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Catastrophic Sedation Errors Can Be Avoided by Using CO_2 Monitoring And Following Guidelines

Alan D. Kaye, MD, PhD

The way Alan D. Kaye, MD, PhD, sees it, Ronnie did not have to die. Although this 50-year-old patient was far from the picture of health, the lower lumbar facet injection that he underwent to manage his pain after a fall at work could have—and should have—been uneventful. Instead, things went very wrong.

After being diagnosed with lumbar spondylosis, Ronnie (all patient names in this article have been changed, although the details of these cases are real) presented for the procedure in early 2017. Among Ronnie's health problems were a BMI of 58 kg/m^2, a four-pack-a-day cigarette habit, and high blood pressure, for which he took medications.

After being placed in the prone position, Ronnie received a large propofol bolus, which caused his oxygen saturation to drop almost immediately to 81%. Several maneuvers by the anesthesiologist saw this value return to 100%, after which the facet injections were performed.

A few minutes after the procedure was finished, Ronnie was noted to be apneic; he was intubated eight minutes later. Although Ronnie was eventually resuscitated, the delay in intubation with inadequate ventilation resulted in irreversible anoxic brain injury. He died in hospice two weeks later. The cause of death was listed as complications of cardiopulmonary arrest associated with propofol sedation and facet injection for lumbar spondylosis.

"I've had more than 100 cases just like this one sent to me for review from around the country," said Kaye, who is the chief academic officer, vice chancellor of academic affairs, provost, pain fellowship program director, and a professor in the Departments of Anesthesiology and Pharmacology, Toxicology, and Neurosciences at Louisiana State University School of Medicine, in Shreveport. Kaye also spent the past 21 years serving as the chairman of anesthesiology at Louisiana State University School of Medicine in New Orleans and Texas Tech Health Sciences Center, in Lubbock, and has been a member of the *Anesthesiology News* editorial advisory board for nearly 25 years.

"Nothing would make me happier than to never see another malpractice case related to sedation, but it's almost like an epidemic. People are suffering catastrophic outcomes during minor procedures.

"It's like a nightmare," Kaye added, "and it literally happens everywhere in America."

Four Primary Problems

According to Kaye, cases like Ronnie's are common. The biggest problem? They are almost always preventable.

"People do not need to be suffering catastrophic neurological injuries, paralysis and death," said Kaye, who also serves as the editor-in-chief of *Pain Physician*, a position he has held for the past eight years. "But clinicians are making the same mistakes over and over again, and nothing seems to be changing."

These problems are broadly summarized in Table 1.

Table 1. Problem Areas Leading to Catastrophic Outcomes
Excessively deep sedation where it is unnecessary
Lack of oversight by anesthesiologists
Lack of adherence to published societal recommendations and guidelines
Lack of proper monitoring, particularly ventilation via quantifiable and continuous end-tidal CO_2


Clifford Gevirtz, MD, MPH

Ronnie was morbidly obese and at high risk for respiratory complications, but nevertheless underwent deep sedation in the prone position. More advisable options, Kaye said, would have been to treat his pain more conservatively or have him undergo the facet injections under local anesthesia with mild sedation. To make matters worse, end-tidal CO_2 (carbon dioxide) monitoring was not employed, which Kaye said would have identified hypoventilation and alerted the clinicians responsible for his care to Ronnie's plight much sooner than pulse oximetry alone.

"In many of these incidents, the patient is prone," noted Clifford Gevirtz, MD, MPH, the medical director of Somnia, Inc. in Harrison, N.Y. "That makes monitoring and rescue much more challenging, because if the patient is face down and you run into airway trouble, you have to get the clinician performing the procedure to stop doing what they're doing, and then flip the patient over, which can be another problem if they're obese, because then you have to call for help and bring in a gurney. And then, only when they're finally supine again, can you begin to resuscitate."

A Multitude of Guidelines

None of this should come as a surprise to any anesthesia practitioner, Kaye said, since several societies have published guidelines and recommendations regarding sedation practices during interventional pain procedures. As far back as 2005, the American Society of Anesthesiologists' Committee on Pain Medicine published its "Statement on

Anesthetic Care During Interventional Pain Procedures for Adults." In that statement, the society made it very clear that the use of moderate (conscious) sedation and/or anesthesia during pain procedures "must be balanced with the potential risk of harm from doing pain procedures in sedated patients."

The statement goes on to say that many patients can undergo interventional pain procedures without the need for supplemental sedation at all, and should simply be treated with local anesthesia. The committee also noted that a second anesthesia provider may be required to manage moderate or deep sedation in selected cases.

"Examples of procedures that typically do not require sedation include but are not limited to epidural steroid injections; epidural blood patch; trigger point injections; injections into the shoulder, hip, knee, facet and sacroiliac joints; and occipital nerve blocks," according to the statement.

In addition, the statement recommends that when moderate (conscious) sedation is provided during pain procedures, it should allow the patient to be responsive during critical portions of the procedure, to report any procedure-related change in pain intensity, function and/or paresthesia.

That was certainly not the case for Elaine, whose physician asked for heavy sedation when she presented for a radiofrequency thermocoagulation in early 2015. Elaine, who was already taking celecoxib, tizanidine and oxycodone/acetaminophen, was given initial doses of 2 mcg of midazolam, 50 mcg of fentanyl and 150 mg of propofol over an eight-minute period. She would go on to receive a total of 300 mg of propofol and 100 mcg of fentanyl.

Kaye noted that with this amount of drugs, Elaine was excessively sedated for the procedure, which was done by her CRNA, to the point where she was likely under general anesthesia and completely incapable of responding to required sensory and motor testing prior to the cervical rhizotomy. Consequently, the patient could not feel when the physician started burning her posterior spinal column soon after. To make matters worse, her anesthesiologist never saw the patient preoperatively or came into the room intraoperatively, and did not visit with her postoperatively in the recovery room.

“The woman was so deeply sedated that when they did the sensory and motor testing before the procedure, she couldn’t tell them they were in the wrong place,” Kaye explained. “They couldn’t say, ‘Are you feeling anything?’ because she was unconscious.

The outcome, Kaye said, was an all-too-common one: Elaine suffered permanent neurologic injury, as well as numerous sleep, pain and psychological problems as a result of the mishap.

Sedation Continuum Often Ignored

Depth of sedation was similarly ignored in the case of Elizabeth, a healthy 62-year-old woman scheduled to undergo a cervical, translaminar epidural steroid injection with intravenous sedation. The procedure was to be performed by a pain management physician, with anesthesia provided by a CRNA and supervised by an anesthesiologist on duty.

In the procedure room, Elizabeth received 180 mg of propofol in divided doses—an amount Kaye said guaranteed she would have been completely insensate and anesthetized at the time the procedure began. The pain physician used an 18-gauge, modified Touhy epidural needle to access what he thought was the epidural space,

followed by catheter insertion and injection of 0.25 mL of contrast agent. He went on to inject 4 mL of 0.25% lidocaine, with nonparticulate dexamethasone, plus the diluted contrast agent. When the physician noticed that the filling pattern "appeared linear without typical lateralization," he terminated the procedure.

Shortly after that, Elizabeth lost complete control of her left arm, hand and leg. A cervical MRI was performed, which suggested traumatic myelopathy possibly secondary to intramedullary injection. Subsequent radiology studies confirmed the patient developed a syrinx within her spinal cord, related to the physician's steroid injection. To this day, Elizabeth lives with the severe, permanent neurologic deficits she suffered as the result of the injection, including paralysis.

Yet, as Kaye explained, the procedure never should have begun without verification that Elizabeth was verbally responsive. That way, she would have been able to respond to the painful stimuli of the needle misplacement as the interventional pain physician traumatically injured her spinal cord, but before any injectate was administered.

According to Kaye, the case highlights the important distinction between various levels of sedation. "Obviously, if she were under mild sedation, which the ASA recommends, this never would have happened," he told *Anesthesiology News*. "But they put her under deep sedation, so she wasn't responsive. So, when the physician stuck a needle in the spinal cord, the patient couldn't scream and alert her interventional pain physician prior to delivering the injectate."

There is little excuse for any anesthesia professional to be ignorant of the continuum that defines depth of sedation, Kaye said. The ASA's Committee on Quality Management and Departmental Administration first published its definition of general anesthesia and levels of sedation/analgesia back in 1999, and the document was most recently amended in 2019.

According to the statement, "minimal sedation (anxiolysis) is 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."

By comparison, the statement considers moderate sedation/analgesia ("conscious sedation") to be "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."

The guidelines define deep sedation/analgesia as 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."

Finally, the statement defines general anesthesia as 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 neuromuscular function. Cardiovascular function may be impaired." Levels of sedation are summarized in Table 2.

Table 2. The Sedation–Analgesia–Anesthesia Continuum

Physiologic Parameter	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

These types of mistakes are not rare events. “I’ve seen it in so many procedures where there’s a real disconnect between the guidelines and individual practice,” Gevirtz said. “It makes you scratch your head. Why are people doing this?”

As Gevirtz explained, excessive sedation not only puts patients at risk for adverse events, but may also cloud the interpretation of test results, particularly those related to pain.

“It seems as though everyone is performing epidural blocks these days,” he said, “and the idea that you need sedation for these blocks is really very questionable. I don’t think it adds anything, and it actually obscures the effectiveness of the procedure.”

The ASA is certainly not alone in describing the dangers of oversedation. The American Society of Interventional Pain Physicians (ASIPP) recently published a similar position statement, titled “Guidelines for Sedation and Fasting Status of Patients Undergoing Interventional Pain Management Procedures” (*Pain Physician* 2019:22[3]:201-207). According to these guidelines, which were co-authored by Kaye, it is “not recommended” and “not appropriate” to use propofol for interventional pain procedures:

“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.”

The ASIPP guidelines acknowledge that while many patients undergoing interventional pain techniques may require mild or moderate sedation, deep sedation and/or general anesthesia is unsafe for most interventional procedures, largely because patients cannot communicate changes in symptoms—as Elizabeth’s case tragically illustrated.

“If clinicians simply followed these guidelines,” Kaye said, “we wouldn’t have patients ending up paralyzed for life. Cervical epidurals are the greatest example of interventional pain procedures that should never be performed with propofol. Believe me, I’ve had plenty of lawsuits sent to me from across the country over the last 20 years.”

Critical Monitoring Often Overlooked

According to Kaye, the problem is exacerbated by the fact that too few practices use end-tidal CO_2, in direct contravention of ASA guidelines. This failure, he said, has resulted in countless deaths and devastating injuries over the years, from delays in responding to hypoventilation, development of respiratory acidosis, and cardiovascular collapse with anoxic brain injury.

Included in these cases is Quincy, a 32-year-old man who initially presented with cellulitis but subsequently required a GI consult and esophagogastroduodenoscopy for persistent nausea, vomiting and diarrhea. Before the procedure, Quincy was evaluated by an anesthesiologist, who failed to document the patient's Mallampati classification, decreased renal function and anemia, and also misclassified the ASA physical status.

Quincy received fentanyl 100 mg by IV push, midazolam 2 mg by IV push, and propofol 120 mg IV. However, he was not given supplemental oxygen, and his end-tidal CO_2 was not measured. In addition, he was started on a continuous propofol drip at 120 mcg/kg per minute.

The patient was transferred to the ICU on a ventilator. After extubation, he remained lethargic and unresponsive; an EEG showed moderate diffuse encephalopathy. Although his condition improved slightly over the next few weeks, he remained confused. Despite aggressive physical and occupational therapy, to this day Quincy requires assistance with activities of daily living related to severe cognitive deficits. Afterward, multiple specialists documented that his cardiac arrest and anoxic encephalopathy were the result of respiratory failure.

"The issue is that in many of these cases, the clinicians believe pulse oximetry is enough," Kaye explained. "Well, we know that's not the case. By the time the pulse oximeter drops, the patient has usually not been breathing for four or five minutes.

"That's why end-tidal CO_2 has been an ASA monitoring requirement since 2010," he continued. "So why are people not using it?

"If a patient is not ventilating, a standard end-tidal CO_2 alarm will go off in 20 or 30 seconds, depending on the brand of monitor. Do you think anyone would die or have brain damage, or their heart would stop or they would need to be coded? No, absolutely not.

"By using quantitative end-tidal CO_2, under any of these situations, the odds of a patient having a bad outcome would decrease to virtually nothing," Kaye said. "It is singularly the most important way to protect patients, and that's why it's one of the ASA standard monitors required for sedation and general anesthesia."

A 2017 study agreed (*BMC Anesthesiol* 2017;17[1]:157). In that investigation, a pair of researchers analyzed the Premier Database to determine the effect of capnography monitoring on the incidence of adverse outcomes and death following gastrointestinal endoscopic procedures.

The study involved 258,262 medical inpatients and 3,807,151 outpatients who were grouped according to the type of monitoring: pulse oximetry only, capnography only, pulse oximetry with capnography, and neither pulse oximetry nor capnography.

The analysis found that among inpatients, capnography monitoring was associated with a 47% estimated reduction in the odds of death at discharge (odds ratio [OR], 0.53; $P<0.0001$). Among outpatients, capnography monitoring was associated with a 61% estimated reduction in the odds of a pharmacologic rescue event at discharge (OR, 0.39; $P<0.0001$) and an 82% estimated reduction in the odds of death at discharge (OR, 0.18; $P=0.16$).

Karen B. Domino, MD, who has done extensive research into the ASA Closed Claims Project, echoed the importance of monitoring to prevent such disasters, but said the problems don't end there. "A lot of these cases occur in cramped, small spaces that may not have the equipment people are familiar with," said Domino, a professor of anesthesiology and pain medicine at the University of Washington School of Medicine, in Seattle.


Karen B. Domino, MD

"Often there's no help, either," she continued. "If someone picks up a ventilation problem in an operating room, there's a lot of people who can be able to help out. But that's not the case in these non–operating room areas."

Lack of equipment may also play a part, Domino explained. "A lot of these procedures are done in offices or ambulatory centers where they only have an Ambu bag, and don't have things like resuscitation drugs, laryngoscopes and other things available. There

have also been situations where someone called for help but there was nobody available to help because they were all in other rooms. Or someone may come, but they may not really know what to do."

Money Before Safety?

What, then, is the motivation for physicians to turn a blind eye to published guidelines, and sometimes put patients in grave danger?

Kaye's answer is blunt: "It's a question of money versus standards."

According to Kaye, one of the primary issues is monitored anesthesia care (MAC), a Centers for Medicare & Medicaid Services billing term that allows anesthesiologists to bill for procedures they do not attend entirely in person, under either "Medical Direction" or "Medical Supervision." Medical direction occurs when an anesthesiologist is involved in two, three or four concurrent anesthesia procedures, or a single anesthesia procedure with a qualified CRNA. Medical supervision refers to cases in which an anesthesiologist is involved in five or more concurrent anesthesia procedures. These situations are distinct from "Personally Performed Anesthesia," which has a physician performing the entire anesthesia service alone.

The problem with MAC, Kaye said, is it can entice clinicians to bill for services they've had little to do with. Even so, clinicians who bill under medical direction or medical supervision are required to meet a set of standards, the so-called TEFRA 7, which dates back to the passage of the Tax Equity and Fiscal Responsibility Act of 1982. According to this act, anesthesiologists cannot be paid for their services unless all seven elements are satisfied. These are listed in Table 3.

Table 3. TEFRA Elements to Satisfy in Care of a Patient

1. Perform a preanesthesia examination and evaluation.
2. Prescribe the anesthesia plan.
3. Personally participate in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence.
4. Ensure that any procedure in the anesthesia plan that he or she does not personally perform is performed by a qualified individual.

5. Monitor the course of anesthesia administration at frequent intervals.
6. Remain physically present and available for immediate diagnosis and treatment of emergencies.
7. Provide indicated postanesthesia care.

TEFRA, Tax Equity and Fiscal Responsibility Act of 1982

According to Kaye, these standards are commonly overlooked. “In most of the lawsuits I see, guess what happened?” he said. “The anesthesiologist never did the preoperative evaluation, they never came into the room, and they never saw the patient postoperatively. They basically had no interaction with the patient, but they billed for MAC anyway.”

The problem, Kaye noted, is that TEFRA 7 allows clinicians to bill under these circumstances if another competent professional is present instead of the anesthesiologist. How such competency is determined, however, is open to interpretation, as in the case of Eileen, whose spinal cord was irreparably damaged under deep sedation provided by her CRNA during a cervical radiofrequency thermocoagulation.

“It was the CRNA’s first time working with this patient, and she was not aware that it was important to do sensory and motor testing prior to the burning, and that the patient had to be alert to answer the question regarding the testing,” Kaye said. “And we know what happened as a result.”

The challenges of meeting the TEFRA 7 criteria were illustrated in a 2012 study by Epstein and Dexter (*Anesthesiology* 2012;116[3]:683-691), which examined the influence of supervision ratios by anesthesiologists on first-case starts and critical portions of anesthesia.

The researchers used one-year data from a tertiary care hospital to determine the timing and duration of critical portions of cases. They then calculated the percentages of days with at least one supervision lapse occurring at supervision ratios between 1:1 and 1:3. The study found that even at a supervision ratio of 1:2, lapses occurred on 35% of days, leading the researchers to recommend staggered starts or additional anesthesiologists working at the start of the day to mitigate such lapses. (The article was subsequently addressed in an editorial from a team of authors representing the ASA [*Anesthesiology* 2012;117(2):437-438; author reply, 438-441], who wrote that its conclusions were based on a "flawed model."

More recently, Domino et al examined the ASA's Closed Claims Project (*Review Anesthesiol Clin* 2017;35[4]:569-581) to determine the safety of non–operating room anesthesia (NORA). The study found a higher proportion of malpractice claims for death in NORA practice settings than in operating rooms. Interestingly, the analysis also found that NORA claims most frequently involved MAC, and that inadequate oxygenation/ventilation was responsible for one-third of all NORA claims.

The researchers concluded that NORA is safe, but adherence to gold-standard clinical practice is important. “Colonoscopies and endoscopies aren’t comfortable, and most people want some sort of sedation,” Domino said. “Most of the problems we see can be avoided by having good care.

“There are several reasons why patients may not get good care,” she added. “Some practitioners may only be trained in moderate sedation. But in moderate sedation, people can go from conversant to unconscious very quickly.”

Problems Easily Solved

Where do we go from here? Kaye said anesthesiologists need to be the vanguards of change, in terms of both education and the examples they set for their peers.

“I’m not saying that any one group of clinicians is incompetent,” Kaye explained. “That’s not the issue, because if they didn’t know what they were doing, they wouldn’t make it past Monday of their first day of clinical practice. What we need to do is educate all stakeholders on safe practices.”

The way Gevirtz sees it, change needs to start at the top. “I think societies such as ASRA [American Society of Regional Anesthesia and Pain Medicine], ASA, ASIPP and SIS [Spine Intervention Society] need to take a position that doing anything more than moderate sedation with pain procedures in the prone position is both unnecessary and dangerous,” he said. “So, I put it back on the societies, who need to police their own better.”

For Kaye, the sedation practice guidelines for interventional pain procedures he developed for ASIPP are a good first step. He believes that by following a few simple points, clinicians can ensure the occurrence of catastrophic sedation errors is reduced to almost nil.

“First of all, clinicians need to realize that in most cases, they don’t need propofol, primarily because patients don’t need deep sedation or general anesthesia for most of these day procedures,” he said. “Second, we need to make sure every single patient is monitored with quantitative, continuous end-tidal CO_2, with no exceptions. Finally, if

anesthesiologists are going to bill for monitored anesthesia care, they'd better make sure they're actually fulfilling all of the TEFRA 7 requirements." Documentation of work performed is key.

With this simple recipe, Kaye sees no reason why needless death and disability must continue to occur. "These are real things that are going on, but they should never go on. We should be leading on this critically important topic of safe sedation."

—Michael Vlessides

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