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Validation of the Reflux Disease Questionnaire for a Turkish Population

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ABSTRACT

Background & Aims: Achieving the correct diagnosis and therapeutic success in gastroesophageal reflux disease (GERD) depends on the patient's self-assessment. Therefore, valid and reliable patient-reported questionnaires are very important. When designing such measurement tools, researchers should focus on their validity, reliability, sensitivity, and, applicability. The reflux disease questionnaire (RDQ) largely meets these important requirements. This study aims to examine The RDQ's psychometric characteristics for the Turkish society (RDQ_{TR}) and its validity in symptoms' evaluation.

Methods The sample of this study comprised 81 patients who were admitted to our institution, GERD study group outpatient clinic. The data collection forms used in the study were the case report forms and RDQ. Three weeks after the first interview, 30 patients were re-interviewed by the phone and the RDQ was re-administered. For the validity studies of the scale, language validity, content validity, and construct validity studies were used, and for the reliability studies, internal consistency and test-retest reliability methods were used.

Results: The content validity index of form was 0.95 (0.93-0.98). The performed factor analysis indicated 3 factors with an eigenvalue over 1.0. Those factors were responsible for 77.66% of the variance. The Cronbach's alpha values were 0.88 for regurgitation sub-dimension, 0.91 for dyspepsia sub-dimension, 0.86 for heartburn sub-dimension, and 0.92 overall. Intraclass correlation coefficient value of the scale was 0.94.

Conclusions: Our study highlights that the RDQ_{TR} is reliable, valid, and responsive to change in Turkey patients with GERD symptomatology.

Key words: validity – reliability – gastroesophageal reflux disease – GERD – reflux disease questionnaire – RDQ.

Abbreviations: CVI: content validity index; GERD: gastroesophageal reflux disease; ICC: intraclass correlation coefficient; PPI: proton pump inhibitor; RDQ: reflux disease questionnaire; RDO_{TR}: RDQ in Turkish population.

INTRODUCTION

Gastroesophageal reflux disease (GERD), resulting from the escape of stomach contents into the esophagus is characterized by symptoms or signs that impair the patient's quality of life [1]. Different epidemiological studies have been performed with different definitions of GERD, one of the most common criteria being the presence of typical symptoms such as heartburn and regurgitation once a week or more common [2, 3]. Therefore, although it is difficult to give a clear information about its frequency, the prevalence of GERD in Turkey was found to be 23%, similar to that in Western societies [4, 5]. The most common symptoms of GERD are heartburn (75-98%) and regurgitation (48-91%) [6]. These symptoms affect the quality of life of patients in many aspects such as daily life activities, human relationships, a good nighttime sleep, eating and drinking patterns [7-9]. Although the 24 hours combined multichannel intraluminal impedance and pH (MII-pH) monitoring is the standard test for GERD, diagnosis is also based on symptoms' history and proton pump inhibitors (PPIs) response. Achieving the correct diagnosis and therapeutic success in GERD depends on the patient's self-assessment. Therefore, valid and reliable patient reported questionnaires are very important [10]. Various patient questionnaires have been developed to evaluate GERD symptoms with standard methodologies [11]. When designing such measurement tools,

researchers should focus not only on their validity, reliability and sensitivity, but also on their applicability [11, 12]. The reflux disease questionnaire (RDQ) developed by Shaw et al. [13] largely meets these important requirements.

The aim of this study is to examine the RDQ's psychometric characteristics for Turkish society (RDO_{TR}), and its validity in symptoms' evaluation.

METHODS

The study group included 81 GERD patients admitted to our outpatient clinic. Patients were included if all of the following criteria were met 1) heartburn and/or regurgitation once a week or more common; 2) erosive esophagitis diagnosed with upper gastrointestinal endoscopy and/or pathologic 24-hour MII-pH monitoring; 3) no major motility disorders identified according to Chicago 3.0; 4) can read and speak Turkish and 5) aged older than 18 years. The data collection forms used in the study was the case report form, which included sociodemographic variables related to the individual, and the RDQ. All questionnaires were completed, and tests were performed when the patients had been off-PPI for at least 10 days considering that the PPIs-induce considerable changes in the symptoms.

All data were analyzed with the Statistical Package for Social Sciences 22.0 (SPSS Inc.; Chicago, IL, USA) program.

The case report form was created by the researchers in accordance with the literature information. The form consisted of questions about socio-demographic characteristics such as age, gender and marital status.

Reflux disease questionnaire, a condition-specific instrument consisted of 12 questions (Supplementary file). Half of the questions were related to the frequency of the symptoms and half to their severity, recording GERD symptoms during the previous week. Frequency and severity of symptoms were measured on 6-point scales (from no occurrence to daily/severe). Patients were asked about the following six symptoms: burning behind breastbone, pain behind breastbone, upper stomach burning, upper stomach pain, acid taste in mouth, and movement of materials [13].

The language validation of the scale was performed according to the MAPI Research Institute guidelines (Table I) [14].

The content validity index (CVI) was defined as the degree to which elements of an assessment instrument were relevant to and representative of the targeted construct for a particular assessment purpose [15]. The Turkish version of the form was evaluated by the ten academicians and clinicians working in the Faculty of Medicine in terms of content validity. The experts were asked to evaluate the suitability, comprehensibility and simplicity of each item in the scale. After four panel sessions, the translation process and content validity were completed. The CVI was evaluated for each item (I-CVI) using the Davis method [15].

Table I. Language validity stages of RDQ [14].

Stages
Forward translation by five independent translators
Merging session [analysis and reconciliation] with the presence of translators and the executive manager
Backward translation by another independent translator
Comparison of the main questionnaire with the backward translation
Review by different experts who are gastroenterology specialists
Final checking and amendment

For the construct validity, the factor structure was studied by the Principal Component Analysis using Varimax with Kaiser Normalization as the Rotation Method. The Kaiser-Meyer-Olkin (KMO) and Barlett sphericity test were used to determine the suitability of the data for factor analysis. KMO value ranged from 0 to 1. The values over 0.50 meant that the data was suitable for factory analysis [16]. To preserve original factor structure of the scale, factor loadings were evaluated for the 3-factor structure. The first factor contained items related to the regurgitation of gastric contents; the second factor described a burning or painful feeling behind the breastbone; and the third factor described complaints in the upper stomach.

Internal consistency is the most widely used reliability determination method. There are many methods in which different statistical formulas are used to calculate the internal consistency coefficient. In this research, Cronbach's Alpha method was used to calculate internal consistency [17].

For the test-retest reliability a total of 81 GERD patient were surveyed. For the reliability and validity studies, it is stated that in the literature the respondent-to-item ratio should be 5:1 (i.e., fifty respondents for a 10-item questionnaire) [18]. It is reported that the number of individuals to be retested should be at least 30 in testing invariance against time [19]. Three weeks after the first interview, 30 patients were re-interviewed by the phone and the RDQ_{TR} was re-administered. The relationship between the scale scores obtained from the test and retest was evaluated by using the intraclass correlation coefficient (ICC) to evaluate the test-retest reliability.

In order to evaluate the validity and reliability of RDQ_{TR}, the necessary permissions were obtained from copyright owners (AstraZeneca pharmaceutical company) and the Ethics Committee of Medical Research (Decision no: 20-1T/66). All directives of the Helsinki Declaration were followed and informed consent was obtained from the participants.

RESULTS

A total of 81 GERD patients were included, and 30 of these individuals were tested twice for the purpose of test-retest. The patients' average age was 46.5±12.4; 58% were males.

Validity

After translation of the scale, CVI was used to determine content validity. The CVI of the scale was 0.95 (0.93-0.98). The KMO value (0.89) and Barlett sphericity test (X^2: 1038.079, df: 26, $p < 0.001$) showed that the data was suitable for the factor analysis. The performed factor analysis indicated 3 factors with eigenvalue over 1.0. Those factors were responsible for 77.66% of variance and rotation, and they converged in 5 iterations.

Reliability

The Cronbach's alpha values, showing the reliability coefficient for the Turkey RDQ were 0.88 for regurgitation

Table II. Factor analysis for reflux disease questionnaire items: rotated component matrix for 3 factors.

	Component		
	Regurgitation	Heartburn	Dyspepsia
1a. Burning feeling behind breastbone: frequency	0.186	0.864*	0.214
1b. Pain behind breastbone: frequency	0.075	0.808*	0.325
1c. Burning feeling in the upper stomach: frequency	0.396	0.443	0.617*
1d. Pain in the upper stomach: frequency	0.437	0.130	0.727*
1e. Acid taste in mouth: frequency	0.870*	0.090	0.148
1f. Movement of materials: frequency	0.801*	0.360	-0.048
2a. Burning feeling behind breastbone: severity	0.149	0.874*	0.334
2b. Pain behind breastbone: severity	0.144	0.731*	0.444
2c. Burning feeling in the upper stomach: severity	0.390	0.396	0.515*
2d. Pain in the upper stomach: severity	0.424	0.172	0.799*
2e. Acid taste in mouth: severity	0.823*	0.080	0.329
2f. Movement of materials: severity	0.705*	0.372	0.139

Extraction Method: principal component analysis. Rotation method: varimax with Kaiser normalization. Rotation converged in 5 iterations.

sub-dimension, 0.91 for dyspepsia sub-dimension, 0.86 for heartburn sub-dimension, and 0.92 overall (Table III).

Table III. Cronbach's alpha Value of the reflux disease questionnaire:

	Cronbach's Alpha
Regurgitation	0.88
Heartburn	0.86
Dyspepsia	0.91
Total	0.92

Intraclass correlation coefficient results of the first and second application of the Turkey RDQ_{TR} were 0.98 for regurgitation sub-dimension 0.98, 0.95 for dyspepsia sub-dimension 0.95, 0.96 for heartburn sub-dimension 0.96, and the overall intraclass correlation coefficient value of the scale was 0.94 (Table IV).

Table IV. Reflux disease questionnaire: test-retest reliability

Component	ICC (Min. – Max.)
Regurgitation	0.98 (0.96 -0.98)
Heartburn	0.96 (0.94 - 0.97)
Dyspepsia	0.95 (0.93 -0.96)
Total	0.94 (0.92 - 0.98)

ICC: interclass correlation coefficient

DISCUSSION

The prevalence of GERD was 22.8% and heartburn is less common (12.7%) than regurgitation (18.7%) in Turkey [20]. The pivotal study results from Olmsted county showed that the population exhibited a different symptom profile consisting of a lower prevalence of regurgitation (6.3%) and a higher prevalence of heartburn (17.8%), similar to other studies from Western countries [20, 21]. The population of Turkey, a predominantly Caucasian country is characterized by both Eastern and Western lifestyles. The frequency of reflux is 23%, one of the highest figures even compared to the western figures [20]. One of the possible reasons is the high prevalence of obesity in Turkey among all European countries [22]. Also, the pattern of endoscopic findings is different from western countries. For example, severe erosive esophagitis is less predominant, and the prevalence of Barrett esophagus was reported to be 0.4% in Turkey in contrast to 5-15% in the west [23]. All these findings implicate that GERD epidemiology is important and needs to be further studied. For this reason, the development and the translation of world-accepted scales into Turkish language gains value [3]. The diagnosis of GERD and the assessment of treatment efficacy can be facilitated by symptom questionnaires. When designing such measuring questionnaires researchers must not only focus on their validity, reliability, and responsiveness but also on their practicability. To a large extent, the RDQ developed by Shaw et al. [13] meets all these four requirements. The goal of the present study was thus to examine the psychometric properties of the Turkish version of RDQ and its validity in symptom assessment.

Translation and back-translation studies on the language validity of the RDQ were conducted according to the MAPI Research Institute guidelines [14]. Content validity index score above 0.80 indicates that the validity of the scope was achieved [15]. In this study, CVI was determined as 0.95 (0.93-0.98), indicating a high validity of the content. Factor analysis is frequently used to evaluate construct validity. By factor analysis, the features that are highly correlated with each other in the measured structure are clustered under one factor. To perform exploratory factor analysis within the context of construct validity, Kaiser-Meyer-Olkin sample adequacy analysis, and Bartlett's test should be performed and a value of 0.60 and above should be obtained [24]. In our study, Kaiser-Meyer-Olkin sample adequacy analysis (KMO: 0.89) and Bartlett's sphericity analysis (X^2: 1038.079, df: 26, $p < 0.001$) were significant. Following these results, construct validity was evaluated with an exploratory factor analysis. As a result of the analysis, the

structure consisting of three factors whose eigenvalue is above 1.0 explains 77.66 % of the total variance. In the German version [25] the three factors explained 69% of the variance and in the Greek version 76.9% [26]. In the literature, it is stated that 50% and above variance rates are accepted as valid [16].

If the alpha coefficient is less than 0.40, the measurement tool is not reliable, with low reliability between 0.40 - 0.59, highly reliable between 0.60 - 0.79, and highly reliable between 0.80 - 1.00 [27]. In the original study of the RDQ developed by Shaw (2001) et al. [13] the Cronbach's alpha value for each factor of the scale was found to be between 0.80 and 0.85 [13]. In the Italian version of the scale, the overall Cronbach alpha was 0.86, ranging from 0.82 to 0.88 among components [28]. In the German version it was among 0.84 -0.86 [25] and in the Greek version it was 0.91 [26]. The further psychometric validation of the questionnaire conducted by Van Zanten et al. [29] was found between 0.79–0.90 [29]. In our study, the overall Cronbach alpha was 0.92, ranging from 0.86 to 0.91 among components. This value is in parallel with the original development study of the scale and other validation studies, being reliable in the literature [27].

Intraclass correlation coefficient was determined to evaluate the time invariance of the RDQ questionnaire in line with the test-retest results and was found to be between 0.95 for dyspepsia and 0.98 for regurgitation. The ICC value varies between 0 and 1.00, reliability is good for values between 0.6-0.8, values above 0.8 indicate that the excellent degree [30]. The values from 0.95 to 0.98 in our study indicated an excellent degree of reliability, being higher than those previously reported [13, 29].

The limitations of our study are represented by the lack of a focus group of patients for content validity. Further studies with focus groups with patients, with larger samples to examine other aspects of validity and reliability such as specificity and sensitivity of the scale are required.

CONCLUSIONS

Our study highlights that the RDQ_{TR} is reliable, valid, and responsive to change in patients with GERD symptomatology. This makes the RDQ_{TR} suitable for use in clinical trials, and as a guide to patient management in a broader primary care population with uninvestigated upper gastrointestinal symptoms and epidemiological studies in cases where there is a need to formally evaluate the treatment effect. Besides, it could also be appropriate for use in international comparison studies, since its psychometric properties are comparable to other versions validated in several countries.

Conflicts of interest: None to declare.

Authors' contributions: S.H., S.B. conceived and designed the study, collected the data and drafted the paper. S.H. performed the statistical analysis. S.B. critically revised the manuscript. The authors approved the final version to be published and agree to be accountable for all aspects of the work.

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