AHC Media

Vol. 19, Issue 6, September 2011
www.ahcmedia.com

Critical Care [ALERT]

A monthly update of developments in critical care and intensive care medicine

SPECIAL FEATURE

PEEP for One and PEEP for All

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Dr. Hess serves as a retained consultant for Philips Respironics, ResMed, Breathe, and Pari, and also receives honorarium from Covidien.

Would you like to start a fight? Just ask a colleague how he or she selected the level of positive end-expiratory pressure (PEEP) for a patient. The response is likely to be emotional, but equally likely to lack support from high-level evidence. Although PEEP is beneficial for most, if not all, mechanically ventilated patients, the available evidence is not particularly helpful in guiding selection of PEEP for an individual patient. In this essay, I will discuss the use of PEEP not only in the setting of acute lung injury/acute respiratory distress syndrome (ALI/ARDS), but also to reduce micro-aspiration, to counterbalance auto-PEEP, to aid the failing heart, to splint airways in the presence of tracheomalacia, and to improve speech in tracheostomized patients with cuff-down technique.

PEEP FOR ALI/ARDS

That ventilator-induced lung injury (VILI) can result from inappropriate ventilator settings is well accepted. Tidal volume and inspiratory pressure limitation are standards of care to avoid over-distention. It also is accepted that cyclical alveolar opening and closing throughout the respiratory cycle is injurious; thus PEEP sufficient to maintain alveolar recruitment also is important. There should be no argument that no PEEP (zero) is harmful in patients with ARDS. But the level of PEEP to be used is controversial.

In three clinical trials,[1-3] tidal volume was held constant at 6 mL per kg of ideal body weight with patients assigned to receive either a higher or a lower level of PEEP. In the groups of patients receiving higher levels of PEEP, there were benefits such as

Financial Disclosure: *Critical Care Alert*'s editor, David J. Pierson, MD, nurse planner Leslie A. Hoffman, PhD, RN, and peer reviewer William Thompson, MD, report no financial relationships to this field of study.

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Critical Care [ALERT]

Critical Care Alert,
ISSN 1067-9502, is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road., NE Building 6, Suite 400 Atlanta, GA 30305.

POSTMASTER: **Send address changes to Critical Care Alert, P.O. Box 105109, Atlanta, GA 30348.**

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Subscription Prices
United States
1 year with free AMA Category 1 credits: $319
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Back issues: $40 Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue's date.

Canada Add GST and $30 shipping. Elsewhere Add $30 shipping.

GST Registration Number: R128870672. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

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Table. Approaches to Setting PEEP in Patients with ALI/ARDS

Gas exchange	
	Oxygenation: PEEP/FIO_2 tables
	Dead space
Respiratory mechanics	
	Compliance (lowest Pplat – PEEP)
	Pressure-volume curve
	Stress index
	Transpulmonary pressure (esophageal balloon)
Imaging	
	Chest CT
	EIT
	Ultrasound

Key: acute lung injury (ALI); acute respiratory distress syndrome (ARDS); computed tomography (CT); electrical impedance tomography (EIT); inspired oxygen fraction (FIO_2); positive end-expiratory pressure (PEEP); end-inspiratory plateau pressure (Pplat)

higher PaO_2/FIO_2, higher respiratory system compliance, less frequent use of rescue therapies for refractory hypoxemia, and a greater number of ventilator-free days. But there was no significant reduction in mortality for patients receiving higher PEEP.

The value of a meta-analysis is that by pooling data from several studies, statistical power is improved. There have been five meta-analyses published on the use of higher vs lower PEEP in patients with ALI/ARDS.[4-8] The results of these meta-analyses are similar: The use of higher levels of PEEP, when compared to use of moderate levels of PEEP, does not lead to lower mortality in groups of unselected patients with ALI/ARDS.[9] Why is this?

If alveolar recruitment potential is low, an increase in PEEP may contribute to over-distention of already open alveoli. This results in a decrease in respiratory system compliance, increased dead space, and redistribution of pulmonary blood flow to unventilated alveoli. But when the potential for recruitment is high, the benefit of higher levels of PEEP may outweigh harm due to over-distention. When the PaO_2/FIO_2 is lower (that is, in ARDS rather than ALI), the potential for recruitment may be greater and this may lead to lower mortality.[4] The potential for recruitment also may be greater when chest wall compliance is reduced.[10] The available evidence suggests that modest levels of PEEP may be more appropriate for ALI whereas higher levels of PEEP should be used for ARDS.[4] Higher levels of PEEP should be reserved for patients in whom alveolar recruitment can be demonstrated. Increasing PEEP while driving up the plateau pressure to harmful levels makes no sense.

A variety of techniques for PEEP selection have been described (*see Table*).[9] Some have suggested a decremental procedure in which PEEP is initially set ≥ 20 cm H_2O and then decreased to identify the level that produces the best compliance. The one study that evaluated this approach did not report a benefit.[11]

PEEP TO REDUCE MICRO-ASPIRATION

It is accepted that the source of contamination of the lower respiratory tract leading to ventilator-associated pneumonia is usually microaspiration of upper airway secretions from around the cuff of the endotracheal tube. This has led to redesigns of the cuff to minimize the creation of longitudinal folds when the cuff is inflated[12] and avoidance of a cuff pressure < 20 cm H_2O.

There are several in vitro studies that report a reduction in leak past the cuff when PEEP is applied.[13-15] Presumably, the tracheal pressure generated by PEEP produces back-pressure, which inhibits

leakage from the upper airway. In a clinical study of intubated postoperative patients with normal lungs, it was reported that the rate of ventilator-associated pneumonia with 5 cm H_2O PEEP was significantly lower than with a PEEP of zero.[16] This suggests that PEEP should be used in a bundle of strategies to reduce the risk of ventilator-associated pneumonia.

PEEP TO COUNTERBALANCE AUTO-PEEP

Auto-PEEP is a threshold pressure that must be overcome by a spontaneously breathing patient before the pressure (or flow) decreases at the proximal airway to trigger the ventilator. Increasing the set PEEP to counterbalance auto-PEEP may improve the patient's ability to trigger the ventilator.[17] Typically, the patient with auto-PEEP will be asynchronous with the ventilator, such that there are inspiratory efforts that do not trigger the ventilator. The PEEP setting is increased until the patient can comfortably trigger the ventilator, provided that there is no increase in plateau pressure. PEEP should be used in patients with chronic obstructive pulmonary disease (COPD) only to unload the respiratory muscles from the auto-PEEP due to expiratory flow limitation. If auto-PEEP is not caused by flow limitation, application of PEEP will cause further hyperinflation, worsening respiratory mechanics, muscle activity, and hemodynamics.[18]

The use of PEEP in the setting of auto-PEEP for acute asthma is more controversial.[19] Whereas small airway collapse and flow limitations occur in COPD, with asthma the site of increased resistance is in central, less collapsible airways. The results of one study suggest that the physiology may be variable, so some patients with acute asthma respond to PEEP with an increase in lung volume, some with no change in lung volume, and some with a paradoxical decrease in lung volume.[20] This suggests that the use of PEEP to counterbalance auto-PEEP in acute asthma must be individualized, balancing the benefit of improved ability to trigger against the risk of worsening dynamic hyperinflation.

PEEP TO AID THE FAILING HEART

The increase in intrathoracic pressure associated with PEEP can aid the failing heart by decreasing preload and afterload. In addition, PEEP increases lung volume, which decreases the work of breathing and improves arterial oxygenation. This is most commonly appreciated with the use of continuous positive airway pressure (CPAP) by facemask in patients with acute cardiogenic pulmonary edema. In a recent Cochrane review,[21] CPAP plus standard medical care compared with standard medical care alone (12 trials, 614 patients) was associated with a significantly lower hospital mortality in CPAP-treated patients (relative risk [RR] 0.58, 95% CI 0.38 to 0.88); this translates into a number-needed-to-treat (NNT) of 9. CPAP plus standard medical care compared with standard medical care alone (12 trials, 616 patients) was associated with a significantly lower rate of endotracheal intubation favoring CPAP-treated patients (RR 0.46, 95% CI 0.32 to 0.65, NNT 6). Available evidence supports the use of mask CPAP as standard therapy for acute cardiogenic pulmonary edema. Similar results occur with noninvasive ventilation.[21]

PEEP TO SPLINT AIRWAYS

Tracheomalacia is a weakness of the trachea that leaves the airway susceptible to collapse. With tracheomalacia, there is accentuation of the physiologic process in which the intra-thoracic trachea dilates with inspiration and narrows with exhalation due to changes in intrathoracic pressure. Tracheal collapse during exhalation results from this narrowing. CPAP, by creating a "pneumatic stent," prevents the collapse of the airway throughout the respiratory cycle. CPAP and PEEP have been used as an effective treatment for tracheomalacia in both infants and adults.[22]

PEEP TO FACILITATE SPEECH

In a patient with a tracheostomy tube, gas can escape through the upper airway during the inspiratory phase if the cuff is deflated. Simple manipulations of the ventilator settings allow the patient to speak during both the inspiratory phase and expiratory phase. This avoids the use of a speaking valve, which provides safety if the upper airway becomes obstructed. If the PEEP setting on the ventilator is zero, most of the exhaled gas exits through the ventilator circuit rather than passing around the deflated cuff and through the upper airway. In this situation, there is little ability to speak during the expiratory phase. If PEEP is set on the ventilator, then expiratory flow is more likely to occur through the upper airway when the cuff is deflated, which increases the ability to speak. A longer inspiratory time and higher PEEP are additive in their ability to improve speaking. Tracheal pressure (important for speech) is similar with the use of PEEP and the use of a speaking valve.[23]

COMPLICATIONS OF PEEP

Some phobia exists related to PEEP with respect to complications such as barotrauma and hemodynamic compromise. However, these complications relate to excessive PEEP, not correctly selected PEEP. If PEEP is appropriately selected, with the risk of over-distention

monitored in the individual patient, complications of PEEP are minor or nonexistent.

SUMMARY

PEEP is beneficial in most, if not all, patients receiving invasive or noninvasive mechanical ventilation. But PEEP has potential for both benefit and harm. It is the job of the bedside clinician to balance benefit against harm as the level of PEEP is selected for an individual patient. Determining the appropriate level of PEEP often involves a bedside n-of-1 experiment (that is, varying the PEEP setting and objectively assessing both the positive and negative effects); the level used needs to be reassessed as the patient's condition changes over time. ■

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ABSTRACT & COMMENTARY

To Brush 'Em or Not: Does Tooth Brushing Prevent Ventilator-Associated Pneumonia?

By Linda L. Chlan, RN, PhD

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Dr. Chlan reports that she receives grant/research support from the National Institutes of Health.

SYNOPSIS: The evidence to date reviewed in this paper does not strongly support tooth brushing in all critically ill patients to prevent ventilator-associated pneumonia and further high-quality research is needed to address the weaknesses in this body of literature.

SOURCE: Ames NJ. Evidence to support tooth brushing in critically ill patients. *Am J Crit Care* 2011;20:242-250.

The purpose of this review paper was to summarize the evidence on the effect of tooth brushing to prevent ventilator-associated pneumonia (VAP) in critically ill adults and children receiving mechanical ventilatory support. The basic premise is that oral-cavity bacteria can cause VAP and that regular tooth brushing removes bacteria from the mouth that cause VAP. The author notes that the main issue with regular oral care, including tooth brushing in mechanically ventilated patients, is the potential for oral-cavity bacteria to enter the bloodstream from the breakdown of mucosal and gingival tissue in those patients with poor dental health. If this occurs, the patient is at risk for bacteremia and hypotension, particularly in those patients who are immunologically compromised. The question remains as to whether regular tooth brushing consistently prevents VAP such that the intervention outweighs the risk for bacteremia.

A total of eight published articles investigating tooth brushing on VAP prevention were reviewed. Of these papers, three were randomized controlled trials (RCTs), one was case-control, and four had observational designs. Only one paper enrolled critically ill children, including nine who were intubated for less than 24 hours. It was noted that this study was the first-ever publication to describe the oral microbiome in children. Five studies measured VAP rates retrospectively and not all designs used a control or usual-care group for comparison. A variety of methods were used to confirm VAP, including the clinical pulmonary infection score (CPIS), cultures, or bacterial composition of the oral microbiome. In addition to VAP rates, other outcomes included length of time mechanically ventilated, length of ICU stay, mortality, and antibiotic-free days. Five of the eight studies had positive findings for the prevention of

VAP with regular tooth brushing. The remaining three studies had non-significant findings for VAP reduction or prevention. There were, however, inconsistent diagnoses of VAP reported across studies using either the CPIS or cultures; not all VAP rates were documented microbiologically or prior to intervention. Further, there was inconsistent adherence to the oral care protocols in some studies. Lastly, there was inconsistency among studies in the reporting and implementation of the oral care regimens, the agent(s) used, and the frequency at which oral care was performed.

The author suggested several areas for improving the rigor and science related to this topic, including the microbiological definition of VAP; determination of the baseline VAP rates prior to the intervention; methods to ensure adherence and integrity of the intervention protocol; and the need for prospective studies including an emphasis on patient safety to include hypotension and bacteremia rates. The author concluded that while tooth brushing may be an important intervention, the importance of tooth brushing in the prevention of VAP cannot be determined from the current evidence. Regardless, it was recommended that every ICU have an oral care procedure that includes oral assessments, suctioning, providing lip and oral mucosa moisture, and taking an oral health history.

COMMENTARY

While not an exhaustive systematic review, this article provides the critical care clinician an overview of the currently available evidence on the effectiveness of tooth brushing for the prevention of VAP in mechanically ventilated patients. This paper did not review VAP prevention care bundles. Based on the evidence, regular tooth brushing requires further scrutiny, particularly for those patients with poor dental health. While twice daily tooth brushing in healthy individuals is a "best practice," critical care clinicians are wise to evaluate the evidence given the limitations and inconsistencies in the literature and the potential for increased patient risk.

As with many literature reviews, individual studies describe varying protocols, definitions, and use different outcome measurements. This makes it difficult to pool results for a meta-analysis. There is a clear need for prospective studies that are adequately powered to detect significant findings. Careful assessment and monitoring of the ICU environment during the conduct of VAP prevention studies should be included in order to determine the impact of any practice changes on the variables of interest. Toward this end, the author provides many excellent areas in which the science can be improved. The suggestions for future research could easily be used as the basis for a research agenda to determine best practices for oral care, which should include the input of dentists. While oral assessment and oral care continue to be important practices in the care of mechanically ventilated patients, the evidence to support widespread tooth brushing is not apparent at this time given the inconsistent findings. ■

ABSTRACT & COMMENTARY

ICU Telemedicine Can Improve Patient Outcomes

By David J. Pierson, MD, Editor

SYNOPSIS: In the ICUs of a well-staffed academic medical center committed to quality improvement, in which closed staffing, multidisciplinary rounds, and the daily use of checklists were already in place, implementation of a 24-hour ICU telemedicine system that was well accepted by the medical staff was associated with impressive improvements in adherence to best practice standards as well as with reductions in hospital mortality and lengths of stay.

SOURCE: Lilly CM, et al. Hospital mortality, length of stay, and preventable complications among critically ill patients before and after tele-ICU reengineering of critical care processes. *JAMA* 2011;305:2175-2183.

Intensive care unit (ICU) telemedicine has been widely embraced in U.S. hospitals as part of the current focus on preventing medical errors and improving an array of measures related to the quality of care. This comprehensive study from the University of Massachusetts sought to document the impact of implementing ICU telemedicine on patient outcomes and the use of best practices that had already been established in the institution. A culture of enthusiasm for and widespread adoption of quality improvement measures was already in place in the authors' two component

hospitals before the study began, as were the following practices:
• An intensivist-led, closed ICU staffing model;
• Daily interdisciplinary ICU rounds;
• Comprehensive staffing and call schedules;
• Multidisciplinary, locally developed protocols for the prevention of venous thrombosis, cardiovascular complications, ventilator-associated pneumonia, and stress ulcers;
• Use of checklists for formulating daily patient care goals.

In a staggered fashion over 10 months, continuous, 7-day, 24-hour ICU telemonitoring was introduced to the 834-bed institution's seven adult ICUs. The intensivists performing the telemonitoring were staff members who also worked in the monitored ICUs. All patients admitted to the three medical, three surgical, and one mixed cardiovascular ICUs for several months before and several months after the switch to telemedicine in the respective units were included in the study. The primary outcome measures were case-mix and severity-adjusted hospital mortality before and after introduction of ICU telemedicine in the ICU in question; others included hospital and ICU lengths of stay, adherence to best practices, and complication rates.

During the prospective, stepped-wedge clinical practice study design period, 6465 patients were admitted to the study ICUs, of whom 6290 met all entry criteria and were evaluated. Slightly more of the telemedicine-period patients had medical rather than surgical diagnoses, and their severity of illness was slightly greater; otherwise the patient population did not change. Hospital mortality declined from 13.6% (95% confidence interval [CI], 11.9-15.4%) to 11.8% (95% CI, 10.9-12.8%) after implementation of telemedicine (adjusted odds ratio, 0.40; 95% CI 0.31-0.52). Concomitantly, adherence to best practices in the ICUs increased (prevention of deep venous thrombosis, 85% vs 99%; stress ulcer prevention, 83% vs 96%; cardiovascular protection, 80% vs 99%; prevention of ventilator-associated pneumonia, 33% vs 52%). The rates of ventilator-associated pneumonia (OR, 0.15; 95% CI, 0.09-0.23) and catheter-related bloodstream infections (OR, 0.50; 95% CI, 0.27-0.93) went down after implementation of ICU telemedicine, and hospital lengths of stay decreased significantly, with no differences between the clinical services (medicine vs surgery) on which the patients were managed.

COMMENTARY

This study demonstrated statistically significant, clinically important improvements in the outcome variables examined after implementation of ICU telemedicine. However, the title of this abstract/commentary was deliberately chosen as "telemedicine CAN improve outcomes" rather than that it WILL do so. A recent systematic review[1] and two thoughtful commentaries by Kahn[2,3] emphasize that positive results from the implementation of an ICU telemedicine system are not automatic and cannot be expected unless several other things are also present.

The meta-analysis by Young et al[1] shows that the research previously published in this area is generally weak and has mainly consisted of observational time-series, which are notoriously susceptible to bias and confounding. In addition, several previous studies have failed to show benefits from implementing ICU telemedicine. As pointed out by Kahn,[2,3] these studies have had at least two important differences from the present study of Lilly et al. First, local physician buy-in of ICU telemedicine has been poor, with only a minority of them participating in the study institutions. The Lilly study took place in an institution in which a culture of quality improvement had already been firmly established. The physicians doing the telemonitoring were fully integrated into the medical staff, and buy-in on the part of the overall staff was excellent. Second, the implemented telemedicine programs in the negative studies have focused primarily on preventing medical errors — and generally only at night — rather than on improving adherence to best practices across the board. As Kahn states, "rather than using ICU telemedicine to prevent medical errors, perhaps we should use it to implement ICU best practices, such as evidence based sedation and mechanical ventilator management."[3]

This study shows that, in the right institutional environment and as part of a comprehensive, system-wide program to improve ICU outcomes by identifying and implementing evidence-based best practices, ICU telemedicine can further those efforts and benefit patients. However, introducing telemedicine in the absence of the other components of the program employed by Lilly et al would seem to offer much less promise of success. ■

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ABSTRACT & COMMENTARY

Respite Staffing Decreases Intensivist Burnout

By Leslie A. Hoffman, RN, PhD
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SYNOPSIS: Intensivists experienced significantly less burnout, work-home life imbalance, and job distress under an interrupted schedule vs a continuous (half-month) schedule. ICU length of stay and mortality were non-significantly higher under continuous scheduling.

SOURCE: Ali NA, et al on behalf of the Midwest Critical Care Consortium. Continuity of care in intensive care units: A cluster-randomized trial of intensivist staffing. *Am J Respir Crit Care Med* 2011;Jun 30. [Epub ahead of print].

This study assessed the impact of two formats, intermittent scheduling (IS) or continuous scheduling (CS), on intensivist and patient outcomes. The study involved five medical ICUs in four academic-affiliated hospitals in the United States. The units were 12-15 bed, closed-model ICUs with care teams that included a board-certified intensivist, internal medicine residents, and ICU fellows. Intensivists were in the ICU or nearby during the day and took calls overnight from home, returning to the ICU at their discretion. Internal medicine residents were continuously present overnight. ICU fellows were present during the day and took home calls overnight. In the CS format, a single intensivist was responsible every day during a half-month rotation. In the IS, a single intensivist was responsible Mondays-Fridays for half the month and each weekend was cross-covered by a different intensivist from the same pool of partners. Weekend-covering intensivists could have non-ICU responsibilities during weekdays, but not during weekend ICU coverage. The ICUs were randomized to one of two sequences (CS-IS-CS or IS-CS-IS) over a 9-month period. Job burnout, job stress, and work-home life imbalance were measured using scales derived from the National Study of the Changing Workforce.

Forty-five intensivists and 1900 patients participated in the study. As expected, continuity of care was higher under CS; 72% of patients had a single intensivist care for them during their entire ICU stay under CS vs 38% under IS ($P < 0.0001$). ICU and hospital length of stay (LOS)were nonsignificantly higher under CS (Δ ICU LOS 0.36 days, $P = 0.20$; Δ hospital LOS 0.34 days, $P = 0.71$; ICU mortality, odds ratio 1.43, $P = 0.12$; hospital mortality, odds ratio 1.17, $P = 0.41$). Intensivists experienced significantly higher burnout, work-home life imbalance, and job distress working under CS.

COMMENTARY

Projections indicate a future imbalance in numbers of intensivists required to meet patient care needs vs those prepared in this specialty. In addition, there is an ongoing debate whether ICUs should be staffed by intensivists around the clock (24/7) to ensure optimal patient care, a factor that would increase staffing needs. A further concern relates to Accreditation Council for Graduate Medical Education (ACGME) requirements that place stringent limits on coverage by house staff. Implementation of these regulations typically requires more frequent handoffs and, consequently, interruptions in the continuity of care, as well as more hours of care by an attending physician. Findings of this article are thus timely and provocative. Despite less continuity of care with weekend-end cross coverage, IS proved better for intensivists in regard to measures of job stress, burnout, and work-life balance and was not associated with worse outcomes for patients. As the authors note, this finding challenges conventional wisdom, but does not contradict existing knowledge. Research showing better outcomes with higher intensity of intensivist involvement has not examined the variable of continuity of care, and studies demonstrating problems related to handoffs — a consequence of discontinuity of care — have used subjective assessment of outcomes. Job burnout is known to predispose to more errors, as are factors that increase job stress (e.g., workload and work duration).

Additional rigorously designed studies are needed to clarify the best way to provide ICU care, including advantages and disadvantages of continuous vs interrupted intensivist staffing, incorporating acute care nurse practitioners into the care team, and use of telemedicine. The design of this study suggests it should be possible to implement designs testing these variables within the same institution by changing providers or provider schedules in a systematic manner and examining patient care outcomes. ■

CME/CNE Questions

26.Which of the following are beneficial effects of PEEP?

a. Maintain alveolar recruitment with ALI/ARDS
b. Counterbalance auto-PEEP with COPD
c. Reduce the risk of microaspiration around the airway cuff
d. Facilitate speech with tracheostomy tube cuff deflated
e. All of the above

27. Which of the following statements is true about setting PEEP in patients with ALI/ARDS?

a. When all patients receive lung-protective tidal volumes of 6 mL/kg ideal body weight, higher PEEP improves oxygenation and reduces the use of rescue therapies for hypoxia.
b. Under the conditions described in (a) above, higher PEEP reduces overall mortality.
c. A decremental procedure in which PEEP is initially set high and then progressively reduced to maintain alveolar recruitment has been shown to improve survival.

28. The major deterrent to regular tooth brushing in all mechanically ventilated patients is:

a. it is just too hard with an endotracheal tube in place.
b. the potential to dislodge bacteria from the oral cavity into the blood stream.
c. nurses don't have time to perform oral hygiene.
d. there are no devices for brushing the teeth of mechanically ventilated patients.
e. None of the above

29. ICU oral care protocols should minimally include which of the following?

a. Four times daily chlorhexidine rinses
b. Oral assessment including an oral health history
c. Three times daily vigorous brushing of the teeth in all mechanically ventilated patients
d. Oral cavity microbiome testing in all ICU patients
e. Sputum cultures in all patients

30. Which of the following statements is true about implementing ICU telemedicine in a given institution?

a. All studies to date have demonstrated improved patient outcomes
b. Buy-in by ICU staff in reported studies has generally been excellent
c. Implementing ICU telemedicine is effective as a stand-alone intervention without the need to carry out other quality-improvement measures
d. All of the above
e. None of the above

31. Which of the following were already in place and well established before the introduction of ICU telemedicine in the study of Lilly et al?

a. A closed-ICU medical staffing model
b. Interdisciplinary rounds
c. Use of standardized checklists for ICU best practices
d. All of the above
e. None of the above

32. With continuous ICU staffing by the same intensivist using a half-month schedule:

a. ICU length of stay was shorter.
b. Fewer patients were readmitted after ICU discharge.
c. Family conferences were more frequent and satisfaction higher.
d. ICU nurses rated satisfaction with patient care higher.
e. Job stress, burnout, and work-life balance were less positive.

CME/CNE Instructions

To earn credit for this activity, please follow these instructions:

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice, or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
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CME/CNE Objectives

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

- identify the particular clinical, legal, or scientific issues related to critical care;
- describe how those issues affect physicians, nurses, health care workers, hospitals, or the health care industry; and
- cite solutions to the problems associated with those issues.

[IN FUTURE ISSUES]

Patient outcomes after failed extubation

Clinical importance of saddle PE

PHARMACOLOGY WATCH

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In this issue: ACEI/ARB therapy for AS; safety alert issued for dronedarone; statins and cancer risk; nesiritide and heart failure; and FDA actions.

ACEI/ARB therapy for aortic stenosis

Drugs that block the renin-angiotensin system are not only safe, they are beneficial in patients with aortic stenosis (AS) according to a new study. This runs counter to current recommendations that suggest that angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) are relatively contraindicated in patients with AS. The study looked at more than 2000 patients with AS in Scotland, of which the majority had mild-to-moderate stenosis, while about one-quarter had severe AS. Of the total number, nearly 700 were on ACEI or ARB therapy. Over a mean follow-up of 4.2 years, just over half the patients died, of which 48% died from cardiovascular (CV) deaths. Those treated with ACEIs or ARBs had a significantly lower mortality rate (adjusted hazard ratio [HR] 0.76; confidence interval [CI] 0.67-0.92; $P < 0.0001$) and fewer CV events (adjusted HR 0.77; 95% CI: 0.65-0.92; $P < 0.0001$) compared to those not on ACEIs/ARBs. The authors conclude that ACEI/ARB therapy is associated with improved survival and lower risk of CV events in patients with AS. These findings were consistent in patients with nonsevere and severe AS. The rate of valve replacement also was lower in patients treated with ACEIs/ARBs (*J Am Coll Cardiol* 2011;58:570-576). This study was a retrospective observational study and prospective, randomized, controlled trials are warranted to confirm these findings. ■

Drug safety alert issued for dronedarone

The antiarrhythmic dronedarone (Multaq) is again coming under scrutiny from the FDA after review of the company-sponsored PALLAS study of more than 3000 patients, which showed that the drug is associated with an increased mortality rate in patients with atrial fibrillation (AF). Dronedarone currently is approved for treatment of paroxysmal AF and atrial flutter. The new study investigated its use in patients with permanent AF. The study was halted early when the mortality rate in the treatment group was found to be double the rate in the placebo group (32 deaths [2%] in the dronedarone arm vs 14 [0.9%] in the placebo arm). The rate of unplanned hospitalization and stroke also was double in the dronedarone group vs the placebo group. All findings were statistically significant. These findings led the FDA to issue a drug safety alert on July 21, 2011. This follows a January 2011 drug safety alert regarding rare but severe liver injury associated with use of dronedarone. Currently, the FDA is recommending that physicians should not prescribe dronedarone to patients with permanent AF while they further evaluate the data (FDA Drug Safety Communication at www.FDA.gov/drugs/drug safety). ■

Statins do not increase risk of cancer

A new retrospective cohort analysis suggests that statins are not associated with an increased risk of cancer. Researchers used the General

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Electric Centricity electronic medical record database of more than 11 million adult Americans to match nearly 46,000 patient pairs by propensity scores receiving and not receiving statin therapy. With an average time in the database of 8 years, the incidence of cancer in patients taking a statin was 11.37% compared with 11.11% in matched patients not taking a statin (HR 1.04; 95% CI: 0.99-1.09). The authors conclude that this analysis demonstrates no statistically significant increase in cancer risk associated with statins, although they do suggest that more research is needed (*J Am Coll Cardiol* 2011;58:530-537). Lingering fears about cancer risk associated with statins was strengthened by the SEAS trial published in 2008, which showed the combination drug simvastatin/ezetimibe (Vytorin) was associated with a two-fold increase in the rate of cancer in a small group of patients. The FDA has continued to study these data along with data from other studies, but this new analysis adds significant evidence of a lack of association between statins and cancer. ■

Nesiritide and heart failure

Nesiritide can no longer be recommended for use in congestive heart failure based on the findings of a new study. The drug is a recombinant B-type naturetic peptide (BNP) that was approved in 2001 for use in patients with acute heart failure. The approval was based on small studies showing a reduction in pulmonary capillary wedge pressure and improvement in dyspnea 3 hours after administration. However, subsequent data raised questions about the drug's safety, especially with regard to worsening renal function and even increased mortality. Based on the recommendations of an independent panel, the manufacturer performed a placebo-controlled randomized trial of more than 7000 patients hospitalized with acute heart failure to assess the drug's safety and efficacy. Patients with heart failure were randomized to receive nesiritide or placebo for 24-168 hours in addition to standard care. The drug was modestly effective at reducing symptoms of dyspnea at 6 and 24 hours. More significantly, however, the rate of rehospitalization for heart failure or death from any cause within 30 days was no different. Nesiritide was not associated with a worsening of renal function but was associated with worsening hypotension. The authors conclude that on the basis of these results, "nesiritide cannot be recommended for routine use in the broad population of patients with acute heart failure" (*N Engl J Med* 2011;365:32-43). ■

FDA actions

The highly anticipated oral factor Xa inhibitor rivaroxaban has been approved by the FDA to reduce the risk of deep venous thrombosis, blood clots, and pulmonary embolism in patients undergoing knee or hip replacement. The once-a-day medication should be taken for 12 days by patients undergoing knee replacement and 35 days for patients undergoing hip replacement. The approval was based on three studies (RECORD 1, 2, and 3) which showed that rivaroxaban is superior to subcutaneous enoxaparin in this role. Bleeding, the primary side effect of the drug, was no more common with rivaroxaban than enoxaparin. Rivaroxaban also has been looked at in phase III trials for stroke prevention in patients with nonvalvular atrial fibrillation, and treatment and secondary prevention of venous thromboembolism, although the FDA has yet to act on approval for these indications. Rivaroxaban was developed by Bayer and is marketed by Janssen Pharmaceuticals as Xarelto.

The FDA has approved ticagrelor, a new antiplatelet drug for patients with acute coronary syndrome, including unstable angina and myocardial infarction (MI). The approval was based on studies that coupled ticagrelor with low-dose aspirin. The approval recommends use with aspirin although it carries a warning that aspirin doses above 100 mg per day may decrease the effectiveness of the drug. Ticagrelor requires twice a day dosing in contrast to the other drugs in this class, clopidogrel and prasugrel, which can be dosed once daily. The approval was based on the PLATO trial, a head-to-head study with clopidogrel which showed that in combination with aspirin, ticagrelor resulted in the lower composite endpoint of cardiovascular death, stroke, or MI (9.8% vs 11.7% with clopidogrel, $P < 0.001$).

The FDA has approved six manufacturers for the 2011-2012 flu vaccine. The strains included this year are A/California7/09 (H1N10), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 — the exact same components as last year's vaccine. One of the manufacturers, Sanofi Pasteur, has received permission to market Fluzone Intradermal, the first flu vaccine administered via a novel intradermal microinjection that is touted as being more comfortable than intramuscular injections. The new intradermal system in approved for adults ages 18-64 years. ■