Assessing Diagnostic Performance of Modifications to the Rome IV Criteria for Irritable Bowel Syndrome

The gold standard symptom-based criteria for diagnosis of irritable bowel syndrome (IBS) are the Rome IV criteria.[1] These are more restrictive than their predecessor, Rome III, because the cardinal feature required to meet criteria for IBS was changed to presence of abdominal pain alone, rather than abdominal pain or discomfort.[2] This change was made because discomfort was believed to be an ambiguous term, with no equivalent in some languages. In addition, symptom frequency required for the presence of abdominal pain was increased to 1 day per week from 2 to 3 days per month. This has led to reduced sensitivity for detecting IBS and a 50% decrease in the prevalence of the disorder in the community.[3,4] In a cross-sectional survey applying both Rome IV and III criteria to people living with IBS, 89% of those with Rome III–defined IBS not meeting Rome IV criteria did not meet Rome IV criteria because of this change in pain frequency.[5] Previous iterations of the Rome criteria have performed only modestly in predicting a diagnosis of IBS.[6–8] However, in a validation study, the Rome IV criteria outperformed Rome III,[9] largely because their more restrictive nature made them more specific than Rome III. We assessed whether modifications to the Rome IV criteria led to a better trade-off between sensitivity and specificity.

The analyses were conducted among well-characterized patients in the aforementioned validation study of the Rome IV criteria.[9] Briefly, unselected, consecutive new patients aged ≥16 years referred to a specialist IBS clinic at Leeds Teaching Hospitals NHS Trust (Leeds, UK), were recruited. There were no exclusions, other than an inability to understand written English. All patients were provided with a questionnaire as part of the clinical assessment at the first appointment. Because the data were collected to guide treatment in routine practice, ethical approval was not required.

Patients underwent a relatively standardized workup. All patients had a full blood count, C-reactive protein count, and celiac serology, either before referral by their primary care physician or at their first appointment. The fecal calprotectin level was checked in patients younger than age 40 years with diarrhea, with a colonoscopy if ≥100 mcg/g. In patients ≥40 years with diarrhea or a recent change in bowel habit, colonoscopy was requested. Colonoscopy also was requested in patients with atypical features for IBS, such as nocturnal symptoms. Irrespective of age, patients with diarrhea underwent 23-seleno-25-homo-tauro-cholic acid scanning to exclude bile acid diarrhea (BAD). Given that the response to bile acid sequestrants is best in moderate to severe BAD,[10] only patients with a retention of less than 10% at 7 days were classified as having BAD.

The reference standard used to define the presence of IBS was lower abdominal pain in association with altered stool form or frequency elicited during the clinical history at the first appointment, in a patient with no evidence of organic gastrointestinal disease after the investigative algorithm described earlier.

We assessed the performance of 2 modifications to the Rome IV criteria vs the reference standard. First, we re-incorporated abdominal discomfort, if present on at least 1 day per week. Second, we included only abdominal pain, but relaxed the required frequency back to 2 to 3 days per month. Sensitivity and specificity were calculated for each. The positive and negative likelihood ratio (LR), and their 95% CIs, also were calculated. The positive LR derives from the following formula: positive LR = sensitivity / (1-specificity); whereas the negative LR is derived from the following formula: negative LR = (1-sensitivity) / specificity. All analyses were performed using StatsDirect version 3.3.6 (StatsDirect Ltd, Sale, Cheshire, England).

Among 567 patients providing complete symptom data allowing modifications to the Rome IV criteria using the presence of abdominal pain or discomfort on at least 1 day per week, 435 (76.7%) (mean age, 35.5 y; 325 [74.7%] women) met these criteria. Among 451 patients with a diagnosis of IBS according to the reference standard, 399 met these criteria, providing a sensitivity of 88.5% (Table 1). Among 116 subjects not judged to have IBS, 80 did not meet these criteria, providing a specificity of 69.0%. The positive LR of this modification was 2.85 (95% CI, 2.21–3.80), and the negative LR was 0.17 (95% CI, 0.13–0.22).

Among 572 patients providing complete symptom data allowing modifications to the Rome IV criteria using the presence of abdominal pain on at least 2 to 3 days per month, 428 (74.8%) (mean age, 35.4 y; 325 [75.9%] women) met these criteria. Among 455 patients with a diagnosis of IBS according to the reference standard,

Abbreviations used in this paper: **BAD, bile acid diarrhea; IBS, irritable bowel syndrome; LR, likelihood ratio.**

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Table 1. Sensitivity, Specificity, Positive and Negative Likelihood Ratios, and Post-Test Probability of Modifications to the Rome IV Criteria for Irritable Bowel Syndrome Compared With the Original Rome IV and Rome III Criteria

	Sensitivity	Specificity	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Post-test probability[a]
Rome IV criteria including the presence of either abdominal pain or discomfort on 1 day per week	88.5%	69.0%	2.85 (2.21–3.80)	0.17 (0.13–0.22)	74.0%
Rome IV criteria including the presence of abdominal pain on 2–3 days per month	88.6%	78.6%	4.15 (2.98–5.95)	0.15 (0.11–0.19)	80.6%
Rome IV criteria for IBS in the original validation study[9]	82.4%	82.9%	4.82 (3.30–7.28)	0.21 (0.17–0.26)	82.8%
Rome III criteria in the original validation study[9]	85.8%	65.0%	2.45 (1.90–3.27)	0.22 (0.16–0.29)	71.0%

[a]Based on a secondary or tertiary care referral population in a University Hospital practice with a prevalence of IBS of 50% or more.

403 met these criteria, providing a sensitivity of 88.6%. Among 117 subjects not judged to have IBS, 92 did not meet these criteria, providing a specificity of 78.6%. The positive LR of this modification was 4.15 (95% CI, 2.98–5.95), and the negative LR was 0.15 (95% CI, 0.11–0.19).

We studied the diagnostic performance of 2 modifications to the Rome IV criteria for IBS, first, by re-incorporating abdominal discomfort but keeping the frequency of pain or discomfort on at least 1 day per week and, second, by keeping abdominal pain only but reducing frequency back to 2 to 3 days per month. In both modifications, specificity was lower than the Rome IV criteria but higher than the Rome III criteria.[9] However, specificity was substantially lower than Rome IV when abdominal discomfort was re-incorporated, meaning the positive LR was much lower than Rome IV, whereas specificity was closer to Rome IV when pain frequency was reduced, meaning the positive LR was similar, but not at the expense of sensitivity, which increased.

Although our study recruited an unselected sample of more than 500 patients with suspected IBS, who underwent a relatively standardized workup, and provided complete symptom data, it is important to point out that these were a group of patients referred to a tertiary care center. The results therefore may not apply to all people with IBS. Similarly, in populations in which the term *discomfort* has no equivalent, these results may not be applicable. Nevertheless, these modifications may be useful in informing future iterations of the Rome criteria, in terms of balancing sensitivity and specificity.

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Conflicts of interest
The authors disclose no conflicts.