

SENTINEL



**Shailesh D. Patel, MD,
FASA, MHA**
PSA PRESIDENT

**“ It's time to sign
up for our exciting
2022 Annual
Scientific Meeting”**

President's Message

Happy 2022! The Pennsylvania Society of Anesthesiologists (PSA) hopes you and yours are staying safe and healthy. As we begin this new year, we here at the PSA are excited by what this year holds for our patients and profession.

It's time to sign up for our exciting 2022 Annual Scientific Meeting. It will be held June 3–5, 2022 in Lafayette Hill, PA and hosted at the Union League Liberty Hill. Participants will have a well-rounded experience in not only meeting internationally renowned speakers and hearing exciting lectures but also in learning about topics ranging from perioperative quality measures to space travel! Participants will learn to navigate everyday challenges ranging from neurocognitive outcomes to opioid disorders. We will have networking events and an opportunity to engage with national leaders. There will also be a hands-on POCUS/Regional Anesthesiology ultrasound guided workshop. The workshop will be limited to 50 participants for a customized experience. Register now to secure your spot! For more information and registration please visit <https://na.eventscloud.com/website/31240/home/>. Sign up early for the special discount pricing! This is one exciting meeting you don't want to miss! (Bring your families and golf clubs!)

This past year, the PSA was part of landmark negotiations between the General Assembly and the Pennsylvania Association of Nurse Anesthetists (PANA). As a result of these negotiations Senate Bill 416 became law, which moved physician supervision of anesthesia services into statute and created a legally recognized title for Certified Registered Nurse Anesthetists (CRNAs). This was a win for patient safety during anesthesia.

Continuing this momentum, the PSA has recently partnered with the Pennsylvania Academy of Anesthesiologist Assistants (PAAA) and Representative Lynda Culver to advocate for House Bill 1956. This piece of legislation would create a license for Certified Anesthesiologist Assistants (CAAs) to practice in Pennsylvania, under the supervision of a physician anesthesiologist.

As you likely know, CAAs are highly skilled and trained non-physician anesthesia providers. CAAs receive highly specialized master's level education which requires 2,600 hours of clinical anesthesia education, knowledge of over 600 anesthetics, and 600+ hours of classroom and laboratory education.

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SENTINEL NEWSLETTER

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President's Message

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Currently, CAAs can practice in 17 states, the District of Columbia, and the Territory of Guam. The COVID-19 pandemic continues to adversely affect the Commonwealth. One of the adverse effects is an ever-increasing shortage of healthcare workers. House Bill 1956 would open Pennsylvania to an entirely new profession of highly skilled non-physician anesthesia providers, allowing CAAs to help mitigate the current healthcare workforce shortage.

House Bill 1956 was introduced and referred to the House Professional Licensure Committee on November 5th, 2021. As we continue through this year, the PSA will continue to advocate and push for this piece of legislation to advance. The PSA will continue to monitor and update you regarding this issue.

If you or any of your colleagues would like to join the PSA's efforts and help advocate for CAA licensure in Pennsylvania, please contact Tyler@millirongoodman.com.



Visit Our **COVID-19 Resource Page**

<https://www.psanes.org/covid-19.html>



EDITORIAL

Random Thoughts



Richard O'Flynn, MD, FASA

Editor, The Sentinel

There are a few issues that I've thought about over the past few months.

Recently there has been an expansion of for-profit entities in both hospital acquisitions and anesthesia practices. The acquisition of anesthesia practices by the for-profit national companies usually comes with a large cash buyout and a requirement to remain with the group for a certain length of time. Following that period, the new employees are usually held to a restrictive covenant and unable to practice within a set geographic area. Is the initial cash buyout worth the potential disruption in practice ability in the future?

With more hospitals looking to the national anesthesia groups as cost saving options, where are the cost savings coming from? Sure, there may be some initial savings due to economy of scale but that only works if the group already has a presence in the immediate area. As we know, anesthesiologist and CRNA salaries are pretty much set by the geographic market and as far as I know, no national group has a magic formula to change market dynamics. If there are cost savings to be realized, it needs to come from practice changes, i.e., either decreased salaries or decreased physician

involvement going from medical direction to medical supervision. Is this really good for patient care and will it lead to the destruction of anesthesiology as a medical specialty?

Finally, does it all really come down to how anesthesiologists are seen by the public? Do you introduce yourself as Doctor... or simply by your first name? While introduction by first name may seem less formal, you worked long and hard to earn the title "Doctor". It is already acknowledged that a good majority of the public don't know that an anesthesiologist is a physician. Is the act of introducing oneself by first name only perpetuating that fact? How many surgeons do you know who introduce themselves to patients by their first name?

Feel free to comment on these topics by sending an email to psasentineeditor@gmail.com.

In this edition of The Sentinel, PSA President Dr. Patel gives an update on past activity/accomplishments and lays out the plan for the future. There are also the usual reports from our legislative counsel and attorney, both with important information.

Dr. Answine shares a review of ketamine, its acceptance as an anesthetic adjunct, and some novel uses for the medication. Additionally, this edition includes an excerpt from a novel by Dr. Steven Orebaugh, an anesthesiologist at UPMC.

Finally, Dr. Cherian has an excellent review on patient positioning during surgery and Dr. Roth provides a useful refresher on CO₂ management.



"It became at once apparent to all the world that surgical anesthesia had become a reality and that pain was no longer the master but the servant of the body."

—J. Collins Warren, MD



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LEGAL UPDATE

Anesthesia Medical Direction Billing Fraud—U.S. Court of Appeals Reinstates Whistleblower Fraud Complaint



Charles I. Artz, Esq.

PSA General Counsel

A recent United States Court of Appeals decision reversing the dismissal of a False Claims Act complaint filed by an anesthesiologist whistleblower is important to consider for compliance purposes for both independent practicing anesthesiologists and anesthesiologists employed by health systems.

In *U.S. ex rel. Mamalakis v. Anesthetix Management, LLC*, 20 F.4th 295 (7th Cir. 2021), an anesthesiologist (Dr. Mamalakis) filed a whistleblower complaint under the False Claims Act alleging other anesthesiologists employed by Anesthetix Management regularly billed the government using the medically directed service code when their services qualified for payment only at the lower rate for medically supervised services. The whistleblower previously worked for a private practice anesthesia group which contracted with the local hospital. There were no CRNAs at the time. All anesthesia services were billed at the personal performance rate. The hospital subsequently terminated the provider contract and awarded the contract to Anesthetix. Dr. Mamalakis then accepted an offer of employment from Anesthetix. Shortly thereafter, Anesthetix was acquired by TeamHealth Holdings, a holding company of providers of clinical services to hospital systems throughout the United States. TeamHealth appears to be financially backed by Blackstone, a large private equity firm.

The federal court dismissed the complaint, ruling Dr. Mamalakis failed to identify fraud with sufficient particularity and specific information. He appealed the dismissal of the whistleblower complaint. The U.S. Court of Appeals reversed the dismissal, allowing Dr. Mamalakis to proceed with the fraud litigation. The court's important rationale and holdings will be summarized briefly.

A. ANESTHESIA BILLING RULES

It is always helpful to summarize the applicable Medicare and anesthesiology billing rules. The U.S. Court of Appeals did so as follows:

1. **Personal Performance**—Anesthesiologists may submit claims for payment to Medicare under one of three billing codes corresponding to the level of services provided pursuant to 42 C.F.R. §414.46(b).
2. The highest billing rate is reserved for cases in which the anesthesiologist **personally performed** the procedure. This rate applies if the anesthesiologist:
 - Performed the anesthesia services alone;
 - Was the teaching physician directing a resident or intern physician during the procedure; or
 - Continuously participated in a single procedure involving a CRNA, anesthesiologist assistant ("AA") or student nurse anesthetist pursuant to 42 C.F.R. §414.46(c).
3. **Medical Direction**—The medical direction rate is half the personal performance rate. An anesthesiologist may bill at the medical direction rate if he or she directed a resident or intern, CRNA, AA or SNA in two, three or four concurrent procedures and the anesthesiologist **personally performed or participated in each** of the following steps in each procedure:
 - Conducted the pre-anesthetic examination and evaluation;
 - Prescribed the anesthesia plan;

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- Participated in the most demanding parts of the plan, including induction and emergence, if applicable;
 - Ensured that any procedure he or she did not personally perform was performed by a qualified individual;
 - Monitored the anesthesia administration at frequent levels;
 - Remained physically present and available for immediate diagnosis and treatment of an emergency; and
 - Provided post-anesthetic care as indicated pursuant to §414.46(d) and §415.110(a)(1).
4. To qualify for payment at the medical-direction rate, the anesthesiologist must personally document that the seven conditions were satisfied and specifically confirm he or she performed requirements 1, 3 and 7 pursuant to §415.110(b).
5. **Medically Supervised**—The lowest billing rate applies when the physician medically supervises anesthesia services performed by other anesthesia professionals. This applies, for example, when the anesthesiologist medically supervises more than four concurrent procedures pursuant to §414.46(f).

B. MEDICAL DIRECTION FAILURES AND NON-COMPLIANCE

After Anesthetix/TeamHealth took over, they hired CRNAs. The plan was to bill medical direction rather than personal performance. The new Anesthetix medical director told all of the anesthesiologists they should sign the patient record as if they were present at every 15-minute interval during the procedure even if they were not. They converted to 100% medical direction across the board in order to generate more revenue. Dr. Mamalakis alleged he had personal information that anesthesiologists:

1. Regularly failed to perform pre-anesthetic exams and evaluations;
2. Did not personally prescribe anesthesia plans;
3. Did not monitor patients at frequent intervals during procedures;
4. Did not participate in the most demanding parts of the procedure; and

5. Sometimes were not physically present to handle emergencies.

The whistleblower alleged Anesthetix/TeamHealth was aware that its anesthesiologists did not comply with these Medicare conditions of payment at the medical direction rate but billed at that rate anyway, thereby knowingly submitting false claims to the government for payment.

He also brought his concerns to the medical director's attention, but she instructed him not to inform the hospital because it might jeopardize the TeamHealth contract. The medical director also directed him to let the CRNAs prescribe the anesthesia plans for his procedures, even though an anesthesiologist must do so in order to bill at the medical direction rate. The medical director insisted that all anesthesia services must be billed as medically directed regardless of whether the procedure qualified for that rate.

C. SUFFICIENTLY PARTICULAR EXAMPLES OF FRAUD

Every fraud case litigated in federal court, including False Claims Act cases, requires the allegations of fraud to be established with factual particularity. The whistleblower must describe the who, what, when, where and how of the fraud. This often includes a requirement to show actual false statements submitted, i.e. false claim form documentation, although it can be accomplished by very specific factual allegations that give rise to a plausible inference of fraud.

Dr. Mamalakis did not have access to TeamHealth's billing records and, therefore, failed to identify specific false invoices. That omission is not fatal to the claim because he had direct knowledge that anesthesiologists regularly falsely coded their procedures for billing purposes after TeamHealth took over the practice group. Specific examples of fraud in which the anesthesiologists failed to comply—sometimes egregiously—with the requirements to submit a bill at the medical-direction rate included the following:

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- One anesthesiologist billed three procedures as medically directed (a general surgery procedure, a urology procedure and a hysterectomy), but he left the hospital **before noon and spent the afternoon waiting for a piano to be delivered to his home.**
- Another anesthesiologist billed a hip replacement as medically directed, but she **left the hospital after inducing anesthesia.** That anesthesiologist called the whistleblower from out of state and asked him to treat the patient's low blood pressure during the procedure.
- An anesthesiologist billed two procedures as medically directed while she was **absent from the hospital.**
- Another anesthesiologist billed a knee arthroscopy as medically directed, but when the patient experienced distress, the CRNA administering the procedure asked the whistleblower to come to the room. When he asked her why the primary anesthesiologist was not there, she said he was **never present for a knee arthroscopy.**
- The same anesthesiologist billed a gynecological procedure as medically directed, but he was **never present in the operating room, didn't prescribe the anesthesia plan, and didn't provide post-operative care.** When the patient suffered distress after emerging from anesthesia, the

billing anesthesiologist was called. He arrived at the hospital more than 30 minutes later, wearing street clothes, and then left without examining the patient, ordering studies or prescribing any treatment. The whistleblower was then called in to help. A CRNA told the whistleblower that the procedure was billed as medically directed.

- Another anesthesiologist billed a cataract extraction as medically directed. But the CRNA told the whistleblower that the anesthesiologist **never entered the operating room** (even after complications), did not create the anesthesia plan, and did not perform the pre-anesthetic examination required for medical direction.

The U.S. Court of Appeals found these examples to be sufficiently detailed, identifying specific doctors and procedures and describing why each procedure should not have been billed as medically directed. The whistleblower became personally involved in some of those procedures after a care provider asked him for assistance, and in several cases entered the operating room himself. The court found those representative examples to be particularized enough to infer that TeamHealth presented false claims to the government.

It goes without saying that anesthesiologists should never participate in knowingly failing to comply with the Medical Direction rules and should call non-compliance to the attention of all necessary individuals.



Excerpt: The Stairs on Billy Buck Hill

Editor Note:

The following is an excerpt from a novel, *The Stairs on Billy Buck Hill*, by Dr. Steven Orebaugh, an anesthesiologist at the University of Pittsburgh. If anyone is interested in reading the entire novel, Dr. Orebaugh has generously offered a 50% discount to the first 25 people who contact him at orebaughsl@gmail.com.

From the Novel:

While all attention at this time is focused on the COVID epidemic, opioids continue to be responsible for an ever-increasing number of deaths. The hidden secret is that physicians and nurses have become addicts themselves. Anesthesiologists and CRNAs, who regularly administer opioids are among the most susceptible.

"The Stairs on Billy Buck Hill relates to one physician's travails as he progresses from the carefully controlled, recreational use of opioid pills to the theft of fentanyl from his patients in the operating room."

Excerpt: The Stairs on Billy Buck Hill

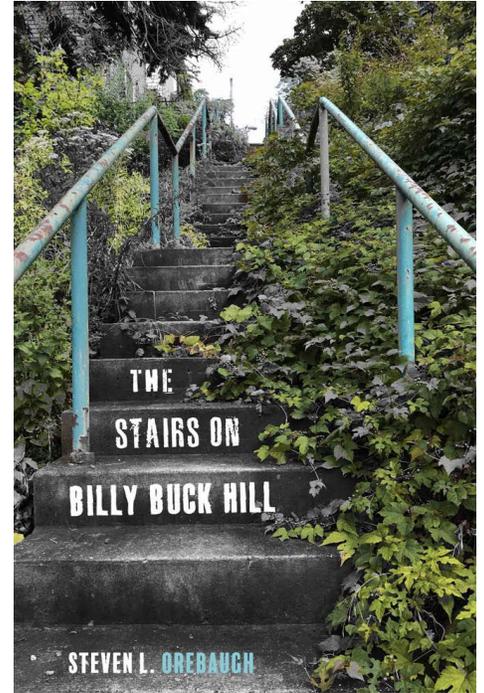
Kurt cracked open the ampule carefully, admiring the clarity of the solution it contained. Peering intently at the delicate, tapered top that he'd removed, he made certain that not a single drop of the elixir had been trapped within, and tossed it aside. Then he swirled the tiny glass container, watching the clear solution cling briefly to its sides, the meniscus of the liquid lurching to and fro. Satisfied, he held the translucent container up to the light and was startled to find that he was salivating. Within, there were two milliliters of fentanyl in solution, less than half a teaspoon, scarcely enough to cover the bottom of a drinking glass or fill a thimble. One of these he would generously provide to the patient before him, an elderly man who was undergoing cataract extraction. On the record, he would attribute the entire ampule of the opioid drug to the case—who would know the difference? The other milliliter he would carry carefully back to his desk, where he would align it with several other ampules that he had requisitioned. Like a platoon of tiny soldiers in formation, they awaited him there for his inspection at the end of the day. With a pipette, he would pool their contents in a single test tube and carry it home for his and Lauren's enjoyment.

Since responsiveness to opioid medications varied widely from person to person, the effect that a single fifty microgram dose of fentanyl would have on a patient was not entirely predictable. So, Kurt need merely note that there was some justification—any justification—for the patient to receive a modest extra dose of the pain-killer, which he would actually sequester for himself. No one would take note of this surreptitious diversion of the drug.

All of this, he thought to himself in a moment of heady self-satisfaction, was a delightful scheme, if somewhat nefarious. Patients were not deprived of their analgesic drug, since he would administer all the opioids that they required for their surgery, even as he exaggerated their need. He could readily acquire five or ten milliliters of fentanyl each day, which was certainly enough to fuel the euphoric, rapturous romps that now filled his evenings. Of course, the cost of the anesthetic care that was billed to the insurance company was increased by a tiny margin, but this would not come directly from the patient's pockets, so he did not trouble himself in the least about the ethics of the arrangement.

A drink or two of wine in the evening, along with some oxycodone tablets, had recently brought him to a blissful plane of existence he'd never experienced, perhaps had not even imagined. But Lauren had been right about the fentanyl, perhaps had even understated the case. This was a whole new playing field. In the three decades of his life, there had been no adventure, no victory, no achievement, no adulation, no monetary reward—not even a throbbing explosion of an orgasm—that had ever been able to bring him the instant joy he experienced with an injection of fentanyl. Even the name of the drug seemed magical, as though specifically created to enhance his life.

It thrilled him, just a bit, to be involved in this illicit, secretive endeavor. Nobody would miss the tiny volumes of fentanyl that he was carrying away each day, and there was no need for a prescription, no documentation, no electronic trail to follow. It was a nearly perfect arrangement.



Know your Equipment: Patient Positioning for Surgery



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Introduction

The aim of positioning a patient for surgery is to provide the best surgical access while minimizing potential risk to the patient. The positions can be broadly classified as supine, lithotomy, prone, lateral, and sitting, with variations in each of these positions. The operating table can also be tilted head down (Trendelenburg), head up (reverse Trendelenburg), or lateral to improve surgical access. The components of safe positioning of a patient involves knowledge, planning, and teamwork.

Anatomical considerations

Each position carries some degree of risk and this is magnified in the anaesthetized patient who is unable to complain! Although the injury to the skin and muscles (pressure induced skin injury, rhabdomyolysis) or the neurovascular bundle (deep vein thrombosis, nerve, and plexus injury) are associated with length of surgery, attention to details while positioning can prevent or reduce these injuries.

- Remove all jewelry, dentures, hearing aids, contact lenses, and removable electronic devices, and support and pad the bony prominences, joints, and body curvatures.
- It is important to ensure that the limbs, head, and

neck are placed in neutral position and the eyes are kept closed without external pressure.

- Safety straps should be used to prevent falls from the operating table. Ensure that no part of the patient is in direct contact with any metal object such as the tabletop, infusion stands, or stirrups.
- Care should be taken to protect the skin from the pressure of intravascular lines, 3-way stop-cocks, and monitoring cables.

During the preoperative clinic visit, an assessment of the range of movement of the limbs and spine and positions that elicit pain, paresthesia, or weakness, provides a good guide to the position that the patient may tolerate under anesthesia. The general rule of the thumb is that the patient should be able to tolerate the position if they were awake and unsedated.

Physiological changes

Reclining from an erect to the supine position increases the venous return to the heart which augments the stroke volume and the cardiac output. The increased arterial pressure activates the baroreceptors in the aorta (Vagus nerve) and the carotid sinus (Glossopharyngeal nerve) to decrease the sympathetic and increase the parasympathetic outflow to the sinoatrial node, the myocardium, and the vascular beds. The atrial reflexes also regulate the renal sympathetic nerves, plasma renin, and arginine vasopressin levels. Therefore, in an unanesthetized person, the arterial pressure is maintained within a narrow range during postural changes. However, general anesthesia, muscle relaxation, and neuraxial blockade impair the autoregulatory mechanisms leading to poor compensation.

Vasodilatation induced by the anesthetic agents and the increase in the mean thoracic pressure due to positive pressure ventilation leads to reduced venous return and hypotension. This is aggravated by low lung compliance in the obese and patients having airway disease or ascites. Placing the subject in lithotomy position or in Trendelenburg tilt increases the venous return. A reverse-Trendelenburg or sitting position decreases it and the resulting hypotension can compromise the cerebral circulation.

In the prone position, care should be taken to keep the abdomen free for respiratory excursions and to avoid pressure on the vena cava which would reduce venous return. Flexion of the hip and knees in the prone position cause venous pooling in the lower extremities.

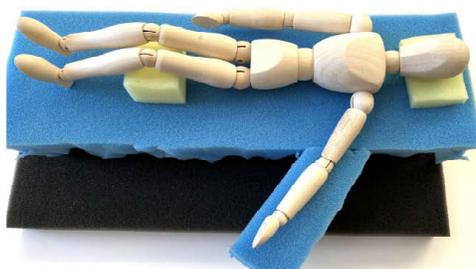
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Know your Equipment: Patient Positioning for Surgery

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When a subject assumes a supine position, the functional residual capacity (FRC) decreases by 20% due to the cephalad displacement of the diaphragm. This is further reduced by 10-15% by induction of anesthesia due to relaxation of the diaphragm. Muscle relaxation and mechanical ventilation do not reduce it any further. However, lithotomy position or Trendelenburg tilt can further decrease the FRC due to pressure of the abdominal contents on to the diaphragm. A 30° head up tilt improves FRC.

Supine or dorsal decubitus position (Figure 1)



This is perhaps the most common position used for surgery. As the entire body is at the level of the heart, the hemodynamics is best preserved. However, since anesthesia dampens the compensatory reserve, minimal changes in the vertical tilt of the table can cause significant cardiovascular changes.

- The upper extremity may be adducted alongside the torso or abducted. When abducted, it should be to less than 90° to minimize the likelihood of injury to the brachial plexus in the axilla by the caudal pressure of the head of the humerus. The cushion and padding on the armrest should be such that the shoulder joint is neutral or flexed ventrally, and not extended, to avoid stretch of the brachial plexus. The hand and the forearm should be kept supinated or neutral with the palm facing the torso. To keep the arm adducted, the 'draw sheet' from under the body should pass over the arm and tucked back under the torso of the patient, and not under the mattress.
- A small pillow or padding under the knees to keep the hips and knees flexed would ease the stretch on the sciatic nerve and reduce the stress on the back and the ventral abdominal musculature.
- The head and neck should be kept neutral and slightly flexed, resting on a soft gel or memory foam pillow. If neck extension is required for surgery on the neck (thyroidectomy, tracheotomy), a roll of towel

is usually placed under the shoulder and the head supported on a pillow. The head may be turned up to 45° from the midline to access the frontal or temporal aspect of the skull, without straining the brachial plexus. If further tilt is required, then a pillow should be placed under the corresponding shoulder and hip to tilt the torso. The eyes should be lubricated with a water-based lotion and kept closed, using a conforming adhesive dressing.

If vertical tilting of the table is anticipated during surgery, a non-skid foam pad or a bean-bag cradle should be placed under the patient. The Trendelenburg position is used for surgery of the lower abdomen or pelvis while the reverse Trendelenburg position helps surgery of the upper abdomen, such as cholecystectomy, hepatic, and bariatric surgery. Shoulder braces are better avoided as it may exert pressure on the brachial plexus with the patient in Trendelenburg position. Safety straps should be used to prevent falls. Whenever the head is at a different level to the heart the effect of the hydrostatic gradient on the cerebral circulation should be considered.

Complications of supine position:

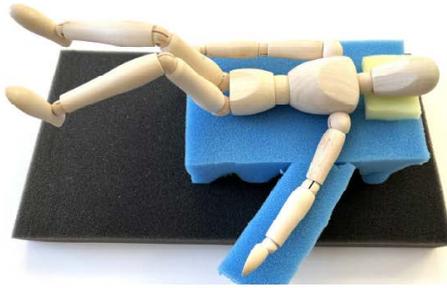
1. Pressure alopecia is caused by ischemia of the hair follicles due to prolonged immobilization. Use of gel or memory foam and periodic rotation of the head during long surgeries may help.
2. Backache can result due to loss of the normal lumbar lordosis under anesthesia, especially in patients with kypho-scoliosis or pre-existing back pain. A small pillow under the knees would ease this strain.
3. Peripheral nerve injury associated with supine position are brachial plexus injury and ulnar neuropathy. These can be minimized by careful positioning of the neck, shoulder, and upper limbs, as described above. The forearm and palm should be supinated or neutral.
4. The aorto-caval compression by an obese abdomen, an intraperitoneal tumor, or a gravid uterus can reduce venous return and cause hypotension. A 15° left lateral tilt can take the pressure off the large vessels and is used routinely for cesarean section or incidental surgery in a parturient.

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Lithotomy position (Figure 2)



This position is frequently used for urologic, anorectal, and gynecological surgeries.

- The hips are flexed 80-100° from the torso and the legs are abducted 30-45° from the midline and flexed. The legs are supported by stirrups, usually a 'candy-cane' or a calf support type. The foot section of the operating table is lowered or removed with the surgeon standing between the patient's legs.
- The legs should be well-padded against the stirrup, especially the lateral aspect of the knee where the common peroneal nerve skirts around the neck of the fibula.
- The arms can be either abducted or adducted next to the torso, like in the supine position.
- While positioning the legs on the stirrups, and while lowering them at the end of the surgery, care should be taken to move both the legs simultaneously to avoid torsion of the lumbar spine. The normal lumbar lordosis is lost which can aggravate any previous back pain.

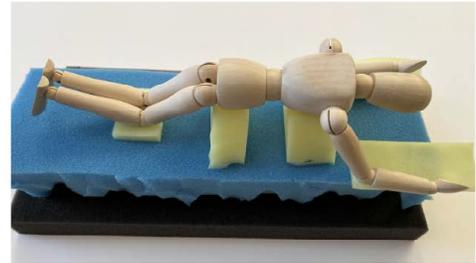
In the lithotomy position, the venous return increases causing an increase in cardiac output. The abdominal viscera are displaced cephalad reducing FRC and lung compliance.

Complications of lithotomy position:

1. If the arms are adducted, injury to the fingers can occur while installing the foot section of the operating table.
2. The hand and the forearm should be kept supinated or neutral with the palm facing the torso to avoid ulnar nerve injury.
3. Injury to the common peroneal nerve can be prevented by adequate padding of the lateral aspect of the knee.

4. Lower extremity compartment syndrome is a rare complication and caused by inadequate tissue perfusion. The arterial perfusion pressure within the calf muscles decreases by 0.78 mmHg for each cm the leg is raised above the heart.

Prone or Ventral decubitus position (Figure 3)



This position is used for surgical access to the posterior fossa of the skull, the spine, the perirectal area, and the posterior surface of the lower extremities.

- The torso should be supported under the chest and the iliac bone leaving the abdomen free for respiratory excursions.
- The head is supported on a head-rest made of gel or foam or it could be stabilized using a Mayfield clamp.

(Figure 4)



Horse-shoe - Gel



Prone-view® - Foam



Mayfield clamp

- The lower extremities should be padded and flexed at the hips and knees. Elastic stockings and active compression devices are used to minimize pooling of venous blood.
- The arms may be tucked alongside the torso, especially when the surgery involves the cranium, the upper thoracic, or cervical spine, or placed next to the patient's head (superman position) when the surgery involves the lower spine. Extra padding under the elbow is needed to prevent compression of the ulnar nerve and to support the shoulder joint in neutral position.
- Care should be taken to prevent pressure on the male genitalia and the breasts in females. The breasts should be placed medial to the gel bolsters.

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Complications of ventral decubitus position

1. Postoperative visual loss (POVL): The most common cause for POVL is ischemic optic neuropathy (ION). This can occur with improper patient positioning causing compression of the eye, raising the intra-ocular pressure and impairing flow in the retinal artery, as in patients positioned prone for spine surgery. Prolonged duration of surgery, excessive hemorrhage and hypotension could be contributing factors; although, hypotension by itself seems to be a rare cause for retinal ischemia. Retinal artery occlusion can occur due to micro-embolus during an open-heart surgery. Other causes for POVL could be cortical blindness and acute glaucoma. Corneal abrasion could lead to irritation and redness of the eyes and cause impaired vision.
2. Brachial plexus & Ulnar nerve injury: Extra padding under the elbow is needed to prevent compression of the ulnar nerve and to support the shoulder joint in neutral position.
3. Pressure sore of soft tissue: Care should be taken to protect the breasts and external genitalia.
4. Poor access to the airway.

A variation of the prone position is the Jack-knife position where the table is flexed such that the buttocks stick out. This position is commonly used for perianal surgery, such as hemorrhoids and pilonidal sinus excision.

Lateral decubitus position (Figure 5)



This position is usually used for surgery involving the thorax, the retroperitoneal structures, and the hip. The patient lies on the non-operative side and is supported by padded supports, rolled sheets, or a deflated beanbag.

- The arms are positioned in front of the patient and neither should be abducted more than 90°.

- The patient's head and neck should rest on a gel or memory foam and be kept in neutral position to prevent stretch injuries to the brachial plexus.
- The dependent ear should be checked to avoid folding or pressure. The eyes should be taped shut and the dependent eye should be checked for external pressure.
- To avoid compression to the dependent brachial plexus or the blood vessels, an 'axillary' roll is placed between the chest wall and the bed, just caudal to the axilla. This roll can be a bag of intravenous fluid or a tightly rolled towel. Some practitioners do not use a roll if the deflated beanbag is supporting the chest wall. A pulse oximeter probe or an arterial line on the dependent arm can detect early signs of vascular compression.
- The dependent lower extremity should be flexed and a padding or pillow placed between the knees.

In the lateral decubitus position, in an awake, spontaneously breathing person, the ventilation (V) and perfusion (Q) are higher in the dependent lung. However, with induction of anesthesia, the decrease in FRC and the weight of the abdominal contents against the dependent hemi-diaphragm makes the upper lung more compliant and easier to ventilate, during both spontaneous and positive pressure ventilation. A Trendelenburg tilt worsens the FRC further.

A variation of the lateral position is the 'kidney' position used to improve exposure of the retroperitoneum for renal surgery. The table is flexed under the iliac crest of the patient with a reverse Trendelenburg tilt.

Complications of Lateral decubitus position:

1. Compression of the neuro-vascular bundle of the dependent arm. This can be prevented by use of an axillary roll under the chest. A pulse oximeter probe or an arterial line on the dependent arm can provide early detection of vascular compromise.
2. Brachial plexus injury due to stretching due to improper positioning of the head and neck.
3. Pressure on the dependent ear and eye can be reduced by use of a gel or memory foam pillow.
4. The 'kidney' position can impair venous return both by the dependency of the lower limbs and the venacaval compression due to acute flexion of the lumbar spine.

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Know your Equipment: Patient Positioning for Surgery

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Sitting position (Figure 6)



Although infrequently used, the sitting position provides good surgical access and a bloodless operative field during surgery on the posterior cervical spine, the posterior fossa, and the tumors in the III ventricle of the brain. The main advantage to the anesthesiologists is good access to the airway, reduced facial swelling, and improved ventilation especially in the obese, when compared to the prone position.

- The head is supported by Mayfield pins. The neck is usually flexed to improve surgical access to the posterior fossa or the cervical spine, but a two-finger distance between the mandible and the sternum is recommended.
- The hips are rotated externally and flexed to reduce stretching of the sciatic nerve and the lower extremity is wrapped in elastic bandage to improve venous return.
- The arms are supported to elevate the shoulders slightly to reduce the traction on the shoulder muscles and the neurovascular structures.

The hemodynamic effects of placing a supine patient in the sitting position is significant and should be attempted in stages with close monitoring of blood pressure and administration of intravenous fluids and vasopressors as needed.

Complications of sitting position

1. Venous Air Embolism (VAE): During neurosurgery in sitting position, since the surgical field is above the heart and the inability of the dural venous sinuses to collapse due to their bony attachment, embolization of air is a constant concern. Precordial Doppler or a transesophageal echocardiography are very sensitive monitors to detect VAE. A sudden drop in end-tidal CO₂ level, arrhythmias, hypotension, and cardiac arrest can occur if sufficient air is embolized. If a patent foramen ovale or an intra-cardiac shunt is present, it can lead to paradoxical embolism

resulting in stroke or myocardial infarction. In the event of VAE, the immediate step is to flood the operative field with saline and cover it with a saline soaked gauze. If safely possible, lower the operative site to a level below the heart and provide supportive care to maintain the blood pressure. One of the maneuvers suggested is to turn the patient left lateral and slightly head-up to contain the air bubble in the right atrium and aspirate it through the previously sited central venous catheter.

2. Cerebral ischemia is an ever-present concern in the sitting position as the cerebral perfusion may be impaired during hypotension. It is prudent to monitor the arterial pressure by placing the pressure transducer at the level of the tragus which aligns to the Circle of Willis. The threshold to use vasopressors to maintain the blood pressure should be low.

A variation of sitting position, the 'beach-chair' position, is frequently used for shoulder surgery as it provides greater access to the shoulder joint from anterior and posterior aspect. This position is also used for breast reconstruction, abdominoplasty, and nasal surgery.

Therefore, patient positioning is an art to provide optimal surgical access while minimizing any potential harm to the patient. It is essential to understand the physiological effects of change in position, especially in an anesthetized patient. It is also important to be aware of the potential complications of the different positions and to be vigilant during initial positioning and the duration of surgery to prevent any long-term problems. Positioning the patient for a surgical procedure is a shared responsibility of the surgeon, the anesthesiologist, and the nurses in the operating room.

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Challenges and Complexities of the Regulation of Health Care

By Donna Kucharski, MD, MBA

“Law is Order, and Good Law is Good Order.”

—Aristotle

PART ONE

The Challenge

The creation of laws to regulate the health care system of the United States presents complexities and challenges in the legislative procedural process. The universal need for health care at some point in each individual's lifetime elevates the importance of the law and regulation surrounding health care. The challenge of organizing independent practitioners, hospital systems, and insurance entities into a free-market framework to meet these needs is unique to the health care regulatory problem.

Our economy has been strained by a health care spending price-tag approaching 20% of the Gross Domestic Product (GDP). What once was “a tranquil service industry dominated by religious orders is now a dynamic sector of the economy driven by a new-found entrepreneurial fervor”⁽¹⁾. Over the past 5 years prior to the pandemic, there were small decreases in the total expenditures using net-neutral health care spending initiatives through targeted elimination of unnecessary utilization, improved care delivery systems, and supply chain efficiencies. Recent data indicate that US health care spending increased 9.7 % resulting from the federal government response to the Covid-19 pandemic.⁽²⁾ Over the longer term, regulation to foster cost control will only be considered successful with coincidental improvement of quality and effectiveness.



The Federal Government Complexities

Our government structure in its most basic form consists of the executive, legislative, and judicial branches. Within this framework, constitutional law (the supreme expression of federal law), statutory law (those laws adopted by legislative bodies), and case law (common law as derived from judicial decisions) must achieve sound health care regulation. The Federal agency system implements, manages and administrates the intent of statutes passed and codified through the legislative process.

The Constitution limits congressional powers to the enumerated powers and the 10th Amendment provides that powers not expressly given to Congress are reserved to the states. The regulatory tension between federal and state constitutional law maintains a balance between centralized government and state self-determination. State regulatory authority for healthcare insurance, established by the McCarran-Ferguson Act of 1944, creates case law which exerts influence over federal regulatory direction of health care legislation.

At the Constitutional Level

Health care in the US relies on the creation and administration of laws which shape all aspects of development and delivery. The Constitution has no provision for the right to health care. The federal government derives its power to create legislation for health care from the Constitution through tangential, implied intent. The Preamble of the Constitution provides to “promote the general Welfare”. Article I, Section 8-1 provides “The Congress shall have Power to lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States...” and Article I Section 8-18 provides “To make all Laws which shall be necessary and proper for carrying into Execution...”.

There are various state constitutional provisions relating to health and provision of health care services which are more expansive than the minimum setting federal regulations⁽²⁾. The 1819 McCulloch v Maryland ruling interpreted the Necessary and Proper Clause (Article I, Section 8) to “afford Congress the implied powers necessary to execute the enumerated powers expanding Congressional powers and ruled in Article

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VI" (2). This Constitution "shall be the Supreme Law of the and" and shall nullify state law in conflict with federal law, thus permitting a workable national government."⁽³⁾ Those states laws expanding the provision of healthcare beyond the federal minimum are not considered to conflict with the federal regulations.⁽⁴⁾

At the Legislative Level

The inception of a law requires passage of a bill by the Legislature which is then signed into law by the President. The signed bill becomes enacted public statutory law and is incorporated into the United States Code. The legislative process required to enact any statutory law involves expertise beyond the Congressional body. Congress has authority under Article 1 of the Constitution to legislate on various matters and "make all laws which shall be necessary and proper for carrying into execution" the enumerated powers.⁽⁵⁾ "Agencies are "bureaucratic institutions entrusted with the implementation, management, and administration of our law and public policy. They are agents of their principals—the three constitutionally created branches of government—who delegate legislative, executive and judicial functions to agencies."⁽⁶⁾ These agencies have been delegated substantial authority to create rules, which are in effect laws although constrained by the enabling legislation.

The Supreme Court has generally recognized that congress has broad constitutional authority to shape the federal bureaucracy.⁽⁷⁾ Federal law defines an agency as any government unit other than the legislature and the courts. Thus, the administrative laws governing those agencies technically address the entire executive branch of government.

Passage of the Affordable Care Act (ACA) health care legislation has proven sweeping in scope. The early implementation of the ACA of 2010 has involved multiple agencies and numerous regulations. The work is ongoing and continues to shape regulatory solutions to the provision of health care within our capitalistic framework. Within any one of the approximately 10 federal agencies involved in the administration of the ACA, regulations are drawn with scheduled public commentary to provide professional opinion, industry position statements, and other relevant information.

Upon review of the material and positions gathered, each agency will release a draft for comment followed by the final regulations.

The complexity is partly illustrated through a comparison of the implementation of the Dodd-Frank Bill, written to restrict the financial industry and protect consumer mortgage transactions, also passed in 2010. The Securities Exchange Commission (SEC), the single agency involved in the Dodd-Frank Bill, has adopted 67 mandatory rule-making provisions of the bill while other necessary rules remain outstanding. Ten years after the passage of the Dodd-Frank Wall Street Reform and Consumer Protection Act, implementation remains incomplete.

In contrast, the regulation of the ACA spans multiple cabinet-level regulatory agencies, including HHS, DOL, IRS and CMS⁽⁸⁾. Due to the complexities presented by the ACA, a new agency, the Center for Consumer Information and Insurance Oversight (CCIIO), was created to assist in the financial regulation of the ACA. CCIIO oversees the implementation of the provisions related to private health insurance and is ordered to work with the states to set up each new Health Insurance Marketplace.

At the Judicial Level

Article III, Section 1 of the US Constitution states, "The judicial Power of the United States, shall be vested in one Supreme Court and in such inferior Courts as the Congress may from time to time, ordain and establish" (US constitution article III, Section 1). Since its inception, the ACA and its elements have been challenged in federal and state Courts. As of January 2022, the ACA has risen to the bench of the US Supreme Court on three occasions.

In 2012, the National Federation of Independent Business v. Sebelius challenged the constitutionality of the individual mandate. The Supreme Court rejected constitutional challenges under the Commerce Clause to the ACA requirement that individuals must maintain health insurance coverage. The Court reasoned that the ACA requirement was not a command to buy health insurance—which Congress would lack the power to enact—but merely a tax for not doing so. The Supreme Court ruled the individual mandate constitutional under the taxing power of the Congress⁽⁸⁾.

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In 2015, the Supreme Court decision in *King vs. Burwell* stabilized the health insurance marketplaces by making health insurance subsidies available at both the state and the national marketplace levels⁽⁹⁾. In December 2017, Congress amended the ACA to eliminate the penalty for not buying health insurance, but Congress did not eliminate the ACA's individual mandate to maintain health insurance coverage.

On June 17, 2022, the Supreme Court rejected a third challenge to the ACA⁽¹⁰⁾. The plaintiffs contended that without a penalty to back up the ACA's individual mandate, the mandate could no longer be justified under Congress' taxing power and that the newly unconstitutional mandate could not be separated from the rest of the ACA. However, the Court held that the individual plaintiffs challenging the law did not suffer an injury traceable to the allegedly unconstitutional individual mandate because the mandate did not force them to do anything; a statute that tells patients to buy insurance but does not include a consequence for noncompliance does not harm anyone.⁽¹¹⁾

At the Executive Level: The Executive Order

Executive Orders have been used by Presidents since George Washington to direct federal agencies to draft new rules or guidance, provide direction over the legislative and judicial bodies, thereby providing influence and viewpoint. Over the years there has been varied application of the executive order with Franklin D. Roosevelt far outnumbering all other president with the release of 3,728 orders. Most other presidents in the past century have released 200-400 orders. The United States Constitution does not expressly provide for the executive order. Article II, Section 1, Clause 1 of the constitution states: "The executive Power shall be vested in a President of the United States of America." and Sections 2 and 3 describe the scope of powers and duties of the office of President, including "he shall take Care that the Laws be faithfully executed".

Presidential Executive orders have the force of law. Congress does have the power to pass legislation that would impede the implementation of any executive order. The U.S. Supreme Court has held that all executive orders from the president of the United States must be supported by the Constitution, whether from a clause granting specific power, or by Congress

delegating such power to the executive branch "The debates of the First Congress also provide evidence of Congress's acknowledgment of what would become the delicate, and at times uneasy, balance between congressional creation and control of agencies and the President's authority to supervise executive officials pursuant to his constitutional obligation to "Take care that the laws be faithfully executed." From the very outset, Congress wrestled with defining the scope of both presidential and congressional control of executive agencies."⁽¹²⁾

Over the past few years, the Executive Order has been used by Trump and now Biden to influence and impact the ACA. During the Trump administration EO 13813, October 12, 2017, Promoting Healthcare Choice and Competition Across the United States, was stated to improve information to the consumer and expanding competition and choice in the healthcare marketplace. There was general concern the EO would siphon healthy patients from the healthcare marketplace and undermine the ACA.⁽¹³⁾ EO 13877, June 24, 2019, Improving Price and Quality Transparency in American Healthcare to Put Patients First requires price list publication for medications and services with differentiation between billed prices and negotiated prices.⁽¹⁴⁾ EO 13951, September 24, 2020, An American-First Healthcare Plan⁽¹⁵⁾ protects patients with previous conditions and importantly contains passages to eliminate surprise medical bills.⁽¹⁶⁾

President Biden issued an Executive Order, 14036, Promoting Competition in the American Economy, in July 2021. The Order involves 72 initiatives by more than a dozen federal agencies to address problems surrounding business competition. Health care topics addressed in EO 14036 are the continued mergers and consolidation of health care systems and unfair drug pricing. Congressional reaction has included labeling portions of the EO 14036 as an application of excessive antitrust enforcement while the methodologies to curb drug prices has brought more favorable dialogue. These major impacts on the healthcare system over the past 5 years represent a rapid paced transformation of the healthcare marketplace. The shift to the executive order to advance the process also challenges our ability as physicians to influence,

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implement and comply with rulings released from the agency level.⁽¹⁷⁾ The details of each ruling impact implementation presenting a need for communication within the specialty and among physicians.

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Refurbishing Medications: The Ketamine Story



Joseph Answine, MD, FASA

ALTERNATE DISTRICT DIRECTOR TO THE ASA

Many medications have indications, whether FDA approved or not, that differ from their initial intended use. The anti-hypertensive and anti-anginal sildenafil is a widely known example. It is a drug that has generated billions of dollars in the treatment of erectile dysfunction under the trade name Viagra. It has also been shown to improve the symptoms of pulmonary hypertension, Raynaud's phenomenon, and high-altitude pulmonary edema. More recently, the antimalarial drug hydroxychloroquine became popular as part of a treatment regimen for COVID-19 infection. The anesthetic ketamine should be included on this list of drugs with novel uses as well. Ketamine is more than 50 years old but continues to be used as an anesthetic. It has newer indications, especially in the treatment of pain and depression.

In the 1950s, Parke-Davis and Company's laboratories (Detroit, Michigan) were looking for an ideal anesthetic. V. Harold Maddox, PhD synthesized phencyclidine (PCP) in March 1956, and in 1958, the first human trials with PCP were performed. The patients experienced amnesia and intense analgesia, along with an increase in blood pressure and respiratory rate, which was not common among the other available anesthetics. As is well known, anesthetics usually cause a profound depression of the cardiovascular and respiratory systems. Also, there was increased salivation and nystagmus (involuntary movement of the eyeball) following administration of PCP. The rapid eye movements of someone on this class of drugs is a very common sign of their use.

So, what they discovered was a potent anesthetic that did not cause a suppression in cardiac and respiratory function and preserved airway reflexes. Sounds perfect? Well, not so perfect. It was eventually deemed unsatisfactory for anesthesia and surgery because it led to a long recovery period and severe post-operative agitation and hallucinations. The excitation and hallucinations sometimes persisted for 12 hours or more.

Then in 1962, Calvin Lee Stevens, PhD, a professor at Wayne State University and a consultant for Parke-Davis, synthesized a derivative of PCP, ketamine. Ketamine was also a potent analgesic but less potent than PCP and with a shorter duration of agitation. The patients receiving ketamine described the effect as "floating in outer space and having no feeling in their limbs". There was a disconnection between the brain and the body as well as the environment; therefore, the term "dissociative anesthetic" was coined.

However, ketamine did not win over doctors in Europe at the time. They concluded that it was a "disaster" as an anesthetic. It subsequently became popular among veterinarians. (That is why it is sometimes called a horse tranquilizer.) Eventually, it became approved by the United States Food and Drug Administration (FDA) in 1970. Furthermore, because it maintained cardiovascular function significantly better than other anesthetics, ketamine became popular as a field anesthetic during the Vietnam War. It also became popular over those early years as a recreational drug due to its hallucinatory effects, sometimes being called "Special K" and "Kit Kat".

Because of the positive effects on the heart and lungs, ketamine has had a special place within the world of anesthesia for patients in shock, especially trauma patients. And, because of its positive effects on respiration and the ability to work when given intramuscularly, ketamine became commonly used with combative patients and children requiring sedation, especially in the emergency room.

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Refurbishing Medications: The Ketamine Story

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Now in the 2000s, ketamine's positive effects with acute and chronic pain as well as depression have led to a resurgence in its use.

The primary mechanism of action is non-competitive inhibition of glutamate at the N Methyl D Aspartate (NMDA) receptor. Glutamate is an excitatory neurotransmitter found throughout the brain and spinal cord. Ketamine is non-competitive because it does not compete with glutamate for its receptor binding site but inhibits activity at the receptor channel as a negative allosteric modulator. It binds elsewhere near the glutamate binding site therefore decreasing the ability of the receptor to bind the neurotransmitter.

However, ketamine is a classic example of a "dirty" drug because it also binds to many other sites in the central nervous system as an antagonist or agonist: opioid receptors (agonist), AMPA receptors (agonist), HCN1 receptors (antagonist), sodium channels (antagonist), calcium channels (antagonist), and GABA receptors (agonist). Ketamine possibly binds to many more sites making a thorough understanding of its effects difficult to impossible. It is also thought to cause an increase in the amount of glutamate in parts of the brain, which may explain the excitatory and hallucinogenic effects of ketamine.

Ketamine, due to its fat solubility and low level of protein binding in the blood, gets to the brain very quickly. To add to the "dirty" nature of the drug, ketamine is metabolized in the liver to several metabolites. One of these metabolites is norketamine, which is also active at the NMDA receptor as well as other sites within the central nervous system. The metabolites are excreted by the kidneys with an elimination half-life of 2-3 hours. The shorter duration of the anesthetic effect of ketamine is due to redistribution into the fat stores of the body due to a high volume of distribution.

As an anesthetic, ketamine rapidly induces unconsciousness at the start of general anesthesia when given intravenously at a dose of 1-4.5 milligram/kilogram or intramuscularly at a dose of 6.5-13 milligram/kilogram. And again, it is a favorite alternative to propofol in patients with cardiovascular

instability, especially due to trauma or infection. Ketamine is used in doses of 0.5-1 milligram/kilogram for sedation for procedures such as stitches in children because it more likely will maintain breathing when compared to other medications such as propofol. It is popular for asthmatics undergoing anesthesia as well due to its bronchodilator effects.

The likely mechanism of action of the anesthetic effect is a reduction in glutamate as an excitatory neurotransmitter in the brain and possibly, to a lesser extent, an increase in the effectiveness of the inhibitory neurotransmitter, GABA in the brain.

It is also used frequently during anesthesia and outside the world of anesthesiology because of its pain reducing ability that results in a decrease in opioid utilization, which is especially appealing with the current opioid crisis.

Ketamine likely exerts its analgesic effect primarily through the blockade of NMDA receptors throughout the central nervous system. NMDA receptor blockade decreases brain excitation and pain signal sensitization. For example, the "windup phenomenon" is depressed by blocking post-synaptic NMDA-type glutamate receptors within the dorsal horn of the spinal cord. The windup phenomenon is most easily explained by having many of the NMDA receptors in the pain pathway temporarily closed with minimal activity but open with continued stimulation, leading to more pain signals traveling to the brain. Other postulated mechanisms of action are the stimulation of norepinephrine and serotonin pain modulation pathways (pathways that come from the brain and lessen pain signals traveling to the brain), as well as the stimulation of opioid receptors (minor effect).

Ketamine is usually given at a dose of 0.1-0.4 milligram/kilogram intravenously for acute pain control. Higher doses increase the likelihood of a dissociative anesthetic effect. For spinal cord injury pain, ketamine infusions of 0.42-0.4 milligram/kilogram/hour from 17 minutes to 5 hours for 7 consecutive days have been used for short-term improvements in pain. For chronic regional pain syndrome (CRPS), ketamine infusions of 22 milligram/hour for 4 days or 0.35 milligram/kilogram/hour over 4 hours daily for 10 days have been shown to provide

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improvements in pain for up to 12 weeks. For mixed neuropathic pain, phantom limb pain, postherpetic neuralgia, fibromyalgia, cancer pain, ischemic pain, migraine headache, and low-back pain, there is little evidence supporting ketamine infusions for immediate improvements in pain.

The most striking use of ketamine is its newfound place in the treatment of depression. First, we need to talk about old and newer theories on the etiology of depression. The **monoamine** theory of depression is based on a relative deficiency of available excitatory monoamines such as serotonin and norepinephrine within the brain. This has been the dominant theory for years and has guided pharmacologic therapy with medications such as tricyclics, SSRIs and SNRIs. The **glutamate theory** of depression is different. Chronic stress injury causes a dysfunction of brain synapses leading to the inability of the brain to form and reorganize synaptic connections (neuroplasticity), especially in response to learning, experience, or following injury. Therefore, abnormal pathways persist leading to depression.

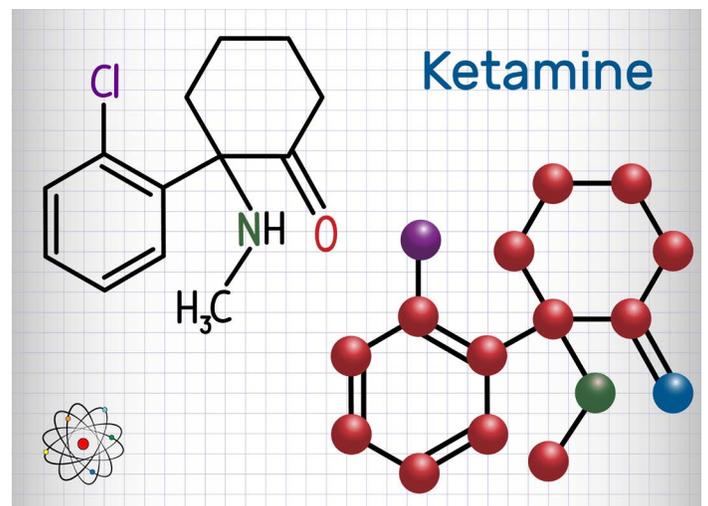
Ketamine may work for depression if the glutamate theory has merit because it has also been shown to increase glutamate transmission by increasing glutamate production and increasing the amount of available AMPA receptors, another group of receptors that bind glutamate post-synaptically. This then leads to an increase in "synaptogenesis" which is an increase in new synaptic connections improving neuroplasticity and the formation of "normal" brain pathways.

Ketamine is commonly used (sometimes emergently) for treatment-resistant severe depression with suicidal thoughts. Where antidepressant medications which raise serotonin and/or norepinephrine levels may take weeks to achieve an effect, ketamine often produces a relative immediate effect. The effect may occur within a couple hours and most patients have a positive response within 24 hours. The effect can last for days to a week. Regimens of 1-3 times per week have been used. There is a concern, however, of potential kidney and liver toxicity with continued use of infusions. A common dosing regimen is

0.5 milligram/kilogram over 40 minutes. Patients should be able to talk and answer questions during the infusion. The recovery time is 30 minutes to 2 hours. Since ketamine is not FDA approved for such treatment, a standard protocol is not available and institutions create their own.

Esketamine is the S(+) isomer of ketamine. It is approved by the United States Food and Drug Administration (FDA) for standard treatment-resistant depression. Esketamine is recommended to be used in conjunction with a conventional antidepressant. The theory behind its use and approval is that esketamine provides rapid relief from depression symptoms until the other "chronic" medications take effect. Esketamine is supplied as a nasal spray. Esketamine is approximately three to four times more potent than R(-) ketamine, potentially translating into lower doses with fewer side effects compared with previously studied ketamine infusions. A common protocol is to give three doses of the nasal spray spaced five minutes apart under doctor supervision. The patient then remains in the outpatient clinic under observation until potential side effects have passed.

So, as we develop new medications, ketamine teaches us there is merit to looking at what we have already collecting dust on the shelf.



LEGISLATIVE UPDATE

Milliron & Goodman GOVERNMENT RELATIONS ^{LLC}

2022 is going to be a busy political year here in the Commonwealth of Pennsylvania. This year the state will elect a new governor and a multitude of other positions both at the state and federal level. With such a busy year ahead, it is vital that our members stay informed. Below is an update regarding some of the PSA's legislative priorities as well as some background information on some of the races happening here in Pennsylvania this year.

House Bill 1956 sponsored by Rep. Lynda Culver would create a license for Certified Anesthesiologist Assistants to practice here in Pennsylvania. This legislation is supported by the Pennsylvania Academy of Anesthesiologist Assistants (PAAA). The PSA has also partnered with the PAAA to advocate on behalf of this legislation.

The PSA is continuing to monitor House Bill 681. This legislation is sponsored by Rep. Torren Ecker and seeks to make covenants not to compete between employers and health care practitioners unenforceable. HB 681 was reported from the House Appropriations Committee on May 26, 2021, and is currently on the House Floor awaiting a final vote.

As the PSA continues to monitor and advocate on behalf of your profession and patients, we would like to remind you that we cannot do this alone! We need your help. If you or any of your colleagues are interested in learning more about the PSA's legislative agenda or volunteering to meet with your legislators, please email Tyler@millirongoodman.com.

Election Update:

All political eyes are firmly affixed to what will happen in Pennsylvania over the course of the next year. This focus on Pennsylvania comes largely from the importance of the 2022 primary and general elections and the question of who will replace Governor Tom Wolf.

Currently, Governor Wolf is in his final year as Governor of Pennsylvania. Gov. Wolf won his second term as governor in 2018 after defeating then-Republican challenger Scott Wagner. While the 2022 gubernatorial primary is not until May 17, the candidate field is filling quickly.

The Republican side of the race is filling up quickly with potential candidates, including Senate President Pro Tempore Jake Corman, Senator Scott Martin, Senator Doug Mastriano and more. On the Democratic side, Attorney General Josh Shapiro is the only candidate at this time.

Outside of the gubernatorial race, Pennsylvania's General Assembly is gearing up for a very busy election season. In 2022, all 203 members of the Pennsylvania House of Representatives will be up for election or reelection. In the Pennsylvania State Senate, 24 of 50 Senators are up for election or reelection this coming year. The PSA is actively engaged and monitoring these races, and as more information develops, we will be sure to keep you up-to-date.

As you can see the upcoming year will be an incredibly busy one for politics and elections. It is now more important than ever to become politically active and engage with your local legislators. If you are already engaged, now is the time to reengage and revisit your local legislators and educate them about the issues that are important to you.





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Topics in Respiratory Physiology and Monitoring



Jonathan Roth, MD

Background

The prototypic physiologic adult male weighs 70 kg. In adults at rest, 1 MET (metabolic equivalent task) = 3.5 ml oxygen consumption per kg per minute. Thus, the minute oxygen consumption ($\dot{V}O_2$) is ≈ 250 ml O₂/min (≈ 70 kg \times 3.5 ml O₂/kg/min). With a typical respiratory quotient (RQ = $\dot{V}CO_2 / \dot{V}O_2$) of 0.8, the minute carbon dioxide production ($\dot{V}CO_2$) is 200 ml CO₂/minute (200/250 = 0.8).

A typical minute ventilation ($\dot{V}A$) is 5,000 ml/minute. At room air, inspiratory oxygen concentration (FiO₂) = 0.21 and expiratory oxygen concentration (FeO₂) = 0.16. The resting oxygen extraction (=FiO₂-FeO₂) is 5% (or 0.05). Thus 5,000 ml/minute \times 0.05 oxygen extracted = 250 ml oxygen extracted/minute, equal to the $\dot{V}O_2$ of 250 mL/minute. At room air, inspiratory carbon dioxide concentration (FiCO₂) is negligible and mean expiratory carbon dioxide concentration (FeCO₂) = 4%. Thus 5,000 ml/minute \times 0.04 = 200 ml / minute carbon dioxide exhaled, equal to the $\dot{V}CO_2$ of 200 ml/minute.

The typical minute oxygen delivery ($\dot{D}O_2$) is $\approx 1,000$ ml per minute. The typical mixed venous oxygen return is ≈ 750 ml/minute. This results in an oxygen utilization of 250 mL/minute (equal to the oxygen extracted during ventilation) and a mixed venous saturation of 75% (=750/1,000).

A typical respiratory pattern at rest would be:

Tidal Volume (TV)	Respiratory Rate (RR)	FiO ₂ -FeO ₂	FeCO ₂ -FiCO	O ₂ extracted per breath	CO ₂ exhaled per breath	O ₂ extracted per minute	CO ₂ exhaled per minute
ml	per minute	fraction	fraction	ml	ml	ml	ml
500	10	0.05	0.04	25	20	250	200

(500 \times 0.05) (500 \times 0.04) (25 \times 10) (20 \times 10)

By definition, 1 atmosphere = 100% = 760 mm Hg. Thus 1% = 7.6 mm Hg, 4% = 30.4 mm Hg, 5% = 38 mm Hg, and 8% = 60.8 mm Hg. With an arterial paCO₂ = 40 mm Hg (5.26%), one would typically measure an end tidal CO₂ (ETCO₂) of 35 mm Hg (4.6%) in a healthy anesthetized patient. The ETCO₂ is not the average ETCO₂; it is a peak picker. The ETCO₂ is a larger value than the average FeCO₂, expected to be 4% (30.4 mm Hg) in this example.

Question: Why does the pCO₂ increase during hypoventilation or decrease during hyperventilation, and why does it reach the steady state value that it does and not continue to increase or decrease?

Answer: In the steady state, the rate of elimination of carbon dioxide equals that of its production. If the rate of CO₂ production is greater than its elimination, CO₂ will accumulate in the body and that will be reflected as a higher paCO₂ (and higher ETCO₂). If the rate of CO₂ elimination is greater than its production, CO₂ content will decrease in the body and that will be reflected as a lower paCO₂ (and lower ETCO₂).

If you decrease the ventilation (in this example by reducing the respiratory rate), you need to eliminate more CO₂ per breath since there are fewer breaths per minute. The paCO₂ will increase until there is enough CO₂ eliminated in each breath to make up for the fewer breaths per minute so that the rate of CO₂ production equals the rate of CO₂ elimination. This is illustrated in the table. Large changes are used to clearly illustrate the concepts.

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Example: Hypoventilation with normal $\dot{V}CO_2$

Tidal Volume TV ml	Respiratory Rate RR breaths/minute	$FeCO_2 - FiCO_2^*$ fraction	CO_2 exhaled per breath ml	CO_2 exhaled per minute ml
At rest: 500	10	0.04	20 (500 x 0.04)	200 (20 x 10)
Decrease RR to 5. The initial first breath will be:				
500	5	0.04	20 (500 x 0.04)	100 (20 x 5)
Thus, CO_2 will accumulate until:				
500	5	0.08	40 (500 x 0.08)	200 (40 x 5)

The rate of production now equals the rate of elimination and $paCO_2$ will no longer increase. These changes require time to reach the new steady state. During apnea, when there is no CO_2 elimination, $paCO_2$ will increase approximately 3 mm Hg per minute after the first minute. During hypoventilation, when there is some CO_2 elimination, the $paCO_2$ increases at a slower rate. (Because the typical venous $pvcO_2$ is 46 mm Hg, the $paCO_2$ will increase approximately 6 mm Hg in the first minute of complete apnea.)

Although there is some variability of these values in the literature, the change in $paCO_2$ as a function of time while apneic can be estimated by:

Time (minutes)	$paCO_2$ mm Hg	$pvcO_2$ mm Hg
0	40	46
1	46	49
2	49	52
3	52	55
4	55	58
5	58	61

*Since $FiCO_2$ is 0 in a properly working nonbreathing (e.g., circle) system (and negligible breathing room air), the $FeCO_2 - FiCO_2$ value is equal to $FeCO_2$. An increase (or decrease) in $paCO_2$ results in an increase (or decrease) in $FeCO_2$. As $FeCO_2$ increases (or decreases), $ETCO_2$ increases (or decreases).

Example: Hyperventilation with normal $\dot{V}CO_2$

Tidal Volume TV ml	Respiratory Rate RR breaths/minute	$FeCO_2 - FiCO_2$ fraction	CO_2 exhaled per breath ml	CO_2 exhaled per minute ml
At rest: 500	10	0.04	20	200
Increase RR to 20. The initial first breath will be:				
500	20	0.04	20	400
CO_2 stores will decrease until:				
500	20	0.02	10	200

The rate of production now equals the rate of elimination and $paCO_2$ will no longer decrease. These changes occur more rapidly than those that occur with hypoventilation.

In the above examples, we examined what happens when $\dot{V}A$ is changed. In the next example, we examine what happens when $\dot{V}CO_2$ is changed.

Question: Why does the $paCO_2$ increase (or decrease) during increases (or decreases) in carbon dioxide production and why does it reach the steady state value that it does and not continue to increase (or decrease)?

Answer: The relationship of $paCO_2$, $\dot{V}CO_2$, and $\dot{V}A$ is given by: $paCO_2 \approx \dot{V}CO_2 / \dot{V}A$. If one increases $\dot{V}CO_2$, then one must increase $\dot{V}A$ to normalize $paCO_2$. If $\dot{V}CO_2$ is increased and $\dot{V}A$ is not changed, then $paCO_2$

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increases. (Absorption of carbon dioxide (e.g., during laparoscopy or colonoscopy) is equivalent to an increased $\dot{V}CO_2$ in these examples as the body needs to eliminate carbon dioxide regardless of its source.)

Example: Increased $\dot{V}CO_2$ with normal $\dot{V}A$

Tidal Volume TV ml	Respiratory Rate RR breaths/minute	$FeCO_2 - FiCO_2$ fraction	CO_2 exhaled per breath ml	CO_2 exhaled per minute ml
At rest: 500	10	0.04	20	200

Now increase $\dot{V}CO_2$ to 400 ml / minute. The rate of production (400 ml/min) is now greater than the rate of elimination (200 ml/min). If there is no change in $\dot{V}A$, CO_2 will accumulate and $paCO_2$ (and $FeCO_2$) will increase until:

500	10	0.08	40	400
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Alternatively, an increased respiratory rate can prevent CO_2 accumulation:

500	20	0.04	20	400
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The rate of production now equals the rate of elimination and $paCO_2$ will no longer increase.

One often notices a continual gradual rise in $ETCO_2$ as the surgical case progresses even though the ventilator settings have not been changed. This is often due to the gradual warming of the patient from forced air warming increasing metabolic rate and hence carbon dioxide production. Waning paralysis can also contribute to increased CO_2 production.

Changes in $ETCO_2$ due to normally encountered changes in $\dot{V}CO_2$ or $\dot{V}A$ are typically gradual. A sudden rapid decrease in $ETCO_2$ means a sudden catastrophic hemodynamic event (e.g., pulmonary embolus, cardiac arrest, rapid blood loss, tension pneumothorax, cardiac tamponade, cardiac rupture, mitral papillary muscle rupture, and other causes of a sudden decrease in cardiac output).

During controlled ventilation, the ventilator settings determine the $paCO_2$. During spontaneous ventilation, the tidal volume and respiratory rate adjust to achieve the $paCO_2$ as determined by the patient's set point.

Question: What about end-tidal oxygen?

In most situations, carbon dioxide production is linked to oxygen consumption. Thus, any change in CO_2 production is positively correlated and proportional to a corresponding change in O_2 consumption (as determined by the respiratory quotient). Prior to capnography, a technique known as closed circuit anesthesia was used to measure oxygen consumption. In current practice, estimates of oxygen consumption can be gleaned from estimates of carbon dioxide production and oxygen extraction.

As discussed above, normal unanesthetized oxygen extraction ($FiO_2 - FeO_2$) is 5%. A 5% extraction of oxygen typically corresponds to a normal carbon dioxide production resulting in an $ETCO_2$ of 35 mm Hg and a $paCO_2$ of 40 mm Hg.

Since oxygen consumption and CO_2 production are generally linked, changes in $FiO_2 - FeO_2$ and $ETCO_2$ generally occur together and in the same direction. However, the $FiO_2 - FeO_2$ difference is less sensitive than changes in $ETCO_2$. A 1% $FiO_2 - FeO_2$ difference is 20% of the entire range (0 to 5%). With capnography, the entire range is from 0 mm Hg to 35 mm Hg; each mm Hg represents just a 3% change of the range. Thus, small changes in $ETCO_2$ will usually not have a corresponding displayed change in $FiO_2 - FeO_2$. Because of rounding, a change in $FiO_2 - FeO_2$ may suggest a large change in $\dot{V}O_2$ when there was actually a small change in $\dot{V}O_2$. For example, a displayed change from 3% to 4% may be due to the actual change from 3.49 to 3.51%. Similarly, a relatively larger actual change (e.g., 3.51% to 4.49%) may go unnoticed; 4% would be displayed for both values when there is an approximately 25% change in value. Having said this, there still are times when $FiO_2 - FeO_2$ may provide useful clinical information.

Since the metabolic rate is decreased under general anesthesia, a typical observed $FiO_2 - FeO_2$ is 3 to 4% when pCO_2 is 40 mm Hg. If a patient is hypoventilating (or hyperventilating), the $FiO_2 - FeO_2$ should increase (or decrease). If you have fewer breaths, you need to extract more oxygen per breath to meet metabolic requirements, and vice versa. At any given $\dot{V}A$, if $\dot{V}O_2$

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increases (or decreases), $\text{FiO}_2\text{-FeO}_2$ should increase (or decrease).

The following table illustrates these concepts.

Tidal Volume TV ml	Respiratory Rate RR breaths/minute	$\text{FiO}_2\text{-FeO}_2$ fraction	O_2 extracted per breath ml	O_2 extracted per minute ml
Awake, at rest:				
500	10	0.05	25 (0.05 x 500)	250 (25 x 10)
Increased $\dot{V}\text{O}_2$ (500 ml/min) but with no increased $\dot{V}\text{A}$ (patient will be hypercarbic), $\text{FiO}_2\text{-FeO}_2$ will increase:				
500	10	0.10	50	500
Increased $\dot{V}\text{O}_2$ but with increased $\dot{V}\text{A}$ (patient will be normocarbic), $\text{FiO}_2\text{-FeO}_2$ will be normal:				
500	20	0.05	25	500
Under general anesthesia, with decreased $\dot{V}\text{O}_2$ (e.g., 150 ml/min) but with no change in $\dot{V}\text{A}$ (patient will be hypocarbic since $\dot{V}\text{CO}_2$ decreased), $\text{FiO}_2\text{-FeO}_2$ will decrease:				
500	10	0.03	15	150
Under general anesthesia, but with decreased ventilation:				
500	5	0.06	30	150
Under general anesthesia, but with increased ventilation:				
500	20	0.015	7.5	150

Assuming there is no other reason for the $\text{FiO}_2\text{-FeO}_2$ to change (reasons for this change are discussed below), if one measures an increased $\text{FiO}_2\text{-FeO}_2$, typically the patient would be hypoventilating and the ETCO_2 should be elevated. If there is an increased $\text{FiO}_2\text{-FeO}_2$ and the ETCO_2 is not elevated, that would imply an increased $\text{paCO}_2\text{-ETCO}_2$ gradient. One possible cause of this situation would be a decreased cardiac output resulting from unrecognized hypovolemia. In an extreme low cardiac output situation, there is insufficient oxygen delivery to meet metabolic requirements and oxygen utilization will be reduced. This will lessen the $\text{FiO}_2\text{-FeO}_2$ gradient.

So even though changes in oxygen consumption should be reflected by changes in ETCO_2 , the changes in $\text{FiO}_2\text{-FeO}_2$ occur virtually immediately whereas it may take some time for the ETCO_2 measurement to achieve the new steady state. Thus $\text{FiO}_2\text{-FeO}_2$ monitoring may provide an earlier indication of a changing clinical situation. Changes in $\text{FiO}_2\text{-FeO}_2$ values may be reassuring that the situation is as expected, or may be an indication that there is a clinical change.

Examples of clinical situations, actual and potential, where changes in $\text{FiO}_2\text{-FeO}_2$ can occur:

Increases in $\text{FiO}_2\text{-FeO}_2$

- Detection of increased metabolic activity
- Waning action of neuromuscular blockade
- Malignant hyperthermia
- Febrile illness
- Iatrogenic hyperthermia
- Shivering
- Hyperthyroidism
- Seizure
- Contraction during labor
- Perfusion to tissues that were previously not adequately perfused
- Correction of hypovolemic shock
- Restoration of circulation to organs previously removed from circulation
- Reperfusion of liver (an increased $\text{FiO}_2\text{-FeO}_2$ suggests that the new liver is functioning)
- Vascular unclamping of aorta
- Orthopedic tourniquet release

Decreases in $\text{FiO}_2\text{-FeO}_2$

- Detection of decreased metabolic activity
 - Hypothermia (without shivering)
 - Muscle relaxants reducing muscle activity
 - Hypothyroidism
 - Fetal distress (decreased oxygen utilization by fetus, currently not clinically feasible to detect)
 - Inability of mitochondria to utilize oxygen (e.g., sepsis, cyanide poisoning, carbon monoxide poisoning)
 - Inadequate perfusion
 - Cardiac arrest
 - Hypovolemic shock
 - Removal of organs from circulation
 - Clamping for hepatectomy
 - Aorta cross clamping
 - Orthopedic tourniquet inflation
- Although analysis of $\text{FiO}_2\text{-FeO}_2$ has generally not been emphasized during anesthesia training, paying attention to $\text{FiO}_2\text{-FeO}_2$ may serve to confirm and reassure that the clinical situation is as expected, or it may provide an early clue to a change in the clinical situation.

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FeO_2 is also used to assess the adequacy of preinduction preoxygenation. Seeking an FeO_2 greater than 80% suggests that the lungs are denitrogenated and filled with nearly the maximum amount of oxygen. (Combined exiting carbon dioxide and water vapor can comprise 10% of the gas in the lungs, thus making 90% the theoretic maximum attainable FeO_2 .) Although not detectable by FeO_2 , continuing preoxygenation for another 3-5 minutes allows more oxygen to be dissolved and stored in the body providing for an additional oxygen reserve that can allow for a longer period of apnea that may occur with an unexpected difficult airway before desaturation occurs.

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