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INSIDE

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Improving Survival When Cardiogenic Shock Complicates Acute MI

ABSTRACT & COMMENTARY

By David J. Pierson, MD, Editor

Director of Pulmonary and Critical Care Medicine, Harborview Medical Center, University of Washington, Seattle

Synopsis: *This prospective 10-year study of 7356 patients with ST-elevation MI who presented in cardiogenic shock showed once again that early mechanical revascularization (as recommended by current guidelines) substantially increases survival; it also suggests that adherence to the guidelines needs to be further improved.*

Source: Babaev A, et al. Trends in management and outcomes of patients with acute myocardial infarction complicated by cardiogenic shock. *JAMA*. 2005;294:448-454.

Based on the results of studies showing that early mechanical revascularization substantially reduces mortality among patients with acute myocardial infarction (AMI) complicated by cardiogenic shock, the American College of Cardiology and American Heart Association classified this intervention as a class I recommendation in their 1999 guidelines.[1] In this study, Babaev and colleagues used the prospectively acquired database of the National Registry of Myocardial Infarction to determine trends in the early use of early mechanical revascularization—percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) surgery—in the participating hospitals from 1995 through 2004. Of 293,633 patients treated in the participating hospitals for ST-elevation AMI during the study period, 25,311 (8.6%) had cardiogenic shock. Babaev et al examined the use of PCI and CABG in relation to outcomes in the 7356 (29%) in the latter group who had cardiogenic shock on initial presentation.

During the 10-year observation period, the rate of cardiac catheterization in this patient population increased from 51.5% to 74.4%. There were concomitant increases in the rate of primary PCI from 27.4% to 54.4%, and of total PCI from 34.3% to 64.1%,

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during this time. Overall CABG surgery rates decreased from 11.5% to 8.8%; the change in the rate of immediate CABG surgery from 2.1% to 3.2% was not significant. Overall in-hospital mortality fell from 60.3% in 1995 to 47.9% in 2004 ($P < 0.001$), paralleling the rise in revascularization rates. Multivariable analysis of mortality adjusted for patient demographics, medical history, clinical presentation, hospital characteristics, year of discharge, and procedures performed showed PCI to remain strongly and independently associated with a lower mortality rate (adjusted odds ratio, 0.46; 95% CI, 0.40-0.53). Among the 7356 patients with cardiogenic shock at presentation, 238 (3.2%) died prior to the median door-to-PCI time without having received PCI.

COMMENTARY

This large observational study of patients with AMI shows that the rate of cardiogenic shock has remained relatively constant, but also that there has been a substantial decrease in mortality in patients with this complication. It further shows that this improvement in outcome is strongly and independently correlated with concomitant increases in early mechanical revascularization—specifically, in the rate of primary PCI. Somewhat surprisingly, it does not show a parallel increase in the use of early CABG surgery, as might have been expected.

These findings strongly reinforce the message of the evidence-based ACC/AHA guidelines, and emphasize the importance of awareness and implementation of the latter. A doubling of the rate of primary PCI (from 27% to 54%) during the 10-year period of this study is encouraging. However, the fact that at the end of the study only about three-fourths of potentially eligible patients were undergoing cardiac catheterization, and only slightly more than half of them were receiving primary PCI, suggests that we still have a lot of work to do if current evidence is to be used to the maximum benefit of our patients. ■

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Erythropoietin Therapy in the ICU: How Expensive?

ABSTRACT & COMMENTARY

By Leslie A. Hoffman, PhD, RN

Department of Acute/Tertiary Care School of Nursing, University of Pittsburgh, PA.

Dr. Hoffman reports no financial relationship to this field of study.

Synopsis: *When study data were used to perform a formal analysis of costs associated with use of erythropoietin, the total cost to avoid one transfusion-related adverse event was $4.7 million*

Source: Shermock KM, et al. Number needed to treat and cost of recombinant human erythropoietin to avoid one transfusion-related adverse event in critically ill patients. *Crit Care Med*. 2005;33:497-503.

USING DATA FROM A RECENT STUDY,[1] SHERMOCK AND colleagues calculated the absolute risk reduction (ARR) of transfusion-related adverse events, the number of patients needed to treat (NNT), and the cost to avoid a transfusion-related adverse event by using recombinant human erythropoietin (EPO) in critically ill patients. The

calculations were based on study data that indicated that the use of 40,000 units of EPO weekly reduced the likelihood of transfusion compared to placebo (50.5% vs 60.4%, respectively). There was a 19% decrease in total units of red blood cells transfused, resulting in an average of 3 transfusions in the placebo group and 2.4 in the experimental group. No difference was detected between the groups in morbidity or mortality (although the study was not powered to detect these). Shermock et al emphasized the benefit of fewer transfusions in terms of a decrease in transfusion-related adverse events.

Using published estimates of the risk and frequency of transfusion-related events, Shermock et al calculated the ARR, the NNT, and the cost to avoid one transfusion-related adverse event. The ARR is defined as the absolute arithmetic difference in rates of bad outcomes between experimental and control participants. The NNT is calculated by dividing the ARR into 1 (ie, 1/ARR). The NNT represents the number of persons who need to receive the experimental treatment to prevent one additional bad outcome.

Based on these calculations, routine use of EPO resulted in an ARR of 191 per million for all transfusion-related adverse events, 35 per million for serious transfusion-related adverse events, and 12 per million for likely fatal events. The NNT was 5,246 to avoid one transfusion-related adverse event (cost, $4.7 million), 28,785 to avoid one serious transfusion-related event (cost, $25.6 million) and 81,000 to avoid one likely fatal transfusion-related event (cost, $71.8 million). The magnitude of these results withstood extensive sensitivity analysis.

COMMENTARY

The main finding of this study was that 5,246 patients would have to be treated with EPO—at a cost approaching $5.0 million—to avoid one transfusion-related adverse event. The cost of this therapy escalated substantially if the focus was a serious or fatal transfusion-related event.

Anemia is a common problem in the ICU. The causes are multiple and include acute blood loss after trauma, hemorrhage, or surgery; prior treatment with chemotherapy; chronic medical illness; and frequent phlebotomy. Blunted erythropoiesis may also be a factor. There is evidence that critically ill patients may not produce appropriate levels of erythropoietin despite anemia and adequate iron stores.

In 1999 the Transfusion Requirements in Critical Care (TRICC) trial produced findings that indicated that 800 critically ill patients randomized to a liberal transfusion strategy (10 g/dL) had a mortality rate similar to those who received a more restrictive protocol (7 g/dL) 30-days post study enrollment. Moreover, the higher hemoglobin did not result in a shorter duration of mechanical ventilation.[2]

Findings of this and other studies led to questions about the potential benefits and risks of transfusions. By choosing transfusion reactions, which are rare, EPO was guaranteed to not be cost effective. Regardless, the magnitude of the cost inefficiency was impressive. Unless "zero risk" is the goal, economic considerations do not support routine use of EPO in critically ill patients. This therapy could be appropriate in some situations, eg, during blood shortages, or if the cost of transfusions continues to rise. There may also be some populations that benefit from this therapy, eg, long-stay ICU patients. Until benefits are better established, the preferred approach would appear to be to set and adhere to a strict transfusion threshold, as suggested by TRICC results, and to reduce blood waste and lab draws. ■

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Intra-Abdominal Hypertension in Severe Acute Pancreatitis

ABSTRACT & COMMENTARY

By David J. Pierson, MD, Editor

Synopsis: *Both intra-abdominal hypertension and evidence for its adverse physiologic effects were common in this retrospective series of ICU patients with severe acute pancreatitis, although there was no association with mortality, and 3 of 4 patients subjected to decompressive laparotomy died.*

Source: De Waele JJ, et al. Intra-abdominal hypertension in patients with severe acute pancreatitis. *Crit Care*. 2005;9:R452-R457; www.ccforum.com/content/9/4/R452. Accessed September 13, 2005.

To examine the incidence of intra-abdominal hypertension (IAH) and physiologic manifestations of the abdominal compartment syndrome (ACS) among

patients with severe acute pancreatitis (SAP), De Waele and colleagues from Ghent University Hospital in Belgium performed a retrospective records analysis from patients with SAP admitted to their ICU over a 39-month period. Data collected included patient demographics, the etiology of SAP, C-reactive protein level (an assessment of systemic inflammation), Ranson score (a pancreatitis-specific assessment of illness severity), APACHE II scores, indices of individual organ function, length of ICU stay, and hospital mortality. Intra-abdominal pressure was assessed via catheter after instillation of 50 mL of saline into the bladder, and pressures over 15 mm Hg (20 cm H_2O) were considered to indicate IAP.

During the study period, 44 patients were admitted to the ICU with SAP. Their mean age was 57 years and 27 were male. SAP was associated with biliary tract stones in 19 patients, alcohol excess in 12, hyperlipidemia in 4, and trauma in 2; the cause was undetermined in 7 patients. The mean Ranson and APACHE II scores on admission were 5.5 and 18, respectively. Nine of the 44 patients died.

Intra-abdominal pressures were not measured as part of routine monitoring but were assessed when considered clinically indicated. Of the 44 patients, 27 had bladder pressure measurements made, and in 21 of them it exceeded 15 mm Hg. Maximum intra-abdominal pressures in these 21 patients averaged 27 mm Hg (SD, 7.8 mm Hg). Patients who developed IAH had higher Ranson and APACHE II scores than those who did not, and the highest measured pressure correlated significantly with APACHE II score. Patients with IAH had significantly more pulmonary, cardiovascular, and renal function impairment than patients with normal intra-abdominal pressures, and also had more pancreatic necrosis and longer ICU and hospital stays. Mortality was not different in the 2 groups, and there were no differences in age, gender, cause of SAP, or C-reactive protein. Of 4 patients with IAH who underwent decompressive laparotomy, 3 died. DeWaele et al conclude that IAH is frequent among patients admitted to an ICU with SAP, that it is associated with a high rate of organ dysfunction, and that surgical decompression may not be advisable in this condition.

COMMENTARY

Organ dysfunction—particularly respiratory, cardiac, and renal impairment—associated with IAH in critically ill patients has been called the abdominal compartment syndrome (ACS). Although patients with ACS typically have severe systemic inflammatory response syndrome and other reasons for organ dysfunction, the physical effects of raised intra-abdominal pressure on airway pressure, lung expansion, venous return to the heart, and perfusion of the kidneys and other abdominal viscera are believed to be a major contributor to the syndrome. ACS has been reported (or at least recognized) most often in patients with trauma, particularly abdominal injuries, and those who have received massive fluid resuscitation. It also occurs in patients with intestinal ischemia, hernias, and SAP. Although the exact mechanism is unknown, the presence of IAH and the ACS are increasingly associated with multi-organ dysfunction and with adverse outcomes of critical illness.

A recently convened consensus group[1] has designated 12 mm Hg as the intra-abdominal pressure above which adverse physiologic effects occur; and using this as the cut-off reports the incidence of IAH and ACS among ICU patients to be 35% and 5%, respectively. Thus, this is by no means a rare disorder. Because the indices used to diagnose ACS—such as peak and static airway pressures, cardiac output, and urine output—typically improve when the pressure is relieved via decompressive laparotomy, the latter has been regarded as the treatment of choice, particularly in patients with trauma or post-surgical IAH, and especially when the intra-abdominal pressure exceeds 20-25 mm Hg. However, there has yet to be a clinical trial of surgical decompression vs non-surgical management.

In the present study little can be said about the effects of abdominal decompression on outcome, although only one survivor out of 4 is hardly encouraging. In fact, the conclusions of this retrospective study are discouraging in 2 respects: IAH appears to be common in patients with SAP, and the usual treatment for it may not work.

This study is of interest because of its examination of an important patient group (those with SAP), in the context of an increasingly important condition (IAH). However, the actual incidence of IAH in SAP cannot be determined from this study because only 27 of 44 patients with SAP had bladder pressures measured. Measurements were done at the discretion of the clinician and thus were presumably more likely to be elevated in the patients in whom they were made. In the discussion DeWaele et al report an overall incidence of IAH of 51%, but I was unable to figure out where that number came from. The incidence in the 27 patients in whom pressure measurements were made was 78% (21 patients). This is undoubtedly higher than would be found in the whole population. At the other extreme, if only those 21 patients out of the total of 44 had had IAH then the incidence would have been 48%. De Waele et al report a very high incidence of respiratory, cardiovascular, and renal failure (95%, 91%, and 86%, respectively) but do not relate this to a particular definition of ACS. These minor issues notwithstanding, this study should heighten the awareness of ICU clinicians with respect to IAH and ACS as possible complications of SAP. ■

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Early Gastrostomy Decreases Ventilator-Associated Pneumonia in Brain-Injured Patients

ABSTRACT & COMMENTARY

By David J. Pierson, MD, Editor

Synopsis: *In a randomized, controlled trial, patients with stroke or head injury who required mechanical ventilation were less likely to develop ventilator-associated pneumonia if they underwent early percutaneous gastrostomy for nutritional support than if they continued to be fed via nasogastric tube.*

Source: Kostadima E, et al. Early gastrostomy reduces the rate of ventilator-associated pneumonia in stroke or head injury patients. *Eur Respir J*. 2005;26:106-111.

THIS CLINICAL TRIAL FROM LARISSA UNIVERSITY Hospital in Greece tested the hypothesis that enteral nutrition via gastrostomy would reduce the incidence of ventilator-associated pneumonia (VAP) as compared to feeding via nasogastric tube. Forty one patients without known pulmonary disease who presented to the ICU with either stroke (25 patients) or head injury (16 patients), who had Glasgow Coma Scale scores less than 6 and required mechanical ventilation, were randomized to receive either a nasogastric tube (21 patients) or a percutaneous gastrostomy (20 patients) within 24 hours of admission. All patients had intracranial pressure monitoring devices and all received ceftriaxone 2 g every 12 h.

VAP was defined as a new and persistent pulmonary infiltrate on chest radiograph, plus at least 2 of the following: temperature > 38.3°C or an increase of > 1°C; leukocyte count > 10,000 and an increase of > 25% from baseline, or < 5000 and a decrease of > 25% from baseline; and purulent tracheal aspirate with > 25 neutrophils per high-power field on Gram stain. Bronchoalveolar lavage fluid colony counts > 10,000 was used to confirm the diagnosis in some but not all patients and was not a requirement for the diagnosis of VAP. Data on the development of VAP were recorded only during the first 3 weeks after intubation.

The 2 patient groups were well matched in terms of demographics, diagnosis, APACHE II scores, development of sinus opacification on CT, and selected comorbidities. Overall duration of mechanical ventilation and length of ICU stay were 37 and 38 days, respectively, in both groups, and mortality (4 and 6 patients in gastrostomy and control groups, respectively) also did not differ. However, VAP developed in 2 patients (10%) in the gastrostomy group as compared to 8 patients (38%) in the nasogastric tube group ($P = 0.036$), and this difference persisted after excluding those who did not complete the study because of extubation or death prior to 3 weeks.

COMMENTARY

VAP is the most lethal nosocomial infection in ICU patients,[1] and its connection with the gastrointestinal tract is an area of intense current interest.[2] Several studies have established the association between nasogastric tubes and VAP, and this study by Kostadima and colleagues supports the notion that not having a tube traversing the upper and lower esophageal sphincters is desirable in this respect. Other measures shown in randomized controlled trials to reduce the incidence of VAP include elevation of the head of the bed to 45 degrees, changing ventilator circuits as infrequently as possible, and avoidance of intubation through the use of noninvasive ventilation.

This study is relatively small. We are not told the Glasgow Coma Scale scores of the 2 patient groups, a potentially important omission if they indicated, for example, that the patients fed via nasogastric tubes had more severely impaired neurological function than those who received gastrostomies. However, the design and execution of the study appear sound in other respects. Whether its findings in severely brain-injured patients are generalizable to other ICU patients is unknown, and additional investigations of this approach to preventing VAP will be important.

Although no important complications from percutaneous gastrostomy tube insertion were noted in this study, placement of these tubes in critically ill patients is not always so benign, and I have seen serious and even fatal complications resulting from the procedure. Of note, in keeping with the findings of studies of several other interventions to reduce the incidence of VAP, no differences in ICU length of stay or hospital mortality were found despite a significant reduction in the number of patients who developed VAP. ■

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Special Feature

Learning and Teaching Bronchoscopy in the ICU

By Stephen W. Crawford, MD

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Dr. Crawford is a consultant for Cubist Pharmaceuticals, and is on the speaker's bureau for Ortho-Biotech.

Introduction

Airway management is an integral and frequent component of care of the critically ill. Problems occur on a regular basis and include endotracheal intubation for respiratory failure, evaluation for intrinsic or extrinsic airway obstruction, obstructive sleep apnea, excessive or retained secretions, endotracheal or tracheostomy tube placement, assessment of endotracheal tube position and evaluation and management of airway bleeding. The skills to manage these complications are integral to the effective critical care physician and are emphasized in training programs and textbooks.

Flexible bronchoscopy is a key adjunct to the evaluation and management of the airway. This modality permits visualization of the airway, can guide treatment interventions, can obtain diagnostic specimens, and can relieve obstructions due to secretions and foreign bodies. In the modern ICU, flexible bronchoscopy is readily available with portable fiberoptic or video scopes. It is used routinely to aspirate retained secretions from endotracheal tubes in many units. Within the common uses in the ICU the use of the flexible bronchoscope is generally safe.

However, training in flexible bronchoscopy appears to be variable. Within combined pulmonary and critical care medicine fellowship training programs, a substantial amount of time is spent in the bronchoscopy suite learning the technique from clinicians with years of experience. Surveys among pulmonary medicine trainees revealed that each performed an average of 77 bronchoscopic procedures per year under supervision of experienced bronchoscopists.[1] The vast majority of these programs utilized one-on-one training. I am unaware of any standardized training received in isolated critical care training programs, or of the qualifications of the supervisors.

Virtual Reality Simulation in Bronchoscopy Training

Virtual reality (VR) simulation is routinely used in aviation and military training to assist with teaching and assessing proficiency. In VR simulation, a computer graphically interfaces with model instruments and provides tactile and visual feedback to operators in a realistic environment without risk to operator, subjects or equipment. Flexible bronchoscopy VR simulation has been in use for several years with a relatively portable model. The simulators allow for the teaching and assessment of several important skills, including basic airway navigation, inspection and bronchial segment identification, as well as endobronchial suctioning, forceps biopsy, and transtracheal or carinal needle aspiration. In contrast to traditional stationary plastic airway models often used in training, VR simulation provides a more realistic experience. VR simulation mimics airway movements of breathing and coughing, airway visual compromise from bleeding, and physiological responses to the procedure and medications with alterations in oxygenation, pulse and blood pressure.

Several centers have studied flexible bronchoscopy VR simulation in the training environment. Ost et al demonstrated that the proficiency at avoiding contact with the lumen walls and identification of bronchial segments with the VR simulator correlated with the number of bronchoscopy procedures performed and years of experience.[2] Moreover, they and others showed that training with the VR simulator significantly improved the performance of novice bronchoscopists.

Importantly for training purposes, the use of a VR simulator for bronchoscopy improves novices' skills quickly. The manual dexterity and accuracy of identifying specific bronchial segments of novice bronchoscopists equaled or exceeded that of those who performed more than 200 procedures with only 4 hours of instruction and 4 hours of individual experience on the simulator.[3] In this study by Colt et al, the performance using the simulator correlated with that using other bronchoscopy models, thus confirming the generalizability of the skills. In an effort to determine how quickly these skills are acquired, Moorthy et al compared novice to experienced bronchoscopists over time. Most of the measurable skills were statistically similar between the groups after 3 to 6 training sessions with the novices.[4] Recently, Blum et al reported a study that is most applicable to the ICU setting.[5] One hour of VR simulation training significantly improved the performance of surgi-

cal residents in performing bronchoscopy in the operating room in patients already under general anesthesia.

These are encouraging results and have important implications for improving the training in bronchoscopy in the ICU. They suggest that basic skills can be acquired more quickly, under more controlled training circumstances and at less risk to patients than the traditional methods of learning primarily in the live-patient clinical setting. This is very important where the training setting is the ICU and the potential risk among critically ill patients is high. Because of clinical instability of the patient often there is no time to teach, review anatomy, and repeat bronchial inspection. This limits the training value of procedure. Alternatively, requiring a critical care medicine trainee to spend valuable training time in an outpatient bronchoscopy setting to learn these skills may detract from the overall educational mission. Use of a VR simulator may address these concerns and provide superior acquisition of skills in less time.

How Many Procedures are Required?

The number of appropriately supervised procedures required to become competent at bronchoscopy is a matter of controversy. In general, experts recommend between 50 and 100 procedures before operators should be considered competent.[6-8] The American Thoracic Society suggests at least 50 supervised flexible bronchoscopic procedures for eligibility to the specialty board examination. However, recent work with VR simulation has cast doubt on the number of procedures necessary to develop basic bronchoscopy competency.

We recently studied specific critical bronchoscopy skills, aside from those of speed, avoiding contact with lumen walls and identification of anatomy.[9] We compared the ability to enter specifically requested bronchial segments on command among bronchoscopists of varying levels of training. Moreover, we assessed knowledge of basic bronchoscopy history, anatomy, and techniques with a computer-based examination. Surprisingly, the ability to consistently and correctly identify and enter specific bronchial segment orifices was not demonstrated by anyone with less than 200 actual bronchoscopies performed. This is much higher than any expert or professional society currently recommends for certification. Equally important to the training of these procedures, there was no correlation between the fund of knowledge about bronchoscopy and the level of training, number of procedures performed, and technical skill at bronchoscopy. This strongly suggests that true "competency" in bronchoscopy should not be assumed based on years of training or on an arbitrary number of procedures performed. Formalized, quantifiable testing should be performed to assess technical and information-based competence.

Other Available Training Resources

Web-based training assistance is now available. "The Essential Bronchoscopist" web site (www.ucihs.uci.edu/com/pulmonary/bronchoscopy) provides computer-based learning and knowledge assessment modules. Completion of these modules is required at the Pulmonary & Critical Care Medicine training program at Naval Medical Center San Diego for bronchoscope training. Also, web-based training programs and bronchoscopy atlases are under development through the following web site and Bronchoscopy International (www.bronchoscopy.org).

The Role of the Bronchoscopy Assistant

The training implications of these studies of bronchoscopy education extend beyond the medical trainees. The results of the studies reviewed here suggest that there is a role for improving, reviewing, and demonstrating maintenance of bronchoscopy skills among critical care providers after completion of training. VR simulation provides quantifiable measures of these skills and would be an adjunct to procedure credentialing by medical staff departments. Additionally, bronchoscopy-training models can be used to train ancillary procedure staff. Technical support staff can become familiar with and proficient in their duties in a safe and reproducible environment.

The role of the assistant in bronchoscopy in the ICU is undefined. However most of us prefer to have an adequately trained technician to assist with equipment and ventilator adjustment during the procedure. At the very least, someone separate from the bronchoscopists must be assigned to monitoring the patient during the procedure.

Non-Physicians as Bronchoscopists

On a more controversial topic, I am confident that bronchoscopy-training models, such as a VR simulator can be used to train non-physician support staff to perform basic bronchoscopy in the ICU. Basic endotracheal tube assessment and airway suctioning are routine ICU procedures. Urgency in performing these procedures is common in the ICU and can task the limited number of busy critical care physicians. Competently trained non-physician staff that demonstrated knowledge and proficiency in airway anatomy, bronchoscopic dexterity and complication mitigation and management could perform many of these bron-

choscopic procedures. Non-physician staff could master basic procedures such as assessment of endotracheal tune location, suctioning of secretions and locating bleeding. The initial situations most likely to benefit from training such bronchoscopist-extenders are military medical theaters and those ICU settings with limited physician support. VR simulation is an ideal modality to teach and demonstrate such proficiency to non-physician support staff and can lead to more complete and safer patient care.

Summary

Bronchoscopy is a commonly performed and essential adjunct to airway management in the ICU. Training in these procedures is not standardized nor is the degree or type of training required. True competency is difficult to determine without reproducible testing measures. Training models such a virtual reality simulators provide both an ideal training and proficiency assessment tool. Web-based educational tools will assist with procedural knowledge and training. Improved and standardized procedural training in bronchoscopy will undoubtedly advance patient care and safety in the ICU.

The opinions expressed are those of the author and do not necessarily reflect those of the US Navy or the Department of Defense.

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CME / CE Questions

1. **According to the guidelines of the American College of Cardiology and the American Heart Association, early mechanical revascularization in patients with cardiogenic shock complicating acute myocardial infarction:**
   a. is a research procedure.
   b. is not recommended.
   c. is optional at the discretion of the clinician.
   d. is a grade I evidence-based recommendation.
   e. None of the above

2. **When using 40,000 units of erythropoietin weekly in critically ill patients, 5,246 patients would need to be treated in order to:**
   a. avoid one transfusion-related fatal event.
   b. reduce morbidity and mortality from transfusion-related events.
   c. produce cost savings from the drug.
   d. reduce blood stream infections.
   e. avoid one transfusion-related adverse event.

3. **Training in flexible bronchoscopy using virtual reality simulators has been shown to:**
   a. delay the acquisition of basic bronchoscopy skills.
   b. decrease complication rates during bronchoscopy.
   c. allow non-physician staff to learn bronchoscopy.
   d. develop bronchoscopy technique comparable to experienced bronchoscopists in a few hours.
   e. None of the above

Answers: 1 (d); 2 (e); 3 (d)

CME / CE Objectives

After reading each issue of *Critical Care Alert*, readers will be able to do the following:

- Identify the particular clinical, legal, or scientific issues related to critical care.
- Describe how those issues affect nurses, health care workers, hospitals, or the health care industry in general.
- Cite solutions to the problems associated with those issues.

In Future Issues: ICU Outcomes in the Very Elderly

PHARMACOLOGY WATCH

Supplement to Clinical Cardiology Alert, Clinical Oncology Alert, Critical Care Alert, Infectious Disease Alert, Internal Medicine Alert, Neurology Alert, OB/GYN Clinical Alert, Primary Care Reports, Travel Medicine Advisor.

The Use of Prophylactic Antibiotics for Neutropenia

Antibacterial prophylaxis is generally not recommended for neutropenic patients undergoing chemotherapy. Two studies in the Sept. 8 issue of the *New England Journal of Medicine* may change that recommendation. The first study from Italy looked at 760 adult patients who were undergoing treatment for acute leukemia, solid tumors, or lymphoma and were at risk for chemotherapy-induced neutropenia lasting more than 7 days. Many were undergoing stem cell transplantation. Patients were randomized received either oral levofloxacin 500 mg daily or placebo from the start of chemotherapy until the resolution of neutropenia. The rate of fever present for the duration of neutropenia was reduced in the levofloxacin group (65% levofloxacin prophylaxis, 85% placebo; RR, 0.76, 95% CI; $P = 0.001$). The levofloxacin group also had a lower rate of microbiologically documented infections (17% absolute difference in risk; $P < 0.001$), bacteremia (16% absolute difference in risk; $P < 0.001$), and single agent gram-negative bacteremias (7% absolute difference in risk; $P < 0.01$), compared to the placebo group. There was no difference in mortality, and there was no difference in outcomes between patients with acute leukemia or those with solid tumors or lymphoma. Treatment was generally well-tolerated. The authors conclude that prophylactic treatment with levofloxacin is an effective and well-tolerated way of preventing febrile episodes and other relevant infection-related outcomes in patients with cancer and profound and protracted neutropenia (Levofloxacin to Prevent Bacterial Infection in Patients with Cancer and Neutropenia. *N Engl J Med*. 2005;353:977-987).

The second study from England looked at 1565 patients undergoing cyclic chemotherapy for solid tumors or lymphoma who were at risk for temporary, severe neutropenia. Since these patients were receiving cyclic chemotherapy, the rate of neutropenia was significantly lower than the first study. Patients were randomized to receive levofloxacin 500 mg daily or placebo for 7 days during the expected neutropenia period. During the first cycle of chemotherapy, 3.5% of patients in the levofloxacin group had a least one febrile episode, compared with 7.9% in the placebo group ($P < 0.001$). During the entire chemotherapy course, 10.8% of patients in the levofloxacin group had a least one febrile episode, compared with 15.2% of patients in the placebo group ($P = 0$ .01); the rate of probable infection was 34.2% and 41.5%, respectively ($P = 0.004$). Hospitalization rates were significantly higher in the placebo group, and the rate of severe infection was twice as high in the placebo group (1.0% vs 2.0% [$P = 0$ .15]). The death rate was same in both groups. The authors concluded that prophylactic use of levofloxacin reduces the rate of fever, probable infection, and hospitalization (Cullen M, et al. Antibacterial Prophylaxis After Chemotherapy for

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Solid Tumors and Lymphomas. *N Engl J Med*. 2005;353:988-998).

An accompanying editorial suggests that these are important studies which provide more data on prophylactic antibiotics in neutropenia that had previously been available. However, further study still needs to define which patients are at highest risk and the period of greatest risk during chemotherapy. Most importantly, the emergence of resistant organisms, which was seen in the Italian study, is a major concern. The author states "If prophylactic antimicrobial therapy is to be adopted at a cancer center, it should be accompanied by vigorous infection-control practices and careful monitoring for the emergence of resistant organisms" (Baden LR. Prophylactic Antimicrobial Agents and the Importance of Fitness. *N Engl J Med*. 2005:353: 1052-1054).

Is It Hot In Here?

Hot flashes are common problem for women undergoing treatment for breast cancer. A new study suggests that gabapentin adjusted 900 mg per day may help alleviate symptoms. Four hundred twenty women, with breast cancer and 2 or more hot flashes per day, were randomly assigned to receive gabapentin 300 mg per day or gabapentin 900 mg/day or placebo in 3 divided doses for 8 weeks. The 900 mg per day does reduce hot flashes by 49% and 46% at 4 and 8 weeks, respectively. The 300 mg dose was not effective at a statistical level. The authors suggest that gabapentin 900 mg per day should be considered for treatment of hot flashes in women with breast cancer (Pandya KJ, et al. Gabapentin for Hot Flashes in 420 Women with Breast Cancer: A Randomised Double-Blind Placebo-Controlled Trial. *Lancet*. 2005;366:818-824).

Homeopathy vs Conventional Medicine

A new study suggests that homeopathy is no better than placebo in treating disease. Researchers from the University of Berne in Switzerland, reviewed over 100 clinical trials of homeopathy and conventional medicine. Eight large homeopathy trials were eventually used in a meta-analysis, along with 6 large conventional medicine trials. The odds ratio for homeopathy was 0.88 and for conventional medicine 0.58. When only the largest trials were used, the odds ratio for homeopathy was 0.96 and for conventional medicine 0.67. This suggests that the benefit from homeopathy is no better than random chance (Shang A, et al. Are the Clinical Effects of Homeopathy Placebo Effects? Comparative Study of Placebo-Controlled Trials of Homeopathy and Allopathy. *Lancet*. 2005; 366: 726-732). An accompanying editorial states "Now doctors need to be bold and honest with their patients about homeopathy's lack of benefit. . ." (The End of Homeopathy. *Lancet*. 2005;366:690). Homeopathy which uses very dilute solutions to treat disease has been popular in Europe; however, this study marks a trend away from homeopathy in England. The Swiss government also recently withdrew insurance coverage for homeopathy after a 5-year trial because it did not meet efficacy and cost effectiveness criteria.

FDA Actions

The FDA has approved a new 4-component vaccine for children aged 12 months to 12 years that includes measles, mumps, rubella, and varicella viruses. The approval was based on data showing effectiveness of the vaccine was similar to that of MMR (measles, mumps, and rubella) and varicella vaccine (Varivax). The new vaccine will be marketed under the trade name ProQuad by Merck & Co.

Sanofi-Synthelabo has received approval to market an extended release formulation of zolpidem (Ambien) for the treatment of insomnia. The new preparation is a bi-layered tablet that delivers the drug in 2 stages, a quick dissolving layer to induce sleep, and a slower release layer to provide sleep continuity. Ambien CR will be marketed in a 12.5 mg dose for adults and a 6.25 mg strength for patients 65 years and older.

The Senate has approved a bill to limit over-the-counter sales of pseudoephedrine, a key ingredient in the illicit manufacturing of methamphetamine. The bill which has bipartisan support, will require decongestant medications containing pseudoephedrine to be sold behind pharmacy counters and would limit how much any individual can buy to 7.5g a month (250 30 mg tablets).The bill also encourages a computer tracking system to limit multiple purchases at different stores and pharmacies. A similar bill is working its way to the House of Representatives.

The FDA is one step closer to approving Pfizer's inhaled insulin powder after an advisory panel voted 7-2 to urge approval. The preparation, which will be marketed under the trade name Exubera, is a short-acting insulin powder that is used before meals. The drug does not replace the need for long acting insulin injections. There have been concerns that Exubera may hamper lung function in diabetics, but Pfizer has been able to show 2-year data that suggest patients experience only minimal decrease in lung capacity that is reversible if the drug is stopped. ■