General

Guideline Title

The role of endoscopy in Barrett's esophagus and other premalignant conditions of the esophagus.

Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

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

- December 14, 2016 – General anesthetic and sedation drugs: The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

Recommendations

Major Recommendations

Definitions for the quality of the evidence (++++, +++O, ++OO, and +OOO) and for the strength of the recommendations ("recommends" or "suggests") are provided at the end of the "Major Recommendations" field.

1. The Practice Committee suggests that endoscopic screening for Barrett's esophagus (BE) can be considered in select patients with multiple
risk factors for BE and esophageal adenocarcinoma (EAC), but patients should be informed that there is insufficient evidence to affirm that this practice prevents cancer or prolongs life (+OOO).

2. The Practice Committee recommends no further endoscopic screening for BE after a screening examination with negative findings (+++O).

3. The Practice Committee recommends against a surveillance esophagogastroduodenoscopy (EGD) 1 year after the initial diagnosis of nondysplastic Barrett's esophagus (NDBE) (+++O).

4. The Practice Committee suggests that if patients with NDBE are enrolled in an EGD surveillance program, a surveillance EGD should be performed no more frequently than every 3 to 5 years, with white-light endoscopy and targeted plus 4-quadrant biopsies at every 2 cm of suspected BE (+OOO).

5. The Practice Committee suggests that only patients with BE who are candidates for therapy if dysplasia is identified be enrolled in EGD surveillance programs (+OOO).

6. The Practice Committee suggests that patients with a diagnosis of BE indeterminate grade dysplasia (IGD) undergoing additional evaluation to clarify the diagnosis. This may include additional pathology review, dose escalation of antiresecretory therapy to eliminate confounding esophageal inflammation, and/or a repeat EGD and biopsy (++OO).

7. The Practice Committee recommends that an expert gastrointestinal (GI) pathologist confirm the diagnosis of low-grade dysplasia (LGD) and/or high-grade dysplasia (HGD) (+++O).

8. The Practice Committee suggests that patients with LGD undergo a repeat endoscopy within 6 months to confirm the diagnosis, then annual surveillance endoscopy using a standard biopsy protocol (++OO).

9. The Practice Committee suggests that ablation be considered in select patients with LGD. Appropriate surveillance intervals after ablation are unknown (+OOO).

10. The Practice Committee recommends that endoscopic resection of nodular dysplastic BE be performed to determine the stage of dysplasia before considering other ablative endoscopic therapy (+++O).

11. The Practice Committee suggests that local staging with endoscopic ultrasound ± fine needle aspiration (EUS ± FNA) is an option in select patients being considered for endoscopic ablative therapy (+OOO).

12. The Practice Committee recommends that endoscopic surveillance in achalasia (+++O).

13. The Practice Committee recommends against routine endoscopic surveillance in achalasia (+++O).

14. The Practice Committee recommends against endoscopic routine screening in patients with aerodigestive cancer (+++O).

15. The Practice Committee suggests that screening for esophageal carcinoma begin at age 30 in patients with tylosis. Surveillance intervals should be every 1 to 3 years (++OO).

16. The Practice Committee suggests that screening for esophageal carcinoma begin approximately 10 to 20 years after caustic injury and performed every 2 to 3 years (++OO).

Definitions:

GRADE (Grading of Recommendations, Assessment, Development and Evaluation) System for Rating the Quality of Evidence for Guidelines

<table>
<thead>
<tr>
<th>Quality of Evidence</th>
<th>Definition</th>
<th>Symbol</th>
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<tbody>
<tr>
<td>High quality</td>
<td>Further research is very unlikely to change confidence in the estimate of effect.</td>
<td>++++</td>
</tr>
<tr>
<td>Moderate quality</td>
<td>Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.</td>
<td>+++O</td>
</tr>
<tr>
<td>Low quality</td>
<td>Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.</td>
<td>++OO</td>
</tr>
<tr>
<td>Very low quality</td>
<td>Any estimate of effect is very uncertain.</td>
<td>+OOO</td>
</tr>
</tbody>
</table>


Recommendation Strength

The strength of individual recommendations is based on both the aggregate evidence quality and an assessment of the anticipated benefits and harms. Weaker recommendations are indicated by phrases such as "the Practice Committee suggests," whereas stronger recommendations are typically stated as "the Practice Committee recommends."
Clinical Algorithm(s)
None provided

Scope

Disease/Condition(s)
- Barrett's esophagus (BE)
- Achalasia
- Aerodigestive cancers
- Tylosis
- Caustic injuries

Guideline Category
Diagnosis
Evaluation
Management
Screening
Treatment

Clinical Specialty
Gastroenterology

Intended Users
Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

Guideline Objective(s)
To discuss the role of endoscopy in the management of premalignant conditions of the esophagus

Target Population
Adults at risk for or with Barrett's esophagus and other premalignant conditions of the esophagus

Interventions and Practices Considered
1. Endoscopic screening for Barrett's esophagus (BE) or esophageal carcinoma
2. Esophagogastroduodenoscopy (EGD) surveillance programs
3. Clarification of BE indeterminate-grade dysplasia (IGD) diagnosis (pathology review, dose escalation of antisecretory therapy, repeat EGD, biopsy)
4. Pathologist confirmation of low-grade dysplasia (LGD) or high-grade dysplasia (HGD)
5. Repeat endoscopy and annual surveillance for LGD
6. Ablation in select patients with LGD
7. Endoscopic resection of nodular dysplastic BE
8. Local staging with endoscopic ultrasonography (EUS) ± fine-needle aspiration (FNA)
9. Eradication with endoscopic resection or radiofrequency ablation (RFA) for flat HGD

Note: The following were considered but not recommended: surveillance EGD 1 year after initial diagnosis of nondysplastic BE (NDBE), routine endoscopic surveillance in achalasia and routine screening in patients with aerodigestive cancer.

Major Outcomes Considered

- Risk factors for Barrett's esophagus and other premalignant conditions of the esophagus
- Sensitivity and specificity of screening/diagnostic tests
- Clinical value of surveillance testing
- Safety and effectiveness of endoscopic procedures

Methodology

Methods Used to Collect/Select the 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

In preparing this guideline, a search of the medical literature was performed using PubMed for the years 1980 to 2012. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When limited or no data exist from well-designed prospective trials, emphasis is given to results of large series and reports from recognized experts.

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

GRADE (Grading of Recommendations, Assessment, Development and Evaluation) System for Rating the Quality of Evidence for Guidelines

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<tr>
<td>High quality</td>
<td>Further research is very unlikely to change confidence in the estimate of effect.</td>
<td>+++++</td>
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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

Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted.

Rating Scheme for the Strength of the Recommendations

The strength of individual recommendations is based on both the aggregate evidence quality and an assessment of the anticipated benefits and harms. Weaker recommendations are indicated by phrases such as "the Practice Committee suggests," whereas stronger recommendations are typically stated as "the Practice Committee recommends."

Cost Analysis

Endoscopic screening for Barrett's esophagus (BE) is controversial because no randomized, controlled trials (RCTs) have demonstrated a decrease in mortality, either in general or from esophageal adenocarcinoma (EAC), as a result of screening. Because of the lack of RCT evidence of the efficacy of screening, some have used models in an attempt to establish a rationale for screening for BE. One such cost-effectiveness model of esophagogastroduodenoscopy (EGD) screening of 50-year-old white men with gastroesophageal reflux disease (GERD), with surveillance reserved for those with dysplastic BE, demonstrated $10,440/quality-adjusted life-year saved with screening compared with no screening or surveillance. The cost-effectiveness of traditional EGD is limited by the associated costs of the procedure and sedation.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This document is a product of the Standards of Practice Committee. The document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.
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 use of endoscopy in the management of premalignant conditions of the esophagus, primarily Barrett's esophagus (BE)

Potential Harms

- Ablative techniques must balance effective elimination of all dysplastic mucosa with the possibility of damaging deeper esophageal layers, which can result in short- and long-term complications.
- Photodynamic therapy (PDT) using 5-aminolevulinic acid or porfimer sodium as photosensitizing agents has been used effectively to eliminate high-grade dysplasia (HGD) (77% over 5 years) and early esophageal adenocarcinoma (EAC). Disadvantages of this technique include the inability to eliminate nondysplastic Barrett's esophagus (NDBE), skin photosensitivity for as long as 1 month, and stricture formation rates of approximately 30%.
- In one study, 3 serious adverse events occurred related to radiofrequency ablation (RFA) treatment (2 cases of chest pain and 1 gastrointestinal [GI] hemorrhage), and the rate of esophageal stricture formation was 6%. A subset of this study population followed for 3 years achieved complete eradication of dysplasia in 98% and complete eradication of BE in 91%, with stricture formation in 7.6%. Chest pain or discomfort is fairly common after RFA treatment, but generally subsides after 1 week.
- Complications of endoscopic mucosal resection (EMR) include bleeding, perforation, and stricture formation. Delayed bleeding is rare, but immediate bleeding can occur in 10% of patients and appears to primarily depend on EMR technique. Perforation is reported in less than 3% to 7% of patients at high-volume centers. Rates of stricture formation vary depending on the circumference and length of mucosa removed by EMR, but can occur in 17% to 37%.

Qualifying Statements

Qualifying Statements

- Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice.
- This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient’s condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.

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
- Staying Healthy

IOM Domain
- Effectiveness
- Patient-centeredness
- Safety

Identifying Information and Availability

Bibliographic Source(s)


Adaptation

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

Date Released

2012 Dec

Guideline Developer(s)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

Source(s) of Funding

American Society for Gastrointestinal Endoscopy

Guideline Committee

Standards of Practice Committee
Composition of Group That Authored the Guideline

Committee Members: John A. Evans, MD; Dayna S. Early, MD; Norio Fukami, MD; Tamir Ben-Menachem, MD; Vinay Chandrasekhar, MD; Krishnavel V. Chathadi, MD; G. Anton Decker, MD; Robert D. Fanelli, MD; Deborah A. Fisher, MD, MHS; Kimberly Q. Foley, RN; Joo Ha Hwang, MD, PhD; Rajeev Jain, MD; Terry L. Jue, MD; Khalid M. Khan, MD; Jenifer Lightdale, MD; Phyllis M. Malpas, MA, RN; John T. Maple, DO; Shabana F. Pasha, MD; John R. Saltzmun, MD; Ravi N. Sharaf, MD; Amundee Shergill, MD; Jason A. Dominitz, MD, MHS (Previous Chair); Brooks D. Cash, MD (Chair)

Financial Disclosures/Conflicts of Interest

The following authors disclosed financial relationships relevant to this publication: Dr Fisher is a consultant to Epigenomics Inc, Dr Fanelli is the owner of New Wave Surgical Inc, and Dr Chathadi is on the Speakers’ Bureau of Boston Scientific. The other authors disclosed no financial relationships relevant to this publication.

Guideline Status

This is the current release of the guideline.

Guideline Availability


Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on June 5, 2013. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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