

Validity and Reliability of the Turkish Version of the Gastroesophageal Reflux Disease Quality of Life Questionnaire

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ABSTRACT

Objective: Gastroesophageal reflux is a disease that is common in society and affects quality of life. The aim of the present study was to test the validity and reliability of the Turkish version of the Gastroesophageal Reflux Disease Quality of Life scale.

Methods: A total of 161 patients with gastroesophageal reflux disease who applied to the gastroenterology outpatient department of a university hospital between July 2017 – October 2017 constituted the sample of this study. The study was a methodological and descriptive study. In the validity and reliability studies, the language validity, content validity, internal consistency (Cronbach's alpha reliability coefficient) and confirmatory factor analysis methods were used.

Results: The Cronbach's alpha reliability coefficient of the Gastroesophageal Reflux Disease Quality of Life scale was $\alpha = 0.885$, while its content validity ranged between 0.84-0.92. According to confirmatory factor analysis, the 4-factor structure of the scale, consisting of 16 items, generally had good fit.

Conclusion: The Turkish version of the Gastroesophageal Reflux Disease Quality of Life scale was found to be a valid and reliable scale that can be used to measure the quality of life of individuals diagnosed with gastroesophageal reflux disease.

Keywords: Gastroesophageal reflux; questionnaire; quality of life; reliability; validity; scale.

1. INTRODUCTION

Gastroesophageal reflux disease (GERD) is a prevalent disease of the upper gastrointestinal tract, typically characterized by heartburn and the escape of stomach contents into the esophagus. Recent studies indicated that the prevalence of GERD is 27.8% in North America, 25.9% in Europe, 7.8% in East Asia and 33.1% in the Middle East. In Turkey, the prevalence of GERD was determined to be 22.8%. Symptoms of the disease include pyrosis dysphagia, regurgitation, bitter water coming into the mouth, odynophagia, lump in the throat, laryngitis, asthma, coughing and chest pain unrelated to the heart (1-3). These symptoms can severely affect the daily lives of individuals with GERD (4). Furthermore, complications such as ulcers, strictures, bleeding, adenocarcinomas, vocal cord granulomas, laryngeal cancer, aspiration pneumonia, asthmatic bronchitis and Barrett's esophagus may develop in GERD patients (5). It was reported patients experience difficulty in moving, changes to their nutrition patterns, disruptions in their social relations and daily lives, and sleep deprivation as a result of their symptoms, severity of

symptoms and complications that develop (4,6). Therefore, it is important to evaluate the quality of life of GERD patients.

It is indisputable that quality of life is evaluated in various disease cases. Studies conducted about quality of life provide the opportunity to determine how patients respond to diseases and solutions for problems that occur during treatment. When planning the development of a special care system regarding gastrointestinal disorders, the individuality of the disorders and quality of life should be taken into consideration (7). Although the evaluation of patients quality of life in assessing the effect of GERD symptoms on the health status of patients is increasingly considered as an indicator of medical outcome, the evaluation of patients quality of life in clinical studies is difficult due to the limited number of standard assessment tools specific to the disease (8). It is recommended that quality of life be evaluated with disease-specific quality of life scales in addition to general quality of life (9,10). Determining quality of life with a disease-specific scale is important for nurses in terms of evidence-based practice and decision making.

Scales developed to assess the quality of life of people with gastrointestinal diseases include Quality of Life Reflux and Dyspepsia (QOLRAD), the Gastrointestinal Quality of Life Index (GIQLI), the Functional Digestive Disorders Quality of Life Questionnaire (FDDQL), the GERD Health-Related Quality of Life (GERD-HRQL), the Quality of Life After Anti-reflux Surgery (QOLARS) questionnaire and Gastroesophageal Reflux Disease Quality of Life Scale (GERD-QOL) (11). Of these scales, only QOLRAD was adapted into Turkish (12). GERD-HRQL is used before and after anti-reflux surgery (11), which does not include all GER patients. GERD-QOL is a scale specific to GERD, which can be applied to patients diagnosed with reflux in any condition, with or without reflux surgery. GERD-QOL was chosen because there is no scale specific to GERD, which has validity and reliability in our country, and to contribute to the literature and make up for this deficiency. In this regard, this study aimed to determine the validity and reliability of the Turkish version of the Gastroesophageal Reflux Disease Quality of Life Scale (GERD-QOL), which is a disease-specific scale developed by Chan et al. (13).

2. METHODS

2.1. Type of Study and Ethical Aspect

The study was conducted methodologically. Prior to conducting the study, permission was obtained from the author who developed the GERD-QOL scale and the institution where the study was conducted. Finally, approval was obtained from the Medicine Faculty Ethics Committee (Ethics Committee Approval Number: 71522473 / 050.01.04 / 13-22.12.16). Before the patients were included in the study, the informed consent form was signed by the patients after the purpose of the study was verbally explained to them.

2.2. Study Population and Selection Criteria

The population of the study consisted of 1162 GERD patients who applied to the gastroenterology clinic. The sample of the study was composed of patients who were diagnosed with GERD by the physician at the clinic, agreed to participate in the study, met the inclusion criteria and had no communication issues. As scale validity-reliability studies require the sample size to be at least five times or ten times the number of items on the scale to be validated (14,15), a sample of 160 patients was determined to be sufficient for this particular scale containing 16 items. The study was eventually completed with 161 patients.

2.3. Design of Study

2.3.1. Gastroesophageal Reflux Disease Quality of Life Scale

The GERD-QOL scale developed by Chan et al (13) in 2009 consists of 16 items and four sub-dimensions, namely daily activity (DA) (Cronbach's alpha: 0.882), treatment effect (TE) (Cronbach's alpha: 0.771), diet (DI) (Cronbach's alpha: 0.644) and psychological well-being (PW) (Cronbach's alpha:

,0.771). Sleep, exercise, rest, work and social effects are evaluated in DA (items 2, 4, 5, 8, 10, 11, 12, 13), discomfort or side effects caused by medical treatment in TE (items 3, 7, 14), worries and anxieties of the patient in PW (items 15, 16) and diet in DI (items 1, 6, 9) (13). In the five-point Likert type scale, 4 points is given for "strongly disagree", 3 points for "partially disagree", 2 points for "neutral", 1 point for "partially agree" and 0 points for "strongly agree". Each item is based on the recollection of dominant reflux symptoms encountered in the last seven days. The scoring of a single sub-dimension is in the range of 0-100, while the total score for the four sub-dimensions varies between 0 and 400. The sub-dimension and total score calculations of the scale are given below. A low score obtained from the scale refers to poor quality of life. The higher the score, the less effect GERD has on the patient. In the calculation of the scores for the sub-dimensions, the points of the items are added together.

$$DA: (Q2+Q4+Q5+Q8+Q10+Q11+Q12+Q13)*100/32$$

$$TE: (Q3+Q7+Q14)*100/12$$

$$DI: (Q1+Q6+Q9)*100/12$$

$$PW: (Q15+Q16)*100/8$$

The total score for the scale is calculated by DA+TE+DI+PW/4.

The GERD-QOL scale was created for GERD patients to determine the effect on their quality of life of their symptoms in the last week. There is no time/hour interval recommended by the developers of the scale.

2.3.2. Study Location and Date of The Research

The study was carried out at the gastroenterology clinic of a university training and research hospital in Turkey between July 2017 and October 2017.

2.3.3. Data Collection

In the first stage of the data collection process, studies for language validity were carried out in order to adapt the GERD-QOL scale to Turkish and determine the validity and reliability of the scale. Before the study, permission was obtained from the author, the developer of the scale, via e-mail. The back translation method was used to translate the scale. Within this scope, the original scale was translated into Turkish separately by five experts who are fluent in both Turkish and English. The most appropriate expressions were selected and the Turkish version of the scale was created based on the adaptation of the translated scale to the original scale. For content validity, the scale was sent to 13 experts, who were asked to evaluate whether the Turkish translation of the scale was compatible with the original scale. The necessary changes were made in line with feedback and recommendations received and the Turkish version of the scale was finalized. Then, the Turkish scale was sent to two experts in the Turkish language field to be evaluated in terms of grammar and wording and the necessary changes were made in accordance with their recommendations. The scale was then translated back into

English by a foreign language lecturer, whose native tongue is Turkish and who did not know anything about the scale, without seeing the English format of the scale. The final version of the scale in English was sent back to the author who developed the scale for approval. After his suggestions, the necessary corrections were made again.

The content validity of a scale is important to determine whether the items in the original scale have the same meaning in the language and culture the scale is adapted to. In this study, the Davis technique was used, in which expert opinions are graded as (a) appropriate, (b) item should be slightly reviewed, (c) item should be seriously reviewed and (d) item is not suitable. In this technique, the number of experts who mark options (a) and (b) is divided by the total number of experts in order to calculate the content validity index (CVI). The value of 0.80 is accepted as the criterion without comparing the calculated value with any statistical criterion (16,17). The number of experts in this study to which the GERD-QOL scale was sent to was 13.

The primary purpose of confirmatory factor analysis (CFA) is to determine the ability of a previously defined factor to match the observed data set. Whether a measurement developed in the past is appropriate to be used in a different society is important when testing scales (18). In some cases, it may be sufficient to only perform confirmatory factor analysis in the adaptation of a scale from a foreign language into Turkish (19). In this study, the CFA method was used in the evaluation of the validity of the scale.

Reliability is an indicator of the stability of the scores obtained in repeated measurements under the same conditions with a measurement tool (20,21). Internal consistency is the calculation of the homogeneity of the questions for a criterion that are assumed to measure a certain area and whether the questions measure only the desired concept. One of the methods used to measure internal consistency is Cronbach's alpha coefficient (17,22). In this study, the Cronbach's alpha ($\alpha = 0.885$) coefficient was calculated in the reliability analysis of the GERD-QOL scale.

2.4. Data Analysis Process

This study was carried out with a total of 161 patients. The data were analyzed by transferring them to the Statistical Package for Social Sciences (SPSS) version 23 and SPSS Analysis of Moment Structures (AMOS) version 23 programs (IBM Corp.; Armonk, NY, USA). In the study; the back translation method was used to measure the language validity of the scale, expert opinions were obtained for content validity, Cronbach's alpha coefficient was calculated in order to determine the internal consistency. The CFA method was used to determine the validity of the scale.

3. RESULTS

In this study, 44% of the patients were between the ages of 20 and 40 years, 76.4% were married, 83.9% had a core family

structure, 41.6% were primary school graduates, 65.7% were unemployed, 44.1% had an equal income-expense balance, 55.9% were smokers, and 93.2% did not consume alcohol. According to the body mass index (BMI) of the patients, 32.9% were overweight while 31.7% were obese. The duration to receive a reflux diagnosis was 61.61 ± 74.78 months and, in addition to GERD, 51.6% of the patients had another disease diagnosed by a physician (data not shown in the Table).

3.1. Content Validity

The CVI values of the items were calculated by the 13 experts to range between 0.84 and 0.92. The Davis technique was applied to determine the content validity of the scale, after the language equivalence studies were completed. No item was removed from the scale as all values were 0.8 or higher. The arithmetic mean and standard deviation values for the items on the GERD-QOL scale are presented in Table 1.

Table 1. GERD-QOL scale expression averages

| | Mean \pm SD | Min-Max |
|-------------|------------------|-----------|
| GERD-QOL 1 | 1.90 \pm 1.685 | 0.0 – 4.0 |
| GERD-QOL 2 | 1.43 \pm 1.560 | 0.0 – 4.0 |
| GERD-QOL 3 | 2.24 \pm 1.654 | 0.0 – 4.0 |
| GERD-QOL 4 | 2.10 \pm 1.629 | 0.0 – 4.0 |
| GERD-QOL 5 | 2.39 \pm 1.597 | 0.0 – 4.0 |
| GERD-QOL 6 | 1.67 \pm 1.669 | 0.0 – 4.0 |
| GERD-QOL 7 | 2.49 \pm 1.538 | 0.0 – 4.0 |
| GERD-QOL 8 | 1.68 \pm 1.719 | 0.0 – 4.0 |
| GERD-QOL 9 | 1.62 \pm 1.628 | 0.0 – 4.0 |
| GERD-QOL 10 | 1.60 \pm 1.686 | 0.0 – 4.0 |
| GERD-QOL 11 | 2.27 \pm 1.609 | 0.0 – 4.0 |
| GERD-QOL 12 | 2.94 \pm 1.340 | 0.0 – 4.0 |
| GERD-QOL 13 | 2.15 \pm 1.633 | 0.0 – 4.0 |
| GERD-QOL 14 | 2.16 \pm 1.683 | 0.0 – 4.0 |
| GERD-QOL 15 | 1.27 \pm 1.593 | 0.0 – 4.0 |
| GERD-QOL 16 | 1.44 \pm 1.608 | 0.0 – 4.0 |

GERD-QOL: Gastroesophageal Reflux Disease Quality of Life Scale

Mean: Average, SD: Standard Deviation, Min: Minimum,

Max: Maximum

3.2. Construct Validity of the Gastroesophageal Reflux Disease Quality of Life Scale

3.2.1. Confirmatory Factor Analysis

Confirmatory factor analysis was performed with the IBM SPSS AMOS 22 program on the data set with 161 samples. In the first stage, the first-degree CFA model consisting of latent variables (4-factor dimension: DA, TE, DI, PW) and indicator variables (expressions forming the factors/dimensions) was created (Figure 1). In order to estimate the parameter values of the non-metric latent variables, the factor in one of the paths drawn from the latent variables to the indicator (observed) variables should be equal to 1 or a value (usually 1) should be assigned to the variance of the latent variable (23).

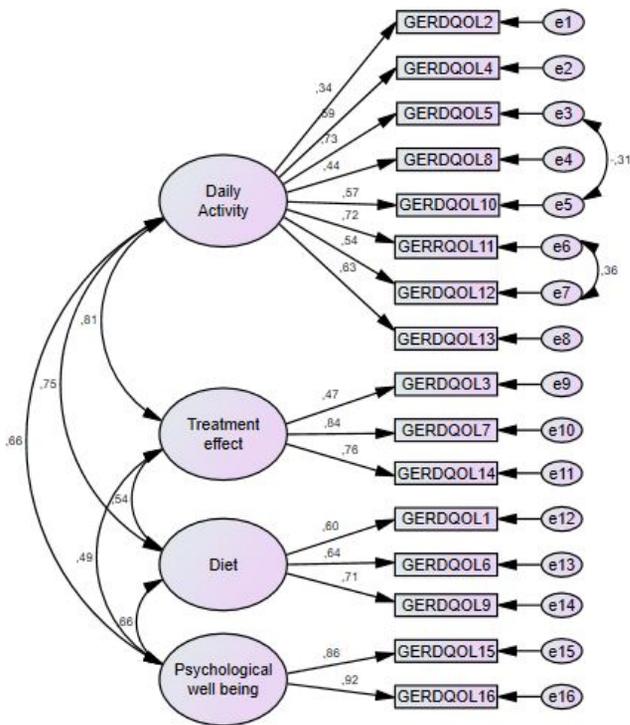


Figure 1. 1st Degree CFA model with 4 sub-dimensions

In the second stage of the confirmatory factor analysis, the maximum likelihood method was applied, which provides reliable results even when the data is not normally distributed in estimating the model and used in structural equation models. By doing so, the aim was to estimate the variances of DA, TE, DI, and PW (latent variables), the regression coefficients for the paths drawn from the latent variables to the observed variables, and parameters including the errors of the observed variables. In order to improve the fit indexes, a bilateral relationship was established between the error terms of questions “GERD-QOL 5” and “GERD-QOL 10”, “GERD-QOL 11” and “GERD-QOL 12” in the GERD-QOL scale, which had the highest modification index (fit index) values. However, a relational addition was made between the dimensions in order to determine the correlation expected between the dimensions. The relationship between the dimensions is shown in Figure 1.

In the final stage, the fit indexes were evaluated for the first-degree CFA model developed with four dimensions. Considering the results, it was determined that the four-factor structure of the GERDQOL scale consisting of 16 items fitted well in general.

Considering the fit values given in Table 2, the values for Chi-square/degree of Freedom (χ^2/df), Incremental Fit Index (IFI), Comparative Fit Index (CFI), Root Mean Square Error of Approximation (RMSEA) and Standardized Root-Mean Square Residual (SRMR) were good, while the values of Turker-Lewis Index (TLI) were unacceptable (24–27). In general, it can be said that the GERD-QOL scale was acceptable in terms of goodness of fit index values.

Table 2. Fit indexes of CFA model

| Index | GERD-QOL Fit Index | Good Fit | Acceptable Fit | Result |
|-------------|--------------------|-----------------------------|--------------------------|------------------|
| χ^2/df | 1.903 | $0 \leq \chi^2/df \leq 3$ | $3 < \chi^2/df \leq 5$ | Good Fit |
| GFI | 0.869 | $0.95 \leq GFI \leq 1$ | $0.90 \leq GFI < 0.95$ | Unacceptable Fit |
| IFI | 0.911 | $0.95 \leq IFI \leq 1$ | $0.90 \leq IFI < 0.95$ | Acceptable Fit |
| TLI | 0.886 | $0.95 \leq TLI \leq 1$ | $0.90 \leq TLI < 0.95$ | Unacceptable Fit |
| CFI | 0.909 | $0.95 \leq CFI \leq 1$ | $0.90 \leq CFI < 0.95$ | Good Fit |
| RMSEA | 0.075 | $0.05 \leq RMSEA \leq 0.08$ | $0.05 < RMSEA \leq 0.10$ | Acceptable Fit |
| SRMR | 0.0684 | $0.05 \leq SRMR \leq 0.10$ | $0.05 < SRMR \leq 0.10$ | Acceptable Fit |

χ^2/df = Chi-square/degree of Freedom; GFI= Goodness of Fit Index; IFI= Incremental Fit Index; TLI= Turker-Lewis Index; CFI= Comparative Fit Index; RMSEA= Root Mean Square Error of Approximation; SRMR= Standardized Root-Mean Square Residual; GERD-QOL: Gastroesophageal Reflux Disease Quality of Life Scale

3.2.2. Reliability Analysis

In the internal consistency analysis performed to determine the reliability of the scale, Cronbach’s alpha value was calculated. The Cronbach’s alpha values for the sub-dimensions of the scale were between 0.694 and 0.882, while this value was found to be 0.885 for the entire scale (Table 3).

Table 3. Reliability of the scale and its sub-dimensions

| | Questions | Item-Total Correlation | Cronbach’s Alpha |
|----------------|--|------------------------|------------------|
| GERD-QOL Scale | Daily Activity Sub-Dimension | GERD-QOL 2 | 0.367 |
| | | GERD-QOL 4 | 0.553 |
| | | GERD-QOL 5 | 0.618 |
| | | GERD-QOL 8 | 0.429 |
| | | GERD-QOL 10 | 0.517 |
| | | GERD-QOL 11 | 0.632 |
| | Treatment Effect Sub-Dimension | GERD-QOL 12 | 0.484 |
| | | GERD-QOL 13 | 0.557 |
| | | GERD-QOL 3 | 0.417 |
| | | GERD-QOL 7 | 0.601 |
| | Diet Sub-Dimension | GERD-QOL 14 | 0.570 |
| | | GERD-QOL 1 | 0.479 |
| | | GERD-QOL 6 | 0.497 |
| | Psychological Well-Being Sub-Dimension | GERD-QOL 9 | 0.601 |
| | | GERD-QOL 15 | 0.606 |
| | | GERD-QOL 16 | 0.647 |
| | | | 0.885 |

GERD-QOL: Gastroesophageal Reflux Disease Quality of Life Scale

4. DISCUSSION

When a scale is translated into another language, items should contain meaningful expressions in the language it is translated into. The items should be simple and easy to understand after translation. The use of terms and idioms that the target population will have difficulty in understanding

should be avoided. Three translation methods can be used in the adaptation of a scale into another language. These are back-translation, one-way translation and group translation(19,28). In this study, the back-translation method was used for the translation of the GERD-QOL scale into Turkish.

Validity is “the ability to measure a characteristic that a measuring tool aims to measure accurately without involving any other characteristics”. As validity is required to be in line with the purpose of a scale, it can vary depending on the purpose, method of application, and the group to which it is applied. The level of validity is determined by calculating the validity coefficient, which has a value between – 1.0 and +1.0. The higher the correlation coefficient, the better the scale serves its purpose (17,20). There are many methods such as content validity, criterion validity and construct validity that can be used to ensure the validity of a scale. In this study, the content validity and construct validity (CFA) methods were used.

The values for all of the items in the GERD-QOL scale were above the standard CVI value of 0.8. Therefore, it can be said that content validity was achieved.

Construct validity is calculated in order to evaluate to what extent the items on the valid scale can measure the desired characteristic. There are four methods, namely factor analysis (explanatory and confirmatory), comparison of contrast or known groups, hypothesis testing, and multivariate-multi-method matrix approach, that can be used to determine construct validity (17,19,29). When developing a new scale, explanatory factor analysis should be performed before confirmatory factor analysis. Confirmatory factor analysis is sufficient when adapting a scale from a foreign language to Turkish (19). Thus, in this study, confirmatory factor analysis was performed.

According to the data in the literature, the χ^2/df value should be equal to or less than five to be acceptable. For a good fit, the RMSA value should be equal to or less than 0.08, the SRMR value should be less than 0.1, the CFI value should be equal to or greater than 0.9, the IFI value should be 0.9 and, the Goodness of Fit Index (GFI) and TLI values should be above 0.9 (18,19). In this study, the scale was acceptable as the calculated CFA sub-dimensions were within the value ranges proposed in the literature.

The GFI statistics in confirmatory factor analysis performed for the purpose of construct validity should be at the determined level to ensure the construct validity (19).

In accordance with the information in the literature and considering the goodness of fit data in this study, it was observed that the χ^2/df , IFI, CFI, RMSEA and SRMR values were good, while the GFI and TLI values were not within the acceptable limits (Table 2). In accordance with the goodness of fit indexes, it was determined that the GERD-QOL scale was acceptable and its structure with four factors containing 16 items had good fit.

Reliability is “the degree in which a measuring instrument measures the variable it wants to measure with consistency or the degree of how free the measurement results are from errors” (17). In addition, it is the consistency of the measurement value calculated in the repeated measurements under the same conditions by using the same scale (20). A scale with either no reliability or low reliability is considered to have low scientific value (19).

Internal consistency is an indicator of the homogeneity of the questions in a scale and whether or not they measure the desired concept. The main view of internal consistency is the assumption that all scale items, that are autonomously developed to achieve a specific goal in a scale, are known and have equal weights(17).

Cronbach’s alpha reliability coefficient is calculated to determine whether the items are reliable in measuring the same dimension (19,30). “It is a weighted standard change average calculated by dividing the sum of the variances of k items by the general variance in the scale”(17). As the Cronbach’s alpha coefficient approaches 1, the internal consistency of the items is higher. Furthermore, a coefficient value between 0.6 and 0.7 indicates that the scale has sufficient reliability level, while a coefficient value between 0.7 and 0.9 indicates that it has a high level of reliability (17).

Implications for Clinical Practice, the Gastroesophageal Reflux (GER) is a chronic and recurrent disease(31). Lifestyle change has great importance in the management of chronic diseases. The care, training and consultancy services provided by healthcare professionals for chronic diseases that negatively affect quality of life are very important. It is important to choose appropriate tools that measure the health dimensions of patients’ private life to evaluate health-related quality of life (32). The GERD-QOL scale is a scale specific to GERD. Using a scale with proven validity and reliability, it is possible to determine which dimension of quality of life is particularly affected in patients with GERD at the individual level. In line with the results obtained with this scale, the needs of the individuals will be determined, the right interventions can be made for these needs, and the quality of life of patients can be improved by increasing the quality of the care service provided. In addition, since the GERD-QOL scale is short (16 items), it will provide the advantage of easy application by nurses in the clinic. The scale is simple for patients to understand and does not contain medical terms. Patients can easily understand and answer the scale questions. This scale is a useful and extensive tool for nurses and another healthcare professionals to assess the quality of life of patients with GERD.

The limitations of the study can be listed as only covering GERD patients in the outpatient clinic, and not evaluating the presence of comorbidities and effect of disease severity on quality of life. It can also be said that collecting data through face-to-face interviews may have increased the clarity of some elements. Test-retest reliability could not be performed because GER-QOL had measured the last week.

5. CONCLUSIONS

In this study, the Cronbach's alpha reliability coefficients of the GERD-QOL scale and its sub-dimensions were calculated. According to the results obtained, the Cronbach's alpha values were found to be 0.885 for the entire scale and between 0.694 and 0.882 for the sub-dimensions. Based on these results, all the items in the scale measure the same characteristic. The characteristics measured by the GERD-QOL scale are homogeneous, and thus, the GERD-QOL scale is a reliable measurement tool.

When the results of the language equivalence, content validity, internal consistency (Cronbach's alpha reliability coefficient) and construct validity (CFA) are evaluated as a whole, it was concluded that the Turkish version of the GERD-QOL scale is a reliable and valid scale that can be used for patients with GERD.

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Author Contributions:

Research idea: HS, ST

Design of the study: HS, ST

Acquisition of data for the study: ST

Analysis of data for the study: HS, ST

Interpretation of data for the study: HS, ST

Drafting the manuscript: HS, ST

Revising it critically for important intellectual content: HS

Final approval of the version to be published: HS, ST

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