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ABSTRACT & COMMENTARY

See No Lights, Hear No Alarms: How to Sleep in the ICU Environment

By Eric Walter, MD, MSc

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Dr. Walter reports no financial relationships relevant to this field of study.

SYNOPSIS: Melatonin supplementation and the use of eye masks and earplugs improved sleep quality among healthy volunteers sleeping in a simulated ICU environment.

SOURCE: Huang HW, et al. Effect of oral melatonin and wearing earplugs and eye masks on nocturnal sleep in healthy subjects in a simulated intensive care unit environment: Which might be a more promising strategy for ICU sleep deprivation? *Critical Care* 2015;19:124.

Sleep deprivation is common in the ICU and may make patients agitated, delirious, or just plain tired. But beyond these effects, data suggest that sleep deprivation possibly affects the immune system, respiratory mechanics, and hormonal balances.[1] The causes of sleep deprivation in the ICU are multifaceted. Excess light and noise, night time evaluations, and procedures cause interrupted sleep. Darkness stimulates normal melatonin secretion and helps maintain routine circadian rhythm, while light interferes with these processes. Critically ill patients lose the

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ability to regulate melatonin secretion in response to light and dark, with levels often measured very low in them. Some ICU clinicians have suggested the use of ear plugs and eye masks to improve sleep quality, along with melatonin supplementation. However, it is unknown if either of these practices actually improves sleep quality in an ICU environment. This study examined the effect of these measures on sleep quality.

Measuring sleep quality in the ICU is challenging. Polysomnography (PSG) in ICU patients is difficult to interpret. Frequent interruptions, hormonal imbalances, medications, neurologic injury, and other factors affect electroencephalographic patterns. To avoid these concerns, Huang and colleagues studied normal subjects in a simulated ICU environment. The study was comprehensive and well thought out. Forty volunteers underwent PSG on eight consecutive nights. This allowed subjects to become used to the equipment on night 1. Data on sleep quality were then collected under both normal sleeping conditions and in a simulated ICU environment on nights 2 and 3. The simulated ICU included previously recorded ICU sounds and lights specifically set to premeasured ICU light levels. The subjects were then randomized to one of four groups: no treatment, placebo, the use of ear plugs and eye masks, or 1 mg of melatonin supplementation. Sleep quality was then measured for three consecutive nights.

As expected, subjects had worse sleep when exposed to the simulated ICU environment. When exposed to ICU sounds and light levels, subjects had more awakenings (14.4 vs 9.9; P = 0.011), longer sleep latency (66.2 vs 23.4 minutes, $P < 0.001$), less REM sleep (15.8 vs 21.9%; $P = 0.006$), and slept about 1 hour less (359.2 vs 424.3 minutes, $P < 0.001$). Subjects also had lower melatonin levels on nights in which they were exposed to the ICU environment compared to their baseline nights. During the intervention portion of the study, several measures of sleep quality (both objective and subjective) improved in both of the groups randomized to the use of ear plugs, eye masks, and melatonin. No improvements were seen in the group randomized to placebo. When compared to ear plugs and eye masks, melatonin improved subjective sleep quality more than ear plugs and eye masks. Melatonin use was also associated with fewer awakenings than ear plugs and eye masks, but all other objective measures of sleep quality were not significantly different.

■ COMMENTARY

At first glance, this article may not seem relevant to the practicing ICU clinician. Huang and colleagues evaluated sleep aids in normal, healthy, volunteer subjects in a simulated ICU environment. It is true these findings may not apply to ICU patients who may be hypotensive, intubated, sedated, or otherwise. However, this study serves as proof of concept. Huang and colleagues show that sleep quality in an ICU environment can improve with the use of ear plugs and eye masks or melatonin supplementation. Hopefully, these background data will be useful to inform future studies in ICU patients. How should the practicing clinician interpret these findings? With caution. It would be overreaching to believe these data prove the efficacy (and safety) of either of these interventions. The data support the concept, but these questions must be further evaluated in future studies.

Obtaining quality sleep may be one of the last priorities in the ICU. Sleep sits below the history and physical exam, nurses admit paperwork, central venous catheters, routine neuro checks, and so on. In fact, sleep sits so low on the ICU totem pole that we routinely schedule blood draws and bathing between 3 a.m. and 5 a.m. Fortunately, the potential negative consequences of poor sleep are beginning to be discussed. Attempts to improve sleep are being implemented, albeit, without much data. It is somewhat naïve to assume we can plug our patient's ears and cover their eyes and they will get a good night's sleep. By the same token, the concept that simply replacing low melatonin levels in sleep-deprived patients will improve sleep sounds good, but belies the fact that we could be potentially causing harm. Although preliminary,

studies such as this provide important data to guide research into how we can best improve our patient's sleep. ■

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ABSTRACT & COMMENTARY

Is Fresh Blood Better?

By Kathryn Radigan, MD, MSc

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Dr. Radigan reports no financial relationships relevant to this field of study.

SYNOPSIS: Critically ill patients transfused with red blood cells less than eight days old do not experience better outcomes than patients transfused with standard-issue red cells.

SOURCE: Lacroix J, et al. Age of transfused blood in critically ill adults. *N Engl J Med* 2015;372:1410-1418.

The transfusion of fresh red blood cells in critically ill patients may improve oxygen delivery and minimize exposure to the toxins and bioactive byproducts related to prolonged storage. With the Age of Blood Evaluation (ABLE) trial, Lacroix et al sought to determine if there was a benefit to the transfusion of fresh red blood cells as opposed to standard-issue red cells. In this multicenter, randomized, blinded trial conducted between March 2009 and May 2014 at 64 centers in Canada and Europe, 1211 patients were assigned fresh red blood cells and 1219 patients were assigned standard-issue red blood cells. The primary outcome measure was 90-day mortality. The fresh red blood cells were stored for a mean of 6.1 ± 4.9 days, and the standard-issue red cells were stored 22.0 ± 8.4 days ($P < 0.001$). After 90 days, 448 patients (37%) in the fresh red blood cell group had died while 430 patients (35.3%) in the standard-blood group had died (absolute risk difference: 1.7%; 95% confidence interval [CI], -2.1 to 5.5). The hazard ratio for death in the fresh red blood cell group as compared to the standard-blood group was not significant at 1.1 (95% CI, 0.9 to 1.2; $P = 0.38$). There were also no significant differences in secondary outcomes, including major illnesses, length of hospital stay, transfusion reactions, and duration of respiratory, hemodynamic, or renal support.

■ COMMENTARY

Anemia is overwhelmingly common in the ICU. Up to 90% of critically ill patients develop anemia by their third day of admission.[1] In fact, 20-40% of critically ill patients are transfused with an average of 2-5 units of red cells per patient.[2] Even though transfusion in the ICU is common, it is associated with increased risk of morbidity and mortality. Red blood cells can be stored for up to 42 days, and this storage is often associated with adverse changes in erythrocytes and their preservation media. These changes may influence erythrocyte oxygen affinity, ability to change shape, membrane stability, and a number of other factors that may affect the efficacy of transfusion.

As there is concern for the potential harmful effects of this stored blood in critically ill patients, there have been multiple animal studies, observational studies, and single-center studies with conflicting findings. The ABLE trial as described above clearly showed that transfusion of fresh red blood cells compared to standard-issue red blood cells did not decrease 90-day mortality among critically ill patients. In addition, there were no differences in secondary outcomes. Most importantly, the trial followed a restrictive transfusion strategy with a mean pre-transfusion hemoglobin level of 7.7 g/dL. The results of the ABLE trial are consistent with several other randomized, controlled trials that compared different durations of red cell storage and found no difference in mortality rates. Although the conclusions from this trial appear to be clear, the TRANSFUSE trial is an additional, multicenter trial being conducted in Australia and New Zealand, consisting of 5000 critically ill patients with a primary outcome of 90-day mortality; completion of the trial is expected in 2016.

The ABLE trial supports the notion that the relative expiration date of red blood cells is not important. For now, we should not have to worry that standard-issue red cells are harming our patients and should continue to focus our attention on limiting transfusions to circumstances supported by evidence-based medicine. ■

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ABSTRACT & COMMENTARY

Decreasing Cross-Transmission of Carbapenemase-Producing Enterobacteriaceae

By Elaine Chen, MD

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Dr. Chen reports no financial relationships relevant to this field of study.

SYNOPSIS: A bundled infection control intervention was shown to decrease cross-colonization, prevalence, and bloodstream infection of *Klebsiella pneumonia* carbapenemase-producing enterobacteriaceae in long-term acute care hospitals, which may have far-reaching effects into the ICU.

SOURCE: Hayden MK, et al. Prevention of colonization and infection by *Klebsiella pneumonia* carbapenemase-producing enterobacteriaceae in long term acute care hospitals. *Clin Infect Dis* 2015;60:1153-1161.

Carbapenem-resistant enterobacteriaceae (CRE) are highly resistant to multiple classes of antibiotics and pose a serious threat to our ability to control infections. *Klebsiella pneumonia* carbapenemase-producing enterobacteriaceae (KPC) are the most common in this group. Colonization usually precedes infection, and colonization is frequently acquired by cross-contamination in healthcare settings, particularly high-prevalence areas. Because prevalence is higher in long-term acute care hospitals (LTACHs) than elsewhere, this study was undertaken to try to decrease incidence of prevalence of KPC in LTACHs.

This quality improvement project was implemented in 4 LTACHs in a single metropolitan area. Baseline prevalence of KPC was measured before the intervention was initiated. The KPC intervention bundle included rectal swabs for KPC for all patients on admission and every 2 weeks thereafter during their hospitalization, contact isolation, geographic separation of KPC-positive patients, chlorhexidine (CHG) baths, and healthcare worker hand hygiene education and monitoring. All healthcare workers underwent a series of mandatory educational sessions. Adherence to all measures but one, including collection of admission and periodic surveillance swabs, geographic isolation of KPC-positive patients, hand hygiene at room exit, and donning gloves and gown before room entry, was greater than 70% during the intervention; adherence to hand hygiene at room entrance was low at 24%.

In the pre-intervention period, average KPC prevalence was 45.8% (95% confidence interval [CI], 42.1-49.5%). In the post-intervention period, following an initial decline, prevalence plateaued at 34.3% (95% CI, 32.4-36.2%; $P < 0.001$ for exponential decline). Admission prevalence remained stable at 20.6%, but incidence rate of KPC colonization decreased from four to two acquisitions per 100 patient-weeks ($P = 0.004$ for linear decline). Rates of KPC in any clinical culture, KPC bloodstream infection, bloodstream infection due to any pathogen, and contaminated blood cultures all decreased significantly during the intervention period.

Overall, this study showed that the implementation of a bundled infection control intervention was able to significantly decrease cross-transmission of a multi-drug-resistant pathogen and decrease healthcare-associated infections in an LTACH population.

■ COMMENTARY

Drug-resistant organisms have been increasing morbidity and mortality in healthcare settings. They are more common in LTACHs than in short-term acute care hospitals, and the chronically critically ill population is particularly at risk due to their high frequency of transfer among healthcare facilities. CRE (including KPC) colonization and infection are an increasing concern in ICUs, and have been associated with significantly longer ICU length of stay and higher mortality.[1] By decreasing KPC cross-transmission and infection in high-prevalence settings, there may be potential to decrease length of stay as well as mortality in both long-term and short-term care units.

This study presents a comprehensive infection control bundle, which was shown to decrease colonization

and infection by KPC. Due to the bundled nature of the intervention, individual components of the bundle leading to improvement could not be identified. The authors speculate that the CHG baths were the intervention most responsible for the decrease in bloodstream infection, and that the bundled intervention is necessary to control cross-colonization. This bundle, as applied in LTACHs, has the potential to slow the regional spread of KPC and to decrease morbidity and mortality in both lower-acuity settings (such as skilled nursing) and higher-acuity settings (such as short-term ICUs). Potential drawbacks to the technique include high cost/benefit ratio and selection of further resistance with CHG baths. The authors propose further testing, including simulation modeling and molecular epidemiologic methods, to evaluate long-term and regional effects of the intervention. ■

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ABSTRACT & COMMENTARY

Inferior Vena Cava Filters and Recurrent Pulmonary Embolism

By Samuel Nadler, MD, PhD

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Dr. Nadler reports no financial relationships relevant to this field of study.

SYNOPSIS: Placement of retrievable inferior vena cava filters in individuals with concurrent deep vein thrombosis does not reduce the risk of recurrent pulmonary embolism.

SOURCE: Mismetti P, et al. Effect of a retrievable inferior vena cava filter plus anticoagulation vs anticoagulation alone on risk of recurrent pulmonary embolism: A randomized clinical trial. *JAMA* 2015;313:1627-1635.

Inferior vena cava (IVC) filters have increasingly been used as add-on therapy in patients with pulmonary embolism (PE), particularly if there is an additional clot burden in the legs, leading to concern that an additional embolism would be life-threatening. However, there are no data from randomized, controlled trials to support this intervention. The PREPIC2 study is a randomized, open-label, blinded endpoint trial that specifically addresses this question. From August 2006 to January 2013, 399 patients with acute symptomatic PE associated with persistent lower limb venous thrombosis who were at high risk for clinical decompensation were randomized to retrievable IVC filter placement for 3 months, plus systemic anticoagulation for 6 months vs anticoagulation alone. High risk was defined as having, in addition to the PE, one of the following: active cancer, chronic cardiac or respiratory insufficiency, ischemic stroke within the last 6 months, deep venous thrombosis (DVT) within the iliocaval segment or bilateral DVTs, signs of right ventricular strain or myocardial injury, and age > 75 years. Exclusion criteria included: previous IVC filter placement, inability to place an IVC filter, full dose anticoagulation for greater than 72 hours before randomization, recent surgery, allergy to contrast media, creatinine > 2.04 mg/dL, pregnancy, life expectancy less than 6 months, or contraindication to systemic anticoagulation. The primary outcome was fatal or symptomatic pulmonary embolism recurrence at 3 months. Secondary outcomes included a 6-month time point, rates of major bleeding or death from any cause, filter complications such as infection, hematoma formation, malposition of the IVC filter, or penetration of the IVC.

At 3 and 6 months, there were no statistically significant differences in rates of recurrent fatal or symptomatic pulmonary embolism between the group that received both an IVC filter and anticoagulation vs anticoagulation alone (6% vs 3%, $P = 0.50$, and 7% vs 4%, $P = 0.54$, respectively). There were no differences between both groups at 3 months for secondary outcomes, such as recurrent DVT (0.5% vs 0.5%, $P > 0.99$), major bleeding (8% vs 10%, $P = 0.63$), and death (15% vs 12%, $P = 0.55$). Similarly, there were no observed differences in either primary or secondary outcomes at 6 months. The two groups were well-matched demographically and had similar rates of anticoagulation with vitamin K antagonists (83% vs 88.9%), INR (2.3 vs 2.3), duration of anticoagulation (median 182 days vs 181 days), and

percentage of time spent with INR within the target range of 2-3 (58.3% vs 61.5%). Remarkably, there was a very high rate of filter retrieval at 3 months; of 193 filters inserted, 153 (79.3%) were removed. Of the 40 filters not retrieved, no attempt was made in 16 patients due to illness, filter thrombosis, patient refusal, or persistent indication for filter placement. Only 11 patients had failure of the filter to be retrieved, three due to adherence to the IVC wall and eight due to a tilted position of the filter.

■ COMMENTARY

Since their introduction, the rates of IVC filter placement for both DVT and PE have increased dramatically.[1] Since the introduction of removable IVC filters around 2001, rates of placement have further risen three-fold. Some of this increase is attributable to prophylactic placement for patients at high risk in whom anticoagulation is contraindicated, but in many instances, IVC filters are placed in individuals with PE who have persistent lower extremity DVTs when there is concern that additional embolism will lead to hemodynamic decompensation. The current study by Mismetti et al questioned the efficacy of this practice, and no benefit was observed with retrievable IVC filter placement.

Previous studies had demonstrated mixed results with non-retrievable IVC filters. The first PREPIC study published in 1998 demonstrated a decreased rate of PE at 12 days after filter placement (1.1% vs 4.8%, $P = 0.03$) in patients with DVTs, but no difference at 2 years in symptomatic PE (3.4% vs 6.3%, $P = 0.16$). However, there was a significant increase in the rates of recurrent DVT (20.8% vs 11.6%, $P = 0.02$).[2] An 8-year follow-up study of this group demonstrated decreased rates of symptomatic pulmonary embolism (6.2% vs 15.1%, $P = 0.008$), but an increased rate of recurrent DVT (35.7% vs 27.5%, $P = 0.042$) without changes in mortality.[3] In that study, anticoagulation was mandated for 3 months only, but 61% of patients with IVC filters placed were anticoagulated at 8 years. There was concern the device was causing recurrent DVTs, and this prompted the notion that retrievable filters would prevent early PE recurrence but avoid long-term DVTs.

The results of the current study seem to indicate that placement of a retrievable IVC filter does not improve outcomes in patients with PE at high risk for decompensation. It should be noted that this study was powered with the assumption of an 8% incidence of mortality at 3 months, and the study demonstrated a far lower rate. Thus, it was underpowered for its primary outcome, and the study was terminated at an interim analysis due to futility. There may be subsets of patients in whom retrievable IVC filters may change mortality. However, this study specifically included those patients at highest risk for decompensation, including patients with residual proximal DVT (69%) and with RV strain (66%), and found no benefit. Even in patients who seem most vulnerable to additional embolism, retrievable IVC filter placement plus anticoagulation did not improve outcomes vs anticoagulation alone. ■

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ABSTRACT & COMMENTARY

When Do Ventilator Modes Matter?

By Richard Kallet, MS, RRT, FAARC, FCCM

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Mr. Kallet reports no financial relationships relevant to this field of study.

SYNOPSIS: Although pressure-controlled ventilation (PCV) and volume-controlled ventilation (VCV) approach mechanical breath delivery differently in terms of inspiratory flow and airway pressure characteristics, this comprehensive review found no significant differences in terms of their impact on breathing mechanics or gas exchange in patients with various forms of acute respiratory failure.

SOURCE: Rittayamai N, et al. Pressure-controlled vs volume-controlled ventilation in acute respiratory failure: A physiology-based narrative and systematic review. *Chest* 2015 Apr 30 [Epub ahead of print].

The study was divided into two parts: 1) a concise description of the working principles of pressure-controlled ventilation (PCV) and volume-controlled ventilation (VCV) modes, and 2) a comprehensive review of the literature. In the first section, the authors reviewed how each breath delivery style functions during both continuous mechanical ventilation (CMV) and partial support modes, such as synchronized intermittent mandatory ventilation (SIMV). In the systematic review, the authors de-limited the search to studies that directly compared modes in critically ill patients with various causes of acute respiratory failure and reported data on respiratory system compliance (Crs), patient work of breathing (WOB), gas exchange, hemodynamics, and patient outcomes. Thirty-four studies met inclusion criteria and included 880 patients using random effects models. Approximately half of these patients had acute respiratory distress syndrome (ARDS). In general, the studies were small, varied widely in terms of quality, and were at high risk for bias.

No statistically significant differences were found between modes in their effects on Crs, oxygenation, ventilation efficiency, hemodynamics, mortality, or ICU length of stay. The only difference distinguishing these modes was a reduction in patient WOB during PCV, and this result was limited to situations when the peak inspiratory flow rate was lower during VCV. The authors concluded that the choice of ventilator mode should be based on the clinical context and focused almost exclusively on whether the impact of patient-ventilator asynchrony on patient WOB was problematic. There was no compelling evidence that the inspiratory flow pattern itself impacts gas exchange in any clinically meaningful way.

■ COMMENTARY

This study is a welcome contribution to the medical literature, as it provides an elegant and masterful description of mechanical ventilation as well as a comprehensive review of the impact of ventilator modes. My own research on the effects of PCV and VCV was piqued by my experiences in the early years of the AIDS epidemic. By the fall of 1981, our medical ICU consisted almost entirely of young men suffering from pneumocystis pneumonia managed with the only modes available at the time: VC-CMV or VC-SIMV. I vividly recall these young men writing detailed notes about their breathing sensations.

Despite tailoring their settings according to their feedback, the improvement in synchrony was at best ephemeral. In April 1982, we purchased our first ventilator with PCV and PSV. Despite a complete lack of evidence, we were desperate to try anything. The positive impact of these modes was immediately noticeable.

The important lessons learned over the past 30 years can be distilled down to the following: First, patient demand for flow and tidal volume reflects the velocity and shortening of the inspiratory muscles. Any mismatch between demand and ventilator performance imposes additional tension on the inspiratory muscles that induces or magnifies dyspnea. Second, the natural response to dyspnea and increased WOB is increase respiratory drive and includes abdominal muscle recruitment to enhance inspiratory muscle performance. Third, the resulting large negative and positive cyclical changes in pleural pressure exaggerate gas exchange dysfunction by enhancing alveolar edema formation on inspiration and derecruitment during expiration. Fourth, the humane impulse to let patients dictate their breathing pattern or use generous amounts of sedation to control breathing are both problematic, as they paradoxically worsen patient outcomes.

The most helpful guide is to place asynchronous patients on a brief trial of continuous positive airway pressure to assess their ventilator demand. This provides immediate feedback about whether satisfying a patient's ventilatory demand significantly increases the risk of ventilator-induced lung injury. It also allows for assessing whether increasing sedation or using paralytics presents even greater risks. Oversedation is often due to an inadequate evaluation of analgesic needs. It is important to emphasize that breathing patterns also express emotional states and bodily sensations.

Moreover, moderately increased WOB and mild asynchrony generally are well tolerated, and therefore, do not necessarily require optimization in those with stable gas exchange or in those not at risk for muscle fatigue. Optimal synchronization and guaranteeing passive ventilation is likely to impact outcomes only during the acute phase among the most critically ill, unstable patients.

Balancing lung protection and sedation are crucial. Modes are of secondary importance in dealing with patient-ventilator asynchrony. It behooves ICU clinicians to possess both an in-depth understanding of the physiology, mechanics, and proprioceptive aspects of the problem and the wisdom to know what context requires meticulous attention to optimizing patient-ventilator asynchrony. ■

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CME/CNE QUESTIONS

1. Based on the study by Hayden et al, which of the following statements is true regarding KPC colonization and control?

a. All skilled nursing facilities should implement a bundled infection control intervention to decrease mortality.

b. To decrease cross-colonization, healthcare providers should increase their hand hygiene at room entrance.

c. Performing serial rectal swabs for KPC has the potential to increase cross-colonization due to fecal transmission.

d. A bundled infection control intervention aimed at decreasing KPC colonization was shown to decrease bloodstream infections by other pathogens.

e. By decreasing prevalence of KPC using the bundle, LTACH discharge rates improved.

2. Compared with systemic anticoagulation alone, IVC filter plus anticoagulation at 3 and 6 months leads to:

a. increased rates of recurrent PE.

b. increased rates of recurrent DVT.

c. increased rates of mortality.

d. increased rates of major bleeding.

e. no change in major clinical outcomes.

3. Which of the following statements is true regarding VCV and PCV?

a. Neither mode is superior in improving Crs.

b. PCV is superior in improving WOB only when its peak flow rate is higher than VCV.

c. The decreasing ramp flow pattern during PCV improves oxygenation better than VCV.

d. VCV reduces duration of mechanical ventilation.

e. Both a and b are true.

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Upon completion of this educational activity, participants should be able to:

- identify the particular clinical, legal, or scientific issues related to critical care;
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