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VALIDAÇÃO DO QUESTIONÁRIO ROMA III PARA O DIAGNÓSTICO DE DISPEPSIA FUNCIONAL EM ADULTOS PORTUGUESES

VALIDATION OF THE PORTUGUESE ROME III QUESTIONNAIRE FOR DIAGNOSIS OF FUNCTIONAL DYSPEPSIA IN ADULTS

VALIDACIÓN DEL CUESTIONARIO III ROMA DE PORTUGAL PARA EL DIAGNÓSTICO DE DISPEPSIA FUNCIONAL EN LOS ADULTOS

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RESUMO

Introdução: A validação de instrumentos é essencial na investigação epidemiológica, especialmente para a definição consensual de caso e comparação de resultados. Atualmente, o instrumento mais utilizado para identificar a dispepsia funcional é o questionário Roma III, o qual não se encontra validado para a população portuguesa.

Objetivos: Validar o questionário Roma III para dispepsia funcional em adultos Portugueses.

Métodos: O questionário foi traduzido seguindo as recomendações de Roma III. Um total de 166 indivíduos responderam ao questionário. A identificação da categoria dispepsia funcional em adultos baseou-se em um ou mais sintomas dos 4 sintomas que a escala permite avaliar através de 6 itens. A consistência interna, reprodutibilidade e análise de conteúdo foram avaliados com recurso ao SPSS 23.0.

Resultados: O coeficiente de alfa de Cronbach no total dos 18 itens avaliados foi de 0.89. Para a categoria dispepsia funcional (avaliada através de 6 itens) foi de 0.76 e o alfa de Cronbach com base em itens padronizados foi de 0.85.

Conclusões: validamos, para Portugal, o Questionário Roma III para o diagnóstico de doenças gastrointestinais funcionais, designadamente para a categoria dispepsia funcional em adultos. Estes resultados sugerem que este instrumento será útil para a investigação na população Portuguesa.

Palavras-chave: dispepsia; adulto; estudos de validação; Portugal.

ABSTRACT

Introduction: The validation tools are essential in epidemiological research, especially for the consensus case definition and comparison of results. Currently, the instrument most commonly used to identify functional dyspepsia is the Rome III questionnaire, which is not validated for the Portuguese population.

Objectives: To validate the Rome III questionnaire for the assessment of functional dyspepsia in Portuguese adults.

Methods: The questionnaire was translated following the recommendations of Rome III. A total of 166 adults completed the questionnaire. The identification of the category of functional dyspepsia among adults was based on the presence of one or more symptoms from the total of 4 symptoms that the scale allows to assess from a total of 6 items. The internal consistency, reproducibility and contents analysis were evaluated using the program SPSS 23.0.

Results: Alpha Cronbach coefficient from the total of 18 items measured was 0.89. For functional dyspepsia category (assessed by 6 items) was 0.76 and the alpha Cronbach's based on standardized items was 0.85.

Conclusions: We validated, for Portugal, the Rome III questionnaire for the diagnosis of functional gastrointestinal disorders, particularly for functional dyspepsia among adults. These results suggest that this tool will be useful for research in the Portuguese population.

Keywords: dyspepsia; adult; validation studies; Portugal.

RESUMEN

Introducción: Las herramientas de validación es esencial en la investigación epidemiológica, especialmente para la definición de caso consenso y la comparación de los resultados. En la actualidad, el instrumento más utilizado para identificar la dispepsia funcional es el cuestionario de Roma III, que no está validado para la población portuguesa.

Objetivos: validar el cuestionario para la dispepsia funcional Roma III en los adultos portugueses.

Métodos: El cuestionario fue traducido siguiendo las recomendaciones de Roma III. Un total de 166 individuos completaron el cuestionario. La identificación de la categoría dispepsia funcional de adultos basada en uno o más síntomas de los 4 síntomas que la escala permite evaluar de un total de 6 artículos. El análisis de consistencia, reproducibilidad y contenido interno se evaluaron con el programa SPSS 23.0.

Resultados: El coeficiente alfa de Cronbach del total de 18 artículos medido fue de 0,89. Para la categoría de dispepsia funcional (evaluado por 6 artículos) fue de 0,76 y de basada en los puntos estandarizados alfa de Cronbach fue de 0,85.

Conclusiones: Hemos validado para Portugal, el cuestionario Roma III para el diagnóstico de trastornos gastrointestinales funcionales, sobre todo para la dispepsia funcional en adultos. Estos resultados sugieren que esta herramienta será útil para la investigación en la población portuguesa.

Palabras Clave: dispepsia; adulto; estudios de validación; Portugal.

INTRODUCTION

Dyspepsia is a very common gastrointestinal syndrome in the general population. The prevalence of dyspepsia, worldwide, ranges between 8.5% and 56%. This variation in the prevalence rates may be related to differences in the definition of dyspepsia and in the various populations studied (Grainger, Klass, Rake, & Williams, 1994; Yazdanpanah et al., 2012). A consensual definition and validation for a number of countries allows comparison of results. Currently, the criteria most used in epidemiological investigation to identify individuals with functional dyspepsia is the Rome III questionnaire, published in 2006. The Rome Foundation developed the questionnaire for the Rome III diagnostic criteria for functional gastrointestinal disorders.

Several dyspepsia and functional dyspepsia definitions have been proposed. Earlier definitions considered dyspepsia as the presence of all abdominal and upper retrosternal sensations. Currently, dyspepsia settings has evolved to become narrower and more focused on the symptoms of the gastroduodenal area. Dyspepsia is defined as a persistent or recurrent pain or discomfort, localized in the upper abdomen, which may or may not be related to type of food consumption or stress. The appearance of dyspepsia or gastrointestinal symptoms can be associated with other upper gastrointestinal disorders such as peptic ulcer disease, gastrointestinal reflux, gastritis, upper gastrointestinal cancer, biliary tract disease and functional dyspepsia (Tack & Lee, 2005). Functional dyspepsia may also be associated with the use of various drugs, self-medication, absenteeism and lost of productivity. Functional dyspepsia is a clinical syndrome characterized by chronic and recurrent gastroduodenal symptoms in the absence of any organic or metabolic disease that is likely to explain the symptoms (Tack et al., 2006; Zagari et al., 2010).

The Rome I and II Consensus Committees considered that dyspepsia should be defined as pain or discomfort centered in the upper abdomen (Talley et al., 1999; Kumar, Patel, & Sawant, 2012). Rome III, a more recent consensus, has defined dyspepsia as the presence of symptoms considered by the physician that originates from the gastroduodenal region and considers the presence of only four possible symptoms (Kumar Patel & Sawant, 2012). The symptoms defined are pain, burning sensation, postprandial fullness and early satiety that are now considered to be specific for the gastroduodenal rather than the ambiguous term discomfort used in the previous Rome I and II (Tack et al., 2006; Perveen Rahman, Saha, Rahman & Hasan, 2014). The sensitivity and specificity of the Rome III classification of functional gastrointestinal disorders showed fairly high values (Perveen Rahman, Saha, Rahman & Hasan, 2014).

There were major changes in the Rome III version - changes in chronological criteria for diagnosis of functional gastrointestinal disorders from 12 months to 6 months for the onset, and from 6 months to 3 months for the activity of the symptoms; subtypes of changes in functional dyspepsia, postprandial distress syndrome and epigastric pain syndromes; more strict criteria for functional disorders of the gallbladder and sphincter of Oddi; and revision of the irritable bowel syndrome subtyping using stool consistency (Park et al., 2011).

Thus, bearing in mind the criteria defined in the Rome III, dyspepsia is defined to be the presence of one or more dyspepsia symptoms (last 3 months with symptom onset at least 6 months before diagnosis) que are considered to originate from the gastroduodenal region, in the absence of any organic, systemic, or metabolic disease that is likely to explain the symptoms (Tack et al., 2006) (Table 1).

Table 1 – Rome III Diagnostic Criteria for Functional Dyspepsia.

Diagnostic Criteria* for Functional Dyspepsia
1. One or more of symptoms:
a. Bothersome postprandial fullness
Uncomfortably full after regular sized meal, more than 1 day/week (question 3>4)
Onset more than 6 months ago (question 4=1)
b. Early satiety
Unable to finish regular sized meal, more than 1 day/week (question 5 >4)
Onset more than 6 months ago. Yes. (question 6=1)
c. Epigastric pain
Pain or burning in middle of abdomen, at least 1 day/week (question 7>3)
Onset more than 6 months ago. Yes. (question 8=1)
d. Epigastric burning
This criterion is incorporated in the same question as epigastric pain
AND
2. No evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms
No question.
* Criteria fulfilled for the last 3 months with symptom onset at least 6 months before diagnosis
Yes. (question 8=1)

Assessment of the category of functional dyspepsia is based on an estimate of 4 symptoms from six questionnaire items related to the last three months.

As mentioned, the ROME III questionnaire is used in several countries for the definition of functional dyspepsia. It has also been validated for Brazil, Korea, Italy, Norway, England and other countries (Song et al, 2013; Perveen Rahman, Saha, Rahman & Hasan, 2014).

In a study designed in Bangladesh, with a sample of 3000 subjects with a mean age of 33.9 ± 16.4 years and using the Rome III questionnaire, the prevalence estimated of functional dyspepsia was 8.3% (Perveen Rahman, Saha, Rahman & Hasan, 2014; Seyedmirzaei, Haghdoost, Afshari, & Dehghani, 2014; Chang et al., 2012).

Another study conducted in Iran, with a sample of 2320 subjects with a mean age of 43.4 ± 16.3 years revealed a prevalence of functional dyspepsia (based on ROME III criteria) of 16.1%, more common among the female gender (17.1% vs. 15.2%, $p=0.03$) (Seyedmirzaei, Haghdoost, Afshari, & Dehghani, 2014). In Taiwan, a study with a final sample of 4275 adults showed a prevalence of gastrointestinal functional disorders of 26.2%, unspecified functional bowel disorder was the most prevalent (8.9%) and the second was functional dyspepsia (5.3%). In the same study, women had a greater prevalence than men (33.2% compared to 22.4%, $p<0.05$) regarding overall gastrointestinal functional disorders (Chang et al., 2012).

We can see that it is essential to define a correct definition in order to allow the development of knowledge about the prevalence, geographic distribution and the comparison of dysfunctional dyspepsia between countries. Most studies presented were based on the identification of individuals with functional dyspepsia through the Rome III criteria, once the clinical diagnosis of functional dyspepsia after the identification of individuals is carried out through a complementary diagnostic test - endoscopy. The difficulty facing epidemiologic studies of functional dyspepsia is creating the necessary conditions to establish a correct diagnosis (Zagari et al., 2010). In this sense, several population-based studies have shown data on the prevalence and risk factors for functional dyspepsia based on symptoms, but the diagnosis of functional dyspepsia based on criteria defined by symptoms and endoscopy are very scarce (Zagari et al., 2010). The Rome III Diagnostic Questionnaire, of which the Diagnostic Questionnaire for Functional Dyspepsia is included, is a valid and reliable instrument for making provisional diagnoses of all functional gastrointestinal disorders with the exception of unspecified functional bowel disorder. It can be used in clinical, epidemiological, or basic research purposes, but to confirm the diagnosis some additional diagnostic tests are needed (Reisswitz, Mazzoleni, Sander & Francisconi, 2010).

The aim of this study was to develop and validate the cross-cultural adaptation of the Rome III questionnaire for diagnosis of functional gastrointestinal disorders in Portugal.

1. METHODS

The systematic translation and the cross-cultural adaptation process are indispensable for research questionnaires.

The research was approved by the Ethics Committee of the Health School and Research Centre for Education, Technology and Health Studies of the Polytechnic Institute of Viseu, Portugal (CI&DETS).

For the translation, adaptation and validation of the Rome III two complementary phases were followed - translation and cultural adaptation of the questionnaire and the statistical validation. The cultural adaptation was performed in order to obtain an equivalent to the questionnaire developed in the original country in order to ensure equivalence of contents and semantics. For this adaptation translation-retroversion method for bilingual people was applied.

The translation process began with two translations from the original questionnaire by two translators, native of Portugal and fluent in English. The translated version was reviewed by a native doctor in Portugal. This was followed retroversion by an independent translator, not knowing the original version in English. Confronting the versions (original and retranslated) to assess the content of items and finally realized the correction of technical terms by a doctor. The end of Portuguese version of the Rome III questionnaire was produced.

The total sample consisted of 166 subjects (56.6% female), aged over 18 years (mean of 46.96 ± 03.17 years). Most of the subjects were married (60.8%), employees (69.7%); 33.2% possessed the 1st or 2nd cycles of school education; 22.9% 3rd cycle or secondary and 43.9% had higher education. The sample was selected at random from the center of Portugal.

1.1. Data collection

Data were collected through a questionnaire between the months of January and March of 2013. The researchers presented the objectives to the research participants and the informed consent and the questionnaire were filled out by each participant

and then returned in a sealed envelope. The ROME III questionnaire consists of 20 questions and the items 3 to 8 assesses the functional dyspepsia category. According to the Rome Foundation, the proposed frequency of symptoms is different for functional dyspepsia and other subtypes that the Rome III questionnaire allows identification. The Rome Foundation also recommends the answer “at least” for weekly symptoms in the definition of functional dyspepsia.

1.2. Statistical Methods

After data collection, statistical analysis was performed using the SPSS software (version 23.0). The majority of the Rome III-Portuguese question items were categorical or dichotomous items, and the test-retest reliability of the Rome III-Portuguese was assessed by determination of the alpha of Cronbach coefficient and Pearson correlation. A coefficient higher than 0.7 Indicates acceptable consistency. The coefficient for each item is presented as a median with a 95% confidence interval.

2. RESULTS

When we conduct a descriptive analysis of items that match assessment of functional dyspepsia, we found that the number of respondents in all items is the same, however the maximum number of response options is different for each item, in which there were differences in corresponding the maximum value of each item. The mean values are low (Table 2).

Table 2 - Descriptive values of Rome III questionnaire items for evaluation of functional dyspepsia.

Items	n	Minimum	Maximum	Mean	Standard deviation
3	166	0	6	1.46	1.76
4	166	0	1	0.45	0.50
5	166	0	5	0.64	1.32
6	166	0	1	0.20	0.40
7	166	0	6	0.89	1.43
8	166	0	1	0.36	0.48

The alpha of Cronbach coefficient for the 18 items of the questionnaire answered was 0.87 for patients. According to the ROME III questionnaire and considering the six items for identification of the functional dyspepsia category the alpha of Cronbach coefficient was 0.76 and the alpha of Cronbach based on standardized items was 0.85.

Analyzing the bivariate Pearson correlation between the items we found that the correlation between items that assess each symptom is good (ranging between 0.702 and 0.771). For the symptom “bothersome postprandial fullness” - rated by items 3 and 4 correlations was 0.702; for the symptom “early satiation” - rated by items 5 and 6 the correlation was 0.769 and to assess the symptoms “epigastric pain” and “epigastric burning” the Pearson correlation for items 7 and 8 was 0.771.

According to table 3, the most interesting analysis are the correlation between the scores of the item and the total range (R), the coefficient of multiple determination (R²) between the item and the other items of the scale and the value of alpha of Cronbach if an item was eliminated from the scale. By the alpha of Cronbach, the items are rated as acceptable, with identical value of alpha in all items (ranging between 0.70 and 0.74) and as no alpha of Cronbach is higher than the general alpha, this suggests that no item should be excluded. The item that has worse R is the item “5” and the item that has a lower correlation with the other items is “4”.

Table 3 - Internal consistency of the ROME III questionnaire items for the category of functional dyspepsia.

Item number	Mean ± Standard Deviation	R	R ²	α without item
3	2.53±10.13	0.64	0.57	0.70
4	3.55±17.40	0.66	0.54	0.73
5	3.36±13.47	0.54	0.61	0.71
6	3.80±18.01	0.65	0.64	0.74
7	3.10±12.36	0.59	0.64	0.70
8	3.64±17.69	0.61	0.60	0.74

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After calculation and analysis of the split-half, we found that the 1st half of the alpha of Cronbach scale was 0.65 and the second half was 0.61. The split-half procedure related to the correlation between the measurements provided by the two halves of the scale is high, the range is consistent with the pattern as a whole and present internal consistency: the two halves test measures the same construct.

3. DISCUSSION

This study aimed to carry out cross-cultural validation, translation into Portuguese and cultural adaptation of the dyspepsia functional category of the Rome III questionnaire. Data was collected by a group of researchers, team members of the “Helicoviseu Project.”

In Portugal, the prevalence of gastrointestinal functional disorders is high. With this gradual public health issue and, given the importance of evaluation of functional dyspepsia in the general population, it is important to assess the case definition. The studies in the field of gastrointestinal functional disorder assessment, in particular of the category functional dyspepsia, in different countries through a common and culturally adapted questionnaire, is key. The Rome III criteria for functional dyspepsia were published in 2006. This is the first validation of one of the Rome III Modulated Questionnaires in Portugal. The Rome III Diagnostic Questionnaire for Functional Dyspepsia was successfully validated, showing good psychometric properties.

A validated questionnaire related to the diagnosis of gastrointestinal functional disorders is crucial to assess the prevalence of these specific diseases and respective categories (including functional dyspepsia) and subscales / symptoms in epidemiological research.

The alpha of Cronbach, which measures internal consistency (that is the extent to which an item is related to other items) was 0.87, within the range considered ideal (0.80-0.90). According to the Rome III questionnaire to identify functional dyspepsia and considering the corresponding items the alpha of Cronbach coefficient was 0.76 and the the alpha of Cronbach based on standardized items was 0.85. The minimum acceptable value for alpha is 0.70; however, the usually preferred alpha values are between 0.80 and 0.90. We can see that the Rome III questionnaire to identify the functional dyspepsia in adults presents an acceptable internal consistency. In the questionnaire validation study ROME III in Korea, the functional dyspepsia scale showed a alpha of Cronbach of 0.84 (range, 0.60-0.86) (Song et al., 2013).

One of the limitations of our study is the fact that the questionnaire was applied in a sample of individuals in a community without a group of cases with clinical diagnosis of functional dyspepsia, and a control group. The small sample size in the validation study may be the limitation.

Still, we note that the epidemiological data of functional dyspepsia in the general population are scarce (Zagari et al., 2010).

The validation of this questionnaire for Portugal is important for a definition of functional dyspepsia criteria and allows the determination of functional dyspepsia prevalences based on criteria and symptoms and not in clinical diagnosis, this done by exclusion through endoscopy (Talley, Vakil, & Moayyedi, 2005; Tack et al., 2006). The underlying difficulty epidemiological studies of functional dyspepsia is that the diagnosis of this condition is essentially a diagnosis of exclusion after endoscopy. Some population-based studies have provided data on the prevalence and risk factors for functional dyspepsia, but clinical diagnosis of functional dyspepsia, based on endoscopy was not performed. The difficulty considered in epidemiological studies of functional dyspepsia is that the diagnosis of this condition is essentially a diagnosis of exclusion after endoscopy, which is very difficult in population-based studies (Piessevaux et al., 2009; Talley, Vakil, & Moayyedi, 2005; Tack et al., 2006).

CONCLUSIONS

We can see that the Rome III questionnaire to identify the functional dyspepsia in adults presents an acceptable internal consistency. The Rome III proved to be a reliable and valid tool, self-reported to identify cases of functional dyspepsia. A validated questionnaire to assess the prevalence of functional dyspepsia in epidemiological studies is crucial. The questionnaire has illustrations to minimize anatomical misunderstandings and increase reliability.

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CONFLICT OF INTERESTS

The authors have no conflicts of interest.

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