Complete Summary

GUIDELINE TITLE

Management of gastroesophageal reflux disease (GERD).

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Management of gastroesophageal reflux disease (GERD). Ann Arbor (MI): University of Michigan Health System; 2002 Mar. 9 p. [4 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Gastroesophageal reflux disease (GERD)

GUIDELINE CATEGORY

Diagnosis
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Pharmacists

Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To implement a cost-effective and evidence-based strategy in the diagnosis and treatment of gastroesophageal reflux disease (GERD)

TARGET POPULATION

Adults with suspected or confirmed gastroesophageal reflux disease (GERD)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. History
2. Testing
    - Esophageal pH monitoring
    - Endoscopy
    - Barium radiology
3. Therapeutic trials of acid suppression therapy

Treatment

1. Lifestyle modifications
    - Head elevation
    - Avoidance of certain foods and large meals
    - Weight loss
    - Smoking cessation and alcohol minimization
    - Avoidance of lower esophageal sphincter (LES) pressure-lowering medications
2. Pharmacologic treatment
    - Histamine type-2 receptor antagonists (H2RAs) (nizatidine [Axid], famotidine [Pepcid], cimetidine [Tagamet], ranitidine [Zantac])
    - Proton pump inhibitors (PPIs) (pantoprazole [Protonix], lansoprazole [Prevacid], rabeprazole [Aciphex], omeprazole [Prilosec], esomeprazole [Nexium])
    - Supplemental acid-neutralizing agents (carafate, antacids)
    - Over-the-counter (OTC) remedies (antacids, combined antacid/alginic acids, H2RAs)
3. Anti-reflux surgery
4. Alternative endoscopic treatments
    - Radiofrequency heating of the gastroesophageal (GE) junction (Stretta)
    - Endoscopic gastroplasty (endocinch)

Maintenance Regimens

1. Step-up therapy. Start with less potent agents and move up for treatment response.

2. Step-down therapy. Start with potent acid suppression initially and decrease dose or agents or treatment response.

Follow Up

1. Referral to specialists
2. Further diagnostic testing for those non-responsive to acid suppression therapy or at risk for complications.
    - Esophagogastroduodenoscopy (EGD)
    - Ambulatory pH monitoring of intraesophageal acidity
    - Esophageal dilation for stricture formation

Management Considerations in Special Circumstances (Older Adults, Asthma and GERD)

Controversial Areas (Screening for Barrett´s Esophagus, Treatment for Helicobacter pylori)

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Rate of symptomatic relief
- Esophagitis healing rates
- Medication and treatment side effects

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search for this project was conducted on Medline prospectively using the major keywords of: gastroesophageal reflux, human adults, English language, clinical trials, and guidelines.

Terms used for specific topic searches within the major key words included: symptoms (1988+), endoscopy (1995+), pH recording (1995+), manometry (1995+), video esophagography (1995+), acid suppression (1996+), lifestyle (1998+); diet therapy; weight loss: life style; health behavior; cacao; peppermint; dietary fats; ethanol; alcoholic beverages; posture; head of bed (hob); recumbent; chocolate; antacids (1976+), alginic acid (1988+), carafate (1988+), prokinetic agents (1995+), H2 receptor antagonists (1978+), proton pump inhibitors (1988+), fundoplication (1980).

Detailed search terms and strategy available upon request. The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was supplemented with very recent

information available to expert members of the panel, including abstracts from recent meetings and results of clinical trials. Negative trials were specifically sought. The search was a single cycle.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

An economic appraisal reviewing different treatment modalities and their cost-effectiveness was reviewed. Proton pump inhibitors were considered more cost effective than H2 receptor antagonists in those with documented erosive esophagitis.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was reviewed at clinical conferences of the University of Michigan Health System (UMHS) family medicine, general medicine, pediatrics, otolaryngology, and by the Guidelines Workgroup (community and UMHS physicians) of MCARE (a managed care organization).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing, possible side effects, and cost of medications; esophagitis classification scale; other interventions; considerations for special patient populations (older adults; patients with asthma, Barrett´s esophagus, or H. pylori positivity). Definitions for the levels of evidence (A, B, C, D) are provided at the end of the Major Recommendations field.

Diagnosis

- History. A well-taken history is essential in establishing the diagnosis of gastroesophageal reflux disease (GERD). If the classic symptoms of heartburn and acid regurgitation clearly dominate a patient´s history, they can help establish the diagnosis of GERD with sufficiently high specificity. The sensitivity toward diagnosis remains low, however. Atypical symptoms, although commonly present, cannot sufficiently make the clinical diagnosis of GERD. (Refer to Table 1 in the original guideline document for details.) [B]
- Testing. No gold standard exists for the diagnosis of GERD [A]. Although pH probe is accepted as the standard with a sensitivity of 85% and specificity of 95%, false positives and false negatives still exist [B]. Endoscopy lacks sensitivity in determining pathological reflux. Barium radiology has limited usefulness in the diagnosis of GERD and thus is not recommended [B].
- Therapeutic trial. An empiric trial of acid suppression therapy can identify patients with GERD who do not have alarm symptoms [A] and may be helpful in the evaluation of those with atypical manifestations of GERD, specifically, noncardiac chest pain (NCCP) [B].

Treatment

- Lifestyle modifications. Lifestyle modifications should be recommended throughout the treatment of GERD but there is little evidence to support this information [D].
- Pharmacologic treatment. Histamine type-2 (H2) receptor antagonists, past prokinetics, and proton pump inhibitors have shown efficacy in the treatment of GERD [A]. Past prokinetics have been as effective as H2 antagonists but are currently not available [A]. Carafate and antacids are ineffective in the treatment of GERD [A], but may be used as supplemental acid-neutralizing agents for certain patients with GERD [D].
    - Documented erosive esophagitis. Initial proton pump inhibitor (PPI) therapy is the treatment of choice in acute and maintenance therapy for patients with documented erosive esophagitis [A].

    - Non-erosive reflux disease. Step-up (H2 antagonists followed by proton pump inhibitor [PPI] if no improvement) and step-down (PPI followed by the lowest dose of acid suppression) therapy are equally effective for both acute treatment and maintenance [C].
    - Proton pump inhibitors. Proton pump inhibitors (PPIs) should be given 30 to 60 minutes prior to a meal to optimize effectiveness [B].
- Surgery. Anti-reflux surgery is an alternative modality in the treatment of GERD in patients who have documented chronic reflux with recalcitrant symptoms [A].
- Other endoscopic modalities. Some alternative endoscopic modalities are less invasive and have fewer complications, but are also likely to have lower response rates than antireflux surgery [C].

Follow Up

- Symptoms unchanged. If symptoms remain unchanged in a patient who has had a prior normal endoscopy, evidence for the need for repeat endoscopy is not known, but currently not recommended [C].
- Warning signs. Patients with warning signs and symptoms suggesting complications from GERD should be referred to a GERD specialist. (Refer to Table 2 in the original guideline document for details.)
- Risk for complications. Consider further diagnostic testing (e.g., esophagogastroduodenoscopy [EGD], pH monitoring) for those who do not respond to acid suppression therapy [C]. Further diagnostic testing should also occur in patients with a chronic history of GERD who are at risk for complications (e.g., Barrett´s esophagitis, adenocarcinoma, stricture). Chronic reflux has been suspected to play a major role in the development of Barrett´s esophagus, yet it is unknown if outcomes can be improved through surveillance and medical treatment [D]. Anti-reflux therapy has been shown to reduce the need for recurrent dilation from esophageal stricture formation [A].

Definitions:

Levels of Evidence

Levels of evidence reflect the best available literature in support of an intervention or test.

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

The original guideline document contains a clinical algorithm for diagnosis and treatment of gastroesophageal reflux disease (GERD).

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see Major Recommendations).

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Appropriate and cost-effective diagnosis and treatment of gastroesophageal reflux disease

Specific Benefits

- Solid evidence from several randomized controlled trials has shown that proton pump inhibitors are more effective than both histamine type-2 receptor antagonists (H2RAs) and placebo in controlling symptoms from erosive reflux disease (83% compared to 60% and 27%, respectively) over a 4 to 8 week period.
- In the treatment of erosive esophagitis, proton pump inhibitors had faster healing rates than either H2 receptor antagonists or placebo (78% compared to 50% and 24%, respectively) over a 4-8 week period. No randomized controlled trials have examined therapy for a longer period of time.

POTENTIAL HARMS

Histamine Type-2 Receptor Antagonists (H2RAs)

Associated with rare cytopenias, gynecomastia, liver function test abnormalities, and hypersensitivity reactions.

Anti-reflux Surgery

Post-surgical complications occur in up to 20% of patients and include:

- Solid food dysphagia, which occurs in 10% of patients with 2% to 3% having permanent symptoms.
- Gas bloating, which occurs in 7% to 10% of patients
- Diarrhea, nausea and early satiety, which occur rarely

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2002 Mar

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

University of Michigan Health System

GUIDELINE COMMITTEE

Gastroesophageal Reflux Disease (GERD) Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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Team Members: Van Harrison, PhD; Joel Heidelbaugh, MD; Timothy Nostrant, MD

Guidelines Oversight Team: Connie Standiford, MD; Lee Green, MD, MPH; Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

Team Member	Company	Relationship
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Timothy Nostrant, MD	Astra Zeneca, TAP, Wyeth, Janssen, Merck, Glaxo	Consultant and speakers bureaus (all)

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available for download (in Portable Document Format [PDF]) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 7, 2003. The information was verified by the guideline developer on February 4, 2003.

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