



Society of Gastroenterology Nurses and Associates, Inc.

POSITION STATEMENT

Statement on the Use of Sedation and Analgesia in the Gastrointestinal Endoscopy Setting

Disclaimer

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Definitions

For the purpose of this document, SGNA has adopted the following definitions:

Anesthesia Professional refers to an anesthesiologist, nurse anesthetist, or anesthesiologist assistant (American Society of Anesthesiologists [ASA], 2016a).

Deep Sedation/Analgesia refers to “a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained” (ASA, 2014a). ** *Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.*

Gastroenterology (GI) Registered Nurse refers to an advanced practice registered nurse (APRN) and a registered nurse (RN).

General Anesthesia refers to “a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of the neuromuscular function. Cardiovascular function may be impaired” (ASA, 2014a).

Minimal Sedation (Anxiolysis) refers to “a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected” (ASA,

2014a).

Moderate Sedation/Analgesia refers to “a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained” (ASA, 2014a).

Monitored Anesthesia Care (MAC) refers to a specific anesthesia service in the care of a patient undergoing a diagnostic or therapeutic procedure. It does not describe the continuum of depth of sedation (ASA, 2014a).

Nonanesthesiologist-Administered Propofol (NAAP) refers to the administration of propofol under the direction of a physician who is not trained as an anesthesiologist, where it is given as a single agent or in combination with other medications. The goal is moderate to deep sedation (American Society for Gastrointestinal Endoscopy [ASGE], 2009).

Nurse-Administered Propofol Sedation (NAPS) refers to the administration of propofol under the direction of a physician who has not been trained as an anesthesiologist, where it is given as a single agent. The goal is deep sedation (ASGE, 2009).

Patient Care in the Gastrointestinal Endoscopy Unit refers to the pre-procedure, intra-procedure, and post-procedure care of the patient undergoing gastrointestinal endoscopy regardless of the setting.

Rescue refers to “an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiological consequences of the deeper than intended level of sedation (such as hypoventilation, hypoxia, and hypotension) and returns the patient to the originally intended level of sedation” (ASA, 2016a).

Sedation and Analgesia refers to a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia (ASA, 2014a).

Background

Sedation is a drug-induced depression in the level of consciousness that exists on a continuum ranging from minimal sedation through moderate, then deep, and finally general anesthesia (Fanti & Testoni, 2010). Sedatives and analgesics are typically given during endoscopic procedures to relieve anxiety, decrease pain and discomfort, and diminish the memory of the event allowing for a better examination (Kochhar et al., 2016). Optimal sedation requires consideration of patient and procedural factors that may influence the level of sedation. These factors include age, weight, medical history, current medications, airway assessment, anxiety, pain tolerance, length of procedure, and/or invasiveness of the procedure (Vargo et al., 2012; Kochhar et al., 2016).

Moderate sedation is commonly used for gastrointestinal endoscopy, but it is not without risk. Moderately sedated patients are able to respond to verbal commands, maintain a patent airway and ventilation, and usually maintain cardiovascular function. Patients are screened in advance in order to identify those at risk for complications.

Education for the non-anesthesiologist responsible for supervising or directly administering moderate sedation must include training on the safe administration of sedation and analgesia to achieve moderate sedation. The level of sedation should be titrated to achieve a safe, comfortable, and technically successful procedure. Individual responses to drugs can inadvertently lead to a level of sedation that is deeper than desired. The individual who administers moderate sedation must be able to recognize the signs and symptoms of progression into deep sedation (ASA & d, 2014; ASGE, 2008; Amornyotin, 2013; Fanti & Testoni, 2010). Training should also include the ability to rescue patients from a deeper level of sedation than intended. The American Society of Anesthesiologists (2016), the American Society of Gastrointestinal Endoscopists (2008, 2009), the American Society for Gastrointestinal Endoscopy & Society of Gastroenterology Nurses and Associates, Inc. (2004), and Centers for Medicare and Medicaid Services (2011) have all published practice guidelines covering this topic.

The role of the GI registered nurse in the use of sedation and analgesia continues to evolve. Propofol is an ultra-short-acting sedative, with amnesic but not analgesic effects, used to achieve deep sedation, and has no reversal agent (ASGE, 2008). Multiple studies support the use of NAPS and NAAP for a select group of patients undergoing gastroenterology procedures (Heuss, Schnieper, Drewe, Pflimlin, & Beglinger, 2003; Rex, 2002; Rex, Heuss, Walker, & Qi, 2005; Slagelse, Vilmann, Hornslet, Hammering, & Mantoni, 2011). The use of propofol for endoscopic sedation and anesthesia is governed by institutional and professional culture, legal and regulatory requirements, training and credentialing, and economic factors (Vargo et al., 2012).

The American Society of Anesthesiologists (ASA) (2012) asserts that only anesthesia professionals and non-anesthesiologist sedation practitioners with specialized training should give deep sedation because of the possibility that the patient could inadvertently progress into general anesthesia. The Centers for Medicare and Medicaid Services have identified those health care providers who are privileged to administer deep sedation (CMS, 2011). Sedation practices may change as new sedation agents and delivery systems become available.

The specialized training required of the non-anesthesiologists planning to administer propofol and monitor patients must include Advanced Cardiac Life Support (ACLS) certification, prior training in moderate sedation, and successful completion of a propofol sedation curriculum. A propofol sedation training curriculum should have four components: didactic training, airway workshop, simulation training, and preceptorship (ASGE, 2009). There should be periodic retraining in airway management and evaluation of performance for patient safety (ASGE, 2009; Regula & Sokol-Kobielska, 2008; Vargo et al., 2012).

Position

Moderate Sedation

The Society of Gastroenterology Nurses and Associates, Inc., supports the position that registered nurses trained and experienced in gastroenterology nursing and endoscopy can administer and maintain moderate sedation and analgesia by the order and supervision of a physician who is credentialed and privileged to do so (Calderwood et al., 2014; ASA, 2016a).

The GI registered nurse has the education, training, and experience in endoscopy; the knowledge of medications used and their safe administration; and the skills to assess, diagnose, intervene, and rescue patients (Cohen et al., 2007; Calderwood et al, 2014). Since moderate sedation usually involves a combination of medications (i.e., sedative and narcotic), it is crucial for the GI registered nurse to understand incremental dosing, the synergistic effects of different drug classes, and the onset and peak of sedation agents (Fanti & Testoni, 2010). The GI registered nurse can be given responsibility for the administration of reversal agents prescribed by the physician. The GI registered nurse is responsible throughout diagnostic and therapeutic endoscopic procedures for monitoring the patient, assessing the maintenance of moderate sedation and analgesia, and documenting the patient's status (SGNA, 2016). Automatic monitoring devices may enhance the ability to accurately assess the patient, but these tools are no substitute for the GI registered nurse's watchful, educated assessment (Cohen et al., 2007). Many clinical scoring systems have been developed to assist in determining the level of sedation and patient responsiveness in order to promote quality care and patient safety (Jarzyna et al., 2011; Vargo et al., 2012).

The GI registered nurse's ability to respond, intervene, and rescue patients from sedation requires current, age appropriate, documented completion of advanced life support education and training such as ACLS or PALS. This is necessary even when a code team is available for such emergencies (ASA, 2016a). The initial training and subsequent retraining must include hands-on practice and supervised demonstration of airway management skills, including jaw-thrust and chin-lift maneuvers, insertion of oral/nasal airways, face mask and positive pressure ventilation (Cohen, 2007).

During moderate sedation, the GI registered nurse monitoring the patient may assist with minor, interruptible tasks once the patient's level of sedation/analgesia and vital signs have stabilized (ASA, 2002; Calderwood et. al, 2014). Adequate monitoring of the patient's level of sedation must be maintained and continues into the post procedure phase of care (ASA, 2012; ASGE, 2008; Kochhar et al., 2016).

Because of the importance of managing the patient who is receiving sedation and analgesia, a second nurse or associate is required to assist the physician with those procedures that are complicated either by the severity of the patient's illness and/or the complex technical requirements associated with advanced diagnostic and therapeutic procedures (ASGE, 2008; SGNA, 2016).

Deep Sedation

Registered nurses and physicians must be aware of the limitations of federal and state regulations, state licensure, state nurse practice act, and current individual institutional policies regarding deep sedation practices. Non-anesthesiologist physicians who are not themselves qualified to administer deep sedation and recognize or rescue patients from general anesthesia may not delegate or supervise these duties to those also not qualified (ASA, 2012).

Deep sedation may occur even when moderate sedation is targeted. The planned targeting of deep sedation raises specific regulatory concerns, which require a higher level of competency in rescue techniques (Vargo et al., 2012). There must be procedures in place to rescue patients who

are sedated deeper than intended (ASGE, 2008; Amornyotin, 2013; CMS, 2011). The individual responsible for patient monitoring during planned or unintended deep sedation must be dedicated solely to that task and may not perform any other function (Calderwood et.al, 2014).

Those who use propofol must be skilled in the recognition of delayed adverse events, which may include symptoms of fever, chills, and myalgias 48 hours after administration (Vargo et al., 2012). Patients receiving propofol, even if moderate sedation is intended, should receive care consistent with that required for deep sedation. The non-anesthesiologist practitioner must be qualified to rescue those patients sedated beyond deep sedation into general anesthesia (ASA, 2014d).

Safety in the Sedation Environment

The GI provider should complete a focused history, conduct a patient physical, and review current medications. A documented risk evaluation should include an airway assessment and an ASA classification prior to the start of sedation (Calderwood et al., 2014). Proper informed consent should include discussion with the patient of the intended sedation plan and the benefits, risks, side effects, and alternatives to sedation, along with a thorough documentation of this discussion. Unless there is an emergency, patients should have the opportunity to have questions answered prior to sedation. A time-out or team pause prior to sedation is necessary for quality and safe patient care; this time-out should also be documented (Harris, Liu, & Saltzman, 2016; Cohen et al., 2007; The Joint Commission, 2017). Emergency medication and resuscitative equipment must be immediately available wherever sedation is administered (ASGE, 2008; Calderwood et al., 2014).

Medications should be securely stored under environmental conditions consistent with the manufacturer's instructions on the label. Controlled substances must be managed and documented in a manner compliant with state and federal regulations. The use of single-dose vials for all sedative and analgesic medications is strongly recommended. Proper hand hygiene and safe medication and injection practices must be followed to prevent hospital acquired infections. Used needles, sharps, syringes, and containers of unused medication should be disposed of, following institutional waste stream management guidelines (CDC, 2011a; CDC and National Center for Emerging and Zoonotic Infectious Diseases, 2012).

Topical pharyngeal anesthetic may be used in addition to sedation for comfort during upper endoscopic procedures. The development of methemoglobinemia has been associated with the use of benzocaine, found in some topical sprays (Goulson & Fragneto, 2009). Patients should be assessed for return of a gag reflex prior to oral intake.

Equipment used in procedural sedation should be inspected and confirmed to be in working order according to manufacturer's guidelines prior to use. There should be documentation of all checks and maintenance. Standard equipment for procedural sedation includes continuous free-flow oxygen, suction for the mouth and airway, and electronic physiological monitoring equipment regardless of the location. Patients should be monitored according to patient condition and procedural factors (e.g., type of sedation, duration and complexity of procedure, patient condition).

Cardiopulmonary monitoring during procedural sedation includes blood pressure, pulse rate, oximetry, and continuous electrocardiography (Harris et al., 2016). At a minimum, this should

be performed and documented at the following stages: before the procedure, after administration of sedatives, at regular intervals during the procedure, and 30 minutes after the last dose of sedation. Monitoring continues throughout the post-procedure phase of care, and just before discharge. The patient's level of consciousness and comfort level should be assessed and documented throughout (Kochhar et al., 2016).

Capnography has been identified by the ASA as a monitoring tool to be used during endoscopic procedures where propofol is used alone or in combination with medications used for moderate sedation (ASA, 2014b). The ASA (2015) further asserts that exhaled CO₂ is to be monitored during moderate sedation, unless the patient's condition, procedure, or equipment precludes or invalidates this. Existing pulmonary disease, obstructive sleep apnea or morbid obesity are examples of conditions that influence not only sedation, but baseline capnograph readings. The use of CO₂ insufflation during endoscopic procedures has a demonstrated benefit, though it is unclear if this technology interferes with capnography. Further research is needed on its safety and effect on patients with pre-existing CO₂ retaining conditions (Dellon et al., 2009). Literature suggests that, while there is inadequate data to support the routine or required use of capnography during endoscopic procedures in adults where moderate sedation is the target, capnography should be considered for endoscopic procedures under deep sedation (ASGE, 2013b; Barnett et al., 2016; Cohen et al., 2007; Kochhar et al., 2016). While GI medical societies state little value for universal adoption of capnography for moderate sedation (Vargo et al., 2012), the non-anesthesiologist practitioner may be required to adhere to monitoring guidelines as outlined by the institution and regulatory agencies (CMS, 2011; Jarzyna et al., 2011).

Continued observation and monitoring of patients recovering from moderate or deep sedation is essential to decrease cardiopulmonary risks. There should be written policies on discharge requirements, following established discharge criteria. Oxygenation, level of consciousness, vital signs, activity, and level of pain should be stable with a return to the patient's pre-procedural state, or within acceptable limits, before discharge (ASA, 2002).

Home care instructions must be individualized, specific to the patient type and procedure. Patients who receive sedation during their endoscopic procedure should be instructed to avoid activities that require physical effort, focused attention (such as driving), judgment, or decision-making. Instructions for post-procedure diet, activity, and medications should be provided in written form, discussed with the patient's authorized designate, and include guidelines for contacting the physician. Patients leaving the endoscopy unit after receiving sedation for their endoscopic procedure should be escorted and discharged to home with a responsible adult. Both patient and caregiver must be alerted to signs and symptoms of post-procedure complications and report them to the physician (ASA, 2002; Cohen et al., 2007; Calderwood et al., 2014; Harris et al., 2016).

General Considerations for Sedation Plan

SGNA supports the position that, when an anesthesia professional is administering the sedation, the GI registered nurse will remain with the patient to provide continuity of care and assist the health care team (SGNA, 2016).

Special considerations related to the sedation plan may be needed for pediatric patients (American Academy of Pediatrics & American Academy Pediatric Dentistry [AAP/AAPD],

2006; ASGE, 2014; Krauss & Green, 2006), the elderly (ASGE, 2013a), pregnant and lactating women (ASGE, 2008, 2012), patients with sleep apnea (ASA, 2013b), and those who have had previous problems with anesthesia or sedation (ASGE, 2008). An anesthesia professional may need to provide sedation when patients have a history of alcohol or substance abuse, are morbidly obese, have neurological diseases or neuromuscular disorders, or are uncooperative or delirious (ASGE, 2008; Cohen et al., 2007). Anesthesia professionals should strongly be considered when the patient is ASA classified IV or V and may be required with patients who have a history of failed moderate sedation (ASA, 2014c).

Endoscopic procedures that may require an anesthesia professional include endoscopic retrograde cholangiopancreatography, stent placement in the upper gastrointestinal tract, endoscopic ultrasound, and complex therapeutic procedures (e.g., endoscopic submucosal dissection, double-balloon endoscopy) (ASGE, 2008; Cohen et al., 2007).

It is expected that the anesthesia professional providing monitored or general anesthesia conduct a pre-anesthetic evaluation of the patient, collaborating and communicating the plan of care with the gastroenterologist. When anesthesia is performed in the endoscopy suite, the anesthesia professional must determine what equipment is necessary, based on the patient's condition. There should be a plan for support when serious adverse events occur. The provider of monitored anesthesia care must be qualified to convert to general anesthesia when necessary (ASA, 2013c). Patients who have been given deep sedation or anesthesia should be recovered in a location where they can receive the same level of post-sedation nursing care and monitoring comparable to the post-anesthesia care unit (PACU). This should be based on the medications received, the patient's risk for developing post anesthesia complications, and the adequacy and competency of staff managing such complications (Goulson & Fragneto, 2009; CMS, 2011). The anesthesia professional conducts a post-anesthesia evaluation, remaining with the patient as long as medically necessary, and provides discharge guidelines from post-anesthesia care (ASA, 2016b).

The goal of procedural sedation is safe, optimal patient outcomes. Open, clear, and ongoing communication among the members of the endoscopy team is essential for the patient's safety and well-being. Endoscopy personnel must follow practice guidelines regarding procedure-related sedation, including documentation, training of staff, rescue equipment, emergency protocols, and quality programs (Cohen et al., 2007). Ongoing education and performance reviews of the clinical practitioner providing sedation can support good patient outcomes (ASA, 2016b). By tracking adverse events related to sedation, consistently assessing policies and procedures, and reviewing sedation practices, nurses can help in improve patient care quality and maintain patient safety goals (Jarzyna et al., 2011).

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SGNA Practice Committee 2016 - 17

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