Systematic review: accuracy of symptom-based criteria for diagnosis of irritable bowel syndrome in primary care

Jellema P, van der Windt DA, Schellevis FG, van der Horst HE

CRD summary
This review concluded that organic disease could not be accurately excluded by symptom-based irritable bowel syndrome criteria alone. The review was generally well conducted, but the possibility of missed studies means that these conclusions should be interpreted with some caution.

Authors’ objectives
To determine the accuracy of symptom-based irritable bowel syndrome (IBS) criteria in excluding organic disease and individual signs and symptoms in diagnosing IBS.

Searching
PubMed and EMBASE were searched to September 2008. Some details of the search were provided and included a diagnostic filter. Reference lists of retrieved studies, relevant reviews, meta-analysis, guidelines and commentaries were screened. The review was restricted to studies in English, Dutch, German or French.

Study selection
Primary diagnostic cohort studies, nested case-control studies and diagnostic case-control studies in which controls were diagnosed with a specific gastrointestinal disease were eligible for inclusion. Included studies needed to evaluate accuracy of externally validated symptom-based criteria or history taking (symptoms) and/or physical examination (signs) for diagnosis of IBS in adults (18 years or more) with non-acute abdominal symptoms (duration two weeks or more) who presented to primary care or outpatient gastrointestinal clinics.

Studies had to report sufficient data to construct a 2x2 table of test performance. For exclusion of IBS, the reference standard had to consist of diagnostic work-up or clinical follow-up of at least one year. For diagnosis of IBS, studies were required to use externally evaluated symptom-based IBS criteria as the reference standard.

Included studies defined IBS as non-organic/functional disease without differentiating between upper and lower disease, lower functional gastrointestinal disease or a diagnosis using symptom-based IBS criteria. In the first two definitions, IBS was a diagnosis by exclusion and in the third, IBS was a positive diagnosis. The following symptom-based IBS criteria were evaluated: Manning, Kruis, Rome I, Rome II, Bellentani, Mazumdar, Talley and Wasson. Only two studies evaluated signs and symptoms as index tests; these used Rome I and Rome II as the reference standard. One study excluded patients with alarm features, two studies explored the influence of alarm features on accuracy. Three studies explicitly excluded patients with upper gastrointestinal disease. Six studies examined the effects on diagnostic performance of including upper functional disease.

Two reviewers independently assessed studies for inclusion. Disagreements were resolved through consultation with a third reviewer.

Assessment of study quality
Two reviewers independently assessed study quality using the modified version of QUADAS (as recommended by Cochrane). Disagreements were resolved through consensus or discussion with a third reviewer.

Data extraction
Two reviewers independently extracted data as 2x2 tables of test performance. Disagreements were resolved through consensus or discussion with a third reviewer.

Methods of synthesis
In the absence of clinical and statistical heterogeneity, the bivariate model was used to estimate summary sensitivity and
specificity together with 95% confidence intervals (CI) when four or more studies assessed a specific index test. The following sources of heterogeneity were investigated: setting (primary versus secondary care); threshold (Manning 2/4 versus 3/6); study population (inclusion/exclusion of patients with alarm features of upper gastrointestinal disorders); and QUADAS items 1, 2 and 8.

Subgroup analyses were performed when each subgroup included data from at least two studies. If at least four homogeneous studies assessed each subgroup then the bivariate model was used to pool data within subgroups; otherwise, ranges in sensitivity and specificity for each subgroup were reported.

**Results of the review**

Twenty five studies were included in the review (n=9,253): 21 diagnostic cohort studies; three nested case-control studies; and one diagnostic case control studies. Three studies used chart review for data collection. Most studies performed well on the QUADAS items related to blinded assessment of the index test, use of an appropriate reference standard and avoidance of partial verification bias. Time between index test and reference standard was poorly described. Five studies scored positive on at least eight of the 11 QUADAS criteria.

**Accuracy of symptom-based IBS criteria for exclusion of organic disease (20 studies)**: There was considerable heterogeneity in both sensitivity and specificity across different criteria and within studies that evaluated the same criteria. The Wasson criteria (three studies) showed consistently low sensitivity (34% to 46%) and high specificity (82% to 91%). Accuracy of Rome II criteria (four studies) was also poor (sensitivity ranged from 31% to 65% and specificity ranged from 30% to 100%). Diagnostic performance of Bellentani, Mazumdar and Talley criteria were considerably worse in the validation cohort compared with development cohorts.

**Accuracy of signs and symptoms for diagnosing IBS (two studies)**: Overall specificity of individual signs and symptoms was higher when IBS was compared with a combination of upper and lower organic diseases than with lower organic diseases. Specificity of the alarm features assessed ranged from 27% to 93%. Specificity of non-alarm features ranged from 42% to 88%.

**Authors’ conclusions**

Organic disease could not be accurately excluded by symptom-based IBS criteria alone.

**CRD commentary**

The review addressed two clear questions supported by clearly defined inclusion criteria. The literature search included appropriate databases, but inclusion of a methodological filter and restriction of the review to studies in certain languages meant that relevant studies may have been missed. Appropriate steps were taken to minimise bias and errors at all stages of the review process. Study quality was assessed using appropriate criteria and results of these assessments were clearly presented and considered in the synthesis of results. Appropriate methods were used to synthesise results that included an evaluation of heterogeneity. The authors’ conclusions were supported by the results presented, but should be interpreted with some caution due to the possibility of missed studies.

**Implications of the review for practice and research**

**Practice**: The authors stated that organic disease could not be accurately excluded by symptom-based IBS criteria alone.

**Research**: The authors stated that they advised validation of the new Rome II criteria in primary care populations that consisted of all patients who consulted their general practitioner because of non-acute abdominal pain or discomfort, including those who demonstrated alarm features.

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