



## Complete Summary

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### GUIDELINE TITLE

Guidelines on the use of esophageal pH recording.

### BIBLIOGRAPHIC SOURCE(S)

American Gastroenterological Association medical position statement: guidelines on the use of esophageal pH recording. *Gastroenterology* 1996 Jun; 110(6):1981.  
[PubMed](#)

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## SCOPE

### DISEASE/CONDITION(S)

Gastroesophageal Reflux Disease (GERD)

### GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness  
Diagnosis  
Evaluation

### CLINICAL SPECIALTY

Gastroenterology  
Internal Medicine

### INTENDED USERS

Physicians

### GUIDELINE OBJECTIVE(S)

To assist the physician in the appropriate use of esophageal pH recording in patient care.

The objects of the review are: (1) to discuss the technical aspects and limitations of performing clinical ambulatory esophageal pH studies; and (2) to summarize current understanding of the diagnostic criteria of gastroesophageal reflux, emphasizing the potential role of 24-hour ambulatory esophageal pH monitoring in diagnosis and management.

#### TARGET POPULATION

Patients with gastroesophageal reflux disease (GERD).

#### INTERVENTIONS AND PRACTICES CONSIDERED

Esophageal pH recording

#### MAJOR OUTCOMES CONSIDERED

Indications for the proper use of esophageal pH recording

### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

This critical assessment was accomplished by retrieving and reviewing data published in the medical literature. For each syndrome, relevant key words were used to search the U.S. National Library of Medicine database between 1980 and September 1994. The descriptors used for the search were hydrogen ion concentration, esophagus or (exploded) esophageal diseases, and (exploded) monitoring, physiologic. The search identified 433 citations. Papers were included in the discussion if (1) they were designed to address one of the clinically relevant objectives enumerated above, (2) the pH recording methodology used was valid and consistent with current methodological standards, and (3) the reported findings were based on an appropriate experimental design. Additionally, selected studies published during the review process of this manuscript (September 1994 to November 1995) that the authors believed to be of great significance were included in the final draft.

#### NUMBER OF SOURCE DOCUMENTS

433 source documents

#### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

#### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Because of variations in study populations and protocols and the lack of a sufficient number of comparable papers, the authors did not believe that a pooled statistical analysis of results was appropriate in addressing clinical utility.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

External Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following external review, the document was approved by the AGA Patient Care Committee on January 25, 1996 and by the AGA Governing Board on February 3, 1996.

## RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

- Esophageal pH recording is indicated to document abnormal esophageal acid exposure in an endoscopy-negative patient being considered for surgical antireflux repair (pH study done after withholding antisecretory drug regimen for > 1 week).

- Esophageal pH recording is indicated to evaluate patients after antireflux surgery who are suspected to have ongoing abnormal reflux (pH study done after withholding antisecretory drug regimen for > 1 week).
- Esophageal pH recording is indicated to evaluate patients with either normal or equivocal endoscopic findings and reflux symptoms that are refractory to proton pump inhibitor therapy (pH study done after withholding antisecretory drug regimen for  $\geq$  1 week if the study is done to confirm excessive acid exposure or while taking the antisecretory drug regimen if symptom-reflux correlation is to be scored).
- Esophageal pH recording is possibly indicated to detect refractory reflux in patients with chest pain after cardiac evaluation using a symptom reflux association scheme, preferably the symptom association probability calculation (pH study done after a trial of proton pump inhibitor therapy for at least 4 weeks).
- Esophageal pH recording is possibly indicated to evaluate a patient with suspected otolaryngologic manifestations (laryngitis, pharyngitis, chronic cough) of gastroesophageal reflux disease after symptoms have failed to respond to at least 4 weeks of proton pump inhibitor therapy (pH study done while the patient continues taking their antisecretory drug regimen to document the adequacy of therapy).
- Esophageal pH recording is possibly indicated to document concomitant gastroesophageal reflux disease in an adult onset, nonallergic asthmatic suspected of having reflux-induced asthma (pH study done after withholding antisecretory drugs for > 1 week). Note: a positive test does not prove causality!
- Esophageal pH recording is not indicated to detect or verify reflux esophagitis (this is an endoscopic diagnosis).
- Esophageal pH recording is not indicated to evaluate for "alkaline reflux."

#### CLINICAL ALGORITHM(S)

None provided

### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Not specifically stated for each recommendation.

The guidelines emanate from a comprehensive review of the medical literature pertaining to the pH recording technique.

### BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

When done in a technically appropriate manner, esophageal pH recording provides quantitative data on both esophageal acid exposure and on the temporal correlation between patients' symptoms and reflux events. It may enable clinicians to perform better and/or more appropriate therapy based on patient status.

## POTENTIAL HARMS

Not stated

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

1. There are no data suggesting that ambulatory pH studies allow the clinician to predict the development of complications.
2. Ultimately, the potential value of any diagnostic test in this population is in guiding therapy and, at present, there are no data showing any advantage to an ambulatory esophageal pH study as opposed to an empirical trial of antireflux therapy in the management of patients with suspected reflux-induced chest pain. Ambulatory esophageal pH monitoring is, however, potentially useful in evaluating patients without typical symptoms of reflux disease or in the management of patients with suspected reflux-induced chest pain whose pain has not improved or resolved with antireflux therapy. However, these uses remain untested in any large, prospective, controlled clinical trial.

## 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  
Living with Illness

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

American Gastroenterological Association medical position statement: guidelines on the use of esophageal pH recording. *Gastroenterology* 1996 Jun; 110(6):1981.  
[PubMed](#)

### ADAPTATION

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

DATE RELEASED

1996 Feb 3 (reviewed 2001)

GUIDELINE DEVELOPER(S)

American Gastroenterological Association - Medical Specialty Society

SOURCE(S) OF FUNDING

American Gastroenterological Association

GUIDELINE COMMITTEE

American Gastroenterological Association Patient Care Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Peter J. Kahrilas; Eamonn M. M. Quigley

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, the Clinical Practice Committee meets 3 times a year to review all American Gastroenterological Association 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.

This guideline has been reviewed by the developer and is still considered to be current as of Dec 2001.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Gastroenterological Association \(AGA\)](#).

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

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Kahrilas PJ, Quigley EM. Clinical esophageal pH recording: a technical review for practice guideline development [107 references]. *Gastroenterology* 1996 Jun; 110(6):1982-96.

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

#### NGC STATUS

This summary was completed by ECRI on June 30, 1998. It was verified by the guideline developer on December 1, 1998.

#### COPYRIGHT STATEMENT

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