The Rome V criteria for the diagnosis of irritable bowel syndrome in secondary care: a diagnostic accuracy study

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Summary

Background The Rome V criteria for irritable bowel syndrome (IBS) were proposed in May, 2026. Their performance for the diagnosis of IBS in clinical practice is as yet unknown. We aimed to conduct a diagnostic accuracy study to examine this issue.

Methods This diagnostic accuracy study was conducted in the specialist IBS clinic in Leeds Teaching Hospitals National Health Service Trust, Leeds, UK. Consecutive adults aged 16 years and older who were referred with suspected IBS between Sept 22, 2016, and June 18, 2024, provided complete symptom data. We applied standardised investigations (including full blood count, C-reactive protein, and coeliac serology), with assessors masked to symptom status. We assessed performance of the Rome V criteria, compared with the previous iterations, Rome IV and Rome III. The reference standard used to confirm IBS was the presence of lower abdominal pain or discomfort in association with altered stool form or frequency combined with no evidence of organic gastrointestinal disease after standardised investigations. Sensitivity, specificity, and positive and negative likelihood ratios were calculated for each of the diagnostic criteria, with 95% CIs.

Findings Of the 745 eligible patients recruited, 726 patients had complete Rome V symptom data (546 [75%] were female, 180 [25%] were male, and mean age was 36·9 years [SD 14·0]). 417 (57%) patients met Rome V criteria for IBS. The level of agreement between the Rome V and either the Rome III or Rome IV criteria was fair to moderate (κ=0·36–0·55). Of patients with complete Rome V symptom data, 590 had IBS according to the reference standard, of whom 390 met Rome V criteria for IBS. Sensitivity of the Rome V criteria was therefore 66·1% (95% CI 62·1–69·9) and specificity was 80·1% (72·4–86·5). Positive likelihood ratio for the Rome V criteria was 3·33 (95% CI 2·40–4·74) and negative likelihood ratio was 0·42 (0·37–0·49). The Rome III and Rome IV criteria for IBS performed differently, with sensitivities of 87·5% (95% CI 84·4–90·3) and 78·9% (75·4–82·1) and specificities of 75·0% (66·3–82·4) and 81·0% (73·4–87·2). Positive and negative likelihood ratios for the Rome III criteria were 3·50 (2·61–4·84) and 0·17 (0·13–0·21) and for the Rome IV criteria were 4·16 (2·98–5·95) and 0·26 (0·22–0·31).

Interpretation The Rome V criteria for IBS identified a different group of patients, with lower sensitivity than either Rome III or IV criteria in this single centre secondary care study. The clinical relevance of this is uncertain.

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Introduction

Irritable bowel syndrome (IBS), a disorder of gut–brain interaction, affects an estimated 5–10% of the population globally, depending on criteria used to define its presence.[1] IBS affects quality of life, work productivity, and health-care costs and is a symptom-based diagnosis, without clear biomarkers. The need for symptom-based diagnostic criteria that could be applied effectively to the large number of patients with IBS seeking medical care led to the Manning criteria, published in 1978,[2] followed by the Rome criteria in 1990, and their subsequent evolution into Rome V in 2026.[3] All iterations of the Rome criteria are the product of expert consensus and include some variation of abdominal pain or discomfort associated with altered bowel habits.

Regardless of the definition used, the goal has remained the same: to define this large group of patients accurately, with minimal investigation, and confer a positive diagnosis. This positive approach provides reassurance that the diagnosis of IBS is correct and allows greater focus on evidence-based treatments that might improve symptoms and quality of life. Although IBS is not associated with increased mortality,[4] anxiety about an underlying serious illness drives increased health-care utilisation and patient concerns.[5] Furthermore, some previous iterations of the Rome criteria performed only modestly,[6–9] and a subset of clinicians view IBS as a diagnosis of exclusion.[10] The Rome IV criteria defined IBS as recurrent abdominal pain, on average at least 1 day per week in the past 3 months, with two or more of the following: related to defecation; a change in stool frequency; or a change in stool form.[11] The increase in symptom frequency, from 3 days per month to a minimum of 1 day per week in the Rome IV criteria, and the removal of the term abdominal discomfort, increased their specificity for IBS compared with previous

Research in context

Evidence before this study

Irritable bowel syndrome (IBS) is a common disorder of gut–brain interaction, without clear biomarkers or known pathological correlates. Symptom-based diagnostic criteria, such as the Rome criteria, were developed to facilitate a positive diagnosis of IBS, without the need for exhaustive investigation. We have validated previous iterations of the Rome criteria for the diagnosis of IBS, finding that some perform only modestly. The Rome V criteria are the current gold standard for diagnosing IBS. In this iteration, presence of abdominal discomfort has been reintroduced as part of the definition of IBS, and the symptom frequency at which abdominal pain or discomfort needs to be experienced to meet criteria for IBS has been reduced back to 3 days per month. However, as part of the Rome V criteria, it has been stipulated that abdominal pain cannot be present continuously, to differentiate IBS from centrally mediated abdominal pain syndrome. A search of MEDLINE, Embase, and Embase Classic from 1946 to May 7, 2026, using the search terms "Rome V", "irritable bowel syndrome", and "diagnosis", with no language restrictions, revealed that the performance of the Rome V criteria in diagnosing IBS has yet to be evaluated independently. This provided the rationale to assess the performance of the Rome V criteria in a diagnostic accuracy study. We aimed to examine the performance of the Rome V criteria in a large cohort of patients referred to a single secondary care centre with suspected IBS, both overall and according to IBS subtype, and to compare this with the Rome III and IV criteria.

Added value of this study

In this diagnostic accuracy study, the Rome V criteria identified a different group of patients, with lower sensitivity than either Rome III or Rome IV. In patients with confirmed IBS according to the reference standard, sensitivity of the Rome V criteria was 66·1%, suggesting that two-thirds of these individuals would be diagnosed as having IBS using these criteria. In particular, the relatively high negative likelihood ratio observed in this study suggests that not meeting the Rome V criteria results in only a small reduction in the likelihood of a patient with suspected IBS truly having the condition. Either many patients with genuine IBS have some element of continuous abdominal pain or a dichotomous questionnaire item addressing continuous abdominal pain is confusing for patients. Such patients would probably now be categorised according to the Rome V criteria as having an unclassified bowel disorder but are still likely to be diagnosed with IBS in a clinical setting.

Implications of all the available evidence

Further refinement of future iterations of the Rome criteria and questionnaire language might be needed to enable a positive diagnosis in patients with IBS in clinical care with minimal investigation.

iterations. These changes improved their diagnostic performance;[6] however, they also led to the Rome IV criteria selecting a group of patients with more severe symptoms and higher levels of psychological comorbidity.[12,13] In moving from the Rome IV criteria to Rome V, presence of abdominal discomfort was reintroduced as part of the definition, and the frequency at which abdominal pain or discomfort needed to be experienced to meet criteria for IBS was reduced back to 3 days per month.[3] However, as part of the Rome V criteria, abdominal pain cannot be present continuously, to differentiate IBS from centrally mediated abdominal pain syndrome (CAPS).[14] In addition, a supportive criterion in Rome V is that, in females, abdominal pain or discomfort should not be only related to menses.

Because IBS accounts for a considerable amount of a gastroenterologist's time in the outpatient department,[15] independent validation of the latest Rome V criteria against a reference standard is important to assess their diagnostic accuracy. Understanding how patients with Rome V-defined IBS compare with those with Rome III-defined and Rome IV-defined IBS is also valuable to give clinicians a frame of reference by which to understand how the populations enrolled in observational studies and clinical trials using this updated definition will differ from those previously enrolled. Thus, we aimed to use a secondary care population to validate the Rome V definition of IBS against a reference standard and compare them with the previous Rome III and IV criteria.

Methods

Study design and participants

This diagnostic accuracy study was conducted in the specialist IBS clinic in Leeds Teaching Hospitals National Health Service Trust, Leeds, UK, which serves a local population of 800 000 people. The IBS clinic does not take tertiary referrals from other centres, instead, it provides a pathway to rapid diagnosis and treatment for patients with suspected IBS referred from local primary care. Two experienced gastroenterologists and two clinical research fellows (VCG, MK, CJB, and ACF) provide services to this clinic. We recruited unselected, consecutive, new patients aged 16 years and older who were referred with suspected IBS between Sept 22, 2016, and June 18, 2024. The only exclusion criterion was inability to understand written English. These patients represent two separate study cohorts,[6,16] although data collection was continuous. At the first appointment, patients were provided with a questionnaire. As data in the first study cohort were collected to guide treatment in routine clinical practice, ethics approval was not required.[6] Data collection for the second study cohort was approved by the Health Research Authority and Health and Care Research Wales ethics committee (research

ethics committee reference 21/SC/0147), with individuals in this study providing written informed consent.[16]

Data collection and synthesis

We prospectively collected demographic, gastrointestinal symptom, and psychological symptom data using the questionnaire, before referral for investigations. We recorded age and self-reported sex assigned at birth, and acquired symptom data using questions from the Rome III and IV questionnaires for IBS in all patients.[11,17] Race and ethnicity were not recorded. The Rome III questionnaire for IBS was provided to a subset of patients in the first cohort,[6] and to all patients in the second cohort.[16] As the symptom items that make up the Rome V criteria are, for the most part, included in the Rome III and IV questionnaires, we were able to assign presence or absence of IBS defined by Rome III, Rome IV, or Rome V according to the exact scoring algorithms proposed (figure 1), without commencing an entirely new study. The presence of continuous abdominal pain was assessed using the following question items from the Rome IV questionnaire: "Has this pain in your abdomen been continuous or almost continuous? (continuous means that it never goes away during waking hours)", with a binary yes or no response in combination with the abdominal pain frequency question. Those reporting continuous abdominal pain that was present on every day of the week were excluded from the Rome V definition of IBS, as recommended.[14] Symptom severity was assessed using the IBS Severity Scoring System (IBS-SSS).[18] The IBS-SSS is a validated seven-item questionnaire measuring presence, severity, and frequency of abdominal pain, presence and severity of abdominal distension, satisfaction with bowel habit, and degree to which IBS symptoms are affecting or interfering with the person's life. The maximum score is 500 points, with less than 75 indicating remission of symptoms, 75–174 indicating mild IBS, 175–299 indicating moderate IBS, and 300–500 indicating severe IBS. We collected psychological symptom data via the Hospital Anxiety and Depression Scale (HADS) and the Patient Health Questionnaire-12 (PHQ-12).[19,20] The total HADS score ranges from 0 to 21 for anxiety or depression. We categorised severity for each as normal (total HADS-anxiety or HADS-depression score 0–7), borderline abnormal (8–10), or abnormal (≥11), as recommended.[19] The PHQ-12 assesses extra-intestinal symptom-reporting[20] and is derived from the validated PHQ-15,[21] but omits the three gastrointestinal symptom items. The total PHQ-12 score ranges from 0 to 24. We entered all questionnaire data into a database at the initial clinic visit, before referral for investigations.

Investigations and tests

Patients underwent standardised investigations according to national UK guidance,[22] as described in our previous studies.[6,16] All patients had blood tests, including full blood count, C-reactive protein, and coeliac serology, the latter regardless of predominant bowel habit. These tests were done either before referral by the primary care physician, or at the first clinic visit. Faecal calprotectin was checked in patients aged 40 years and older with diarrhoea, with colonoscopy if greater than or equal to 100 µg/g, as per our local threshold for an abnormal faecal calprotectin. Colonoscopy was requested in patients aged 40 years and older with either diarrhoea or a recent change in bowel habit, or at the discretion of the consulting physician in any patient with atypical features for IBS, such as nocturnal symptoms. Patients with diarrhoea with higher stool frequency or nocturnal symptoms underwent 23-seleno-25-homo-tauro-cholic acid (SeHCAT) scanning to exclude idiopathic bile acid diarrhoea. Response to bile acid sequestrants is best in moderate or severe bile acid diarrhoea;[23] therefore, only patients with a 7-day SeHCAT retention of less than 10% were classed as having bile acid diarrhoea. We requested anorectal physiology studies in patients with constipation if symptoms suggestive of obstructive defecation were reported. Any other investigations, such as faecal elastase or small bowel investigations, including wireless capsule endoscopy or magnetic resonance enterography, were at the discretion of the consulting physician, and in line with UK guidelines.[24]

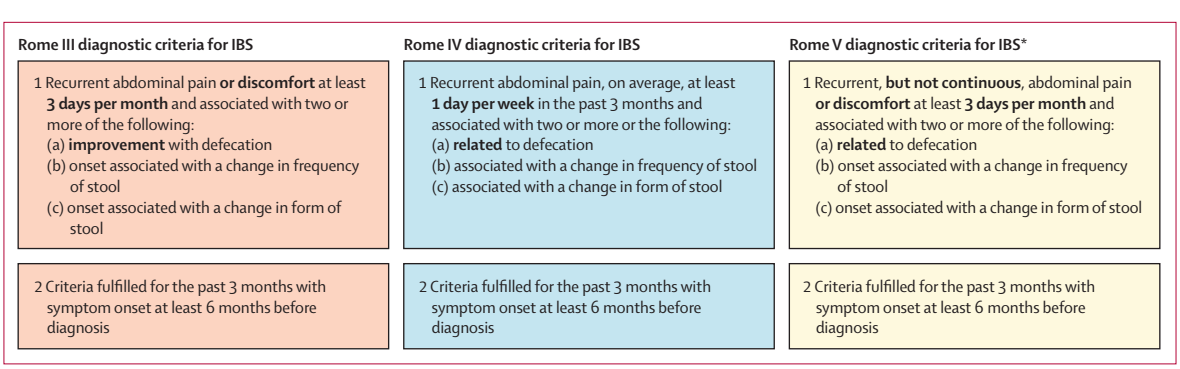


Figure 1: **Rome V, IV, and III diagnostic criteria for IBS**
Key differences between criteria are highlighted in bold. IBS=irritable bowel syndrome. *Supportive criteria: abdominal pain or abdominal discomfort should not be only related to menses.

All clinicians performing endoscopic examinations, radiological or physiological investigations, or histological interpretation of biopsy specimens were masked to questionnaire data. We classified coeliac disease, Crohn's disease, ulcerative colitis, inflammatory bowel disease-unclassified, microscopic colitis, ischaemic colitis, radiation enteritis, colorectal carcinoma, bile acid diarrhoea, or exocrine pancreatic insufficiency (faecal elastase <200 µg/g), found after investigation, as being consistent with organic gastrointestinal disease and, therefore, responsible for gastrointestinal symptoms. Conditions such as diverticulosis, colorectal adenoma, haemorrhoids, or anal fissures were not considered as organic gastrointestinal disease in the context of this study. We used these data to assign presence or absence of organic gastrointestinal disease after investigation.

Reference standard

The reference standard used to define IBS was the presence of lower abdominal pain or discomfort in association with altered stool form or frequency elicited during the clinical history at the first clinic visit, in a patient with no evidence of organic gastrointestinal disease after applying the investigative algorithm described. This definition is similar to reference standards used in other diagnostic accuracy studies in patients with IBS.[2,6,7,9,16,25]

Statistical analysis

The primary aim was to describe the performance of the Rome V criteria in evaluating the presence of IBS versus the reference standard. We also performed a sensitivity analysis incorporating the supportive criterion that, in female patients, abdominal pain or discomfort cannot be only related to menses. Secondary aims were comparing the performance of the Rome V criteria for IBS with the previous iterations, the Rome IV and III criteria. We measured agreement between the Rome V, IV, and III criteria, and the reference standard, using a κ statistic, where values of 0–0·20 indicate slight agreement, 0·21–0·40 fair agreement, 0·41–0·60 moderate agreement, 0·61–0·80 substantial agreement, and 0·81–1·0 almost perfect agreement. These statistical analyses were performed using SPSS version 30.0. Sensitivity, specificity, and positive and negative predictive values, and their 95% CIs, were calculated for the Rome V, Rome IV, and Rome III criteria, and by subtype (IBS with constipation [IBS-C], IBS with diarrhoea [IBS-D], and IBS with mixed bowel habits [IBS-M]) for Rome V. The positive and negative likelihood ratios and their 95% CIs were also calculated, where positive likelihood ratio = sensitivity/(1−specificity) and negative likelihood ratio = (1−sensitivity)/specificity. These analyses were performed using StatsDirect version 3.2.10. Likelihood ratios are useful for assessing accuracy of a diagnostic test because they vary to a lesser degree than predictive values when the prevalence of a disease changes. Positive likelihood ratios greater than 1 increase the probability of the disease of interest being present if the test is positive (eg, a positive likelihood ratio of 2 increases probability by 15%, 5 by 30%, and 10 by 45%), whereas negative likelihood ratios decrease the probability of the disease of interest being present if the test is negative (eg, a negative likelihood ratio of 0·5 decreases probability by 15%, 0·2 by 30%, and 0·1 by 45%).[26]

Role of the funding source

There was no funding source for this study.

Results

We recruited 745 patients undergoing complete investigation to the level deemed required by the consulting physician. 564 (76%) patients were female, 181 (24%) were male, and mean age was 36·8 years (SD 13·9). Of these patients, 726 provided sufficient data to make a Rome V IBS diagnosis (546 [75%] female, 180 [25%] male, and mean age 36·9 years [SD 14·0]), 729 provided sufficient data to make a Rome IV IBS diagnosis (549 [75%] female, 180 [25%] male, and mean age 36·9 years [SD 14·0]), and 634 provided sufficient data to make a Rome III IBS diagnosis (474 [75%] female, 160 [25%] male, mean age 37·0 years [SD 14·1]; figure 2). Demographic, gastrointestinal symptom, and psychological symptom data for those meeting Rome V, IV, and III criteria are in table 1. In this secondary care population, most patients had moderate to severe disease, as per the IBS-SSS, with patients with Rome IV IBS having the highest rates of severe symptoms, but patients with Rome III IBS also having more severe symptoms than the patients with Rome V IBS. HADS-anxiety, HADS-depression, and PHQ-12 scores were high in all groups, with patients meeting either Rome IV or Rome III criteria reporting a higher psychological symptom burden, compared with Rome V.

The κ statistic for the degree of overlap between the three Rome definitions of IBS and the reference standard is shown in table 2. The overlap according to each of the criteria in only those meeting the reference standard for IBS is shown in figure 3. Levels of

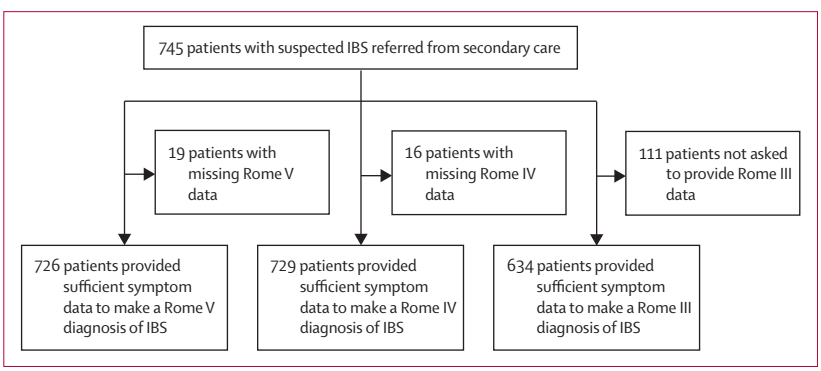


Figure 2: **Study flow diagram**
IBS=irritable bowel syndrome.

	Met Rome V criteria for IBS (n=417)	Met Rome IV criteria for IBS (n=493)	Met Rome III criteria for IBS (n=480)
Sex			
Female	308 (74%)	370 (75%)	352 (73%)
Male	109 (26%)	123 (25%)	128 (27%)
Mean age, years	36·0 (14·0)	35·5 (13·6)	36·4 (13·9)
IBS subtype			
Constipation	92 (22%)	107 (22%)	101 (21%)
Diarrhoea	158 (38%)	186 (38%)	185 (39%)
Mixed bowel habits	160 (38%)	187 (38%)	183 (38%)
Unclassified	6 (1%)	10 (2%)	9 (2%)
Missing data	1 (<1%)	3 (1%)	2 (<1%)
Mean IBS-SSS score	286·0 (94·9)	329·7 (93·0)	303·8 (99·6)
IBS-SSS severity			
Remission	5 (1%)	1 (<1%)	5 (1%)
Mild	51 (12%)	29 (6%)	51 (11%)
Moderate	173 (42%)	156 (32%)	175 (36%)
Severe	179 (43%)	297 (60%)	242 (50%)
Missing data	9 (2%)	10 (2%)	7 (1%)
Mean HADS anxiety score	9·9 (4·6)	10·7 (4·9)	10·5 (4·7)
HADS anxiety			
Normal	131 (31%)	137 (28%)	137 (29%)
Borderline abnormal	101 (24%)	99 (20%)	99 (21%)
Abnormal	177 (42%)	248 (50%)	233 (49%)
Missing data	8 (2%)	9 (2%)	11 (2%)
Mean HADS depression score	6·3 (4·4)	7·1 (4·6)	6·8 (4·5)
HADS depression			
Normal	262 (63%)	275 (56%)	277 (58%)
Borderline abnormal	76 (18%)	100 (20%)	94 (20%)
Abnormal	69 (17%)	106 (22%)	95 (20%)
Missing data	10 (2%)	12 (2%)	14 (3%)
Mean PHQ-12 score	9·2 (4·1)	10·3 (4·3)	9·8 (4·4)

Data are n (%) or mean (SD). HADS=Hospital Anxiety and Depression Scale. IBS=irritable bowel syndrome. IBS-SSS=Irritable Bowel Syndrome Severity Scoring System. PHQ-12=Patient Health Questionnaire-12.

Table 1: **Characteristics of patients meeting the Rome V, IV, or Rome III Criteria for IBS**

	Rome V criteria	Rome V criteria incorporating supportive criterion*	Rome IV criteria	Rome III criteria	Reference standard diagnosis of IBS
Rome V criteria	..	0·90	0·36	0·55	0·31
Rome V criteria incorporating supportive criterion*	0·90	..	0·31	0·48	0·28
Rome IV criteria	0·36	0·31	..	0·66	0·47
Rome III criteria	0·55	0·48	0·66	..	0·56
Reference standard diagnosis of IBS	0·31	0·28	0·47	0·56	..

IBS=irritable bowel syndrome. *Incorporating the criterion that, in females, abdominal pain or discomfort should not only be related to menses.

Table 2: **κ statistic for levels of agreement between the Rome V, IV, and III criteria and the reference standard diagnosis of IBS after investigation**

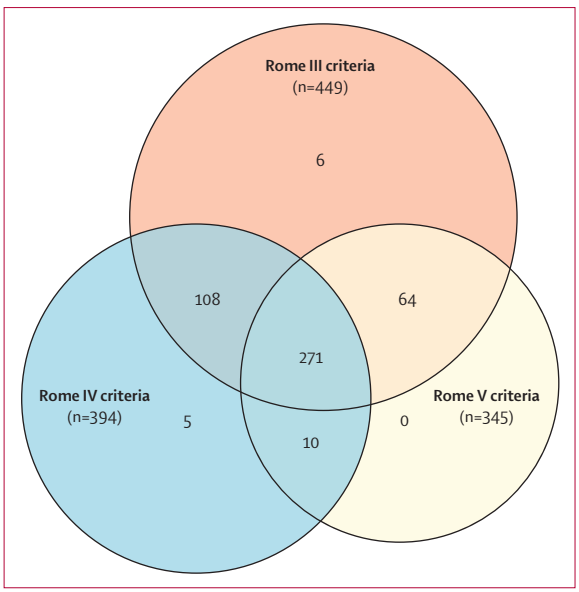


Figure 3: **Agreement Between the Rome III, Rome IV, and Rome V criteria in those meeting the reference standard for irritable bowel syndrome**

agreement were highest between the Rome IV and Rome III criteria (κ=0·66; substantial agreement), and between either the Rome IV or Rome III criteria and the reference standard (Rome IV κ=0·47, Rome III κ=0·56; both moderate agreement). Agreement between the Rome V criteria and any of the other definitions was fair to moderate (κ=0·31–0·55). Incorporating the supportive criterion that, in females, abdominal pain or discomfort should not only be related to menses into the Rome V definition did not lead to any notable increase in agreement with the other definitions (κ=0·28–0·48), although agreement between this and the Rome V definition was almost perfect (κ=0·90), because only 35 (11%) of 308 female patients meeting Rome V criteria reported that abdominal pain or discomfort were only related to menses.

Of 726 patients with complete Rome V symptom data, 417 (57%) met Rome V criteria for IBS. Of the 590 patients with IBS according to the reference standard, 390 met Rome V criteria for IBS, giving a sensitivity of 66·1% (95% CI 62·1–69·9; table 3). 142 (71%) of the other 200 patients meeting the reference standard did not meet Rome V criteria because they reported continuous abdominal pain present on every day of the week. Of the 136 patients without IBS according to the reference standard, 27 (20%) met Rome V criteria, giving a specificity of 80·1% (72·4–86·5). The positive likelihood ratio for a diagnosis of IBS according to Rome V criteria was 3·33 (95% CI 2·40–4·74), with a negative likelihood ratio of 0·42 (0·37–0·49). The Rome V criteria performed best in patients with IBS-C (positive likelihood ratio 51·54 [5·90–493·83], negative likelihood ratio 0·34 [0·27–0·43]; table 3). Incorporating the supportive criterion related to menses led to a decrease in sensitivity

	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)
Rome V criteria for IBS (n=726)	66·1% (62·1–69·9)	80·1% (72·4–86·5)	93·5% (90·7–95·7)	35·3% (29·9–40·9)	3·33 (2·40–4·74)	0·42 (0·37–0·49)
Rome V criteria for IBS-C (n=177)	66·1% (57·6–73·9)	98·7% (88·6–99·9)	99·5% (95·1–99·9)	44·8% (34·0–55·9)	51·54 (5·90–493·83)	0·34 (0·27–0·43)
Rome V criteria for IBS-D (n=256)	66·3% (59·5–72·7)	58·3% (43·2–72·4)	87·3% (81·1–92·1)	28·6% (19·9–38·6)	1·59 (1·17–2·33)	0·58 (0·43–0·80)
Rome V criteria for IBS-M (n=260)	66·8% (60·3–72·9)	77·4% (58·9–90·4)	95·6% (91·2–98·2)	24·0% (16·0–33·6)	2·96 (1·66–5·89)	0·43 (0·34–0·58)
Rome V criteria for IBS incorporating supportive criterion* (n=726)	60·8% (56·8–64·8)	83·1% (75·7–89·0)	94·0% (91·1–96·1)	32·8% (27·9–38·1)	3·60 (2·51–5·30)	0·47 (0·42–0·54)
Rome IV criteria for IBS (n=729)	78·9% (75·4–82·1)	81·0% (73·4–87·2)	94·7% (92·4–96·5)	47·0% (40·5–53·6)	4·16 (2·98–5·95)	0·26 (0·22–0·31)
Rome III criteria for IBS (n=634)	87·5% (84·4–90·3)	75·0% (66·3–82·4)	93·8% (91·2–95·7)	58·4% (50·2–66·3)	3·50 (2·61–4·84)	0·17 (0·13–0·21)

IBS=irritable bowel syndrome. IBS-C=IBS with constipation. IBS-D=IBS with diarrhoea. IBS-M=IBS with mixed bowel habits. *Incorporating the supportive criterion that, in females, abdominal pain or discomfort should not only be related to menses.

Table 3: **Sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios for the Rome V, IV, and Rome III criteria for IBS**

(60·8% [95% CI 56·8–64·8]) and an increase in specificity (83·1% [75·7–89·0]), with a positive likelihood ratio of 3·60 (2·51–5·30) and a negative likelihood ratio of 0·47 (0·42–0·54). Analysis by sex showed that the Rome V criteria performed differently in female patients (sensitivity 66·0% [95% CI 61·4–70·4], specificity 85·3% [76·9–91·5], positive likelihood ratio 4·49 [2·87–7·27], and negative likelihood ratio 0·40 [0·34–0·47]) than male patients (sensitivity 66·4% [58·2–74·0], specificity 64·7% [46·5–80·3], positive likelihood ratio 1·88 [1·25–3·13], and negative likelihood ratio 0·52 [0·38–0·75]).

Of 729 patients with complete Rome IV symptom data, 493 (68%) met Rome IV criteria for IBS. Of 592 patients with IBS according to the reference standard, 467 met Rome IV criteria (sensitivity 78·9% [95% CI 75·4–82·1]) and of 137 patients without IBS according to the reference standard, 26 met Rome IV criteria (specificity 81·0% [73·4–87·2]), giving a positive likelihood ratio of 4·16 (2·98–5·95) and a negative likelihood ratio of 0·26 (0·22–0·31; table 3). Of 634 patients with complete Rome III symptom data, 480 (76%) met Rome III criteria. Of 514 patients with IBS according to the reference standard, 450 met Rome III criteria (sensitivity 87·5% [84·4–90·3]) and of 120 without IBS according to the reference standard, 30 met Rome III criteria (specificity 75·0% [66·3–82·4]), giving a positive likelihood ratio of 3·50 (2·61–4·84) and a negative likelihood ratio of 0·17 (0·13–0·21; table 3).

Rates of organic gastrointestinal disease according to all three Rome criteria are in table 4. Organic gastrointestinal disease occurred in 5% of patients meeting the three iterations of the criteria, the commonest being idiopathic bile acid diarrhoea.

	Met Rome V criteria (n=417)	Met Rome IV criteria (n=493)	Met Rome III criteria (n=480)
Total with organic disease	21 (5%)	25 (5%)	23 (5%)
Small bowel Crohn's disease	1 (<1%)	1 (<1%)	0
Microscopic colitis	1 (<1%)	1 (<1%)	1 (<1%)
Bile acid diarrhoea	16 (4%)	20 (4%)	19 (4%)
Moderate (5·0–9·9% retention)	11 (3%)	14 (3%)	14 (3%)
Severe (<5·0% retention)	5 (1%)	6 (1%)	5 (1%)
Exocrine pancreatic insufficiency	3 (<1%)	3 (1%)	3 (1%)

Data are n (%).

Table 4: **Prevalence of organic disease in patients meeting the Rome V, Rome IV, or Rome III criteria for irritable bowel syndrome**

Discussion

In this group of patients referred to secondary care with suspected IBS, we validated the Rome V criteria for IBS against a reference standard, and compared their performance with their immediate predecessors, the Rome III and IV criteria. We found that less than 60% of patients presenting with suspected IBS from primary care met Rome V criteria for IBS, compared with 76% meeting the Rome III or 68% meeting the Rome IV criteria. For patients with confirmed IBS according to the reference standard, the sensitivity of the Rome V criteria was 66·1%. The sensitivities of the Rome III and Rome IV criteria according to the same reference standard were better, and in excess of 85% and 75%, respectively. As would be expected with lower sensitivity, specificity of the Rome V criteria was higher than the Rome III criteria but not higher than for Rome IV. Perhaps not surprisingly, given the reintroduction of abdominal discomfort and the relaxation of abdominal pain or discomfort frequency back to 3 days per month, the Rome V criteria performed similarly to Rome III, in terms of their positive likelihood ratio. However, the negative likelihood ratio was higher for Rome V than either the Rome III or Rome IV criteria, meaning that if a patient with suspected IBS does not meet the Rome V criteria, the reduction in the likelihood of them truly having IBS is much smaller than for either Rome III or Rome IV. These differences in the test characteristics between iterations translated into fair to

moderate agreement between Rome V and either the Rome III or Rome IV criteria. As was the case with the Rome IV criteria in a previous validation study,[6] the Rome V criteria performed better in patients with suspected IBS-C or IBS-M, although again negative likelihood ratios remained relatively high even in these patients. However, numbers of participants meeting criteria for each subtype of Rome V IBS were smaller, explaining the wide 95% CIs around the estimate for the positive likelihood ratio in IBS-C. Hence, the results pertaining to the performance of the Rome V criteria according to IBS subtype should be viewed with caution.

The Rome V criteria arrive at a time when gastroenterology as a specialty is seeking to move away from symptom-based diagnostics and towards precision medicine. Thus far, that goal has been elusive in the field of disorders of gut–brain interaction, and the previous iteration of the Rome criteria, Rome IV, were controversial due to their high specificity, which led to the selection of a more severely affected group of patients.[6,12,13,27] The removal of abdominal discomfort from the Rome IV IBS definition left patients with milder symptoms, who probably had IBS, instead classified as having another functional bowel disorder,[28] despite being likely to benefit from IBS-specific therapies.[29] In this diagnostic accuracy study, more than 70% of those meeting the reference standard diagnosis of IBS who did not meet the Rome V criteria did so because of the presence of continuous abdominal pain on every day of the week. Although Rome V reintroduced abdominal discomfort to the definition of IBS and reduced the required symptom frequency back to 3 days per month, the requirement for non-continuous abdominal pain in the Rome V definition affects their diagnostic performance and might be too restrictive. We would suggest that either most patients with genuine IBS have some element of continuous abdominal pain or that patients find a dichotomous questionnaire item addressing continuous abdominal pain confusing. Most clinicians would readily acknowledge that IBS is usually an episodic condition related to defecation, but the most frequent temporal pattern appears to consist of clusters of symptoms lasting 2–5 days on average,[30] during which patients might have continuous pain.

The Rome V process recognises that CAPS can sometimes represent the extreme of the IBS clinical spectrum, and that the two can overlap,[3] although in the case of CAPS the pain must have either no association or only a variable association with physiological events, such as defecation. However, CAPS is likely to encompass only a minority of patients who might be otherwise diagnosed with IBS in a clinical setting and in whom pain is both severe and the predominant symptom requiring treatment. Under Rome V, these patients who no longer meet diagnostic criteria for IBS due to reporting continuous abdominal pain, are still likely to report troublesome bowel symptoms, such as diarrhoea or constipation. For the patient, these will be a priority for treatment. Therefore, it is unlikely that CAPS is the correct diagnosis for such patients, and they are more likely to instead be labelled according to Rome V criteria as having an unclassified bowel disorder,[3] which might not be clinically useful and will exclude them from clinical research studies in IBS. Hence, this modification made to the Rome V criteria for IBS to distinguish between IBS and CAPS, while understandable and desirable, might be overly restrictive and prone to patient misunderstanding. We did a sensitivity analysis incorporating the supportive criterion that abdominal pain or discomfort cannot only be related to menses in females. The incorporation of this as a supportive criterion is relevant, as women with endometriosis are three times as likely to have IBS as women without endometriosis.[31] Endometriosis is a gynaecological condition characterised by chronic pelvic pain, often exacerbated by menses. In fact, many women with IBS report worsening of their symptoms around menses, whether endometriosis is present or not. IBS and endometriosis might share some common underlying pathophysiology, including visceral hypersensitivity, brain–viscera axis dysregulation, and age and hormonal influences.[32] However, incorporating this supportive criterion did not improve the performance of the Rome V criteria substantially, and few women reported that abdominal pain or discomfort were only related to menses, suggesting this is not driving the discrepancies between the Rome V criteria, the reference standard, and previous iterations of the Rome criteria. This finding is supported by our analysis by sex, in which the positive likelihood ratio was higher in female participants and male participants, due to increased specificity, but negative likelihood ratios were relatively similar in male and female participants.

A fair assessment of the Rome V criteria should note a larger proportion of this secondary care referral population with Rome V-defined IBS fall into the mild-to-moderate category, in terms of their symptom severity, compared with those meeting Rome III or IV criteria. In fact, the mean IBS-SSS score was in the moderate range for patients with Rome V-defined IBS compared with the severe range in patients with Rome III-defined or Rome IV-defined IBS. Similarly, a smaller proportion of patients with Rome V-defined IBS had high anxiety or depression scores, and levels of extra-intestinal symptom-reporting on the PHQ-12 were lower. These psychological symptom data also suggest that those with Rome V-defined IBS are more mildly affected, suggesting these criteria might perform more accurately in a primary care setting as a first-pass screening instrument, rather than in a more severely affected secondary care population, although this is speculative.

Similar to previous iterations, applying the Rome V criteria without further investigation would not lead to much missed organic disease in a secondary care population, as many patients will have been screened for organic gastrointestinal conditions that IBS might mimic

before referral from primary care. Therefore, we cannot exclude the possibility that the diagnostic performance of the Rome III, IV, and V criteria in the current study is a reflection of alternative gastrointestinal diseases being more readily identified in this setting before referral on to secondary care. Only 5% of those with Rome V-defined IBS were found to have an alternative organic disease as a cause for their symptoms, with bile acid diarrhoea being the most common. Hence, the performance of the Rome V criteria was most modest in those with IBS-D.

Strengths of this study include the large sample size, representing typical individuals with presumed IBS seeking secondary gastroenterological care. Additionally, all patients underwent relatively standardised investigations consistent with current guidelines to rule out conditions that IBS might mimic. Finally, patients were recruited from secondary care, meaning those included are likely to be more generalisable than cohorts recruiting from tertiary care centres. We acknowledge several limitations, including recruitment of quite a homogenous patient population seeking care in a specialist centre in a small geographical area of the UK. That said, to our knowledge, the current study cohort represents the first independent validation of the Rome V criteria for IBS to date and encompasses patients with varying degrees of disease severity, psychological comorbidity, and extra-intestinal symptom reporting. Because there is no biological marker for IBS, any reference standard is, to some degree, an artificial construct as it must be based on typical symptoms and absence of organic disease that IBS might mimic. The reference standard we used included symptom data that are included in the Rome questionnaires, which might have overestimated the accuracy of all the criteria studied. However, this is similar methodology to other validation studies in this field.[2,6,7,9,16,25] Finally, we did not follow patients longitudinally after an initial diagnosis of IBS according to the reference standard. As such, it is possible that some patients might have developed alternative diagnoses, although a diagnosis of IBS is thought to be relatively stable over time, even with further investigation.[33,34]

In conclusion, our diagnostic accuracy study of the Rome V criteria for IBS shows one-third of patients with IBS according to a reference standard would not meet current diagnostic criteria for the condition. This was largely due to reporting of continuous abdominal pain. Moreover, these latest criteria show relatively low agreement, overall, with the previous Rome III and Rome IV criteria. This suggests that Rome V are identifying a slightly different group of patients with IBS, relative to previous definitions. The negative likelihood ratio observed in this study indicates that not meeting the Rome V criteria for IBS results in only a small reduction in the likelihood of a patient with suspected IBS truly having the condition. Further refinement of questionnaire language might be needed in future iterations of the Rome criteria to enable a positive diagnosis in a population of patients with IBS in clinical care with minimal investigation, and questioning patients about the presence of continuous abdominal pain will need to be incorporated into clinical practice. In addition, validation of the criteria in other patient populations with suspected IBS will be required, ideally simultaneously in different countries using identical methodology, particularly as clinical phenotypes might vary by geographical region.

Contributors

ACF is guarantor. He accepts full responsibility for the work and the conduct of the study, had access to the data, and controlled the decision to publish. ACF attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. All authors conceived and drafted the study. VCG, MK, CJB, and ACF collected all data. KS, CJB, and ACF analysed and interpreted the data. KS, CJB, and ACF drafted the manuscript. All authors have approved the final draft of the manuscript. All authors had full access to all data and accepted responsibility to submit for publication.

Declaration of interests

KS: research support from Ardelyx and consultant to AbbVie, Ardelyx, Atmo, Ferring, Gemelli, Laborie, Mahana, Mindset Health, Salix, and Takeda. All other authors declare no competing interests.

Data sharing

Individual-level patient data are available to share under reasonable request to the corresponding author.

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