

PORTUGUESE VALIDATION OF THE ROME III DIAGNOSTIC QUESTIONNAIRE FOR FUNCTIONAL DYSPEPSIA

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ABSTRACT – *Context* - Validated questionnaires are essential tools to be utilized in epidemiological research. At the moment there are no Rome III diagnostic questionnaires translated to Portuguese. *Objective* - To validate the Portuguese version of the Rome III Diagnostic Questionnaire for Functional Dyspepsia. *Methods* - The questionnaire has been translated following the Rome III recommendations. Hundred and nine consecutive patients with functional dyspepsia answered the questionnaire. The control group comprised 100 healthy consecutive blood donors, without digestive problems. Internal consistency, reproducibility, responsiveness, discriminate validity and content analysis were evaluated. *Results* - Cronbach's α coefficient was 0.92. The questionnaire showed reliability: the patients answered it in a similar way on two distinct occasions and their responses were substantially very similar ($P = 1.00$). The questionnaire was able to demonstrate changes when they occur ($P < 0.01$). Two "blinded" gastroenterologists agreed that the questionnaire adequately evaluated Functional Dyspepsia. When we compared the answers between patients and controls, the questionnaire showed that 5.3% of controls had Functional Dyspepsia symptoms compared with 91.2% of the patients ($P < 0.01$). *Conclusion* - The Rome III Diagnostic Questionnaire for Functional Dyspepsia is ready to be used in clinical researches in lusophone countries, as it has been successfully validated in Portuguese.

HEADINGS – Dyspepsia. Questionnaires. Translation.

INTRODUCTION

Functional dyspepsia (FD) is defined as pain or discomfort located in the upper abdomen, without structural or biochemical explanation for the symptoms, which include pain, postprandial fullness, early satiety and bloating. Despite its high prevalence, FD is still difficult to study due to the lack of adequate tools to measure significant outcomes. This happens because FD does not have a measurable anatomical or physiopathological substrate and as a consequence outcomes of medical interventions on FD rely mainly on subjective concepts. The diagnostic criteria for FD were established by specialists in consensus statements known as the Rome criteria, the last one being Rome III⁽¹⁴⁾.

Population based studies have shown prevalence of dyspepsia that vary from 7% to 63%, a very wide range, partly due to being the lack of consensus in the definition of dyspepsia in different studies. We consider, based on the studies that have been done, that the real prevalence is around 25%^(1,6). Its prevalence is larger in women and reduces with the age. Dyspeptic

symptoms are responsible for 7% of medical visits to the general practitioner's office and for 40% to 70% of gastroenterological complaints in speciality practice⁽⁶⁾.

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 (FGID) with the exception of unspecified functional bowel disorder. It can be used for clinical, epidemiological, or basic research purposes, but users must recognize that laboratory diagnostic tests and clinical judgment are required to confirm some diagnoses⁽¹⁷⁾.

The term 'cross-cultural' research in FGIDs is usually applied to the results of prevalence studies, for example in comparative studies of irritable bowel syndrome prevalence in different countries and ethnic groups. The validity of these comparisons is challenged by the lack of uniformity in research methods. In addition to prevalence studies, cross-cultural research can make a significant contribution in areas such as molecular biology, genetics, psychosocial factors, symptom presentation, extra-intestinal comorbidity,

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The authors have no conflict of interest to declare.

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diagnosis and treatment, determinants of disease severity, health care utilization, health-related quality of life and all issues that can be affected by culture, ethnicity and race. Cross-cultural research in any of these areas is of potential interest and importance⁽¹¹⁾. Validated questionnaires are essential tools to be used in these different scenarios.

The aim of this study was to validate the Rome III Diagnostic Questionnaire for Functional Dyspepsia in Portuguese, as a base for future research in Brazil.

METHODS

Patients

Patients who responded to the questionnaire were more than 18 years old, were recruited by media advertisement and had been diagnosed with FD based on the Rome III criteria⁽¹⁴⁾. For the questionnaire validation, all patients who had the FD diagnosis had been screened by upper gastrointestinal endoscopy with normal results. Patients were included independently of their *Helicobacter pylori* (*H. pylori*) status. The patients answered the questionnaire in three separate stages: C1) when they came to the first consultation, C2) 15 days after C1 with an upper gastrointestinal endoscopy being performed in this interval of time, and C3) 3 months after C2. Between C2 and C3 patients participated in a double blind placebo controlled trial for eradication of *H. pylori*. Rescue medication was offered during this period of trial. To assure the concealment of the *H. pylori* status, side effects of the medication were kept in closed envelopes. Neither the doctors nor the patients knew in which group — eradication or placebo — they were. The questionnaires were completed before the endoscopy consultations, so the endoscopy results could not influence the answers given. Neither the family nor the patients received any information from the doctors about the endoscopy results.

The control group were healthy consecutive blood donors from the Blood Bank of the Hospital de Clínicas de Porto Alegre, RS, Brazil (HCPA). After blood donation, the controls were asked about gastrointestinal symptoms. If they did not have any gastrointestinal complaints, they were invited to join the study answering the questionnaire.

The Research Ethics Committee of HCPA approved the study protocol (Number 07-035) and informed written consent was obtained from all participants.

Sample size calculation: a) internal consistency: as 10 patients per question were needed to calculate the Cronbach's α coefficient, 180 questionnaires were answered (90 patients and 90 controls). b) Reproducibility and responsiveness: McNemar's χ^2 test was used assuming a negligible difference from 0% to 10%, considering a discrepancy of 5%, with a significance level of 5% and a power of 80%. For these purposes 53 pairs were necessary. Reproducibility was measured by test-retest method, patients answered the questionnaire when they came to the first consultation (C1) and when they came to the second consultation (C2) they answered the questionnaire again, before knowing the endoscopy results. Responsiveness was evaluated comparing the questionnaire results in C2 and

C3. Between these visits, one group received omeprazole and antibiotics (clarithromycin and amoxicillin); the other one received omeprazole and antibiotic's placebo. After this treatment, patients came back to C3 3 months later and answered the questionnaire again. c) Discriminant validity: 57 patients with FD and 57 patients without gastrointestinal symptoms (controls) matched for age and gender were evaluated. The questionnaire's results were analysed by Pearson's χ^2 test, to show the difference between the dyspepsia assumed prevalence of 25%^(1,6) on the controls and of 90% on the patients group, with 90% of power and a significance level of 5%.

Content analysis is not a statistical approach but rather a judgment by specialists in the field about representativeness and relevance of the items proposed in the scale. It was assessed by two experienced gastroenterologists blinded to the purpose of the questionnaire. They were asked to determine what construct the questionnaire was supposed to measure. Then they were asked to confirm that the questionnaire sampled the full range of symptoms of FD.

Questionnaire translation

Two independent forward translations of the original questionnaire were produced by two professional translators, native speakers of Portuguese and fluent in English. Based on the two forward translations and consulting a specialist in Gastroenterology in Brazil, a new version of the questionnaire was developed in Portuguese. A backward translation of this Portuguese version into English was produced by one professional translator, native speaker of English and fluent in Portuguese. A comparison of the original and the backward translation version was done by a third professional translator to analyse possible inconsistencies. A second version in Portuguese was made and experienced gastroenterologists provided critical feedback. This allowed the development of a Portuguese version; this version was tested in a focus group comprised of 15 patients of pre-testing to assess the clarity, appropriateness of wording and acceptability of the translated questionnaire. Based on these results a final Portuguese version was developed^(9, 10, 13, 17).

RESULTS

The group of patients with FD comprised 109 consecutive subjects between 18 and 68 years old, 92 female (84.4%). The average age was 44 ± 14.44 years (mean \pm standard variation).

The control group comprised 100 consecutive subjects between 18 and 66 years old, 40 female (40%). The average age was 38.8 ± 11.5 years.

The healthy controls were significantly younger than the patients ($P = 0.003$) and had significant more males ($P < 0.001$).

Table 1 presents the demographics of the two groups.

Internal consistency

Cronbach's α coefficient for the 18 questions of the questionnaire answered was 0.79 for patients, 0.90 for controls and 0.92 combined.

TABLE 1. Demographics

	FD group n (%)	Control group n (%)
Gender		
Male	17 (15.6%)	60 (60%)
Female	92 (84.4%)	40 (40%)
Age		
18–20 years	4 (3.67%)	6 (6%)
21–30 years	19 (17.43%)	18 (18%)
31–40 years	17 (15.59%)	33 (33%)
41–50 years	27 (24.77%)	27 (27%)
51–60 years	32 (29.35%)	11 (11%)
>60 years	10 (9.18%)	5 (5%)
Average age	44 ± 14.44	38.8 ± 11.5

FD = functional dyspepsia

Reproducibility

The results of the questionnaires answered by 109 patients with FD in the first and the second consultation (C1 and C2) were compared. As shown in Table 2, the questionnaire indicates that 83.5% of the patients presented FD symptoms at C1 and 82.6% at C2. The answers were evaluated by McNemar's χ^2 test, that showed that 10 patients (9.2%) had FD in C1 but not in C2. Nine patients (8.3%) had FD in C2 but in C1 they were classified as non-dyspeptic. McNemar's test shows that this discordance occurred by chance ($P = 1.00$).

TABLE 2. Comparison of the proportion of patients with FD in C1 and C2

		FD C2		
		N	Y	Total
FD C2	N count	9	9	18
	% of total	8.3%	8.3%	16.5%
	Y count	10	81	91
	% of total	9.2%	74.3%	83.5%
	Total count	19	90	109
	% of total	17.4%	82.6%	100.0%

FD = functional dyspepsia

C1 = consultation 1

C2 = consultation 2

Y = yes

N = no

Responsiveness

Responsiveness was evaluated comparing the questionnaire results of 66 patients in C2 and C3. Between these consultations, patients received medication for pain and indigestion plus omeprazole and antibiotics or antibiotic's placebo. As we can see in Table 3, 87.9% of patients were classified as functional dyspeptics in C2 and 12.1% as non-dyspeptic. But when they answered the questionnaire after the treatment (C3), 47.0% of the patients had FD and 53.0% were non-dyspeptic. The answers were evaluated by McNemar's χ^2 test that showed that 45.5% of the patients that had FD in C2, were classified as non-dyspeptic in C3 and only 4.5% of non-dyspeptic patients in C2 were classified as dyspeptic in C3. This difference between C2 and C3 was statistically significant ($P < 0.01$), indicating that the questionnaire identified the improvement caused by the treatment.

TABLE 3. Comparison of the proportion of patients with FD in C2 and C3

		FD C3		
		N	Y	Total
FD C2	N count	5	3	8
	% do total	7.6%	4.5%	12.1%
	Y count	30	28	58
	% of total	45.5%	42.4%	87.9%
	Total count	35	31	66
	% of total	53.0%	47.0%	100.0%

FD = functional dyspepsia

C2 = consultation 2

C3 = consultation 3

Y = yes

N = no

Content analysis

The two "blinded" gastroenterologists agreed that the questionnaire adequately evaluated FD. They concluded that the items sampled the full range of symptoms of FD and were relevant to this disease. The clarity of the questions was also considered to be adequate.

Discriminant validity

The questionnaire was answered by 57 patients with FD and 57 patients without gastrointestinal symptoms (controls) matched for gender and age (2 years above or below). The questionnaire indicated that 5.3% of controls had FD, against 91.2% of the dyspeptic patients. Table 4 shows that Pearson's χ^2 test indicated that this difference between patients and controls had statistical significance ($P < 0.01$). The McNemar's χ^2 test was also used to evaluate the pairs of patients and controls, showing the same significance ($P < 0.01$).

TABLE 4. Comparison of the proportion of FD in patients and controls

		Patients with FD	Controls	Total
FD	N count	5	54	59
	% do total	8.8%	94.7%	51.8%
	Y count	52	3	55
	% do total	91.2%	5.3%	48.2%
	Total count	57	57	114
	% do total	100.0%	100.0%	100.0%

FD = functional dyspepsia

Y = yes

N = no

DISCUSSION

This is the first validation of one of the Rome III Modulated Questionnaires in Portuguese. The Rome III Diagnostic Questionnaire for Functional Dyspepsia was successfully validated, showing excellent clinimetric properties.

To translate the questionnaire, we followed the Rome III^(13, 17) recommendations, which has similar steps to the Sperber's et al.^(9, 10) recommendations, which is often used in validation studies^(3, 4, 7, 8).

Sperber et al.⁽¹⁰⁾ recommend validation of the translation by formal comparison of original instrument and back-translation. Each item in the two versions is ranked in terms

of comparability of language and similarity of interpretability. They suggest that the ranking should be performed by at least 30 raters who must be fluent in the source language. The raters must be independent of the investigators and the translators are not to be included. We could not do this it being impossible to find at least 30 available raters fluent in the source language. We are confident that the English to Portuguese translation was adequate because the steps followed in our work were carefully controlled by the authors, who are familiar with the English language and by five people fluent in both languages, who administered the translation and back translation. Furthermore our translation process followed the Rome Foundation recommendation for translating the Rome III scientific content.

Cronbach's α , which measures internal consistency (that is the extent to which an item is related to other items) was, at 0.79, within the range considered ideal (0.70–0.90)^(2, 12). This indicates that when the questionnaire is completed by patients with FD it does not have redundant questions and does not evaluate more than one construct^(2, 12). When the control group completed the questionnaire, Cronbach's α was 0.90, which is the upper limit. This can indicate a little redundancy but, because these persons did not have FD, this result was expected, most of them having answered all questions negatively, with consequent redundancy.

The Portuguese version of the Rome III Diagnostic Questionnaire for Functional Dyspepsia was also shown to be reproducible when submitted to the test-retest procedure. Despite the endoscopy procedure being performed between C1 and C2, results were very similar. Even though the endoscopy could potentially have resulted in bias in patient's answers, for its placebo effect in producing symptomatic benefits — especially if the endoscopy result is normal — answers in C2 were remarkably similar to C1. To avoid this potential bias factor the questionnaire was carried out before the patients knew the endoscopy report and at the endoscopy day neither the patients nor the family received any information about the endoscopy results. Our results strongly suggest that this kind of bias did not affect the reproducibility of the questionnaire.

Responsiveness was adequate as the questionnaire was capable of detecting changes in symptoms resulting from medication and placebo effect. This is an essential characteristic for instruments that are going to be used in clinical trials. There was a reduction of 40.9% in the number of patients with FD from C2 to C3. This reduction is similar to the values found in clinical trials of FD^(15, 16) where placebo effect results are in the 46% range and the drug, if successful in the trial, around 15%–20% superior to placebo.

Content validity, evaluated through qualitative interviews, showed good item clarity and relevance.

Discriminate validity, that compares two different groups, one with and one without FD, obtained good results. The Portuguese version of the questionnaire was capable of markedly differentiating a group of people without digestive symptoms or any other relevant clinical conditions as blood donors, from a group with FD. Controls have been matched

by gender and age. According to the Portuguese version, 5.3% of the controls, despite the fact that they denied gastrointestinal symptoms during the screening interview, did have FD when answering the questionnaire. When The Rome III Questionnaire Committee validated this questionnaire, FD was also found in 5.9% of the control group⁽¹⁷⁾. The difference between the prevalence of FD in the patients and the controls is statistically significant.

The questionnaire was completed by the subjects, so there was not interference from the researcher in the responses. All questionnaires were applied by the same researcher. Despite this study having been made in HCPA, which is a referral hospital, our study population was not part of that hospital's patients. Rather the hospital was merely used as a convenient facility. Invitations were via TV, radio and journals advertisements, with broad socio-economic and demographic viewership, thus ensuring an unskewed sample.

Blood donors were chosen as controls in our, as well as in other studies⁽⁵⁾, because they are healthy, naturally volunteers, usually willing to participate in the kind of social action typified by our research. The healthy controls were significantly younger than the patients ($P = 0.003$) and the sample had significantly more males ($P < 0.001$). These differences only exist when we compare the whole sample, but to calculate the discriminant validity, we used a sample matched by age and gender, therefore controlling this kind of bias. In the Rome III validation process of this questionnaire a younger control group was also observed⁽¹⁷⁾.

The importance of using validated instruments in any kind of research — clinical, epidemiological or basic — involving patients with FGID has been stressed⁽¹⁷⁾. In sophisticated cross cultural research, the same study is done in different countries, with different cultures, using the same methods⁽¹¹⁾. To reach this level of sophistication in research projects, involving Brazilian patients, it is of fundamental importance to validate the instruments to be used in our country, so that we can use the same instrument in the same kind of study developed in other countries, in our population.

In conclusion, the Rome III Diagnostic Questionnaire for Functional Dyspepsia has been successfully validated in Portuguese. The Portuguese version of the questionnaire has been shown to have adequate clinimetric properties to be used in clinical trials, thus becoming an important validated research instrument to be used in research related to FD in lusophone countries.

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QUESTIONÁRIO

Nome: _____
 Prontuário: _____ Data de Nascimento: ____/____/_____
 Data: ____/____/_____
 Pcte. n.º: _____

1. Nos últimos 3 meses, com que frequência você teve dor ou desconforto no meio do seu peito (não relacionada a problemas cardíacos)?

- () 0 - Nunca
- () 1 - Menos de um dia por mês
- () 2 - Um dia por mês
- () 3 - Dois a três dias por mês
- () 4 - Um dia por semana
- () 5 - Mais de um dia por semana
- () 6 - Todos os dias

2. Nos últimos 3 meses, com que frequência você teve azia (um desconforto ou dor de queimação no seu peito)?

- () 0 - Nunca
- () 1 - Menos de um dia por mês
- () 2 - Um dia por mês
- () 3 - Dois a três dias por mês
- () 4 - Um dia por semana
- () 5 - Mais de um dia por semana
- () 6 - Todos os dias

3. Nos últimos 3 meses, com que frequência você se sentiu desconfortavelmente cheio (saciado) depois de uma refeição de tamanho habitual?

- () 0 - Nunca ---> Pule para questão 5.
- () 1 - Menos de um dia por mês
- () 2 - Um dia por mês
- () 3 - Dois a três dias por mês
- () 4 - Um dia por semana
- () 5 - Mais de um dia por semana
- () 6 - Todos os dias

4. Você teve esta sensação desconfortável de estar cheio após as refeições por 6 meses?

- () 0 - Não
- () 1 - Sim

5. Nos últimos 3 meses, com que frequência você foi incapaz de terminar uma refeição de tamanho habitual?

- () 0 - Nunca ---> Pule para questão 7.
- () 1 - Menos de um dia por mês
- () 2 - Um dia por mês
- () 3 - Dois a três dias por mês
- () 4 - Um dia por semana
- () 5 - Mais de um dia por semana
- () 6 - Todos os dias

6. Você teve esta incapacidade de terminar refeições de tamanho habitual por 6 meses ou mais?

- () 0 - Não
- () 1 - Sim

7. Nos últimos 3 meses, com que frequência você teve dor ou queimação no meio do seu abdome, acima do seu umbigo, mas não no seu peito?

- () 0 - Nunca ---> Pule para questão 14.
- () 1 - Menos de um dia por mês
- () 2 - Um dia por mês
- () 3 - Dois a três dias por mês
- () 4 - Um dia por semana
- () 5 - Mais de um dia por semana
- () 6 - Todos os dias

8. Você teve esta dor ou queimação por 6 meses ou mais?

- () 0 - Não
- () 1 - Sim

9. Esta dor ou queimação ocorre e depois desaparece completamente durante o mesmo dia?

- () 0 - Nunca ou raramente
- () 1 - Às vezes
- () 2 - Muitas vezes
- () 3 - Maioria das vezes
- () 4 - Sempre

10. Normalmente, quão severa era a dor ou queimação no meio do abdome, acima do seu umbigo?

- () 1 - Muito suave
- () 2 - Suave
- () 3 - Moderada
- () 4 - Severa
- () 5 - Muito severa

11. Essa dor ou queimação era aliviada com o uso de antiácidos?

- () 0 - Nunca ou raramente
- () 1 - Às vezes
- () 2 - Muitas vezes
- () 3 - Maioria das vezes
- () 4 - Sempre
- () 5 - Não uso antiácidos

12. Essa dor ou queimação normalmente melhorava ou passava após a evacuação ou eliminação de gases?

- () 0 - Nunca ou raramente
- () 1 - Às vezes
- () 2 - Muitas vezes
- () 3 - Maioria das vezes
- () 4 - Sempre

13. Com que frequência essa dor ou desconforto aliviou com movimentos ou trocas de posição do seu corpo?

- () 0 - Nunca ou raramente
- () 1 - Às vezes
- () 2 - Muitas vezes
- () 3 - Maioria das vezes
- () 4 - Sempre

14. Nos últimos 6 meses, com que frequência você teve dor constante no meio ou na área superior direita do seu abdome?

- () 0 - Nunca ---> Pule as questões restantes.
- () 1 - Menos de um dia por mês
- () 2 - Um dia por mês
- () 3 - Dois a três dias por mês
- () 4 - Um dia por semana
- () 5 - Mais de um dia por semana
- () 6 - Todos os dias

15. Esta dor durou 30 minutos ou mais?

- () 0 - Nunca ou raramente
- () 1 - Às vezes
- () 2 - Muitas vezes
- () 3 - Maioria das vezes
- () 4 - Sempre

16. Essa dor aumentou de intensidade até ficar muito forte e contínua?

- () 0 - Nunca ou raramente
- () 1 - Às vezes
- () 2 - Muitas vezes
- () 3 - Maioria das vezes
- () 4 - Sempre

17. Esta dor desapareceu completamente entre os episódios?

- () 0 - Nunca ou raramente
- () 1 - Às vezes
- () 2 - Muitas vezes
- () 3 - Maioria das vezes
- () 4 - Sempre

18. Essa dor o impediu de realizar suas atividades usuais ou levou-o a ir urgentemente ver um médico ou ir a um serviço de emergência?

- () 0 - Nunca ou raramente
- () 1 - Às vezes
- () 2 - Muitas vezes
- () 3 - Maioria das vezes
- () 4 - Sempre

Critérios diagnósticos*

Devem incluir:

1. Um ou mais de:

a) Plenitude pós-prandial

Desconfortavelmente cheio (saciado) depois de uma refeição de tamanho habitual, mais de um dia por semana (questão 3>4)

Início há mais de 6 meses. Sim. (questão 4=1)

b) Saciedade precoce

Incapaz de terminar uma refeição de tamanho habitual, mais de um dia por semana (questão 5 >4)

Início há mais de 6 meses. Sim. (questão 6=1)

c) Dor epigástrica

Dor ou queimação no meio do seu abdome, pelo menos 1 dia por semana (questão 7>3)

Início há mais de 6 meses. Sim. (questão 8=1)

d) Queimação epigástrica

(Este critério é incorporado na mesma questão que dor epigástrica)

1. Sem evidência de doença estrutural (incluindo endoscopia alta) que explique os sintomas.

Nenhuma questão.

* Critérios preenchidos nos últimos 3 meses com sintomas iniciando pelo menos 6 meses antes do diagnóstico.

Sim. (questão 8=1)

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RESUMO – Contexto - Questionários validados são ferramentas essenciais para serem utilizados em estudos epidemiológicos. No momento não existem questionários diagnósticos de Roma III traduzidos para português. **Objetivo** - Validar a versão em português do Questionário Diagnóstico de Roma III para Dispepsia Funcional. **Métodos** - O questionário foi traduzido seguindo as recomendações de Roma III. Cento e nove pacientes consecutivos com dispepsia funcional responderam ao questionário. O grupo controle foi composto por 100 doadores de sangue consecutivos, sem problemas digestivos. Consistência interna, reprodutibilidade, sensibilidade, validade discriminante e análise de conteúdo foram avaliadas. **Resultados** - O coeficiente α de Cronbach foi de 0,92. O questionário mostrou reprodutibilidade: os pacientes responderam-no de forma semelhante em duas ocasiões distintas e suas respostas foram substancialmente semelhantes ($P = 1,00$). O questionário foi capaz de demonstrar alterações quando elas ocorreram ($P < 0,01$). Dois gastroenterologistas “cegos” concordaram que o questionário avalia a dispepsia funcional adequadamente. Quando comparadas as respostas entre pacientes e controles, o questionário mostrou que 5,3% dos controles e 91,2% dos pacientes tinham sintomas de dispepsia funcional ($P < 0,01$). **Conclusão** - O Questionário Diagnóstico de Roma III para Dispepsia Funcional está pronto para ser utilizado em pesquisas clínicas em países lusófonos, como foi validado com sucesso para o português.

DESCRIPTORES – Dispepsia. Questionários. Tradução (processo).

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