ONTARIO ASSOCIATION OF GASTROENTEROLOGY

Guidelines for sedation/deep sedation/anaesthesia
during Gastrointestinal Endoscopy

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This is one of a series of statements from the Ontario Association of Gastroenterology to describe standards for GI endoscopy in common clinical practice. 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 from expert consultants. Where little data exists from well-designed prospective trials, emphasis was given to results from large series and reports from recognized experts. In this era of evidence-based medicine, mention is made of quality of evidence (using the classification of the Canadian Task Force on the Periodic Health Examination). The American Society for Gastrointestinal Endoscopy (ASGE) has recently issued a series of statements on sedation and endoscopy, which are the most comprehensive and recent reviews available.\(^1\)\(^2\) The Canadian Association of Gastroenterology has not developed its own formal guidelines as yet, and the ASGE guidelines have been adopted as the interim CAG guidelines for now.

These current guidelines modify the ASGE guidelines in a Canadian clinical context.

Introduction

Providing adequate sedation and analgesia is an integral part of GI endoscopy. In many countries a large proportion of procedures are done with little or no sedation.\(^3\) The reasons behind such a marked difference in sedation requirements between neighbouring countries have not been explained.

Some patients will not require any sedation for certain endoscopic procedures. In Canada most endoscopic procedures are performed with the patient under moderate sedation and analgesia, defined as “conscious sedation” (see table 1). ASGE guidelines echo this statement.\(^1\) Different patients may require different levels of sedation for the same procedure, and the same patient may attain different levels of sedation during the same procedure.

At the level of moderate sedation the patient is able to make a purposeful response to verbal or tactile stimulation, and both ventilatory and cardiovascular functions are maintained. This is usually accomplished by the use of a narcotic and/or a benzodiazapine. By comparison patient responsiveness during “deep sedation” involves purposeful responses to painful stimuli. Airway support may be required.
At the level of general anaesthesia, the patient cannot be aroused even through painful stimuli. Airway support is frequently required and cardiovascular functions may be impaired.

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.

The level of sedation should be discussed by the patient and the endoscopist prior to the procedure. The level may depend on many factors such as patient anxiety, patient preference, pain tolerance, and possibly the comments the patient has heard from other patients. Generally, the minimum sedation necessary to complete the procedure to the satisfaction of the endoscopist and the patient should be used. It is recommended that the risks of sedation (as well as the risks involved with different levels of sedation/anaesthesia) be discussed with the patient prior to the procedure. This consent process should take place in a calm setting, such that the patient does not feel pressured into making a decision.

**Risks with Sedation**

Several series suggest that up to 50% of the risks of endoscopy are sedation related, usually cardio-pulmonary complications. Although there is little published data, it is possible that with lighter sedation there will be a lower complication rate. A 1995 British study showed that the risk of immediate complications was 2/1000, with the thirty-day mortality rate being 1/2000. At the time of the study many units were staffed inadequately, with little supervision of trainees. This study spurred more as yet unpublished safety data. A 1991 American study showed cardiovascular complication rate at 5.4/1000 procedures (including transient hypoxemia as a complication). There have been few large series documenting risks for unsedated endoscopies. A recent prospective study of 15,000 unsedated gastroscopies and colonoscopies showed the complication rate to be essentially zero.

**Unsedated Endoscopy**

Anecdotal evidence suggests that the use of this modality is relatively common in Canada, particularly for upper endoscopy. This modality has not received widespread attention in the US as yet, but it is widely used and is in fact the standard in many countries. Ultra-thin endoscopes offer promise in trans-nasal endoscopy.

**Procedural Monitoring**

All patients undergoing endoscopic procedures require pre-procedural evaluation to assess their risks and to help manage problems related to pre-existing medical conditions. Patient history, physical examination, review of medications, allergies and relevant lab results should be reviewed. The ASGE mandates no specific pre-endoscopy laboratory testing.
Intravenous access for delivery of medications should be secure. Supplemental oxygen should be available. During the procedure, the oxygen saturation levels should be measured continuously with a device such as a pulse oximeter. Note should be made if there is a drop in the saturation level, and what measures are used to restore the saturation to an acceptable level (jaw-thrust manoeuvre, administration of more oxygen, bagging, administration of medication etc).  

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 change in pulse, blood pressure, ventilatory status, cardio-electrical activity, clinical and neurological status, before clinically significant compromise occurs. Standard monitoring of sedated patients undergoing GI endoscopic procedures includes recording the heart rate, blood pressure, and oxygen saturation. Although electronic monitoring equipment often facilitates assessment of patient status, it does not replace a well-trained and vigilant assistant.

Continuous electrocardiogram (EKG) monitoring is potentially useful in high-risk patients.

Any patient going for an endoscopic procedure should have access to emergency equipment if required (extra oxygen, Ambu bag, equipment for endotracheal intubation and artificial ventilation, crash cart). Specific reversal agents such as anexate and naloxone should also be readily available.

Post-Procedural Monitoring

After completion of endoscopic procedures, patients are to be observed for adverse effects from either instrumentation or sedation. Patients may be discharged from the endoscopy unit or recovery area once vital signs are stable, and the patient has reached an appropriate level of consciousness. It is well-recognized that patients may have a prolonged period of amnesia or impaired judgment and reflexes after sedation. Because of this prolonged period of impaired cognition that may occur, they should be instructed prior to the procedure to not drive, operate heavy or harmful machinery, or make legally-binding decisions until the following day. When sedatives are administered, a competent companion for discharge may accompany the patient from the recovery area. Written instructions upon discharge are useful as the amnestic period following sedation is variable. Post-procedure instructions on the signs and symptoms of potential adverse outcomes and complications are also advisable. Patients should be given instructions on steps to follow in the event of a complication.

Medications

The choice of sedatives is largely operator-dependent, but generally consists of benzodiazepines used either alone or in combination with an opiate. Most endoscopists favour midazolam for its fast onset of action, short duration of action, and high amnestic
properties. Opiates such as meperidine or fentanyl intravenously provide both analgesia and sedation. Combinations of benzodiazepines and opioid agents are frequently used, especially for longer procedures, but this may increase the risk of oxygen desaturation and cardiorespiratory complications. Two studies reported that the addition of meperidine to midazolam added no specific benefit to the patient. ³

**Benzodiazepines**

Several agents are commonly used including valium, diazemuls, and midazolam. ¹ Smaller doses may be needed in the elderly and those with multiple co-morbidities. If narcotics or other CNS depressants are co-administered, the midazolam dose should be reduced by 30%.

Symptoms of over-dosage include respiratory depression, hypotension, coma, stupor, confusion, and apnea. Treatment for benzodiazepine overdose is supportive. Flumazenil has limited efficacy in reversing respiratory depression and may have a relatively short-lived effect. Acute withdrawal, including seizures, may be precipitated after administration of flumazenil to patients receiving long-term benzodiazepine therapy.

**Opiates**

Meperidine and fentanyl are the agents in general use.¹ In patients requiring both benzodiazepines and opiates, in the event of respiratory depression, nalaxone should be given first generally before considering flumazenil. The initial dose of the opioid antagonist nalaxone is 0.4 mg given intravenously, a smaller dose in elderly individuals.

**Topical Pharyngeal Anaesthesia**

Commonly used topical agents include benzocaine, tetrocaine, and xylocaine.¹ The effects may last for one hour. Data on their benefit are conflicting. There may be little benefit when used with intravenous conscious sedation. Methemoglobinemia may occur after administration of topical anaesthesia, and should be suspected in the presence of clinical cyanosis in the face of a normal arterial pO₂.

**Droperidol**

This is an agent used in conjunction with narcotics and benzodiazepines in moderate sedation for complex endoscopic procedures.² It has been associated with QT prolongation and the development of torsade de pointes. This agent should be avoided if the QT is prolonged, or if the patient is at risk of developing prolonged QT syndrome. The patient should remain on a cardiac monitor during the procedure and for two or three hours afterwards.
Deep Sedation or General Anaesthesia

Some patients undergoing prolonged therapeutic procedures have benefitted from deep sedation, and occasionally general anaesthesia, with benzodiazepine/opiate combinations with or without propofol. The use of deep sedation/anaesthesia in routine upper and lower endoscopic procedures is controversial, and may provide little benefit over standard moderate sedation. Professional organizations have co-operated, and practice guidelines have been put forward by the American Society of Anaesthesiologists’ committee for sedation and anaesthesia by non-anaesthesiologists, and have been approved by the ASGE. A recent statement on continuous quality improvement in colonoscopy suggested that the American Society for Anaesthesia (ASA) classification for each patient be recorded as well as a statement on the level of sedation required during the procedure.

There is an interesting dichotomy in that the trend in the USA is to go deeper with sedation, whereas in parts of Canada and western countries, there is a trend towards lighter sedation. Patient expectation, and possibly pre-procedure explanation and reassurance may play a role in decreasing sedation requirements. An accomplished colonoscopist, Professor J. Waye, noted that while almost all his American patients wished to be “knocked out,” they were in fact able to tolerate the procedure very well with light conscious sedation (even after receiving propofol for a previous colonoscopy), reinforcing the necessity of careful endoscopic technique as a method of reducing sedation requirements, and also of reducing complications.

Adjuncts to medications

The use of adjuncts to intravenous medications may decrease the dosage of medication used, thus reducing the cardio-respiratory risks of the procedure. In general these have not been well-studied and probably deserve greater attention. These include: provision of a relaxed environment, including soothing music and/or visual distraction; nitrous oxide as a short-acting anxiolytic; commercially available CO2 insufflators; and variable stiffness colonoscopes, overtubes, and other endoscopic technique to decrease abdominal discomfort during colonoscopy.

The Use of Propofol in Endoscopy

This short-acting agent has received widespread attention in many procedural areas of medicine- in the emergency room, to use in reducing dislocated limbs, for cardioversion, and now also in gastroenterology. Until recently used only by anaesthetists, it is now used by many specialities. There have been many debates about which physicians should use this agent, and in what circumstances, and new data is available monthly. The data show that propofol can be used safely by appropriately trained gastroenterologists (with the drug administered by gastroenterologists with or without another dedicated professional to actually administer the agent and monitor the patient).
This agent is classified by the FDA as a short acting hypnotic agent that provides amnesia but minimal levels of analgesia.\textsuperscript{20} It increases the likelihood of deep sedation, but has a risk of a rapid and profound decrease in the level of consciousness and of cardio-respiratory function, which may culminate in general anaesthesia. While using this drug, special monitoring may be useful. Transcutaneous CO\textsubscript{2}, arterial CO\textsubscript{2} and electroencephalogram (EEG) monitoring are all promising, but do not have widespread clinical use at this moment.\textsuperscript{21}

Low complication rates from the use of propofol for endoscopy have been documented in large series. It is reasonable that complication rates from deep sedation/anaesthesia may be higher than from a moderate level of sedation, but this has not been conclusively shown in studies as yet.\textsuperscript{17} Published complication rates from nurse-administered propofol sedation (NAPS) and gastroenterologist-administered propofol sedation show very low complication rates – desaturation in 1\% or less, no respiratory arrests.\textsuperscript{22} Data from anaesthetist-administered propofol procedures are scant, but do not show lower complication rates.\textsuperscript{23} The endoscopy team must be able to rescue and manage the apneic patient (this is a necessary requirement even for moderate sedation, and certainly for deep sedation by whatever agents, including propofol). However, since the effects of propofol are short-lived, desaturation and respiratory embarrassment if they occur are short-lived.

Although there is little published literature on this topic, a recent German national survey,\textsuperscript{5} as well as anecdotal evidence,\textsuperscript{11} suggest that with very deep sedation/anaesthesia with propofol, there may be a higher perforation rate at colonoscopy. Another potential concern with deep sedation/analgesia is the fact that the patient is completely unresponsive, and may not be able to change positions, which may impair advancement of the colonoscope.\textsuperscript{6}

Guidelines published thus far have suggested that personnel specifically trained in the administration of propofol with experience in emergency airway management must be present during the procedure, and be dedicated to constantly monitor the patient’s physiological parameters. These guidelines are further elaborated in the ASGE document on guidelines for use of deep sedation and anaesthesia for GI endoscopy,\textsuperscript{2} and for the use of propofol for gastrointestinal endoscopy.\textsuperscript{20,23} The ASA, ASGE, and the manufacturer of propofol (Astra-Zeneca) do not mandate that an anaesthetist must be present while propofol is being administered.

Although the initial experience with propofol was with an anaesthetist administering and monitoring propofol, there have been other techniques developed to deliver this agent:

\textit{a) Nurse-administered propofol sedation (NAPS)} – This has achieved widespread use in the USA, with some 35,000 cases being done thus far with very low complication rates.\textsuperscript{24} Worldwide, over 50,000 cases have been reported,\textsuperscript{25} with negligible complication rates, no mechanical ventilation and no deaths. Uncomplicated use has been documented in series with decompensated cirrhotic patients, and with ASA Class IV patients.
b) **Gastroenterologist-administered propofol** – Two recent American studies demonstrated its use safely by a gastroenterologist with one nurse in the endoscopy room, for over one thousand routine upper and lower procedures, including polypectomy.\(^{17,22}\) These results were duplicated by the first published Canadian propofol study,\(^{18}\) reporting on its use in patients at EUS procedures, including with biopsy. Unpublished Toronto experience is identical.

c) **Patient-administered propofol** – Patient-controlled sedation/analgesia has been studied in several series, and found to be both safe and efficacious.\(^{15,26}\)

Some studies have used propofol as monotherapy,\(^{27}\) while others have used propofol in conjunction with standard opiate/benzodiazepine combinations.\(^{17}\) The New York, Canadian, and the very large Swiss experience (over ten thousand patients) used gastroenterologist-administered propofol at low doses to produce moderate sedation only, with very low complication rates. This technique has the potential to achieve both the rapid recovery that propofol enthusiasts espouse, while minimizing complications because of the moderate sedation only (as compared to many American studies using propofol, which aimed for deep sedation).

Recent ASGE guidelines review the steps for gastroenterologists to follow to safely perform endoscopy with gastroenterologist-administered propofol.\(^{23}\) Currently, institution-based guidelines should be followed, with the involvement of an anaesthetist in the initial few months.

A recent study found that although anaesthetist-administered propofol shortened procedure times marginally, there was no net benefit to the endoscopy unit to using propofol, after taking total costs into consideration.\(^{28}\) This unit returned to standard sedation regimens. The Canadian study found propofol use cumbersome, with utility in high-sedation requirement patients.\(^{18}\)

**Use of an Anaesthetist at Endoscopy**

The presence of an anaesthetist at endoscopy may be useful in the management of certain patients undergoing endoscopic procedures, particularly with long and complicated procedures. Five recent publications from the ASGE indicate that the routine assistance of an anaesthetist for average-risk patients undergoing standard upper and lower endoscopic procedures is not warranted and is cost-prohibitive.\(^{1,2,20,23,29}\) One study calculated costs, with the use of an anaesthetist increasing costs double to triple.\(^{30}\) A joint statement was released in March 2004 by the three main GI societies in the USA (AGA, ASGE, ACG) reiterating the above points.\(^{29}\)

An older 2002 ASGE\(^2\) guideline suggested that anaesthetist assistance *may be considered* (not suggested nor necessary) in the following situations:
- prolonged or therapeutic endoscopic procedure requiring deep sedation.
- anticipated intolerance to standard sedatives.
• increased risk for complications because of severe co-morbidity (ASA Class III or greater).
• increased risk for airway obstruction because of anatomic variant.

There are no clinical trials or data supporting the superiority or safety of gastroenterologist or anaesthetist administered sedation/anaesthesia for endoscopic procedures, whether aiming for moderate or deep sedation. 31,32,33

Suggested sedation level for specific procedures

Gastroscopy: variable—some units do many procedures with no sedation, other units use anaesthesia for all gastroscopies.

Colonoscopy: variable—some units do many procedures with no sedation, other units use anaesthesia for all colonoscopies.

Sigmoidoscopy: almost always done with no sedation.

Complex procedures such as ERCP and EUS: almost always done with sedation.

Personnel

Standard practice in Canada is to have one assistant/nurse in the endoscopy room with the endoscopist and the patient. For patients undergoing complex procedures, prolonged procedures, or therapeutic procedures, up to two assistants or nurses may be present, which agrees with the CSGNA position statement on nursing staffing for procedures.34

REFERENCES

7. M. Veeraraghavan (personal communication)


34. CSGNA website.