



## Complete Summary

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### GUIDELINE TITLE

Guidelines for conscious sedation and monitoring during gastrointestinal endoscopy.

### BIBLIOGRAPHIC SOURCE(S)

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] [PubMed](#)

### 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.

On Monday, February 13, 2006, the U.S. Food and Drug Administration (FDA) issued a Public Health Advisory to notify healthcare professionals and patients about adverse events, including methemoglobinemia, associated with the use of benzocaine sprays used in the mouth and throat. Benzocaine sprays are used in medical practice for locally numbing mucous membranes of the mouth and throat for minor surgical procedures or when a tube must be inserted into the stomach or airways. On February 8, 2006, the Veterans Health Administration (VA) announced the decision to stop using benzocaine sprays for these purposes. The FDA is aware of the reported adverse events and is reviewing all available safety data, but at this time is not planning action to remove the drugs from the market. The FDA is highlighting safety information previously addressed by the Agency, has provided other information for the consideration of clinicians in the PHA and will make further announcements or take action as warranted by the ongoing review. See the [FDA Web site](#) for more information.

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

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## SCOPE

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

Gastrointestinal endoscopy-appropriate diseases or conditions

### **GUIDELINE CATEGORY**

Evaluation  
Management

### **CLINICAL SPECIALTY**

Anesthesiology  
Gastroenterology

### **INTENDED USERS**

Physicians

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

To provide recommendations for conscious sedation during gastrointestinal endoscopy

### **TARGET POPULATION**

Adults with conditions requiring sedation for gastrointestinal endoscopy

### **INTERVENTIONS AND PRACTICES CONSIDERED**

#### **Evaluation**

1. History, physical examination, review of current medications and allergies, and assessment of cardiopulmonary status
2. Monitoring of heart rate, blood pressure, respiratory rate, and oxygen saturation
3. Continuous electrocardiogram (EKG) if indicated

**Note:** Capnography and bispectral monitoring were considered but not recommended for routine use

## **Management**

1. Benzodiazepines (midazolam, diazepam) alone or with an opiate
2. Opiates (fentanyl, meperidine)
3. Flumazenil or Naloxone if needed
4. Pharyngeal anesthesia (benzocaine, tetracaine, lidocaine)
5. Droperidol (in select patients)
6. Promethazine
7. Post-procedural monitoring including observation and vital sign monitoring
8. Post-procedure written instructions for patients
9. Endoscopic procedure without sedation
10. Deep sedation or general anesthesia

## **MAJOR OUTCOMES CONSIDERED**

Not stated

## **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**

In preparing this guideline, a MEDLINE literature search was performed, and additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants.

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

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

Expert Consensus

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

Not applicable

### **METHODS USED TO ANALYZE THE EVIDENCE**

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**

Not applicable

## **COST ANALYSIS**

The guideline developers reviewed published cost analyses.

## **METHOD OF GUIDELINE VALIDATION**

Not stated

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

Not applicable

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Recommendations are followed by evidence grades (A-C) identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

### **Procedural Monitoring**

All patients undergoing endoscopic procedures require pre-procedural evaluation to assess their risk and to help manage problems related to pre-existing medical conditions. A history and focused physical examination, review of current medications and drug allergies, as well as an assessment of cardiopulmonary status at the time of the procedure are necessary to adequately provide for the safety of the patient. Patients undergoing endoscopic procedures should have continuous monitoring before, during and after the administration of sedatives. Monitoring may detect early signs of patient distress, such as changes in pulse, blood pressure, ventilatory status, cardiac electrical activity, and clinical and neurologic status, before clinically significant compromise occurs. Standard monitoring of sedated patients undergoing gastrointestinal endoscopic procedures includes recording the heart rate, blood pressure, respiratory rate, and oxygen saturation. Refer to the original guideline document for information on pulse oximetry, capnography, and bispectral (BIS) monitoring.

Continuous electrocardiogram (EKG) monitoring is reasonable in high-risk patients, although the necessity for such monitoring has not been shown conclusively in controlled trials. Patients who may benefit from EKG monitoring include those who have a history of significant arrhythmia or cardiac dysfunction, elderly patients, and those for whom prolonged procedures are anticipated.

## **Medications**

The choice of sedative is largely operator dependent, but generally consists of benzodiazepines used either alone or in combination with an opiate. The most common benzodiazepines are midazolam and diazepam. The efficacy of sedation using these two benzodiazepines is comparable. However, most endoscopists favor midazolam for its fast onset of action, short duration of action, and high amnestic properties. Opiates, such as meperidine or fentanyl administered intravenously provide both analgesia and sedation. Fentanyl has a rapid onset of action and clearance and reduced incidence of nausea compared to meperidine. Morphine is usually avoided due to concern about stimulating smooth muscle contraction and inducing spasm of the sphincter of Oddi, which may be a particular problem during endoscopic retrograde cholangiopancreatography (ERCP). Combinations of benzodiazepine and opioid agents are frequently used, especially for longer procedures. However, such combinations may increase the risk of desaturation and cardiorespiratory complications. Specific antagonists of opiates (naloxone) and benzodiazepines (flumazenil) are available and should be present in every endoscopy unit to treat over-sedated patients.

## **Benzodiazepines**

Benzodiazepines are used in the majority of endoscopic procedures. They can induce relaxation and cooperation and often provide an amnestic response. Doses are titrated to patient tolerance depending upon age, other illnesses, use of additional medications, and the level of complexity of the procedure. In addition to the desired effects, significant respiratory depression can occur. This effect is synergistically increased with the use of intravenous opiates.

Midazolam binds to stereospecific benzodiazepine receptors on the postsynaptic gamma-aminobutyric acid (GABA) neuron at several sites within the central nervous system, including the limbic system, and reticular formation. Enhancement of the inhibitory effect of gamma-aminobutyric acid on neuronal excitability results by increased neuronal membrane permeability to chloride ions. This shift of chloride ions results in hyperpolarization (a less excitable state) and stabilization. Midazolam has been found to cross the placenta and is not recommended for use during pregnancy. It also enters breast milk and is not recommended for nursing mothers.

Midazolam causes anterograde amnesia. Paradoxical reactions, including hyperactive or aggressive behavior have been reported. Midazolam has no analgesic, antidepressant, or antipsychotic properties. For dosing information on midazolam and other medications mentioned below, see the original guideline document.

Diazepam has similar properties to midazolam, although there is longer half-life and a greater chance of phlebitis and it has less amnestic capabilities. Symptoms

of overdose include respiratory depression, hypotension, coma, stupor, confusion, and apnea. Treatment for benzodiazepine overdose is supportive. Flumazenil has been shown to selectively block the binding of benzodiazepines to its receptor, resulting in reversal of central nervous system (CNS) depression. For this reason, patients who develop severe respiratory depression after being given an opioid agent and a benzodiazepine should generally receive naloxone before being given flumazenil. Acute withdrawal, including seizures, may be precipitated after administration of flumazenil to patients receiving long-term benzodiazepine therapy.

## **Opiates**

Fentanyl binds with stereospecific receptors at many sites within the CNS and increases pain threshold, alters pain reception, and inhibits ascending pain pathways. The half-life is 2 to 4 hours. Meperidine also binds to opiate receptors in the CNS, causing inhibition of ascending pain pathways and altering the perception of pain.

Naloxone is an opioid antagonist used to reverse the sedation and respiratory depression caused by opiates. Appropriate additional supportive measures, such as fluid resuscitation and even vasopressor agents, may be required to manage cardiovascular compromise resulting from narcotic overdose. Since naloxone may be cleared faster than meperidine, individuals who receive high doses of meperidine followed by naloxone reversal must be observed carefully to detect the development of re sedation. Administration of naloxone causes the release of catecholamines, and thus should be used with caution in elderly individuals and those with cardiac diseases to avoid cardiovascular complications. In addition, administration to patients who regularly take narcotic agents may result in considerable pain and precipitate an acute withdrawal syndrome.

All narcotic agents must be used cautiously in patients taking other central nervous system depressants, such as other narcotic agents, sedatives, tranquilizers, phenothiazines, and antihistamines. Most of the drug interactions with monoamine oxidase (MAO) inhibitors have been described with meperidine. However, other narcotics should also be avoided in patients on an MAO inhibitor when possible. Narcotics will also lower the seizure threshold in patients with a history of a seizure disorder, and the dose should be lowered accordingly.

## **Pharyngeal Anesthesia**

Pharyngeal anesthesia is often used to suppress the gag reflex during procedures involving the upper gastrointestinal tract. Commonly used topical anesthetics include benzocaine, tetracaine, and lidocaine. They are administered by aerosol spray or gargling. The effects last for up to one hour. Despite their widespread use, there are conflicting data on their benefit.

There are numerous case reports on the occurrence of methemoglobinemia after administration of topical anesthetics. This should be suspected by the presence of clinical "cyanosis" in the face of a normal arterial partial pressure of oxygen (PO<sub>2</sub>). The blood in methemoglobinemia has been variously described as dark-red, chocolate, or brownish to blue in color, and does not change with the addition of oxygen. Pulse oximetry is inaccurate in monitoring oxygen saturation in the

presence of methemoglobinemia. The treatment of methemoglobinemia is with intravenous methylene blue. Routine use of topical anesthesia for upper endoscopy should be re-evaluated. It probably provides little benefit for most patients receiving the doses of intravenous sedation typically used in the United States. It may be acceptable to use topical anesthesia for some patients, particularly if light or no conscious sedation is administered.

### **Droperidol**

Droperidol is a butyrophenone neuroleptic tranquilizer that may be used in combination with narcotics and benzodiazepines in conscious sedation for complex endoscopic procedures. It produces an anti-emetic and anti-anxiety effect. It also has mild sedative and alpha-adrenergic inhibitory action. The most common side effects are mild to moderate hypotension and tachycardia. Prolonged post-procedure drowsiness has been reported. Extrapyramidal side effects, such as dystonia, can occur.

Droperidol has been associated with QT prolongation and the development of torsades de pointes in at least 20 patients. These events have occurred in patients with no known risk factors for QT prolongation and some have been fatal. The Food and Drug Administration has issued a warning about the QT prolongation and/or torsade de pointes in patients given droperidol. This will probably greatly reduce the use of droperidol in the endoscopy setting. The drug was removed from the European market in March 2001. Droperidol should be used only in select patients with anticipated intolerance of standard sedatives and anticipated long procedure time. It should be avoided if the QTc is prolonged (>440 msec males, >450 msec females). It should be used with caution in patients at risk for development of prolonged QT syndrome, such as those with congestive heart failure (CHF), bradycardia, cardiac hypertrophy, hypokalemia, or hypomagnesemia, or if they are taking other drugs known to prolong the QT interval. Patients should remain on a cardiac monitor during the procedure and for 2 to 3 hours afterward.

### **Promethazine**

Promethazine is an antiemetic medication which blocks postsynaptic mesolimbic dopaminergic receptors in the brain, exhibits a strong alpha-adrenergic blocking effect, and depresses the release of hypothalamic and hypophyseal hormones. It competes with histamine for the H1-receptor and reduces stimuli to the brainstem reticular system. It may be used as an adjunct to benzodiazepines and/or narcotics during endoscopy or to combat the nausea associated with these medications. Rapid administration may produce a transient fall in blood pressure. All available evidence suggests that use of occasional low doses is safe during pregnancy.

### **Post-procedure Monitoring**

Following completion of endoscopic procedures, patients are to be observed for adverse effects from either instrumentation or sedation. The length of the follow-up observation is dependent upon the perceived risk to the patient. Patients may be discharged from the endoscopy unit or post-procedure recovery area once vital signs are stable, and the patient has reached an appropriate level of

consciousness. Despite the appearance of appropriate recovery, it is well recognized that patients may have a prolonged period of amnesia and/or impaired judgment and reflexes following intravenous medications administered to induce sedation.

Patients should be advised prior to the administration of sedatives that a prolonged period of impaired cognition may occur. They should be instructed to make plans not to drive, operate heavy or potentially harmful machinery, or make legally binding decisions. When sedatives are administered, a competent companion for discharge must accompany patients from the recovery area.

Written instructions upon discharge are necessary as the amnestic period following sedation is variable. Post-procedure instruction on the signs and symptoms of potential adverse outcomes and complications is also advisable. Patients should be given written instructions on steps to follow in the event of a complication, including a phone number where 24-hour-a-day coverage is available in the event of an emergency.

Elective use of naloxone or flumazenil may be considered to reduce the recovery room time following endoscopy. The routine use of flumazenil has been shown to be associated with quicker awakening and reversal of amnesia, without an increased risk of re-sedation compared to placebo. Administration of antagonists following endoscopic procedures will not obviate the need for appropriate post-procedure observation and safe discharge planning. More data are needed before this becomes a recommended routine practice for outpatient endoscopy.

### **Special Circumstances**

#### **No Sedation**

Ultrathin endoscopes with diameter from 5.3 to 6 mm can improve the tolerability of upper endoscopy. These instruments have been used through a transnasal or peroral route. They permit diagnostic evaluation of the same regions of the upper digestive tract that are accessible by standard peroral endoscopes and permit the passage of pediatric biopsy forceps to obtain tissue samples without sedation. Several studies have demonstrated comparable or improved comfort using the ultrathin upper endoscope in unsedated patients compared to standard sedated peroral upper endoscopy using standard diameter endoscopes. However, because of their small caliber, the ultrathin endoscopes are somewhat less sensitive than standard endoscopes for detecting lesions. The peroral route may be easier to perform and may be slightly better tolerated than the transnasal approach. Improvement in the equipment and increased experience with this approach will help to establish its role.

Older patients, men, patients who are not anxious, or patients without a history of abdominal pain may have better tolerance of upper endoscopy or colonoscopy with little or no sedation. For procedures performed without medications, it is still prudent to utilize varying levels of monitoring as the situation demands.

#### **Deep Sedation or General Anesthesia**

Some patients undergoing prolonged therapeutic procedures have benefited from medication such as propofol to induce deep sedation. This has been demonstrated to be superior to standard benzodiazepine/narcotic sedation for complex procedures such as endoscopic retrograde cholangiopancreatograph (ERCP). Deep sedation requires more intensive monitoring by trained individuals. Sedation-related risk factors, the depth of sedation, and the urgency of the endoscopic procedure all play important roles in determining whether or not the assistance of an anesthesiologist is needed.

Sedation-related risk factors include significant medical conditions, such as extremes of age; severe pulmonary, cardiac, renal or hepatic disease; pregnancy; the abuse of drugs or alcohol; uncooperative patients; or a potentially difficult airway for intubation. The American Society of Anesthesiologists (ASA) Taskforce states that airway management may be difficult in the following situations:

1. Patients with previous problems with anesthesia or sedation
2. Patients with a history of stridor, snoring, or sleep apnea
3. Patients with dysmorphic facial features, such as Pierre-Robin syndrome or trisomy-21
4. Patients with oral abnormalities, such as a small opening (<3 cm in an adult); edentulous; protruding incisors; loose or capped teeth; high, arched palate; macroglossia; tonsillar hypertrophy; or a non-visible uvula
5. Patients with neck abnormalities, such as obesity involving the neck and facial structures, short neck, limited neck extension, decreased hyoid-mental distance (<3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, or advanced rheumatoid arthritis
6. Patients with jaw abnormalities, such as micrognathia, retrognathia, trismus, or significant malocclusion.

The ASA Taskforce guidelines recommend that the presence of one or more sedation-related risk factors, coupled with the potential for deep sedation, will increase the likelihood of adverse, sedation-related events. In this situation, if the practitioner is not trained in the rescue of patients from general anesthesia, then an anesthesiologist should be consulted. The routine assistance of an anesthesiologist for average risk patients undergoing standard upper and lower endoscopic procedures is not warranted and is cost-prohibitive.

### **Summary**

- A focused history and physical is required prior to the administration of moderate sedation (**C**).
- Routine monitoring of the patient's pulse rate, blood pressure, oxygen saturation, are useful identifying early problems (**B**). Monitoring of EKG recordings may be helpful in selected cases (**C**). Capnography, measurement of carbon dioxide retention, may be useful in prolonged cases (**A**).
- The use of benzodiazepines and/or opiates will result in a satisfactory outcome in nearly all patients (**B**). Endoscopists prefer the combination of these drugs, but it adds little benefit from the patient's viewpoint (**A**).
- Specific antagonists of opiates (naloxone) and benzodiazepines (flumazenil) are available and should be present in every endoscopy unit to treat over-sedated patients (**C**).

### **Definitions:**

- A. Randomized controlled trials
- B. Non-randomized studies
- C. Expert opinion

### **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is identified and classified for the recommendations using the following scheme:

- A. Randomized controlled trials
- B. Non-randomized studies
- C. Expert opinion

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

### **POTENTIAL BENEFITS**

- Appropriate attention to patient monitoring before, during and after the procedure will help to minimize complications as well as recognize early signs of distress, so that appropriate resuscitative measures can be instituted.
- Supplemental oxygen administration has been shown to reduce the magnitude of oxygen desaturation when given during endoscopic procedures.
- Patients who may benefit from electrocardiogram (EKG) monitoring include those who have a history of significant arrhythmia or cardiac dysfunction, elderly patients, and those prolonged procedures are anticipated.
- *Benzodiazepines* can induce relaxation and cooperation and often provide an amnestic response.
- *Fentanyl* has a rapid onset of action and clearance and reduced incidence of nausea compared to *meperidine*. It increases pain threshold, alters pain reception, and inhibits ascending pain pathways.
- *Meperidine* also causes inhibition of ascending pain pathways and alters the perception of pain.
- *Droperidol* produces an anti-emetic and anti-anxiety effect. It also has mild sedative and alpha-adrenergic inhibitory action.
- The routine use of *flumazenil* has been shown to be associated with quicker awakening and reversal of amnesia, without an increased risk of re sedation compared to placebo.
- Deep sedation has been demonstrated to be superior to standard benzodiazepine/narcotic sedation for complex procedures such as endoscopic retrograde cholangiopancreatography (ERCP).

### **POTENTIAL HARMS**

- Combinations of *benzodiazepine* and *opioid* agents may increase the risk of desaturation and cardiorespiratory complications.
- *Benzodiazepines* can induce significant respiratory depression. This effect is synergistically increased with the use of intravenous opiates.
- Midazolam causes anterograde amnesia. Paradoxical reactions, including hyperactive or aggressive behavior have been reported.
- *Diazepam* has similar properties to midazolam, although there is a greater chance of phlebitis. Symptoms of diazepam overdose include respiratory depression, hypotension, coma, stupor, confusion, and apnea.
- Acute withdrawal, including seizures, may be precipitated after administration of *flumazenil* to patients receiving long-term benzodiazepine therapy.
- *Naloxone* should be used with caution in elderly individuals and those with cardiac diseases to avoid cardiovascular complications. In addition, administration to patients who regularly take narcotic agents may result in considerable pain and precipitate an acute withdrawal syndrome.
- All *narcotic agents* must be used cautiously in patients taking other central nervous system depressants, such as other narcotic agents, sedatives, tranquilizers, phenothiazines and antihistamines. Most of the drug interactions with monoamine oxidase (MAO) inhibitors have been described with meperidine. However, other narcotics should also be avoided in patients on an MAO inhibitor when possible. Narcotics will also lower the seizure threshold in patients with a history of a seizure disorder, and the dose should be lowered accordingly.
- There are numerous case reports on the occurrence of methemoglobinemia after administration of *topical anesthetics*.
- The most common side effects of *droperidol* are mild to moderate hypotension and tachycardia. Prolonged post-procedure drowsiness has been reported. Extrapyramidal side effects, such as dystonia, can occur. Droperidol has been associated with QT prolongation and the development of torsades de pointes in at least 20 patients. Some of these cases have been fatal.
- Rapid administration of *promethazine* may produce a transient fall in blood pressure.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

The information in this guideline is intended only to provide general information and not as a definitive basis for diagnosis or treatment in any particular case. It is very important that patients consult their doctor about their specific condition.

## 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  
Safety

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

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] [PubMed](#)

### ADAPTATION

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

### DATE RELEASED

2003

### 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

Not stated

### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the [American Society for Gastrointestinal Endoscopy \(ASGE\) 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.

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