Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Endoluminal treatments for gastroesophageal reflux disease (GERD).

Bibliographic Source(s)

Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Endoluminal treatments for gastroesophageal reflux disease (GERD). Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2013 Feb. 22 p. [45 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions of the levels of evidence (+, ++, +++, ++++) and the grades of the recommendations (weak or strong) are provided at the end of the "Major Recommendations" field.

EsophyX

Long term data is not yet available for EsophyX. In short term follow-up, from 6 months to 2 years, EsophyX may be effective in patients with a hiatal hernia ≤2 cm with typical and atypical gastroesophageal reflux disease (GERD). Further studies are required to define optimal techniques and most appropriate patient selection criteria, and to further evaluate device and technique safety.

Quality of Evidence: (++). GRADE Recommendation: Weak

Stretta

Stretta is considered appropriate therapy for patients being treated for GERD who are 18 years of age or older, who have had symptoms of heartburn, regurgitation, or both for 6 months or more, who have been partially or completely responsive to anti-secretory pharmacologic therapy, and who have declined laparoscopic fundoplication.

Quality of Evidence: (++++). GRADE Recommendation: Strong

Definitions:

Quality of Evidence

Both the quality of the evidence and the strength of the recommendation for each of the guidelines were assessed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.* There is a 4-tiered system for quality of evidence:

Quality of Evidence	Definition	Symbol Used
High quality	Further research is very unlikely to alter confidence in the estimate of impact	++++
Moderate quality	Further research is likely to alter confidence in the estimate of impact and may change the estimate	+++
Low quality	Further research is very likely to alter confidence in the estimate of impact and is likely to change the estimate	++
Very low quality	Any estimate of impact is uncertain	+

Strength of Recommendations

There is a 2-tiered system for strength of recommendation (weak or strong):

Strong: It is very certain that benefit exceeds risk for the option considered

Weak: Risk and benefit well balanced, patients in differing clinical situations would make different choices, or benefits available but not certain.

*Adapted from Guyatt GH, Oxman AD, Vist GE, et al; GRADE Working Group. GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336:924-6.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Gastroesophageal reflux disease (GERD)

Guideline Category

Assessment of Therapeutic Effectiveness

Management

Treatment

Clinical Specialty

Family Practice

Gastroenterology

Internal Medicine

Pediatrics

Thoracic Surgery

Intended Users

Physicians

Guideline Objective(s)

- To provide physicians who manage and treat gastroesophageal reflux disease (GERD) a clinical spotlight review regarding the endoluminal treatment of GERD
- To critically review the endoluminal treatment of GERD techniques and the available evidence supporting their safety and efficacy

Note: Although a mainstay of GERD therapy for many patients, a discussion of long-term pharmacologic therapy, and its hazards, falls outside the scope of this document. Instead, the remainder of this review will focus on techniques designed to impact the anatomic mechanisms associated with GERD and its remedy.

Target Population

Adult patients with gastroesophageal reflux disease (GERD)

Note: Considerations in the pediatric population for EsophyX and Stretta are included in the original guideline document.

Interventions and Practices Considered

Endoluminal Treatments for Gastroesophageal Reflux Disease (GERD)

1. EsophyX for transoral incisionless fundoplication (TIF)
2. Stretta for radiofrequency treatment

Major Outcomes Considered

- Quality of life
- Degree of symptom relief and restoration of physiologic function
- Implications of treatment failures related to endoluminal therapies
- Medication usage (antacids, proton-pump inhibitors)
- Risks of esophagitis, esophageal stricture, Barrett's esophagus, adenocarcinoma of the esophagus

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A systematic literature search was performed using PubMed for each of the technologies discussed in this Clinical Spotlight Review. The literature was reviewed through the dates as listed below for the individual technologies (June – September, 2012).

The volume of literature available for each procedure varied, mostly depending on the length of existence of each device.

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

Quality of Evidence

Both the quality of the evidence and the strength of the recommendation for each of the guidelines were assessed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.* There is a 4-tiered system for quality of evidence:

Quality of Evidence	Definition	Symbol Used
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Very low quality	Any estimate of impact is uncertain	+

*Adapted from Guyatt GH, Oxman AD, Vist GE, et al; GRADE Working Group. GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336:924-6.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The volume of literature available for each procedure varied, mostly depending on the length of existence of each device. Strength and level of evidence therefore is variable, too, and is determined by review of available literature.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Both the quality of the evidence and the strength of the recommendation for each of the guidelines were assessed according to the Grading of

Recommendations Assessment, Development and Evaluation (GRADE) system.*

There is a 2-tiered system for strength of recommendation (weak or strong):

Strong: It is very certain that benefit exceeds risk for the option considered

Weak: Risk and benefit well balanced, patients in differing clinical situations would make different choices, or benefits available but not certain

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Cost Analysis

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

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Guidelines, spotlight reviews, and recommendations are developed under the auspices of the Society of American Gastrointestinal Endoscopic Surgeons and its various committees, and approved by the Board of Governors. Each clinical spotlight review has been systematically researched, reviewed and revised by the guidelines committee, and, when appropriate, reviewed by an appropriate multidisciplinary team. The recommendations are therefore considered valid at the time of production based on the data available.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

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

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate endoluminal techniques for gastroesophageal reflux disease (GERD)

Potential Harms

- Some endoluminal therapies may not offer the same degree of relief provided by surgery, but might still represent viable alternatives for patients seeking relief from lifelong dependence on pharmacologic therapy, its cost, associated side effects, and long-term adverse outcomes.
- Some patients had ongoing symptoms and required daily proton-pump inhibitor (PPI) medication after transoral incisionless fundoplication (TIF); they were deemed treatment failures.
- Some patients experienced minor adverse outcomes after Stretta, which consisted of temporary post procedure chest discomfort, mild fever, transient vomiting and transient dysphagia. A single major adverse event occurred in one patient with prolonged but transient gastroparesis.
- A few patients developed significant delay in gastric emptying after undergoing the second Stretta treatment.

Qualifying Statements

Qualifying Statements

- Guidelines for clinical practice and spotlight reviews are intended to indicate preferable approaches to medical problems as established by experts in the field. These recommendations will be based on existing data or a consensus of expert opinion when little or no data are available. Spotlight reviews are applicable to all physicians who address the clinical problem(s) without regard to specialty training or interests, and are intended to convey recommendations based on a focused topic; within the defined scope of review, they indicate the preferable, but not necessarily the only acceptable approaches due to the complexity of the healthcare environment. Guidelines and recommendations are intended to be flexible. Given the wide range of specifics in any health care problem, the surgeon must always choose the course best suited to the individual patient and the variables in existence at the moment of decision.
- Guidelines, spotlight reviews, and recommendations are developed under the auspices of the Society of American Gastrointestinal Endoscopic Surgeons and its various committees, and approved by the Board of Governors. Each clinical spotlight review has been systematically researched, reviewed and revised by the guidelines committee, and, when appropriate, reviewed by an appropriate multidisciplinary team. The recommendations are therefore considered valid at the time of production based on the data available.

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

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

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

Date Released

2013 Feb

Guideline Developer(s)

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

Source(s) of Funding

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

Guideline Committee

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Guideline Committee

Composition of Group That Authored the Guideline

Committee Members: Edward D. Auyang, Patrice Carter, Thomas Rauth, Robert D. Fanelli

Financial Disclosures/Conflicts of Interest

Society of American Gastrointestinal Endoscopic Surgeons (SAGES) leadership members, committee members, and guidelines authors disclose real and potential conflicts on a yearly basis and whenever they change, and real and potential conflicts are mitigated through mechanisms approved by the SAGES Conflict of Interest Task Force.

Auyang - No disclosures; Carter - No disclosures; Fanelli - No relevant disclosures

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Web site .

Print copies: Available from the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064; Web site: www.sages.org .

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

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