



## Complete Summary

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### GUIDELINE TITLE

Sedation and anesthesia in GI endoscopy.

### BIBLIOGRAPHIC SOURCE(S)

Standards of Practice Committee of the American Society for Gastrointestinal, Lichtenstein DR, Jagannath S, Baron TH, Anderson MA, Banerjee S, Dominitz JA, Fanelli RD, Gan SI, Harrison ME, Ikenberry SO, Shen B, Stewart L, Khan K, Vargo JJ. Sedation and anesthesia in GI endoscopy. *Gastrointest Endosc* 2008 Nov;68(5):815-26. [72 references] [PubMed](#)

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates previous versions: Waring JP, Baron TH, Hirota WK, Goldstein JL, Jacobson BC, Leighton JA, Mallery JS, Faigel DO. Guidelines for conscious sedation and monitoring during gastrointestinal endoscopy. *Gastrointest Endosc* 2003 Sep;58(3):317-22. [36 references]

Faigel DO, Baron TH, Goldstein JL, Hirota WK, Jacobson BC, Johanson JF, Leighton JA, Mallery JS, Peterson KA, Waring JP, Fanelli RD, Wheeler-Harbaugh J. Guidelines for the use of deep sedation and anesthesia for GI endoscopy. *Gastrointest Endosc* 2002 Nov;56(5):613-7. [23 references]

## \*\* 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.

- [January 16, 2009 – Topical Anesthetics](#): The U.S. Food and Drug Administration (FDA) issued a public health advisory to remind patients, healthcare professionals, and caregivers about potentially serious hazards of using skin numbing products, also known as topical anesthetics, for relieving pain from mammography and other medical tests and conditions. FDA is concerned about the potential for these products to cause serious, life-threatening adverse effects, such as irregular heartbeat, seizures, breathing difficulties, coma and even death, when applied to a large area of skin or when the area of application is covered. See the Advisory for recommendations on safe use of these products.

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

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## SCOPE

### **DISEASE/CONDITION(S)**

Diseases or conditions requiring gastrointestinal endoscopy

### **GUIDELINE CATEGORY**

Evaluation  
Management

### **CLINICAL SPECIALTY**

Anesthesiology  
Gastroenterology  
Surgery

### **INTENDED USERS**

Physicians

### **GUIDELINE OBJECTIVE(S)**

- To provide guidelines for the use of sedation and anesthesia during gastrointestinal endoscopic procedures
- To update three previous American Society of Gastrointestinal Endoscopy documents

### **TARGET POPULATION**

Adults with conditions requiring sedation and anesthesia for gastrointestinal endoscopy

### **INTERVENTIONS AND PRACTICES CONSIDERED**

1. Preprocedure preparation and assessment
2. Use of unsedated endoscopy
3. Use of topical anesthesia
4. Choice of sedation and analgesia agents used for endoscopy
  - Benzodiazepine alone or in combination with an opiate
  - Adjuncts to the benzodiazepine/narcotic combination, including droperidol, promethazine, or diphenhydramine
5. Use of propofol for endoscopic sedation
6. Intraoperative monitoring
7. Anesthesiologist assistance for endoscopic procedures

## **MAJOR OUTCOMES CONSIDERED**

- Effectiveness of sedation and anesthesia in patients undergoing endoscopic procedures
- Risks and adverse effects of sedation and anesthesia

## **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**

In preparing this guideline, a search of the medical literature was performed by using MEDLINE and PubMed databases through May 2008 that related to the topic of "sedation and anesthesia for gastrointestinal endoscopy" by using the key word(s) "sedation," "anesthesia," "propofol," "gastrointestinal endoscopy," "endoscopy," "endoscopic procedures," and "procedures." The search was supplemented by accessing the "related articles" feature of PubMed, with articles identified on MEDLINE and PubMed as the references. Pertinent studies published in English were reviewed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts.

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

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

Expert Consensus  
Weighting According to a Rating Scheme (Scheme Given)

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

See "Rating Scheme for the Strength of the Recommendations."

### **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 utilization of endoscopy are based on a critical review of the available data and expert consensus.

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

#### **Definitions:**

<b>Grade of Recommendation</b>	<b>Clarity of Benefit</b>	<b>Methodologic Strength Supporting Evidence</b>	<b>Implications</b>
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Strong recommendation; likely to apply to most practice settings
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice

<b>Grade of Recommendation</b>	<b>Clarity of Benefit</b>	<b>Methodologic Strength Supporting Evidence</b>	<b>Implications</b>
			settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ, depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation; likely to change as data become available

Adapted from Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors. *Users' guides to the medical literature*. Chicago: AMA Press; 2002. p. 599-608.

## **COST ANALYSIS**

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

## **METHOD OF GUIDELINE VALIDATION**

Not stated

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not applicable

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Definitions for the grades of recommendations (1A to 3) are given at the end of the "Major Recommendations" field.

1. Adequate and safe sedation can be achieved in most patients undergoing routine esophagogastroduodenoscopy and colonoscopy by using an intravenous benzodiazepine and opioid combination **(1B)**.
2. In patients who are not adequately sedated with an intravenous benzodiazepine and opioid combination, the addition of other intravenous agents such as droperidol, promethazine, or diphenhydramine (Benadryl) may allow adequate and safe sedation to be achieved **(1B)**.
3. Sedation providers must have a thorough understanding of medications used for endoscopic sedation and the skills necessary for the diagnosis and treatment of cardiopulmonary complications **(3)**.
4. Noninvasive blood measurement and pulse oximetry are supplemental to-and do not replace- clinical observation of the patient during endoscopic sedation. Newer methods of monitoring are available but data to assess their impact on clinical outcomes is lacking, and their routine use for sedation must be individualized **(2B)**.
5. During moderate sedation, the person assigned responsibility for patient assessment may also perform tasks that are interruptible and of short duration. When deep sedation is planned, this individual should be dedicated to observation and monitoring and have no other procedure-related responsibilities **(3)**.
6. Extended monitoring techniques may provide sensitive measures of patient's ventilatory function (capnography) and level of sedation (bispectral [BIS] index monitoring); however, there is insufficient evidence in the literature to support the routine use of extended monitoring devices during moderate sedation. The American Society of Anesthesiologists (ASA) states that automated monitoring for apnea (capnography) should be considered for patients receiving deep sedation and for all patients in whom ventilatory function cannot be observed adequately **(1B)**.
7. Propofol has the advantages of more rapid onset of action and shorter recovery time compared with traditional sedative regimens. However, clinically important benefits in average-risk patients undergoing upper

- endoscopy and colonoscopy have not been consistently demonstrated with regard to patient satisfaction and safety. Therefore, the routine use of propofol in average- risk patients cannot be endorsed **(1B)**.
8. Propofol can be safely and effectively given by nonanesthesiology physicians and nurses provided they have undergone appropriate training and credentialing in administration and rescue from potential pulmonary and cardiovascular complications **(1C)**.
  9. A patient targeted for one level of sedation may become more deeply sedated than planned. Therefore, an individual administering sedation/analgesia should be trained to and possess the skills necessary to rescue a patient who has reached a level of sedation deeper than that intended. Thus, a physician targeting moderate sedation must be able to rescue a patient who is deeply sedated. Similarly, an ability to rescue a patient from general anesthesia is necessary when providing deep sedation **(3)**.
  10. The assistance of an anesthesia specialist should be considered for ASA physical status III, IV, and V patients. Other possible indications for involvement of an anesthesia professional during sedation include emergency endoscopic procedures, complex endoscopic procedures, and patients with a history of (1) adverse reaction to sedation, (2) inadequate response to moderate sedation, (3) anticipated intolerance of standard sedatives (e.g., alcohol or substance abuse), and (4) those at increased risk for sedation-related complications, such as patients with severe comorbidities or with anatomic variants predictive of increased risk for airway obstruction or difficult intubation (e.g., morbid obesity or sleep apnea) **(3)**.
  11. An anesthesia specialist is not cost-effective for average-risk patients undergoing routine upper and lower endoscopic procedures **(3)**.

**Definitions:**

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<b>Grade of Recommendation</b>	<b>Clarity of Benefit</b>	<b>Methodologic Strength Supporting Evidence</b>	<b>Implications</b>
		observational studies	can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
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## **CLINICAL ALGORITHM(S)**

None provided

## **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").

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

Achieving the appropriate level of sedation will allow for a safe, comfortable, and technically successful endoscopic procedure.

### **POTENTIAL HARMS**

- Cardiopulmonary complications of sedation and anesthesia: in general, the presence of one or more sedation-related risk factors couple with the potential of deep sedation will increase the likelihood of adverse sedation-related events.
- Topical anesthetic agents have been associated with serious adverse effects, including aspiration, anaphylactoid reaction, and methemoglobinemia.
- Propofol is a pregnancy category B drug and should be used with caution during lactation.
- Pain on injection of propofol is frequent, occurring in up to 30% of patients receiving an intravenous bolus.
- The cardiovascular effects of propofol include decreases in cardiac output, systemic vascular resistance, and arterial pressure. Negative cardiac inotropy and respiratory depression can be seen with the use of propofol. Transient hypoxia occurs in 3% to 7% and transient hypotension in 4% to 7%. In one retrospective review of 36,000 endoscopies in which propofol was used, the rate of clinical adverse events ranged from 0.1% to 0.2%.

## **CONTRAINDICATIONS**

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- The Food and Drug Administration (FDA) black box warning for droperidol states that the drug should be used only when first-line sedative agents fail to provide adequate sedation. The use of droperidol is contraindicated in patients with prolongation of the QTc interval (defined as >440 milliseconds in men and >450 milliseconds in women), and its use should be avoided in

- patients who are at an increased risk for the development of a prolonged QT interval. These risks include a history of congestive heart failure, bradycardia, diuretic use, cardiac hypertrophy, hypokalemia, hypomagnesemia, and use of other drugs that prolong the QT interval. Other risk factors may include age more than 65 years, alcohol abuse, and use of agents such as benzodiazepines, volatile anesthetics, and intravenous opiates.
- Propofol is contraindicated in patients with propofol allergy or hypersensitivity to eggs or soybean. Allergies/reactions to bisulfites must be taken into account in bisulfite-containing preparations of propofol.

## QUALIFYING STATEMENTS

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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  
Staying Healthy

### IOM DOMAIN

Effectiveness  
Patient-centeredness  
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**

2003 (revised 2008 Nov)

#### **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**

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#### **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

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## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [American Society for Gastrointestinal Endoscopy Web site](#).

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 on April 15, 2004. The information was verified by the guideline developer on May 12, 2004. This summary was updated by ECRI on February 21, 2006 following the U.S. Food and Drug Administration (FDA) advisory on benzocaine sprays. This summary was updated by ECRI Institute on March 10, 2009, following the U.S. Food and Drug Administration advisory on Topical Anesthetics. This summary was updated by ECRI Institute on June 15, 2009.

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