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APSF Highlights 12 Perioperative Patient Safety Priorities

by Meghan Lane-Fall, MD, MSHP

In February 2018, the APSF Board of Directors voted on a series of perioperative patient safety topics to focus the Foundation's attention on developing priorities for research, education, and practice innovations. This list follows a tradition dating back to 1999, the first time that the APSF published patient safety priorities.[1] The priority list was derived from multiple sources, including the published literature and submissions to and correspondence from readers of the *APSF Newsletter*. The multidisciplinary APSF Board, which includes anesthesiologists, certified registered nurse anesthetists, surgeons, nurses, industry representatives, pharmacists, risk managers, and hospital administrators, decided upon this series of priorities after real-time head-to-head voting took place on pairs of safety topics. These topics were derived from a poll sent to the board members prior to the February meeting by Dr. Warner, the APSF president. Some of the topics, such as airway management (#8) and medication safety (#4) are familiar, while others like the culture of safety (#3) and communication concerns (#7) reflect our evolving understanding of the complexity involved in creating safe conditions. We hope this list generates conversation, critical evaluation of clinical practice, performance improvement initiatives, and patient safety research.

Table 1. APSF Perioperative Patient Safety Priorities*

1.	Preventing, detecting, and mitigating clinical deterioration in the perioperative period
2.	Safety in non-operating room locations
3.	Culture of safety
4.	Medication safety
5.	Perioperative delirium, cognitive dysfunction, and brain health
6.	Hospital-acquired infections and environmental microbial contamination and transmission
7.	Patient-related communication issues, handoffs, and transitions of care
8.	Airway management difficulties, skills, and equipment
9.	Cost-effective protocols and monitoring that have a positive impact on safety
10.	Integration of safety into process implementation and continuous improvement
11.	Burnout
12.	Distractions in procedural areas

*Published on the APSF website: https://www.apsf.org/patient-safety-initiatives/

Dr. Lane-Fall is assistant professor of anesthesiology and critical care at the Perelman School of Medicine of the University of Pennsylvania. She is a member of the APSF Board of Directors and is assistant editor of the APSF Newsletter.

She has no conflicts of interest related to the content of this article.

REFERENCE

1. Stoelting R. APSF survey results identify safety issues priorities. *APSF Newsletter* 1999;14:6–7. https://www.apsf.org/article/apsf-survey-results-identify-safety-issues-priorities/ Accessed on August 18, 2018.

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The *APSF Newsletter* is the official journal of the Anesthesia Patient Safety Foundation. It is widely distributed to a variety of anesthesia professionals, perioperative providers, key industry representatives, and risk managers. It is published three times a year (February, June, and October). **Deadlines for each issue are as follows: 1) February Issue: November 15th, 2) June Issue: March 15th, 3) October Issue: July 15th.** The content of the newsletter typically focuses on anesthesia-related perioperative patient safety. Decisions regarding content and acceptance of submissions for publication are the responsibility of the editors. Some submissions may go in future issues, even if the deadline is met. At the discretion of the editors, submissions may be considered for publication on our APSF website and social media pages.

Types of articles include:

(1) **Review articles or invited pro-con debates** are original manuscripts. They should focus on patient safety issues and have appropriate referencing (see https://www.apsf.org/authors-guide.php). The articles should be limited to 2,000 words with no more than 25 references. Figures and/or tables are strongly encouraged.

(2) **Q&A articles** are anesthesia patient safety questions submitted by readers to knowledgeable experts or designated consultants to provide a response. The articles should be limited to 750 words.

(3) **Letters to the editor** are welcome and should be limited to 500 words. Please include references when appropriate.

(4) **Dear SIRS** is the "Safety Information Response System." The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and response from manufacturers and industry representatives. Dr. Jeffrey Feldman, current chair of the Committee on Technology, oversees the column and coordinates the readers' inquiries and the response from industry.

(5) **Invited conference reports** summarize clinically relevant anesthesia patient safety topics based on the respective conference discussion. Please limit the word count to less than 1000.

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Early Warning Systems: "Found Dead in Bed" Should be a Never Event

by Bradford D. Winters, MD, PhD, FCCM

A PATIENT SAFETY PROBLEM

Clinical deterioration on the general hospital wards is common and all too often results in patients progressing to cardiopulmonary arrest, which carries significant morbidity and mortality.[1-5] Occasionally, this progression is not witnessed or perhaps even worse, observed but unrecognized,[1,6] resulting in an unmonitored/unwitnessed arrest. These events are currently categorized as a serious adverse event (AE) by several reporting metrics including the American Heart Association's *Get with the Guidelines®*[7] and the Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Indicators (PSIs).[8] Surgical patients may be prone to cardiopulmonary arrest due to their underlying diseases (especially conditions such as obstructive sleep apnea and cardiac disease), the surgical procedure, and the administration of opioids coupled with residual anesthesia.[9,10] This is a major concern for anesthesia professionals who help determine if the patient is safe to go to an unmonitored floor or should request a monitored bed which may be a limited resource.

THE RAPID RESPONSE SYSTEM AS A PATIENT SAFETY INTERVENTION

In the mid-1990s, Rapid Response Systems (RRS) were implemented to address this patient safety problem.[4,11,12] RRSs are composed of two main elements. The most visible element is the team that responds to the call for help for the deteriorating patient. These teams are often, though not always, made up of intensive care unit providers and are referred to as the "efferent limb" of the response. The "afferent limb" refers to the process and criteria by which clinical deterioration is recognized and a rapid response team is activated. The afferent limb uses activation criteria, education programs, and policy changes to encourage providers to activate the efferent limb whenever a patient's condition appears to be deteriorating. Understanding and developing effective and valid activation criteria is perhaps the most crucial component of the RRS[2], even though the rapid response team (efferent limb) is essential to the success of these systems. Therefore, these activation criteria have evolved over time into a wide range of Early Warning Scores (EWS).

Beginning in the early 1990s, common predictors of clinical deterioration were identified from the medical records of patients that had arrested on the general ward.[2,5,6] The predictors identified were primarily physiological changes (elevated heart rate, low blood pressure, or mental status change) and were often found to be present for many hours prior to the arrest event. The ability to identify these changes indicated potential opportunities for early intervention. Presumably, the earlier warning signs are recognized, the more effective the intervention could be. Even though RRS have been successful in reducing in-hospital mortality and unanticipated cardiopulmonary arrest, they have failed to achieve their full potential.[4,9,10] Failure of health care professionals to recognize the deteriorating patient and the inability of existing data systems to trigger an appropriate response in a timely manner remain pervasive.

ADDRESSING AFFERENT LIMB FAILURE USING EARLY WARNING SCORES

Efforts to address deficiencies in early identification of clinical deterioration (i.e., afferent limb failure) have taken several approaches including education programs, nurse empowerment initiatives, and increasingly the use of data-driven systems to improve clinical response. Initially, hospitals used single vital sign parameter thresholds in combination with "clinical concern" about the patient by the bedside nursing staff as activation criteria and many still do. Many hospitals subsequently developed and implemented "early warning scores" (EWSs) that attempt to integrate vital signs and laboratory data (e.g., lactic acid) to improve the sensitivity and specificity for earlier detection. Some studies of EWSs have shown improvement in patient outcomes compared with single parameter vital signs systems while others have shown little difference in outcomes.[3,13-36] These differences in study findings may result from use of overly strict or loose criteria for signaling a deterioration (e.g., extreme heart-rate cutoffs), use of nonequivalent outcomes (such as total cardiac arrest rate vs. non-ICU cardiac arrest rate), ineffective education programs to encourage appropriate RRS activation, lack of policies to support the intervention, poor project implementation, and variable acceptance in the medical care culture, among others.

A number of EWSs are worth focusing on. One of the earliest published in the literature was by Subbe et al. in 2003.[13] This group developed a manual multiparameter scoring system, which assigned points based on the degree of abnormality of each parameter. Their EWS included mental status in addition to physiologic vital signs. When patients exceeded a threshold score (> 4), they were referred for clinical evaluation. Unfortunately, its initial implementation did not show an improvement in outcomes. In 2006, Green and Williams reported the results of an "Early Warning Clinical Marker Referral Tool," which incorporated single parameter vital signs. While the authors were unable to demonstrate improved outcomes with the EWS, it did result in patients being referred for ICU admission with fewer markers of instability and illness suggesting that such a score could

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A Variety of Early Warning Systems Are Available

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lead to earlier recognition of deterioration. In another study, Rothschild et al.[18] implemented a single parameter EWS for patients on general medical wards. They found that while early warning conditions used to activate RRS teams were only fair predictors of acute deterioration, early signs of respiratory failure during routine monitoring were strongly associated with future life-threatening adverse events. In that same year, Prytherch et al. described an EWS called ViEWS (VitalPAC™ EWS, Sussex Place, London).[17] This data-aggregated and weighted "track and trigger" system was developed to potentially become a national standard in the United Kingdom's National Health Service. When ViEWS was applied to previously collected datasets, its ability to predict cardiac arrest and death was superior to other existing EWSs.[17,19] A simplified version of ViEWS was then validated in a Canadian regional hospital on actual patients where it was found to be effective for general ward medical and surgical patients.[16] Table 1 includes a list of several clinically evaluated EWSs.

A 2014 systematic review of the EWS literature for use on general ward patients included 1 randomized controlled trial and 20 observational studies that evaluated 13 different EWS systems. Some EWSs used in the studies consisted of single parameters systems while others used integrated scoring systems. Some sought to identify specific clinical conditions such as sepsis. Eight studies (all observational) examined the ability of an EWS to predict death or cardiopulmonary arrest. Collectively, these studies showed that EWSs perform well for prediction of cardiac arrest and death within 48 hours. Thirteen studies examined the impact of EWS on health outcomes and resource utilization with mixed results.[37] This suggests that EWSs' impact on outcome is uncertain, but they may be able to identify deteriorating patients.

More recently, predictive algorithms using machine learning and big data have been proposed and developed, with improved ability

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Table 1. Table of Selected Early Warning Scores

EWS Name	Study First Author	Date of publication	Country	Single vs. combined scoring	# of parameters	Effect on Incidence of Cardiac Arrest	Effect on Mortality
MEWS	O'Dell[31]	2002	UK	combined	5 items	Not studied	Not studied
MEWS	Subbe[13]	2003	UK	combined	5 items	Not studied	No statistical change
MEWS	Smith[33]	2006	UK	combined	6 items	Not studied	Not studied
Clinical Marker Tool	Green[26]	2006	Australia	combined	7 items	Not clear*	No effect
MEWS	Maupin[28]	2009	USA	combined	5 items	Not Clear†	Not studied
None	Rothschild[18]	2010	USA	single	13 items	Not studied	Not studied
"ViEWS"	Prytherch[17]	2010	UK	combined	7 items	Not studied	Not studied
MEWS	Mitchell[29]	2010	Australia	combined	7 items	Not studied	Not studied
MEWS	Albert[24]	2011	USA	combined	12 items	Not studied	Not studied
"PatientTrack"	Jones[27]	2011	UK	combined	5 items	2 sub-groups showed no change and one showed a significant increase	No statistical change
MEWS	Patel[32]	2011	UK	combined	6 items	Not studied	No statistical change
MEWS	Moon[30]	2011	UK	combined	7 items	Significantly improved	Significantly improved
CART (Cardiac Arrest Risk Triage)	Churpek[20]	2012	USA	combined	4 items	Not studied	Not studied
MEWS	Churpek[21]	2012	USA	combined	5 items	Not studied	Not studied
Modified "ViEWS"	Kellet[16]	2012	Canada	combined	6 items	Not studied	Not studied
MEWS	De Meester[25]	2012	Belgium	combined	6 items	Not studied	No statistical change
NEWS	Smith[19]	2013	UK	combined	7 items	Not studied	Not studied

EWSs reported in Systematic Review by Smith et al.[36] MEWS—Modified Early Warning Scores. NEWS—UK national EWS. All multiple parameter MEWS used heart rate, blood pressure and respiratory rate. Most also used temperature and one half used oxygen saturation. (*) showed a statistically significant reduction in incidence of arrest events but did not provide denominator data to calculate rates. (†) showed a reduction from 0.77 to .39/1000 patient days but did not provide statistics.

Further Research Required to Determine True Outcome Benefits Using EWS

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to predict clinical deterioration.[38] Machine learning is an artificial intelligence process whereby computer algorithms "self-learn" and improve their performance through training on datasets without the need for reprogramming. While conceptually appealing, EWSs need to demonstrate that their implementation can improve clinical outcomes.

Several explanations have been proposed to explain the failure of existing EWSs in improving clinical outcomes. First, the frequency of vital sign acquisition on the wards may be insufficient to allow detection of clinical deterioration.[6] A second possible explanation is that vital sign values may have inaccuracies and audits of vital sign data confirm this.[39] Electronic health records (EHRs) do little to improve this situation as their performance is dependent on the intermittently and sometimes inaccurately collected data points. Third, recognition, response, and communication to the clinical team may not be timely enough. Therefore, it is not surprising that EWSs and the afferent limb of RRS don't necessarily live up to their presumed potential.

Surveillance monitoring may be a better way to collect and act on clinical data for a patient who is deteriorating on a general ward.[40,41] Surveillance monitoring is distinguished from "condition monitoring," which is employed in ICUs where the patients are unstable or are at risk for instability and the staff-to-patient ratio is adjusted accordingly. In contrast, general ward patients are generally at low risk for instability and the staff-to-patient ratio is much lower. Surveillance monitoring seeks to identify the infrequent occurrence of clinical deterioration in otherwise low-risk patients. General medical patients and especially postsurgical patients on the wards are at risk of a variety of complications including arrhythmias, myocardial ischemia, sepsis, respiratory insufficiency, and bleeding complications. Surveillance monitoring offers the possibility of improving upon many of the limiting features of existing EWSs that are thought to be at the core of afferent limb failure; it is continuous, relies less on fallible humans, is potentially more accurate,and, if automatically linked to an activation hierarchy such as a pager or mobile phone escalation protocol, may be able to circumvent the continued lack of appreciation of the patient's developing deterioration.

Surveillance monitoring still needs to overcome several hurdles that may be challenging. First, it needs to be mobile and wireless since general ward patients are usually ambulatory as compared to monitoring of ICU patients, who are much less so. Wireless technology has advanced tremendously in the last decade, and wireless systems now exist that may meet this need.[42] Embedded in the use of this technology is the need to meet ever-changing and more stringent security standards to protect not only patients' information, but also hospitals' health information technology systems. A second requirement is the need for the mobile surveillance monitor to have adequate battery life. The need for frequent battery changes/recharges would make such a system impractical. A third requirement is the need for the monitor to be comfortable and relatively unobtrusive. Ambulatory general ward patients will not likely tolerate wearing heavy or uncomfortable monitoring equipment. Fourth, the vital-sign data collection should be continuous, since use of intermittently collected data may miss early signs of deterioration. Fifth, it needs to have an acceptable accuracy and a manageable false alarm rate. Condition monitoring in the ICU (e.g., certain ECG alarms) has a high false alarm rate. These high false alarm rates may lead to alarm fatigue, which is a widely recognized patient safety issue in which alarms are ignored or there is a delayed response.[43] An acceptable false alarm rate for clinical monitoring of ward patients is uncertain. However, the need to control alarm fatigue must be balanced against the potential benefit that may be derived by obtaining continuous higher fidelity data.

Studies of surveillance monitoring are still limited but the results are encouraging. Several studies have demonstrated success using primarily pulse oximetry surveillance monitoring in post-surgical patients.[44-49] A recent study[42] examined a multiparameter wireless surveillance monitoring system on a neurological/neurosurgical ward and found that the average alarm rate for all alarms (SpO_2, HR, RR, NIBP) was 2.3 alarms/patient/day and the RRS activation rate was reduced. Other measured outcomes, such as readmission to the ICU, did not show a statistically significant improvement though there was a positive trend in the right direction. We have tested a similar system on a general postsurgical ward and found similar trends.[50]

CONCLUSION

Unrecognized and unattended clinical deterioration on general hospital wards must be avoided. The implementation of RRSs has reduced the occurrence of such events but better methods to predict early deterioration and to link this to interventions are needed to further improve outcomes. Despite improvements in EWS and surveillance monitoring, it will still be necessary for providers to act in a timely manner, develop an appropriate differential diagnosis quickly, gather additional relevant data as needed, and institute effective evidence-based therapies including necessary triage to a higher level of care to improve patient outcomes.

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He reports no conflicts of interest pertaining to this article.

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https://www.apsf.org/wp-content/uploads/newsletters/2018/3302/Early-Warning-Systems-References.pdf

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Anesthesia Patient Safety Foundation

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FEBRUARY 1, 2019

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Instructions for submitting a Letter of Intent can be found at:

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Hilton San Francisco Union Square

7:45 am – 5:00 pm

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Is a Concussed Brain a Vulnerable Brain? Anesthesia after Concussion

by Arnoley S. Abcejo, MD and Jeffrey J. Pasternak, MD

Concussion awareness has increased significantly among both medically trained individuals and among the general population over the last few decades. This can be attributed to a greater understanding of the effects of both acute and chronic repeated concussion on brain pathophysiology. Despite advances in our understanding of the effects of concussion on the brain, few data exist to guide the periprocedural management of patients with either acute or chronic repeated concussion. Many questions remain. Does the perianesthetic period represent a time for increased risk for brain injury in those patients with recent acute concussion or chronic repeated concussion? Should elective procedures requiring anesthesia be delayed following a concussion, and if so, for how long? What specific complications may be attributed to anesthesia in patients with concussion? Are there any periprocedural factors that can be modified to minimize risk? These and many other questions remain unanswered by the current medical literature.

CONCUSSION DEFINITIONS AND EPIDEMIOLOGY

Concussion refers to the functional manifestations of mild traumatic brain injury (mTBI) that may result from any blow, jolt, or strike to the cranium with or without loss of consciousness.[1] Although sports-related concussion have probably received the most attention, concussions can result from other mechanisms including motor vehicle accidents, falls, and assaults. Furthermore, many individuals who suffer a concussion may not seek medical care, making the determination of the true prevalence of acute concussion very difficult. For example, in 2010, the Centers for Disease Control (CDC) estimated 2.5 million traumatic brain injuries resulted in an emergency room visit, hospitalization, or death—of which 75–95% were mTBIs and concussions.[2] These data omit concussions treated without medical care or with care, but in an outpatient office-based setting. In 2011, Daneshvar et al.[3] estimated that 1.6–3.8 million sports-related concussions alone occurred in the United States. However, these data did not include concussions due to non-sport-related injuries. These data and the CDC strongly support the notion that concussion is a significant public health problem.

Table 1. Clinical Manifestations in Athletes with Recent Concussion

Symptom	Prevalence of Symptoms (%)
Headache	93
Unsteadiness	75
Difficulty concentrating	67
Confusion	46
Photophobia	38
Nausea	29
Drowsiness	27
Amnesia	24
Sensitivity to noise	19
Tinnitus	11
Irritability	9
Hyperexcitability	2

Adapted from Meehan WP, 3rd, d'Hemecourt P, Comstock RD. High school concussions in the 2008–2009 academic year: mechanism, symptoms, and management. *Am J Sports Med* 2010;38:2405–9, with permission of the publisher, SAGE Publications, Inc./Corwin.

CONCUSSION DIAGNOSIS

The diagnosis of concussion is clinical. Radiographic imaging after mTBI is often nondiagnostic, nonpredictive, nor specific for concussion. The most common concussive symptom is headache.[4] The prevalence of signs and symptoms following acute concussion are summarized in Table 1. The majority of concussive symptoms abate within one week.[5] However, not all concussive symptoms resolve so quickly, especially in patients who have sustained a prior concussion.[5]

PERSISTENT PATHOPHYSIOLOGY OF ACUTE CONCUSSION

Following concussion, the brain enters a state of altered physiology and homeostasis. Immediately following head injury, cerebral metabolic rate increases and may account for the initial alterations in consciousness.[6,7] In the hours, days, and even weeks following concussion, the brain enters a state of increased blood flow, reduced metabolism, and altered vascular responsiveness to changes in systemic blood pressure, arterial carbon dioxide tension, and brain activity.[8-13] In addition, functional magnetic resonance imaging suggests damage to and dysfunction of neuronal axons in the brain following concussion that may persist for weeks.[14] There is also evidence that resolution of the clinical manifestations of concussion may not be a reliable marker for a return to normal cerebral physiology.[9]

TREATMENT FOR ACUTE CONCUSSION

Patients with suspected concussion should be immediately removed from regular activity and evaluated by a medical professional. A central pillar of any management strategy for concussion involves *rest*: both physical and cognitive. Removal from activities reduces risk

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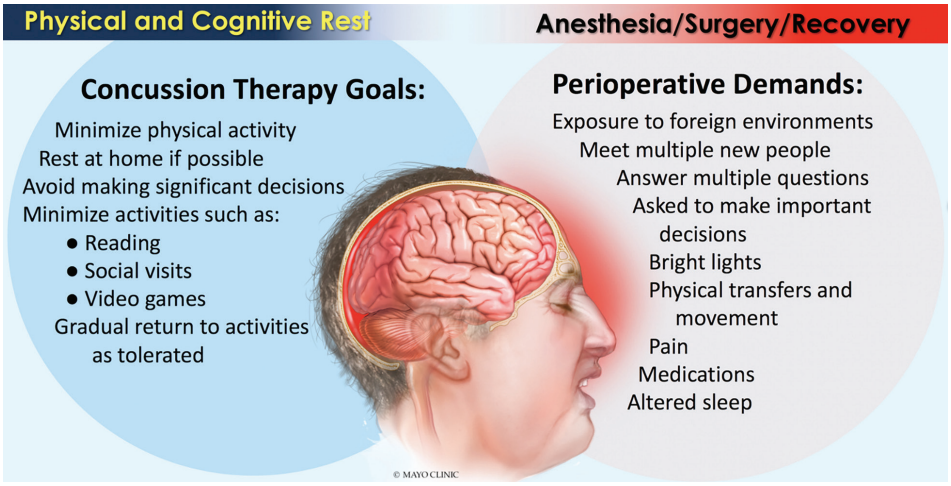

Figure 1. Cognitive Rest vs. The Perioperative Environment.
Reproduced and modified with permission from the Mayo Clinic, Rochester, MN.

Anesthesia After Concussion is Common

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for subsequent head or other injuries and minimizes activities that could result in harm, such as driving or making important decisions. Cognitive rest potentially minimizes physiologic stress on the injured brain.[15,16] Though some data suggest mild activity after concussion can expedite recovery from concussion, the overall consensus for concussion management focuses on gradual return to physical and cognitive activity while monitoring for exacerbation of post-concussive symptoms (Figure 1).[17-19]

CHRONIC REPEATED CONCUSSION

In 2005 and 2006, Omalu et al.[20,21] described the widespread deposition of beta-amyloid and neurofibrillary tangles, pathology often appreciated post-mortem in patients with Alzheimer's Disease,[22] in the brains of Mike Webster and Terry Long, both former professional football players. This characterization of chronic traumatic encephalopathy (CTE) was suspected to be due to multiple repeated concussive injuries. Using brains donated to the Concussion Legacy Foundations "Brain Bank," Mez et al. reported that widespread neuropathologic findings, including deposition of beta-amyloid and neurofibrillary tangles, were found with increasing frequency in those with longer football careers.[23] Lower rates of neurohistopathologic findings were associated with high-school-only football involvement and much higher rates among professional football players. At this point, no data exist in the current literature that describe changes in cerebral physiology in those with suspected CTE.

ANESTHESIA AFTER CONCUSSION

Anesthesia may be required for patients suffering a concussion. Our group retrospectively described the use of anesthesia for surgery and other procedures in patients who had recently suffered a concussion at **our institution**.[24] We observed the following:

- Anesthesia after concussion is common. Anesthesia was provided to almost 15% of patients with a concussion within a year of their injury. Surprisingly, almost **half** (44%) of all anesthetics occurred within **one month** of the injury and almost a third occurred within the first week of injury.
- Sports injury was not the most common cause of concussion in individuals requiring anesthesia. Motor vehicle accident-related concussions required the greatest utilization of anesthesia and comprised 36% of patients and 49% of all anesthetics. Falls were the second most common cause for anesthesia utilization comprising 35% of patients and 31% of anesthetics. Patients with sports-related concussion requiring anesthesia consisted of only 20% of the cohort and 13% of all anesthetics.
- Elective procedures requiring anesthesia were not uncommon after recent concussion. Twenty-nine of 552 patients (5%) underwent elective procedures requiring anesthesia that were completely unrelated to the injury that resulted in concussion within one week following their concussive injury.
- Anesthetics were provided to patients prior to the formal diagnosis of concussion. Seven percent of all patients did not receive a formal diagnosis of concussion until at least one week *after* the injury. In addition, 29 anesthetics (1.6%) were provided to patients before a concussion diagnosis was formally made.

THE PERIANESTHETIC PERIOD SHOULD NOT BE CONSIDERED REST

If the management of concussion centers around physical and cognitive rest, it is difficult to argue that anesthesia and the demands of a surgical procedure fulfills the prescription. First, patients presenting for surgical or diagnostic procedures requiring anesthesia enter a hospital or surgical center—a foreign environment—where they meet many different individuals, are asked a multitude of questions, and are also asked to make significant decisions. The lights are often bright in these locations. Physical demands are made when patients are asked to move to different locations or to different procedural tables or beds. Following the procedure, patients may be dealing with excessive pain, and are frequently disturbed, even during sleep, for medications and various assessments by health care providers.

Frankly, the periprocedural period is NOT a restful period! However, it is true that many surgical and diagnostic procedures requiring anesthesia are necessary in patients with an acute concussion. Therefore, clinicians should be aware that elective procedures following acute concussion likely pose the antithesis of rest for the patient.

THE CONCUSSED BRAIN MAY BE A VULNERABLE BRAIN

Significant physiologic perturbations are common in the perianesthetic period. These can include significant and rapid changes in blood pressure due to pain, surgical stimulation, blood loss, alterations in autonomic function, and pharmacologic effects. These changes in blood pressure could potentially be detrimental to an acutely concussed brain that likely has an impaired ability to autoregulate its blood flow,[13,25] making it susceptible to hypo- and hyperperfusion. Additionally, patients may be susceptible to hypoxia and alterations in other physiologic variables, such as carbon dioxide tension and blood glucose concentration—factors that could serve as a source of secondary injury to a potentially vulnerable brain.[26,27] Taken together, the perianesthetic period likely represents a time where an acutely concussed brain with altered physiology may be at risk for secondary injury.

Given the clinical findings of cognitive impairment, dementia, and frank motor symptoms along with brain histopathologic findings in patients with chronic repeated concussion,[23] it seems obvious that the chronically concussed brain, even in the absence of recent concussion, also represents a vulnerable brain. At this point, clinicians have little guidance from the medical literature in terms of expected cerebral pathophysiology and optimal management in this cohort of patients.

IS RECENT CONCUSSION A POSSIBLE PATIENT SAFETY RISK?

The idea of a "vulnerable brain" in the perioperative period is being investigated in a variety of patient cohorts such as children, those with pre-existing brain injury (i.e., prior stroke, traumatic brain injury), and elderly adults. It is hard to argue that both the acutely concussed brain and the brain that has suffered chronic repeated concussions do not also represent a vulnerable brain. There is a concerted effort to identify best safety practices for the vulnerable brain to promote brain health and minimize risk for adverse events.

For now, we advocate for the following:

- Anesthesia professionals should have heightened awareness for concussion—diagnosed or undiagnosed—especially in patients with recent trauma.
- Clinicians should be aware that not all concussions are the result of sports-related injuries. Many may be due to motor vehicle accidents, falls, or assaults.
- Anesthesia professionals should be cautious if persistent postconcussive symptoms are present (Table 1) and may consider delaying elective procedures at least until those symptoms resolve or new data support a different end point. A discussion with the patient regarding these symptoms and the theoretical risk of exacerbating or prolonging postconcussion symptoms should be considered.

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More Research Required to Quantify Perianesthetic Risk to Patients With Concussion

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- More research is needed to quantify perianesthetic risk in patients with both acute and chronic repeated concussions and help guide clinicians to minimize risk to a potentially vulnerable brain.

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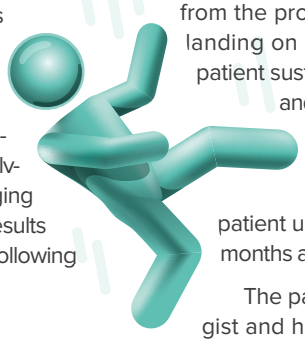
Catch Me If You Can: Patient Falls in the Anesthesia Workplace

by Brian J. Thomas, JD

DEFENDING PATIENT FALLS LITIGATION

Hundreds of thousands of patient falls occur in hospitals in the United States every year with an estimated 30–50 percent resulting in injury.[1] While many patient falls in the anesthesia workplace result in transient injuries, some result in serious patient harm.[2,3] Patient falls frequently result in litigation, medical and nursing board investigations, and other significant consequences. This article examines the relatively rare but preventable adverse events, highlights a case study, and offers risk management analysis and strategies to prevent patient falls in the anesthesia workplace.

As members of the surgical care team involved in positioning, monitoring, and transferring patients, anesthesia professionals have an important role and share in the duty to keep patients safe from falls. Patients, families, and juries will not accept that patient falls are a known risk and complication. In most cases, these adverse events result in litigation against anesthesia professionals and other team members present. Defending litigation involving patient falls is extremely challenging for multiple reasons and frequently results in settlements, as highlighted by the following case study.



CASE STUDY

A 20-year-old female with chronic lower back pain and sciatica was receiving epidural steroid injections for treatment. The anesthesiologist started an epidural steroid injection with local anesthesia without the assistance of another health care professional. During the epidural procedure, the patient fainted and fell from the procedure table onto the floor, landing on her face and shoulder. The patient sustained lacerations to her face and bruises to her lips. However, no fractures were found on x-ray and she was referred to a plastic surgeon. The patient underwent a laminectomy two months after the incident.

The patient sued the anesthesiologist and hospital, alleging negligence with respect to her fall in the procedure room. The patient claimed she had to take a semester off from college due to her pain and subsequent surgery resulting in additional

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Accidental Patient Falls Can Lead to Legal and Practice Consequences

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tuition costs. The patient's initial settlement demand was $150,000. She reported suffering a head injury with continuing headaches, facial scar, and exacerbation of her pre-existing back condition that required laminectomy.

The defense expert could not support performing an epidural steroid injection without the assistance of a nurse. However, he stated that the nature of the patient's fall should not have exacerbated her low back condition. He indicated the patient's chronic low back condition was steadily deteriorating, and she would have needed a laminectomy regardless of the fall. The patient's medical records also confirmed she had reported a history of headaches prior to the fall.

The hospital was dismissed prior to trial. Despite several rounds of negotiations, a mutually agreeable settlement amount could not be reached, and the parties proceeded to trial. On cross-examination, defense counsel questioned the patient regarding her significant medical history of back pain and her academic challenges prior to the fall. Based on her testimony and concessions, her attorney lowered the settlement demand and the case settled for $35,000 in indemnity with $33,327 incurred defense costs (loss adjustment expense [LAE]).

Risk Management Analysis

The hospital policy for epidural steroid injections required the presence of a nurse or other health care assistant before the procedure could begin. The violation of the hospital policy and the resulting fall was a deviation from the standard of care. Additionally, the anesthesiologist admitted he made a mistake and apologized to the patient following this incident. Based on these facts, the defense admitted liability and tried this case only on damages. While not a common defense strategy, this prevented the patient's attorney from attacking the anesthesiologist's credibility and allowed the defense to challenge the patient's damages claims.

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LEGAL CONSIDERATIONS

Most patient falls in the anesthesia workplace are considered preventable.[4] Plaintiff's attorneys typically argue preventing patient falls is a shared responsibility, and each member of the surgical care team has a duty to prevent these potentially devastating and life-threatening complications. Litigation involving patient injuries from falls also allows plaintiff's attorneys to argue "res ipsa loquitur" (Latin for "the thing speaks for itself"), which is the legal doctrine that infers negligence from the very nature of the injury and allows plaintiffs to meet their burden of proof without the need for expert testimony.[5] In most cases, jurors simply will not accept that these types of accidents and resulting injuries occur without negligence.

Given these defense challenges, plaintiff's attorneys typically evaluate these cases as having increased settlement value, even when the injuries may not be severe. Based on the uncertainty of allowing a jury to calculate the amount of damages to be awarded to a patient who is injured from an arguably preventable fall, most anesthesia professionals and their professional liability carriers settle these cases rather than defend them at trial.

Legal and other consequences of these settlements may include[3]:

- National Practitioner Data Bank reporting of event
- State medical licensing board investigations and penalties that may include fines, published reprimands, and compulsory continuing medical education and training
- Centers for Medicare and Medicaid Services and third-party payer investigations and disciplinary actions
- Possible revocation of privileges at practice facilities
- Unfavorable media coverage

CAUSES OF PATIENT FALLS

A number of key elements have been identified as contributing to patient falls in the perioperative workplace[3]:

- Patient attributes—obesity, age, positioning other than supine, sedated or altered consciousness, and agitation during induction or emergence
- Provider actions and inactions—distractions, shifting attention from patient to other unrelated or related OR tasks, assumption that other providers are securing the patient, and vulnerability to production pressure
- OR table factors—new or unfamiliar OR tables and controls, improper function or use of locking mechanism on certain spinal tables or other mechanical table failures, extremes in positioning (e.g., side tilt, steep or reverse Trendelenburg position)
- Absence or inadequacy of safety restraints
- Table tipping

Risk Management Recommendations

Anesthesia professionals, as patient safety advocates, should help focus perioperative team attention on three primary contributors to minimize the risk of patient falls:

1. Familiarity with the controls, operations, and the safe weight limits of all OR tables used in their facility; or have ready access to such information or to knowledgeable personnel
2. Coordination of all patient movements/transfers with the perioperative team
3. The entire perioperative team should understand their specific roles and proactively discuss patient observation responsibilities for all phases of intraoperative and near-perioperative periods.

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Anesthesia Professional Burnout—A Clear and Present Danger

by Natalie Tarantur, CRNA, and Mark Deshur, MD, MBA

INTRODUCTION

As anesthesia professionals, we are confronting challenging times. Our specialty is experiencing a period of mergers, rapid consolidation of practices, and a trend toward employed providers that has dramatically affected our autonomy. Bundled payments, declining reimbursements, electronic health record systems (EHRs), and acronyms like merit-based incentive payments (MIPS), and Medicare Access and CHIP Reauthorization Act (MACRA) consume our daily vernacular. We are experiencing rising demand for anesthesia services while simultaneously facing a national shortage of nurses and physicians.[1] Furthermore, our practices are inundated with internal and external pressures to meet or exceed national benchmarks in hospital quality indicators and patient satisfaction/loyalty ratings to effectively compete with local competitors.[2,3] Over the past decade, health care has also seen a significant rise in provider burnout, and it is clear that anesthesia professionals are not exempt from this growing epidemic. This article will review the causes of burnout and potential solutions to reduce risk.

WHAT IS BURNOUT AND WHAT CONTRIBUTES TO IT?

Burnout is a pattern of symptoms, with providers reporting extremely low physical and emotional energy levels, cynicism, and decreased work effort.[2] This can lead to significant consequences, both personally and professionally. For example, studies have shown physicians who are burned out are more likely to have broken relationships, increased incidence of alcohol and drug abuse, and a higher risk of depression and even suicide.[3]

The Mayo Clinic outlines a handful of dimensions that can play an important role in burnout, such as workload, work-life balance and sense of community (Table 1).[3] According to Shanafelt et al., anesthesiologists report higher than average rates of burnout than other physicians. In fact, over 50% of anesthesiologists reported feeling burned out in 2014, a marked increase from 2011, and a rate twice as high as the general working population.[4,5]

Over the past few years, our workplaces have seen a significant increase in number of cases, hours, and work effort per provider. The Medical Group Management Association (MGMA) data support this as a larger trend across our specialty.[6] Anesthesia professionals are working longer hours, spread over more locations, spending more time in front of electronic health records, and have less control over their schedules. Adding to this challenge is the fact that work/life balance is a top priority for Millennials, the fastest growing segment of our anesthesia workforce.[7]

Professionals with burnout are less productive, have a higher likelihood of turnover, and are more likely to reduce their work effort in the coming years. Not surprisingly, this can have a significant impact on patients. Providers experiencing burnout may deliver lower quality care with associated lower patient satisfaction scores and are more likely to make medical errors.[8] Therefore, health care professional distress may be a quality indicator that is worth measuring in medical centers.[3]

Table 1. Dimensions that can play an important role in burnout[3]

Workload and job demands
Control and flexibility
Work-life balance
Social support / community at work
Alignment of individual and organizational values
Production pressures
Degree of meaning derived from work

At the bedside, one study showed a dose-response relationship between burnout scores and medical errors.[8] Burnout is represented here in a bidirectional relationship where errors lead to stress and stress leads to errors.[9] As anesthesia professionals, we are not immune to poor patient outcomes or patient death. One study suggested that 84% of anesthesiologists were involved with at least one unanticipated death or serious injury of a patient, leading many to feel personally responsible.[10] These experiences can lead to provider depression, alcohol abuse, or even consideration of a career change. Despite 67% of respondents feeling as though their practice could be compromised in the immediate future, only 7% were given time off to collect their thoughts and begin personal recovery.[10]

OUR EFFORTS TO REDUCE BURNOUT

A variety of studies performed at the Mayo Clinic, Rochester, MN, suggest that the factors listed in Table 1 may influence overall satisfaction and provider engagement, and should be addressed at an organizational level. A careful focus on each dimension can help to minimize burnout while creating a culture of highly engaged professionals.[11]

MITIGATING BURNOUT AT OUR INSTITUTION

Our practice has experienced rapid growth and now covers four hospitals and five ambulatory centers. This necessitated increasing

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Potential Methods to Reduce Burnout

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creativity in how we schedule our professionals. During a typical week, our anesthesia professionals may have to travel to three or four different locations. This became a significant source of dissatisfaction, in particular for our Certified Registered Nurse Anesthetists (CRNAs) who were primarily responsible for the increased travel to different locations.

To address this, we developed a novel system that allows our CRNAs to rank the locations where they prefer to work. A real-time decision support algorithm now prioritizes which CRNAs should provide care in each facility, balancing the location desires of each individual against their peers. With the present system, we are now able to send CRNAs to their first or second choice over 80% of the time. Most importantly, a recent survey (with scale from 1–5, 5 being extremely satisfied) of our CRNAs (of which 36 out of 70 responded) suggested that 86% are either very satisfied or extremely satisfied with the locations they are assigned to work, a marked improvement from baseline.[12]

We also believe it is important to foster a culture of candor by educating our providers on the causes and symptoms of burnout and encouraging open discussion. Our practice has experienced several significant, personal tragedies recently. We expeditiously sought the counsel of outside wellness experts to help provide departmental leadership with the necessary expertise to successfully navigate these unexpected events. It is too soon to conclude if the wellness initiatives will result in long-term benefits, but a recent survey suggests cause for optimism. Of those anesthesiologists and CRNAs surveyed (N=90), 70% planned to attend future wellness events, and 42% stated that the event provided at least some information or skills that will improve their overall job satisfaction.[13]

Flexibility in hours worked is also becoming increasingly critical to our changing workforce demographic. Studies show this can increase provider satisfaction, yet does not adversely impact patient satisfaction, quality of delivered care or efficiency.[14] Over the past 15 years, our department has seen a considerable change in the proportion of professionals who work full-time. Part-time employment has offered our professionals additional flexibility as to when they work, as well as enabled our practice to flex up or down depending on daily staffing needs.

We surveyed our staff to assess risk factors for stress and burnout, after our efforts to increase satisfaction and work life balance (N=90).[13] Results revealed that 54% of our department is satisfied with their job and 36% report they are very satisfied with their job. In addition, 70% of our anesthesia professionals reported they usually or always have an adequate work/life balance.[13] We also surveyed our staff to assess their average stress levels at work, their overall impression of how run down or drained they feel, their sympathy towards patients, and achievement at work. Forty-seven percent of the respondents reported a moderate amount of stress, and 24% of staff reported experiencing a lot of stress. In addition, 20% of the respondents noted feelling run down a lot, and 32% reported being run down a moderate amount. The survey results also revealed that only 8% of the respondents reported moderately less sympathy for their patients and 52% reported no decrease in their sympathy towards patients since they started working. Lastly, when asked if they are achieving less at work than they feel they should, 38% reported experiencing this sometimes, and 57% reported they rarely or never experienced these feelings.[13]

CONCLUSION

Greater than half of our anesthesia professionals are suffering from burnout.[4,15] With appropriate education and awareness, we can give our professionals, practices, and organizations the tools needed to ameliorate this growing trend. We need to confront the ever-changing health care landscape with focused attention, creativity, and an open mind. As former US Surgeon General Vivik Murthy, MD, said, "If health care providers aren't well, it's hard for them to heal the people for whom they are caring."[16] More than ever, it is imperative that culture, morale, and provider well-being become part of our core values.

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Neither author has conflicts to declare as they relate to this article.

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APSF Recognizes Best Practices for Safe Medication Administration during Anesthesia Care

by Jeffrey Feldman, MD, MSE

The APSF has identified improving medication safety during anesthesia care as one of its primary priorities for several years. In 2010, APSF hosted a special conference on medication safety which resulted in the recommendation to follow the Standardization, Technology, Pharmacy, Culture (STPC) paradigm as a means to enhance safe medication practices.[1] Medication safety was again revisited at the 2018 Stoelting Conference. Prior to the conference, the APSF solicited applications for an award to recognize best practices for safe medication administration during anesthesia care. The request for submissions had several specific criteria that followed the STPC paradigm emphasizing practices that have been implemented and also evaluated using a methodology to assess the impact on safety.[2] Submissions were reviewed by a subcommittee of the APSF Committee on Technology, and three finalists were selected. Collectively, these programs provide examples of the current best practices for using prefilled syringes, smart pumps and bar coding, and, more importantly, the need for a culture dedicated to eliminating medication errors. The awardees are as follows:

FIRST PLACE

University of Washington Medical Center Anesthesia Drug Safety Bundle, submitted by **T.A. Bowdle MD, PhD**, Professor of Anesthesiology and Pharmaceutics, Department of Anesthesiology, University of Washington.

The submission was notable for a comprehensive approach to improving medication safety dating back to 2002, which utilized repeated data collection to assess the impact on medication errors. As a result of this department's efforts, the rate of self-reported errors was reduced from 0.63% to 0.23% over an approximate 12-year interval. Their experience teaches us about the benefits and challenges to implementing technology solutions, in particular the use of bar code scanning at the bedside.

SECOND PLACE

Michigan Medicine Anesthesia Medication Safety Initiatives, submitted by **Deborah S. Wagner PharmD, FASHP**, Clinical Professor of Anesthesiology/Medicine, Department of Anesthesiology, University of Michigan.

This submission also described a comprehensive program to reduce medication errors founded on a collaboration between the Departments of Pharmacy and Anesthesiology. In addition to focusing on bedside medication administration, their program seeks to monitor and detect drug diversion. The cultural commitment is most notable as evidenced by the formation of a multidisciplinary medication safety task force that meets biweekly to assess medication practices and reduce error. They also have developed dashboards to continuously assess current medication administration practices.

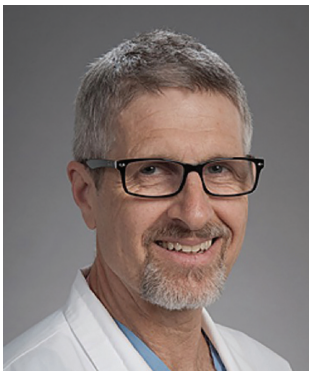
HONORABLE MENTION

The Codonics Safe Label System®: utilizing technology to increase medication labeling compliance and charge capture while maintaining user acceptability in pediatric operating rooms submitted, by **James J. Thomas, MD,** Department of Anesthesiology, University of Colorado School of Medicine, Children's Hospital Colorado.

This submission was focused specifically on integrating a syringe label printer and bar coding with medication inventory and electronic medical record systems. The impact was an improvement in compliance as well as charge capture and provider acceptance.

Without question medication errors continue to place patients at risk for preventable adverse events. Anyone involved with the practice of anesthesia can learn from the work of these awardees to find ways of eliminating medication errors in their own practice. The details of each of these submissions can be found on the APSF website at https://www.apsf.org/grants-and-awards/safety-recognition-award/.

AWARDEES



First Place:
T.A. Bowdle, MD, PhD

Second Place:
Deborah S. Wagner, PharmD, FASHP

Honorable Mention:
James J. Thomas, MD

Jeffrey Feldman, MD, MSE, is professor of clinical anesthesiology and critical care at the University of Pennsylvania, attending anesthesiologist at the Children's Hospital of Philadelphia, and chair of the APSF Committee on Technology.

Dr. Feldman serves as a member of the Clinical Advisory Board, ClearLine MD, Boston, MA. Dr. Feldman has received consulting compensation from Dräger Medical, GE Medical, and Medtronic.

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Multimodal Analgesia and Alternatives to Opioids for Postoperative Analgesia

by Veena Graff, MD, and Taras Grosh, MD

The International Association for the Study of Pain (IASP) defines pain as *"an unpleasant sensory and emotional experience"* associated with actual or potential tissue damage, or described in terms of such damage.[1] Although pain management continues to be a major societal issue, approximately 116 people die each day from opioid overdose in the United States.[2] Given the concern that abuse sometimes starts with opioids prescribed in the course of medical care, health care systems throughout the world have adopted a multimodal approach to acute and chronic pain management to reduce opioid prescriptions.[2] This article describes the rationale for use of multimodal analgesia and discusses nonopioid medications that can be used as part of a multimodal approach to postoperative pain relief. It is worth noting that the medications listed here can be adjuncts to a general, regional, or neuraxial anesthetic.

Abandoning the old opioid-centric model, physicians are focusing more on nonsteroidal anti-inflammatories, acetaminophen, gabapentinoids, NMDA antagonists, alpha-2-agonists, and sodium and calcium channel blocking agents. Such multimodal therapy has at least two desirable effects. First, a multimodal approach may decrease the use of opioids and associated side effects (e.g., delirium, and respiratory depression), tolerance, and diversion.[3-5] Second, a multimodal approach may be a more effective pain control strategy, potentially decreasing the complications associated with suboptimal pain control, such as pneumonia, deep venous thrombosis, and postoperative cognitive dysfunction.[3-5]

Poor pain control impedes postoperative rehabilitation, reduces patients' health-related quality of life, causes significant personal burden, and adds to national health care expenditure.[6,7] Moreover, inadequate analgesia in the acute postoperative period may not only lead to the development of chronic pain, but also significant postoperative cognitive dysfunction.[8] While an opioid-sparing multimodal approach to pain management is important, it is not a panacea. Pharmacologic nociceptive modulation is most effective when combined with behavioral modification as procedural anxiety may result in worse postoperative outcomes and the development of chronic pain.[9]

The following pharmacologic agents can be used in the perioperative setting to optimize multimodal analgesia techniques and reduce opioid consumption during the perioperative period (Table 1).

Alpha-2-agonists: The two common alpha-2-agonists used in clinical practice today are clonidine and dexmedetomidine.[10] The primary mechanism of antinociception is the direct stimulation of the alpha-2-adrenoreceptors in the central nervous system and spinal cord.[10] At the cellular level, alpha-2-agonists inhibit cyclic adenosine monophosphate, which reduces potassium efflux and calcium influx causing a hyperpolarized state of the adrenergic neurons.[11] When hyperpolarization occurs, there is reduced norepinephrine release, which is postulated to be the mechanism of hypnosis and sedation.[11] Direct stimulation of alpha-2-receptors also inhibits nociceptive neuronal firing, thereby reducing the release of substance P, a key excitatory neuropeptide responsible for painful responses.[11] Dexmedetomidine has a much higher affinity (approximately 8:1) than clonidine at the alpha-2 receptor site.[10] Both agents may significantly reduce opioid consumption, postoperative nausea/vomiting, anxiety, postoperative shivering, and stress responses intraoperatively.[12] The most common side effects of alpha-2-agonists are hypotension and bradycardia.[10,12]

Anticonvulsants: Gabapentin and pregabalin are anticonvulsant agents commonly used as perioperative analgesics. Both agents bind to voltage-gated calcium channels and promote antinociceptive actions by inhibiting the release of excitatory neurotransmitters.[13] These medications were initially used for treatment of chronic neuropathic pain, but they may also work to prevent and reduce acute pain and opioid consumption. Recent evidence also suggests that they may reduce chronic postsurgical pain (CPSP), although more clinical trials are needed.[14,15] Common side effects of gabapentin include increased sedation, peripheral extremity swelling, and weight gain.

Ketamine: Ketamine is a nonbarbiturate dissociative anesthetic agent that has hypnotic, analgesic, and amnestic effects. It has been used clinically in subanesthetic doses for the treatment of neuropathic, acute, and chronic pain syndromes.[16] Ketamine analgesia is mediated through inhibition of the N-methyl-D-aspartate (NMDA)-gated calcium channel. NMDA receptors are important for the progression of long-standing changes in neuronal excitability and to the development of allodynia and hyperalgesia. Ketamine may produce anti-hyperalgesic effects through the reduction of NMDA-receptor activity.[17] The side effects of ketamine include increased sympathetic activity, elevated intracranial pressure, increased salivation, nystagmus, and hallucinations. Therefore, caution is advised when using ketamine in patients with coronary artery disease, intracranial pathology, and psychiatric comorbidities.

Local anesthetics: These drugs are useful in a wide range of procedures, as they can be administered subcutaneously, intravenously, and utilized in peripheral nerve blocks and neuraxial anesthetics. Multiple studies have evaluated the efficacy of intravenous lidocaine for colorectal surgery. While some studies suggest a benefit in terms of improved gastric motility and reduced hospital length of stay, the overall findings are not consistent.[18-20] The mechanism of action of lidocaine is blockage of sodium channels; however, the mechanism of action in systemic pain control is still not entirely understood.[19] A recent Cochrane review showed low quality of evidence and uncertainty as to whether systemic lidocaine infusions improve pain perioperatively in a variety of patient populations; however there was heterogeneity in dosing and administration between studies and surgical cases.[20] A protocol-driven approach across institutions may help answer this question definitively in the future. Nevertheless, IV lidocaine has analgesic, antihyperalgesic, and anti-inflammatory properties that make it another potential option for perioperative pain control.[19]

Acetaminophen & NSAIDs: The use of acetaminophen and nonsteroidal anti-inflammatory drugs in the perioperative period can reduce perioperative opioid use and pain.[17,21] Acetaminophen and NSAIDs can be administered orally and intravenously. However, the onset of action is slightly faster when administering both of these agents intravenously rather than orally.[17] There are numerous side effects of NSAIDs including gastric irritation, gastric bleeding, platelet dysfunction, increased risk of cardiovascular disease, and worsening renal function.[21] Therefore, caution is advised in selecting the appropriate drug for a patient. The primary side effect of acetaminophen administration is potential liver toxicity, and caution is advised in patients with pre-existing liver dysfunction.

See "Multimodal Analgesia" Next Page

Multimodal Analgesia May Reduce Unwanted Effects from Opioids

From "Multimodal Analgesia," Preceding Page

CONCLUSION

The opioid-sparing multimodal analgesic options discussed above are integral for optimal pain management in the perioperative period. Nevertheless, opioids still have a critical role in acute postoperative pain management especially for procedures where a primary regional, neuraxial, or local infiltration is not possible. This article is not intended to deter clinicians from using opioids as an analgesic altogether, especially after surgery; instead, it offers strategies to mitigate the opioid-related side effects, improve perioperative analgesia, and reduce the incidence of cognitive dysfunction. As anesthesia professionals, we should take a more active role in the perioperative management of patients' analgesic regimens. This may reduce the unwanted effects of uncontrolled pain and accidental overdoses of opioids.

Drs. Veena Graff and Taras Grosh are assistant professors specializing in acute and chronic pain management as well as regional anesthesiology at the Hospital of the University of Pennsylvania in Philadelphia, PA.

Neither author has anything to disclose as it pertains to this article.

Table 1. Nonopioid pharmacologic agents frequently used as part of a multimodal approach to analgesia

Class	Drug	Dose	Important Considerations
Alpha-2-agonists	Dexmedetomidine*†	IV loading dose: 0.5–1 mcg/kg over 10 min Infusion: 0.2–1.7 mcg/kg/hr	Can cause severe bradycardia and hypotension Can cause severe hypertension during loading dose Consider dose reduction in geriatric patients
	Clonidine*†	PO†: 0.2 mg BID Epidural: 30–40 mcg/hr	Can cause severe hypotension Can lead to withdrawal if stopped abruptly after regular use Epidural use approved only for severe cancer pain
Anti-convulsants	Gabapentin*†	PO: 300–1200 mg TID	May reduce postoperative pain if given preoperatively[14] Can cause dizziness, drowsiness, water retention Manufacturer recommends discontinuation over 1 week
	Pregabalin*†	PO: 150–600 mg per day in 2–3 divided doses	90% bioavailability vs. gabapentin[13] Starting dose: 150 mg in 2–3 divided doses
NMDA Antagonist	Ketamine[16,†]	IV bolus: 0.3–0.5 mg/kg[16] Infusion: start at 0.1–0.2 mg/kg/hr[16]	Intensive monitoring suggested for bolus doses > 0.35 mg/kg or infusion rates > 1 mg/kg/hr[16] Can cause dysphoria and excessive salivation
Local anesthetics	Lidocaine[17,†]	IV bolus: 1.5 mg/kg[17] Infusion: 1–2 mg/kg/hr[17]	Can cause conduction block, dizziness, seizures, bradycardia[17]
Acetaminophen*		PO: 325–650 mg q 4–6hr IV: 1000 mg q 6 hr IV if >50 kg; if <50 kg, 15 mg/kg q 6 hr	Do not exceed 4 gm/24 hr Reduce to 2 gm/day in chronic alcohol use Potentiates warfarin anticoagulation PO and IV dosing are equivalent
NSAIDS	Diclofenac*	PO: 100–200 mg per day in 2–3 divided doses	Dose-dependent relief Should start at lowest possible dose Prolonged use predisposes to GI, CV, and renal dysfunction For IV and PO ketorolac: limit to 5 days PO ketorolac should only be used to continue therapy after IV initiation Increases lithium levels Prone to gastric ulceration with bisphosphonates
	Ibuprofen*	IV: 400 mg first dose, followed by 100–200 mg q 4–6 hr PO: 1200–3200 mg per day in 3–4 divided doses	
	Ketorolac*	IM or IV: 15–30 mg every 4–6 hr PO: 10 mg q 4–6 hr	
	Meloxicam*	PO: 7.5–15 mg daily	
	Celecoxib*	PO: 50–200 mg daily in a single dose or 2 divided doses	

*Doses and important considerations are derived from manufacturers' prescribing information retrieved from the United States Food and Drug Administration "Drugs@FDA" database (https://www.accessdata.fda.gov/scripts/cder/daf/, Accessed 8/15/2018). Prescribing information for each drug is current as of the following dates: dexmedetomidine—July 2015; clonidine (IV)—May 2010; clonidine (PO)—October 2011; gabapentin—April 2009; pregabalin—June 2011; ketamine—April 2017; lidocaine—February 2010; acetaminophen—October 2015; diclofenac—February 2011; ibuprofen (IV)—November 2015; ibuprofen (PO)—January 2007; ketorolac (IM/IV)—November 2011; ketorolac (PO)—February 2013; meloxicam—March 2012; celecoxib—December 2008.

†Indicates that use for perioperative analgesia is "off label," meaning that it is permissible but not an indication in the manufacturers' prescribing information. BID: two times daily (Latin: bis in die); CV: cardiovascular; GI: gastrointestinal; IV: intravenous; NMDA: N-methyl-D-aspartate; PO: oral (Latin: per os); TID: three times daily (Latin: ter in die).

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Medication Safety Alerts for Anesthesia Professionals

by Ronald S. Litman, DO, ML, and William D. Ryan

The Institute for Safe Medication Practices (ismp.org) receives reports of medication safety issues from health care providers and regulatory agencies worldwide. On a biweekly basis these are collated and published in the *ISMP Acute Care Medication Safety Alert Newsletter*. In this current issue of the *APSF Newsletter*, we highlight two reports of interest to the anesthesia community that were recently published in the June 2018 ISMP Newsletters.

The first report of note is a case of an anesthesia resident who intended to administer 2% lidocaine with epinephrine through an epidural in a patient scheduled to undergo a cesarean section. This local anesthetic solution had been removed from the anesthesia drug tray due to hospital shortages. However, the resident was able to access an automated dispensing cabinet (ADC) that contained the drug, which was listed on the ADC screen under the patient's name. He retrieved a vial, but did not fully read the vial label before administering the drug through the epidural. The resident didn't realize that it was a multiple-dose vial containing methylparaben, a preservative, and was labeled "Not for caudal or epidural use" [1] (Figure 1).

It has been standard practice to avoid preservative-containing solutions in this clinical situation, although toxicity from neuraxial administration of methylparaben preservative has not been clearly elucidated. Furthermore, multidose vials are no longer standard of care for any route of administration because of a higher risk of contamination than properly used single-use vials.[1]

The removal of preservative-containing local anesthetic products from the labor and delivery area and other areas where use of neuraxial local anesthetics is common (e.g., the operating room) should be considered. Health care professionals who work in these areas and those who stock these areas should be aware of the differences between these drugs.[1]

The second report stems from drug shortages and, in this case, involved look-alike lidocaine vials. Some hospitals have been forced to use products from more than one manufacturer, due to lidocaine shortages. The problem is that the 1% strength of lidocaine from one manufacturer (Figure 2) looks like the 2% concentration from another pharmaceutical company: the AuroMedics (East Windsor, NJ) 2% lidocaine looks like West-Ward Pharmaceutical's (Cherry Hill, NJ) 1% lidocaine. The hospital that reported this hazard sent an email to pharmacy staff to make them aware of product similarities. ISMP recommends the use of barcode scanning in the pharmacy for drug verification.[2]

Figure 1. Demonstrates the similarities between multi-dose 2% lidocaine with epinephrine (on left), and single-dose without (on right), methylparaben. Modified and reproduced with permission from the ISMP.

If you have encountered medication errors, near misses or hazardous conditions you'd like others to learn about, please report them, in confidence, to ISMP (https://www.ismp.org/report-medication-error).

Dr. Ronald S. Litman, is an anesthesiologist in the Department of Anesthesiology and Critical Care Medicine at The Children's Hospital of Philadelphia. He presently serves as Medical Director of the Institute for Safe Medication Practices.

William D. Ryan is an undergraduate student at Drexel University in Philadelphia, PA.

They have no conflicts of interest to disclose.

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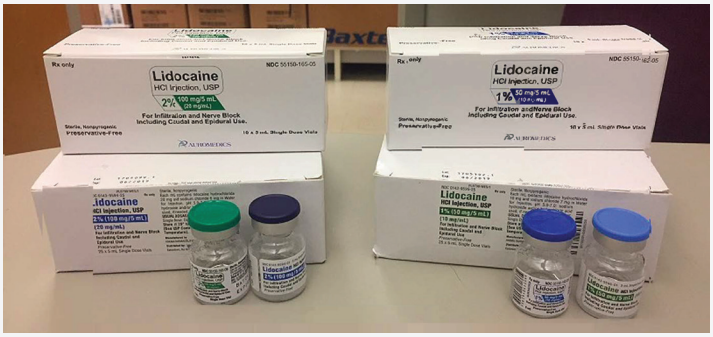

Figure 2. Depicts the similarities between two different concentrations of lidocaine made by two different companies.

Multimodal Analgesia

From "Multimodal Analgesia," Preceding Page

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Dear SIRS:
SAFETY INFORMATION RESPONSE SYSTEM

Burette Malpositioned Shut Off Valve Could Lead to Venous Air Embolism

Dear SIRS:

Venous air embolism (VAE) is a life-threatening emergency. Extensive causes of air embolism have been described in the literature.[1] Embolisms from peripheral intravenous (IV) infusions are extremely rare, especially in the pediatric population. However, they can still occur[1-5] and have the potential to be fatal.[6] We present a potential cause of VAE due to a malpositioning of a 150 mL burette (ICU Medical Inc., Burette Set, B33839) resulting in failure of the shut-off valve. This problem has not been previously described in the literature.

At our institution, 150 mL burettes are attached to Normal Saline (NS)/Lactated Ringer's (LR) 500 mL solution collapsible bags for IV fluid administration in children less than nine years old (Figure 1). A shortage of NS/LR 500 mL bags prompted the use of NS/LR 1000 mL bags. However, the NS 1000 mL bag caused the burette to hang at an angle, which in turn, led to a malpositioned shut-off valve (Figure 2). Theoretically, if all the fluid in the burette had been administered and the vent (Figure 3) remained open, the Venturi effect at the venous access site could have allowed air in the IV tubing to enter the circulation. This process could lead to a VAE. If the burette vent is closed, air is prevented from reaching the patient. Fortunately, for our patient, the vent was closed, preventing air from eventually reaching the venous circulation.

The National Quality Forum considers VAE a "never event" and the Joint Commission lists it as one of their reportable "sentinel events."[7] VAEs due to peripheral venous infusions can occur due to a variety of errors: inadequately primed tubing,[2,6] use of an IV pump without an air detection alarm,[3] and manipulation of peripheral IVs.[4,5] The outcomes can be devastating, especially in infants or patients with congenital heart disease since paradoxical emboli are more likely to occur with a patent foramen ovale or a right-to-left shunt.[2-5] The addition of a micron air filter to the distal end of peripheral IV tubing can substantially decrease the risk of VAE.[1-2] However, these filters can add significant resistance and may hinder gravity infusion, especially in conjunction with small gauge peripheral IVs. Air detection devices (albeit more expensive) meticulously de-airing of infusion sets, and inline air removal devices (such as, autoventing filters) may reduce the VAE risk.[8,9]

While the 150 mL burette is ideal to administer the appropriate amount of IV fluid to smaller pediatric patients via gravity infusion, the anesthesia professional should be aware of the possible increased risk of venous air embolism due to the rigid nature of the burette. The built-in shut off-valve helps mitigate this risk, but only if the burette is hanging

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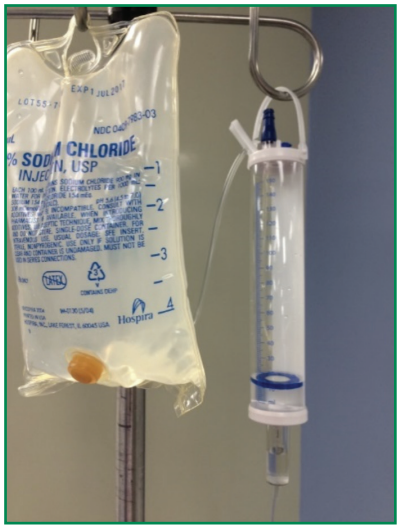

Figure 1. Burette perpendicular to floor with 500 mL NS Bag.

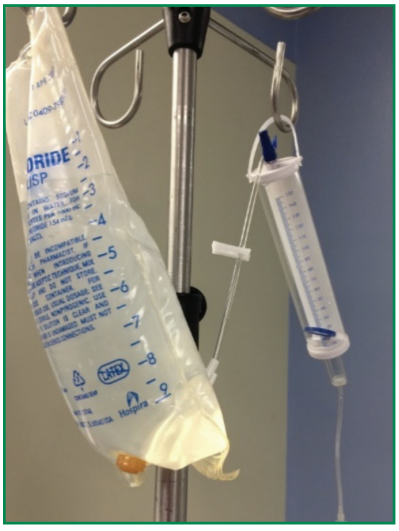

Figure 2. Burette angled to floor with 1000 mL NS Bag.

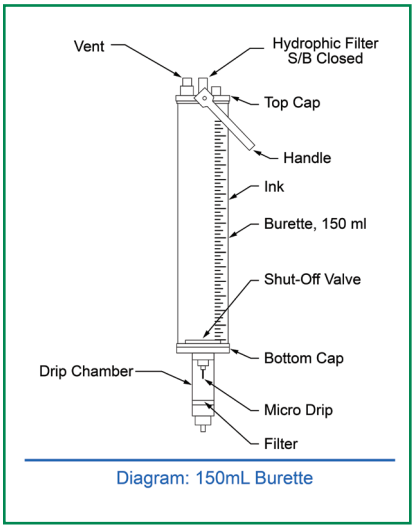

Figure 3. Depicts the setup of the burette. Reproduced and modified with permission from ICU Medical Inc.

Dear SIRS refers to the **S**afety **I**nformation **R**esponse **S**ystem. The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and responses from manufacturers and industry representatives. Dr. Jeffrey Feldman, current chair of the APSF Committee on Technology, is overseeing the column and coordinating the readers' inquiries and the responses from industry.

Dear SIRS SAFETY INFORMATION RESPONSE SYSTEM

Near Miss Venous Air Embolism

From "Dear SIRS," Preceding Page

perpendicular (straight) to the floor (Figure 3). If a 1000 mL fluid bag is required, the simple addition of a rubber band or similar device which lowers the burette in relation to the fluid bag allows it to hang in vertical orientation, eliminating the risk of a malpositioned shut-off valve (Figure 4). We recommend the addition of a micron air filter if the health care provider does not have direct visualization of the chamber while fluids are being administered, and especially in those patients at highest risk of paradoxical emboli.

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Reply:

We thank the editors for the opportunity to respond to this report. This case describes the use of a burette set to administer fluid while hanging in a non-vertical position. In this case, no patient injury was reported and ICU Medical has not received the product described in the report for further evaluation.

As the authors illustrate, a non-vertical burette orientation may impact the function of a floating shut off valve. In the product described, the shut off valve functions by floating on the surface of the fluid in the burette and coming to rest on the floor of the burette as the fluid level drops to occlude the tubing outlet and subsequently limit flow. When the burette is hanging in a vertical position, the float valve is in a horizontal position aligned with the burette floor (Figure 1). When the burette is non-vertical, the float valve continues to float horizontally on the fluid surface, but the burette floor is in a non-horizontal position, which may impede the shut off valve's ability to rest properly on the floor of the burette and limit flow when the fluid level drops (Figure 2).

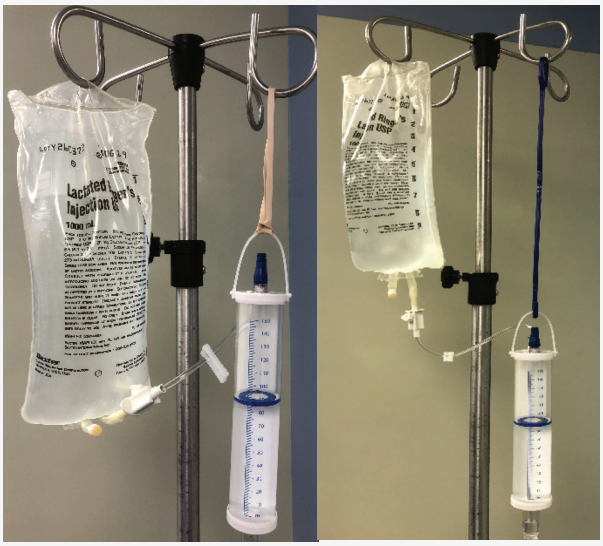

Figure 4. Burette with addition of rubber band or device with 1000 mL LR Bag.

Based on this report, ICU Medical has initiated a review of our burette set products and associated labeling. The directions for use of burette products will be reviewed in consideration of adding specific recommendations to use the burette only in the vertical position for the shutoff valve function. Additionally, alternative shut off valve designs will be evaluated for performance comparison to the float valve. Proximal tubing length (between the solution container and the burette) will be assessed in consideration of length extension to prevent burette pull when connected to a 1000 ml flexible container. The addition of air-eliminating filters on our burette sets will be considered as a customer option.

Utilization of an infusion pump with an air trap and/or an air-in-line detector is an additional option for patients who require precise fluid management and are at risk for air embolism. Infusion pumps enable accurate delivery of infusion volumes, detection of air, and utilize administration sets available in multiple configurations including those with needle-free injection ports, air filters, and burettes.

In summary, ICU Medical thanks the authors for sharing this report with the anesthesia community. We appreciate the opportunity to provide this response and details for the safe and effective use of burette sets.

Sincerely,
JW Beard, MD, MBA
Medical Director, Medical Affairs
ICU Medical Inc.

APSF EXECUTIVE COMMITTEE INVITES COLLABORATION

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Safe Use of High-Flow Nasal Oxygen (HFNO) With Special Reference to Difficult Airway Management and Fire Risk

by Jeremy Cooper, MB, ChB, FANZCA; Benjamin Griffiths MBBCh, FRCA; and Jan Ehrenwerth, MD

INTRODUCTION

High-Flow Nasal Oxygen (HFNO) administration is a relatively new technique that is used in the intensive care unit (ICU), and increasingly in the operating room (OR). HFNO has become popular in the ICU for management of patients with acute hypoxemic respiratory failure when attempting to avoid intubation or to help after extubation. In some anesthesia contexts, HFNO has been referred to as THRIVE—an abbreviation for Transnasal Humidified Rapid-Insufflation Ventilatory Exchange. Active research is ongoing as to the wider applications of HFNO. This brief current review will discuss the underlying mechanisms of HFNO, its potential use in clinical anesthesia practice, and the risks and benefits of such use. It focuses on the use of HFNO in adult patients, not children.

HFNO MECHANISM AND COMPONENT PARTS

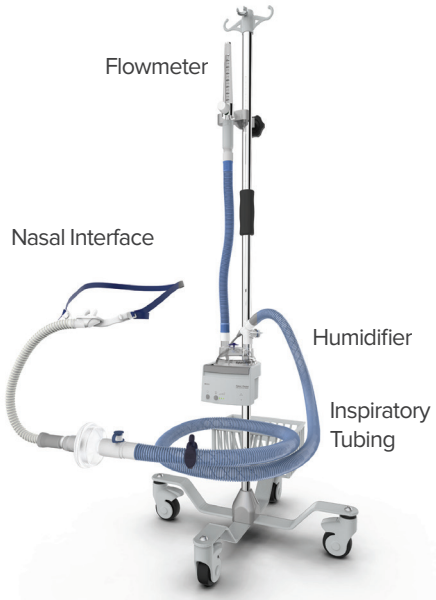
There is a marked difference between oxygen administration with standard low flow nasal cannulae and HFNO. When patients are administered low flow nasal O_2, the oxygen flow rates are typically between 2–10 liters/minute (L/M). Spontaneously breathing patients typically have an inspiratory flow rate (IFR) of 20–40 L/M. Once the IFR exceeds the flow of O_2 coming from the nasal cannulae, room air will be entrained which dilutes the FiO_2. The effective delivered oxygen concentration (which reaches the lungs) is usually 25–30%, if a patient is receiving 2–4 L/M of nasal O_2.

In contrast, HFNO uses oxygen flows of 50–100 L/M. With this technique, the high flows delivered via the specially designed nasal cannulae now exceed the patient's IFR. Therefore, there is little entrainment of room air which allows the delivery of a high FiO_2 (95–100%).

The components of a HFNO system are

1. An electrically powered high-pressure oxygen/air supply (ideally with a blender to blend air into the gas flow to reduce the FiO_2 if needed)
2. A flowmeter capable of flows of up to 100 liters per minute
3. A humidifier capable of fully humidifying the inspired oxygen/air mixture
4. Wide bore tubing to deliver gas from the gas supply to the nasal cannulae
5. Specialized wide bore nasal cannulae, which convey the oxygen/air blend from the gas tubing to the patient's nose.

HFNO System



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BENEFICIAL PHYSIOLOGIC EFFECTS OF HFNO

HFNO has a number of beneficial effects not provided by standard nasal cannula. At high flow rates, it can provide continuous positive airway pressure (CPAP), washes out CO_2 from the respiratory dead space, and assists the process of oxygen diffusion into the alveoli (replacing oxygen which has been absorbed).[1-3] In addition, it can reduce the work of breathing and reduce airway resistance.[4]

HFNO is capable of delivering very high gas flows with high FiO_2 or oxygen/air blends to anesthetized, sedated, or awake patients. Depending on the physiology of the patient, HFNO may have benefits for clinical anesthetic management, but it is important to recognize that use of HFNO has its own inherent risks. Several applications of HFNO are described below, each with its potential benefits and risks.

Clinical applications of HFNO with specific benefits and risks:

1. **Improving preoxygenation before induction of general anesthesia (GA)**

   Preoxygenation using HFNO can be a good alternative to standard preoxygenation, which is usually performed with an FiO_2 of 1.0 delivered via a closed anesthesia breathing circuit and an appropriately fitted face mask.[5,6] HFNO is well-tolerated by awake patients at flow rates of 30–40 liters per minute, provides effective preoxygenation without the use of a facemask, and provides ongoing CPAP, which reduces pulmonary shunting. In addition, the preoxygenation with HFNO can be continued into the peri-intubation period of oxygenation.

2. **Providing ongoing oxygenation and CO_2 removal for patients during intubation**

   The use of HFNO during the intubation process can extend the time interval until critical desaturation through the delivery of apneic oxygenation. This is especially attractive during a Rapid Sequence Intubation (RSI), where mask ventilation is not performed prior to intubation.[1] Another benefit of providing HFNO during intubation is that CO_2 accumulation is limited, especially in the first 20 minutes,[1] due to the effect of HFNO washing out CO_2. This effect can be especially useful for difficult intubations which may require more time to secure the airway. One important aspect of HFNO use to be aware of in this context is that the patient is not receiving a volatile anesthetic. Thus, supplemental intravenous anesthesia should be provided during this time period. In addition, if the time interval of HFNO is prolonged (more than 20 minutes), then methods for providing additional ventilation and CO_2 removal are required.[1] Twenty minutes is a guideline, and will vary depending on the physiology of the patient.

3. **Providing effective oxygenation during awake oral or nasal fiberoptic or videoscopic intubation**

   With HFNO use, patients undergoing awake orotracheal intubation have improved O_2 delivery and receive some CPAP while the oral airway is unobstructed for intubation. Surprisingly, CPAP is delivered even if the mouth remains open although it is less effective than when the mouth is closed.[2] Topical anesthetic preparation and subsequent fiberoptic nasal intubation can be achieved by working around the nasal cannula, when a nasal intubation is desired. However, the nasal cannula on the side of intubation must be removed prior to nasotracheal tube placement. HFNO may also benefit patients with partially obstructed airways undergoing awake intubation because of its ability to reduce both the work of breathing and airway resistance.

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Indications and Contraindications for High-Flow Nasal Oxygen (HFNO)

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4. **Providing respiratory support after extubation**

   Patients who have recently been extubated and require partial respiratory support to maintain oxygenation/ventilation may benefit from HFNO.[2,3] HFNO provides a well-tolerated form of CPAP (at the level of 3–4 cm H_2O with the mouth open) in addition to oxygen delivery. It does not cover the mouth so patients can talk while using HFNO. It is arguably a simpler technology to set up and use compared to many CPAP/ventilator machines and masks. However, one identifiable risk is that casual removal of the HFNO (by providers assuming it is "standard low-flow nasal oxygen") may result in an acute hypoxemia and respiratory insufficiency.

5. **Providing oxygenation, reducing work of breathing, and facilitating CO_2 elimination for use during surgical procedures**

   HFNO can be beneficial for sedated or even anesthetized (with IV medications) patients who are breathing spontaneously and even with some procedures requiring periods of apnea.[1,7] The benefit is that adequate oxygenation and ventilation can be provided, and yet the oral aperture, larynx, face, neck and all other areas apart from the nose are free to be operated upon. This could include cases with a partially obstructed airway, such as patients undergoing a tracheostomy.

CONTRAINDICATIONS TO AND RISKS OF HFNO

Suggested relative contraindications to HFNO are

1. Partial nasal obstruction
2. Disrupted airway, e.g., laryngeal fracture, mucosal tear, or tracheal rupture
3. Need for laser or diathermy (electrosurgery) in proximity to the administration of HFNO which increases fire risk. (This changes to an absolute contraindication under many circumstances that involve an FiO_2 of >30%.)
4. Contagious pulmonary infections, such as tuberculosis
5. Nasal infection resulting in pulmonary seeding with HFNO use is a theoretical concern. However, there is no evidence to date that demonstrates pulmonary seeding with HFNO
6. Contraindications to high concentrations of oxygen (e.g., prior bleomycin chemotherapy)
7. Inability to tolerate hypercarbia if HFNO is used with prolonged apnea (e.g., patients with sickle cell anemia, pulmonary hypertension, intracranial hypertension, and some forms of congenital heart disease)
8. Children under the age of 16. Cases of air-leak syndrome (i.e., pneumothorax) have been reported with HFNO use in children below the age of 16.[8] These were serious events and suggest that research and expert guidance is warranted to determine the safe use of HFNO in children.

Absolute contraindications to HFNO are

1. Use of alcohol-based skin preparation solutions in combination with HFNO, which increases the fire risk
2. Known or suspected skull base fractures, CSF leaks, or any other communication from the nasal to the intracranial space
3. Significant pneumothorax which has not been treated with a chest tube. The CPAP effect may expand the pneumothorax.[9]
4. Complete nasal obstruction
5. Active epistaxis or recent functional endoscopic sinus surgery (FESS).

The application of a tightly sealed mask on top of HFNO cannulae could potentially create too much pressure if the anesthetic machine APL valve is closed, which is why the manufacturers of one HFNO device advise against this (The Fisher and Paykel Optiflow. Fisher and Paykel Healthcare Limited, Panmure, Auckland 1741, New Zealand).

Some additional scenarios posing potential risks with HFNO use

The authors are not advocating for or against the use of HFNO for these scenarios. We are simply pointing out some of the more important considerations in the risk/benefit analysis of this approach, which is especially important as it is already part of existing practice for some clinicians.

1. **HFNO delivery under the surgical drapes**

   A <u>specific risk</u> apart from those mentioned under contraindications is the potential fire risk when HFNO is delivered under surgical drapes. The oxygen-rich environment created with high FiO_2 HFNO only needs a trigger (such as diathermy) to ignite, while drapes and swabs in the surgical field can serve as a potential fuel source.[10] The risk with this kind of oxygen "pollution" has been seen in videos of mock ignition.[11] Important factors impacting the fire ignition risk include duration of HFNO use, adhesion of drapes to create barriers to O_2 flow, flow rate, FiO_2 of HFNO, and OR room air exchange rates. If HFNO is used in this context, particular care must be taken with all three parts of the fire ignition triad—namely the HFNO flow rate and FiO_2, the fuel sources, and the use of ignition devices. The FiO_2 can be adjusted (down to room air) with an air/oxygen gas blender. This will reduce the fire risk, while maintaining some benefits of HFNO to patient care.

2. **Performing an emergent awake tracheostomy in patients with partial airway obstruction**

   Performing an emergent awake tracheostomy may be required for patients who have severe partial airway obstruction.[12,13] HFNO has been employed for performing an emergent awake tracheostomy in this context, which may also include the use of sedation.[14] The <u>benefits</u> of the HFNO-with-sedation technique include improved oxygenation and time to desaturation, decreased work of breathing, and potentially a more cooperative patient. The <u>specific risks</u> include the potential <u>loss of the airway and hypoxia</u>. Furthermore, depending on the amount of FiO_2 used with HFNO, the risk of airway fire may be increased compared with traditional methods of oxygen delivery.

3. **Elective airway surgery**

   HFNO may be useful during elective surgical procedures such as on the airway (e.g., microlaryngoscopy) where sedation or IV GA

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The Fire Triangle

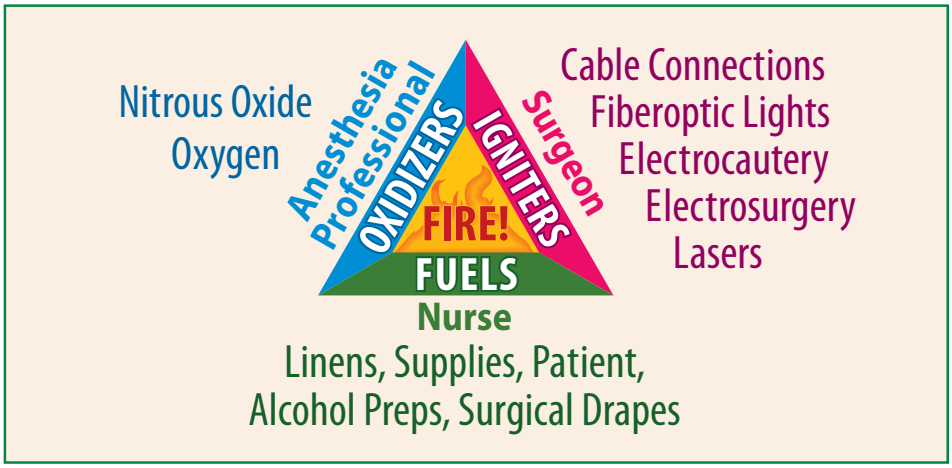

Figure 1. Illustrates the three elements needed to initiate a fire: oxygen, fuel, ignition source.

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Precautions Should Be Taken to Prevent HFNO-Related Fires

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is often used.[1,6] In this setting, HFNO can be used with spontaneous ventilation. If periods of apnea are required, intermittent bag mask ventilation can be used to address the slow build-up of CO_2. The benefits of HFNO in this setting include improved oxygenation (even with prolonged apnea), decreased work of breathing, and even some CO_2 removal which results from HFNO washout.

The risk of HFNO use for elective airway surgery is oxygen contamination of the operative field, which increases the fire risk both at the surgical site and the upper half of the patient covered by surgical drapes. This risk is especially relevant where lasers or diathermy (ESU) are used (Figure 1).

Providers must balance the benefits of improved oxygenation and ventilation provided by HFNO with the potential fire risk. Modern jet ventilators that are used during microlaryngoscopy[15] have specific safety features to lower the FiO_2 when a laser will be used. Jet ventilation frequently entrains room air, which will decrease the FiO_2. However, the resultant FiO_2 is variable and, therefore, frequently unknown to the anesthesia professional. Part of the risk profile of HFNO is that it is often configured for use only with 100% oxygen, and there may be no way to reduce the FiO_2.

The manufacturers of one version of a commonly used HFNO system—The Fisher and Paykel Optiflow (Fisher and Paykel Healthcare Limited, Panmure, Auckland 1741, New Zealand)—clearly state: "To avoid burns...Do not use the system near any ignition source, including electrosurgery, electrocautery, or laser surgery instruments. Exposure to oxygen increases the risk of fire." The medical warning is clear. In addition, this statement will likely be part of any medico-legal action if a fire should occur while using HFNO. This caution, however, has not stopped the use of HFNO in clinical practice and research into the use of HFNO during laser laryngeal surgery.[7] An OR fire case involving HFNO has already been reported.[16]

GUIDING CONSIDERATIONS TO ASSESS FIRE RISK OF HFNO USE:

- Some authors have distinguished between accidental flash flames and spreading flames the latter of which causes more damage (burns).[17] Reports of HFNO fires have not been reported frequently enough to make a judgement about the kinds of flames produced and more research is indicated.
- We do not have a clear idea of overall ignition frequency with cases performed under alternative ventilation techniques; thus, comparative fire risk is unknown.
- Using an oxygen/air blender to reduce the FiO_2 with HFNO should help to reduce the risk of fire.
- HFNO is a new technology and the reports of two fires described at this early stage of adoption may herald more fires in the future as HFNO gains in popularity.*[16] Practitioners must exercise extreme care to reduce the fire risk.
- To date, no patient harm has been reported.
- The oxygen "pollution" around the head and neck area from HFNO use has not been comprehensively studied. An APSF video which focuses on intraoperative fire risk indicates that any oxygen concentration greater than 30% in the head and neck area creates an increased fire risk, especially for procedures in that area.[18]

FUTURE CONSIDERATIONS

It is likely that an increasing number of anesthesia professionals will utilize HFNO in the operating room. One obstacle is that the HFNO equipment must be brought into the operating room and assembled every time it is used. In the future, HFNO could be designed to directly connect to the anesthetic workstation for easier use. Due to regulatory and manufacturing limitations, however, it is unlikely that such modifications to incorporate HFNO apparatus will soon be available. Anesthesia professionals should encourage manufacturers to recognize these issues and work towards adding this feature to the next generation of machines.

CONCLUSIONS

HFNO is a novel system of respiratory support, which allows delivery of oxygenation at variable concentrations, reduces the work of breathing, provides CPAP, and assists in CO_2 removal. While it has a number of potential uses in anesthetic and perioperative practice, it also has definite relative and absolute contraindications. The potential risks of harm with HFNO use are probably underappreciated. Many questions regarding benefits and safety in specific clinical contexts remain. Before using HFNO, education and insight into its use is highly recommended.

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Both Dr. Cooper and Griffiths have assisted with clinical research in HFNO for Fisher and Paykel Ltd, but have received no funds or other compensation from this entity. Dr. Ehrenwerth reports no conflicts of interest.

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*Unpublished data from personal communication, July 1, 2018.

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Dear SIRS:
SAFETY INFORMATION RESPONSE SYSTEM

LTA Tip Breaks in Patient's Airway

Dear SIRS:

Anesthesia equipment malfunction may contribute to increased patient morbidity and mortality. We present a complication resulting from an accidental break in the Laryngotracheal Analgesia Device (International Medical Systems (IMS) Lidocaine Laryng-O-Jet Kit® (LOJ)), Figure 1.

A 59 year-old, morbidly obese male with symptomatic atrial fibrillation and rapid ventricular response required anesthesia for a transesophageal echocardiogram with subsequent cardioversion. The decision was made to perform general endotracheal anesthesia by providing topical airway anesthesia (TAA) via a Lidocaine Laryng-O-Jet Kit®. This device was used to decrease airway reactivity without the use of opioids in order to potentially reduce the risk of opioid-induced ventilatory impairment.

Using video laryngoscopy, the LTA was passed through the vocal cords and upon withdrawal, the tip broke off and remained in between the patient's vocal cords, Figure 2. Multiple attempts at retrieval via Yankauer suction were unsuccessful. An endotracheal tube was advanced through the vocal cords over the retained portion of the LTA in order to provide oxygen to the patient during this time. Pulmonology was consulted, and the foreign body was retrieved successfully via bronchoscopy with a snare device. The planned procedure was completed and patient was successfully extubated.

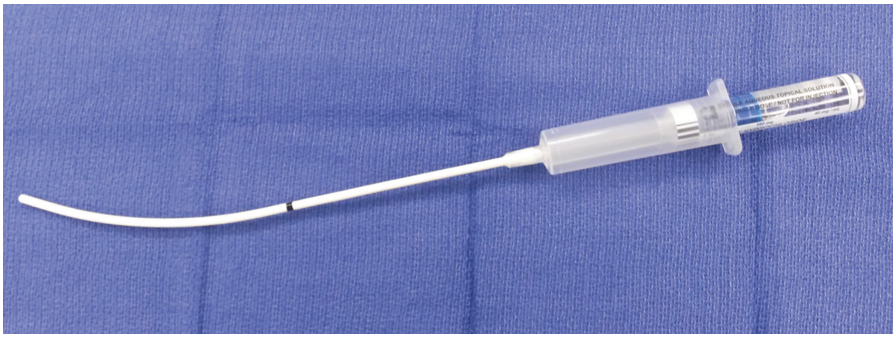

Figure 1. Depicts an intact Laryngotracheal Analgesia Kit at University of Texas, Southwestern Medical Center.

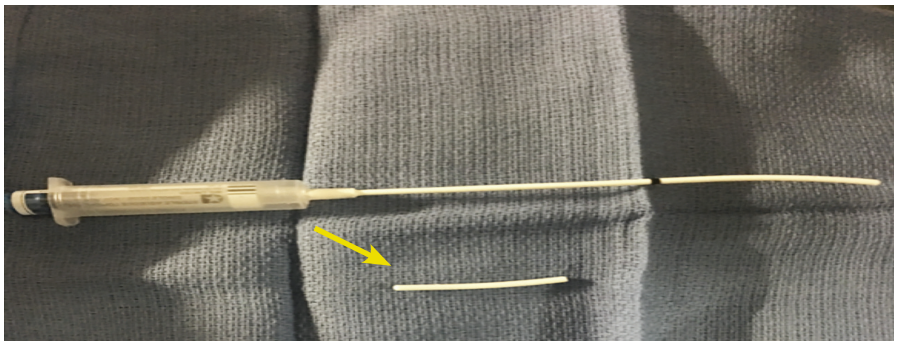

Figure 2. Depicts the horizontal image of a broken Laryngotracheal Analgesia Kit discussed in the reported case.

AUTHOR'S RECOMMENDATIONS

This event did not result in any long-term sequelae. The February 2018 *APSF Newsletter* reported a similar incident with a mucosal atomizer.[1] The present article provides potential management strategies in case an LTA fracture occurs: 1) Avoid repeated attempts at retrieval via suction or forceps because the broken portion may cause tracheal rupture or vocal cord injury. 2) Secure the airway and subsequently retrieve the device via bronchoscopy with a snare with a specialist's assistance, if available.

Osamudiamen Obanor, MD, is a resident anesthesiologist in the Department of Anesthesiology and Pain Medicine at the University of Texas Southwestern Medical Program, Dallas, TX.

Omaira Azizad, MD, is a staff anesthesiologist in the Department of Anesthesiology and Pain Medicine at the University of Texas Southwestern Medical Program, Dallas, TX.

Irina Gasanova, MD, PhD, is a staff anesthesiologist in the Department of Anesthesiology and Pain Medicine at the University of Texas Southwestern Medical Program, Dallas, TX.

None of the authors have any conflicts of interest/disclosures as they relate to this article.

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Reply:

This is in response to Dr. Obanor's report regarding International Medical Systems (IMS) Lidocaine Laryng-O-Jet Kit (LOJ), Lot No. DL067G7, Stock No. 6300, in which it was reported that upon removal of the device, the tip of the cannula broke and was lodged between the patient's vocal cords. Upon receipt of this report, an investigation was conducted to determine the root cause that may have contributed to the reported incident.

The batch records for this lot were reviewed and no anomalies were noted at the time of manufacturing, testing, or release. We inspected the reserve samples from Lot DJ067G7 and all other product lots that were manufactured with the same Laryng-O-Jet

See "LTA Tip Break," Next Page

Dear SIRS SAFETY INFORMATION RESPONSE SYSTEM

Product Label Warns Providers Not to Bend Laryngotracheal Analgesia Kit Tubing

From "LTA Tip Break," Preceding Page

injector lots used in Lot DJ067G7. All of the reserve samples inspected passed visual inspection including the inspection of the injector's tubes for cracks or breakage. The reserve samples were also inspected for the alignment of the holes on the cannula and all units met specification. Random sample units from each lot were also inspected for functionality, and all units inspected met specification.

The subject unit was not available to be returned for investigation. However, a photo was provided showing a unit with a broken tip. It was reported that at the time of the incident, the device was inserted using the assistance of a video laryngoscope and the product did not get stuck on anything and was not bent during the insertion. Upon attempted removal of the device, the end of the cannula was found to have broken off. The patient underwent bronchoscopy for removal of the broken piece and was subsequently discharged with no further complications.

The Laryng-O-Jet applicator tubes are manufactured with Makrolon® Polycarbonate. During the injector assembly process, the assembled LOJ Injector is subjected to a glue curing tunnel and to a bending fixture, neither one of which degrades the Makrolon material. The bend in the LOJ tube is created with a pre-determined amount of heat and is anatomically curved for administration of lidocaine in the larynx and trachea. The LOJ tube is 100% inspected under magnification at the conclusion of the assembly process; if any crack or breakage is found, the tube is culled out at the time. Additionally, the finished product is inspected twice under magnification for any damage before final packaging. Per the product labeling, the LOJ tube should not be further bent or manipulated prior to use. Additionally, per the product labeling, caution is needed with laryngoscope use to avoid cannula breakage. We have received no other similar reports from other customers for Lot DJ067G7. Please note that the report of the incident was submitted to the FDA via the Safety Reporting Portal as an expedited report.

We value our customers' concerns. The feedback we receive provides us with valuable information for evaluating our processes and maintaining our quality standards.

Sincerely,
Alan Go
Manager, Quality Systems

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Annual Meeting of the American Society of Anesthesiologists
Saturday, October 13, 2018

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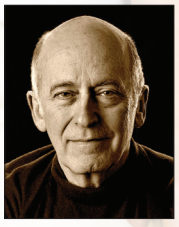
Room 206
4:45 pm – 5:45 pm

Co-Moderators:

Richard D. Urman, MD, MBA



Jeffrey B. Cooper, PhD

Dear SIRS:
SAFETY INFORMATION RESPONSE SYSTEM

Potential Burn Hazard from General Electric MRIs

Dear SIRS:

Our department recently received a warning from General Electric regarding the potential hazard of patients suffering burns during magnetic resonance imaging (MRI) with its equipment. I am not aware that any patient has actually been burned, even though the potential for burns exists. Why are we exposing patients to burns? Why does General Electric expect providers to assume some of the burden and liability of protecting patients from this potentially dangerous equipment-related issue? In the 1999 Institute of Medicine report,[1] "To Err is Human," the Institute of Medicine found that fixing "system problems" was better than depending on fallible providers to prevent injury: "Commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them."[1] General Electric's warning is a "system problem" that should not be fixed by asking anesthesia professionals to insulate patients from the MRI bore during sedation or general anesthesia when patients are unable to respond to heat. Once the patient is in the MRI bore, it is difficult to visualize patient contact with the bore and prevent potential burns. An alternative solution and possibly a more appropriate one to this hazard is for General Electric to insulate the magnet bore so that burns are not possible.

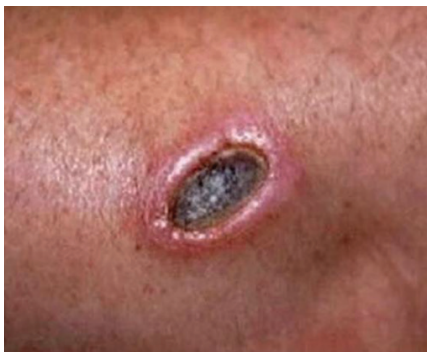


Figure 1. Depicts an example of an MRI radiofrequency-related burn.

Reproduced and modified with permission from GE Healthcare.

Sincerely,
Donald H. Lambert, MD, PhD
Professor of Anesthesiology, Boston University School of Medicine and Anesthesiologist in the Department of Anesthesiology at Boston Medical Center, Boston, MA.

The author has no disclosure as it pertains to this article.

REFERENCE

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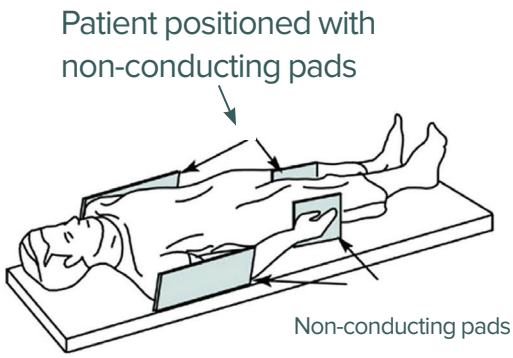

Figure 2. Depicts where nonconducting pads can be placed to reduce the risk of MRI-related burn. Figure 2 is an extract from a GE Healthcare MRI Operator Manual addressing patient padding. Reproduced and modified with permission from GE Healthcare.

- Use additional pads to immobilize the patient and make them comfortable.
- Preventing patient warming is one of the most important safety measures you must take into consideration as you prepare a patient for MR exam. Appropriate RF padding and proper patient positioning are the most effective means of preventing injury related to RF heating. The following are a few golden rules to remember as you position and pad your patients:
  - Only use GE-approved RF padding.
  - Use non-conductive padding that is at least 0.25 inches (0.635 cm) thick between the patient's skin and the magnet bore.
  - Appropriate padding must be used EVERY time without exception.
  - Sheets and gowns are not a substitute for approved RF padding.
  - Never allow your patient's skin to come in direct contact with the scanner bore or any surface coil or cable.
  - Never allow skin-to-skin contact.
  - If a patient does not fit in the MR scanner bore with the required padding, another modality should be used to scan the patient.
- While some of these rules may seem a little tough to follow at times, remember that RF injury, which can in extreme cases include burns such as the one you see above, can happen very quickly and your patient may not have time to warn you in time to prevent an injury.

See "MRI Burns," Next Page

Potential Burn Hazard from MRI

From "MRI Burns," Preceding Page

Reply:

As a medical imaging device manufacturer, we employ a "design for safety first approach" when developing magnetic resonance imaging (MRI) equipment. In some cases, however, MR imaging does require that MR operators follow well-established safety procedures to mitigate potential safety risks.

During an MRI exam, radiofrequency (RF) energy is used to excite protons within the body to create images from the anatomy of interest. The source of this energy is a whole-body RF transmit coil, which is a resonant electrical structure that uses time-varying current and voltage to generate the RF field. This device resides at the center of the MRI magnet and provides the mechanical structure for the patient bore.

A consequence of the whole-body RF transmit coils' operation is the induction of localized electric and magnetic fields within the patient's body. As the anatomic structure of interest moves closer to the coil, the intensity of these fields can increase. Under certain conditions, the induced electric fields can result in warming of the tissue and in extreme cases, result in an RF burn (Figure 1). While uncommon, this represents a patient safety issue during MR imaging that must be taken into account during MR procedures by trained MR operators.

The MRI industry has developed safety procedures to address and mitigate the potential for RF burns during MR imaging. To prevent RF burns, every patient must be appropriately padded (Figure 2) using non electrically-conductive pads. These pads are placed between the patient's skin and magnet bore. These pads should be a minimum of 0.25 inches thick and are furnished with every MR system (Figure 2).

For the issue described by Dr. Lambert, GE Healthcare has discovered a design issue with the RF body coil used in GE's Discovery MR750w 3.0T scanner that may result in focal heating of the bore wall, above the 41 degree Celsius patient contact limit as defined by IEC60601-1 3.1, under certain conditions. The focal heating has been isolated to the circuit boards within the RF body coil assembly located at 0 (bottom), 90 (right), 180 (top), 270 (left) degrees on the table end of the patient bore (Figure 3).

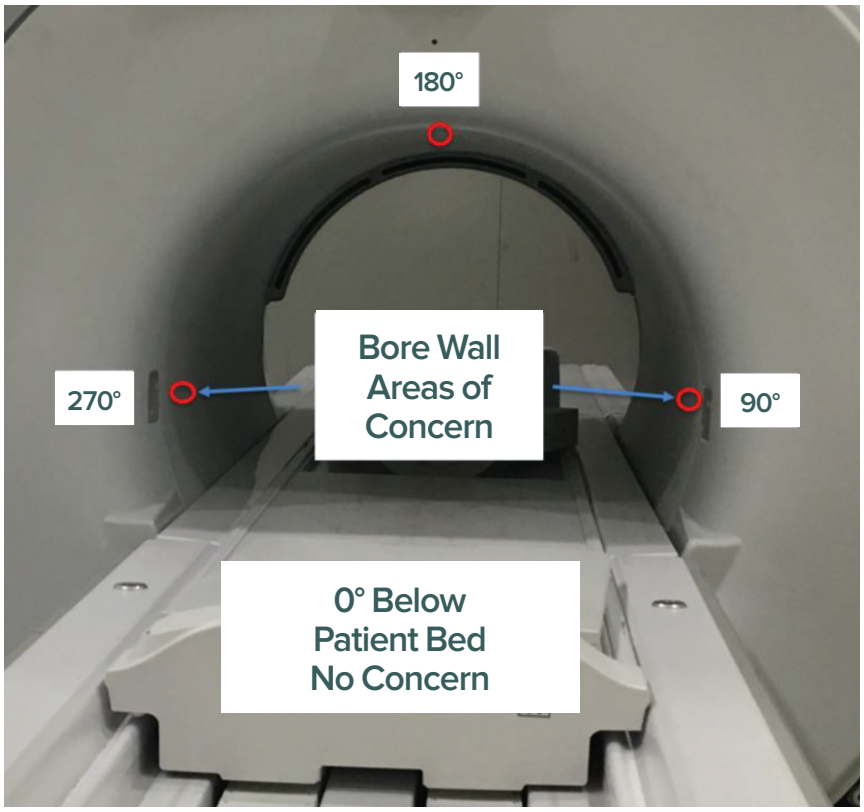

Figure 3. Depicts the particular areas where patients may be at increased risk for burn in MRI. Reproduced and modified with permission from GE Healthcare.

In response, GE Healthcare has issued an URGENT MEDICAL DEVICE CORRECTION Ref# 60937 and will be correcting all affected Discovery MR 750W 3.0T products at no cost to the customer. While unrelated to RF burns, the safety instructions detailed in the letter are consistent with mandatory safety procedures described above and should be used as a mitigation for this focal heating issue. These instructions are designed to ensure customer awareness of the potential bore heating issue and remind MR operators of the required MR safety operating procedures.

Once again, thank you for providing GE Healthcare with the opportunity to reinforce the importance of following MR safety procedures.

Sincerely,
Bryan J. Mock, PhD
General Manager, Global 3.0T MR Segment
GE Healthcare – Imaging

Successful Implementation of a Two-Hour Emergency Manual (EM) Simulation Instructor Training Course for Anesthesia Professionals in China

by Jeffrey Huang, MD

Optimal outcomes in crisis situations require that critical steps are performed in a timely manner. Increasing evidence suggests that checklists facilitate completion of critical steps in crisis management. For example, a recent simulation-based study in the operating room (OR) revealed that teams only missed 6% of critical steps when crisis checklists were used, compared to 23% of critical steps when they were not.[1] Evidence suggests that Emergency Manuals (EMs) are being successfully used during clinical critical events in the OR.[2] Furthermore, a published article has demonstrated that EMs have been incorporated into use throughout many centers in China.[3] Two major anesthesia societies in China have encouraged anesthesiologists to incorporate the use of EMs into the management of critical events after appropriate multidisciplinary training.[4]

Studies suggest that simulations significantly influenced provider EM use during critical events,[2,3] although training is currently lacking in many hospitals in China. To address this problem, a nationwide EM simulation training movement was initiated. Simulation workshops, demonstrations, and training competitions have been tested as effective ways to promote multidisciplinary simulation training and implementation of operating room emergency manuals in China.[5] Volunteer teachers, who were already experienced in EM simulation training, traveled to hospitals that did not have anyone experienced in that type of training.[6] They taught health care providers within these hospitals how to conduct multidisciplinary simulation training and ensured that they could conduct this kind of training independently.[6]

Figure 1. The 2018 Chinese Association of Anesthesiologists (CAA) annual meeting Operating Room Emergency Manuals simulation instructor training workshop.

Training a trainer is one of the most efficient ways to spread new medical practices.[7] While simulation training can be obtained by attending workshops, they are often time-consuming events that require participation, fees, and travel costs. Many anesthesia professionals are unable to participate in multiday simulation instructor workshops because of their busy work schedules and hospital policy. We recently explored the effectiveness of a two-hour EM simulation instructor training course during the Chinese Association of Anesthesiologists (CAA) annual meeting (Figure 1). Attendees of the annual meeting were able to receive EM simulation training and become qualified teachers.

A training course announcement was advertised two months before the meeting, in order to recruit participants. Participants were required to register (in advance via email and social media). Each course attendee participated in three standardized simulation scenarios (anaphylaxis, difficult airway, local anesthetic toxicity), which were developed by the course facilitators. Scripts for the simulation scenarios, which included debriefing questions, were sent to registered participants in advance of the course. The participants were encouraged to review the scripts and related topics in anesthesia textbooks. Prior to the meeting, the course participants were divided into three groups. The facilitators for the course were EM simulation instructors in their home institutions and came from the USA and China. The facilitators included Drs. Jeffrey Huang, Jinlei Li, Jingping Wang, Qi Li, Fan Ye, Yiqi Chen, Meijuan Yan, and Jiayan Wu.

The course was organized around the simulation scenarios with two facilitators assigned to each station. Each station conducted the same scenario for the whole training course. Each of the three groups used different simulators to provide participant experience with different simulation tools and fidelity. One station used a

See "Simulation Training," Next Page

Effective Simulation Training

"Simulation Training" From Preceding Page

a high-fidelity simulator Laerdal mannequin (Laerdal, Wappingers Falls, NY, USA) in conjunction with an anesthesia machine. Another used a CPR mannequin and an iPad, which displayed simulated vitals generated by the SimMon application (Castle Andersen ApS, Denmark). The final group used a self-made simulator created from a facilitator's jacket and table cloth. Each scenario lasted 40 minutes, which included debriefing. During the first round, the participant was assigned a role by the facilitators. The roles included an anesthesia provider, attending physician, a chief physician surgeon, operating room nurses, additional helpers, and an EM reader. The team was introduced to each scenario by a facilitator who provided the clinical background and answered questions with regards to the scenario and demonstrated use of the simulation equipment. The participant then took part in the scenario, which included an EM reader role. The EM reader was instructed to read the scenario-relevant chapter from the manual while the team followed the instructions and performed the tasks. During the debriefing, participants evaluated their own performance. Technical and nontechnical problems related to performance and teamwork were discussed. Clinical errors were identified either by the team members or by the facilitators. During this process the participants learned to utilize the debriefing questions provided to them with the scenario scripts. Through this training, the participants became familiar with the simulation organization and the training process. Attendees of the CAA meeting who did not register for the training course were allowed to observe and provide feedback.

After 40 minutes, the group switched to a different station. By the second and third stations, it was apparent (from the perspective of the experienced mentors) that the participants were more confident in their simulated roles and were acquiring the skills of a facilitator capable of conducting simulation training and organize debriefing.

A post-course evaluation survey was sent to all participants. The response rate was 87.5% (35/40). The training course received very positive feedback from the participants and facilitators. The participant satisfaction with the workshop was very high. Eighty percent of the participants agreed that they obtained the basic skills of EM simulation training. More than 97% of the participants agreed that they will organize EM simulation training in their hospitals. A follow-up survey two months after the training course revealed that 40% of the course participants had organized EM simulation training in their hospitals, and two of the participants had organized their own EM simulation training workshop. Attendees of the CAA meeting that did not directly participate in the course also benefited. They were able to share the training skills they observed with their home institutions. Some observers also may have organized simulation training in their hospitals. Therefore, the number of people who benefited from this training program may have been substantially higher than the actual number of course participants.

In summary, the two-hour EM simulation training course provided during the CAA meeting was well received. However, it required careful planning, the participants' strong passion to learn, the facilitators' meticulous preparation, and CAA leadership support. This experience can be applied in different regional or national meetings to train more qualified teachers.

Dr. Huang is program director of HCA Anesthesiology Residency at Oak Hill Hospital, program director of HCA Transitional Year Residency at Oak Hill Hospital; professor at the University of Central Florida College of Medicine. He serves on the APSF Committee on Education and Training and on the ASA Committee on International Collaboration.

Dr. Huang has no conflicts of interest to declare.

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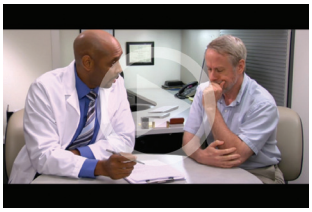

APSF Presents Simulated Informed Consent Scenarios for Patients at Risk for Perioperative Visual Loss from Ischemic Optic Neuropathy (18 minutes)

APSF Presents Prevention and Management of Operating Room Fires (18 minutes)

Dear SIRS:
SAFETY INFORMATION RESPONSE SYSTEM

Defective Central Venous Catheter Introducer Needle

Dear SIRS:

We are writing to describe an incident we experienced involving a central line kit that has implications for patient safety. The case involved a 70-year-old morbidly obese patient scheduled for emergency craniotomy for intracranial hemorrhage. Due to lack of intravenous access and need for vasopressors, an ARROWgard Blue PLUS® Two-Lumen AK-42802-CDC (Lot 13F17L0206) 8 French 16 cm length central venous catheter kit was utilized for attempted central venous access. Ultrasound guidance and aspiration of dark colored blood via a 22 gauge finder needle was utilized to confirm location of the internal jugular vein. However, no blood could be aspirated when utilizing the 18 gauge introducer needle attached to the 5 ml Arrow® Raulerson Spring-Wire Introduction Syringe included in the kit. The 5 ml syringe was replaced by another Luer-Slip syringe which was attached to the hub of the introducer needle, but still we were unable to aspirate blood despite ultrasound visualization of the needle tip in the vein. The procedure was aborted, and a saline aspiration test was performed using the 18 gauge introducer needle, however, only air could be aspirated (Figure 1). Close inspection of the introducer needle revealed air entry via a crack not visible to the naked eye at the plastic hub of the introducer needle (Figure 2). After the central line kit was replaced with a new kit, the internal jugular vein was accessed with one attempt. Postoperatively, a hematoma was noted at the central venous puncture site from multiple venous punctures due to the initial defective introducer needle. Ultrasound visualization of needle tip in the vein was helpful in early diagnosis of equipment malfunction. Although introducer needle defects are a rare event, routine saline aspiration testing of introducer needles for integrity prior to venous puncture should be considered in conjunction with ultrasound guidance. The authors are not aware of any other published reports of this type of needle equipment failure. Arrow International, Inc., a subsidiary of Teleflex, Inc., was informed of the incident, and the introducer needle was sent back to manufacturer for analysis.

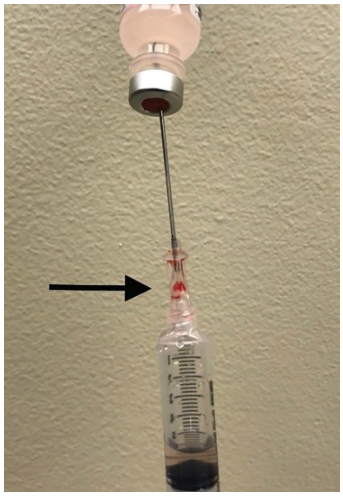

Figure 1. This figure depicts air aspirated into syringe instead of saline from vial due to a defect in the hub of the introducer needle. Arrow points to hub defect location.

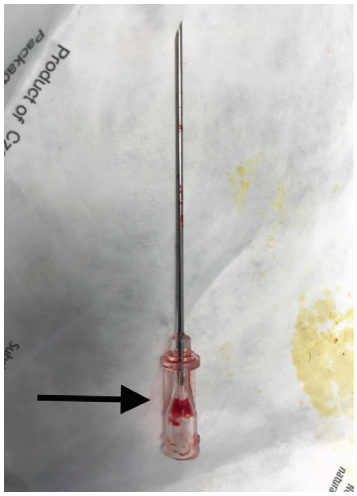

Figure 2. This figure depicts the 18 gauge introducer needle with a defect in the hub resulting in an inability to aspirate fluid. Arrow points to hub defect location.

Dr. Jackson Su is an associate professor in the Department of Anesthesiology and Perioperative Medicine at the University of Texas MD Anderson Cancer Center.

Dr. Allen Holmes is a clinical associate professor in the Department of Anesthesiology and Perioperative Medicine at the University of Texas MD Anderson Cancer Center.

The authors have no disclosures pertinent to this article.

Reply:

An incident was recently brought to my attention, in which there was an issue with our ARROWgard Blue PLUS® Two-Lumen, 8 French, 16 cm central venous catheter kit. I also was provided with a copy of a letter/case report submitted by Dr. Su, describing the incident in more detail, and it was appropriately forwarded to our Complaints Team at Teleflex. A sample of the product was eventually returned to us (including the introducer needle, syringe, and lidstock) for evaluation as well.

Cracks in the introducer needle hub may theoretically be caused by excessive stress or tension on the hub when it is attached to the syringe (either by the user/clinician during use of the device or during the manufacturing and/or assembly process). A device history record review was performed for this complaint type, and no relevant or significant manufacturing issues were identified. A risk evaluation assessment has been completed, and further investigation is being conducted to determine a root cause. Teleflex will continue to monitor this issue through post-market surveillance and implement any corrective and preventive actions if deemed necessary. Thus far, we have not noted an unacceptably high frequency of occurrence of this particular issue. However, close inspection of all the components in the procedural kit is always recommended when possible.

On behalf of Teleflex, I would like to thank you for bringing this to our attention. Teleflex takes patient safety very seriously, and I can assure you that—if necessary—every attempt will be made to mitigate any potential risks from our vascular access products in the future.

If you have any further questions or concerns, please feel free to contact me at any time.

Sincerely,
Chris Davlantes, MD, FACEP
Medical Director – Clinical and Medical Affairs
Teleflex Incorporated

Letter to the Editor:

A Novel Approach to Eliminating Wrong-Site Blocks

by Adam Blomberg, MD; Joseph Loskove, MD; Cameron Howard, MD; David Sacks, MD

Wrong-site procedures are considered "Never Events," but still occur at an estimated national rate of 7.5 per 10,000 procedures.[1] Wrong-side nerve blocks are likely to continue to occur as multimodal anesthetic management gains popularity as a way to reduce opioid-based anesthetics. Consequently, Envision Physician Services, a national multispecialty physician group, approached Memorial Healthcare System in Hollywood, Florida, with the idea of bringing hospital staff together to develop strategies that would help avert wrong-site blocks. This led to the implementation of two new protocols: a visual confirmation with a colored bracelet of the correct side and a patient-directed timeout procedure led by the patient.

NEW PROTOCOLS

Envision and Memorial Healthcare System enlisted a large cross-functional team that consisted of Envision Physician Services senior leadership to provide insights from a clinical and patient care perspective. Registered nurses were also brought in to ensure that the workflow could be adopted among nursing staff.

Visual confirmation of the correct procedure location is performed by both the patient and nurse placing a bright green wristband marked with the word "yes" on the side corresponding to the surgery. The wristband can be seen from anywhere in the room and may reduce the risk of performing the procedure on the incorrect side, especially when the patient changes positions before the nerve block is administered. If a bilateral regional anesthetic is performed, such as a transverse abdominis plane (TAP) block the patient reads the script in the preoperative area and green bands are placed on both arms.

The second measure involves giving the patient a script to lead the anesthesia timeout (Figure 1). The script includes eight steps and confirms personal information such as allergies, surgery type and block location with proper identification markers. Providers from Envision and Memorial Healthcare System observed that with the patient as the leader, the timeout seems to proceed in an orderly manner, and all members of the medical team may remain focused and engaged in a consistent, thorough, and standardized timeout process. The new patient-led timeout process still incorporates all the major aspects of a timeout recommended by the Joint Commission,[2] including proper documentation and conducting the timeout before the procedure is administered, involving all appropriate clinical team members, and at minimum, confirming the patient identity, procedure type, and site of the procedure.

IMPROVED PATIENT SATISFACTION AND SAFETY

The team noticed that the new protocols may have helped boost satisfaction for both patients and clinicians. By becoming active participants, patients may gain a sense of empowerment and control over their care and confidence in the clinical team. The wristband also may increase clinician confidence by providing an immediate visual prior to initiation of any procedure. This has been so well received that the surgeons have started to request similar wristbands for procedures regardless of whether or not a regional anesthetic is performed.

Additionally, the patient-led timeout may safeguard against confirmation bias among the clinical team. For example, if a physician leads the timeout and asks the patient if the surgery is on the left side when it should be on the right, a nervous patient may agree, and the nurse may assume that the physician and patient identified the correct side. The script helps the care team avoid confirmation bias by using general phrases such as, "Put the wristband on the same side on which you're having the surgery." The patient then has ownership in their care for indicating the correct side. If a patient is unable or unwilling to lead the timeout process or is unable to verify the information, the team proceeds with the traditional timeout led by the nurse and physician. When the patient takes the lead, it may reduce provider fatigue, as the clinical team may often be rushed from doing multiple timeouts back to back, leading to shortcuts and distractions, and may reinvigorate those same health care professionals to respect the value of the "timeout."

NATIONAL ROLLOUT

Memorial Regional Hospital South in Hollywood, Florida, piloted the innovative protocols for nearly two years, during which time more than 100 patients participated. In early 2018, Memorial Healthcare System, one of the largest public health care systems in the United States, rolled out the protocols to all six of its hospitals.

Envision Physician Services is now building on that momentum and plans to roll the procedures out to all of its anesthesia professionals in the next year as a standardized practice. These adjustments to how we approach delivering care hopefully will increase patient satisfaction, while reducing the risk of wrong-site blocks. Leadership from Envision Physician Services plans to study many of these outcomes as they apply to the implementation of the present protocol. However, the authors wish to share the cultural change and processes so other practices may start thinking about the option to introduce these initiatives.

Figure 1. Depicts the patient directed timeout before a regional nerve block. Patient also wears a bright green colored bracelet to alert providers to the side on which the nerve block will be placed.

Adam L. Blomberg, MD, is the chief of Anesthesiology for Memorial Healthcare System in Hollywood, Florida, and the regional medical director and national education director for Envision Physician Services' Anesthesia Division. Joseph Loskove, MD, is Envision Physician Services senior vice president of Anesthesia. Cameron Howard, MD, is regional director of enhanced recovery for Memorial Healthcare System and vice chief of Anesthesia at Memorial Hospital West. David Sacks, MD, is the chief of Anesthesiology for Memorial Regional South Hospital. Dr. Blomberg and Dr. Sacks led the implementation of the pilot program at Memorial Regional South and rollout to the health system.

Dr. Blomberg, Dr. Loskove, Dr. Howard, and Dr. Sacks have no conflicts of interest to declare regarding the content in this article.

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Dear SIRS:
SAFETY INFORMATION RESPONSE SYSTEM

Volatile Anesthetic Unintentionally Not Delivered

Dear SIRS:

My hospital had three incidents in the last four years that may be related to volatile anesthetics unintentionally not being delivered to the patient. After each of these incidents we reported to GE (we use GE Healthcare Aisys™ anesthesia machines) that we felt there should be an alarm on the machine to alert providers if the following circumstances occur:

1. if the ventilator is in operation, but no volatile anesthetic (VA) or nitrous oxide was turned on
2. if the ventilator is in operation, and the VA was turned off due to cassette change, but not turned back on.

We welcome a reply from representatives from GE.

Sincerely,
Dr. Joshua Berris
Chairman, Department of Anesthesiology
Beaumont Hospital, Farmington Hills, MI

Reply:

Dear Dr. Berris,

Thank you for writing about this important issue, which is critical to patient safety during the perioperative period. When using the GE Healthcare Aisys or Aisys CS2 anesthesia systems and "start case" is selected, the system allows the clinician to begin the case with either:

a) manual ventilation by moving the bag/vent switch to "bag" or
b) mechanical ventilation by toggling the bag/vent switch from "bag" to "vent."

The system allows this flexibility so the clinician can decide which mode of ventilation is appropriate for that phase of the case. Similarly, the system allows the clinician to decide when to turn ON inhalation anesthetic agent during the case. This is not done automatically since total intravenous anesthesia (TIVA) may be the selected method of anesthesia delivery, and automatically enabling inhalation anesthetic may result in an unsafe level of total anesthetic delivered. In addition, an alarm that inhalation anesthetic is OFF is not provided since it would result in a nuisance alarm for the TIVA cases. However, the vaporizer setting does clearly display "Off" and the monitored inhalation anesthetic concentrations display "---." If the user does turn ON inhalation anesthetic and if the agent cassette was removed while the agent concentration setting was non-zero, the anesthesia machine will annunciate a low priority "insert cassette" alarm. If the clinician may want to refill an agent cassette during a patient case, to avoid the alarm, the clinician can set the agent concentration to "Off" before removing the cassette. This mirrors the workflow with a mechanical vaporizer, where the clinician would normally turn it off before removing it from the anesthesia machine or filling it with agent. The Aisys and Aisys CS2 remember the last non-zero agent concentration setting when an agent cassette is removed during that patient case. When an agent cassette of the same agent type is re-inserted, the system displays the last non-zero agent concentration setting, sounds a single low priority alarm tone, flashes the setting at a 1 Hz rate, and displays the message "Confirm?" under the setting. This behavior is a prompt to the clinician to confirm the previous agent concentration setting or to enter and confirm a new agent setting. If the clinician does not confirm an agent concentration setting in 30 seconds, the agent concentration will revert to the current agent delivery, which is Off (zero), and sounds a single reject tone. The prompt to confirm the previous agent concentration setting (or enter and confirm a new agent setting) may not occur if certain other higher priority menus are open. If the agent is changed, the clinician needs to start from "Off" as we do not know what setting would be appropriate. Since some clinicians stop agent delivery by simply removing the cassette rather than setting agent delivery to "Off," it would not be appropriate to automatically resume agent delivery when the cassette is reinserted since the user intent is unknown. However, if the clinician wanted to restart agent delivery during the maintenance phase and missed the audible and visual clues to reinitiate the vaporizer, then the anesthetic agent monitoring alarms should catch the event if the alarm limits are set appropriately. I hope this clarifies the Aisys and Aisys CS2 functionality and the rationale behind it.

Regards,
Tim McCormick
Principal Engineer
Anesthesia & Respiratory Care
GE Healthcare

Obesity and Robotic Surgery

by Allison Dalton, MD

INTRODUCTION

Obesity is a worldwide health problem that increases morbidity and mortality.[1] In the United States, the prevalence of obesity is roughly 35% in adults.[2] As the prevalence of obesity increases, one can expect the prevalence of surgery for obese patients to also increase. In pelvic surgeries (i.e., urologic, gynecologic, distal colorectal surgery), robotic assistance conveys certain advantages. For patients with increased subcutaneous tissue, robotic surgery can decrease the physical demand and strain on the surgeon while increasing precision and mobility with the use of wristed surgical instruments.[3] In order to optimize surgical view of the pelvic organs, steep Trendelenburg positioning is utilized in most robotic pelvic procedures. The steep Trendelenburg position, which is defined as 30–40 degrees in the head down position, is associated with risks including hemodynamic changes, altered pulmonary function, airway edema, increased intracranial and intraocular pressure, mechanical sliding, and nerve injury (Table 1).[4] Implementing strategies for risk reduction in the operating room is imperative in this patient population (Table 2).

HEMODYNAMICS

Robotic assisted laparoscopic pelvic procedures require pneumoperitoneum in addition to steep Trendelenburg positioning for optimal surgical visualization. Insufflation of the abdomen with carbon dioxide while in steep Trendelenburg increases systemic vascular resistance (SVR) and mean arterial pressure (MAP) likely secondary to direct compression of the abdominal arteries. Although cardiac output (CO) is usually maintained during the procedure, small decreases may be observed.[5,6] Regional changes in blood flow may occur with insufflation of the abdomen. Mesenteric flow may decrease secondary to increased intraabdominal pressure. Central venous pressure (CVP) may initially be elevated upon initiating steep Trendelenburg position due to increased intrathoracic pressure secondary to pneumoperitoneum as well as cephalad pressure from the intraabdominal contents on the diaphragm.[5] Therefore, under these conditions, CVP may not accurately reflect a patient's intravascular volume status. At a constant insufflation pressure, despite the increases in intraabdominal and intrathoracic pressures, venous return appears to be maintained secondary to the effects of steep Trendelenburg.[5]

Table 1. Risks of robotic pelvic surgery in obese patients

Cardiovascular	• Elevated CVP • Decreased mesenteric blood flow
Respiratory	• Decreased FRC • Decreased ERV • Hypoxia • Hypercapnia • Atelectasis • Respiratory failure
Airway	• Airway edema • Subcutaneous emphysema • Increased risk of respiratory depression with use of analgesics, sedatives, residual anesthesia, residual neuromuscular blockade, Obstructive Sleep Apnea (OSA) or Obesity Hypoventilation Syndrome (OHS)
Nervous System	• Increased ICP • Increased IOP • Visual changes or loss
Positioning	• Nerve injury • Compartment syndrome • Rhabdomyolysis

CVP – central venous pressure; ERV – expiratory reserve volume; FRC – functional residual capacity; ICP – intracranial pressure; IOP – intraocular pressure; OSA – obstructive sleep apnea; OHS – obesity hypoventilation syndrome.

RESPIRATORY SYSTEM

Obesity is associated with various changes in pulmonary physiology. Due to increased intraabdominal pressure and decreases in lung and chest wall compliance, obesity is associated with a restrictive pulmonary process.[7] In addition, obesity is accompanied by decreases in functional residual capacity (FRC) and expiratory reserve volume (ERV) leading to rapid desaturation with apnea or hypoventilation both intraoperatively and postoperatively.[7] Depressed FRC below closing capacity may lead to airway closure during tidal breathing. The degree of airway closure can be correlated with arterial oxygenation and hypoxemia.[7] These physiologic pulmonary changes are amplified under general anesthesia and in steep Trendelenburg.

Pneumoperitoneum with carbon dioxide may lead to significant increases in the partial pressure of carbon dioxide ($PaCO_2$) and

Table 2. Risk reduction for obese patients undergoing robotic pelvic surgery

Cardiovascular	• Ensure adequate volume status • Ensure adequate MAP
Respiratory	• Use lowest peritoneal insufflation pressures possible
Airway	• Re-confirm proper ETT positioning once in steep Trendelenburg • Judicious fluid use to decrease edema risk • Perform cuff leak prior to extubation • Judicious use of opioids, sedatives • Monitor continuous pulse oximetry postoperatively • Postoperative supplemental oxygen is advised • Consider postoperative CPAP as appropriate
Nervous System	• Ensure adequate MAP • Ensure lack of external compression on eyes • Preoperative consultation with neurosurgeon for patients at risk for increased ICP • Preoperative consultation with ophthalmologist for patients at risk for increased IOP
Positioning	• Ensure adequate IV access prior to positioning • Ensure pressure points adequately padded • Decrease sliding risk (i.e., antiskid bedding, lithotomy positioning, padded cross torso straps) • Use the least degree of Trendelenburg possible • Ensure the shortest duration of steep Trendelenburg possible

CPAP – continuous positive airway pressure; ETT – endotracheal tube; ICP – intracranial pressure; IOP – intraocular pressure; MAP – mean arterial pressure.

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Physiologic Changes Associated With Robotic Surgery

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end-tidal carbon dioxide measurements ($EtCO_2$) via absorption of gas from the insufflated abdomen. Increasing minute ventilation and decreasing intraperitoneal CO_2 pressure may abate hypercapnia and acidosis, but ventilation/perfusion (V/Q) mismatch and underlying lung pathology (i.e., obesity and chronic obstructive pulmonary disease) may prevent normalization of $PaCO_2$ or $EtCO_2$. Permissive hypercapnia is generally well tolerated if normocapnia cannot be achieved.[5] Steep Trendelenburg positioning results in increased peak and plateau airway pressures especially in obese patients (Figure 1). However, for the same airway pressure, the transpulmonary pressure, which is the difference between alveolar and intrapleural pressures, is likely lower in the anesthetized morbidly obese patient, secondary to decreased chest wall compliance and higher intraabdominal pressure.[8] Transpulmonary pressure is directly related to the pressure required to distend alveoli. Therefore, the likelihood of barotrauma at any given airway pressure is lower in obese patients than in patients of normal weight. Additionally, due to the increased pressure on the diaphragm from intraabdominal organs, the transpulmonary pressure is lower in the steep Trendelenburg position than in the supine position.[8] Obesity and steep Trendelenburg seem to have protective effects against higher airway pressures. In fact, many experts advocate for accommodating higher airway pressures in obese patients to prevent against alveolar collapse and atelectrauma.[8,9]

There is no ideal ventilation strategy for obese patients undergoing robotic surgery. Increasing evidence supports limitation of tidal volumes to 6–8 mL/kg of ideal body weight, which may result in tidal volumes below 400 mL per breath for some patients.[10] With lower tidal volumes a higher fraction of inspired oxygen (FiO_2) may be required to maintain adequate oxygenation in obese patients.[10] This strategy has been associated with significant atelectasis with resultant hypoxia and hypercapnia. In order to optimize ventilation and minimize hypercapnia for obese patients in steep Trendelenburg, a pressure control ventilation mode may be considered. With pressure control modes (PCV), there is evidence of improved oxygenation and elimination of carbon dioxide while maintaining better alveolar recruitment and decreasing peak airway pressures.[7] The higher inspiratory flow utilized in PCV may result in increased alveolar recruitment and improvement in ventilation/perfusion ratio. PCV may improve hemodynamics and decrease the likelihood of barotrauma, but may be associated with hypoventilation and hypercapnia, which can be particularly detrimental for this patient population.[7] The addition of positive end expiratory pressure (PEEP) can improve oxygenation and guard against alveolar collapse and atelectrauma.[8]

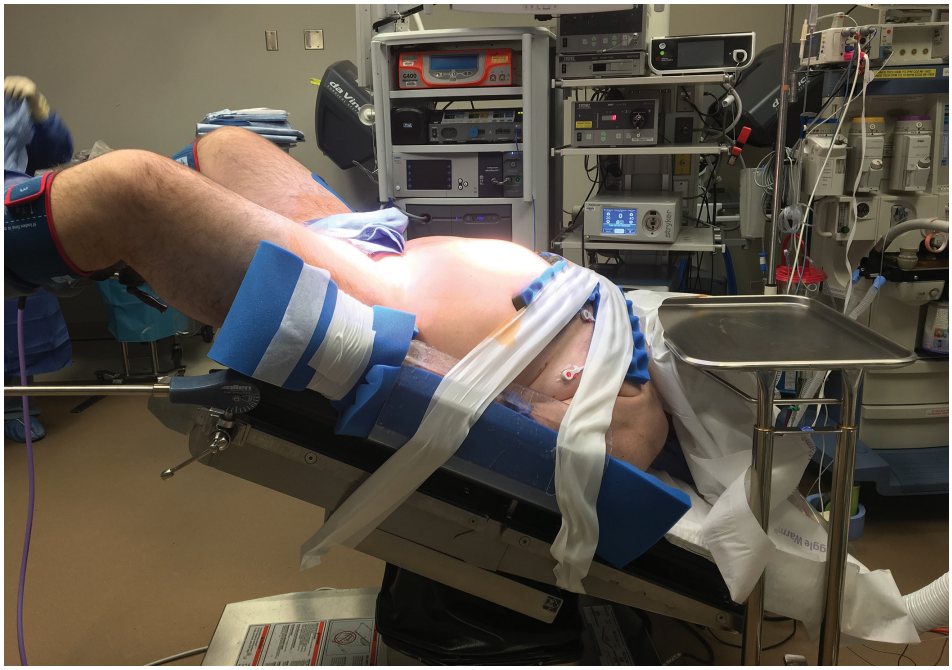

Figure 1. This figure depicts an obese patient in the steep Trendelenburg position being prepared for robotic surgery.

In addition to potentially difficult intraoperative management, obese patients are at risk for postoperative re-intubation following robotic surgery.[11] Many obese patients suffer from obesity hypoventilation syndrome or obstructive sleep apnea resulting in increased risk of hypoventilation postoperatively. Especially when combined with sedatives and opioid medications, patients are at risk for respiratory depression and respiratory failure. Intraoperatively, pneumoperitoneum and fluid administration in steep Trendelenburg are associated with the development of subcutaneous emphysema and airway edema, respectively.[5] Because there is no direct correlation between the degree of facial edema and the presence or severity of pharyngeal or laryngeal edema, performing a cuff leak test prior to extubation may be considered.[5] For patients that cannot ventilate around a decompressed endotracheal tube cuff, anesthesia professionals may need to contemplate temporary postoperative intubation and ventilation.[5]

Obesity is associated with a significantly higher incidence of obstructive sleep apnea as compared to patients of normal weight. With almost half of obese patients suffering from OSA, postoperative monitoring and treatment of hypoxia is obligatory.[12] Postoperatively, patients with OSA are at increased risk for morbidity and mortality associated with increased airway obstruction related to residual anesthetics and sedatives as well as with comparatively small doses of opioid medications.[12] Ahmad and colleagues have shown that obese patients with polysomnograms negative for OSA can have significant postoperative desaturation events despite treatment with supplemental oxygen.[12] Continuous postoperative pulse oximetry should be considered for obese patients with OSA following robotic surgery in steep Trendelenburg.[13] Medications that depress the respiratory drive should be carefully titrated. Supplemental oxygen and CPAP, as appropriate, are recommended to prevent or lessen the severity of hypoxic events.[12,13] Routine ICU admission is not indicated.[12]

CENTRAL NERVOUS SYSTEM

Cerebral blood flow (CBF) is autoregulated under normal physiologic conditions. Although it initially increases with the institution of steep Trendelenburg, cerebral perfusion pressure (CPP) may decrease throughout a robotic procedure especially as the CVP rises due to head-down positioning.[14] As long as MAP is maintained, CPP should remain adequate to support cerebral processes. Due to pneumoperitoneum, positioning,

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Safety Considerations for Obese Patients Undergoing Robotic Surgery

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and increased intraabdominal pressure from obesity, intracerebral pressure (ICP) rises. Hypercarbia causes cerebral vasodilation and increased intraperitoneal and intrathoracic pressure. This in turn, decreases cerebrospinal fluid (CSF) drainage, resulting in elevations in ICP.[14] Despite increases in ICP and evidence of facial and laryngeal edema from steep Trendelenburg positioning, there is no evidence to support the routine development of cerebral edema.[5] For patients in whom abnormal cerebral autoregulation or changes in the blood-brain barrier exist or are suspected (i.e., a space occupying brain lesion), consultation with neurosurgery may be considered.

Ischemic optic neuropathy has been reported after procedures in which steep Trendelenburg has been employed. Steep Trendelenburg is associated with significant increases in intraocular pressure (IOP).[15] Elevations in central venous pressure (CVP), end-tidal carbon dioxide($EtCO_2$), and surgical duration are associated with increased IOP, all of which can be exacerbated by obesity.[15] In steep Trendelenburg, despite maintenance of cerebral and ophthalmologic perfusion pressures, IOP may increase, and ocular perfusion pressure (OPP) may decrease.[16]

POSITIONING

Due to steep head-down positioning, patients are at risk for cephalad slippage on the operating room table.[17] Sliding may result in dermal, nerve, and robotic trocar site-related injuries. Mechanical slipping can be prevented by use of antiskid bedding, knee flexion or lithotomy positioning, shoulder braces, beanbag cradling, and padded cross torso straps.[18] However, shoulder braces and beanbag positioners in particular are associated with increased risk of brachial plexus injury.[19,20] In a simulation study using mannequins of different weights, Nakayama and colleagues found an association between increasing weight and increased cephalad sliding in steep Trendelenburg. Lithotomy positioning decreased the risk of cephalad displacement.[21] Although there is no documented weight limit for steep Trendelenburg, one must continuously ensure proper positioning to prevent against injury. In an effort to decrease risks associated with steep Trendelenburg positioning, Ghomi and colleagues suggested that robotic assisted benign gynecologic surgery can be performed safely in Trendelenburg position with a mean angle of only 16 degrees.[22] However, the patients included in this study had a mean BMI of 28. Additional research must be done to determine the appropriate and safe angle for use in obese patients.

Steep Trendelenburg positioning is associated with risk of nerve injury. Positioning devices may result in injury especially to the brachial plexus. Devices that result in excess pressure on the head may result in injury to the cervical spine. Caudad pressure on the shoulders in steep Trendelenburg may result in stretch injury to the brachial plexus.[5] Prolonged lithotomy positioning increases patient risk for common peroneal nerve injury, compartment syndrome, and rhabdomyolysis.[5,23]

Few data exist regarding weight or timing guidelines for steep Trendelenburg positioning in obese patients. Kalmar and colleagues note that patients of normal weight can safely tolerate even prolonged periods (>6 hours) of steep Trendelenburg.[5] Due to lack of evidence of the time to incur morbidity and mortality in steep Trendelenburg, certain authors advocate for limiting steep Trendelenburg time to less than 5 hours.[18] Due to lack of specific data in obese patients, additional research must be done to determine whether there is an association between duration of steep Trendelenburg and morbidity and/or mortality.

CONCLUSION:

Robotic pelvic surgery may be performed safely in obese patients. Anesthesia professionals must consider that robotic surgery predisposes obese patients to various hemodynamic changes, alters respiratory system physiology, and increases risk for central and peripheral nervous system damage. MAP, CVP, and SVR increase as a result of positioning and abdominal insufflation. Pneumoperitoneum with carbon dioxide leads to elevations in carbon dioxide, which may be difficult to eliminate due to decreased lung and chest wall compliance and elevated airway pressures in obese patients in steep Trendelenburg. Postoperatively, obesity predisposes to increased risk of respiratory depression and airway compromise. Vigilance must be maintained throughout the perioperative period to avoid morbidity and mortality in this vulnerable population.

Dr. Dalton is assistant professor in the Department of Anesthesia & Critical Care at the University of Chicago.

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ALSO IN THIS ISSUE:

Table 1. APSF Perioperative Patient Safety Priorities*

1.	Preventing, detecting, and mitigating clinical deterioration in the perioperative period
2.	Safety in non-operating room locations
3.	Culture of safety
4.	Medication safety
5.	Perioperative delirium, cognitive dysfunction, and brain health
6.	Hospital-acquired infections and environmental microbial contamination and transmission
7.	Patient-related communication issues, handoffs, and transitions of care
8.	Airway management difficulties, skills, and equipment
9.	Cost-effective protocols and monitoring that have a positive impact on safety
10.	Integration of safety into process implementation and continuous improvement
11.	Burnout
12.	Distractions in procedural areas

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