

Guidelines

ASIPP Guidelines for Sedation and Fasting Status of Patients Undergoing Interventional Pain Management Procedures

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Many of the patients undergoing interventional procedures have daily regimens of medications including analgesics, muscle relaxants, and other drugs that can have significant additive/synergistic effects during the perioperative period. Further, many patients also present with comorbid states, including obesity, cardiovascular, and pulmonary disease. Consequently, in the perioperative period, a significant number of patients have suffered permanent neurologic injury, hypoxic brain injury, and even death as a result of over sedation, hypoventilation, and spinal cord injury. In addition, physicians are concerned about aspiration, subsequent complications, and as a result, they ask patients to fast for several hours prior to the procedures.

Based on extensive literature and consensus, a minimum fasting period is established as 2 hours before a procedure for clear liquids and 4 hours before procedure for light meals, rather than having all patients fast for 8 hours or even fasting beginning at midnight the night before the procedure. Gastrointestinal stimulants, gastric acid secretion blockers, and antacids may be used, even though not routinely recommended.

Due to the nature of chronic pain and anxiety, many patients undergoing interventional techniques may require mild to moderate sedation. Deep sedation and/or general anesthesia for most interventional procedures is considered as unsafe, since the patient cannot communicate acute changes in symptoms, thus, resulting in morbidity and mortality, as well as creating compliance issues. We are adapting the published standards of the American Society of Anesthesiologists for monitoring patients under sedation, regardless of the location of the procedure, either office-based, in a surgery center, or a hospital outpatient department. These standards include monitoring of blood pressure, cardiac rhythm, temperature, pulse oximetry, and continuous quantitative end tidal CO₂ monitoring. Sedation must be provided either by qualified anesthesia or non-anesthesia providers, with appropriate understanding of the medications, drug interactions, and resuscitative protocols.

Key words: Guidelines, sedation, fasting status, monitoring, neurological complications

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I. BACKGROUND

Tens of thousands of patients undergo interventional pain procedures annually in the U.S. (1-6). Many of these patients have daily regimens of medications

including analgesics, muscle relaxants, and other drugs that can have significant additive/synergistic effects during the perioperative period. Additionally, many of these patients have co-morbid states, including obesity,

obstructive sleep apnea, cardiovascular and pulmonary disease. Patients have suffered permanent neurologic injury, hypoxic brain injury, and even death as a result of over sedation, hypoventilation, and spinal cord injury (7-14). The American Society of Interventional Pain Physicians (ASIPP) has developed guidelines for the best practice delivery of sedation for interventional pain procedures (15-17).

Three major potential complications associated with the use of sedation and anesthesia for procedures should be appreciated by every interventional pain practitioner. First, if a needle is inserted incorrectly in a location such as the spinal cord, the patient will not be able to communicate sudden paresthesias, dysesthetic pain, or any other aberrant sensations to the interventional pain practitioner while under deep sedation or general anesthesia. This feedback information from the patient can be vital to reduce the potential for severe and permanent complications during and interventional procedure. Needle penetration into the spinal cord itself may not cause pain or irreversible damage; rather, intramedullary deposition of as little as 0.5-1 mL of injectate will most likely result in neurologic deficit due to syrinx formation and disruption of neuronal pathways (13,18). The second potential complication is related to the requirement of prone positioning for most interventional pain procedures, which may incur additional risk and complicate the provider response when adverse events do occur. Thirdly, the inherent risk of deep sedation and/or general anesthesia per se should be considered, which can result in hypoventilation, pulmonary compromise, anoxic brain states, and/or death.

In addition to the above complications, physicians should be concerned about aspiration risk and complications related to keeping patients NPO for the required period of time prior to the procedure.

It should be noted that under appropriate circumstances, properly managed sedation can improve patient comfort and facilitate performance of interventional procedures. However, given the inherent hazards, particularly with deep sedation and general anesthesia, the risk versus benefit ratio for specific patients should be assessed. It would not seem prudent to use sedation for every patient without appropriate evaluation or based solely on revenue considerations for the practice.

II. FASTING STATUS

In 1883 Lister (19) recommended that patients may drink clear liquids about 2 hours before surgery,

but there should be no solid matter in the stomach. For the next 80 years, textbook fasting guidelines were 2 to 3 hours for clear liquids and 4 to 6 hours for easily digestible foods. In 2017, the American Society of Anesthesiologists (ASA) published an updated report on Practice Guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration (20). They defined perioperative pulmonary aspiration as aspiration of gastric contents occurring after induction of anesthesia, during a procedure, or in the immediate postoperative period. They also defined preoperative fasting as a prescribed period before a procedure when patients are forbidden from oral intake of liquids or solids. Their recommendations included limiting clear liquids to 2 hours before and light meals 6 hours before anesthesia, in line with the earlier recommendations of 4 to 6 hours.

A single study available in the interventional pain management literature (21) demonstrated a lack of complications in patients without fasting and undergoing sedation for interventional techniques. The authors concluded that postoperative nausea, vomiting, and respiratory depression are rare and aspiration almost nonexistent, despite almost all patients receiving sedation without preoperative fasting prior to provision of the interventional techniques. In radiology, a prospective observational study (22) showed an extremely low incidence of nausea and vomiting of 0.071% and no aspiration with enhanced CT examination. They concluded that the occurrence of nausea and vomiting has no correlation with the preoperative solid food consumption status. In contrast, an assessment of patients exposed to non-ionic contrast media (23) examined the incidence and risk factors for nausea and vomiting associated with preparatory fasting. The results showed mild nausea occurring in 2.9% of patients and no vomiting with a 6 hour preparatory fast from solid food. Many patients underwent excessive fasting for fluids, as well as solid food, and their fasting durations were not associated with the development of peri-procedural nausea. However, they also showed that a history of drug hypersensitivity was an independent risk factor for nausea. In an earlier manuscript, which assessed the relationship between oral food intake and nausea caused by intravenous injection of iodinated contrast material, the incidence of nausea was 6.7% in the high osmolarity contrast medium group and 1.4% in the low osmolarity contrast medium group (24). However, the incidence of nausea and vomiting increased with

the interval between the oral intake of food and the intravenous injection of contrast medium, leading to the conclusion that fasting before contrast computed tomography (CT) enhanced the adverse effects of nausea and vomiting, rather than reducing it.

Based on extensive literature and the ASA recommendations, for patients undergoing sedation, a minimum fasting period of 2 hours for clear liquids and 4 hours for a light meal should be established rather than NPO for 8 hours or requiring that all patients remain NPO after midnight. Gastrointestinal stimulants such as metoclopramide, gastric acid secretion blockers such as cimetidine, famotidine, ranitidine, omeprazole, and lansoprazole may be used but are not routinely recommended (20). Antacids, sodium citrate, sodium bicarbonate, magnesium trisilicate, antiemetics, and ondansetron may be used as monotherapy or in combination but are not recommended as empiric therapies (20).

III. LEVELS OF SEDATION FOR INTERVENTIONAL PAIN PROCEDURES

Numerous publications, though not extensive (21-29), have provided discordant information in reference to the need for sedation during interventional pain management techniques; however, multiple LCDs, medical guidelines, and society guidelines describe their policies for sedation for interventional pain procedures with many patients requiring only local anesthesia or mild sedation (29-40). Given that patients undergoing pain procedures typically are anxious and in pain, mild to moderate sedation is acceptable for many patients. Deep sedation and/or general anesthesia for most interventional pain procedures may be unsafe because the patient cannot communicate injury-related pain (e.g., spinal cord injection), which can result in morbidity and/or mortality as well as create compliance issues. Another major concern is that most patients undergoing interventional pain procedures are taking potent medications that possess synergistic sedative-hypnotic properties. Drug-drug interactions may result in over sedation and complications. Deeper sedation should only be undertaken in the presence of anesthesia providers and for patients who have high anxiety, complex pharmacotherapy, or a low pain threshold when undergoing more painful interventional pain procedures. In special cases, the risk of patient movement during a procedure resulting in potential inadvertent injury may justify a deeper anesthetic state.

IV. MONITORING

The ASA has published standards for monitoring patients under sedation, regardless of location of a procedure, e.g., office based, surgery center, and hospital. These standards are identical regardless of the setting and require blood pressure monitoring, assessment of real-time EKG, temperature measurement (if indicated or anticipated variance), pulse oximetry, and continuous quantitative end tidal CO₂ monitoring. The omission of end tidal CO₂ monitoring can significantly delay identification of hypoventilation and appropriate airway support, and result in catastrophic complications including anoxic brain injury and even death (29,41-43). Supplemental oxygen by nasal cannula is also recommended, particularly for deep sedation (44).

V. SEDATIVE MEDICATIONS

- i. **Providers:** Qualified anesthesia and non-anesthesia providers administer sedation for patients for a variety of diagnostic, therapeutic, and/or surgical interventional pain procedures. Practitioners should aim to provide patients with the benefits of sedation and/or analgesia while minimizing the associated risks. Individuals responsible for patients receiving sedation and/or procedural analgesia should understand the pharmacology of the agents being administered as well as the role of pharmacologic antagonists for opioids and benzodiazepines to rescue patients.
- ii. **Sedation Goals for Interventional Pain Procedures:** Combinations of sedative-hypnotics and analgesics should be administered in a titrated fashion, using as little as is reasonable to accomplish the stated goals, and as appropriate for the procedure being performed and the condition of the patient. Many patients undergoing interventional pain procedures only require local anesthesia infiltration and no additional sedation. Mild to moderate sedation is acceptable in carefully selected patients. Deep sedation and/or general anesthesia, and the drugs most commonly utilized for such purposes (e.g. propofol, ketamine, and etomidate), are not appropriate for most interventional pain procedures (44).
- iii. **Drug Interactions:** Potential drug interactions require the clinician providing sedation to appreciate potential drug-drug effects, which can lead to morbidity and mortality, primarily from cardio-respiratory depression. Additive and/or synergistic

effects of two or more sedatives are well described and may result in central nervous system and respiratory depression. Anesthesia providers spend years studying and refining their practice; this is not always the case for the non-anesthesia sedation provider. Therefore, it is strongly recommended that healthcare providers develop a comprehensive understanding of the side effects as well as potential drug-drug interactions of the agents they are using in each clinical setting. This must include over the counter agents and herbals, of which there are over 29,000 available, many of which can interact in unfavorable ways with conventional sedative medications (45-48).

VI/ DRUG SELECTION

- i. Benzodiazepines possess anxiolytic, amnesic, and sedative properties (49). Commonly administered benzodiazepines include midazolam (Versed), diazepam (Valium), and lorazepam (Ativan). The most commonly used benzodiazepine for sedation is midazolam. It is rapidly redistributed from the brain to other tissues and metabolized by the liver. Thus, it has a short duration of action. Metabolism in the liver is by hydroxylation, and midazolam is excreted by the kidneys after conjugation. Terminal elimination half-time of midazolam is about 1-4 hours. The elimination half-time may be doubled in the elderly as a result of age-related decreases in hepatic blood flow and possibly by enzymatic activity. Midazolam should be used with caution in the morbidly obese related to their increased volume of distribution and its prolonged half-life.
 - ii. Opioids are potent analgesics commonly used to provide analgesia before, during, and/or after procedures. Opioids are often utilized in combination with benzodiazepines to provide sedation and analgesia. Some of the more commonly used opioid agonists are morphine, fentanyl (Sublimaze), hydromorphone (Dilaudid) and meperidine (Demerol). In the setting of interventional pain procedures, fentanyl's analgesic effects are 75-125 times more potent on a mg-mg basis than morphine (50). Fentanyl is often used as the analgesic component in sedation because of its rapid onset of clinical action and minimal histamine release. A single dose of fentanyl IV has a more rapid onset and shorter duration of action than an equianalgesic dose of morphine.
- The greater lipid solubility of fentanyl compared to morphine explains its more rapid onset and greater potency. The short duration of a single dose of fentanyl associated with a rapid fall in plasma concentration reflects its rapid redistribution into inactive tissue sites such as skeletal muscle and fat. However, when multiple IV doses of fentanyl are administered, or with continuous infusion, progressive saturation of inactive tissues occurs. As a result, duration of analgesia and depression of ventilation may be prolonged when the plasma concentrations of the drug do not decrease rapidly. Metabolism of fentanyl occurs in the liver. IV fentanyl results in clinical effects within 30 seconds to 1 minute. Peak effects occur within 10 minutes and duration of action is 30-60 minutes following a single dose. Analgesic concentrations of fentanyl greatly potentiate the effects of midazolam. Synergism of opioids and benzodiazepines plays an important role in achieving hypnotic states for potentially painful procedures. However, the combination can easily result in respiratory depression (51). Chest wall rigidity has been reported in adults receiving analgesic doses of fentanyl and is best avoided by slow injection of low doses (52).
- iii. Propofol (Diprivan) is not recommended for interventional pain procedures because of its potency, which can result in rapid deep sedation and/or general anesthesia states, making the patient unable to communicate when a needle is inadvertently placed incorrectly as well as resulting in dose-dependent respiratory depression. Propofol is a short-acting sedative-hypnotic agent with antiemetic properties (53). Propofol is highly lipid-soluble, which explains the drug's rapid onset. Propofol is well suited for deep sedation because it allows for prompt recovery without residual sedation and a low incidence of nausea and vomiting. Even at low doses, propofol can cause decreased oxygen levels, increased carbon dioxide levels, and inhibit airway reflexes. Because of its pronounced respiratory depressant effects and narrow therapeutic range, propofol should only be administered by individuals trained in airway management and should not be utilized for interventional pain procedures under mild to moderate sedation. In this regard, dosing regimens should be further modified for sedation in elderly patients and those with severe systemic disease.

VII. CONCLUSION:

Sedation for interventional pain procedures should be done with caution and, if deeper sedation is required, the interventional pain physician must take precautions to protect their patients from the risks of over sedation. This includes ensuring that personnel skilled in airway management are available to resolve potential complications, anticipate over-sedation and maintain antagonists and reversal agents readily at hand, and consider neuromonitoring during procedures requiring deep sedation which incur heightened risk of neurologic injury. Appropriate vital sign monitoring should be considered for patients receiving sedation, including blood pressure, EKG, temperature, pulse oximetry, and continuous quantitative end-tidal CO₂ monitoring. The availability of supplemental oxygen should be easily accessible or given prophylactically to patients who are sedated. In preparation for sedation, the interventional physician should assess the NPO status of their patients and have a protocol in place to reduce the risk of aspiration complications. The minimum recommended NPO status is 2 hours for clear liquids and 4 hours for a light meal in lieu of NPO after midnight for all patients.

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Conflict of Interest

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