Complete Summary

GUIDELINE TITLE

American Gastroenterological Association medical position statement: evaluation of dyspepsia.

BIBLIOGRAPHIC SOURCE(S)

Talley NJ. American Gastroenterological Association medical position statement: evaluation of dyspepsia. Gastroenterology 2005 Nov;129(5):1753-5. [16 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Gastroenterological Association medical position statement: evaluation of dyspepsia. Gastroenterology 1998 Mar;114(3):579-81.

According to the guideline developer, the Clinical Practice Committee meets three times a year to review all American Gastroenterological Association Institute (AGAI) guidelines. This review includes new literature searches of electronic databases followed by expert committee review of new evidence that has emerged since the original publication date.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

May 2, 2007, Antidepressant drugs: Update to the existing black box warning
on the prescribing information on all antidepressant medications to include
warnings about the increased risks of suicidal thinking and behavior in young
adults ages 18 to 24 years old during the first one to two months of
treatment.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Functional dyspepsia and the major organic diseases causing dyspepsia (i.e., gastroduodenal ulcer, atypical gastroesophageal reflux, and gastric cancer)

GUIDELINE CATEGORY

Diagnosis Evaluation Management

CLINICAL SPECIALTY

Family Practice Gastroenterology Internal Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To assist the primary care physician and gastroenterologist with the diagnosis and treatment of new-onset dyspepsia
- To review all the available management strategies in the literature and critically evaluate them to help develop practice recommendations for dyspepsia and functional (nonulcer) dyspepsia

TARGET POPULATION

Adult patients with new-onset dyspepsia

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Differential diagnosis of dyspepsia: clinical history for alarm symptoms (e.g., weight loss, recurrent vomiting, progressive dysphagia, evidence of bleeding or anemia, or family history of cancer), upper endoscopy
- 2. Management options for new-onset dyspepsia:
 - Empirical H2-receptor antagonist therapy

- Empirical proton pump inhibitor (PPI) therapy
- Testing for Helicobacter pylori infection by ¹³C- urea breath test or stool antigen test and treatment of positive cases followed by acid suppression if the patient remains symptomatic
- Early endoscopy alone
- Early endoscopy with biopsy for *H. pylori* and treatment if positive
- Acid suppression followed by endoscopy and biopsy if the patient remains symptomatic
- H. pylori test and treat with endoscopy if the patient remains symptomatic

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Prevalence of gastric cancer
- Reduction of dyspeptic symptoms
- Cost-effectiveness of treatments

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE and Current Contents searches were performed from April 1997 (the date of completion of the previous report) to July 2004 using the Medical Subject Heading (MeSH) terms dyspepsia, nonulcer dyspepsia, functional dyspepsia, and *H. pylori*. In addition, specific searches were performed with the support of the Cochrane Upper Gastrointestinal and Pancreatic Disease Group, and these are highlighted in the appropriate sections of the original guideline document. The reports that considered management of dyspepsia and functional dyspepsia were retrieved and reviewed, and their reference lists were checked for additional citations. The authors met to review the available data in order to produce currently applicable recommendations for the United States.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendations are based upon the interpretation and assimilation of scientifically valid research, derived from a comprehensive review of published literature. Ideally, the intent is to provide evidence based upon prospective, randomized placebo-controlled trials; however, when this is not possible the use of experts' consensus may occur.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developer performed a systematic review of published decision analysis where various methods and results of cost analyses were considered in the larger context of decision-making. Refer to the technical companion document for details.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The American Gastroenterological Association (AGA) Clinical Practice and Economics Committee approved this guideline on April 22, 2005. The American Gastroenterological Association Governing Board approved it on October 6, 2005.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Management Recommendations

Patients 55 years of age or younger without alarm features should receive *Helicobacter pylori* test and treat followed by acid suppression if symptoms remain (see Figure 2 in the original guideline document). *H. pylori* testing is optimally performed by a ¹³C-urea breath test or stool antigen test. Proton pump inhibitors (PPIs) are the drug class of choice for acid suppression. Those who are *H. pylori* negative should be prescribed an empirical trial of acid suppression with a PPI for 4 to 8 weeks. Empirical PPI therapy is the most cost-effective approach in populations with a low prevalence of *H. pylori* (10% or less). The recommendation to test and treat is based on randomized controlled trials and the possible impact of eradication in preventing future gastric adenocarcinoma.

Patients who respond to *H. pylori* test and treat or PPI therapy can be managed without further investigation. Endoscopy usually adds little in young patients who continue to have upper gastrointestinal symptoms without alarm features despite *H. pylori* test and treat and PPI therapy. There is a very low probability of finding relevant organic disease in this group of patients. Endoscopy may reassure some young patients with continued symptoms, but evidence suggests this is not the case in those who are most anxious and that many *H pylori* test-and-treat patients can be managed in the long term without further investigation. Endoscopy may be appropriate for some young patients who continue to have dyspepsia, but this should be considered in the wider context of reevaluating the symptoms and the diagnosis. Endoscopy appears not to be a cost-effective use of resources compared with alternatives such as screening for colorectal cancer (see Figure 3 in the original guideline document).

The value of alarm symptoms in younger patients is controversial. A systematic review of alarm symptoms suggests that these are not very useful in diagnosing upper gastrointestinal malignancy. However, although the yield of endoscopy is low, it is recommended for patients older than 55 years of age and for younger patients with alarm features (e. g., weight loss, progressive dysphagia, recurrent vomiting, evidence of gastrointestinal bleeding, or family history of cancer) presenting with new-onset dyspepsia. Upper gastrointestinal malignancy becomes more common after age 55 years. Biopsy specimens should be obtained for H. pylori at the time of endoscopy, and eradication therapy offered to those who are infected because this may reduce the risk of subsequent peptic ulcer disease and gastric malignancy. Endoscopy should be preferred over upper gastrointestinal radiography because it has greater diagnostic accuracy and biopsy specimens can be taken for H pylori infection. After endoscopy, and H. pylori eradication therapy if positive, treatment should be targeted at the underlying diagnosis. Most patients will have functional dyspepsia and can be offered acid suppression therapy.

Patients of any age who continue to have symptoms despite appropriate investigations, therapy, and reassurance are a difficult group to manage (see Figure 4 in the original guideline document). Symptoms should be reassessed and prokinetic agents, antidepressant therapy, or psychological treatments considered, although the benefits of these approaches are not established.

CLINICAL ALGORITHM(S)

Clinical algorithms are provided in the original guideline document for:

- Initial Management of Dyspepsia
- Management of Dyspepsia Based on Age and Alarm Features
- Endoscopy in Patients Who Have Failed Empirical Therapy
- Management of Functional Dyspepsia

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

The recommendations are based upon the interpretation and assimilation of scientifically valid research, derived from a comprehensive review of published literature.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The management of dyspepsia using the recommendations should result in fewer upper gastrointestinal endoscopies performed, particularly in patients 55 years of age and younger. There will be an increase in the number of noninvasive *Helicobacter pylori* tests performed and treatments for the infection. Because these are less expensive than endoscopy, the overall cost of managing dyspepsia should decrease and the number of patients with dyspepsia receiving effective treatment should increase.

POTENTIAL HARMS

The risks of upper endoscopy are very low; they have varied between 1 in 330 to 1 in 2700, but recent data are limited. Cardiopulmonary complications have been reported to be most frequent (varying from 1/690 to 1/2600) followed by perforation (1/900 to 1/4200) and bleeding (1/3400 to 1/10,000). Deaths are rare (ranging from 1/3300 to 1/40,000. These rates include therapeutic endoscopies, which account for a disproportionate proportion of the complications. The risks of simple diagnostic endoscopy at present probably correspond to the lowest figures listed.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

 The results of all decision analyses on management of dyspepsia critically depend on the assumptions included. These may not reflect current clinical practice and the results of the decision analyses must be viewed very cautiously because they may overestimate the benefits of *Helicobacter pylori* eradication in economic terms.

- The recommendations made in this report are a framework for the management of dyspepsia in a North American population. Select populations with a high incidence of gastric cancer in young individuals or communities of recent immigrants in the United States may need a different strategy. The recommendations are not intended to replace clinical judgment in these settings.
- The Medical Position Statements (MPS), developed under the aegis of the American Gastroenterological Association (AGA) and its Clinical Practice Committee (CPC), were approved by the AGA Governing Board. The data used to formulate these recommendations are derived from the data available at the time of their creation and may be supplemented and updated as new information is assimilated. These recommendations are intended for adult patients, with the intent of suggesting preferred approaches to specific medical issues or problems. They are based upon the interpretation and assimilation of scientifically valid research, derived from a comprehensive review of published literature. Ideally, the intent is to provide evidence based upon prospective, randomized, placebo-controlled trials; however, when this is not possible the use of experts' consensus may occur. The recommendations are intended to apply to healthcare providers of all specialties. It is important to stress that these recommendations should not be construed as a standard of care. The AGA stresses that the final decision regarding the care of the patient should be made by the physician with a focus on all aspects of the patient's current medical situation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Nov 8 (revised 2005 Nov)

GUIDELINE DEVELOPER(S)

American Gastroenterological Association Institute - Medical Specialty Society

SOURCE(S) OF FUNDING

American Gastroenterological Association Institute

GUIDELINE COMMITTEE

American Gastroenterological Association Clinical Practice and Economics Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author: Nicholas J. Talley

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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databases followed by expert committee review of new evidence that has emerged since the original publication date.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Gastroenterological Association</u> Institute (AGAI) Web site.

Print copies: Available from American Gastroenterological Association Institute, 4930 Del Ray Avenue, Bethesda, MD 20814.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Talley NJ, Vakil NB, Moayyedi P. American Gastroenterological Association technical review on the evaluation of dyspepsia. Gastroenterology 2005 Nov;129(5):1756-1780 [160 references].

Electronic copies: Available from the <u>American Gastroenterological Association</u> Institute (AGAI) Web site.

Print copies: Available from American Gastroenterological Association Institute, 4930 Del Ray Avenue, Bethesda, MD 20814.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 1, 1998. It was verified by the guideline developer on December 1, 1998. This NGC summary was updated by ECRI on January 16, 2006. The updated information was verified by the guideline developer on February 15, 2006. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs.

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