



## Guidelines for conscious sedation and monitoring during gastrointestinal endoscopy

*This is one of a series of statements discussing the utilization of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy prepared this text. 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. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts.*

*Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus. Further controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.*

### INTRODUCTION

Providing adequate sedation and analgesia is an integral part of the practice of GI endoscopy. Selected patients may not require any sedation for certain endoscopic procedures. However, most endoscopic procedures are performed with the patient under moderate sedation and analgesia, which is also known as "conscious sedation." At this level of sedation, the patient is able to make a purposeful response to verbal or tactile stimulation, and both ventilatory and cardiovascular function are maintained. This is usually accomplished by the use of a narcotic and/or a benzodiazepine. By comparison, patient responsiveness during "deep sedation" involves purposeful responses to painful stimuli. Airway support may be required. The ASGE has recently published guidelines on the use of deep sedation and general anesthesia during endoscopic procedures.<sup>1</sup> At the level of general anesthesia, the patient is unarousable, even to painful stimuli. Airway support is frequently required and cardiovascular function may be impaired. The endoscopist must decide the level of sedation that will be required before the procedure. The endoscopy team must be able to recognize the various levels of sedation and analgesia and rescue a patient who exhibits loss of responsiveness, airway protection, spontaneous respiration, or cardiovascular function.

GI endoscopy is a safe procedure. Significant complications can occur as a result of instrumentation, such as bleeding, perforation, and infection, with a frequency that approximates 0.1% for upper endoscopy and 0.2% for colonoscopy.<sup>2-4</sup> Cardiopulmonary complications may account for over 50% of all reported complications, with the majority because of aspiration, oversedation, hypoventilation, vasovagal episodes, and airway obstruction.<sup>2,5,6</sup> In a prospective survey of 14,149 upper endoscopies, the rate of immediate cardiopulmonary incidents was 2 per 1000 cases.<sup>7</sup> The 30-day mortality rate, which included cases of aspiration pneumonia, pulmonary embolism, and myocardial infarction, was 1 per 2000 cases. A retrospective review of 21,011 procedures found the rate of cardiovascular complications was 5.4 per 1000 procedures.<sup>8</sup> Here, complications ranged from mild transient hypoxemia to severe cardiorespiratory compromise and death.

The risk of cardiovascular complications is related to both the patient's underlying condition and the endoscopic procedure being performed. Patients who are elderly or who have concomitant medical problems, including cardiovascular, pulmonary, renal, hepatic, metabolic and neurologic disorders, and morbid obesity, may be at increased risk from sedation.<sup>9,10</sup> These patients may require more complex or intensive monitoring during endoscopic procedures. Patients who are already taking sedative or anxiolytic medications, or opiates may also be at a greater risk for oversedation. The risk for emergency or therapeutic procedures, such as control of bleeding, polypectomy, laser treatment, stent placement or ERCP are all associated with higher risk to the patient.<sup>11-13</sup> 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.

### PROCEDURAL MONITORING

All patients undergoing endoscopic procedures require preprocedural 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 with moderate or deep sedation must 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, clinical, and neurologic status before clinically significant compromise occurs. Standard monitoring of sedated patients undergoing GI endoscopic procedures includes recording the heart rate, blood pressure, respiratory rate, and oxygen saturation. Although electronic monitoring equipment often facilitates assessment of patient status, it does not replace a well-trained and vigilant assistant.

A pulse oximeter measures oxygen saturation and enhances the assessment of respiratory status in patients under sedation and analgesia.<sup>14</sup> Supplemental oxygen administration has been shown to reduce the magnitude of oxygen desaturation when given during endoscopic procedures.<sup>15,16</sup>

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 cardiac or pulmonary disease, elderly patients, and those in whom prolonged procedures are anticipated.

Transcutaneous CO<sub>2</sub> and end tidal CO<sub>2</sub> monitoring are noninvasive methods for measuring respiratory activity. Capnography is based on the principle that carbon dioxide absorbs light in the infrared region of the electromagnetic spectrum. Quantification of the absorption leads to the generation of a curve, which represents a real-time display of the patients respiratory activity. Capnography more readily identifies patients with apneic episodes and when used to guide sedation results in less CO<sub>2</sub> retention.<sup>17</sup> Capnography is a superior way to evaluate ventilation, compared with pulse oximetry measurement, which assesses oxygenation.<sup>18</sup> Whether routine use of capnography improves outcome in patients undergoing conscious sedation has not been demonstrated.

Bispectral (BIS) monitoring uses continuous electroencephalogram (EEG) recordings to generate an objective assessment of degree of sedation. A value on a linear scale from 100 (fully awake) to 0 (no brain-wave activity) is continually updated during a procedure to reflect recent brain wave activity. BIS values correlated well with the Observer's Assessment of Alertness/Sedation (OAA/S) scale in a study of 50 patients undergoing endoscopy.<sup>19</sup> This technology has the potential to prevent oversedation, but is not

currently a standard monitoring device for patients having routine endoscopy.

## 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 commonly used benzodiazepines are midazolam and diazepam. The efficacy of sedation with these two benzodiazepines is comparable.<sup>20</sup> 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 with meperidine. Combinations of benzodiazepine and opioid agents are frequently used, especially for longer procedures. However, such combinations may increase the risk of oxygen desaturation and cardiorespiratory complications. One study found no difference in pain experienced during colonoscopy in patients receiving midazolam, meperidine, or both.<sup>21</sup> Another report suggested that the addition of meperidine to midazolam was favored by endoscopists compared with midazolam alone for upper endoscopy, but added no benefit from the patient's viewpoint.<sup>22</sup> 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 GABA neuron at several sites within the central nervous system, including the limbic system and reticular formation. Enhancement of the inhibitory effect of GABA on neuronal excitability results by increased neuronal membrane permeability to chloride ions. This shift in chloride ions results in hyperpolarization (a less excitable state) and stabilization. Midazolam has been found to cross the placenta and is pregnancy category D. It also enters breast milk.

Midazolam causes anterograde amnesia. Paradoxical reactions, including hyperactive or aggres-

sive behavior have been reported. Midazolam has no analgesic, antidepressant, or antipsychotic properties. The starting dose for conscious sedation is 0.5-2 mg given slowly intravenously and titrating to the desired effect by repeating doses every 2 to 3 minutes if needed. The usual total dose is 2.5 to 5 mg. Smaller doses may be used in the elderly. Larger doses may be necessary in some patients to achieve the desired effect. If narcotics or other central nervous system (CNS) depressants are administered concomitantly, the midazolam dose should be reduced by 30%.

Diazepam has similar properties to midazolam, although there is a longer half-life, a greater chance of phlebitis, and it has less amnestic capabilities. It is administered with an initial bolus of 2.5 to 5.0 mg. Incremental doses of 2.5 mg can be given in 3- to 4-minute intervals. Diazepam is pregnancy category D.

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 CNS depression. It has limited efficacy in reversing respiratory 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. Flumazenil dosage is 0.2 mg intravenously and may be repeated up to 3 mg. Flumazenil is pregnancy category C.

### 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 typical dose for sedation is 25 to 50 µg, repeated every 1 to 2 minutes until the desired effect is achieved. The usual total dose is 50 to 200 µg for routine procedures. 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. It produces generalized CNS depression. The usual dose for routine procedures is 50 to 100 mg. Some patients may require larger doses to achieve the desired effect.

Naloxone is an opioid antagonist that is 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 car-

diovascular compromise resulting from narcotic overdose. The usual dose of naloxone given to reverse an oversedated patient with respiratory depression is 0.4 mg given intravenously. Smaller doses may be used for elderly individuals. Because 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 disease to avoid cardiovascular complications. In addition, administration to patients who regularly take narcotic agents, prescribed or otherwise, may result in considerable pain and precipitate an acute withdrawal syndrome.

All narcotic agents must be used cautiously in patients taking other CNS 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. Meperidine should be used cautiously in patients with significant renal impairment as accumulation of metabolites may lead to seizures. Fentanyl in high doses may cause chest wall rigidity and difficulty with respiration. Fentanyl and meperidine are both pregnancy category C. Naloxone is pregnancy category B.

### PHARYNGEAL ANESTHESIA

Pharyngeal anesthesia is often used to suppress the gag reflex during procedures involving the upper GI tract. Commonly used topical anesthetics include benzocaine, tetracaine, and lidocaine. They are administered by aerosol spray or gargling. The effects last for up to 1 hour. Despite their widespread use, there are conflicting data on their benefit.<sup>23,24</sup> One study has suggested that topical anesthesia produced no additional benefit when used with intravenous conscious sedation.<sup>23</sup> Another study suggested that the benefit might be greatest for patients who are less than 40 years old, those undergoing the procedure for the first time, or patients who are particularly anxious.<sup>25</sup> 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 PO<sub>2</sub>.<sup>26</sup> 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 (2 mg/kg). Routine use of topical anesthesia for upper endoscopy should be re-evaluated.<sup>27</sup> 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 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.<sup>1,28,29</sup> It produces an anti-emetic and anti-anxiety effect. It also has mild sedative and alpha-adrenergic inhibitory action. The initial dosage is 1.25 to 2.5 mg. Additional doses should be in 1.25 mg aliquots to achieve the desired effect. The maximum dose is generally 5 mg. The most common side effects are mild to moderate hypotension and tachycardia. Prolonged postprocedure 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. Cardiac events have been reported in at least 74 patients.<sup>30</sup> 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 torsades de pointes in patients being given droperidol. This will probably greatly reduce the use of droperidol in the endoscopy setting. Droperidol should be considered only in select patients with anticipated intolerance of standard sedatives or anticipated long procedure time. It should be avoided if the QTc is prolonged (>440 ms males, >450 ms females). It should be used with caution in patients at risk for development of prolonged QT syndrome, such as congestive heart failure, bradycardia, cardiac hypertrophy, hypokalemia, 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. There is no reversal agent for droperidol. Droperidol is pregnancy category C.

### PROMETHAZINE

Promethazine is an antiemetic medication that blocks postsynaptic mesolimbic dopaminergic recep-

tors 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 combat the nausea associated with these medications. The usual dose is 12.5 to 25 mg intravenously. It should be diluted to a maximum concentration of 25 mg/mL and infused at a maximum rate of 25 mg/minute. Rapid administration may produce a transient fall in blood pressure. Promethazine is pregnancy category C.

### POSTPROCEDURE MONITORING

After 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 on the perceived risk to the patient. Patients may be discharged from the endoscopy unit or postprocedure 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 after intravenous medications administered to induce sedation.

Patients should be advised before 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. Postprocedure 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 after 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 with placebo.<sup>31,32</sup> Administration of antagonists after endoscopic procedures will not obviate the need for appropriate postprocedure observation and safe discharge planning. More data are needed before this becomes a recommended routine practice for outpatient endoscopy.

## SPECIAL CIRCUMSTANCES

### No sedation

Selected patients may be able to undergo endoscopic procedures with no sedation. Ultrathin endoscopes with diameter from 5.3 to 6 mm can improve the tolerability of upper endoscopy and may be used without sedation.<sup>33-35</sup> In general, topical anesthesia is used. There are several studies demonstrating successful colonoscopy in patients who receive no sedation or sedation only if needed.<sup>36-39</sup>

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 use varying levels of monitoring as the situation demands.

### DEEP SEDATION OR GENERAL ANESTHESIA

Some patients undergoing prolonged therapeutic procedures have benefited from medications, such as propofol to induce deep sedation.<sup>1</sup> This has been demonstrated to be superior to standard benzodiazepine/narcotic sedation for complex procedures such as ERCP. Use of deep sedation in routine upper and lower endoscopic procedures is controversial and provides little benefit over standard moderate sedation.<sup>1</sup>

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.<sup>11</sup> 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 nonvisible 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; and (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 of sedation-related risk factor, 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 patients pulse rate, blood pressure, oxygen saturation are useful in 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)

Legend: (A), Prospective controlled trials. (B), Observational studies. (C), Expert opinion.

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