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The Turkish version of the Rome III criteria for IBS is valid and reliable

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Original Article

ABSTRACT

Background/Aims: In this study, we aimed to provide the usage of the Rome III criteria for irritable bowel syndrome (IBS) in the healthcare field by conducting validity and reliability studies in Turkey and to facilitate diagnosis of these patients.

Materials and Methods: Item analysis of the Rome III criteria was performed, and the test was applied to 79 patients after their consistency had been validated with expert opinion. After the first application, the retest was applied to 77 cases, and the consistency between the two applications was examined by kappa analysis. IBS was diagnosed by expert opinion, which was accepted as 'the gold standard'.

Results: Cronbach's alpha of the Rome III criteria was calculated as 0.90. When the compliance between expert assessment and IBS Rome III diagnostic criteria was compared, the diagnostic criteria's sensitivity was determined as 78.6%, and their specificity was 82.9%. When the Rome III criteria test-retest agreement was analysed, the sensitivity, specificity and negative and positive predictive values of the Rome III diagnostic criteria were determined as 97.4%.

Conclusion: In this study, the internal consistency of the Rome III criteria for diagnosis of patients with IBS in our country was found to be an important criterion because of the fact that the Rome III criteria have high internal consistency and validation, they are a reliable measurement tool, they are able to distinguish IBS-positive and -negative cases with the same rate as a specialist and their application is very easy.

Keywords: Rome III, irritable bowel syndrome, validity, reliability, validation

INTRODUCTION

Functional gastrointestinal disorders are variable combinations of chronic or recurrent gastrointestinal symptoms, which are attributed to all parts of the gastrointestinal tract and in which no structural or biochemical pathology is determined. Irritable bowel syndrome (IBS) is the most common and most widely studied of these disorders (1,2).

The symptoms of functional gastrointestinal disorders are very heterogeneous, and there is a lack of objective diagnostic criteria, making the diagnosis of these diseases very difficult. For nearly 30 years, there have been attempts to develop diagnostic criteria for these diseases.

The basis of these criteria for IBS was obtained from the development of the Manning criteria in 1978. In 1984, Kruis and his colleagues developed the 'Kruis Criteria' by adding a few symptoms to Manning's criteria. However, the 'Kruis Criteria' was insufficient for specific differentiation of IBS. The correction of these criteria was completed in 1990 and the Rome I criteria were published; the Rome II criteria were published after the revision of the Rome I criteria in 1999 (3).

The emergence of new evidence in literature has made the update of these criteria necessary. Therefore, today IBS is defined according to the Rome III diagnostic criteria which was published in 2006, comprising all the functional gastrointestinal disorders (1,4-9).

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According to the Rome III committee, IBS is defined as criteria fulfilled for the last 3 months with symptom onset at least 3 months prior to diagnosis and recurrent abdominal pain or discomfort ('discomfort' is defined as an uncomfortable sensation, not pain) at least 3 days/month in the last 3 months associated with two or more of the following without any underlying systemic, organic or metabolic causes (10):

1. Pain decreasing or disappearing with defecation
2. Onset of pain associated with a change in the frequency of stool
3. Onset of pain associated with a change in the form (appearance) of stool

In this study, we aimed to provide usage of the IBS Rome III criteria in the healthcare field by conducting validity and reliability studies in our country and to make the diagnosis of IBS cases simpler.

MATERIALS AND METHODS

This study was planned to be methodological and determinative regarding the validity and reliability of the IBS Rome III criteria. This study was conducted with 79 consecutive cases that were referred to a colonoscopy laboratory and whose colonoscopic examination revealed no organic pathology between 01.06.2008 and 01.10.2009 in Ege University Medical Faculty Hospital, Department of Gastroenterology.

A total of 120 patients were accepted to participate in the study, who were able to communicate verbally in Turkish and were over the age of 18. They were requested to fill in the data collection form and a form listing the criteria included in the Rome III criteria for IBS. The subjects were asked to answer 27 questions about the IBS Rome III criteria, the psycholinguistics (language version) and psychometric (validity and reliability) properties of which had been examined. Forty-one subjects were excluded from the study, including 23 who completed the form partially and 18 who wanted to withdraw from the study while filling in the form. The study was conducted with the remaining 79 cases. The diagnosis of IBS was made by the assessment of a single gastroenterology specialist (RV), which was accepted as 'the gold standard'.

Written permissions had been received from the Ethics Committee of Ege University Medical Faculty Hospital and also from the subjects of the study.

Investigation of psycholinguistics characteristics/language version

The back translation method was used to minimize the difference in expression and conceptualization in language adaptation of the Rome III criteria. Four independent translators were asked to translate for this method. Two of them translated the original English IBS Rome III questions into Turkish, and the other two translators translated these Turkish criteria into the original (English) language. The translators did not consult with each other and worked independently. The investigator and three gastroenterology specialists made the last corrections, sharing their views about the translated texts.

Examination of psychometric properties (validity-reliability)

Validity and reliability of the questionnaire

Expert views: The content and extent of validity of the Rome III criteria were provided by an expert group's views, consisting of physicians, nurses, academic staff and Turkish teachers. The expert group evaluated each of the Rome III criteria's items as: '5 points-Very suitable' and '1 point - Not suitable'. In accordance with the recommendations of the experts, some changes were made to the inappropriate items. Finally, the questions in Turkish were checked by a Turkish language expert in the Ege University Department of Turkish Language and Literature.

As a result of Kendall's W analysis, which was done for the appropriateness and compliance of the Turkish version of the Rome III criteria in terms of language and content, Kendall's W number was calculated as 0.16 with a p value of 0.001. In conclusion, according to expert opinions, the language of the Rome III criteria was validated, and the Rome III criteria were ready to be evaluated by the subjects.

Test-retest: To determine the criteria's invariance with respect to time, test-retest was applied. Seventy-nine cases were included in the first application of the Rome III criteria. The retest was applied to 77 of these cases. Fifteen days from the first application, subjects were retested by telephone. Individuals who informed that they would be unable to come, when they were called to make an appointment, took the retest by telephone interview.

Internal consistency: Test-retest was applied for the internal consistency of the Rome III criteria, and the item-total correlation and Cronbach's alpha reliability coefficient was analysed. The item-total correlation determines whether each of the Rome III criteria carry the addible feature in the form of questions. Cronbach's alpha reliability coefficient is an indication of the internal consistency and homogeneity of the Rome III criteria. To make an informed evaluation, the contribution of each question of the Rome III criteria to the alpha coefficient should be examined, and the value of Cronbach's alpha of the Rome III criteria is determined by item-total correlation analysis when each item is deleted.

Split-half (two-half) consistency analysis was performed with the 'split-test analysis' technique to determine the internal consistency. The correlation between the two semi-consistent analyses of the test was examined by splitting the test half and half. Cronbach's alpha values were calculated as 14 questions for the first half and 13 questions for the second half.

Table 1. Test-retest compliance of Rome III criteria

Rome III diagnostic criteria	Kappa value	Compliance
1	0.85	Very good
2	0.81	Very good
3	0.90	Very good
4	0.85	Very good
5	0.85	Very good
6	0.85	Very good
7	0.84	Very good
8	0.82	Very good
9	0.85	Very good
10	0.87	Very good
11	0.84	Very good
12	0.87	Very good
13	0.83	Very good
14	0.91	Very good
15	0.89	Very good
16	0.91	Very good
17	- (*)	- (*)
18	0.82	Very good
19	0.83	Very good
20	0.87	Very good
21	0.89	Very good
22	0.89	Very good
23	0.85	Very good
24	0.85	Very good
25	0.89	Very good
26	0.84	Very good
27	0.87	Very good

*Kappa value could not be accounted for the test-retest analysis of the 17th Rome III criteria, because there were no matching data

Table 2. The reliability of the questionnaire assessed by its internal consistency

	First questionnaire	Second questionnaire	p value
Questions	Mean answer	Mean answer	
1	4.71	4.64	0.40
2	2.50	2.47	0.71
3	0.73	0.63	0.06
4	2.15	2.16	0.85
5	1.45	1.41	0.31
6	2.47	2.46	0.95
7	2.52	2.52	0.91
8	1.26	1.27	1.00
9	2.56	2.47	0.30
10	1.72	1.65	0.39
11	1.42	1.36	0.47
12	1.73	1.68	0.10
13	1.94	1.87	0.13
14	2.38	2.36	0.65
15	2.58	2.61	0.41
16	2.13	2.20	0.02
17	1.42	1.50	0.16
18	2.30	2.30	1.00
19	1.39	1.42	0.41
20	1.94	2.01	0.09
21	2.42	2.46	0.31
22	1.23	1.20	0.48
23	1.13	1.15	0.70
24	2.53	2.64	0.08
25	1.90	1.97	0.12
26	5.10	5.12	0.95
27	1.58	1.63	0.25

The Wilcoxon signed-rank test was used. A p value of ≤0.05 was considered significant

All data were analysed with the SPSS 16.0 (Statistical Package for the Social Sciences 16.0) program sing percentage, Wilcoxon, variance, item-total correlations and reliability tests.

RESULTS

The mean age of the cases was 46.6±1.2 years, 51.9% (41/79) were male, and 55.7% of cases were diagnosed as IBS.

Reliability

Test-retest/reproducibility: When the Rome III diagnostic criteria test-retest compliance was examined, the lowest weighted kappa value was calculated as 0.81, and the highest weighted kappa value was calculated as 0.91. These values for all Rome III criteria were determined to be 'very good' and were found to be highly statistically significant (0.81<weighted kappa<1.00). Weighted kappa values between 0.81 and 1.00 showed almost perfect test-retest compliance (Table 1).

Internal consistency: There was no meaningful difference between test and retest (except question 16) when all of the answers were analysed in the Rome III criteria questions form (Table 2; p value >0.05).

The applied scale was divided into two parts consisting of 14 and 13 questions, and the first part of the scale was compared with the second part. It was determined that the first section

Table 3. The split-half reliability statistics of the IBS Rome III diagnostic criteria

Cronbach's Alpha			
	Part 1	Value	0.88
		N of items	14[a]
	Part 2	Value	0.78
		N of items	13[b]
	Total	N of items	27
Correlation Between Forms			0.71
Guttman Split-Half Coefficient			0.79

[a]The items are: Questions 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, and 14.
[b]The items are: Questions 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, and 27

values of Cronbach's alpha was 0.88 (highly reliable), and that of the second section was 0.78 (very reliable). In addition, the split-half test reliability (two-half) value was 0.79, and this value was also statistically significant (Table 3).

The calculated Cronbach alpha internal consistency coefficient for the reliability of the IBS Rome III diagnostic criteria was 0.90, and this was also highly significant.

Cronbach's alpha coefficient's, being close to +1.00, indicated that the internal consistency of Rome III criteria, consisting of 27 questions, was high. Moreover, this coefficient investigates whether the questions are complete and sufficient to explain a homogeneous structure (Table 4).

Table 4. The corrected item-total correlation analysis for the Rome III criteria for IBS

Rome III criteria about IBS	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Question 1	53.22	292.20	0.81	0.89
Question 2	55.45	310.89	0.77	0.89
Question 3	57.26	343.17	0.21	0.90
Question 4	55.82	306.86	0.82	0.89
Question 5	56.51	329.43	0.82	0.90
Question 6	55.43	316.50	0.61	0.90
Question 7	55.49	310.53	0.65	0.90
Question 8	56.63	332.28	0.53	0.90
Question 9	55.45	314.79	0.60	0.90
Question 10	56.17	324.55	0.53	0.90
Question 11	56.54	331.99	0.47	0.90
Question 12	56.17	337.01	0.34	0.90
Question 13	55.93	342.98	0.21	0.90
Question 14	55.54	336.55	0.33	0.90
Question 15	55.34	324.84	0.56	0.90
Question 16	55.74	327.42	0.48	0.90
Question 17	56.53	344.97	0.21	0.90
Question 18	55.62	332.31	0.39	0.90
Question 19	56.56	349.14	0.16	0.90
Question 20	56.07	329.91	0.46	0.90
Question 21	55.62	329.67	0.42	0.90
Question 22	56.79	341.88	0.30	0.90
Question 23	56.88	339.15	0.40	0.90
Question 24	55.50	328.12	0.46	0.90
Question 25	56.11	331.79	0.48	0.90
Question 26	52.81	309.92	0.54	0.90
Question 27	56.36	337.67	0.58	0.90

IBS: irritable bowel syndrome

Table 5. The comparison of IBS diagnosis with the Rome III diagnostic criteria and a gastroenterology specialist's diagnosis

		The diagnosis of IBS according to Rome III criteria		
Gastroenterology specialist's diagnosis of IBS		**IBS negative**	**IBS positive**	**Total**
IBS negative	Count (n)	29	6	35
	% Within specialist's diagnosis	82.9	17.1	100.0
	% Within Rome III criteria	76.3	15.4	45.5
	% of total	37.7	7.8	45.5
IBS positive	Count (n)	9	33	42
	% Within specialist's diagnosis	21.4	78.6	100.0
	% Within Rome III criteria	23.7	84.6	54.5
	% of total	11.7	42.9	54.5
Total	Count (n)	38	39	77
	% Within specialist's diagnosis	49.4	50.6	100.0
	% Within Rome III criteria	100.0	100.0	100.0
	% of total	49.4	50.6	100.0

IBS: irritable bowel syndrome

Table 6. The compliance with diagnosis of IBS and test-retest according to the Rome III diagnostic criteria

		According to retest diagnosis of IBS		
According to Rome III diagnosis of IBS		**IBS negative**	**IBS positive**	**Total**
IBS negative	Count (n)	37	1	38
	% Within Rome III criteria test	97.4	2.6	50.0
	% Within Rome III criteria retest	97.4	2.6	100.0
	% of Total	48.7	1.3	50.0
IBS positive	Count (n)	1	37	38
	% Within Rome III criteria test	2.6	97.4	50.0
	% Within Rome III criteria retest	2.6	97.4	100.0
	% of total	1.3	48.7	50.0
Total	Count (n)	38	38	76
	% Within Rome III criteria test	50.0	50.0	100.0
	% Within Rome III criteria retest	100.0	100.0	100.0
	% of Total	50.0	50.0	100.0

IBS: irritable bowel syndrome

The item average of the IBS Rome III criteria ranged between 52.81 and 57.26, and Cronbach's alpha value of the scale ranged between 0.89 and 0.90. No item was excluded from the Rome III criteria, consisting of 27 questions, because Cronbach's alpha value of each item was less than or equal to the overall Cronbach's alpha value of the Rome III criteria (α=0.90). In addition, the item-total correlation of the 27 questions was determined to range between 0.16 and 0.82 (Table 4).

When the homogeneity between items was examined, the variance was 62.07 in the 26 degrees of freedom, and this value was found to be highly significant (p=0.000).

When the 'expert assessment' and 'the Rome III diagnostic criteria' were compared in terms of compliance, the sensitivity of the Rome III diagnostic criteria was 78.6% and its specificity was 82.9% (Table 5). The negative predictive value of the diagnostic criteria was 76.3% and the positive predictive value was 84.6%.

When the Rome III criteria for test-retest compliance were analysed, the Rome III diagnostic criteria's sensitivity and specificity were 97.4%. The negative and positive predictive values were 97.4% in the compliance of the diagnostic criteria's test and retest (Table 6).

DISCUSSION

Irritable bowel syndrome is defined according to the Rome III diagnostic criteria published in 2006. Because a validity and reliability study has not been conducted, the use of these criteria has not been widespread in Turkey. In this study related to the Rome III diagnostic criteria, the kappa value, indicating test-retest compliance, was determined to range between 0.81 and 0.91. The reliability coefficient, which can be considered adequate on a Likert-type scale, should be close to 1 as much as possible (11).

The kappa value of this study was statistically 'very good'. Also, Cronbach's alpha value was 0.90.

In Switzerland, a study carried out by Molinder et al. (12) regarding the Rome II diagnostic criteria validation (2009), revealed a kappa value of 0.47 and a Cronbach's alpha value of 0.61, when IBS test-retest compliance was analysed.

In Cash and Chey's review of validation studies about IBS diagnostic criteria, it was stated that there is a good match between the different diagnostic criteria, and the kappa value was over 0.70 (13).

In the validation study of the Rome III diagnostic criteria of Sorouri et al. (14) in Iran (2009), test-retest reliability was good, and the Cronbach's alpha value was 0.70.

Cronbach's alpha value of our study was similar to the ones in other studies in the literature.

In the study of Mollinder et al. (12) (2009), the positive predictive value of the diagnosis of IBS with the Rome II criteria was 63.2% and the negative predictive value was 81.1%. In Cash and Chey's review of validation studies about IBS diagnostic criteria in evidence-based applications, the positive predictive value of the Manning criteria, which are the most common assessment criteria, ranged between 65%-75%. Furthermore, the sensitivity of the Rome I criteria was 65%, its specificity was 100% and its positive predictive value was 98% (13). In the same study, when the diagnostic criteria were applied to more than 1000 women, the Rome II criteria were found to have less sensitive than the Rome I criteria (49% vs. 83%, $p<0.001$). The sensitivity difference between these two diagnostic criteria resulted largely from the Rome II criteria being more limited regarding the determination of the need for pain. In addition, the compliance between the Rome I and II diagnostic criteria, which was 47% and a kappa value of 0.29, was supported by evidence-based applications (13).

In Chang's study, it was reported that Whitehead formulated the validity and specificity of the Rome III criteria. As a result of this study, the validity of the Rome III criteria was stated as excellent, and its specificity was good (15).

In the validation study of Lee et al. (16) in Malaysia, the validity of the IBS Rome III criteria was good at 0.99. Furthermore, the sensitivity of the Rome III criteria was 80.65%, and the specificity and positive predictive value were 100%.

The positive predictive value was found to be 84.6%, and the negative predictive value was 76.3% between the expert opinion and the Rome III diagnostic criteria in our study. As a result of the comparison between the Rome III diagnostic criteria and the gastroenterologist's diagnosis for IBS, the sensitivity and specificity of the Rome III diagnostic criteria were very high. In fact, the Rome III criteria revealed the same diagnosis as the gastroenterologist.

The fact that the Rome III criteria show such high sensitivity, specificity and predictive value supports the usage of these criteria. Because the compliance between the Rome III criteria and the gastroenterologist is very good, it supports its use in Turkey. Furthermore, these criteria are determined to be important for the diagnosis of IBS, a disease that affects the quality of life for patients.

To distribute limited medical resources, facilitate making clinical decisions for the diagnosis of IBS, help patients for independent decision-making and plan and regulate the necessary treatment and care, common usage of the Rome III criteria by members of the medical team is recommended.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Ege University Faculty of Nursing.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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