THE GREAT DEBATE ON NURSE-ADMINISTERED PROPOFOL SEDATION (NAPS)—WHERE SHOULD WE STAND?

The American College of Gastroenterology, the American Gastroenterological Association, and the American Society of Gastrointestinal Endoscopy issued a joint statement on propofol sedation for endoscopy. Among their recommendations that have important implications for dentistry are:

- Compared to standard doses of benzodiazepines and narcotics, propofol may provide faster onset and deeper sedation. . . . More rapid cognitive and functional recovery can be expected with the use of propofol as a single agent.
- There are data to support the use of propofol by adequately trained nonanesthesiologists. Large case series indicate that with adequate training, physician-supervised nurse administration of propofol sedation can be done safely and effectively.

Armed with these recommendations and a dozen more, they are lobbying to convince state regulatory boards, surgicenters, and hospitals to accept nurse-administered propofol sedation (NAPS) for their endoscopic procedures. The American College of Gastroenterology has even petitioned the Food and Drug Administration (FDA) to remove the warnings on the propofol labeling that currently state, "Only those persons trained in the administration of general anesthesia should administer the drug," and "Only those persons not involved in the conduct of the surgical/diagnostic procedure should administer the drug."

NAPS is gaining popularity among gastroenterologists as an alternative to the traditional midazolam-fentanyl conscious sedation techniques. Rather than certified registered nurses or anesthesiologists, nurses with no formal anesthesia training are administering propofol deep sedation under the guise of "supervision of conscious sedation" by non-anesthesia-trained physicians to cut costs. Using propofol decreases recovery time and allows more patients to be seen in a day than with traditional conscious sedation techniques. Even though endoscopists cannot charge separately for any kind of sedation they provide under Medicare rules, their use of propofol nevertheless increases their bottom line at the expense of reducing the margin of safety for the patient. There are several large case studies that the proponents claim are proof that NAPS is safe. In 1 study with 9152

endoscopic cases, there were no intubations needed (or at least none attempted) and no deaths. Another study of 2574 cases of NAPS again demonstrated that there were no intubations and no deaths. Does this prove that NAPS is safe because no one died in these studies, or does it indicate that the endoscopist might never consider it necessary to intubate anyone because they lack the confidence and skill to actually do it?

What was reported but seemingly glossed over is the fact that 43 of the 2574 patients in 1 study sustained hypoxemia and 6 of these needed mask ventilation for more than a minute. In the other large study of 9152 patients, there were 3 laryngospasms, 3 cases of prolonged apnea, and 1 aspiration that required hospitalization of the patient. Luckily, all of the laryngospasms resolved with positive pressure ventilation, but what if they had not? Could the endoscopists have rescued them from these near-misses with disaster? The aspiration patient, who perhaps should have been intubated but wasn't, also may have been fortunate to survive his near-miss. What wasn't mentioned at all was that if these patients had not survived because of factors that sometimes make it difficult for even a seasoned anesthesiologist to successfully mask-ventilate a patient, the "proof of safety" claim could have been just the opposite. Passing an Advanced Cardiac Life Support course every 2 years does not make one skilled enough to reliably be able to mask-ventilate an unconscious patient in laryngospasm who has a full beard or a severely retrognathic mandible while the patient is lying in the lateral position during a colonoscopy under NAPS deep sedation. There is no substitute for general anesthesia training and experience whenever deep sedation is administered.

Physician anesthesiologists claim that their mortality rate for healthy patients is approximately 1 : 250,000 to 1 : 300,000 administrations of anesthesia. The fact that none of the NAPS near-misses resulted in a fatality among only 11,726 patients studied is not a very significant determinant of safety and certainly does not come close to proving ultimate safety. In fact, NAPS could have 10 times the risk of mortality (1 : 25,000) of anesthesiologist-administered general anesthesia, yet with only 11,726 NAPS patients studied in these 2 articles, it would not be a surprise for no deaths to occur in that comparatively small cohort of patients. These reported near-misses also indicate that NAPS is most likely deep sedation or general anesthesia for some of the cases rather than a true conscious sedation technique. In aviation safety, 7 near-misses but no crashes

does not demonstrate safety, but rather that major safety problems likely exist.

There are several other fallacies in the safety arguments of the NAPS proponents. In the large study noted above, a physician anesthesiologist supposedly “trained” the endoscopists and nurses for 17 months in the proper way to administer intermittent small boluses of propofol before supposedly allowing them to do it independently in that ambulatory surgery center, where it is possible that the anesthesiologist could have been immediately available had a more serious emergency occurred. This is undoubtedly an artificial situation that is not likely to become the standard for training of nurses or endoscopists if the NAPS model becomes widely accepted, because there are no formal deep sedation training courses for endoscopists other than an anesthesiology residency. Additionally, endoscopists and nurses who leave the safety net of an ambulatory surgery center to practice in isolated medical offices may not be able to rescue the patient soon enough if calling 911 is their only backup for treating prolonged apnea or laryngospasm emergencies that are usually only simple, routine urgencies for anesthesia-trained practitioners to manage.

Proponents of NAPS correctly claim that patients receiving propofol should receive care consistent with deep sedation, but that is exactly why non-anesthesia-trained practitioners should not be using propofol. They just are not adequately trained and experienced in managing the potentially devastating complications of propofol that, unlike the case with midazolam, can be so easily produced and cannot be pharmacologically reversed. Endoscopists also state that although the routine assistance of an anesthesiologist/anesthetist for average-risk patients undergoing NAPS for endoscopic procedures is not warranted, complex procedures and procedures in high-risk patients may justify the use of an anesthesiologist/anesthetist to provide conscious and/or deep sedation. Obviously the question to be asked is, can the non-anesthesia-trained endoscopist and nurse accurately identify all patients who are the ones at high risk for anesthesia complications with NAPS, and, if not, can they manage the complications of those at high risk who will pass through the screening process undetected?

Just as in the typical oral surgeon’s office, NAPS supporters suggest that a separate person should monitor the patient during the procedure and be there to assist the physician in case of an anesthetic emergency. However, unlike the oral surgeon, who has 4 months of training and experience in mask ventilation and tracheal intubation during their general anesthesia rotation in the operating room, the endoscopist typically has no such

training. How can the endoscopist with minimal training or experience in general anesthesia supervise a nurse who also has minimal training and no experience? The margin of safety with NAPS is lowered when the untrained are supervising the untrained.

The American Society of Anesthesiologists and the American Association of Nurse Anesthetists have finally found some common ground for cooperation. Both groups are lobbying to stop NAPS before patients of endoscopists experience the same types of tragic outcomes as when they and others first began several decades ago to substitute equal numbers of milligrams of midazolam for diazepam with no appreciation for the differences in potency between the 2 drugs. Numerous deaths resulted and midazolam was almost removed from the market by the FDA as a result.

The fallout of this great debate could perhaps directly affect the use of propofol by oral surgeons, who may unfortunately become categorized with endoscopists as being nonanesthesiologists because their practices are somewhat similar. NAPS endoscopists utilize the same type of auxiliary staff that most oral surgeons use to monitor their patients while they perform surgery, and both groups use propofol. There are, however, some major differences. Oral surgeons have formal general anesthesia training and experience, but endoscopists do not. Oral surgeons have the background to truly supervise their auxiliaries and are trained and experienced to manage anesthesia emergencies, but endoscopists are not. Anesthesia given by oral surgeons is highly regulated by state dental boards, whereas there are few limitations on physicians by medical boards. If NAPS is eventually regarded as a disastrous experiment, propofol will not be banned by the Food and Drug Administration, but rather, state legislatures could pass legislation to outlaw the use of propofol by all nonanesthesiologists or to prohibit the administration of propofol by those who are simultaneously performing the procedure. Oral surgeons must be aware that they could be mistakenly included with endoscopists and other nonanesthesiologists if they are not given the opportunity to explain why they should be included with anesthesiologists, dentist anesthesiologists, and certified registered nurses as qualified to administer propofol.

As far as changing the labeling on propofol to accommodate NAPS, that would also be a mistake. It is appropriate to limit propofol’s use to those trained in general anesthesia. Considering that oral surgeons administer propofol in the context of a team approach rather than as a single individual physically doing both the anesthesia and the surgery simultaneously, it is my interpretation that the current statement warning practitioners not to do both is still acceptable because it does not

apply to the oral surgery team model of practice. The result of discarding these warnings would be to open the administration of propofol to anyone who can start an IV or has a sedation permit. In the name of patient safety, dentistry should support the limitation of admin-

istration of propofol to only those who have formal general anesthesia training.

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