

## Current Prospects of Rome Criteria for the Diagnosis of Irritable Bowel Syndrome

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### ABSTRACT

Irritable bowel syndrome (IBS) is a worldwide health problem. It is often diagnosed by periodically- updated Rome symptom-based criteria, but the effects of recent updates on IBS diagnosis are not well clarified. This article overviews Rome III and IV IBS criteria, highlighting changes and updates that may impact IBS diagnosis. PubMed, Medline, Science Direct, Clinical trials.gov, and WHO databases were searched through to July 2021. Rome IV criteria are more restrictive, specific, and precise in patients' diagnosis, selection, prognosis, and follow-up than Rome III criteria, in turn, IBS prevalence and number of patients with IBS-unspecified and IBS-mixed subtypes decrease, but overall symptom severity and patients' homogeneity increase. In essence, the slight difference between Rome III and IV criteria reflects a considerable influence on IBS diagnosis, subtyping, and prevalence. Rome IV IBS patients form a homogeneous subset of Rome III IBS patients with more severe symptoms. Thus, in-depth research is warranted.

**Keywords:** Irritable bowel syndrome, Rome I, II, III, IV criteria.

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### INTRODUCTION

Irritable bowel syndrome (IBS) is one of the most common disorders of gut-brain interactions (DGBI), formerly known as functional gastrointestinal disorders (FGID). It is a major health problem affecting a substantial proportion of the global population (Sperber

et al., 2020 and 2021; Camilleri, 2021). The epidemiology of IBS has been studied extensively worldwide. The IBS prevalence data vary between countries due to heterogeneity in diagnostic methods or due to genuine differences between countries (Oka et al., 2020; Sperber et al., 2020 and 2021). The worldwide pooled IBS

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prevalence is 9.2 % when using Rome III and 3.8% when using Rome IV criteria (Oka et al., 2020).

IBS is a heterogeneous disorder with no specific laboratory or imaging tests (Irvine et al., 2017; Camilleri, 2021). The IBS etiology is poorly understood, and its diagnosis is challenging, as symptoms change over time and overlap with other disorders (Slattery et al., 2015; Irvine et al., 2017). Traditionally, IBS diagnosis is based on the exclusion of all other diseases with similar features (Oka et al., 2020). Thus, patients may undergo several unnecessary evaluations, tests, and surgeries, which unfortunately do not improve the diagnosis or treatment (Oka et al., 2020). In essence, over the years, worldwide efforts have been gathered to improve IBS understanding and diagnosis and create and define criteria for an easy and accurate diagnosis; once the diagnosis is made correctly, the treatment becomes easier and better results are expected (Palsson et al., 2020).

Nowadays, the condition is better understood, and the interactions between the brain, the gut, and their related diseases or syndromes are much clearer (Camilleri, 2021). The current IBS diagnosis is based on well-defined criteria that are updated frequently with the evolved knowledge and understanding of the condition (Rome, 2021). The Rome diagnostic criteria which are set forth by the Rome Foundation are the most adopted criteria for IBS diagnosis (Drossman, 2016; Rome, 2021). It is a culmination of the evolution of a series of iterations, started as Rome I criteria (Drossman et al., 1994), where every 6-10 years, these criteria (Rome II, III, and IV) are revised and updated based on newly emerged scientific data (Drossman et al., 2006; Schmulson and Drossman, 2017). The Rome IV criteria are the latest version published in 2016 (Drossman, 2016). This version is an evidence-based diagnosis where it is updated to be a multicultural-oriented clinical application (Schmulson and Drossman 2017; Black et al., 2020 and 2021). Although these criteria are updated to overcome the limitations of the previous criteria, the impact of these

updates in both population-based and clinical studies is still a controversial topic, and more evaluation is needed.

This article provides an overview of the evidence for the Rome IBS symptom-based criteria, highlighting the Rome III and Rome IV versions over the past two decades and discussing how changes and updates of these criteria may impact IBS diagnosis.

## METHODS AND SEARCH STRATEGY

An up-to-date literature search was conducted to review the evidence for the IBS symptom-based Rome criteria emphasizing the Rome III and Rome IV versions. The search was limited to the most recent English publications, focusing on those covering the last two decades. Relevant articles were principally identified through an online search of the Cochrane Central Register of Controlled Trials, PubMed, Medline, Clinical trials.gov, Google Scholar, Science Direct, ADI, and WHO database. The search process was performed using the following keywords or combinations: IBS diagnosis, IBS symptom-based criteria, IBS, Rome I criteria, Rome II criteria, Rome III criteria, and Rome IV criteria. Included articles were mainly original experimental, clinical, intervention trials, and cross-sectional research in humans. Lead review articles were also used. For search accuracy, the references' lists of works were checked for additional publications from the major databases.

## AN OVERVIEW OF THE DIAGNOSIS OF IRRITABLE BOWEL SYNDROME

Traditionally, medical diagnosis of any disease requires observed physiological or anatomical abnormalities, and then the description of the disease symptoms follows naturally (Thompson, 2006). This way of diagnosis is impossible in functional disorders since there are no observed pathophysiological defects (Lacy et al., 2016). Thus, diagnosis only relies on the words of patients and the exclusion of other diseases with clear

organic or anatomical abnormalities through extensive tests, consultations, and surgeries, which at the end are unfruitful and do not lead to a proper diagnosis (Thompson, 2006; Lacy et al., 2016). This issue considerably affects the subject's selection and description in randomized clinical trials, and their results end up with uncertain applicability. In 1988, for example, a critique by Klein et al., (1988) of 43 clinical trials of treatment concluded that "not a single IBS treatment trial reported to that date used an adequate operational definition of IBS". Therefore, the need for a more positive approach with unified criteria for diagnosis and descriptions is a global need and a must for functional disorders, including IBS. The evolution of the symptom-based criteria for IBS has started by Manning criteria (Manning et al., 1978), followed by the highly accepted Rome criteria that are published by Rome Foundation every 6-10 years (Drossman, 2016; Palsson et al., 2016; Whitehead et al., 2017). Table 1 shows a summary of the diagnostic criteria of IBS and the year of emergence.

**Table 1:** Reported diagnostic criteria of irritable bowel syndrome and related disorders

Reference	Diagnostic criteria
Manning <i>et al.</i> , 1978	Manning Criteria for IBS
Kruis <i>et al.</i> , 1984	Kruis Criteria for IBS
Thompson <i>et al.</i> , 1989	Rome I Guidelines for IBS
Drossman <i>et al.</i> , 1990	Rome I Classification System for FGID
Thompson <i>et al.</i> , 1992	Rome I Criteria for IBS
Drossman <i>et al.</i> , 1994	Rome I Criteria for FGID
Thompson <i>et al.</i> , 1999	Rome II Criteria for IBS and FGID
Drossman <i>et al.</i> , 2006	Rome III Criteria
Drossman <i>et al.</i> , 2016	Rome IV Criteria

Abbreviations: IBS: irritable bowel syndrome; FGID: functional gastrointestinal disorders

The Rome Foundation, which is an independent, not-for-profit organization, based in North Carolina, United States, leads the scientists and efforts worldwide in the creation and developments of the Rome Criteria (Rome, 2021). The Rome Foundation aims to support the creation of educational information and scientific data that help in the diagnosis and treatment of all FGID, later known as DGBI, including IBS. It also aims to promote the legitimization and global recognition of DGBI, advance the scientific understanding of their pathophysiology, optimize patient clinical management, and develop and provide educational resources and tools to accomplish these goals (Rome, 2021). Although the Rome criteria as symptom-based criteria are initially developed to guide researchers, these criteria nowadays are widely used in research, clinical, and prevalence studies (Drossman, 2016). It has also undergone several revisions periodically to make them more clinically useful and relevant (Sperber et al., 2017; Lin and Chang, 2020).

International guidelines recommend a positive diagnosis of symptom-based diagnostic criteria, such as the Rome Criteria, and minimization of exhaustive and expensive investigations (Whitehead et al., 2017). In clinical practice, besides symptoms-based criteria, extra evaluations may enhance the diagnosis with little cost, particularly investigation of the patient's history, including diet, medications, surgeries, and psychosocial status (Ford et al., 2018). Conducting a complete blood count, complete metabolic panel, and measuring C-reactive protein are also reasonable according to current literature (Palsson et al., 2020). Checking on some "red flags" known as warning signs for other diseases, such as onset at greater than 50 years of age, anemia, haematochezia, unintentional weight loss, family history of colorectal cancer or inflammatory bowel disease are additional reasonable evaluations (Lacy and Patel 2017; Ford et al., 2018). The thyroid profile should be obtained only if the clinical suspicion for thyroid disease is high and exclusion of celiac disease and inflammatory

conditions may be recommended, especially in non-constipated patients with IBS (Begtrup et al., 2013). Once the diagnostic criteria are satisfied, the absence of warning symptoms, normal blood tests, and historical and physical examinations suggest IBS, the risk for overlooking organic disease may be as low as 1-3% (Palsson et al., 2020). In practice, in cases where no warning symptoms appear, the IBS expert consensus states that the evaluation should be limited to fulfilling the Rome criteria (Palsson et al., 2020).

### THE ROME DIAGNOSTIC CRITERIA

In 1988, a group of international experts met in Rome- Italy, to discuss all of the FGID, later known as DGBI, including IBS (Thompson et al., 1999). Their goal was to classify the FGID using a symptom-based classification scheme and highlight the fact that patients report symptoms despite a lack of physiological, chemical, or radiological abnormalities. The expert team used a ‘‘Delphi’’ method of decision making, which depends on fostering the team to produce constancy and consensus in opinion, to answer tough clinical questions that could not be answered through available scientific evidence at the time, and ultimately present and publish the results of the meeting (Thompson et al., 1989). The discussions and recommendations concluded in the publication of the Rome guidelines for IBS (Thompson et

al., 1990), classification criteria for FGID (Thompson et al., 1999), and the following years, the Rome I criteria for IBS was published in 1992 (Thompson et al., 1992), and in 1994 the FGID was published too (Drossman et al., 1994). Table 2 presents the different versions of Rome’s diagnostic criteria of irritable bowel syndrome.

The Rome I criteria for IBS diagnosis need at least three months of continuous or recurrent abdominal pain that is relieved with defecation or associated with a change in stool consistency with at least 2 of the following on at least 25% of days: altered stool frequency, altered stool form, altered stool passage, the passage of mucus, bloating or abdominal distension (Drossman et al., 1994; Thompson et al., 1999). In the early 1990s, these publications formed the cornerstone that increased the awareness and shaped the future research, diagnosis, and treatment of FGID, especially the IBS (Thompson et al., 1989; Thompson et al., 1992; Drossman et al., 1994). By the end of the 1990s, the use of diagnostic criteria and the concept of FGID classification were promoted and adopted by the United States Food and Drug Administration, which recommended the use of the Rome criteria for IBS diagnostic for pharmaceutical studies (Whitehead et al., 2017).

**Table 2:** Different versions of Rome Diagnostic criteria of irritable bowel syndrome

Criteria	Diagnosis criteria	IBS*- subtype
<b>Rome I (Thompson et al., 1992)</b>	Abdominal pain and discomfort that is relieved with defecation and/or associated with a change in frequency of stool, and/or associated with a change in the consistency of stool, and two/more of the following at least on one-fourth of occasions/days: <ul style="list-style-type: none"> <li>• Altered stool frequency</li> <li>• Altered stool form</li> <li>• Altered stool passage</li> <li>• Passage of mucus and/or bloating or feeling of abdominal distension.</li> </ul>	Not defined

<b>Rome II</b> (Thompson <i>et al.</i> , 1999)	Abdominal pain or discomfort for at least twelve weeks that need not be consecutive in the preceding twelve months associated with two or more of the following: <ul style="list-style-type: none"> <li>• Relieved with defecation and/or</li> <li>• Onset associated with a change in frequency of stool and/or</li> <li>• Onset associated with a change in the appearance of stool.</li> </ul>	Not defined
<b>Rome III</b> (Drossman <i>et al.</i> , 2006)	Recurrent abdominal pain or discomfort at least three days/month in the last three months is associated with two or more of the following: <ul style="list-style-type: none"> <li>• Improvement with defecation</li> <li>• Onset associated with a change in frequency of stool</li> <li>• Onset associated with a change in the appearance of stool</li> </ul> Criteria fulfilled for the last three months with symptom onset at least six months before diagnosis.	Defined
<b>Rome IV</b> (Drossman <i>et al.</i> , 2016)	Recurrent abdominal pain, on average, at least one day/week in the last three months, is associated with two or more of the following criteria: <ul style="list-style-type: none"> <li>• Related to defecation</li> <li>• Associated with a change in frequency of stool</li> <li>• Associated with a change in the appearance of stool</li> </ul> Criteria fulfilled for the last three months with symptom onset at least six months before diagnosis.	Defined

\*Abbreviation: IBS: irritable bowel syndrome.

Rome II criteria are released after reviewing the first version, taking advantage of the worldwide feedback from the investigators, regulatory agencies, practitioners, and available scientific literature (Thompson *et al.*, 1999). Rome II criteria contain some additional terms in the definition, especially the term discomfort, with an inclusion of a new criterion, noting that two of the three abdominal pain-related criteria are required for the diagnosis of IBS to ensure that altered bowel habit is present. However, Rome I and II criteria do not categorize patients into specific subtypes (Thompson *et al.*, 1999).

Rome III criteria are different from Rome I and II in using more evidence-based rather than consensus-based data (Drossman *et al.*, 2006). The most significant change is having a model for IBS classification into different subtypes based on stool consistency rather than stool frequency. The IBS subtypes are IBS-C, IBS-D, IBS-M, and IBS-U, where C, D, M, and U refer to constipation,

diarrhea, mixed, and unsub-typed (Longstreth *et al.*, 2006). Another significant change is the removal of bloating as a primary symptom from the definition. This change is based on the view that bloating as a symptom is neither sensitive nor specific for IBS alone, and it is a widespread symptom of other diseases (Longstreth *et al.*, 2006).

The IBS Rome III criteria are widely accepted and fairly well implemented worldwide (16). However, given the emerging science and information on the IBS pathophysiology in the 10 years since the launch of Rome III, the Rome Foundation announced the Rome IV criteria in 2016 with slight changes. The description of IBS as DGBI replaces the term FGID and the role of the microbiome, intestinal permeability, and inflammatory signaling pathways in symptom development is recognized (Barandouzi *et al.*, 2021). Besides the inclusion of new treatment options, such as the use of eluxadoline, linaclotide, rifaximin, probiotics, and low

fermentable oligosaccharides, monosaccharides, and polyols diets (Herndon et al., 2020). In Rome IV criteria, IBS is defined as recurrent abdominal pain on at least one day per week on average, over the past 3 months, which must be associated with two or more of the following symptoms: abdominal pain related to defecation and a change in bowel frequency and stool form (Schmulson and Drossman, 2017).

### KEY CHANGES IN ROME DIAGNOSTIC CRITERIA

Over the years, the Rome criteria for IBS diagnosis are periodically revised and updated. Each version has undergone several main changes that are summarized in the following key points. Firstly, in Rome IV, the word onset is removed compared to Rome II and III, as the onset of abdominal pain is not concurring with a change in stool frequency or form in all patients (Schmulson and Drossman, 2017). Secondly, the criteria are changed from "abdominal pain relieved with defecation" in Rome I and II or "improvement of abdominal pain with defecation" in Rome III to "abdominal pain related to defecation" in Rome IV as some IBS patients reported worsening of abdominal pain after defecation (Drossman, 2016; Herndon et al., 2020; Black et al., 2021).

Thirdly, the term "discomfort" is removed from Rome III, as some languages do not have synonym words for discomfort, or it has different meanings in different languages. Thus, this term is considered nonspecific and ambiguous, and some patients consider the "discomfort" to be mild pain, while others explain it as urgency or bloating (Schmulson and Drossman, 2017). This change considers pain as a characteristic factor for IBS to help distinguish it from other functional bowel disorders, such as functional constipation and functional diarrhea that have little or no pain compared to IBS (Drossman, 2016). In essence, it is intended to make Rome IV more culturally adapted and well understood globally.

Fourthly, the minimum abdominal pain frequency required for diagnosis is increased from three days a month in the last three months in Rome III to once a week in Rome IV. This change is based on the findings of large population studies that aim to increase the sensitivity and specificity of the criteria (Palsson et al., 2016; Whitehead et al., 2017; Palsson et al., 2020). As a result of this change, some studies show a decrease in IBS prevalence, while in others, the prevalence is unchanged (Vork et al., 2018; Aziz et al., 2018).

Fifthly, concerning the IBS subtypes, Rome III is the first to classify IBS patients into subtypes. This classification is very useful as it helps focus treatment on the predominant and the most bothersome symptom (Algera et al., 2019). In Rome III, the IBS is divided into IBS-D, IBS-C, IBS-M, and IBS-U based on the proportion of all bowel movements that are hard/lumpy or loose/watery, considering all bowel movements and not only the symptoms. Patients can have large periods with normal stool consistency, and a large number of patients are classified into IBS-U. Besides, it has been shown that IBS subtypes will be more reliable if based only on the days of abnormal bowel movements and not on all bowel movements (Lacy et al., 2017). Therefore, the Rome IV criteria change the subtypes based on the patient's perception of their predominant type of abnormal stool consistency rather than the frequency of defecation. The Bristol Stool Form Scale (BSFS) is often used for this purpose (Heaton and Lewis, 1997). This scale is a visual tool and a convenient way for patients to describe their bowel habits, basically developed in the 1990s in the Bristol Royal Infirmary in England (Heaton and Lewis, 1997).

In BSFS, stool types 1 and 2 are being associated with constipation, while stool types 6 and 7 are associated with diarrhea, besides stool type 5 to some degree (Heaton and Lewis, 1997). Stool types 3 and 4 are considered normal (Heaton and Lewis, 1997). Thus, in Rome IV, patients with IBS-C have >25% of their bowel

movements associated with BSFS 1 or 2, while those with IBS-D have >25% of their bowel movements associated with BSFS 6 or 7. Patients with the mixed subtype of alternating constipation and diarrhea (IBS-M) have >25% of their bowel movements associated with BSFS 1 or 2 and >25% of their bowel movements associated with BSFS 6 or 7 (Lacy and Patel, 2017; Ford et al., 2020). In

Rome IV, the predominant term is add/ed to types, and patients' perceptions of the predominant type of abnormal consistency of stools are the determinants of the types. This modification reduces the IBS-U group and identifies other IBS subtypes (Drossman, 2016; Ford et al., 2018). Table 3 exhibits a summary of the comparison between IBS subtypes in Rome III versus Rome IV.

**Table 3:** Subtypes of irritable bowel syndrome in Rome III vs. Rome IV.

Rome III criteria* (Drossman <i>et al.</i> , 2006)		Rome IV criteria** (Drossman <i>et al.</i> , 2016)	
IBS-subtype	Description	IBS-subtype	Description
<b>IBS-C</b> (IBS with constipation)	Hard/lumpy stools >25% and loose/watery stools <25% of bowel movements	<b>IBS-C</b> (IBS with predominant constipation)	>25% of bowel movements with Bristol stool form type 1–2 and <25% of bowel movements with Bristol stool form types 6–7
<b>IBS-D</b> (IBS with diarrhea)	Loose/watery stools >25% and hard/lumpy stools <25% of bowel movements	<b>IBS-D</b> (IBS with predominant diarrhea)	>25% of bowel movements with Bristol stool form type 6–7 and <25% of bowel movements with Bristol stool form types 1–2
<b>IBS-M</b> (IBS mixed)	Hard/lumpy stools >25% and loose/watery stools >25% of bowel movements	<b>IBS-M</b> (IBS with mixed bowel habits)	>25% of bowel movements with Bristol stool form type 1–2 and >25% of bowel movements with Bristol stool form type 6–7
<b>IBS-U</b> (IBS-unsubtyped)	Insufficient abnormality of stool consistency to meet criteria for IBS-C, D, and M	<b>IBS-U</b> (IBS-unclassified)	Patients who meet criteria for IBS, but do not fall into one of the other three subgroups according to Bristol stool form type

\*Classification based on all bowel movements in last month. \*\*Classification based on only days with symptomatic bowel movement. IBS: Irritable bowel syndrome.

## VALIDITY OF ROME DIAGNOSTIC CRITERIA

Since there is no specific biomarker for the IBS diagnosis, the sensitivity and specificity of a diagnostic tool cannot be tested as per standard conventional measures, especially in samples of the general population (Whitehead and Drossman, 2010; Algera et al., 2019). There is no gold standard to allow independent confirmation of diagnosis. Sensitivity across the different IBS criteria ranges from 0.4 to 0.9 depending on the experience of the practitioners and researchers, possibly reflecting variation in confidence to use criteria for

positive diagnosis (Whitehead et al., 2006; Whitehead and Drossman, 2010).

In general, all of the known IBS diagnostic criteria have modest specificity of about 0.7 to diagnose IBS in patients with the organic gastrointestinal disease, as the symptoms experienced in IBS are overlapped with other gastrointestinal disorders (Whitehead and Drossman, 2010). This specificity can be increased to 0.9 when extensive evaluation is done for the patient to look for red flags such as anemia, rectal bleeding, and weight loss that are present only in just 3% of patients and used to exclude other organic diseases (Whitehead and Drossman, 2010). In secondary care, the sensitivity of the

Rome III criteria is 68·8%, and specificity is 79·5% (Whitehead et al., 2006). However, as mentioned earlier, enhancement of the performance of criteria is attained when more investigation is done to assess the patient's clinical history, including the absence of nocturnal stools, the presence of anxiety, depression, or extraintestinal symptoms, and a normal full blood count and C-reactive protein (Thompson et al., 1999).

A frequent criticism of the Rome III criteria is that they are not validated. Therefore, the Rome Foundation sponsored several validation studies for the Rome IV criteria before its publication (Palsson et al., 2016). The threshold of IBS symptoms such as pain and altered stool frequency is based on experts' opinions and not on evidence-based studies. These symptoms are common in a healthy individual and only may be an issue in IBS when there are abnormal pain and frequency. Hence, in Rome IV, the threshold of pain frequency is changed from 3 days per month to once per week to have a positive IBS diagnosis; this change is based on a study that surveyed the frequency of IBS symptoms in a sample of 1665 from the USA (Palsson et al., 2016; Drossman, 2016).

In clinical validation, where there is no biological marker for IBS, the symptom criteria are validated against one of the two reference standards, diagnosis by exclusions done by expert practitioners or by negative endoscopy in patients with abdominal pain (Whitehead and Drossman, 2010). The sensitivity and specificity of Rome III and IV criteria are clinically tested in a study involving 427 patients and showed that, compared to Rome III, Rome IV correctly identify a fairly lower percentage of patients diagnosed with IBS (sensitivity), but they are less likely to identify a person wrongly as having IBS (specificity) (Whitehead and Drossman, 2010). Current data show that Rome IV criteria are more specific and less sensitive than Rome III criteria as evidenced by a population-based study evaluating the prevalence of IBS using both criteria among 5931

individuals from the USA, UK, and Canada (Palsson et al., 2020). In that study, the prevalence of IBS reduced from 10.7% when using Rome III to 5.7% when using Rome IV (Palsson et al., 2020).

### **IMPACTS OF UPDATES OF ROME III TO ROME IV ON CLINICAL PRACTICE**

Despite the minor change in the IBS diagnostic criteria between Rome III and IV, these changes have a considerable influence on the IBS subtyping, prevalence, specificity, sensitivity, and clinical management (Whitehead and Drossman, 2010; Whitehead et al., 2017; Vork et al., 2018). In fact, since the launch of the Rome IV criteria in 2016, several studies evaluated the effect of possible changes on the IBS prevalence and other factors (Vork et al., 2018; Aziz et al., 2018; Wang et al., 2019; Lin and Chang, 2020). Vork et al., (2018) conducted a large cohort study to determine the IBS prevalence using different tools and the differences between Rome IV-positive and Rome IV-negative, the results showed that the Rome IV IBS population is likely to reflect a subgroup of Rome III IBS patients, with more severe gastrointestinal symptomatology, psychological comorbidities, and lower quality of life. This implies that results from Rome III IBS studies may not be directly comparable to those from Rome IV IBS populations (Vork et al., 2018).

On the other hand, Aziz et al., (2018) examined how the change in IBS criteria impacts the clinical characteristics and pathophysiological factors of the disease. They revealed that most Rome III-positive IBS patients who are seeking healthcare fulfill the Rome IV IBS criteria, and Rome IV-positive subjects are significantly more likely to have poorer quality of life, greater pain severity, bloating, and fatigue than Rome IV-negative subjects (Aziz et al., 2018). In China, a study by Wang et al., (2019) that used the Rome IV criteria showed that the number of IBS patients is reduced, accompanied by an increase in the percentage of unspecified functional

bowel disorders. Besides, the updated criteria also have great impacts on clinical parameters, sleep quality, and the psychological state of IBS patients. They concluded that a large-scale evaluation is needed before adopting the Rome IV criteria (Wang et al., 2019).

In early 2020, Black et al., (2020) published important results of the largest survey study that evaluated the impact of change between Rome III and Rome IV and surveyed 1375 adults in the United Kingdom who self-identified for having IBS. They found that about 78.9% of the participants met the Rome III criteria for IBS, whereas only 59.1% of the sample met the Rome IV criteria (Black et al., 2020). Further, many of those who did not meet the Rome IV criteria met other functional disorders that overlap in symptoms with IBS, such as functional constipation, functional diarrhea, and functional abdominal bloating or distention (Black et al., 2020 and 2021). Similar results are also reported earlier elsewhere (Aziz et al., 2018; Vork et al., 2018). In this context, Black et al., (2020) also showed that patients who met Rome IV criteria have more severe symptoms that are more likely to interfere with activities of daily living.

On the other hand, to compare the IBS prevalence between different studies using different tools, two large meta-analyses are published in 2020 for the worldwide prevalence of IBS. The first meta-analysis showed that the pooled prevalence of IBS is 9.2% in 53 studies that used the Rome III criteria, and is only 3.8% in six studies that used the Rome IV criteria from 34 countries (Oka et al., 2020). The second meta-analysis about the worldwide prevalence of FGID, including IBS, showed similar results of less prevalence of IBS in Rome IV vs. Rome III in both internets (4.1% vs. 10.1%) and household surveys (1.5% vs. 3.5%) (Sperber et al., 2021). The reduction of IBS prevalence in studies that used Rome IV is not surprising, as the frequency of pain needed for positive IBS diagnosis increased from three

times per month to at least one time per week, and thus the specificity is increased somehow at the expense of the sensitivity (Whitehead et al., 2017). This is the primary aim of the Rome Foundation as these criteria are a key factor in the research. This is especially important for IBS patients' inclusion in clinical and pharmaceutical trials, as more homogenous samples often lead to more precise results (Black et al., 2020).

The subtyping in the Rome III criteria is based on all bowel movements, whereas in the Rome IV criteria, it is dependent only on abnormal movements. This change affects both clinical practice and epidemiological studies, as in Rome IV criteria, the IBS subtype depends on the patients' perception of their predominant type of abnormal stool consistency, which leads to reducing the number of patients with (IBS-U) and (IBS- M), as classified by Rome III. Further, this may affect the clinical management, as several medications, such as linaclotide and lubiprostone, are approved by the FDA only for the treatment of IBS-C, while other medications, like eluxadoline and rifaximin, are approved only for IBS-D, and none are approved for the treatment of IBS-M or IBS-U (Schmulson and Drossman, 2017; Black et al., 2020; Oka et al., 2020).

Currently, the treatments for IBS symptoms are not approved based on the criteria of diagnosis, rather the treatments are designed for the most bothersome symptoms, regardless of the criteria used (Black et al., 2020). Black et al., (2020) concluded that when patients are not diagnosed with IBS by Rome IV criteria, most of them are diagnosed with other functional gastrointestinal disorders, such as functional diarrhea or functional constipation, that share overlapped symptoms with IBS. Thus, practitioners may use the same medications for the same symptoms. Indeed, this matter merits further research (Lin and Chang, 2020).

## CONCLUSION

There is a scarcity of studies that implement Rome IV criteria in the prevalence of IBS, compared to Rome III criteria that are used extensively in many epidemiological studies in the last 15 years. Despite this, the current evidence shows that the prevalence of IBS decreases, and the overall severity of IBS symptoms increases when Rome IV criteria are used, rather than Rome III criteria. The benefit of Rome IV can be seen in research and clinical application for being more specific and thus more precise in patient's diagnosis, selection, prognosis, and follow-up in clinical intervention trials. Nevertheless, Rome IV as more restrictive criteria might be less suitable than Rome III for population-based epidemiological surveys. Besides, for the clinical

application and treatments of IBS patients, the current evidence does not assess the difference in treatments for different patients with IBS diagnosed on different criteria. These aspects need in-depth evaluation in future studies.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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## الآفاق الحالية لمعايير روما لتشخيص متلازمة القولون العصبي

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### ملخص

متلازمة القولون العصبي هي مشكلة صحية عالمية. وغالبًا ما يتم تشخيصها من خلال المعايير المستندة إلى أعراض روما المحدثة بشكل دوري، ولكن آثار التحديثات الأخيرة على تشخيص القولون العصبي لم يتم توضيحها بشكل جيد. ويلقي هذا المقال نظرة عامة على معايير روما الثالثة والرابعة لمتلازمة القولون العصبي، ويسلط الضوء على التغييرات والتحديثات التي قد تؤثر على تشخيصه. وتم البحث في قواعد البيانات العالمية العلمية الرئيسية حتى يوليو 2021. وكانت معايير روما الرابعة أكثر تقييدًا وتحديثًا ودقة في تشخيص المرضى واختيارهم والتنبؤ بهم ومتابعتهم مقارنة بمعايير روما الثالثة، وفي المقابل، ينخفض انتشار متلازمة القولون العصبي وعدد المرضى الذين يعانون من أنواع فرعية غير محددة ومختلطة من القولون العصبي، ولكن تزداد شدة الأعراض الإجمالية والتجانس لدى المرضى. وفي الأساس، يعكس الاختلاف الطفيف بين معايير روما الثالثة والرابعة تأثيرًا كبيرًا على تشخيص القولون العصبي، والتصنيف الفرعي، والانتشار. وبشكل المرضى المشخصين بمعايير روما الرابعة مجموعة فرعية متجانسة من المرضى المشخصين بمعايير روما الثالثة مع أعراض أكثر حدة، وبالتالي، فإن البحث المتعمق له ما يبرره.

**الكلمات الدالة:** متلازمة القولون العصبي، معايير روما الأولى والثانية والثالثة والرابعة.

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