CRITICAL CARE ALERT®

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

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INSIDE

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How Big a Problem is DVT in the ICU?

ABSTRACT & COMMENTARY

By Uday B. Nanavaty, MD

Pulmonary and Critical Care Medicine, Rockville, MD

Dr. Nanavaty reports no financial relationships related to this field of study.

Synopsis: *In this prospective study, despite the use of currently recommended prophylactic measures, nearly 10% of patients developed deep venous thrombosis during their ICU stay.*

Source: Cook D, et al. Deep venous thrombosis in medical-surgical critically ill patients: prevalence, incidence, and risk factors. *Crit Care Med*. 2005;33:1565-1571.

In this prospective study, Cook and associates looked at prevalence and incidence of deep vein thrombosis (DVT) as diagnosed by compression ultrasonography in ICU patients. Although the DVT prophylaxis was universal, the incidence of DVT was nearly 10%. Further studies are needed to define the group at highest risk of DVT and to assess the risk benefit ratio of aggressive preventive strategies.

Cook et al performed a prospective cohort study to determine the prevalence and incidence of proximal lower extremity DVT in critically ill patients admitted to a university-affiliated medical-surgical ICU. Patients who were older than 18 years and who were expected to have longer than 72 hours of ICU stay were enrolled. Patients with admitting diagnoses of trauma, orthopedic surgery, or pregnancy, or in whom life support was withdrawn, were excluded. To measure the prevalence of DVT, compression ultrasonography was performed in both lower extremities within 48 hours of admission in all patients. To measure the incidence of DVT, compression ultrasonography was performed twice weekly and upon clinical suspicion for DVT. The screening continued until development of DVT, ICU death, or ICU discharge.

Over one year, 817 patients were admitted to Cook et al's ICU and 261 were enrolled in the study. These patients were relatively sick (average APACHE II score, 25.5); the majority were mechanically ventilated (88.9%), and they experienced relatively high ICU

and hospital mortality rates (27.2% and 39.5%, respectively). Of the 261 patients, 10 had active bleeding and did not receive any anticoagulant prophylaxis. Of the remaining 251 patients, 18 did not receive any anticoagulant prophylaxis due to a variety of contraindications; 205 patients (81.7%) received unfractionated heparin (UFH) via the subcutaneous route for DVT prophylaxis. An additional 17 patients needed UFH intravenously for therapeutic anticoagulation. Ten patients received low molecular weight heparin in therapeutic doses for acute coronary syndromes, and one patient was on therapeutic warfarin.

The prevalence of occlusive DVT at the time of admission (within the first 48 hours) was 2.7 % (7 patients out of 261). In only 3 of these 7 patients was DVT clinically suspected based on a structured clinical examination. During their ICU stay (median, 10 days), 25 patients developed DVT, for an incidence of 9.6%, in spite of near universal thromboprophylaxis. Only 3 out of these 25 DVTs were clinically suspected. Out of all the 32 DVTs identified, only 3 were related to a catheter. In 3 patients with DVT, pulmonary embolism was diagnosed.

In univariate analyses, a personal or family history of venous thrombosis, thrombophilia, chronic hemodialysis, femoral central venous catheter, surgical operation, platelet transfusion, and vasopressor administration were identified as risk factors for lower limb DVT. In multivariate analysis, a personal or family history of DVT (hazard ratio [HR], 4.0), end-stage renal disease (HR, 3.7), platelet transfusion (HR, 3.2) and vasopressor administration (HR, 2.8) were found to be independent risk factors for development of DVT.

Patients with DVT in general had longer ICU stays (median, 17.5 days compared to 9 days in patients without DVT); they required longer mechanical ventilation (median, 9 days vs 6 days), and had longer overall hospital stays (median, 51 days vs 23 days). There was no statistically significant difference in ICU mortality (25% vs 27.3%) or hospital mortality (53% vs 37.4%) among patients with or without DVT.

COMMENTARY

Venous thrombosis and pulmonary embolism are dreaded complications often thought to go unrecognized in the ICU. Almost all patients admitted to critical care units are believed to be at risk of venous thromboembolism (VTE), and hence guidelines have been established to increase the awareness of a VTE problem in the ICU as well to reduce the morbidity and mortality from VTE. Different units have differing policies to prevent VTE. When its use is not contraindicated, unfractionated heparin in a dose of 5000 Units 2 or 3 times a day is the standard of care. Low molecular weight heparin has been used as effective prophylaxis against VTE in orthopedic surgery patients. In the neurosurgical literature, especially in patients with intracranial hemorrhage, as well as in other patients with life threatening hemorrhage, compression stockings and or sequential pneumatic compression devices have been shown to be effective at reducing the incidence of DVT.

This particular study has several important highlights. At least in this study, in more than 200 patients where UFH was used, no episode of heparin-induced thrombocytopenia was reported. Also, although it is not clear from the paper, I believe the dose of UFH was twice a day as opposed to 3 times a day. Thrice daily dosing of UFH may further reduce the incidence of DVT. In addition, although 3 episodes of pulmonary embolism were reported, no fatality due to VTE occurred in this study. It is possible that since DVT was

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Statement of Financial Disclosure

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diagnosed even when not suspected, and could have resulted in the decision to therapeutically anticoagulate the patients, hence subsequent episodes of pulmonary embolisms may have gone undetected. This study is reaffirms the old saying, "an ounce of prevention is worth a pound of cure," as far as VTE is concerned. ■

Depression, Post-Op Infections, and Wound Healing after CABG Surgery

ABSTRACT & COMMENTARY

By Karen Johnson, RN, PhD

Professor, School of Nursing, University of Maryland

Dr. Johnson reports no financial relationship to this filed of study.

Synopsis: *When assessed 2 or 3 days after extubation, at hospital discharge, and again 6 weeks following coronary artery bypass grafting, patients with depressive symptoms had more wound infections and delayed wound healing than patients without evidence for depression.*

Source: Doering LV, et al. Depression, healing, and recovery from coronary artery bypass surgery. *Am J Crit Care.* 2005;14:316-324.

Doering and colleagues used a nonrandomized, comparative, longitudinal design to study 72 patients after CABG surgery to investigate the association among depressive symptoms, infections, and impaired wound healing. Data were collected at 3 time points post-operatively: within 48 hours after extubation, at the time of discharge from the hospital, and 6 weeks after discharge. Depressive symptoms were measured using the Multiple Affect Adjective Check List (MAACL). Physical recovery was measured by using the 6-minute walk test, the Wolfer-Davis Recovery Index, the physical health composite score of the Short Form 12 (SF-12) and a chart review to determine documented infections and episodes of prolonged wound healing required treatment.

Mean scores for the depressive symptoms were high at all 3 time points: mean scores for depressive symptoms on the MAACL were 19.8 (SD, 6.3), 18.8 (SD, 7.1), and 16.4 (SD, 7.8) respectively. At these 3 respective time points, this represents 92%, 88%, and 72% of the patients in the sample scoring higher than the population norm of 11. The highest incidence of depressive symptoms occurred within 48 hours of extubation (typically post-op day 2-3). Patients with higher depression scores at discharge were 3.7 times more likely than patients with lower depression scores to experience wound infections and wound healing problems 6 weeks after discharge (odds ratio, 3.7; 95% CI, 1.15-12.0; P = .03). These findings persisted even when the effects of age, diabetes and obesity were statistically controlled for. Patients with higher depressive scores also had shorter walking distances on the 6-minute walk test than did patients with lower depressive scores.

COMMENTARY

This is one of the first studies to establish a relationship between depressive symptoms and infections and impaired wound healing after CABG. This study found a high prevalence of depressive symptoms after CABG, and linked these symptoms to adverse outcomes after surgery.

The high prevalence of depressive symptoms reported in this study is alarming. The highest scores were within 48 hours post-extubation, typically on post-op day 2-3. Although this prevalence is striking, it is not clinically surprising. It is typically on about post-op day 2-3 that patients—irrespective of the type of surgery done—seem to have bad days. We tell them to expect it, but we do little about it. Doering et al postulate that feelings of depression are intensified in the first few post-op days as a result of pain, sleep deprivation, isolation, and loss of control. We have to continue to strive to do a much better job at controlling these factors.

Since Doering et al did not begin data collection until 48 hours post-extubation, we do not know how many of these patients were depressed pre-operatively. There is a long-standing link between depression and chronic cardiovascular disease. Over a third of the patients in this study carried diagnoses of chronic cardiovascular disease, because 36% of them had had a previous myocardial infarction or CABG procedure. It would be interesting to see if these findings could be replicated in patients with no previous experience with myocardial infarction or CABG, and in non-cardiac surgery patients postoperatively.

The association between depression, delayed wound healing, and infection is most likely due to hypothalamic-pituitary-adrenal (HPA) reactivity as a response to the stress. Critical illness, anesthesia, surgery, trauma, burns, hemorrhage, infection, pain, cold, fever, and emotional disorders are stressors that activate the HPA axis.[1,2] When faced with such a stressor, the hypothalamus releases corticotropin releasing hormone, which in

turn stimulates the anterior pituitary to release adrenal corticotropin hormone (ACTH), which then stimulates the adrenal cortex to release both the mineralocorticoid, aldosterone (to promote intravascular fluid retention) and the glucocorticoid, cortisol (to increase availability of substrates for metabolism and modulate the immune/inflammatory response). The HPA axis is an essential component of the general adaptation to stress, and plays a crucial role in cardiovascular, metabolic, and immunologic homeostasis. However, cortisol has a profound effect on the inflammatory process as it inhibits the functions of almost every cell involved in inflammation. This inhibition is mediated by altering the transcription of cytokine genes (eg, for Interleukins 1 and 6) and by inhibiting the production of proinflammatory substances (such as leukotrienes and prostaglandins).[3]

If we are going to make an impact on the negative association between depression and impaired wound healing, we need to start with controlling or mitigating the physical and emotional response to the stress of surgery and the environments we place patients to heal. This study highlights the importance of assessing our patients' emotional health, in addition to their physical health postoperatively, because emotional health influences patient outcomes. ■

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Potential Adverse Impact of HIPAA on Clinical Research

ABSTRACT & COMMENTARY

By David J. Pierson, MD, Editor

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

Synopsis: *Because of the requirement for advanced written consent prior to patient contact for a telephone interview, participation in a follow-up study using an established registry of patients after acute coronary syndromes fell from 96% in the pre-HIPAA period to 34% in the post-HIPAA period.*

Source: Armstrong D, et al. Potential impact of the HIPAA privacy rule on data collection in a registry of patients with acute coronary syndrome. *Arch Intern Med*. 2005;165:1125-1129.

Implementation of the Health Insurance Portability and Accountability Act (HIPAA), and especially its Privacy Rule, has affected everyone who works in health care. This study from the University of Michigan sought to determine the potential effect of the Privacy Rule on the conduct of clinical research in the form of a telephone interview-based follow-up study. The patients were a consecutive group of patients with acute coronary syndrome prior to implementation of the HIPAA rules, and a similar group of patients after the HIPAA rules were put into effect. Armstrong and colleagues used a quasi-experimental pretest-posttest study design to assess participation rates in a telephone follow-up study in these cohorts. The pre-HIPAA period included telephone interviews, conducted 6 months after hospitalization for an acute coronary syndrome, for which verbal informed consent was sought from the patients. In the post-HIPAA period, telephone contact could not be initiated until written informed consent had been received by Armstrong et al, using a mailed form requesting permission to conduct the interview. Armstrong et al determined incremental costs involved in this study once the HIPAA rules were put into force, as well as the percentage of patients who provided consent.

There were 1221 patients in the pre-HIPAA group and 967 patients in the post-HIPAA group. Overall success in obtaining 6-month follow-up occurred in 1177 patients (96.4%) in the pre-HIPAA period and in 329 (34.0%) patients in the post-HIPAA period ($P < 0.01$). In the post-HIPAA period, 343 patients returned a completed consent form, 95.9% of whom granted consent; 112 forms were not sent out, in part because of "administrative oversights associated with instituting several simultaneous requirements" of HIPAA, and 490 patients failed to respond to the mailed request. Only 14 of the patients (4.1%) who returned the form refused consent. The authors calculated that the additional costs of HIPAA compliance, over and above the other costs of conducting this study, were $8704.50, including $4146.00 in start-up costs and $4558.50 per year in ongoing costs.

■ COMMENTARY

No one working in US health care has been unaffect-

ed by the implementation of HIPAA. The act has reduced inappropriate divulgence of protected health information, but the methods by which this important goal has been achieved have also created headaches for both clinicians and researchers. This article reports the impact of the HIPAA requirement for written informed consent prior to telephone contact for the purposes of research. Armstrong et al, established investigators at a major academic medical center with an established registry of patients who had experienced an acute coronary syndrome, found that their ability to contact the patients and do the research was markedly impaired, at least under the conditions of this investigation.

As Armstrong et al note, this experience at a single center may not be representative of those of clinical researchers elsewhere. The initial period of HIPAA implementation has been a time of learning and adjustment for everyone. It is possible that investigators at other centers will be more successful in carrying out their work in the face of the HIPAA Privacy Rule. Armstrong et al admit that they employed a conservative interpretation of the rule in designing this study, although they point out that the harsh penalties mandated by the HIPAA Privacy Rule create a strong incentive for research centers to interpret it strictly. They caution that "although everyone agrees that maintaining patient privacy is a laudable goal, the HIPAA Privacy Rule may create a substantial burden and prohibit the development of valuable research."

The impact of the new, more stringent privacy regulations, both on clinicians' access to needed information for patient management and on investigators' abilities to carry out valid clinical research, remains to be fully demonstrated. Clinicians and researchers-as well as patients and their families-should follow future study findings and policy rulings relating to this issue closely. ■

Special Feature

Human Simulation Training in the ICU: Applicability, Value, and Disadvantages

By John O'Donnell, MSN, CRNA, Michael Beach, MSN, CRNP, and Leslie A. Hoffman, RN, PhD

Mr. O'Donnell is Director, Nurse Anesthesia Program, University of Pittsburgh School of Nursing; Mr. Beach works in the Acute Care Nurse Practitioner Program, University of Pittsburgh School of Nursing, and Dr. Hoffman works in the Department of Acute/Tertiary Care School of Nursing, University of Pittsburgh

Mr. O'Donnell, Mr. Beach, and Dr. Hoffman report no financial relationship to this field of study.

Introduction

Simulation training has a long history with examples ranging from "modeling" in the animal kingdom (eg, a lion teaching hunting skills to a cub), to "war games" designed to better prepare soldiers for battle.[1,2] In health care, simulation can be used in a broad range of situations, ranging from simple part-task trainers, such as IV arms, to computer-driven mannequins that emulate adult, pediatric, and obstetric events.[3-13] In its most complex form, high fidelity human simulation provides a mechanism to provide safe, realistic training for a wide range of common, emergent and/or rarely encountered situations across multiple practice domains.

The introduction of advanced yet affordable simulators has encouraged clinical critical care educators to learn more about this form of education. Simulation training is not a panacea or replacement for traditional clinical education. In our experience, this approach is a valuable adjunct to traditional education that allows educators to enhance cognitive and psychomotor skills in a safe environment and thereby improve practice. This essay will review advantages and disadvantages of simulation training and describe lessons that we have learned in our work in this area.

Advantages

Ethical Issues. Traditionally, health care professional education has extensively relied on the apprenticeship model. Typically, clinical experience begins with a lecture, followed by demonstration and, when the time is right, performing a procedure or managing a case with faculty supervision. This approach has several notable disadvantages. First, clinical settings are designed to provide care, not educational experiences. Second, expertise in critical care practice is acquired over time. There is no guarantee that appropriate exposure will occur before a novice practitioner must make critical decisions.[4,6-9,12] Prior to the development of lower-cost, high fidelity simulators, no reasonable alternative existed. With simulation, it is possible to train critical care practitioners to manage common and rarely occurring events before encountering them in clinical practice. Third, simulation provides a forgiving environment.

Trainees can respond to scenarios designed to mimic critical care practice and observe consequences of their actions, effective or ineffective.[4,6-9] Using computer feedback logs and integrated audio-visual capability, faculty can review actions taken during these scenarios in a debriefing session. Together, faculty and trainees can collaboratively critique decision-making and identify more appropriate actions. Trainee errors can be used to learn from one's mistakes—a powerful teaching tool.[2,4] This training can be very realistic because scenarios can be designed to branch in several directions, dependent on participant actions. Also, presenting conditions can be designed to be ambiguous to better mimic critical care events, since most real life critical care situations do not have clear decision points.

With simulation, learning occurs during and after the event. Lighthall and colleagues[6] evaluated the performance of medicine, anesthesia and surgery residents who participated in scenarios designed to replicate medical crises, or observed while others performed the scenarios. A number of common errors were noted that were categorized as technical (improper drug selection or dosage), vigilance related (failure to notice dysrhythmias, ventilator alarms), judgment related (inappropriate delay of therapy, uncorrected abnormality) or communication related (ineffective use of personnel). The residents easily recognized many of these errors and, in debriefings, agreed they were everyday occurrences in medical emergencies. Using such observations, it is possible to refine teaching and reduce the likelihood of such events.

Rare Event Training. One particular benefit of simulation is that all trainees can experience rare events and receive immediate feedback with an opportunity for expert modeling and correction. Barsuk et al[13] assessed the performance of 36 physicians who completed Advanced Trauma Life Support (ATLS) training using simulation scenarios and noted practice errors. They modified the training to include an additional 45 minutes of simulation that incorporated skills involved in ATLS training and repeated testing in a second group of 36 physicians. The addition of simulation produced a significant decrease in the number of individuals not performing critical actions or taking appropriate steps in the recognition and management of tension pneumothorax, hypovolemic shock, and cervical spine mobilization.

Common Event Training. With simulation, it is possible to train large groups of providers in patient scenarios that are common, but which pose a threat if performed incorrectly. **Examples include:**

1. procedures such as endotracheal intubation, difficult airway management, central line insertion, and fiberoptic bronchoscopy;
2. management of acute pathophysiologic conditions, such as shock, arrhythmia, hypotension, or hemorrhage; and
3. team response during cardiac arrest, trauma resuscitation, or out-of-hospital rescue. The ability to teach crisis management skills is a particular advantage.[6]

When the apprenticeship model is used, students may be pushed to the background or asked to leave the room in the interest of patient safety. In a simulated environment, trainees are forced to assume a lead position and direct care. Marsch and colleagues[12] tested ability of first responders to adhere to algorithms of cardiopulmonary resuscitation using a simulated cardiac arrest in an intensive care environment. The physician-nurse teams functioned well in areas such as recognizing the arrest and calling for help, but there were significant delays in the initiation of basic life support and defibrillation. Such observations called attention to the need to provide additional training in crisis team management.

Training Efficiency. Training efficiency is an often overlooked advantage of simulation training. Abrahamson and colleagues[8] compared outcomes following usual training of anesthesiology residents to usual training plus simulation. The residents were able to attain proficiency in a smaller number of elapsed days, thus effecting a time saving of personnel, and achieved proficiency in a smaller number of trials in the operating room, thereby posing a significant lower burden of supervision and threat to patient safety. Our experience has been similar. Since introduction of simulation training, we have reduced the amount of time nurse anesthesia students require before assuming responsibility for intubation from 3 months to less than one day. Concurrently, the role of the faculty has changed from performing skills while students observe or directing student performance to coaching, cuing, and prompting. Simulation also appears to promote learning retention.[12]

Recruitment. An additional unique advantage of simulation education relates to recruitment and retention of personnel. We routinely schedule visits of applicants to our simulation training center as part of recruitment efforts. Students, prospective house staff and fellows immediately perceive the value of hands on practice and training and seek out these experiences when available.

Critical Thinking. One of the most important critical care competencies involves the ability to apply critical decision-making skills in routine, as well as emer-

gent situations. Simulation training can facilitate learning to manage such situations independently or with support analogous to that available in the critical care setting. Such training provides an ideal opportunity to evaluate and refine communication skills required for effective clinical practice.[10] Simulation training can also be used to explore common communication errors within professions and across multidisciplinary teams.[10] Findings from qualitative studies suggest that this approach helps students work through problems, acquire skills and build confidence that can be transferred to the clinical setting. Faculty also benefit from simulation education by refining their clinical knowledge base and learning to develop innovative educational strategies.

Trainee Feedback. When formal evaluation is incorporated into simulation training, evaluations are almost unanimously positive. In anecdotal reports, trainees have expressed gratitude for being adequately prepared through the simulation experience. A recent nursing graduate recounted being present in a cardiac arrest situation during the night shift. She was able to function effectively until the cardiac arrest team arrived because she had prior simulation experience managing a code in the role of a critical care nurse. In our training, we use two facilities, a single high-fidelity human simulator (Laerdal SimMan™) located in the School of Nursing and the WISER Center (www.wiser.pitt.edu) which houses 16 high-fidelity simulators and conducts training for approximately 6,000 practitioners yearly from within and outside the University.

In summary, simulation education offers the ability to provide a customized educational experience and, if administered as a component of an educational program that includes objectives, pre-course didactic preparation, well designed simulator programming, and effective evaluation tools, can be reliable and valid with development of true performance benchmarks. Reported benefits of simulation education include improved appreciation of team work, the ability to recognize and handle anxiety provoking situations, improved communication skills, and a potential for incorporation of skills developed through simulation into improving patient outcomes.

Disadvantages

Artificial Environment. Although students state that they find the simulation training realistic and valuable, simulation is not reality. Manikins can provide realistic physical responses which mimic various pathologies. Many manikins have accurate airways which can be manipulated to demonstrate a range of easy to difficult airway scenarios. Few manikins have realistic eyes. Some allow for line placement or chest tube insertion. Many mimic bowel, lung, and heart sounds. At least one can talk, but none have the ability to mimic conversation with a patient, limiting patient provider interaction

Paucity of Supporting Evidence. An important challenge facing those who advocate this training relates to the need to objectively validate benefits of this training through methodologically sound studies. To date, few validation studies have been performed. Studies are needed to demonstrate the ability to improve knowledge and skills and transfer this knowledge to actual patient situations.

Equipment and Personnel Costs. Developing and maintaining a simulation program is costly. Computer-based high-fidelity human simulation will cost more than $50,000 for the manikin and support equipment. The environment necessary for full utilization of the experience, cameras and recording equipment, a dedicated area in which to establish the equipment, additional manikins of varied ages and physical conditions, adds significantly to this cost. Time is also a consideration. Simulation training involves a substantial amount of time in set up and evaluation. Although the scenarios or experiences may take a relatively short period of time, analysis of the student's actions, mistakes and options can be time consuming. Lectures can be provided to a large number of students, but the number that can participate in a simulation activity is dependent on the number of manikins and faculty. Others may observe and add to their learning experience, but it is not hands-on experience.

Perhaps the most costly aspect is the expense of providers being away from the clinical setting for training. In undergraduate nursing programs, this problem can be solved by having the faculty who would be supervising students in the clinical setting involved in simulation training. Other programs do not have the same access to faculty who can leave the bedside. An additional problem involves finding and training a cadre of faculty to run simulation courses. Despite the standardized, open-ended programming capability of the Laerdal SimMan™ and SimBaby™ products, many clinicians have little interest in creating their own programming for scenarios or do not feel they have time to do this writing. This represents a substantial burden for technical staff associated with simulation facilities, but will likely be minimized in the near future with the emergence of commercial simulation educational products.

Lessons Learned

Despite challenges, affordable high fidelity simulator devices (such as the Laerdal SimMan™, among others) are becoming increasingly integrated into the education of critical care professionals. Although simulation education cannot replace all aspects of traditional clinical training, it is clearly a valuable supplement. The key to a successful simulation program includes several important considerations. **These include:**

1. at least one dedicated advocate within the clinical faculty who is willing to catalyze the effort;
2. strong administrative support for the effort; and
3. the ability and dedication conduct studies that quantify the value of training in regard to translation to the clinical setting and thereby data that can be used to evaluate training and modify this as needed.

As research in this area continues, we believe that simulation training will become essential for evaluation and benchmarking of key cognitive and psychomotor skills. This benchmarking will provide assurance that all personnel have the requisite skill and ability to safely practice in an increasingly complex clinical environment. ■

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CME / CE Questions

23. Despite administration of appropriate prophylactic therapy in nearly all patients, what percent of patients developed DVT during their ICU stay?

a. 1.2%
b. 2.4%
c. 4.8%
d. 9.6%
e. 19.2%

24. In the study by Doering and colleagues, CABG patients postoperatively had a high incidence of:

a. infections and impaired wound healing.
b. depression, infection and impaired wound healing.
c. immobility.
d. hypercortisolemia.
e. All of the above

Answers: 23 (d); 24 (b)

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.

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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.

Beta-Blockers May Be Useful for Noncardiac Surgery

High risk patients benefit from perioperative beta-blockers when undergoing major noncardiac surgery according to new study. Researchers from Tufts University reviewed the records of 782,969 patients in 2000 and 2001 at 329 hospitals throughout the United States. Patients were graded with the Revised Cardiac Risk Index (RCRI), which takes into account high-risk surgery, ischemic heart disease, cerebrovascular disease, renal insufficiency, and diabetes. The RCRI is graded on a 0-5 point scale, with 5 representing the highest risk. High risk surgery included all intrathoracic, intraperitoneal, and superinguinal vascular procedures. Patients with contraindications to beta blocker therapy were excluded. Over 660,000 patients had no contraindications to beta-blockers, and 120,338 patients received beta-blocker treatment during the first 2 hospital days. The relationship between perioperative beta-blocker treatment and the risk of death varied directly with cardiac risk. Patients with an RCRI of 0 or 1 were found to have no benefit from beta-blocker treatment, whereas for patients with an RCRI of 2, 3, or 4, or more the adjusted odds ratio for death in the hospital, were 0.88 (95% CI, 0.80, 0.80-0.98), 0.71 (95% CI, 0.63 - 0.80) and 0.58 (95% CI, 0.50-0.67), respectively. The authors conclude that perioperative beta-blocker therapy is associated with a reduced risk of in-hospital death among high-risk patients undergoing major noncardiac surgery. They also noted that there was no benefit for low risk patients (Lindenauer PK, et al. Perioperative Beta-Blocker Therapy and Mortality After Major Noncardiac Surgery. *N Engl J Med*. 2005;353:349-361). An accompanying editorial points out that perioperative beta-blocker therapy has been somewhat controversial because of conflicting data in recent years. The current study shows an apparent benefit in high-risk patients, but they also look forward to the results of 2 ongoing randomized trials that will help clarify the role of beta-blockers for low-risk and intermediate-risk patients (Poldermans D, et al. Beta-Blocker Therapy in Noncardiac Surgery. *N Engl J Med*. 2005;353:412-414).

Promising New Weight Loss Drug?

More data shows that topiramate (Topamax) is associated with weight loss and, in this latest study, may also lower blood pressure in obese, hypertensive patients. In a study from Norway, 531 obese patients with hypertension were randomized to placebo, topiramate 96 mg/day, or topiramate 192 mg/day. All patients received the same diet, exercise, and behavioral modification advice. Patients were followed for 28 weeks. Mean weight loss was 1.9% for placebo and 5.9% and 6.5% for the 96 mg and 192 mg doses, respectively ($P < 0.001$ for each compared with placebo). Diastolic blood pressure was reduced 2.1, 5.5, and 6.3 mm Hg, respectively ($P < 0.015$ vs placebo). Systolic blood pressure was reduced 4.9, 8.6, and 9.7 mm Hg, respectively (P = NS). Paresthesia occurred in 33% of the active treat-

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ment group. The authors conclude that topiramate produced clinically relevant effects in reducing body weight and BP, with generally mild to moderate adverse effects (Tonstad S, et al. Efficacy and Safety of Topiramate in the Treatment of Obese Subjects with Essential Hypertension. *Am J Cardiol.* 2005;96:243-251).

Treating Shift-Work Disorder

Modafinil (Provigil) may be of some value for people with excessive sleepiness associated with shift-work sleep disorder. Researchers from Harvard randomized 209 patients with shift-work sleep disorder to receive either 200 mg of modafinil or placebo before the start of each shift. Modafinil resulted in modest improvement in nighttime sleep latency (1.7 ± 0.4 vs 0.3 ± 0.3 minutes, respectively; $P = 0.002$). More patients also had improvement in their clinical symptoms based on multiple objective tests and patients diaries (74% vs 36%, respectively; $P < 0.001$). Patients taking modafinil also had reduction in frequency and duration of lapses in attention during nighttime testing of performance, and proportionally fewer patients reported having had accidents or near accidents while commuting home (both $P < 0.001$). These benefits, however, were mild, and patients treated with modafinil continued to have excessive sleepiness and impaired performance at night. The authors conclude that modafinil 200 mg at the beginning of a shift may improve shift-worker's performance as compared to placebo, although the benefit is modest (Czeisler CA, et al. Modafinil for Excessive Sleepiness Associated with Shift-Work Disorder. *N Engl J Med*. 2005;353:476-486). An accompanying editorial urges caution when interpreting these results and suggests "the current study does not adequately assess the clinical value of this particular drug in shift-work sleep disorder, nor does it justify writing more prescriptions for modafinil." The authors do note that up to 20% of workers in industrialized nations are shift-workers and calls for "further scientific studies to address in a cohesive manner the serious health and safety issues that surround us by virtue of us having become, to a large extent, a shift-working society" (Basner RC. Shift-Work Sleep Disorder--The Glass is More Than Half Empty. *N Engl J Med*. 2005;353:519-521).

Another Flu Vaccine Shortage?

With the flu season looming, Chiron Corp. is again having difficulty with flu vaccine production. Last year the company found contamination at its Liverpool production plant, a situation that cause severe shortages of vaccine in the United States. This year, the company has discovered contamination at a German plant and is stating that it can only provide vaccine for the US market. The German plant was primarily the source of the Begrivac flu vaccine, which was sold on the world market. The company is making "substantial progress" in fixing problems at the Liverpool plant where the US vaccine is made. Meanwhile, Acambis plc is working on a universal flu vaccine that could offer permanent protection against all types of influenza. The company hopes to generate a universal vaccine that would not require annual changes in formulation and would protect against both influenza A and B including avian strains. The company, however, states that it may require years of clinical trials before earning approval. Fears of avian influenza pandemic have prompted the French company Sanofi-Aventis to work on a vaccine for the avian H5N1 strain that has killed millions of birds and 50 people in Asia. Preliminary results are promising, however, full-scale production could take months, according to Anthony Fauci, MD, Director of the National Institute of Allergy and Infectious Diseases.

FDA Actions

The FDA has approved the first of the new class of drugs for the treatment of insomnia characterized by difficulty with sleep onset. Takeda Pharmaceutical's ramelteon (Rozerem) is a selective agonist at 2 melatonin receptors in suprachiasmatic nucleus, receptors that are thought to regulate circadian rhythm and sleepiness. Recently marketed sleeping medications target GABA receptors (ambien, lunesta) and, although these drugs are associated with less addiction and sleep latency then benzodiazepines, they are still designated as Schedule IV drugs. Ramelteon has shown no evidence of abuse or dependence potential and will, therefore, be marketed as a unscheduled drug. It is also approved for long-term use and has not been associated with memory impairment or impairment of motor ability. The most common adverse events associated with ramelteon were somnolence, fatigue and dizziness (> 2% over placebo).

Plan B, Barr Pharmaceutical's "morning-after pill" is being considered for over-the-counter approval by the FDA. The issue has become a political hot potato, and even briefly held up the Senate's confirmation of Lester Crawford, MD, as Commissioner of the FDA. It is expected that decision will be made by September. ■