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## Comparison of Manning, Rome I, II, and III, and Asian diagnostic criteria: Report of the Multicentric Indian Irritable Bowel Syndrome (MIIBS) study

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### Abstract

**Background** Attempts to diagnose and subtype irritable bowel syndrome (IBS) by symptom-based criteria have limitations, as these are developed in the West and might not be applicable in other populations.

**Objectives** This study aimed to compare different criteria for diagnosing and subtyping of IBS in India.

**Method** Manning's and the Rome I, II, and III criteria as well as the Asian criteria were applied to 1,618 patients (from 17 centers in India) with chronic lower

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gastrointestinal (GI) symptoms with no alarm features and negative investigations.

**Results** Of 1,618 patients (aged 37.5 [SD 12.6] years; 71.2 % male), 1,476 (91.2 %), 1,098 (67.9 %), 649 (40.1 %), 849 (52.5 %), and 1,206 (74.5 %) fulfilled Manning's, Rome I, II, and III, and the Asian criteria, respectively. The most common reason for not fulfilling the criteria was absence of the following symptoms: "more frequent stools with onset of pain," "loose stool with onset of pain," "relief of pain with passage of stool," "other abdominal discomfort/bloating," and, in a minority, not meeting the duration criterion of 3 months/12 weeks. By stool frequency, constipation-predominant IBS (<3 stools/week) was diagnosed in 319 (19.7 %), diarrhea-predominant IBS (>3 stools/day) in 43 (2.7 %), and unclassified in 1,256 (77.6 %). By Bristol stool form, constipation, diarrhea, and unclassified were diagnosed in 655 (40.5 %), 709 (43.8 %), and 254 (15.7 %) patients, respectively. By their own perception, 462 (28.6 %), 541 (33.4 %), and 452 (27.9 %) patients reported constipation-predominant, diarrhea-predominant, and alternating types, respectively.

**Conclusion** By Manning's and the Asian criteria, a diagnosis of IBS was made frequently among Indian patients with chronic functional lower GI symptoms with no alarm features; the Rome II criteria gave the lowest yield. By the stool frequency criteria, a majority of patients had unclassified pattern, unlike by the stool form and patients' perception of their symptoms.

**Keywords** Abdominal pain · Constipation · Diarrhea · Functional bowel disorders · Functional gastrointestinal disorders

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## Introduction

The reported prevalence of irritable bowel syndrome (IBS) in Asian communities varies from 4 % to 9 % [1–5]. Common symptoms of IBS include abdominal pain, discomfort or bloating, altered stool form and passage, and mucus with stool. Currently, IBS is diagnosed by symptom-based criteria, initially proposed by Manning and subsequently modified and quantified in the Rome I, II, and III criteria [6–10]. Recently, a group of Asian experts proposed criteria for the diagnosis of IBS in Asia, but these have not been validated [11]. A few studies have attempted to validate the Manning and Rome I, II, and III criteria in Asia [12–15]. A recent study from China that compared the Rome II and III criteria found the latter to be better [14].

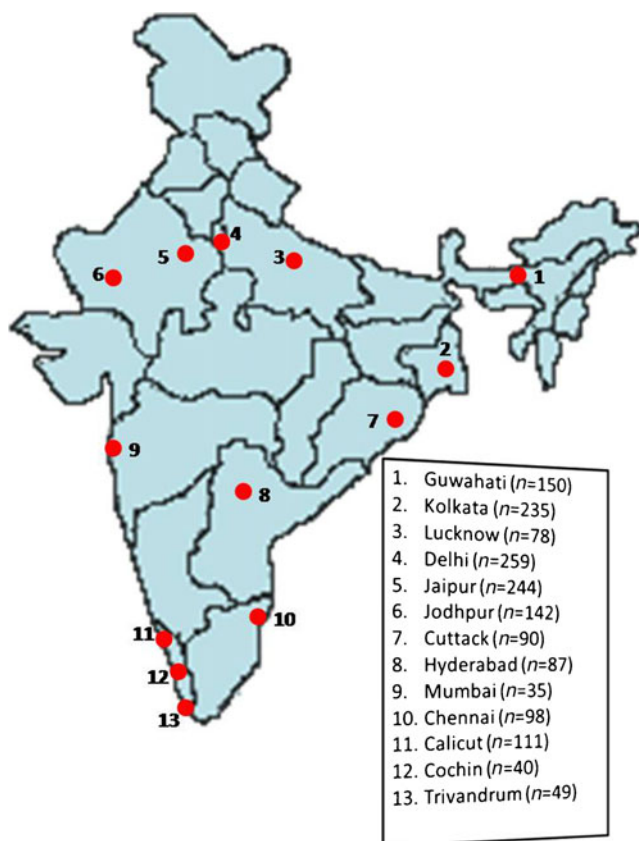
IBS has been classified into constipation- and diarrhea-predominant types using combinations of stool frequency and form and difficulty in stool passage. Stool frequency-based criteria rely on Western studies that reported normal bowel habit to vary from three stools per week to three per day [16, 17]. However, in several Asian countries, over 90 % of people pass one to two stools per day [1, 3, 18–21]. In Bangladesh, India, and Japan, 64 %, 57 %, and 9 % of patients with IBS could not be classified based on stool frequency criteria [3, 22, 23]; in fact, Indian patients who considered themselves to have constipation or diarrhea had similar stool frequency [3]. On the other hand, patients could classify themselves as having constipation, diarrhea, or alternating types by their own perception [3]. It appears logical to consider patients' perception of their bowel pattern for classification.

Stool form (Bristol scale) is reported to be a better marker of constipation and slow colonic transit [24–27]. In the Rome III criteria, stool form has been given more importance than frequency. In the recent Asian consensus, Bristol stool forms 1–3 have been defined as constipation and 5–7 as diarrhea [11]. However, there is no validation of this classification in Asia.

We conducted this multicenter study in India to compare Manning's, Rome I, II, and III, and the Asian criteria to diagnose IBS in patients with chronic functional lower gastrointestinal (GI) symptoms with no alarm feature, who would commonly be considered by the practicing physician as having IBS, and to compare these criteria and their components with the patients' perception of their bowel pattern, in order to classify IBS.

## Methods

This multicenter study included 1,632 adult patients (≥18 years) attending 17 centers from different parts of India with chronic lower GI symptoms with no alarm features and negative investigations during a 2-year period (January 2010 to January 2012). Figure 1 shows the regional distribution of data collection in the country. Of them, 14 patients were excluded due to incomplete data. Evaluation for organic disease included a



**Fig. 1** Map of India showing location of centers in the country, which recruited patients in the study. Data within the *parenthesis* denote number of patients recruited by each place

structured history based on a questionnaire including alarm features, thorough physical examination, and normal/negative investigations including stool for occult blood and microscopy, hemogram, blood biochemistry including sugar, thyroid function tests as indicated, and sigmoidoscopy or colonoscopy when considered appropriate by the treating gastroenterologist. The questionnaire included all features mentioned in the Manning, Rome I, II, and III, and the Asian criteria, although this meant an overlap among questions. Data on demography and socioeconomic and education status were also collected.

Each patient was also asked for his/her perception of own bowel pattern, ie. whether they felt they had predominant constipation or diarrhea or alternating bowel habit. They were also asked what was their predominant stool form according to the Bristol stool chart that had both pictorial representation as well as descriptors.

The study protocol was approved by the ethics committee of the coordinating center (SGPGIMS, Lucknow) and participating patients gave consent to be included in the study.

#### Definitions

The *Manning criteria* for the diagnosis of IBS include any four of the following: (a) abdominal pain that is relieved with a

bowel movement, (b) pain associated with looser stools, (c) pain associated with more frequent stools, (d) sensation of incomplete evacuation, (e) passage of mucus, and (f) abdominal distention [6].

The *Rome I, II, and III criteria* for the diagnosis of IBS are summarized in the online supplementary Table 1 [7–10].

Asian criteria include recurrent abdominal pain, bloating, or other discomfort for  $\geq 3$  months associated with one or more of the following: (a) relief with defecation, (b) change in stool form (show patient the Bristol Stool Scale), and (c) change in stool frequency [11].

*Classification of IBS Patients* were classified into constipation- or diarrhea-predominant groups on the basis of stool frequency (diarrhea  $\geq 3$  stools/day and constipation  $< 3$  stools/week) and Bristol Stool Form scale (stool types 1–3 constipation and 5–7 diarrhea), as proposed earlier [11]. Patients were asked to classify their bowel pattern by their own perception into predominant constipation, predominant diarrhea, and alternating types.

#### Data analysis

The data were entered by a data entry operator and accuracy was cross-checked randomly. Statistical analysis was done using R and Epicalc software version R2.9.0 (R Development Core Team, Vienna, Austria) and Statistical Program for Social Science 15.0 (Chicago, IL, USA). Data were checked for normal distribution using Shapiro–Wilk's test. The categorical and continuous data were presented as proportion and mean and standard deviation, respectively. Differences between non-parametric unpaired continuous and categorical variables were analyzed using Wilcoxon rank sum test and chi-square test with Yates' correction as applicable, respectively; *p*-values below 0.05 were considered significant. Sensitivity of each criterion to diagnose IBS was calculated by a standard formula. The agreement between various criteria was evaluated by kappa statistics. Values for kappa  $\geq 0.81$  were considered excellent agreement, 0.61–0.80 as good agreement, and below 0.60 as poor agreement.

#### Results

The mean age of the patients was 37.5 (SD 12.6) years; 1,152 (71.2 %) were males. Data on hemoglobin were available in 1,412 patients, on ESR in 1,292 patients, fasting blood sugar in 1,001 patients, postprandial blood sugar in 921 patients, and on thyroid-stimulating hormone in 1,036 patients. The values of these tests were normal. Six hundred and fifty-six (40.5 %) underwent colonoscopy, 637 (39.3 %) sigmoidoscopy, and 325 (20.1 %) did not undergo either. The symptoms in

these patients are shown in Table 1. Most patients had symptoms for long duration (median 36, range 1–600 months). Sixteen of 1,618 (0.9 %) had symptom duration of  $\leq 1$  month, 28/1,618 (1.7 %) between  $>1$  and  $\leq 2$  months, and 38 (2.3 %) between  $>2$  and  $\leq 3$  months.

**Manning criteria**

Of the 1,618 patients, 1,476 (91.2 %) fulfilled Manning's criteria for IBS (Table 2). Among those who did not fulfill the criteria, “more frequent stools with onset of pain,” “loose stool with onset of pain,” and “relief of pain with passage of stool” were absent in 97.9 %, 97.2 %, and 93.7 % of patients, respectively (Table 3). Of 1,476 patients fulfilling Manning's criteria, 11 had symptom duration  $\leq 1$  month, 22 between 1 and  $\leq 2$  months, and 34 between 2 and  $\leq 3$  months.

**Rome I criteria**

Of the 1,618 patients, 1,098 (67.9 %) fulfilled the Rome I criteria for IBS (Table 1). Among those who did not fulfill the criteria, more frequent stools with onset of pain, loose stool with onset of pain, and relief of pain with passage of stool were absent in 92.5 %, 92.5 %, and 71.9 % of patients, respectively (Table 4). The median (range) duration of symptoms of patients fulfilling Rome I criteria ( $n=1,080$ ) was 36 (3–600) months. Of 1,098 patients fulfilling the Rome I

**Table 1** Symptoms in the patients with functional lower gastrointestinal disorder ( $n=1,618$ )

Duration of symptoms (months) (median, range)	36 (1–600)
Abdominal pain/discomfort	1,492 (92.2)
Abdominal distension	1,102 (68.1)
Abdominal distension $>25$ % of days	1,102 (68.1)
Visible abdominal distension	516 (31.9)
Abdominal bloating	903 (55.8)
Any other abdominal discomfort	561 (34.7)
More frequent stool with onset of pain	829 (51.2)
Loose stool with onset of pain	745 (46)
Relief of pain with passage of stool	1,100 (68)
Passage of mucus with stool	994 (61.4)
Passage of mucus with stool $>25$ % of days	842 (52)
Feeling of incomplete evacuation	1,046 (64.6)
Urge to pass stool after most meals	840 (51.9)
Straining during passage of stool	772 (47.7)
Stool frequency per day (median, range)	2 (0–23)
Stool frequency per week (median, range)	14 (1–120)
Symptoms after milk intake	636 (39.3)
Stopped milk intake for these symptoms	593 (36.7)
Relief in symptoms after stopping milk	496 (30.7)

Data are as  $n$  (percent) unless otherwise specified

**Table 2** Frequency of IBS using the Manning, Rome I, Rome II, and Rome III, and Asian criteria in patients with lower functional gastrointestinal disorder ( $n=1,618$ )

Diagnostic criteria	Positive	Negative
Manning	1,476 (91.2)	142 (8.8)
Rome I	1,098 (67.9)	520 (32.1)
Rome II	649 (40.1)	969 (59.9)
Rome III	849 (52.5)	769 (47.5)
Asian	1,206 (74.5)	412 (25.5)

Data are as  $n$  (percent)  
IBS irritable bowel syndrome

criteria, 28 had symptom duration of 3 months and none had lesser duration of symptom.

**Rome II criteria**

Of the 1,618 patients, 649 (40.1 %) fulfilled the Rome II criteria for IBS (Table 2). Among those who did not fulfill the criteria, more frequent stools with onset of pain, loose stool with onset of pain, and relief of pain with passage of stool were absent in 73.8 %, 74.2 %, and 49.8 % of patients, respectively (Table 5). The median (range) duration of symptoms of patients fulfilling Rome II criteria ( $n=564$ ) was 48 (12–600) months. Of 649 patients fulfilling Rome II criteria, none had symptom in 3 months or less.

**Rome III criteria**

Of the 1,618 patients, 849 (52.5 %) fulfilled the Rome III criteria for IBS (Table 2). Among those who did not fulfill the criteria, more frequent stools with onset of pain, loose stool with onset of pain, relief of pain with passage of stool and ‘abdominal pain/discomfort at least 3 days/month’ were absent in 91.4 %, 89.2 %, 61.6 % and 25.5 % of patients, respectively (Table 6). The median (range) duration of symptoms of patients fulfilling Rome III criteria ( $n=728$ ) was 36 (3–600) months. Of 849 patients fulfilling Rome III criteria,

**Table 3** Absent symptoms in patients negative by the Manning criteria for IBS ( $n=142$ )

Symptoms	Absent
Visible abdominal distension	124 (87.3)
More frequent stools with onset of pain	139 (97.9)
Loose stool with onset of pain	138 (97.2)
Relief of pain with passage of stool	133 (93.7)
Passage of mucus with stool	123 (86.6)
Feeling of incomplete evacuation	79 (55.6)

Data are as  $n$  (percent)  
IBS irritable bowel syndrome

**Table 4** Absent symptoms in patients negative by Rome I criteria for IBS (*n*=520)

Symptoms	Absent
Abdominal pain/discomfort	121 (23.3)
More frequent stools with onset of pain	481 (92.5)
Loose stool with onset of pain	481 (92.5)
Relief of pain with passage of stool	374 (71.9)
Passage of mucus with stool	338 (65)

Data are as *n* (percent)

IBS irritable bowel syndrome

15 had symptom duration of 3 month and none had lesser duration of symptom.

Asian criteria

Of the 1,618 patients, 1,206 (74.5 %) fulfilled the Asian criteria for IBS (Table 2). Among those who did not fulfill the criteria, more frequent stools with onset of pain, loose stool with onset of pain, relief of pain with passage of stool, “any other abdominal discomfort,” and “abdominal bloating” were absent in 23.5 %, 94.2 %, 79.1 %, and 54.4 % of patients, respectively (Table 7). The median (range) duration of symptoms of patients fulfilling the Asian criteria (*n*=1,206) was 36 (1–600) months. Of 1,206 patients fulfilling the Asian criteria, 2 had symptom duration ≤1 month, 1 between 1 and ≤2 months, and 31 between 2 and ≤3 months.

Subtyping

Of the 1,618 patients, 319 (19.7 %) and 43 (2.7 %) could be classified into diarrhea- and constipation-predominant disease according to the stool frequency criteria; 1,256 (77.6 %) patients could not be classified as their stool frequency was within the normal range. Using the Bristol Stool Form scale, 709 (43.8 %) and 655 (40.5 %) were classified as having diarrhea and constipation, respectively; 254 (15.7 %) patients reported passing type 4 (“normal”) stool; of these 254 patients,

**Table 5** Absent symptoms in patients negative by Rome II criteria for IBS (*n*=969)

Symptoms	Absent
Abdominal pain/discomfort	126 (13)
More frequent stools with onset of pain	715 (73.8)
Loose stool with onset of pain	719 (74.2)
Relief of pain with passage of stool	483 (49.8)
Abdominal pain/discomfort at least 12 weeks (need not be consecutive)	346 (35.7)

Data are as *n* (percent)

IBS irritable bowel syndrome

**Table 6** Absent symptoms in patients negative by Rome III criteria for IBS (*n*=769)

Symptoms	Absent
Abdominal pain/discomfort	120 (15.6)
More frequent stools with onset of pain	703 (91.4)
Loose stool with onset of pain	686 (89.2)
Relief of pain with passage of stool	474 (61.6)
Abdominal pain/discomfort at least 3 days/month	196 (25.5)

Data are as *n* (percent)

IBS irritable bowel syndrome

Manning's, Rome I, II, and III, and Asian criteria diagnosed IBS among 215 (85 %), 140 (55 %), 74 (29 %), 102 (40 %), and 162 (64 %) patients, respectively.

Based on their own perception, 462 (28.6 %), 541 (33.4 %), and 452 (27.9 %) patients, respectively, classified themselves as having diarrhea- or constipation-predominant disease and diarrhea alternating with constipation; 163 (10.1 %) patients did not respond to the questions about self-classification of their bowel habit.

Concordance among different diagnostic criteria

There was a poor agreement between the Manning criteria and Rome I (kappa 0.3), II (kappa 0.1), and III (kappa 0.2) criteria. The agreement between the Rome III criteria and Rome II (kappa 0.75) and Rome I (kappa 0.66) criteria was good, although Rome III did not correlate as well with the Asian criteria (kappa 0.54). The Asian criteria had good agreement with the Rome I criteria (kappa 0.78), but not with the Rome II criteria (kappa 0.37).

Discussion

The present multicenter study from India suggests that the Manning criteria are the most sensitive ones for the diagnosis of IBS among Indian patients with functional lower GI disorders;

**Table 7** Absent symptoms in patients negative by the Asian criteria for IBS (*n*=412)

Symptoms	Absent
Abdominal pain/discomfort	97 (23.5)
More frequent stools with onset of pain	387 (93.9)
Loose stool with onset of pain	388 (94.2)
Relief of pain with passage of stool	388 (94.2)
Any other abdominal discomfort	326 (79.1)
Abdominal bloating	224 (54.4)

Data are as *n* (percent)

IBS irritable bowel syndrome

Rome II was the least sensitive among the Rome criteria. The recently proposed Asian criteria did reasonably well but were less sensitive than the Manning criteria. A large proportion of patients remained unclassified into constipation- and diarrhea-predominant bowel pattern by the stool frequency criteria, but all patients could classify themselves by their own perception as having constipation, diarrhea, or an alternating pattern, and most patients could be classified by Bristol stool forms.

The results of our study are in accordance with earlier community studies that showed that the prevalence of IBS was lower when Rome II criteria were applied than when Rome I criteria were used [28–32]. In an earlier Indian study from Hyderabad, among 132 patients with functional bowel disorder, Rome I criteria diagnosed 83 % of patients as having IBS compared to 31 % by the Rome II criteria [13]. In a recent multicenter Chinese study, among 754 outpatients, more patients met the Rome III than the Rome II criteria (97.5 % vs. 67.6 %) [14]. The Rome II criteria have therefore been criticized as being quite restrictive [33].

However, in a recent systematic review on diagnostic criteria for IBS, the authors concluded that the Manning criteria are the most valid and accurate criteria [15]. More importantly, Rome III criteria have not been validated and cannot be easily adopted in clinical research trial enrollment. Considering our results, and the results of the recent systematic review [15] that suggested that these criteria have been most validated, the Manning criteria deserve renewed consideration for use in clinical practice. Rome criteria, which have been proposed particularly for research, need modification during their subsequent iteration for widespread application in research and clinical practice as well.

The Manning criteria, however, do not consider duration of symptoms for diagnosis [6]. The Rome criteria paid particular attention to duration of symptoms—“at least 3 months of continuous or recurrent symptoms” (Rome I criteria), “at least 12 weeks, which need not be consecutive, in the preceding 12 months” (Rome II criteria), and “at least 3 months, with onset at least 6 months previously”—to avoid including patients with short-duration symptoms, which may suggest organic rather than functional disease [7–10, 33]. However, in an attempt to be more precise, the Rome criteria have become restrictive [33]. It is worth remembering that clinical parameters alone can never be adequate to exclude organic problems. For example, celiac disease, small intestinal bacterial overgrowth, fecal evacuation disorders, microscopic colitis, and lactose malabsorption may present with symptoms overlapping those of IBS, with long duration as well. Hence, in addition to symptom-based criteria, appropriate investigations are needed to exclude these disorders [34, 35]. However, current algorithm does not require mandatory testing for these disorders before a diagnosis of IBS is made. Therefore, though a proportion of our patients reported improvement in symptoms after milk withdrawal, still they will be considered as IBS as per current

guidelines. Is it possible that those who qualified Rome II (lowest “sensitivity”) are the only ones who actually had IBS and that Manning criteria overdiagnosed? This is unlikely. It is important to mention that there is no biomarker, which can be considered as a gold standard for the diagnosis of IBS. Hence, IBS should be considered as a disorder with chronic lower GI symptoms likely functional in origin sufficient to impair patients' quality of life and/or need for consultation with physician. A functional disease like IBS should be defined by the patients rather than by physician-driven criteria. Though some of our patients had short symptom duration, we did not exclude them as Manning criteria do not take symptom duration into consideration. However, the number of such patients is so small that they are unlikely to alter the conclusion of this study. Twenty percent of patients did not undergo lower GI endoscopy. This is a limitation of our study.

Our data also showed that patients with IBS could more often be classified as having constipation- or diarrhea-predominant bowel pattern by the Bristol stool form and by the patients' own perception than by the stool frequency criteria. Previous studies showed that in Bangladesh, India, and Japan, 64 %, 57 %, and 9 % of patients with IBS could not be classified based on stool frequency criteria [3, 22, 23], though by the patients' perception, all from India could be classified [3]. This can be attributed to the fact that the definition of constipation by stool frequency was based on studies on normal bowel frequency in the Western populations where three stools/day to three stools/week were considered normal [16, 17]. Stool frequency in Asian populations is different: normal stool frequency in populations in China (mean 7.1/week), Iran (12.5 [SD 7.3] per week in men and 14 [8] in women), and India (7–14/week in 99 %) is higher than that of Western populations [3, 19, 20]. Whereas stool form is known to be a good predictor of colonic transit [24–27, 36], patients' own perception of their bowel pattern should be given due consideration in any such exercise.

In conclusion, this study suggests that the Rome criteria, particularly Rome II, may be too restrictive for use to diagnose IBS in the Indian population; the Manning criteria appear to be the best for this purpose. The sensitivity of the Asian criteria is 74.5 %. Western criteria based on stool frequency are poor at classifying IBS into constipation- and diarrhea-predominant type in India; the Bristol stool form and patients' perception of their pattern are better measures. Our data may be applicable to populations with similar symptom profile of IBS and similar bowel habits. Clinicians caring for patients with IBS in these populations need to consider these data for the diagnosis of IBS. The data of the present study need to be considered for future iteration or revision of Rome criteria, so that globally acceptable criteria are developed for diagnosis of IBS in the future. The data should also prove useful for developing protocols for drug trials in these populations.



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