

CONSCIOUS SEDATION

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The debate has now raged on for years. Propofol or older drugs? Administration by an anesthesiologist or a nurse anesthetist, or even a staff nurse? End-tidal CO2 monitoring or just pulse oximetry?

Newer drugs may not be as "proven" as older ones; both sides of the administration debate can offer good arguments to support their positions; and some more traditional practitioners may prefer to play it safe with older technology that they have experience with.

These days, however, not every decision is left to the practitioner. State legislations are getting in on the act, restricting or expanding the medication-administering powers of the nurse anesthetist.

"Each state board of nursing deals with new nursing practices in varying manners," says Jan Odom-Forren, MS, RN, CPAN, FAAN, a doctoral student at the University of Kentucky's College of Nursing, and co-editor of the *Journal of Perianesthesia Nursing*. "No state board of nursing (BON) has determined that administration of moderate sedation is not within that scope of practice for a registered nurse (RN).

Some states have no specific position statement and just require education and competency. Others have specific position statements or advisory opinions. So administration of moderate sedation by a competent and appropriately educated RN is common practice."

New Advances in Sedation

The science continues to advance for sedation, and is trending toward greater patient involvement. "I have read a couple of articles lately about patient-controlled propofol sedation," Odom-Forren says. "The patient controls the button, so when they are sedated, they are not pushing the button, and when they are waking up, they can push it. They control the amount of propofol (within parameters). I've seen one research article on dental patients and one in the endoscopy setting with colonoscopy patients."

And, she continues, "I have been saying for a few years now that we may see Precedex move into the moderate sedation arena. I saw a research article the other day in which they used Precedex on cataract patients under sedation. We may see more of that in the future."

Precedex, she explains, is currently used with ventilated patients in the intensive care unit (ICU). "It has sedative and analgesic effects without respiratory depression," she explains. "I understand that they are trying to get it approved for use in the operating room (OR), which has already happened off-label. And they are looking at the sedation arena also."

According to the manufacturer, Precedex is indicated for the sedation of initially intubated and mechanically ventilated patients and should be administered by continuous infusion not to exceed 24 hours. It is the only relatively selective alpha2-agonist approved for continuous intravenous (IV) sedation in the intensive care setting. It can be used before, during and after extubation.

Patient monitoring has also been undergoing a process of evolution. "For deep sedation, it is becoming common to use the capnograph to monitor end tidal carbon dioxide," Odom-Forren says. "It is mentioned in several position statements for deep sedation (such as propofol) that the capnograph should be used to aid in determination of ventilatory adequacy."

Sedatives

"The most common sedative at present is midazolam (brand name Versed), and the most common analgesic is fentanyl (brand name Duragesic and Ionsys)," Odom-Forren explains. "Keeping the patient at the level of moderate sedation is safer for the patient than deep sedation. The further along the continuum the patient moves, the greater chance there is of a complication. Midazolam is shorter acting and water-soluble — better than diazepam (brand name TQuil, Valrelease, Valium). Fentanyl is a shorter-acting opioid. It is perfect for the outpatient setting, although meperidine (brand name Demerol) and morphine (brand name MS Contin) are still used with success. To perform deep sedation with propofol or any other agent, there are many T's to cross and I's to dot — a multidisciplinary team's writing policy, board of nursing rulings, other state regulations, professional organization position statements, legal issues, involvement by the anesthesia department, etc. Those who are using propofol believe it is best because it is shorter-acting. There are articles that talk about patient satisfaction and decreases in length of stay (LOS). However, one article I read talked about a facility where they decided not to use propofol even though it decreased LOS by a few minutes, because it did not noticeably increase patient satisfaction and was not worth the legal hassles."

The Problem With Propofol

The problem with propofol (brand name Diprivan) is that it is considered by the FDA to be an anesthetic agent, and should be administered by persons trained in the administration of general anesthesia. "So right now we have some states that have said explicitly that administration of propofol for sedation is not within the scope of practice for RNs (e.g., Florida), some that say that it is within the scope of the RN to administer drugs such as propofol for sedation, but no anesthetic agents for anesthesia (e.g., Maine),"

Odom-Forren explains. "There are states that have addressed new practices in rather vague terms, in which they incorporate decision trees to aid healthcare facilities and RNs in deciding whether a new practice is appropriate or not with proper education and competency (e.g., Kentucky). There are many states that have not specifically addressed the issue of propofol administration."

"Although many practitioners in the endoscopy suite may disapprove, it is nonetheless true that the package insert information for propofol specifically states that when the drug is used in patients who are not intubated, mechanically ventilated or being treated in a critical care unit, the drug 'should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure,'" says John P. McDonough, CRNA, EdD, ARNP, professor and director of the nurse anesthetist program at the University of North Florida in Jacksonville.

"Further, many state boards of nursing have also published declaratory opinions prohibiting RNs who are not nurse anesthetists from administering propofol to non-intubated patients. One may debate, and many have, the wisdom of this position," he continues. "But the fact remains that unless the endoscopy RN practices in a state that has specifically permitted NAPS, the FDA-approved warnings and rulings by several state boards of nursing make it clear that if propofol is administered by either a non-anesthetist RN or a gastroenterologist performing an endoscopy, they do so at their own legal peril."

The most important thing to remember when considering conscious sedation is to understand what the actual term means, McDonough points out. "During conscious sedation, the patient is supposed to remain 'conscious'. This obviously means that the patient is expected to remain awake and be able to answer questions and cooperate with requests. Excluding the use of propofol, this goal remains most commonly achieved through the use of the combination of a narcotic and a benzodiazepine, commonly meperidine. These drugs are certainly by no means new, but they remain the mainstay of truly 'conscious' sedation."

The most commonly used benzodiazepine for GI sedation remains midazolam, McDonough continues. "Although it works well and is better tolerated than its oil-based predecessor diazepam, one must recall that the patient response is clearly not related to a mg/Kg dosing scale. The patient reactions are very individualized. Physical signs are a more reliable indicator of therapeutic effect. For instance, when a patient is displaying slurred speech, amnesia of that period will likely result, regardless of the dose administered."

"The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) concurs with the American Society of Anesthesiologists and the American Association of Nurse Anesthetists in their 2004 joint statement regarding propofol, which created new standards to address the growing Propofol concern," says David Brimm, press contact for the association.

"The statement mandates that whenever propofol is used for sedation/ anesthesia, it should be administered only by those trained in the administration of general anesthesia, who are not simultaneously involved in these surgical or diagnostic procedures. This restriction is in accord with specific language included in the propofol package insert, and failure to follow these recommendations could put patients at increased risk of significant injury or death," he points out.

Guidelines

The American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG), and the American Society for Gastrointestinal Endoscopy (ASGE) have already issued a joint statement supporting nurse administered propofol by nonanesthesiologists for endoscopy, adds Odom-Forren.

"And the American Society of Anesthesiologists (ASA) and American Association of Nurse Anesthetists (AANA) issued a joint statement that propofol should be administered only by persons trained in the administration of general anesthesia who are not also involved with the procedure," she says. "This was based on their belief that sedation is a continuum, and you can't predict how a patient will respond. That propofol can cause rapid and profound changes, and there is not reversal for propofol."

The fact that there is no reversal agent for propofol is one of the reasons behind some practitioners' preferences for older drugs. They may cause more side effects, but they also have a reversal agent if things go sour.

"The AAAASF requires that only anesthesiologists or nurse anesthetists administer propofol in facilities with their accreditation," Odom-Forren adds. "ASA did go on to develop a statement on safe use of propofol by non-anesthesiologists even though they do not approve of the practice. It emphasizes that the person who administers the propofol should be qualified to rescue patients whose level of sedation could move to general anesthesia, and has specific requirements for physicians and nurses, such as advanced cardiac life support (ACLS) certification."

The ACG has filed a citizen's petition with the U.S. Food and Drug Administration (FDA) asking for a change in the warning label, so that it would state that only those trained in administration of general anesthesia and not involved in the procedure should administer propofol.

"The ASA has responded with an extensive paper to the FDA on their reasons why the warning label should not be changed," continues Odom-Forren. "The Institute for Safe Medication Practices issued an alert last year to discuss the issue. The article talked about the issue and gave some examples of complications. The article suggests that an interdisciplinary team (including anesthesia) should establish the policies while considering state boards of nursing and their preferences, as well as professional organization position statements and state laws. It also gives suggestions for detailed policies if the team decides that nurse-administered propofol sedation (NAPS) is appropriate for the facility."

The Society of Gastroenterology Nurses and Associates (SGNA) has also issued a position statement, which gives specific criteria for deep sedation as opposed to moderate sedation, and does not rule out sedation via propofol.

The ASA's guidelines for non-anesthesiologists also differentiates care of the patient receiving moderate sedation and deep sedation, with more stringent requirements for the patient undergoing deep sedation. "As you can see, the jury is still out," Odom-Forren observes.

Propofol has certainly become more widespread in the last few years, but recent reports submitted to the Pennsylvania Patient Safety Authority show that, in untrained hands, propofol can be deadly.¹ "The Pennsylvania Patient Safety Reporting System (PA-PSRS) has received over 100 reports in which the use of propofol has been cited," according to a news release on Medical News Today, an online news source.

"Sixteen percent of these reports have been classified as 'serious events,' including four patient deaths in which propofol may have played a role. In many cases, the events show that the practitioners involved in administering the drug were not fully trained in the use of propofol and other heavy sedation drugs."

And therein lies the problem. Suggested uses for propofol are clear in that the administering healthcare professional must be solely devoted to the patient's sedation, not busy doing other tasks related to endoscopy. But this is happening despite recommendations.

Propofol can be dangerous in untrained hands because it can be so unpredictable. "Propofol dosing and titration is variable, as it is based on the patient's response and tolerance to the drug," says the Pennsylvania Patient Safety Authority.²

Respiration can change dramatically in a very short time, deteriorating to full respiratory arrest, even when propofol is given in low doses. Individual responses to this medication cannot be absolutely predicted.

If a facility decides to allow nurse-administered propofol, it is necessary for the multidisciplinary team to specify when a nurse can administer the drug, and what specific education and mentorship she must undergo, as well as how her competency will be evaluated, and how frequently. "Keep in mind that ACLS certification alone may not be sufficient for this purpose," the authority cautions.

An article in the March 2006 *Patient Safety Advisory*, a quarterly newsletter put out by the patient safety reporting authority, describes the differences between professional societies in their recommendations. The American College of Gastroenterology, American Society for Gastrointestinal Endoscopy and the Society of Gastroenterology Nurses and Associates, for example, endorse nurse-administered propofol, consistent with state regulations, if the nurse is trained to use the medication and can resuscitate patients from general anesthesia or severe respiratory depression. But the American Society of Anesthesiologists, American Association of Nurse Anesthetists, and the American Association of Ambulatory Surgical Facilities disagree and have stricter guidelines for propofol and similar sedation drugs.²

The article, "Who Administers Propofol in Your Organization?" includes several practices to minimize the risk involving propofol and other sedatives. To view a PDF of the article in full, visit www.psa.state.pa.us/psa/lib/psa/advisories/mar_2006_advisory_v3_n1.pdf.

Another article, "Propofol Administration: A Contentious Issue," from the *Nursing Spectrum* issue of Sept. 25, 2006, documents several cases in which patients died after propofol was administered inappropriately.³

Propofol's popularity is due to several characteristics that render it superior to other sedatives in terms of side effects and duration — these include:

- Rapid onset and short duration of action
- Shorter waking and recovery times
- Reduced need for opioids, resulting in less nausea and vomiting

"If an organization has not taken a position on the administration of this medication, a place to start is with a multidisciplinary team or ad hoc committee," according to the *Nursing Spectrum* article. "To assure all stakeholders have an opportunity to address their issues, include representatives from administration, nursing, pharmacy, and medicine. In particular, subspecialty representation should include anesthesia, emergency, gastroenterology, radiology, surgery, and other physicians who administer or monitor patients medicated with propofol."

"Based on the action and nature of propofol and the number of error reports submitted to PA-PSRS and other organizations, the safest strategy is to limit propofol use to health care professionals with specialized training in administering, monitoring, and treating its untoward effects," the article concludes.

Works Cited

1. www.medicalnewstoday.com/medicalnews.php?newsid=40846

2. www.psa.state.pa.us/psa/lib/psa/advisories/mar_2006_advisory_v3_n1.pdf
3. <http://community.nursingspectrum.com/MagazineArticles/article.cfm?AID=23581>