CRITICAL CARE ALERT®

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

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INSIDE

Effect of Kinetic Therapy on Pulmonary Complications

ABSTRACT & COMMENTARY

Synopsis: *Kinetic therapy decreased pneumonia and atelectasis but not length of stay in the ICU, length of stay in the hospital, or mortality.*

Source: Ahrens T, et al. *Am J Crit Care*. 2004;13:376-383.

THE PRIMARY OBJECTIVE OF THIS STUDY WAS TO DETERMINE whether patients receiving mechanical ventilation who tolerate kinetic therapy have better pulmonary function than patients treated with standard turning. A secondary objective was to assess the cost-effectiveness of kinetic therapy. This was a prospective multicenter study including 234 medical, surgical, and trauma patients (137 control patients and 97 patients receiving kinetic therapy). There were an additional 21 patients assigned to receive kinetic therapy who were not included in the analysis because they did not tolerate the therapy.

Kinetic therapy significantly decreased the occurrence of ventilator-associated pneumonia ($P = 0.002$) and the development of lobar atelectasis ($P = 0.02$). The length of stay in the intensive care unit and in the hospital did not differ between the patients receiving kinetic therapy and control patients. Charges for intensive care were not significantly different between the groups. Mortality was the same in both groups. Ahrens and colleagues concluded that kinetic therapy helps prevent ventilator-associated pneumonia and lobar atelectasis in critically ill patients.

COMMENT BY DEAN R. HESS, PhD, RRT

Beds for kinetic therapy rotate in a turn of at least 40 degrees, whereas beds for continuous lateral rotation therapy rotate less than 40 degrees. The use of these beds has become popular in many intensive care units—attributable, in part, to the marketing efforts of their manufacturers. Due to the high costs associated with these beds, their use remains controversial. Studies to date have been single-center studies with small sample sizes and have failed to clearly make a case for or against the use of these beds. Therefore, I was initially excited

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to see this multi-centered, prospective, randomized, controlled trial of the effect of kinetic therapy on pulmonary complications.

However, there are several methodological issues that seriously limit the generalizability of the results published here:

1) Ahrens et al claim that this is a prospective randomized trial. However, close examination of the methods reveals that patients were assigned to the kinetic therapy group or the control group on an alternate month basis. This is not a randomized design and suffers the same risk of assignment bias as use of medical record number for group assignment.

2) It is unclear how valid was the detection of ventilator-associated pneumonia and lobar atelectasis. The assessors were not blinded to the therapy and their skills to identify ventilator-associated pneumonia and lobar atelectasis are not validated. A ventilator-associated pneumonia rate of 33% and a lobar pneumonia rate of 43% are reported for the control group—these are extraordinarily high, calling into question their validity!

3) Dropping 21% of the patients from analysis because they did not tolerate kinetic therapy is problematic. One in 5 patients did not tolerate the therapy! An appropriate analysis would be intention-to-treat rather than dropping these patients from the study. This analysis might have significantly biased the analysis.

4) The reporting of hospital charges is meaningless. It is well known that there is virtually no relationship between charges and costs.

Despite the limitations of this study, the results are similar to several meta-analyses that have been published on this use of kinetic therapy.[1,2] That is, although the use of kinetic therapy may decrease the risk of ventilator-associated pneumonia and atelectasis, it does not affect other important outcomes such as mortality or hospital length of stay. Thus the cost-benefit of this therapy remains ambiguous. Some will argue that a decrease in the risk of ventilator-associated pneumonia is reason enough to use these beds. Others will demand additional patient-important outcomes such as mortality or cost of care.

An important question might be how kinetic therapy decreases the pneumonia rate without this translating into important outcomes like mortality? Perhaps the diagnosis of ventilator-associated pneumonia is over-reported. When the diagnosis is made on clinical criteria and the individuals making the diagnosis are not blinded to the study group, this is a strong possibility. Perhaps the antibiotic therapy chosen to treat the pneumonia is effective. Or, perhaps most likely, pneumonia is only one factor (and maybe a relatively minor factor) affecting patient outcome.

Unfortunately, the cost-effectiveness of these beds remains unknown even with the publication of this paper. What is debatable is whether a reduction in ventilator-associated pneumonia is sufficient evidence to support the use of these beds. This is likely to remain controversial until a properly designed study demonstrates an improvement in an important outcome like survival or the cost-effectiveness of the beds can be established using accepted methodology for such analysis. ■

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Does Early Tracheostomy Improve Outcomes?

ABSTRACT & COMMENTARY

Synopsis: *This prospective, randomized trial evaluated the role of early percutaneous tracheostomy in critically ill adults projected to require more than 14 days of mechanical ventilation. They found significant reductions in ICU length of stay, the incidence of ventilator-associated pneumonia, and mortality.*

Source: Rumbak MJ, et al. *Crit Care Med*. 2004; 32(8):1689-1694.

Percutaneous dilatational tracheostomy (PDT) is now a common procedure in the intensive care unit (ICU). Typically, it is performed when a patient fails weaning from mechanical ventilation or has a prolonged need for an artificial airway because of a neurological disorder. However, the optimal timing for performing PDT remains uncertain. Previous studies have not been conclusive as to whether early tracheostomy offers any advantage. Therefore, Rumbak and colleagues studied the effects of early (within 48 hours) or late (14-16 days) PDT on the outcome of mechanical ventilation, ICU length of stay. and mortality in a select group of mechanically ventilated critically ill adults.

Rumbak and colleagues performed a prospective randomized trial involving patients requiring intubation for acute respiratory failure in medical ICUs in United States. The inclusion criteria called for patients to be older than 18 years with a projected need for mechanical ventilation > 14 days, APACHE II score > 25 and the availability of informed consent. Patients were excluded from the study if a) they had had a previous tracheostomy; b) they were not a candidate for PDT due to neck deformity; c) the platelet count was < 50,000/mm^3 or another bleeding tendency was noted; and d) positive end-expiratory pressure (PEEP) was > 12 cm H_2O, or e) they had already been on mechanical ventilation for > 48 hours. The patients were cared for under a protocol with low tidal volume, standard precautions for prevention of ventilator-associated pneumonia (VAP) were observed, and invasive methods were used to diagnose VAP. A standard protocol was used for weaning.

A total of 120 patients were enrolled in the study. All 60 patients in the early tracheostomy group, and 50 out of 60 assigned to delayed tracheostomy, received the procedure. The overall mortality was significantly lower in the early tracheostomy group (19 out of 60, 31.6%) as compared to the delayed group (37 out of 60, 61.7%; $P < 0.005$). VAP developed in 3 patients (5%) in the early group as compared to 15 (25%; $P < 0.005$) in the delayed group. Similarly, days of mechanical ventilation, days in ICU, and days sedated were significantly lower ($P < 0.001$ for all 3 outcomes) in the early tracheostomy group (4.8±1.4 days, 7.6±4.0, and 3.2±0.4 days respectively) compared to the delayed group (16.2±3.8 days, 17.4±5.4 days, and 14.1±2.9 days). Rumbak et al conclude that PDT is not only safe but also a very effective procedure in improving outcomes of critically ill patients.

COMMENT BY UDAY B. NANAVATY, MD

There is ample evidence in the literature that PDT can be safely performed at the bedside in critically ill patients. PDT requires much less time compared to traditional surgical tracheotomy performed in the operating room. The procedure is relatively easy to learn, and since intensivists can perform it at the bedside, the procedure is often accomplished much faster than when it must be scheduled in an operating room, even when elective. In both published studies and practice, complication rates are very low. It has been shown before that tracheostomy is well tolerated by patients compared to translaryngeal endotracheal intubation, resulting in more comfort, less sedative use and perhaps less incidence of VAP.

One thing that remains unclear is the appropriate timing for doing the procedure. After initial enthusiasm for early tracheostomy in the 1980s, benefits of performing this procedure early have been questioned. The present study is the first to show such a dramatic improvement in outcome, including mortality, by performing early PDT. An earlier, larger, randomized clinical trial in mainly trauma and other surgical ICU patients compared early vs late surgical tracheostomy and failed to show any significant improvement in outcome.[1]

Which variables did Rumbak et al use to predict the need for mechanical ventilation for greater than 14 days? It was evidently a very accurate prediction model since more than 80% of patients in their "delayed" group indeed needed a tracheostomy. One previous study[2] suggests that physicians and nurses can correctly predict the need for < 3 or < 7 days of mechanical ventilation about 60% of the time. If an accurate predictor for prolonged mechanical ventilation need can be established, then early tracheostomy is clearly a favorable procedure. At this point, I find it hard to convince myself, and the relatives of critically ill patients, that PDT should be performed within first 48 hours. More

studies are needed to confirm the successful prediction of the need for prolonged mechanical ventilation, as well as the benefits of early (within 48 hours of intubation) vs later PDT. ■

References

1. Sugerman HJ, et al. *J Trauma*. 1997;43(5):741-747.
2. Afessa B, et al. *Chest*. 1999;116(2):456-461.

■ **COMMENT BY DAVID J. PIERSON, MD**

No hypothesis relating to respiratory care in the ICU has proved more difficult to study in an objective fashion than the commonly held tenet that tracheostomy facilitates ventilator weaning. The study by Sugerman et al, referred as reference #1 above, is testimony to that statement. A project of the Western Trauma Association Multi-Institutional Study Group, it took considerably longer to complete, and wound up rather differently than originally planned. Some member centers declined to participate because of the strongly held opinion that it was inappropriate to perform a tracheotomy in the first few days—and others refused to join because they felt it inappropriate not to do the procedure early. Investigators at other centers enrolled patients but failed to complete data collection, and there were numerous protocol violations. The study failed to demonstrate any advantage to early tracheostomy. More than anything else, though, it showed how deeply rooted—and divergent—clinicians' biases are with respect to the timing of this procedure.

That definitive studies of early vs late tracheostomy have been hard to come by has not been for want of trying. However, several major obstacles stand in the way of any attempt at a large-scale, randomized clinical trial. The inability to blind the investigators to the patient groupings is a big problem. So is the lack of uniformity among criteria for successful weaning, extubation, and reintubation, and also the increasing use of noninvasive ventilation in recent years to avoid reintubation. In addition, today, the performance or withholding of a tracheostomy may be a function of reimbursement and disposition considerations rather than clinical factors: some patients cannot be transferred to long-term weaning facilities unless the receiving institution rather than the referring hospital performs the procedure.

Into this context comes the clinical trial of Rumbak et al, involving somewhat fewer patients than the study of Sugerman and colleagues, with the striking findings that early PDT markedly shortens ventilator time and ICU LOS, reduces the incidence of pneumonia by 75%, and cuts the overall mortality rate in half. These are pretty dramatic outcomes, considering the less dramatic findings of previous studies and the fact that it was essentially just the timing of an elective procedure that was studied.

Rumbak et al make the following statement in their conclusion: "Early tracheotomy in critically ill medical patients who undergo ≥14 days of ventilation may have significant benefits over delayed tracheotomy." A primary selection criterion for including patients in the study was the clinicians' judgment that ventilatory support would be required for at least 14 days. The finding that patients in the early tracheostomy group were in fact ventilated for only 7.6±4.0 days has 3 possible explanations: first, that early PDT somehow makes respiratory failure resolve more quickly; second, that even experienced clinicians cannot tell in the first 2 or 3 days of critical illness which patients will require prolonged mechanical ventilation; or, third, that some aspect of our management tends to keep patients on the ventilator when they no longer need to be. Which of these possibilities is most likely to occur cannot be answered from this study, and definitely needs further investigation. ■

Maximum Sterile Barriers for CVC Insertion Save both Money and Lives

ABSTRACT & COMMENTARY

Synopsis: *This cost-effectiveness analysis based on available published data suggests that the routine use of maximum sterile barriers for central venous line insertion would reduce the incidence of line-related infections and save both money and lives.*

Source: Hu KK, et al. *Clin Infect Dis*. 2004;39: 1441-1445.

Hu and colleagues at the VA Puget Sound Health Care System in Seattle previously performed a systematic, evidence-based review of the effectiveness of maximum sterile barriers (MSBs) for central venous catheter (CVC) insertion in reducing the incidence of infectious complications, particularly catheter-related bloodstream infections (CR-BSI).[1] In the present study, these same investigators performed a cost-effectiveness analysis to determine the economic as well as clinical impact of MSB use in hospitalized patients most at risk for CR-BSI.

Hu et al created a decision-analytic model to assess the outcomes of MSBs vs less-stringent sterile

barrier techniques in a hypothetical cohort of hospitalized patients requiring a multi-lumen CVC. This cohort was modeled to represent the types of patients for whom CVCs are most often used in the short term—that is, patients in the ICU, who are immunocompromised, or who receive total parenteral nutrition. Relative risks for local catheter infection, CR-BSI, and death were determined by pooling the data from available studies, and the authors deliberately used conservative estimates for associated costs and mortality.

In this analysis, the use of MSBs lowered costs from $621 to $369 per catheter insertion, and decreased the incidence of local infection (from 5.5% to 2.9%), CR-BSIs (from 5.3% to 2.8%), and death (from 0.8% to 0.4%). Based on these results, the authors estimated that, for every 270 CVCs placed using MSBs instead of a less-rigorous technique, $68,000 would be saved, and 7 episodes of CR-BSI and 1 death would be avoided. They recommend that MSBs be used for all non-emergent CVC insertions in hospitalized patients.

COMMENT BY DAVID J. PIERSON, MD

The MSB technique for CVC insertion includes all the components listed in the accompanying table. Hu et al estimated the incremental materials cost of using this technique at $15 per line insertion. In addition, on the basis of interviews with physicians at a tertiary-care academic center, a VA hospital, and a community hospital, they estimated that the average additional clinician time it took to adhere to the MSB standard was 20 minutes; however, the range was 2-30 minutes depending on whether the unit stocked the required materials, ideally in an all-inclusive CVC insertion kit. The estimated $40 overall additional cost for using MSB rather than a lesser degree of sterile technique was dramatically overshadowed by the cost savings from a lower incidence of catheter-related infections.

Two other measures for reducing the frequency of CVC-related infectious complications are the use of antimicrobial-impregnated catheters and skin antisepsis with chlorhexidine gluconate solution. Although this area has seen a certain amount of controversy, the current evidence base supports the use of these measures. The combination of these things with MSB technique deserves clinical study, but for now it appears that we should be using them—for both economic and clinical reasons. ■

Table

Maximum Sterile Barriers for Reducing the Incidence of Local and Systemic Catheter-Related Infections and Mortality

- Person inserting the central venous catheter wear all of the following:
  - Head cap
  - Face mask
  - Sterile body gown
  - Sterile gloves
- Full-size sterile drape around insertion site

Reference

1. Hu KK, et al. *Am J Infect Control*. 2004;32:142-146.

Should Patients with End-Stage Liver Disease be Intubated?

ABSTRACT & COMMENTARY

Synopsis: *Mortality among patients with advanced cirrhosis who required intubation and mechanical ventilation was related more to the derangement of liver function than to the severity of critical illness as assessed by APACHE II or SAPS.*

Source: Rabe C, et al. *Intensive Care Med*. 2004;30(8): 1564-1571.

Critical illness, and particularly the requirement for invasive mechanical ventilation, has a very poor prognosis in patients with advanced cirrhosis (end-stage liver disease, [ESLD]) although the reasons for this are uncertain. This study examined the hypothesis that outcome among ESLD patients requiring mechanical ventilation was primarily a function of the severity of the underlying liver disease rather than the acute problem resulting in ICU admission. Rabe and colleagues at the University of Bonn retrospectively reviewed the records of 76 consecutive medical ICU admissions of patients with ESLD who required intubation and ventilatory support between 1993 and 2003. All patients admitted during this interval whose records were complete were included, although subsequent admissions of the same patient were excluded.

The 46 men and 30 women had a mean age of 55 years (range, 18-77). Gastrointestinal bleeding was the reason for ICU admission in 57% of patients, and hepatic encephalopathy in 25%. Intubation was per-

formed for airway protection in 46%, because of respiratory failure in 38%, and for shock or other reasons in 16%. Fifty-nine percent of the patients died during the ICU stay, with the majority of deaths due to refractory shock and exsanguination. Although measures of hepatic compromise such as serum protein, bilirubin, prothrombin time, ALT, and the Child-Pugh score (class A, B, or C) were all strongly associated with mortality by univariate analysis, there was no clear relationship between severity of illness (as measured by acute physiology scores, APS) and mortality until very high APS scores (20 or higher) were reached.

Mortality in patients with Child-Pugh scores < 10 (classes A and B) was 33% (5/15), as compared with 66% (40/61) in patients with Class C. Among patients in Class C, survival was 16% among patients with initial Child-Pugh scores of 12-13, and only 8% among those with scores of 14-15. Using a modification of the TISS score to assess the intensity of nursing care and need for other ICU resources on the day of intubation, the authors found no difference in outcome between survivors and nonsurvivors. Mortality was very high even among patients who were intubated only for airway protection.

COMMENT BY DAVID J. PIERSON, MD

This retrospective study found death among ESLD patients who required intubation and mechanical ventilation in the setting of critical illness to be related primarily to the severity of the liver disease rather than to such measures of illness severity as APACHE II score, SAPS, and resource use. Receiver-operating characteristics curves with regard to ICU outcomes showed areas under the curve of 0.87 for the Child-Pugh score, as compared to 0.66 for the APACHE II score and 0.60 for the APS, indicating that the first performed substantially better as a predictor of ICU death.

While numerous studies have documented the poor survival of ESLD patients who require intubation and mechanical ventilation, this may be the first to demonstrate that this is due much more to the underlying liver disease than to the temporal reason for ICU admission. This finding, in Rabe et al's words, ". . .may enable clinicians to focus ICU resources on patients such as Child-Pugh A/B or mild Child-Pugh C (< 12 points). . . and not admit patients such as advanced Child-Pugh C (> 14 points) cirrhotic patients who are unlikely to benefit from ICU care." Whether ICU admission should be withheld from patients with ESLD is a murky area. However, the findings of this study may be helpful in discussing the appropriateness of continued aggressive care with ESLD patients and their families when rapid improvement does not occur in the setting of critical illness that requires invasive ventilatory support. ■

Special Feature

The Highly Reliable ICU

By Stephen W. Crawford, MD

We who work there can generally agree that the intensive care unit (ICU) can be a hectic environment. The flux of patients can be rapid and the clinical condition of those patients can change rapidly. Personnel can be challenged to manage multiple complex and evolving scenarios that include numerous medical treatments and medications in an increasingly technological world. As a result, iatrogenic complications and hospital-acquired infections pose a constant threat to our patients, as well as to the caregivers. The ICU seems to be a microcosm of the problem described in the report of the Institute of Medicine's (IOM's) Committee on Quality of Health Care in America, *To Err is Human; Building a Safer Health System*.[1] Adverse events and hospital deaths are common, and when these are combined, a large proportion of deaths are deemed preventable. Are there *organizational* approaches we can adopt in the ICU that will create a safer place?

Part of the problem in changing the present working condition may be that we think of the ICU as a *system*; highly integrated, rational and organized. However, we behave as though we are the center of an informational network. Rather than being an interdependent part among many in a complex system, we believe we are autonomous players who work within, and direct, the ICU structure. We behave as though our responsibility to safety is through personal improvement in medical technique and clinical knowledge. In action, we tend to minimize the role of systematic organizational improvements that require "group-think" to envision.

Karl E. Weick, a University of Michigan professor of organizational behavior and psychology, argues that organizations function best when they act as a single entity.[2] In the case of the ICU, improved function directly leads to fewer errors and better system safety. Our failure to view us as components in a larger ICU system decreases our mindfulness of the interactions of diverse people and processes in the ICU. People thinking as a team are better at seeing and acting upon small system errors earlier.

An improved awareness of the fine details can lead to

a reduction in errors. Weick described a concept widely used in organizational psychology and management: the "highly reliable organization" (HRO).[3] HROs share 2 essential characteristics: They constantly confront the unexpected, and they operate with remarkable consistency and effectiveness.

The ICU qualifies for the first characteristic, easily. Do we operate with remarkable consistency and effectiveness? I suspect most do not. I suspect also, that we all want to view our ICU as an HRO. Weick's analysis of HROs offers important lessons. His message: The best way for any organization, and its people, to respond to unpredictable challenges is by building an effective organization that expertly spots the unexpected when it crops up and then quickly adapts to meet the changed environment.

A model that is used to illustrate an HRO in everyday practice is that of naval aviation. Flight operations at sea on an aircraft carrier involve highly dangerous maneuvers, performed with precision and with strict timing around the clock in a variety of weather conditions, and often under very stressful political situations. These operations on the flight deck are managed for the most part by sailors who are only 19 to 20 years old! If the Navy can create a culture of safety to these young sailors, why is it so hard to do in the ICU staffed by highly schooled health care professionals?

There are at least 5 habits of an HRO, and these are not routinely incorporated into the structure and culture of the ICU.[4] These are habits our ICUs should cultivate in order to become safer and more efficient:

1. **Do not be tricked by successes.** HROs are preoccupied with their failures. They are incredibly sensitive to their own lapses and errors, which serve as windows into the vulnerability of their systems. They pick up on small deviations—and they react early and quickly to anything that doesn't fit with their expectations. HROs create climates where people feel safe trusting their gut-instincts. They question assumptions and report problems. They quickly review unexpected events, no matter how inconsequential. They encourage members to be wary of success, suspicious of quiet periods, and concerned about stability and lack of variety, both of which can lead to carelessness and errors.

2. **Defer to your experts on the front line.** There are so many deviations out there, so much dissonance. How do we know what's really worth paying attention to? The answer: Listen to your experts—the people on the front line, the nurses and therapists.

People at the top, physicians and nurse managers, may think that they have the big picture. More accurately, they have a picture, certainly not *the* picture, and certainly not bigger in the sense that it includes more data.

The picture that frontline workers see is different. It is drawn from their firsthand knowledge of the unit's operations, strengths, and weaknesses. What is important about the frontline workers' view is that these people capture a fuller picture of what the organization faces and what it can actually do. In most cases, they see more chances for bold action than the managers at the top. So it's better for HROs to allow decisions to migrate to frontline expertise rather than to the top of pre-established hierarchies.

3. **Let the unexpected circumstances provide your solution**. When something out of the ordinary happens, your stress level rises. The safest prediction for what will happen next is that your perception will narrow; you will get tunnel vision, and you will miss a lot of stuff. You have to be able to resist that dramatic narrowing of cues, because within everything that is happening unexpectedly, you will find what you need for a remedy.

The root cause analysis (RCA) approach is an effective tool for determining the remedies from disasters. The RCA is recommended by patient safety organizations, including Joint Commission on Accreditation of Healthcare Organizations for sentinel adverse events.

4. **Embrace complexity**. Medicine is complex, in large part because it is unknowable and unpredictable. In the face of all of this complexity, HROs are reluctant to accept simplification. They understand that it takes complexity to sense complexity.

We all instinctively try to simplify the data that we receive, but there are better and worse simplifications. Better simplifications arise from a deeper knowledge of the environment along with a deeper understanding of the organization and its capabilities. That knowledge and understanding develops when people attend to more things, entertain a greater variety of interpretations, differentiate their ideas, argue, listen to one another, work to reconcile differences, and commit to revisiting and updating whatever profound simplicities they settle on as guidelines for action. A complex organization is made up of diverse people with diverse experience. Its complexity fosters adaptability.

5. **Anticipate, but also anticipate your limits**. We try to anticipate as much as we possibly can. But we can't anticipate everything. There's such a premium on planning, on budgeting. In the face of all that, the notion of resilience has an affirming quality: You don't have to get it all right in advance.

Good strategy does not rely on anticipation alone. It's built on a smaller scale, updated more frequently, and driven by actions. It's not: "Think, and then act." Instead,

it's: "Think by acting." By actually doing things, you'll find out what works and what doesn't.

That doesn't mean you should stop anticipating. But you should add in two subtleties. First, focus your attention on key mistakes that you do not want to make. Second, trust your anticipations, but be wary of their accuracy. You can't see the whole context that is developing. Your anticipation is probably a reasonable first approximation of what might be happening, but no matter how shrewd you are, it won't cover some key features.

If safety was *really* important . . .

The keys to creating an HRO are rooted in the attitudes of the organization's leaders. We can model our ICUs after the HROs. We can do this by actually relying on frontline (bedside) expertise in our units and allowing (or insisting) that the person with specific expertise makes decisions. We can implement clear-cut procedures and policies and constantly train our staffs. Safety drills are an effective means of reinforcing and monitoring training on procedures.

Every ship's officer and aviator aboard an aircraft carrier believe safety is paramount. The belief is constantly reinforced by actions; repeated training, drills and accountability. Those safety officers and chief patty officers responsible for training the junior enlisted personnel are held accountable to the air-boss and commanding officer for mistakes and lapses of those in their charge. If safety is paramount in our ICUs, what actions do we take that send that clear message to those working at the bedside? The accountability starts with the behavior of the leadership which must mirror precisely what we expect of the staff. At sea, safety is everyone's responsibility. In the ICU, the directors and managers have to be part of the team and are every bit as responsible for the safe operation as the person at the bedside.

The culture of medicine does not lend itself easily to creating an HRO. Many physicians, by nature and training, function autonomously and decisively. Allowing the decision authority to migrate to the level of the bedside does not come readily. Moreover, we tend to believe in personal responsibility for training and education. Implementing repetitive training for the ICU staff and then conducting drills is unnatural. However, it is these actions of the ICU leadership that will foster a safer environment. ■

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3 Weick KE, Sutcliffe KM. *Managing the Unexpected: Assuring High Performance in an Age of Complexity*. Jossey-Bass; 2001.
4. Hammonds, KH. *Five Habits of Highly Reliable Organizations*. Fast Company. May 2002;58:124.

CME / CE Questions

24. Which of the following have been shown to decrease the incidence of catheter-related bloodstream infections?
a. Maximum sterile barrier technique
b. Use of antimicrobial-coated catheters
c. Skin antisepsis with chlorhexidine solution
d. All of the above

25. The use of kinetic therapy has been shown to decrease:
a. ventilator-associated pneumonia.
b. hospital cost.
c. sedation requirement.
d. minute ventilation.
e. All of the above

26. In the study of early percutaneous dilatational tracheostomy, which of the following were considered contraindications for the procedure?
a. Previous tracheostomy
b. Platelet count less then 50,000/mm^3
c. PEEP greater than 12 cm H_2O
d. All of the above
e. None of the above

Answers: 24 (d); 25 (a); 26 (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:

Sedative Use During Withdrawal of Life Support

PHARMACOLOGY WATCH

Hypertension: Therapy vs Calcium Channel Antagonists

Pharmacotherapy of hypertension has been much in the news in the last 2 months. Standard therapies such as atenolol have been challenged, while calcium channel antagonists may be making a comeback.

Researchers from Sweden performed a meta-analysis of 9 randomized, controlled trials that looked at the effectiveness of atenolol on cardiovascular morbidity and mortality in patients with hypertension. Four of the studies compared atenolol with placebo or no treatment, and 5 studies compared atenolol with other antihypertensive drugs. Although atenolol was effective at lowering blood pressure, there were no outcome differences with regard to all cause mortality (RR 1.01; 95% CI, 0.89-1.15), cardiovascular mortality (RR 0.99; 95% CI, 0.83-1.18), or myocardial infarction (RR 0.99; 95% CI, 0.83-1.19), compared to placebo. The risk for stroke was lower with atenolol, compared to placebo (RR 0.85; 95% CI, 0.72-1.01). When compared with other antihypertensives, no difference in blood pressure lowering was noted between treatment groups, but the meta-analysis revealed a higher mortality with atenolol, compared with other treatments (RR 1.13; 95% CI, 1.02-1.25). This included a higher risk of cardiovascular mortality and stroke. The authors suggest that the results "cast doubts on atenolol as a suitable drug for hypertensive patients." They further postulate that atenolol's low lipophilic profile, which theoretically may reduce its ability to prevent cardiac arrhythmias, could be responsible for these findings (*Lancet.* 2004; 364: 1684-1689). Some have criticized the study because it did not include newer well-designed trials in which atenolol was used in combination with other drugs including diuretics. In these studies, including ALLHAT and SHEP, the addition of atenolol resulted in overwhelming benefit. In the meantime, use of atenolol as monotherapy needs to be reevaluated, however, addition of atenolol to an existing regimen will probably remain a part of most clinical guidelines.

GEMINI Trial

Speaking of beta-blockers, a new study suggests that carvedilol may be a better choice for diabetic patients than metoprolol. The Glycemic Effects in Diabetes Mellitus: Carvedilol-Metoprolol Comparison in Hypertensives (GEMINI) trial was designed to compare the effects of beta-blockers with different pharmacological profiles on glycemic and metabolic control in diabetic patients who were already receiving renin-angiotensin system (RAS) blockade with either a ACEI or ARB. Over 1200 patients with diabetes and hypertension were randomized in GEMINI. The main outcome was change in baseline HbA1c after 5 months of therapy. A difference was noted in mean change of HbA1c for baseline between the drugs (0.13%;95%CI -0.22%-0.4%. *P*=.004) The mean HbA1c increased with metoprolol (0.15% [0.04%]; *P* < .001), but not for carvedilol (0.02% [0 .04%]; *P* =

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.65). Insulin sensitivity also improved with carvedilol but not with metoprolol, and progression to microalbuminuria was less frequent carvedilol than with metoprolol (6.4% vs 10.3%; *P* = .04). The drugs were used in equipotent doses to achieve similar blood pressure lowering effects. The authors conclude that the carvedilol, used in the presence of RAS blockade, does not effect glycemic control, and improves some components of metabolic syndrome relative to metoprolol in patients with diabetes and hypertension (*JAMA.* 2004;292:2227-2236). The study points out again that beta-blockers, with variable pharmacologic effects, may result in different clinical outcomes. Carvedilol is a nonselective beta antagonist, but has alpha 1 antagonist properties and mild vasodilatory properties.

CAMELOT Trial

The calcium channel antagonist amlodipine has beneficial cardiovascular effects in heart patients even if they have normal blood pressure according to new study. The Comparison of Amlodipine vs Enalapril to Limit Occurrences of Thrombosis (CAMELOT) study compared amlodipine 10 mg, enalapril 20 mg or placebo in patients with documented CAD and diatolic blood pressures < 100 mm Hg. The outcome measures were incidence of cardiovascular events and a second outcome was the use of intravascular ultrasound to measure atheroma volume. Nearly 2000 patients were followed over 24 months. New cardiovascular events (cardiovascular deaths, non-fatal myocardial infarction, resuscitated cardiac arrest, coronary revascularization, hospitalization for angina actors, hospitalization for congestive heart failure, fatal or non-fatal stroke or transient ischemic attack, or new diagnoses of peripheral vascular disease) occurred in 23.1% of placebo treated patients, 16.6% of amlodipine treated patients (HR 0.69; 95% CI, 0.54-0.88 [*P* = .003]) and 20.2% of enalapril treated patients (HR, 0.85; 95% CI, 0.67-1.07 [*P* = .16]). Plaque volume by ultrasound showed a trend towards less progression of atherosclerosis in the amlodipine group vs placebo (*P* = .12), with significantly less progression in the subgroup of patients with higher systolic blood pressures (*P* = .02). Compared with baseline atheroma volume progression in the placebo group (*P* < .001), the study showed a trend towards progression in the enalapril group, and no progression in the amlodipine group. The authors conclude that amlodipine reduced cardiovascular events and slowed progression of atherosclerosis in patients with CAD and normal blood pressure (*JAMA.* 2004;292:2217-2225). An accompanying editorial reviews the data and suggests mechanisms for the findings. More than any other factor, the editorialists suggest that lowering blood pressure to a systolic in the 120 mm Hg range may be the most important factor of all in patients with CAD (*JAMA.* 2004;292:2271-2273).

INVEST Trial

The INVEST study suggests that verapamil is as effective as atenolol with regard to benefit and side effects in diabetic patients with hypertension (*Hypertension* 2004;44:614-615). The PEACE trial looked at patients with coronary disease and normal or slightly reduced left ventricular function to assess whether addition of an ACE inhibitor would convey benefit, and found no benefit for these patients (*N Engl J Med.* 2004; 351:2058-2068).

The Dangers of Vitamin E

And vitamin E? Don't expect it to prevent cardiovascular disease or cancer for that matter. As vitamin E doses increase, so does all cause mortality, according to a large meta-analysis. Nineteen trials, which included nearly 136,000 participants, were evaluated in the analysis, of which 11 tested high dose vitamin E (400 IU/d). The pooled all-cause mortality risk difference for the high-dosage vitamin E was 39 per 10,000 (95% CI, 3-74 per 10,000; *P* = .035). For doses less than 400 IU/d, the mortality risk difference was 16 per 10,000 (CI, -41 to 10 per 10,000; *P* > .2). A dose-response analysis revealed an increase in all cause mortality with vitamin E dosages > 150 IU/d. The authors suggest that an increased mortality with higher doses of vitamin E is biologically plausible. Low doses of vitamin E may have some antioxidant effects, but higher doses may be pro-oxidant, particularly to LDL cholesterol. High doses of vitamin E may also displace other fats soluble antioxidants, disrupting the natural balance of antioxidant systems. Vitamin E may also be a mild anticoagulant, which may explain the increased hemorrhagic stroke seen in some vitamin E trials. This study was felt important enough to warrant early release online, since many people worldwide take vitamin E supplements on a daily basis far in excess of 400 IU/d. The full study will be published in the January 2005 *Annals of Internal Medicine*.

FDA Actions

The FDA has approved a new biologic for the treatment of relapsing forms of multiple sclerosis. Natalizumab is a monoclonal antibody that is given intravenously once a month. It will be marketed by Biogen as Tysabi.