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RESEARCH LETTERS

Assessing the Impact of Changes to the Rome IV Criteria for Clinical Practice in Irritable Bowel Syndrome

Modifications to the Rome IV criteria for clinical practice have been proposed.[1] For irritable bowel syndrome (IBS), these include relaxing the minimum symptom frequency threshold, provided the cardinal symptoms are present and impact on quality of life by being bothersome (eg, leading to consultation with a physician), and removing the 6-month minimum symptom duration. We have shown that the Rome IV criteria for IBS select a group of patients with severe symptoms and high levels of psychological comorbidity.[2] We have also demonstrated that the Rome IV criteria are an improvement over the Rome III criteria in facilitating a diagnosis of IBS, but because of their more restrictive nature, almost 20% of people believed to have IBS according to a physician do not meet these criteria.[3] We assessed how the proposed modifications impact on patient selection and diagnostic performance.

We used data from 2 studies reported elsewhere.[2,3] The first was a cross-sectional survey of individuals self-reporting IBS assessing clinical and psychological characteristics of those meeting the Rome IV criteria.[2] Briefly, we collected complete demographic, symptom, and psychological health data, using validated questionnaires, from 1375 adults registered with 3 UK organizations. Some individuals had consulted a primary care physician, some a gastroenterologist, and some had never consulted a physician, meaning the participants are likely to be generalizable to many individuals living with IBS in the United Kingdom. In this study we showed that applying the Rome IV criteria, instead of Rome III, reduced the proportion of individuals who self-reported IBS meeting diagnostic criteria for IBS from 79% to 59%. Individuals with Rome IV-defined IBS had more severe symptoms and worse psychological health compared with those who only met the Rome III criteria. We used this dataset to assess the effect of the modifications on symptom severity and psychological health in those meeting the new modified Rome IV criteria compared with all other individuals self-reporting a diagnosis of IBS.

The second study was a diagnostic accuracy study of the Rome IV criteria for the diagnosis of IBS.[3] In this study we collected data, prospectively, from 577 consecutive patients attending a specialist IBS clinic in the United Kingdom, all of whom underwent a relatively standardized workup, with assessors blinded to symptom status. The reference standard used to confirm IBS was the presence of lower abdominal pain associated with altered stool form or frequency in patients with no evidence of organic gastrointestinal disease after investigation. Sensitivity and specificity of the Rome IV criteria were 82.4% and 82.9%, respectively, with positive and negative likelihood ratios of 4.82 (95% confidence interval [CI], 3.30–7.28) and 0.21 (95% CI, 0.17–0.26), respectively. We used this dataset to assess performance of the modified Rome IV criteria.

In both datasets we redefined Rome IV IBS approximating the proposed modifications (Supplementary Table 1).[1] Patients reporting 2 or more of abdominal pain related to defecation, softer or harder stools at onset of abdominal pain, and more or less frequent stools at onset of abdominal pain, of 3 months duration or more, were classified as meeting modified Rome IV criteria, provided symptoms were bothersome enough to have led to consultation with a physician.

In the cross-sectional survey, 1272 participants (92.5%) met modified Rome IV criteria for IBS. Characteristics of these individuals, compared with those with self-reported IBS who did not meet modified Rome IV criteria, are provided in Table 1 and are compared with the original Rome IV data. When data were compared between all 1272 individuals who now met the modified Rome IV criteria and the 102 subjects who did not, higher rates of anxiety (49.0% vs 37.3%, $P = .001$), somatization (47.5% vs 28.4%, $P < .001$), and gastrointestinal symptom–specific anxiety (33.8% vs 15.7%, $P < .001$) persisted, but rates of depression and severe symptoms were no longer higher.

In the diagnostic accuracy study, among 573 patients providing complete data, 518 (90.6%) met the modified Rome IV criteria. Of 456 patients with a diagnosis of IBS according to the reference standard, 452 met the modified Rome IV criteria, yielding a sensitivity of 99.1%. Among 117 without IBS, 50 did not meet the modified Rome IV criteria, giving a specificity of 42.7%. Positive and negative likelihood ratios for the modified Rome IV criteria were 1.73 (95% CI, 1.48–2.02) and 0.02 (95% CI, 0.01–0.06), respectively. Among 67 patients meeting the modified Rome IV criteria who were not diagnosed with IBS according to the reference standard, 23 had organic disease. Seventeen patients had bile acid diarrhea, 3 exocrine pancreatic insufficiency, 1 small-bowel Crohn's disease, 1 ulcerative proctitis, and 1 microscopic colitis. The remainder were believed to have another disorder of gut–brain interaction.

This reanalysis of data demonstrates that modifications to the Rome IV criteria for clinical practice led to lower absolute differences in symptom severity, compared with people with self-reported IBS who do not meet these criteria. Rates of severe symptoms and anxiety were also lower in patients defined according to these modified criteria compared with when the original Rome IV criteria

Abbreviations used in this paper: CI, confidence interval; IBS, irritable bowel syndrome.

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Table 1. Characteristics of Individuals Meeting Modified Rome IV Criteria Compared With Those not Meeting Modified Rome IV Criteria for IBS

	Original study data			Reanalysis of data		
	Met Rome IV criteria for IBS (n = 811)	Did not meet Rome IV criteria for IBS (n = 562)	P^a	Met modified Rome IV criteria for IBS (n = 1272)	Did not meet modified Rome IV criteria for IBS (n = 102)	P^a
IBS subtype						
Constipation	142 (17.5)	126 (22.4)		247 (19.4)	23 (22.5)	
Diarrhea	311 (38.4)	206 (36.7)		480 (37.8)	37 (36.3)	
Mixed stool pattern	331 (40.9)	185 (32.9)		484 (38.1)	31 (30.4)	
Unclassified	26 (3.2)	41 (7.3)	<.001	57 (4.5)	10 (9.8)	.054
IBS-SSS symptom severity						
Mild	90 (11.2)	202 (36.0)		262 (21.4)	31 (31.4)	
Moderate	333 (41.5)	212 (37.8)		517 (42.1)	27 (30.0)	
Severe	379 (47.3)	100 (17.8)	<.001	448 (36.5)	32 (35.6)	.009
IBS limits activities ≥50% of the time	573 (70.8)	253 (45.2)	<.001	791 (62.4)	37 (36.3)	<.001
HADS-A categories						
Normal	202 (24.9)	226 (40.2)		380 (29.9)	48 (47.1)	
Borderline	167 (20.6)	117 (20.8)		269 (21.1)	16 (15.7)	
Abnormal	442 (54.5)	219 (39.0)	<.001	623 (49.0)	38 (37.3)	.001
HADS-D categories						
Normal	434 (53.5)	373 (66.4)		749 (58.9)	59 (57.8)	
Borderline	191 (23.6)	103 (18.3)		273 (21.5)	21 (20.6)	
Abnormal	186 (22.9)	86 (15.3)	<.001	250 (19.7)	22 (21.6)	.89
PHQ-15 categories						
Mild somatization	6 (0.7)	23 (4.1)		20 (1.6)	8 (8.8)	
Low somatization	78 (9.6)	138 (24.6)		187 (14.7)	29 (28.4)	
Medium somatization	270 (33.3)	225 (40.0)		461 (36.2)	35 (34.3)	
High somatization	457 (56.4)	176 (31.3)	<.001	604 (47.5)	29 (28.4)	<.001
VSI tertiles						
Low	196 (24.3)	268 (47.8)		408 (32.2)	57 (55.9)	
Medium	281 (34.8)	179 (31.9)		432 (34.0)	29 (28.4)	
High	331 (41.0)	114 (20.3)	<.001	429 (33.8)	16 (15.7)	<.001

Values are n (%).
IBS-SSS, Irritable Bowel Syndrome Severity Scoring System; HADS-A, Hospital Anxiety and Depression Anxiety Score; HADS-D, Hospital Anxiety and Depression Depression Score; PHQ-15, Patient Health Questionnaire-15; VSI, Visceral Sensitivity Index.
[a]*P* value for Pearson χ^2 for comparison of categorical data.

were used in this study population.[2] However, our observations could relate to a lack of power because of the smaller number of patients not meeting modified Rome IV criteria.

When used to diagnose IBS, although the modified criteria were more sensitive, they were less specific, leading to a much lower positive likelihood ratio than observed with the original Rome IV criteria.[3] The Rome III criteria performed only modestly in diagnosing IBS in previous validation studies,[4,5] so this improvement in performance of the original Rome IV criteria was welcome. Nevertheless, these modifications may be useful. The high sensitivity seen with the modified criteria means if these are not met at the outset, then a final diagnosis of IBS is highly unlikely, and further investigation should be pursued. Finally, prevalence of organic disease among the 525 patients who met these modified criteria was low at <5%.

Our approximation of these modified criteria means the results are preliminary and need to be confirmed by other studies, designed with this specific purpose in mind. It is also important to point out that these modified criteria are intended for use in clinical practice, not in clinical trials or epidemiologic or pathophysiologic studies.

Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Gastroenterology* at www.gastrojournal.org and at https://doi.org/10.1053/j.gastro.2022.01.021.

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References

1. Drossman DA, et al. Gastroenterology 2022;162:675–679.
2. Black CJ, et al. Clin Gastroenterol Hepatol 2020; 18:392–398.
3. Black CJ, et al. Gut 2020;70:1110–1116.
4. Ford AC, et al. Gastroenterology 2013;145:1262–1270.
5. Sood R, et al. Am J Gastroenterol 2016;111:1446–1554.

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Conflicts of interest
The authors disclose no conflicts.

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Supplementary Table 1. Modifications to the Rome IV Criteria for IBS and our Approximations of Them

Modified Rome IV criteria as proposed by Drossman et al[1]	Modified Rome IV criteria as approximated in this study
Recurrent abdominal pain, on average, at least 1 day per week in the last 3 months and associated with 2 or more or the following: Related to defecation Associated with a change in frequency of stool Associated with a change in stool form Criteria fulfilled for the last *8 weeks* Patients should have sufficiently bothersome symptoms to *seek care or affect daily activity*	Recurrent abdominal pain, on average, at least 1 day per week in the last 3 months and associated with 2 or more or the following: Related to defecation Associated with a change in frequency of stool Associated with a change in stool form Criteria fulfilled for the last *3 months* Patients should have sufficiently bothersome symptoms to *seek care*

Note: Key differences between the modified Rome IV criteria and our approximation are shown in italic text.

Reference

1. Drossman DA, et al. Gastroenterology 2022;162:675–679.