

Research article

Do published guidelines for evaluation of Irritable Bowel Syndrome reflect practice?

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Abstract

Background: The only US guidelines listed in the National Guideline Warehouse for the diagnosis of Irritable Bowel Syndrome (IBS) are the expert opinion guidelines published by The American Gastroenterology Association. Although the listed target audience of these guidelines includes family physicians and general internists, the care recommended in the guidelines has not been compared to actual primary care practice. This study was designed to compare expert opinion guidelines with the actual primary care provided and to assess outcomes in the 3 years following the IBS diagnosis.

Methods: This is a retrospective medical record review study using a random sample of incident IBS cases from all Olmsted County, Minnesota providers diagnosed between January 1, 1993 and December 31, 1995. Data was collected on all care and testing provided to the subjects as well as 3-year outcomes related to the IBS diagnosis.

Results: Of the 149 IBS patients, 99 were women and the mean age was 47.6 years. No patient had all of the diagnostic tests recommended in the guidelines. 42% had the basic blood tests of CBC and a chemistry panel. Sedimentation rate (2%) and serum thyroxine level (3%) were uncommon. Colon imaging studies were done in 41% including 74% of those over the age of 50. In the 3 years following the diagnosis, only one person had a change in diagnosis and no diagnoses of gastrointestinal malignancies were made in the cohort.

Conclusions: Primary care practice based diagnostic evaluations for IBS differ significantly from the specialty expert opinion-based guidelines. Implementation of the specialty guidelines in primary care practice would increase utilization with apparent limited improvement in diagnostic outcomes.

Background

Irritable bowel syndrome is a gastro-intestinal (GI) disorder of unknown etiology often described as a function-

al bowel problem. [1–3] The diagnosis of IBS rests on the occurrence of a set of symptoms and the exclusion of other GI pathology. [4–7] The only published US guidelines

for evaluation of patients with possible IBS have been developed by the American Gastroenterological Association (AGA).[3] Due to the lack of higher levels of evidence, the guidelines are based on expert opinion and are likely to reflect the clinical experience of these specialists with the small percent (6 to 8%)[8] of all IBS patients seen by gastroenterologists in the US. [9] Little has been written about the potential implications of implementing the only currently available IBS diagnostic guidelines[10] or how the guidelines compare to existing community practice.

Using a community population-based sample of subjects with an incident diagnosis of IBS, we reviewed the GI-related health care utilization and diagnostic evaluations completed around the time of first (incident) IBS diagnosis and compared those evaluations to the AGA guidelines for the diagnosis of IBS. In addition, we evaluated the utilization implications of implementing the AGA guidelines in this patient population. The purpose of the study is not to validate the guidelines but to see how they compare to current primary care practice and to understand the potential implications of full guideline implementation.

Methods

Setting

Olmsted County is a metropolitan statistical area (MSA) of 135,000 people 90 miles south of Minneapolis, Minnesota. The population is estimated to be 92 percent white non-Hispanic. [11] Olmsted County has local resources for primary, and specialty care. Previous studies estimate that over 98 percent of all Olmsted County residents' health care is delivered within Olmsted County [11] by the Mayo Medical Center (MMC), the Olmsted Medical Center (OMC) or the single solo practice family physician's office in Rochester.

Data Collection

The cohort was identified using the database of the Rochester Epidemiology Project (REP)[11,12] that collects all diagnoses made within all Olmsted County medical facilities and links all people in Olmsted County to all sources of health care they use. All people with a diagnosis of functional or irritable bowel syndrome (564.1) or spastic colon – psychogenic (306.4) during 1993–1995 were identified from the database. Broad criteria were used for the search to increase sensitivity at the risk of reducing specificity. This type of search strategy was possible since final subject selection relied on medical record review rather than only administrative data. [13] The initial search identified 1245 potential cases (a combination of incident and prevalent cases) of which 36 (2.9%) had previously refused general record review research authorization and thus could not be included in the study

according to Minnesota statute.[14] The goal was to identify 150 subjects for in-depth review using data from all sources of medical care each individual has used within the county. The sample size was selected based on the desire to have a sufficient sample to provide estimates of compliance with individual elements of the guidelines with confidence intervals of $\pm 5\%$ for those tests with very high and very low compliance and $\pm 8\%$ for those near 50% compliance. This is a descriptive study and therefore no other types of sample size calculations were made.

The 1245 people identified by the initial search of the REP database, were put into a random order and the medical records of potential subjects' were screened until the final cohort of 150 patients who met the inclusion criteria were identified. A total of 416 potential IBS subjects were screened to identify the final incident cohort of 150 subjects who had lived in Olmsted County for at least 3 years and had no previous diagnoses of IBS listed in any medical records in the county. The minimum of 3 years of residency within Olmsted County was used to improve the likelihood that review of the complete available medical records would identify prevalent rather than incident cases of IBS. The assurance that patients represented an incident diagnosis of IBS was especially important in this study comparing diagnostic evaluations completed to the recommended guidelines for initial evaluation. Potential subjects from the group of 416 were excluded during screening primarily for 1 of 3 reasons: they were prevalent rather than incident cases of IBS ($n = 67$), no actual diagnosis of IBS was documented in any of the subject's medical records ($n = 41$) or they had been an Olmsted County resident for < 3 years ($n = 93$). Another 65 people had a group of miscellaneous reasons for exclusion including incident diagnosis date outside the window of this study, age < 16 at diagnosis, and missing records.

All medical records of the 150 subjects in the final cohort (those meeting the eligibility criteria) were reviewed in detail to abstract data on demographic characteristics, visits for gastro-intestinal or abdominal problems, and non-GI symptom-related visits from 10 years before the first IBS diagnosis to 3 years after. GI symptom-related visits were those in which any symptom, sign or complaint referable to the GI tract was recorded. This included such complaints as diarrhea, abdominal pain, constipation, change in stool habits, and vomiting. All other visits were considered non-GI related. Information on the presenting complaint, specialty of physician seen, tests ordered and site of the visit (emergency department, office, or hospital) was recorded. Data collection began at the earliest visit that occurred 10 years or less before the incident IBS diagnosis. Long term data were

available for most patients (mean = 7.3 years, median 7 years) and were used to assure that there was no previous diagnosis of IBS. The data of most interest for this comparison of diagnostic evaluations completed and the testing recommended in the guidelines were visits in 2 years before the diagnosis of IBS. Diagnostic outcomes were assessed during the 3 years after the incident diagnosis. These data were present in 100% of subjects.

Data analysis

One subject revoked general research authorization (required by Minnesota statute) during data analysis and thus the analysis was completed for the remaining 149 subjects. Descriptive information is presented as summary statistics.

Health care utilization was stratified into 2 major time periods: a) the 60 days surrounding the incident IBS diagnosis (30 days before to 30 days after) called the immediate diagnostic period; and b) the 2 years prior to the diagnosis, excluding the 30 days before termed the extended diagnostic period. For referral to a GI specialist we also included the 1 year after the diagnosis since referral for non-urgent conditions may take a considerable period of time. The designation of the 60-day "diagnostic period" was based on the clinical judgement of the authors and was felt to reflect the usual time required to complete a diagnostic evaluation. The percent of subjects using each of the recommended services was calculated for the diagnostic period and then for the extended immediate diagnostic period (included the 2 year period prior to the incident diagnosis). The extended window of time was important for such tests as colonoscopy that may not be repeated within 2 years of a normal examination.

Comparisons of test utilization between age groups, genders and those who did and did not have a gastroenterologist involved in their care were made using the Wilcoxon rank-sum test. Chi-square tests were used to compare frequencies of events.

The potential impact of fully implementing the AGA guidelines (Table 1) was assessed. The additional tests that would be needed for full implementation was calculated by subtracting the tests provided in this study from tests that would need to be completed if all subjects' evaluations met the guidelines. Diagnostic outcomes (e.g. changes in diagnoses from IBS to another GI disease in the 3 years following first IBS diagnosis) is reported as a single percent of total diagnosis.

This study was approved by the Olmsted Medical Center and the Mayo Medical Center Institutional Review Boards. The funding agency had no role in study design

Table 1: Diagnostic evaluation recommended based on US American Gastroenterological Association guidelines.

| |
|--|
| 1. History and physical examination |
| 2. Diagnostic testing |
| CBC |
| Chemistry panel |
| Sedimentation rate |
| Stool for O & P |
| Stool for occult blood |
| Flexible sigmoidoscopy |
| IF > 50, colonoscopy or barium enema and sigmoidoscopy |
| For diarrhea predominant: |
| Small bowel radiograph |
| Lactose/dextrose H2 breathing test |
| For constipation predominant: |
| Fiber trial |
| For pain predominant: |
| Plain film of abdomen |

or right of approval of manuscripts submitted for publication. The author who worked for the funding agency was one of the epidemiologist members of the design team and reviewed the final draft of the manuscript.

Results

Two thirds of the 149 subjects (n = 99) were women. The mean age of the subjects at the time of diagnosis was 47.6 years (s.d. 17.8 years and range 16 to 91 years) and was the same for men and women. Most of the IBS diagnoses (94%) were made by family physicians and general internists with 13% of subjects seeing a gastroenterologist at any time in the period 2 years before to 1 year after the diagnosis.

Table 2 summarizes the percent of people having each test or group of tests that are recommended for diagnostic evaluation by the AGA guidelines. In this cohort, testing did not vary significantly by sex. Only the completion of some type of colon imaging (flexible sigmoidoscopy, colonoscopy or barium enema) varied by age with 74% (n = 46) of those 50 and older at diagnosis versus 38% (n = 33) of those younger than 50 at diagnosis having one of the tests documented. Since the guidelines were developed by a panel of gastroenterologists, the compliance with the guidelines in those subjects seeing a GI specialist was also calculated (n = 19). All types of colon imaging were more common in those with GI specialty visits [79% (n = 15) versus 50% (n = 64), p > 0.05] but only the increase in flexible sigmoidoscopies reached statistical significance [53%, (n = 10) versus 19%, (n = 25), p < 0.05]. The only other diagnostic tests that were statistically more likely to be completed in those seen by a gastroenterologist were stool testing for ova and parasites [53%,

Table 2: Diagnostic testing proximate to the incident IBS diagnosis

| Test | Diagnosis Period n (%) | -2yr to + 30 day n (%) | Additional number of subjects (%) needing to complete testing to comply with IBS evaluation guidelines N = 149 (%) |
|---------------------------|---------------------------|---------------------------|--|
| CBC | 53 (36) | 68 (46) | 96 (64) |
| Chemistry panel | 50 (34) | 64 (43) | 99 (66) |
| Sedimentation Rate | 3 (2) | 5 (3.3) | 146 (98) |
| Stool for O & P | 26 (17) | 31 (21) | 123 (83) |
| Stool for Occult blood | 16 (11) | 17 (11) | 133 (89) |
| Flexible sigmoidoscopy | 25 (17) | 10 (7) | 112 (76) |
| Colon imaging+ | 61 (41) | 79 (53) | 70 (47) |
| Referral to GI specialist | 6 (4) | 13 (9) | NA |

+ colonoscopy, barium enema or flexible sigmoidoscopy (to allow greater inclusiveness by adding alternatives to flexible sigmoidoscopy)

(n = 10) versus 16%, (n = 21), p < 0.05] and fecal occult blood [26%, (n = 5) versus 9% (n = 12), p < 0.05].

The final column of Table 2 reflects the additional number of people (and percent of the subjects) who would require each category of test to comply with the AGA guidelines [3] for diagnosis of IBS.

In those subjects with primarily diarrhea (n = 82), the guidelines suggest a small bowel radiograph and a lactose/dextrose H2 breath test. Twelve subjects (15%) had a small bowel radiograph and none had H2 breath testing. For those with abdominal pain (n = 110) the guidelines recommend a plain film of the abdomen. Thirteen of these patients (12%) had a flat plate.

In the three years after the diagnosis of IBS, only one subject had any change in diagnosis from IBS to another condition related to the symptoms. This 23-year old subject was diagnosed with inflammatory bowel disease approximately one year after the initial IBS diagnosis. No subject was diagnosed with any type of GI-related malignancy and there were no deaths in the cohort.

Discussion

The evaluation of IBS in this community population-based cohort of primary care patients differed significantly from that recommended by the AGA guidelines [3] for IBS evaluation. The evaluation of GI-related signs and symptoms appeared to be based primarily on history and physical examination with minimal specific testing or imaging of the GI tract. The inclusion of a GI specialist in the subject's care increased but did not guarantee compliance with the AGA guidelines.

The diagnostic guidelines developed and published by the AGA are available in several formats including as part of the guideline warehouse sponsored by the Agency for Health Care Research and Quality (AHRQ) [www.guidelines.gov/ibs] where they are listed as applicable to family medicine, internal medicine, gastroenterology and primary care. Physicians who are familiar with the medical literature will know that almost all elements of the IBS guideline required expert opinion since little other evidence was available. Unfortunately, the level of evidence used is not clearly stated. [15] Furthermore, the AGA guidelines were developed by a panel limited to gastroenterologist physicians. However, gastroenterologists see only a minority of IBS patients.[8] Over 94% of the subjects in this sample were initially evaluated by family physicians and general internists with only 13% ever seeing a gastroenterologist in the 7 years before or 3 years after the incident IBS diagnosis. Therefore, subspecialty developed guidelines may not be appropriate for the majority of IBS care especially when the guidelines have to be based primarily on opinion which likely reflects only the experience of physicians included in the guideline development panel.

The complete printed position statement that accompanies the original publication of the AGA guidelines does note the potential lack of applicability to primary care patients (> 85% of all IBS patients) stating "...Primary care patients may be different and may be followed with expectant management". [3] However, expectant management is not specified nor are the specific indications for referral to a specialist presented. The position paper also recognizes that "...there is a risk of overdoing the diagnostic evaluation to rule out organic disease". Within the guideline warehouse [www.guidelines.gov] these

modifiers are missing. No data are presented in any format that provide any rationale for extending the AGA guidelines to primary care practice.

The additional testing that would be required to meet the AGA guidelines [3] is extensive (Table 2) and would likely result in significant increases in health care expenditures. Even if the guidelines were applied only to those visiting a gastroenterologist (assumed to be 13% of subjects in our study), additional health care utilization would be required. The anticipated gain in improved diagnostic accuracy appears to be limited since in this cohort only one diagnosis was changed from IBS in the 3 years of follow up after the incident IBS diagnosis.

The value of completing all of the additional testing recommended by the guidelines cannot be completely assessed with this data set. However, the outcome of no new GI malignancies in the three years of follow up of this cohort is comparable to other studies of prognosis in IBS [16] and suggests additional testing would be of limited value in identifying life threatening conditions. The value of the additional testing or referrals on the patient's quality of life or other health conditions is not known and requires additional research. The format of that additional research might be similar to the studies for other guidelines such as the study of the cost implications of implementing guidelines that recommend radiographs for evaluation of low back pain. [17] Such a study for IBS guidelines would need to assess the added value of the extensive work-up recommended by the specialty guidelines in a larger population over a longer period of time and could be compared to the outcomes (including patient satisfaction) of a group assigned to more limited evaluation as completed in this study. It would be important to determine if the additional tests or referrals would identify other diseases, serve to more fully reassure the patient or simply have become what patients and specialist expect to occur with a GI specialty visit. [18]

Failure to comply with one aspect of the guidelines is worth specific mention. While subjects over age 50 were more likely to have colon-imaging studies, 25% of them had no colon imaging studies or assessment of fecal occult blood. This is not consistent with the published evidence based U.S. Preventive Services Task Force (USPSTF) guidelines for routine screening and preventive care related to colon cancer for **asymptomatic** people 50 years and older and appear to represent missed screening opportunities. [19,20] The addition of a GI specialist in the patient's care increased but did not guarantee compliance with the USPSTF guidelines for screening studies of the colon.

The AGA[3] had little evidence of any higher level than expert opinion on which to base IBS guidelines. The disparity between the testing family physicians and general internists choose to evaluate potential IBS and that recommended in the guidelines highlights the potential impact of using subspecialty experts to define recommended care in a primary care condition with limited research based evidence. If indeed gastroenterologists do see a sicker or otherwise different group of people with IBS than seen by family physicians and general internists then more extensive evaluation by gastroenterologists would be appropriate to consider. If the GI specialty patients are no more likely to have other diseases but are just more likely to be dissatisfied with care and need additional reassurance, more testing may not be the most cost effective solution. Alternative considerations such as group therapy, support groups or additional education may be a better use of resources and time. [21] In this population, the disparity between the care given and that recommended reinforces the value of understanding the full spectrum of disease when developing opinion based guidelines as well as the importance of developing evidence based guidelines as opposed to expert opinion based guidelines whenever possible.

This is a relatively small cohort of primary care patients from a single county. Practices in other communities and with patients of more diverse racial and ethnic background may be different. Medical records rarely reflect every thing that happens during any medical encounter. It is possible that additional testing did occur. However, tests often involve people other than the physician, are billable items in the non-capitated care environment we studied and therefore significant amounts of undocumented testing is unlikely. The use of medical records did allow the date of the incident diagnosis to be pinpointed and allowed us to assess diagnostic evaluation in temporal relation to the incident diagnosis making comparison with diagnostic guidelines possible. Our limited sample size may not have been sufficient to allow accurate assessment of missed GI malignancies.

Conclusion

Community based evaluation of IBS differs from the consensus based guidelines developed by specialists. The limited testing done in this population appeared to limit health care expenditures without adversely impacting the recognition of life threatening GI disease. To allow physician assessment of the potential applicability of published guidelines, the guidelines should always be accompanied by information regarding the target population (i.e. primary care patients versus specialty care patients) and the evidence basis of the guidelines.

Competing interests

None declared

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