The utility of diagnostic tests in irritable bowel syndrome patients: a systematic review

Cash B D, Schoenfeld P, Chey W D

Authors' objectives
To quantify the prevalence of organic gastrointestinal (GI) disease, and to estimate the diagnostic accuracy of the most commonly used tests for organic GI disease amongst patients who meet symptom-based criteria for irritable bowel syndrome (IBS).

Searching
MEDLINE and EMBASE were searched from 1980 to 2001; the search terms were reported. Bibliographies of retrieved articles and abstracts from the meetings of two American gastroenterology societies were also searched.

Study selection
Study designs of evaluations included in the review
Study designs were not specified as part of the inclusion criteria. There was a mixture of case-control and cohort studies.

Specific interventions included in the review
The inclusion criteria stated that studies of commonly applied diagnostic tests for organic GI compared with a reference standard were eligible. The included tests were: colonic investigations including flexible sigmoidoscopy, barium enema and colonoscopy; laboratory tests including serum chemistries, complete blood count (CBC), faecal occult blood test (FOBT), antibodies (anti-glindin and flexible endomysial) and serological testing for thyroid dysfunction (TSH); stool analysis for ova and parasites; hydrogen breath test; and abdominal ultrasound.

Reference standard test against which the new test was compared
The inclusion criteria stated that tests had to be compared with an appropriate 'gold' standard test for organic GI disease and/or prior diagnosis of patients with an additional or alternative diagnosis of disease being made, based on the test result. Only one study compared the test results with a reference standard and this study used duodenal biopsy. Other studies used symptom-based criteria (Manning, Rome I, Rome II or International Congress of Gastroenterology criteria) to diagnose disease before application of the diagnostic test.

Participants included in the review
Studies of patients with symptom-based criteria for IBS were eligible for inclusion. The average age of the patients ranged from 39 to 56 years, between 71 and 82% of patients were female, and the prevalence of organic disease ranged from 0 to 78% (median 1.02%).

Outcomes assessed in the review
The outcomes specified by the inclusion criteria were diagnostic accuracy and a change in the diagnosis of organic disease resulting from the test results. The outcomes reported were: the prevalence of organic GI disease in the study population; the pre-test probability of colitis/IBS, colorectal cancer, coeliac disease, GI infection, thyroid dysfunction and lactose malabsorption; and the numbers of patients with an alternative diagnosis resulting from the test results. This abstract only reports the results for diagnostic accuracy and changes in diagnosis resulting from the test results.

How were decisions on the relevance of primary studies made?
Two authors independently screened studies for inclusion in a blinded fashion.

Assessment of study quality
Study validity was assessed using the following criteria: study population (clinical cohort or case-control); comparison of diagnostic test with a reference test; blinded interpretation of the results; consecutive patient selection; prospective data collection; sufficient details of the diagnostic test and reference test reported; sufficient details of the patient...
The total score ranged from 0 to 8, with low-quality studies being those in the lowest tertile and studies scoring above this classed as medium to high quality.

The authors did not state how many reviewers performed the validity assessment.

Data extraction
Two reviewers extracted the data independently, with any disagreements resolved by discussion. Details of the population, symptom-based criteria, diagnostic test, ‘gold’ standard and outcomes (prevalence and diagnostic accuracy) were extracted. The sensitivity and specificity of tests for the presence of organic GI disease were calculated where sufficient data were available.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative.

How were differences between studies investigated?
Differences between the studies were described in the text and tables.

Results of the review
Six studies (n approximately 2,121) were included, some of which evaluated more than one diagnostic test.

Two studies scored 6 out of 8 for methodological quality and the rest scored 5. All studies had consecutive patient selection, prospective data collection and reported sufficient details of the test and control populations. Only one study compared the diagnostic test with a ‘gold’ standard test and one other study had blinded test interpretation. In all studies the diagnosis of IBS was made using only symptom-based criteria and before any diagnostic tests were applied.

Colonic examinations.
Four studies assessed flexible sigmoidoscopy, barium enema or colonoscopy with 0% (0 out of 89), 0% (0 out of 125), 1% (3 out of 196) and 1.3% (4 out of 306) of patients receiving alternative diagnoses to explain their GI based on the test results. One study assessed rectal biopsies and no patients from the sample of 89 suspected cases and 59 controls received an alternative diagnosis.

Laboratory evaluations.
Two studies assessed CBC, FOBT or serum chemistries, but neither study found that the laboratory test results led to an alternative diagnosis.

Stool analysis.
Two studies assessed stool analysis: one found that 1.7% (19 out of 1,154) of patients with suspected IBS had evidence of an intestinal pathogen; the other found no patients had enteric infection.

TSH testing.
Two studies assessed TSH: one found that 6% of patients (67 out of 1,200) had thyroid function abnormalities, but it was unclear if these were responsible for the IBS symptoms as there was no report of symptom relief after treatment (the gold standard); the other study found one patient (out of 171) with an abnormal TSH, similarly there was no report of symptom relief after treatment.

Hydrogen breath testing.
Two studies assessed hydrogen breath testing for lactose malabsorption in patients with suspected IBS. One found that
23% (256 out of 1,122) of patients with suspected IBS demonstrated impaired lactose absorption when given a 25-g dose of lactose. The other study found a similar prevalence of malabsorption with 25.8% of patients (48 out of 186) having abnormal results after a 50-g dose of lactose. Neither study reported symptom relief on treatment.

Imaging studies.

One study assessed abdominal ultrasound and found 20% (of 100 women) and 8% (of 25 men) had an abnormality following an abdominal scan, and 10% of women had pelvic abnormalities. The identification of an abnormality was not correlated to any GI symptoms and did not lead to additional treatment in any patient.

**Authors’ conclusions**

There was insufficient evidence to recommend routinely carrying out a standardised battery of diagnostic tests in patients who already met symptom-based criteria for IBS. As the pre-test probability of coeliac disease in the population included in this review was higher than that in the general population, routine performance of serological tests for coeliac disease may be useful for these patients, although further research is needed.

**CRD commentary**

This review had two clearly stated aims: to assess the prevalence of organic GI disease and to determine the diagnostic accuracy of tests used in its diagnosis in patients with symptoms of IBS. The search seemed appropriate and made attempts to locate unpublished studies, although it was not reported if any language restrictions were applied. Two independent reviewers performed the study screening and data extraction processes, which helps prevent errors and bias in the review process. Study quality was assessed using relevant questions for diagnostic accuracy studies, although quality was not discussed in relation to the results of each study.

The authors planned to report the sensitivity and specificity of each diagnostic test but these diagnostic accuracy measures were not reported for any of the studies, including the only one to compare a test with a reference standard. The narrative synthesis was appropriate but the description of the results was difficult to follow as it appears that some studies reported results for multiple tests. The methods of this review were appropriate and the authors’ conclusion about insufficient evidence appears reliable, but no conclusions about the diagnostic accuracy of tests for IBS can be drawn from the data presented in this review.

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

Practice: The authors stated that diagnostic testing for coeliac disease may be considered routinely in patients who fulfil symptom-based criteria for IBS. They also stated that a diagnostic evaluation is indicated if a patient has alarm symptoms such as being aged over 50 years, weight loss, gross haematochezia, or systemic signs of infection or colitis.

Research: The authors stated the need for further research. Specifically: an assessment of the overall rate of compliance with published clinical practice guidelines for IBS diagnosis; and large, well-designed prospective trials with adequate follow-up to examine the yield and accuracy of commonly used diagnostic tests in IBS. The authors also stated that performing rigorous, invasive and expensive diagnostic evaluations in patients who clearly fulfil symptom-based criteria may not be necessary.

**Funding**

Novartis Pharmaceuticals Corporation.

**Bibliographic details**


**PubMedID**
Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.