kulich et al. (22) The Pearson product-moment correlation values were as follows in study of Kulich et al. (22) on six countries: 0.31 and 0.50 in the African version, 0.40 and 0.76 in the Hungarian version, 0.36 and 0.69 in the Italian version, 0.26 and 0.55 in the Polish version, and 0.33 and 0.55 in the Spanish version. In the Japanese version of Hongo et al. (19), the lowest value was between the Physical Function and Emotional Distress as 0.09 and the highest value was between the Social Function and Physical/Social Function as 0.63. In the Iranian version of Tofangchiha et al., negative correlations were found and the highest value was 0.74. The values obtained from our study are at the level of acceptable due to the fact that they are higher than the values of these two studies and correlate positively (11,19-26).

In conclusion, the QoLRAD questionnaire, which measures quality of life in patients with GERD diagnosed by upper gastrointestinal endoscopy and/or 24-hour intraesophageal impedance-pH monitoring and performed at a clinic that is the third reference center, was found to be valid and reliable. The questionnaire must be tested in different clinical situations, such as pre-post-PPI or anti-reflux surgery.

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Informed Consent: Written informed consent was obtained from subjects who participated in this study.

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