

Delfini Group™, LLC

*Evidence-based Clinical Consults,
Medical Education Seminars, Training & Tools*

Delfini Systematic Review Summary

Study Reference: Cash BD, Schoenfeld P, Chey WD. The utility of diagnostic tests in irritable bowel syndrome patients: a systematic review. *Am J Gastroenterol.* 2002 Nov;97(11):2812-9.

Date: 02/20/03

Reviewer: Michael Stuart MD

Type of study: Systematic Review

Study Purpose or Hypothesis: To determine the accuracy of the most commonly used tests for diagnosing organic GI in patients who meet symptom-based criteria for IBS.

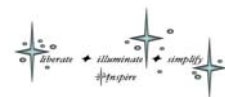
Outcomes: Pretest probability of the following conditions compared to prevalence of the conditions in the general population as determined by the best available evidence:

- Colitis
- Colorectal cancer
- Celiac disease
- Gastrointestinal infection
- Thyroid dysfunction
- Lactose malabsorption

STUDY CHARACTERISTICS – SYSTEMATIC REVIEWS

Clearly stated questions to the literature, determined in advance: Yes

- ✓ **Documented comprehensive search strategy:** Yes. A search of the online bibliographic databases MEDLINE and EMBASE identifying all relevant articles published between 1980 and 2001. Search terms: “colonic diseases, functional diagnosis” or “irritable, functional, or spastic” adjacent to “bowel or colon” along with key words: “blood,” “parasite,” “stool analysis,” “radiography,” “hydrogen breath testing,” “flexible sigmoidoscopy or colonoscopy or barium enema.”



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✓	Explicit, documented selection criteria chosen in advance for included studies: Yes. Studies with patients who met symptom-based criteria (symptom-based criteria used (Manning, Rome I/II, International Congress of Gastroenterology) for IBS along with the following criteria were included: 1) use of a cohort of IBS patients explicitly diagnosed via symptom-based criteria (Manning, Rome I, Rome II, or International Congress of Gastroenterology criteria); 2) performance of a commonly applied diagnostic test with a blinded comparison with an appropriate gold standard diagnostic test for organic GI disease; and/or 3) quantification of the results as either normal or abnormal in which an additional or alternative diagnosis of organic disease was made, based upon the test result, the quality and validity of trials about diagnosis .
✓	Explicit method for determining validity: Yes. The quality of each study selected for this systematic review was determined by assessing each study and assigning quality scores based on the following characteristics: 1) study population; 2) verification; 3) interpretation of test results; 4) patient selection; 5) data collection; 6) details of test; 7) details of reference test; and 8) details of population. Two evaluators using validity forms and the above criteria selected studies for review (>95% agreement—non agreements were resolved through discussion). The total score ranged from 0 to 8. Of 154 potentially relevant studies 6 were accepted as valid studies.
✓	Explicit method for combining results: Yes. Data were extracted from the 6 valid studies. To determine the pretest probability of organic GI disease in patients meeting symptom-based criteria for IBS, the prevalence of organic GI disease was extracted from study results and subsequently compared with the background prevalence based upon agreed upon published estimates of general population prevalence. The sensitivity and specificity of each diagnostic test to accurately rule in or rule out a specific organic GI disease among the patient population was calculated when adequate data were available. Because of the wide variation of study methodology, meta-analysis was not performed. Studies were classified as low quality if they scored in the lowest tertile or as medium-high quality if they scored in the middle-to-high tertile.
✓	Conclusions are supported by the evidence: Yes

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Reported Results: Among patients meeting symptom-based criteria for IBS, the pretest probability of inflammatory bowel disease, colorectal cancer, or infectious diarrheas is less than 1%. The pretest probability of IBD, lactose malabsorption, and thyroid dysfunction in patients with suspected IBS was similar to the prevalence of these disorders in the general population. Currently recommended diagnostic tests rarely identify organic GI disease in patients fulfilling symptom-based criteria for IBS. However, the pretest probability of celiac disease in patients meeting symptom-based criteria for IBS was 10 times higher than the prevalence of celiac disease in the general population.

Table 1: Summary of Diagnostic Tests and Prevalence of Organic Disease in Patients with IBS

Diagnostic Test	Gender (% Female)	Prevalence of Organic Disease (%)	Quality Score (Max 8)
Flex Sig, Barium Enema, Colonoscopy	72-82	0-1.31	5-6/8
Rectal Biopsy	82	0	6/8
CBC	71-81	0-0.33	5-6/8
Chemistries	81	1.02-1.33	5-6/8
Anti-gliadin antibody, flexible endomysial antibody (for diagnosis of Celiac Disease)	71	4.67	6/8
Fecal Occult Blood Testing	72-81	0-1.65	5/8
Hydrogen Breath Test	72-81	22.8-78	5/8
Abdominal Ultrasound	80	0	5/8

Table 2: Pretest Probability of Organic GI Disease in IBS Patients and Prevalence of Organic Disease in The General Population

Organic GI Disease	IBS Patients (Pretest Probability %)	General Population (Prevalence %)
Colitis/Inflammatory Bowel Disease	0.51-0.98	0.3-1.2
Colorectal Cancer	0-0.51	4-6
Celiac Disease	4.67	0.25-0.5
Gastrointestinal Infection	0-1.7	Unable to quantify: estimated to be 10-15%
Thyroid Dysfunction	6	5-9
Lactose Malabsorption	22-26	25

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Authors' Conclusions: Our results suggest that performing rigorous, invasive, and expensive diagnostic evaluations in potential study participants who clearly fulfill symptom-based criteria for IBS may not be necessary.

Reviewer's Conclusions: There are no lethal threats to validity in this systematic review of diagnostic tests for IBS. However, the one study evaluating the association of adult celiac disease with IBS was a case control study done at a referral center (university hospital in south Yorkshire, UK). Even though the methodology of the study was sound, this is a single study with case control methodology and subjects included in the study may not be representative of patients seen in primary care (population bias).

There is insufficient evidence to conclude that any of the evaluated diagnostic tests for irritable bowel syndrome results in improved outcomes for patients with IBS. There is insufficient evidence to recommend routine testing for organic disease following history and physical exam in patients who meet symptom-based criteria for IBS and have no warning symptoms or signs.

Clinical Implications: Patients should be made aware of this evidence and a shared decision-making process between clinician and patient should be utilized in determining whether diagnostic testing is to be performed. Some patients and clinicians may derive reassurance from knowing a diagnostic evaluation has ruled out organic disease. Others may wish to undergo basic laboratory testing, but not radiologic or endoscopic procedures. (The incidence of colon perforation in one study was found to be 1.96/1000 colonoscopies and 0.88/1000 sigmoidoscopies (21). Some patients may choose to undergo no diagnostic testing other than a hematocrit to rule out anemia. A diagnostic evaluation is indicated if the patient has "alarm" symptoms (see Box A algorithm), and management of these patients is beyond the scope of this guideline. Colon cancer screening and other screening or routine testing are not addressed in this guideline.