

## Rome I criteria are more sensitive than Rome II for diagnosis of irritable bowel syndrome in Indian patients

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**Aim:** To assess the utility and efficacy of Rome I and Rome II criteria for the diagnosis of irritable bowel syndrome (IBS) in India. **Methods:** Patients referred with a diagnosis of IBS by general practitioners answered a questionnaire about clinical features, including those listed in the Rome I and Rome II criteria. All patients underwent investigations to determine the cause of their symptoms. Sensitivity, positive predictive value and percent agreement of final diagnosis with Rome I and II criteria were calculated. **Results:** Among 138 patients studied, 6 patients had organic disease. Amongst 132 patients with functional bowel disease, Rome I criteria diagnosed more patients as IBS than Rome II criteria (110 [83.3%] vs. 41 [31.1%]); 36 patients fulfilled both the criteria. Of the patients positive by Rome I, 32.7% fulfilled Rome II criteria, and of those diagnosed by Rome II criteria, 87.8% fulfilled Rome I criteria. Seventeen patients did not fulfill either Rome I or Rome II criteria, and were classified as functional abdominal bloating, functional diarrhea or functional constipation. **Conclusion:** Rome I criteria are more sensitive than Rome II criteria for the diagnosis of IBS in the Indian population. [*Indian J Gastroenterol* 2005;24:164-166]

The diagnosis of irritable bowel syndrome (IBS) is based on symptom criteria and exclusion of organic disease. Manning and colleagues in 1978 reported a set of criteria to differentiate between IBS and structural diseases of the gut.<sup>1</sup> In an effort to develop criteria for all functional gastrointestinal disorders, the Rome I criteria were developed in 1991 by international consensus.<sup>2</sup> However, these criteria were relatively complex and difficult to use and were later revised.<sup>3</sup> The latter (Rome II) criteria are simpler, require presence of symptoms over one year, have more specific requirements for abdominal pain and place less emphasis on stool form.<sup>4</sup>

The Rome criteria have been applied primarily in clinical research but not as commonly in clinical practice.<sup>5</sup> The Rome I criteria have shown good agreement with the Manning criteria.<sup>6,7</sup> However,

few studies have compared the Rome I and Rome II criteria. Several important issues about the Rome criteria, including geographic and cultural differences, remain unexplored. Further, few studies have addressed the utility of the Rome I and Rome II criteria in tropical countries.<sup>8</sup>

### Methods

The study was approved by the institute ethics committee and was conducted over a period of six months from April to September 2004. Adult patients diagnosed with IBS by community general physicians were recruited in the study after they gave informed consent. Functional bowel disease was diagnosed when the patients had chronic or recurrent gastrointestinal symptoms of lower abdominal pain, altered bowel habits and bloating for at least two years and no organic cause was identified.<sup>4</sup> Patients with 'red flag signs'<sup>4</sup> of weight loss, nocturnal symptoms, blood in stools, family history of colon cancer, and abnormal physical findings were excluded.

All patients answered a questionnaire that included information on symptoms of IBS included in the Rome I or Rome II criteria (Table 1). IBS was diagnosed if the patient fulfilled either Rome I or Rome II criteria. Subsequently all patients underwent tests including abdominal ultrasound scan, upper gastrointestinal endoscopy, colonoscopy, and barium meal follow-through study. Routine stool examination, blood sugar and thyroid profile were also done.

### Statistical analysis

Numeric data were summarized using means, median and ranges as appropriate, and categorical data as percentages. Continuous and categorical data were compared using Mann-Whitney and chi-square test, respectively. Agreement between Rome I and Rome II criteria was analyzed using kappa statistic, which represents a chance-corrected measure of degree of agreement between two observations with -1.0 representing perfect disagreement, 0 indicating chance agreement and +1.0 indicating perfect agreement.

**Table 1: Questionnaire used for the study**

(Asked in the local language by health-care worker)

- 1) In the past 12 months, have you had continuous or repeated discomfort or pain in your lower abdomen for a total of three months or longer? *Yes / No / Not sure*
- 2) When did you have continuous or repeated pain or discomfort in lower abdomen or bowels? *Months ago / >1 year ago / Never*
- 3) a. Is this pain or discomfort relieved by bowel movement? *Yes / No*  
 b. Is this pain associated with change in number of motions? *Yes, from the onset / Yes, but not at onset / No*  
 c. Is this pain associated with a change in consistency of stools? *Yes, from the onset / Yes, but not at onset / No*
- 4) Which of the following did/do you also experience during the episodes of pain?
  - a. Greater than 3 motions per day *Yes / No*
  - b. Less than 3 motions per week *Yes / No*
  - c. Loose or watery stools *Yes / No*
  - d. Hard or lumpy stools *Yes / No*
  - e. Strain or sudden urge during bowel movement *Yes / No*
  - f. Feeling of incomplete sense of evacuation *Yes / No*
  - g. Mucus in the stool *Yes / No*
  - h. Feeling of fullness, bloating or swelling in the abdomen *Yes / No*

Rome I criteria: 1 or 2 and at least one of 3a, 3b, 3c and at least one of 4a or b, c or d, e or f, g and/or h

Rome II criteria: 2 and at least two of 3a, 3b, 3c

## Results

Of the 138 patients recruited, six had organic disease (Table 2). One hundred and thirty two (95.7%) patients were diagnosed to have functional bowel disease. This included 17 patients who did not fulfill either Rome I or Rome II criteria and were classified as having functional abdominal bloating, functional diarrhea or functional constipation.

In 132 patients with functional bowel disease, the median age was 37 years (range 17-85). Eighty-two were men, and 86 (65.8%) had graduate or

**Table 2: Organic disease in patients initially diagnosed as irritable bowel syndrome**

Rome I	Rome II	Final Diagnosis	Test
+	-	Hypothyroid	Thyroid function tests
+	-	Hypothyroid	Thyroid function tests
+	+	Hyperthyroid	Thyroid function tests
-	+	Proctitis	Colonoscopy / biopsy: ulcerative colitis
+	+	Crohn's disease	Barium study and capsule endoscopy
-	+	Ileocecal TB	Colonoscopy: terminal ileal ulcerations Biopsy: epithelioid granulomas

'+' indicates fulfillment of particular criteria and '-' their non-fulfillment

**Table 3: Patients analyzed using Rome I and Rome II criteria**

Final diagnosis	Rome I criteria		Total
	Positive	Negative	
IBS	110	22*	132
Not IBS	4	2	6
Total	114	24	138

  

Final diagnosis	Rome II criteria		Total
	Positive	Negative	
IBS	41	91*	132
Not IBS	4	2	6
Total	45	93	138

  

Rome II criteria	Rome I criteria		Total
	Positive	Negative	
Positive	36	5	41
Negative	74	17	91
Total	110	22	132

\* Includes 17 patients negative by both Rome I and Rome II criteria and labeled as functional bloating / constipation

higher qualifications. Only 37 (28%) were smokers and 7 (5.3%) chewed tobacco. Alcohol consumption was reported by 25 (18.9%). The majority (69; 52.3%) had normal bowel habits. Diarrhea (37; 27.7%) and constipation (22; 16.9%) were less common; the alternating type was least common (3.1%).

One hundred and ten of 132 patients were diagnosed as IBS using Rome I criteria, and 41 by Rome II. The Rome I criteria diagnosed more patients than Rome II criteria (83.3% vs. 31.2%;  $p < 0.01$ ). Eighty-one patients reported that they had experienced recurring or continuous pain or discomfort in their lower abdomen but not within the last one year. Additionally, the change in consistency or frequency of stool and altered bowel habits did not correlate with the onset of pain (as per the questionnaire).

There was 40% agreement between Rome I and Rome II (kappa score 0.44). Of the patients diagnosed with IBS using Rome I criteria, only 36 (32.7%) fulfilled Rome II criteria; in comparison, 36 (87.8%) patients diagnosed using Rome II criteria also fulfilled Rome I criteria (Table 3). Rome I therefore resulted in more patients fulfilling the criteria for IBS than Rome II.

## Discussion

We have shown that the Rome I criteria are more sensitive than Rome II for a community-based diagnosis of IBS in India.

The majority of our patients with irritable bowel syndrome had normal bowel habits. Pain was the

dominant feature in our patients with normal bowel habits and diarrhea; however this was not the case in up to a third of patients with constipation.

The reported prevalence of IBS using Rome II is less compared to that with Rome I. Studies using the Rome I criteria showed prevalence rates ranging from 9.5% to 15% whereas with the Rome II criteria they ranged from 2.3% to 6.9%.<sup>9</sup> It has been suggested that the Rome II criteria are unnecessarily restrictive in clinical practice.<sup>10,11</sup>

We found that the Rome I criteria diagnosed more number of cases as IBS than the Rome criteria. This is in concordance with a number of studies.<sup>11-14</sup>

A recent analysis suggested that Rome II-positive subjects actually represented a subgroup of Rome I-positive subjects with more severe symptoms, and the remaining should be labeled as functional bowel disorder.<sup>9</sup> Our sample included primarily referral cases with prolonged or severe symptoms. The Rome II sensitivity is low compared to Rome I in this setting too.

Twelve percent of our patients diagnosed as IBS by the general practitioner did not fulfill either Rome criteria. Levy and colleagues have also reported that primary-care physicians diagnosed a far greater percentage of patients with IBS than actually fulfilling the Rome criteria.<sup>15</sup>

In the present study additional investigations altered the diagnosis in six patients. Two patients had hypothyroidism and improved on medication. The third patient was a young lady with subclinical hyperthyroidism. One patient had small intestinal strictures suggestive of Crohn's disease. Colonoscopy showed ileocecal ulcerations with granuloma on histology in one case; ulcerative proctitis was seen in another.

A number of factors must be considered while interpreting our results. Ours is a tertiary-care referral center and the patients referred had symptoms for more than two years. Hence, a selection bias may be present. Additionally the diagnosis of IBS is influenced by how abdominal pain or discomfort is defined and comprehended; some experiences can have different meanings in different languages and cultures. Our questionnaire was translated into the local language, Telugu.

In conclusion, the Rome I criteria are more sensitive than Rome II and most patients with a general-practitioner diagnosis of IBS do not fulfill the Rome II criteria.

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