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Validation of the Reflux Disease Questionnaire into Greek

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Abstract

Primary care physicians face challenges in diagnosing and managing gastroesophageal reflux disease (GERD). The Reflux Disease Questionnaire (RDQ) meets the standards of validity, reliability, and practicability. This paper reports on the validation of the Greek translation of the RDQ. RDQ is a condition specific instrument. For the validation of the questionnaire, the internal consistency of its items was established using the alpha coefficient of Chronbach. The reproducibility (test-retest reliability) was measured by kappa correlation coefficient and the criterion of validity was calculated against the diagnosis of another questionnaire already translated and validated into Greek (IDGP) using kappa correlation coefficient. A factor analysis was also performed. Greek RDQ showed a high overall internal consistency (alpha value: 0.91) for individual comparison. All 8 items regarding heartburn and regurgitation, GERD, had *good* reproducibility (Cohen's κ 0.60-0.79), while the remaining 4 items about dyspepsia had a *moderate* reproducibility (Cohen's $\kappa=$' 0.40-0.59) The kappa coefficient for criterion validity for GERD was rather poor (0.20, 95% CI: 0.04, 0.36) and the overall agreement between the results of the RDQ questionnaire and those based on the IDGP questionnaire was 70.5%. Factor analysis indicated 3 factors with Eigenvalue over 1.0, and responsible for 76.91% of variance. Regurgitation items correlated more strongly with the third component but pain behind sternum and upper stomach pain correlated with the second component. The Greek version of RDQ seems to be a reliable and valid instrument following the pattern of the original questionnaire, and could be used in primary care research in Greece.

Introduction

Gastroesophageal reflux disease (GERD) is a common condition in Western populations with a prevalence of around 20% for weekly reflux symptoms that are estimated to make up 4% of consultations to family physicians.[1-3] Reviews have highlighted the effect of frequency and severity of GERD symptoms in patients' everyday life.[4-6]

There is evidence that primary care physicians face challenges in making an accurate diagnosis of GERD and in managing it effectively.[7] Heartburn, when present as the predominant symptom, may be the sole basis for the diagnosis of GERD while the imprecise definitions of GERD symptoms, and the overlap between reflux and other upper abdominal symptoms, challenge the diagnostic efficacy of primary care physicians.[8] What is more, endoscopy is not a substitute for careful evaluation of symptoms since most patients with troublesome reflux symptoms do not have any evidence of endoscopic esophagitis.[9] Although the 24-h ambulatory pH monitoring was initially proposed as gold standard, it is not sufficiently sensitive; furthermore, it is expensive, invasive and technically demanding, particularly in the primary care setting.[10] As an alternative, a brief treatment trial with a proton pump inhibitor may be the most sensitive and specific diagnostic modality.[11] However, studies on the diagnostic accuracy of the test raise certain concerns.

A European study of primary care patients with GERD indicates that a structured questionnaire could promote better communication and patient management in primary care.[12,13]

Several questionnaires have been developed for the assessment of GERD symptoms in clinical practice or for the general population.[12-16] The criteria of an ideal evaluative GERD symptom assessment tool are: sensitivity in GERD patients, covering all symptom dimensions (multidimensional construct), assessment of frequency and intensity of *typical* and *atypical* GERD symptoms, practical and economical, easy to understand, responsive over short time intervals, use as a patient self-assessment tool, amenable to daily use, psychometrically validated, and being translated into many languages with cross-cultural adaptation.[17] So far, 14 instruments have been developed to assess GERD symptoms and these can potentially be used to evaluate treatment response during a therapeutic trial in GERD patients.[18]

The Reflux Disease Questionnaire (RDQ), developed by Shaw *et al.* meets the standards of validity, reliability and responsiveness but also these of practicability and feasibility.[16,19-21] An observational study in primary care in Greece has focused on the psychometric quali-

ties of the Greek RDQ and its potential use in research for clinical practice in primary care. With this in view, this paper reports on the validity of the RDQ in the Greek primary care setting.

Materials and Methods

Questionnaire

The RDQ is a condition-specific instrument consisting of 12 questions. Half of the questions are related to the frequency of the symptoms and half to their severity, recording GERD symptoms during the previous week. Symptoms' frequency and severity are measured on 6-point scales (from *no occurrence* to *daily/severe*). Patients are asked about the following six symptoms: *burning behind breastbone*, *pain behind breastbone*, *upper stomach*

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burning, *upper stomach pain*, *acid taste in mouth*, and *movement of materials*. The RDQ questionnaire was translated into Greek by a research group from the AstraZeneca GR pharmaceutical company. The authors requested permission from the holders of the rights of the RDQ to validate the questionnaire and adopt it to the Greek conditions.

Setting, sampling and target population

The psychometric properties of the Greek version of the RDQ were explored by the administration of the questionnaire to patients with upper gastrointestinal symptoms, seeking primary care in five rural practices serving primary care in Crete and Northern Greece. Eligible patients were recruited for ten consecutive working days. The inclusion criteria were: age over 18 years, absence of alarm symptoms or history of cancer and inflammatory bowel disease. All participants were residents of the practices' area of responsibility. Power analysis showed that in order to discover significant differences higher than 10% between the responses, the sample size should be 172 individuals, achieving statistical power of 75% at a significance level of 0.05.

Measurements

Reliability was assessed through internal consistency and test-retest reliability.[22-24]

Internal consistency was determined by checking the components of a questionnaire against each other, using Chronbach's alpha.[25,26] A minimum value of 0.70 for group and 0.90 for individual comparisons is generally desirable.[27,28]

Reproducibility (test-retest reliability) is a significant measure of association for determining the stability of the questionnaire's results over time because it corrects the lack of independence between measurement intervals.[23] The Cohen's kappa coefficient was also estimated.[24]

Criterion validity refers to the extent to which the instrument correlates with a gold standard.[28] In order to define the criterion validity of the questionnaire, the diagnoses of the already validated questionnaire, Identification of Dyspepsia in General Population (IDGP), were used as a gold standard to the outcome of the RDQ questionnaire.[29] The IDGP is the only questionnaire translated and validated which is available in Greek, suitable for the general population and general practice. Kappa analysis was used in order to assess agreement between the diagnoses (GERD, dyspepsia). The diagnosis of GERD using the RDQ was made by the positive response to one of the items 1a, 1b, 2a and 2b (heartburn) and/or to one of the items 1e, 1f, 2e and 2f (regurgitation of any frequency).

Dyspepsia was diagnosed when there was at least one positive answer to items 1c, 1d, 2c and 2d. A factor analysis was performed in order to identify the separate factors, which make-up this questionnaire and highlight the way the items group together.[30] The factor structure was studied by Principal Component Analysis using Varimax with Keiser Normalization as Rotation Method. Both of the Kaiser criteria for applicability were fulfilled.[31] An analysis of the patients' symptoms as described in the RDQ questionnaire (items 1a, 1b, 1c, 1d, 1e, 1f, 2a, 2b, 2c, 2d, 2e, 2f) was performed and a factor was considered as important if its Eigenvalue value exceeded 1.0. A Bartlett's test of sphericity with $P<0.05$ and a Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy of 0.734 were used in this factor analysis (Figure 1).

Ethics

The Scientific and Ethics Committee of the University Hospital of Heraklion, Crete, approved the observational study (protocol n. 11873 - 25/10/2006) that aimed to identify the applicability of RDQ in Greek primary care. All participants were informed of the purpose of the study and the confidentiality and anonymity of the process and gave their written consent.

Results

Sample characteristics

Patients' demographic and clinical characteristics are presented in Table 1. The final sample consisted of 160 individuals. Twelve individuals who initially entered the study left it early, reducing the statistical power to 72%.

Questionnaire characteristics

Using the IDGP as the gold standard, the RDQ questionnaire had the following characteristics. For GERD: sensitivity 88.1%, specificity 29.8%, positive predictive value (PPV) 74.4%, negative predictive value (NPV) 51.9%. For dyspepsia: sensitivity 50.0%, specificity 25.7%, PPV 5.3%, NPV 86.0%.

Table 1. Demographic characteristics of the sample.

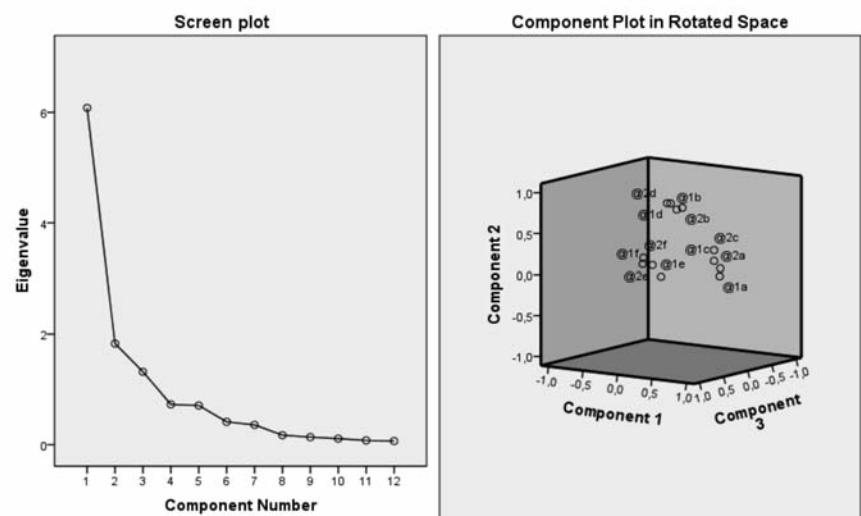|	Men	Women	Total
Age in years*	64.93/13.02	60.36/12.60	61.74/12.86
Body mass index (Kg/m²)*	32.71/39.51	28.67/4.61	29.98/22.76
Education level			
None	2 (4%)	9 (8%)	11 (7%)
Elementary	49 (96%)	97 (92%)	146 (93%)
Married	50 (100%)	105 (100%)	155 (100%)

*Mean/standard deviation.

Figure 1. Screen plot and component plot in rotated space.

Reliability

The RDQ questionnaire showed a high overall internal consistency (alpha value 0.91) for individual comparison. Each diagnostic group also showed acceptable alpha values: 0.82 for heartburn, 0.88 for regurgitation and 0.83 for dyspepsia. All 8 items regarding heartburn and regurgitation (GERD) had *good* reproducibility (Cohen's kappa coefficient 0.60-0.79), while the remaining 4 items about dyspepsia had a *moderate* reproducibility (Cohen's kappa coefficient 0.40-0.59).[23] Results are shown in Table 2.

Validity

The kappa coefficient for criterion validity for GERD was quite fair [0.20, 95% confidence interval (CI): 0.04, 0.36] and the overall agreement between the results of the RDQ questionnaire and those based on the IDGP questionnaire was 70.5%. Regarding dyspepsia, and as expected, the kappa coefficient was poor (-0.05, 95% CI: -0.12, 0.02) and the overall agreement between the results of the RDQ questionnaire and those based on the IDGP questionnaire was 27.5%.

The performed factor analysis indicated 3 factors with eigenvalue over 1.0. Those factors were responsible for 76.9% of variance and rotation, and they converged in 5 iterations (Table 3). While regurgitation items correlated more strongly with the third component, pain behind sternum and upper stomach pain correlated with the second component.

Discussion

Main findings

The RDQ has been found to be reliable, valid, responsive and above all practical.[16,31-33] Also, the RDQ was specially designed for use in the primary care setting.

An important feature of the RDQ is the fact that symptoms are described in a figurative, non-technical manner. Previous studies have shown that patients are often confused by terms such as *heartburn*.[12] Because of this, the original developers of the RDQ conducted cognitive interviews with patients in order to clarify the obscure questions. Thus, instead of *heartburn* or *regurgitation*, researchers used word pictures such as *burning behind the breastbone* or *acid taste in mouth*. This characteristic has been retained in the Greek translation. The Greek version of the RDQ showed a high overall internal consistency. The diagnosis of GERD in particular, showed good reproducibility. The criterion validity concerning overall agreement between RDQ and IDGP was rather poor for the diagnosis of GERD and poor for the diagnosis of dyspepsia. The poor agreement could be attributed to the fact that the

RDQ was designed in order to identify GERD rather than exclude dyspepsia, whereas IDGP was designed to identify dyspepsia. Even though we have tried to eliminate this difference by using only those IDGP questions that could lead to a diagnosis of GERD, we are not sure whether the use of another gold standard would have led to different results.

The Greek RDQ has demonstrated high reliability in assessing heartburn and regurgitation. The questions referring to dyspeptic complaints are problematic in the Greek translation, and this was experienced from the Italian and German translations, too.[34,35] Nevertheless, in their validation Shaw *et al.*[16] decided not to delete the dyspepsia-related questions from the RDQ, not only because of their good psychometric results overall but also for the typically overlapping nature of reflux and dyspepsia complaints. In Rome III criteria, GERD is also taken into consideration when dyspeptic patients present symptoms of acid regurgitation or heartburn.[36]

Strengths, limitations and general discussion about the applicability of reflux disease questionnaire

As in usual clinical practice, the diagnosis of GERD was made on the basis of patients' symptoms. However, a comparison using other parameters, such as 24-h ambulatory pH monitoring or upper endoscopy could have been more accurate. We intended to use endoscopy as a gold standard but this was not possible in our study population due to the low compliance of patients; this problem has been analyzed elsewhere.[37] Consequently, our best approach was considered to be the use of the IDGP questionnaire as being the closest to the reality of Greek primary health care. Future research should rely on more accurate diagnostic tools, and probably another comparison would be preferable for the estimation of RDQ criterion validity. Another characteristic of the Greek validation is that it was performed on people aged over 60 years old, with a low level of edu-

Table 2. Reflux Disease Questionnaire: reproducibility (test- retest reliability).

Symptom	Item	K*	P
Heartburn	1a	0.753	<0.001
	1b	0.690	<0.001
	2a	0.616	<0.001
	2b	0.779	<0.001
Regurgitation	1e	0.651	<0.001
	1f	0.627	<0.001
	2e	0.704	<0.001
	2f	0.655	<0.001
Dyspepsia	1c	0.531	<0.001
	1d	0.568	<0.001
	2c	0.515	<0.001
	2d	0.548	<0.001

*Cohen's kappa coefficient.

Table 3. Factor analysis for Reflux Disease Questionnaire items: rotated component matrix for 3 factors.

Item-symptom	Component		
	1	2	3
Heartburn			
1a. Burning behind sternum (frequency)	0.884*	0.061	0.257
1b. Pain behind sternum (frequency)	0.219	0.797*	0.199
2a. Burning behind sternum (severity)	0.865*	0.146	0.218
2b. Pain behind sternum (severity)	0.273	0.817*	0.159
Regurgitation			
1e. Acid taste (frequency)	0.383	0.077	0.757*
1f. Movement of materials (frequency)	0.162	0.215	0.823*
2e. Acid taste (severity)	0.272	0.207	0.776*
2f. Movement of materials (severity)	0.167	0.290	0.814*
Dyspepsia			
1c. Upper stomach burning (frequency)	0.801*	0.235	0.257
1d. Upper stomach pain (frequency)	0.072	0.858*	0.187
2c. Upper stomach burning (severity)	0.767*	0.356	0.208
2d. Upper stomach pain (severity)	0.134	0.864*	0.203

* Highest coefficients.

cation and this could be considered to be a critical drawback its use in the general population. Nevertheless, it is estimated by country statistics that 60% of the patients visiting primary care practices in rural areas of Greece are over 60 years of age and have a low level of education. Consequently, the common educational base of the subjects who participated in the research contributes to the strength of the study. The finding that RDQ showed substantial reproducibility is a further advantage of this study. However, its statistical power was not the preferred one (72% instead of 75%), mainly due to some participants leaving the study.

The RDQ had already been translated into Greek by a research group from Astra-Zeneca. Since there is no literature referring to the translation of RDQ in the Greek language, issues such as the cultural adaptation of the questionnaire cannot be guaranteed by the translating team.

RDQ also focuses on heartburn and regurgitation, and although these are the most typical and prevalent GERD symptoms, there are other symptoms, such as hoarseness or chronic cough, which are not included. This is a general limitation of the questionnaire and should be considered when it is used without any other diagnostic tool.

Implications of the study

Implications of the validated questionnaire can be demonstrated on a primary care level. It is anticipated that this will represent a practical instrument for primary care physicians in Greece. It can be applied in daily practice for identifying patients with GERD and could be used in epidemiological studies.

Conclusions

We have accumulated sufficient evidence to show that the Greek version of the RDQ provides a reproducible, reliable and valid instrument in the primary care setting. In addition, the questionnaire is considered to be a useful tool for clinical research in this context. It could also be appropriate for use in international studies, since its psychometric properties are comparable to other versions validated in several countries.

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