Should RNs be giving propofol in GI lab?

Should RNs be giving propofol (Diprivan) for sedation in the GI lab? It’s a hot issue.

Advocates point to propofol’s advantages—patients can be sedated quickly, awakened quickly, and discharged sooner than with conventional sedation. One study found an average time of 18 minutes from the end of the procedure to discharge. Most patients preferred propofol to the usual sedatives because they don’t have a hangover and feel they are back to normal sooner.

Three outcome studies with more than 11,000 patients have found no major complications. Though moderate sedation is still the norm in the GI setting, advocates would like to expand nurse-administered propofol sedation (NAPS), saying it not only is safe but is less costly than using an anesthesia provider.

But opinion is sharply divided.

Critics note that the package insert says propofol should be given only by persons trained in general anesthesia. Patients can slip into deep sedation more easily than with the usual drugs used in endoscopy, and it takes expertise to monitor them and respond to any complications.

“It’s great, but it’s a tricky drug, and you need to know what you’re doing,” says Beverly K. Philip, MD, a professor of anesthesiology at Harvard, who has been working on the issue for 2 years as chair of the Ambulatory Surgical Care Committee of the American Society of Anesthesiologists (ASA).

Statements in conflict

Gastroenterology and anesthesia societies have issued conflicting statements.

In July, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of Gastroenterology Nurses and Associates (SGNA) posted a joint statement outlining the role of RNs in managing patients during sedation, including deep sedation with propofol.

Three gastroenterology societies issued a statement pointing out there is data “to support the use of propofol by adequately trained nonanesthesiologists” with adequate supervision.

In contrast, a joint statement by ASA and the American Association of Nurse Anesthetists (AANA) echoes the package-insert warning that only persons trained in general anesthesia should administer propofol.

The gastroenterology and anesthesia communities are holding high-level discussions on the issue, but those involved would not discuss specifics.

Guidance for nurses

SGNA decided to join ASGE in making the statement because it recognized some nurses are working in GI labs where propofol is given and need guidance, says Jo Harbaugh, RN, BSN, CGRN, immediate past president of SGNA.

“We want to make sure there is a safe environment for all patients regardless of the setting and to have protocols in place if they are going to give propofol,” notes Harbaugh, who is administrator of Digestive Disease Consultants and executive director of the Digestive Disease Endoscopy Center, Normal, Ill. Nurses in her endoscopy center do not administer propofol.

Some key points in the ASGE/SGNA statement:

• Each endoscopy unit should have sedation policies that spell out the responsibilities for each member of the team.

• A nurse who gives sedation does so under the direct order of the physician.

• A nurse who gives deep sedation is responsible for monitoring the patient and should have no other responsibilities.
Management of complications is the responsibility of the physician.

Physicians and nurses should have “adequate training” for sedation; for deep sedation, this includes additional training in airway management and treatment of cardiovascular complications.

NAPS faces obstacles

Though advocates say outcome data for NAPS is strong, they acknowledge there are barriers to expanding the practice.

Douglas K. Rex, MD, a professor of medicine at Indiana University, president of the American College of Gastro-enterology, and author of one of the outcome studies, has been a leader in developing a protocol for NAPS.

“We developed this program as a potential alternative to expand use of propofol without an enormous increase in costs,” he says. Using anesthesia providers for most GI procedures would be cost prohibitive, he and others say.

“I personally believe [NAPS] is safe if people are properly trained and patients are properly selected,” he adds. Nevertheless, because of obstacles, he doesn’t view NAPS as feasible now for most GI units.

Among the obstacles:

The package insert

The package insert’s statement that propofol should be administered by those trained in general anesthesia is a medical-legal barrier. SGNA considered the package insert in developing the statement, but because administering propofol is within the Nursing Practice Act in some states, SGNA thought it needed to provide direction, Harbaugh explains.

Dr Rex thinks the package insert is outdated.

“I don’t think there is an evidence base to support the package insert,” he says. “In fact, the evidence would suggest the package insert is outdated and needs to be reevaluated.” But that can be done only by the company that owns the drug, AstraZeneca.

The package insert creates civil liability problems for nurses and physicians who aren’t anesthesia providers and give propofol sedation, comments a nurse attorney, Deborah Krohn, RN, JD, of Baltimore, who works part-time as an endoscopy nurse.

The package insert “would be part of a plaintiff attorney’s arsenal” if there were a lawsuit involving injury to a patient in a case where a nurse gave propofol sedation, Krohn says. The attorney would likely refer to the insert as one element defining the standard of care for patients in these cases. She describes how a nurse’s deposition might go: “Susan, can you read? Do you think these package inserts are throw-aways? Or do you think they provide real information and guidance?”

Patchwork of state laws

State boards of nursing are split on the issue.

In an informal survey of state boards earlier this year (chart), Krohn found 21 boards prohibit RN-administered propofol for procedural sedation, and 22 say it is permissible or have no prohibition. The other 7 did not have a clear statement, had

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Note: NAPS = Nurse-administered propofol sedation.
Source: Deborah Krohn, RN, JD, 2004.
A number of states use broad language, making it hard for nurses to know where
they stand. There also are nuances. Some say it is all right if there is anesthesia sup-
port. Some say it is permissible in the ICU for intubated patients but not for proce-
dures.

“I think the debate is in its infancy,” says Krohn.

Financial issues
There are financial issues on both sides of the issue. The reimbursement picture
is mixed.

According to the ASA, Medicare considers sedation given by an endoscopist to
be bundled into the procedure and does not reimburse for sedation separately.

Medicare does cover anesthesia for endoscopy, however, when it is given by an
anesthesia provider and considered “medically necessary.” That is determined by
each Medicare carrier.

Actually, anesthesia-delivered propofol is expanding rapidly in some areas
where anesthesia providers can bill, Dr Rex notes. Freestanding endoscopy centers
find it is efficient and less costly to use anesthesia providers because they can bill
separately.

Endoscopists may also see an advantage in giving propofol themselves or using
NAPS because of efficiencies they achieve from the rapid sedation and recovery.

How much more efficient is NAPS? A study by Wurz and Bernstein compared
procedure and postprocedure times for propofol with the usual sedation regimens.
They found propofol saved 5.3 minutes per case, which they judged was not enough
for their hospital to change its current practice when the other issues were consid-
ered.

How much training?
Defining training for nurses is probably the biggest issue with NAPS, Harbaugh
notes. There is no standard.

The ASGE/SGNA statement calls for MDs and RNs giving deep sedation to
have, besides training for moderate sedation, additional training in “advanced air-
way management and treatment of cardiovascular complications.”

That goes beyond ACLS, she says, though ASGE and SGNA endorse ACLS.

“ACLS alone is not sufficient. There also has to be the ability for anyone admin-
istering deep sedation to rescue a patient who slips into a deeper level of sedation
that can progress to general anesthesia,” she says.

That should include intubation, pharmacology of sedatives and reversal agents,
and patient monitoring as well as recognition and drug management of complica-
tions.

At Indiana University, training for NAPS is outlined in a protocol developed in
collaboration with anesthesiologists (sidebar). Finding someone to give the training
can be difficult if anesthesia providers do not want to be involved.

Not surprisingly, Dr Philip, as an anesthesiologist, believes “adequate training”
entails being prepared as an anesthesia provider or being credentialed by the organ-
ization to manage patients under general anesthesia. The way to assess whether
there is “adequate training,” she notes, is to ask whether the organization would
grant someone with that training privileges to administer general anesthesia as
required by its accrediting organization.

Dr Philip is concerned not only about the content of the training but also whether
clinicians will use their skills enough to maintain proficiency.

“You have to know how to manage patients who are having acute medical comp-
llications and how to intubate. These are tough skills to keep up unless you are
doing them regularly,” Dr Philip says. “They may have bits of the right skills, but to
pull them all together at the right time in an emergency takes a lot of ongoing prac-
tice.”

Enough data?
Though advocates say the outcome studies show nurse-administered propofol is
safe, Dr Philip has reservations.

In the largest published study, by John A. Walker, MD, and colleagues from Medford, Ore, which involved more than 9,000 patients, Dr Philip noted there were 7 cases of significant respiratory compromise, all of which occurred in a subgroup of 1,830 upper-GI endoscopy patients. Of these, 3 developed prolonged apnea accompanied by hypoxemia, 3 developed laryngospasm, and 1 was a 74-year-old man who aspirated and was hospitalized. None of the patients required intubation, laryngeal mask airway, or rescue by an anesthesiologist.

In a study published by Dr Rex and his colleagues in 2002 reporting on their initial 2,000 cases of NAPS, Dr Philip notes 4 patients had desaturation to less than 85%, which the authors attributed to excessive administration of propofol and apnea; there also were 11 episodes of desaturation between 85% and 90%. These cases occurred despite administration of oxygen at 4 L per min. No patients were admitted or had other long-term problems.

Though there were no long-term complications, she asks, “Is that OK? That would be up to the cautious consumer.”

She questions whether there is enough data.

“Mortality for general anesthesia in healthy patients is about 1 in 300,000. This 11,000 cases is a fantastic beginning, but we don’t know enough yet.”

For their part, gastroenterologists say they are not aware of evidence that establishes that propofol for endoscopy is safer when given by anesthesia specialists than by RNs supervised by physician endoscopists.

The debate is likely to continue for some time. ☽

—Pat Patterson

References
Studies examine NAPS outcomes

Swiss researchers compared outcomes for 1,370 high-risk patients (ASA III and IV) and 642 patients (ASA I and II) who had NAPS during gastroscopies and/or colonoscopies. There were no major complications, though oxygen desaturation occurred in 3.6% of the ASA II and IV patients versus 1.7% of the ASA I and II patients. Four patients in the ASA III and IV group needed mask ventilation versus 1 in the ASA I and II group. The authors concluded NAPS during GI endoscopy is safe even for high-risk patients with careful monitoring.


Researchers randomized 80 ASA I and II patients to have either propofol or midazolam plus meperidine given by a nurse supervised by an endoscopist in a hospital outpatient GI lab. In all, 4 patients on midazolam plus meperidine had minor complications compared with 1 on propofol. Patients who received propofol expressed greater satisfaction. After 1 hour, 88% of propofol patients had been discharged compared with only 42% of patients on midazolam and meperidine.


A study of 9,152 endoscopies in an ambulatory surgery center in Medford, Ore, followed outcomes of a NAPS protocol developed by an anesthesiologist. There were 7 cases of respiratory compromise (3 prolonged apnea, 3 laryngospasm, and 1 aspiration requiring hospitalization), all with upper GI endoscopy. In all, 5 patients required mask ventilation, but none required intubation. Patient satisfaction was high. Mean time from end of procedures to discharge was 18 min.

A NAPS protocol

Nurses have been giving propofol sedation in the GI lab at Indiana University Hospital for about 4 years under a deep-sedation protocol developed in collaboration with anesthesiologists. This protocol for nurse-administered propofol sedation (NAPS) also applies to RNs who give propofol in the hospital’s bronchoscopy lab and electrophysiology labs.

Key features of the protocol:

Patient selection

Patients are excluded from NAPS if they are at risk of aspiration, might be difficult to intubate (such as patients with sleep apnea using CPAP machines and those who are extremely overweight), or are ASA class III and higher because of cardiac or pulmonary disease. Patients having upper GI endoscopies are more likely to be excluded because they are more likely to desaturate because of weight, among other reasons.

Training of nurses

Training involves a series of steps.

1. Nurses review written material and take a written exam.
2. Nurses observe trained nurses giving propofol. They then administer propofol under supervision for 2 to 3 weeks until deemed ready to begin giving it independently under supervision of an endoscopist. Training does not include advanced cardiac life support (ACLS), which nurses and endoscopists are already expected to have.
3. Data is collected on all NAPS procedures to monitor the safety record.

Staffing

The staffing pattern for NAPS includes:

- the endoscopist
- the RN who administers the drug and monitors the patient as his or her only responsibility
- a technician to assist the endoscopist.

The endoscopist is expected to manage any complications that occur.