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INSIDE

Which Vasopressor Is Best in Patients with Shock?

ABSTRACT & COMMENTARY

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

This article originally appeared in the June 2010 issue of Critical Care Alert. *It was edited by David J. Pierson, MD, and peer reviewed by William Thompson, MD. Dr. Pierson is Professor, Pulmonary and Critical Care Medicine, Harborview Medical Center, University of Washington, Seattle, and Dr. Thompson is Staff Pulmonologist, VA Medical Center; Associate Professor of Medicine, University of Washington; they both report no financial relationships relevant to this field of study*

Synopsis: *This randomized, multicenter trial showed no differences in 28-day mortality in patients with shock who received either norepinephrine or dopamine, but did reveal a higher incidence of arrhythmia in the dopamine-treated group.*

Source: De Backer D, et al; SOAP II Investigators. Comparison of dopamine and norepinephrine in the treatment of shock. *N Engl J Med.* 2010;362:779-789.

Consensus guidelines recommend the use of either dopamine or norepinephrine as first-line therapy for patients with shock, but recent observational evidence suggests norepinephrine may be associated with better outcomes. De Backer et al sought to confirm these results in a prospective manner by evaluating whether one of these agents was associated with a lower mortality rate in patients with shock.

They conducted a double-blind, randomized trial at eight centers in three countries in which they enrolled patients at least 18 years of age who required a vasopressor for management of shock, defined as mean arterial pressure (MAP) < 70 mm Hg or SBP < 100 mm Hg despite receiving fluids, or having a central venous pressure (CVP) > 12 with signs of tissue hypoperfusion. Patients with all forms of shock, including septic, cardiogenic, and hypovolemic, were included. Patients were excluded if they had already received a vasopressor for

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> 4 hours during the current shock episode or had a serious arrhythmia (e.g., rapid atrial fibrillation).

Enrolled patients were randomized to receive either dopamine or norepinephrine. Dopamine was titrated in increments of 2 mg/kg/min up to a maximum of 20 mg/kg/min, for a target blood pressure determined by the treating physician, while norepinephrine was titrated in increments of 0.02 mg/kg/min up to a maximum dose of 0.19 mg/kg/min. Patients who remained hypotensive on the maximum dose of either agent were then started on open-label norepinephrine, while any patients on vasopressors at baseline were changed over to the study drug. Patients could still receive either hydrocortisone or recombinant activated protein C as part of sepsis management. The primary study endpoint was the rate of death at 28 days, while secondary endpoints included rates of death in the ICU, hospital, and at 6 and 12 months, ICU length of stay, number of days without organ support (e.g., mechanical ventilation, renal replacement therapy), time to reach MAP > 65 mm Hg, and use of dobutamine and other inotropic agents. The incidence of adverse events including arrhythmias, myocardial necrosis, skin necrosis, distal ischemia, or secondary infections, was also recorded.

A total of 1679 patients were enrolled in the study, including 858 in the dopamine group and 821 in the norepinephrine group. The groups were well matched in terms of major baseline characteristics including the use of hydrocortisone or activated protein C, but there were small differences in baseline physiologic variables such as the heart rate, $PaCO_2$, and PaO_2/FiO_2 (P/F ratio). The majority (62%) of patients had septic shock, while 16.7% had cardiogenic shock and 15.7% had hypovolemic shock. With regard to the primary endpoint, there were no differences in the rate of death at 28 days between the dopamine and norepinephrine groups (52.5% vs. 48.5%; $p = 0.10$) and the trial was subsequently stopped due to a lack of evidence of benefit for one agent over the other. Of note, however, was the fact that the mortality rate in patients with cardiogenic shock was higher in those treated with dopamine than those treated with norepinephrine. ICU and hospital mortality and death rates at 6 and 12 months also showed no difference between the two groups. The incidence of adverse events was similar between the two groups except more patients in the dopamine group had arrhythmias, the most common of which was atrial fibrillation.

■ COMMENTARY

Vasopressors are such commonly used medications in the ICU that it would be nice to have some data as to which agent is more effective for resolving hypotension and improving outcomes in critically ill patients. It is not clear, however, that this trial provides an adequate answer to that question, as there were some methodological issues that warrant concern. For example, patients received a fairly limited amount of intravenous fluids before the transition to vasopressors, and restrictions were placed on the doses of the vasopressors in an attempt to achieve "equipotent" doses despite the lack of data supporting such a practice.[1]

The biggest problem with the trial by De Backer and colleagues, however, is that they included patients with all forms of shock and did not restrict their study, for example, to patients with septic shock. It was particularly surprising that they included patients with hypovolemic shock, as the primary treatments for that problem are usually to stop any bleeding and restore intravascular volume with aggressive fluid administration. Given differences in the underlying pathophysiology and hemodynamic issues between the different forms of shock, the management of fluids and other medications in the different patient groups would be expected to vary significantly and perhaps make it difficult to tease out differences that one could attribute to one of the particular vasopressors. When one considers variations in physician practices not just between institutions but also between countries, it is not hard to see how many other factors may have been affecting outcomes beyond the choice of vasopressor.

Despite this issue, there are several interesting items that emerge from this study. The first pertains to the safety of using norepinephrine in the ICU. Many of us likely remember the days of reluctance to use that medication out of concern we might have been doing harm to our patients. The phrase "Levophed … Leave 'em dead" was a not uncommon refrain early in my training before the institution

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made a broader move toward using that vasopressor and physicians became more comfortable with its application. This study and another recent study comparing vasopressin and norepinephrine[2] provide reasonable evidence that such concerns are unwarranted and the medication is not associated with more severe adverse events when compared to dopamine.

The second item of note is the observed differences in mortality in the subgroup of patients with cardiogenic shock. From a theoretical point of view, one would expect a vasopressor with significant alpha-1 adrenergic activity to be problematic in patients with cardiomyopathy as the increase in afterload would impair left ventricular outflow. Dopamine has typically been favored in such situations because of its more prominent inotropic effects. The data from this study suggest, however, that the theoretical rationale may not hold in practice and perhaps give clinicians a little more leeway in their use of vasopressors in these patients, although further research is warranted to confirm this subgroup analysis finding before we make a wholesale change in practice. The fact that norepinephrine was associated with less arrhythmia than dopamine would be another advantage in this patient group. ■

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Cerebral MRI in Endocarditis

ABSTRACT & COMMENTARY

By Michael H. Crawford, MD

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This article originally appeared in the June 2010 Clinical Cardiology Alert. *It was peer reviewed by Ethan Weiss, MD. Dr. Weiss is Assistant Professor of Medicine, Division of Cardiology and CVRI, University of California, San Francisco. Dr. Weiss reports no financial relationships relevant to this field of study.*

Source: Duval X, et al. Effect of early cerebral magnetic resonance imaging on clinical decisions in infective endocarditis. *Ann Intern Med*. 2010;152:497-504.

THE PRESENCE OF CEREBRAL COMPLICATIONS OF INFECTIVE ENdocarditis (IE) can affect diagnostic and treatment decisions. Thus, this group from Paris, France, evaluated whether early cerebral MRI would affect the diagnosis and management of hospitalized patients suspected of having IE. In addition to blood cultures, echocardiograms, and other routine tests, cerebral MRI was performed within seven days of admission and evaluated independently by blinded neuroradiologists. A cardiologist and an infectious-disease specialist evaluated the patients < 24 hours before the MRI, as well as after the MRI results were known. The patients were followed for six months. Of the 274 patients admitted for suspected IE, 150 were included in the study. Of these, 20 were excluded for inadequate MRI images or because the diagnosis of IE was immediately excluded. Of the remaining 130 patients, 59% had definite IE, 38% possible IE, and IE was ultimately excluded in 2%. Neurologic abnormalities were present in 16 patients; 13 of these 16 patients had CT scans that indicated lesions likely due to IE. MRI detected cerebral lesions in 106 (82%), including ischemic lesions in 68, microhemorrhages in 74, and aneurysms in 10. Based upon these findings, 17 of the 53 non-definite IE cases (32%) were upgraded to definite or possible IE, and therapeutic plans were changed in 24 of the 130 patients (18%). Overall, 36 of 130 patients (28%) had their diagnosis or therapeutic plan modified by the MRI results. The authors concluded that many patients with IE but no symptoms had cerebral lesions identified by MRI that modified their diagnosis and treatment.

■ COMMENTARY

Autopsy studies have shown a high incidence of cerebral lesions in confirmed IE cases, but most patients do not have neurologic symptoms (12% in this series). Given the difficulty in diagnosing IE and the high mortality despite modern diagnostic and therapeutic approaches, any test that would augment the diagnosis and refine therapy would be welcome. These investigators sought to evaluate whether cerebral MRI is such a test. Routine early MRIs in this study demonstrated lesions in 82% of suspected IE cases. The most common finding was microhemorrhages, which are not specific for IE. Microhemorrhages are seen in hypertension, amyloid vasculitis, and other conditions. Second most common were ischemic lesions, and third were aneurysms, both of which are more likely to be IE complications and are included as minor criteria in the Duke classification. Excluding microhemorrhages, and based upon the more specific MRI findings, almost one-third of patients were upgraded to definite or possible IE by the Duke criteria. Therapeutic plans were altered based upon the MRI in most of these patients. Although this would seem beneficial, there are no data to suggest that outcomes are different in this ob-

servational study. Also, the costs of routinely performing cerebral MRI in all suspected IE cases were not explored. Not only would the direct cost of the MRI be relevant, but the indirect costs of false-positive diagnoses, more surgery, etc., would be as well.

Another problem with an observational study is that there are no control groups and no age-matched normal groups. Consequently, we not only don't have relative outcome data, but we don't know how specific these MRI findings are for IE. Mycotic aneurysms would be expected to be specific, but only 8% had them. Cerebral abscesses would also likely be due to IE, but only 6% had them. Ischemic lesions were much more common, but their specificity is not completely known. On the other hand, all the findings on the MRI in this series could represent vascular phenomena due to embolic, generalized vasculitis or immune phenomena of IE. Since vascular phenomena are a minor criterion in the Duke criteria, these findings would skew the diagnosis toward IE and would likely alter therapy, as was seen in this study. Interestingly, the total mortality in this series was 15%, which is low for an IE series. However, patients who went straight to surgery, or were too sick to have an MRI, were excluded.

The diagnosis of IE has evolved over the last 40 years. In the mid-20th century, it was clinical exam and blood cultures; then, echocardiography, especially transesophageal, changed things. In most patients, the diagnosis is now made by echo before the blood cultures are back. MRI and other imaging modalities may now alter our diagnostic approach again, and we may soon need new diagnostic criteria. ■

Does Therapeutic Hypothermia Affect Predictive Value of Somatosensory Evoked Potentials After CPR?

ABSTRACT & COMMENTARY

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

This article originally appeared in the June 2010 issue of Neurology Alert. *It was edited by Matthew E. Fink, MD, and peer reviewed by M. Flint Beal, MD. Dr. Fink is Vice Chairman, Professor of Neurology, Weill Cornell Medical College; Chief, Division of Stroke and Critical Care Neurology, NewYork-Presbyterian Hospital, and Dr. Beal is Professor and Chairman, Department of Neurology, Cornell University Medical College. Drs. Fink and Beal report no financial relationships relevant to this field of study.*

Synopsis: *Bilateral absence of N20 responses in the setting of therapeutic hypothermia does not preclude neurologic recovery in comatose survivors of cardiac arrest.*

Source: Leithner C, et al. Does hypothermia influence the predictive value of bilateral absent N20 after cardiac arrest? *Neurology* 2010;74:965-969.

Predicting neurologic recovery in comatose survivors of cardiac arrest is a challenge faced routinely by neurologists in the inpatient setting. To date, therapeutic hypothermia (TH), where the patient's core temperature is maintained at 32-34° C for 12-24 hours following resuscitation, is the only treatment modality that has been shown to improve neurologic outcome in this population. Because the currently accepted prognostic indicators of outcome after cardiac arrest were validated (and subsequently outlined in the 2006 AAN practice parameter) prior to the widespread use of TH, the accuracy of these indicators in patients treated with hypothermia is not yet clear. Of the established predictors, bilateral absence of the cortical N20 response in median nerve somatosensory evoked potential (SSEP) testing is considered to be the most reliable early indicator of a poor neurologic outcome and, in one small study, appeared equally useful in the setting of hypothermia. Prompted by a case of a patient who had a favorable neurologic recovery after TH despite an initially absent N20 bilaterally, Leithner and colleagues set out to examine the predictive value of bilateral absent N20 in the setting of therapeutic hypothermia.

In this study, the authors retrospectively analyzed the records of 185 consecutive patients treated with hypothermia following cardiac arrest. Of 185 patients, 112 had SSEP testing. Testing was performed more than 24 hours after resuscitation using a standard technique. The N20 responses were categorized as: absent, pathologic (prolonged latency and/or reduced amplitude of the cortical response), or normal. Using a clinical database, baseline and follow-up information regarding neurologic outcome was obtained. Outcomes were determined at the time of the ICU discharge and assessed using the Pittsburgh cerebral performance category (CPC).

The findings revealed that N20 was absent in 36 (32%) patients, pathologic in 22 (20%) patients, and normal in 54 (48%) patients. Of the 36 patients with bilaterally absent N20 responses, 35 (97%) had poor outcome (CPC 4 or 5). One patient with initially absent N20 response three days after cardiac arrest (after normothermia) had an excellent outcome (CPC1) with subsequent recovery of the N20 response at 18-month follow up testing. In this patient, the peripheral (N9) and cervical (N13) responses were significantly delayed on both initial and follow-up testing. Though the peripheral response delay alone is unlikely

to explain the initial absence of the cortical response, it does indicate a coexisting peripheral abnormality, which the authors suggest was due to alcoholic polyneuropathy and reduced extremity temperature at the time of the initial testing. The authors also identified another case in which the cortical response amplitudes were severely diminished such that the N20 was nearly absent three days after resuscitation (during normothermia). This patient also had a favorable outcome (CPC1) and recovery of normal N20 response amplitude nine days after cardiac arrest.

The authors conclude that their results reaffirm the high negative predictive value of bilaterally absent N20 responses in comatose survivors of cardiac arrest in the setting of TH. However, the identification of two cases of absent, or nearly absent, N20 responses after cardiac arrest treated with hypothermia with subsequent recovery of both neurologic functioning and cortical somatosensory evoked responses suggests that the certainty of this prediction may be diminished in patients treated with hypothermia. The authors propose that hypothermia may allow for a delayed functional recovery of somatosensory evoked responses well beyond the established one- to three-day period post-resuscitation during which the test is typically performed.

■ **COMMENTARY**

This study highlights the importance of rigorous re-evaluation of the standard indicators of neurologic prognosis following cardiopulmonary resuscitation in patients undergoing therapeutic hypothermia. Inherent in hypothermia treatment is the use of sedative and paralytic agents which hinder clinical assessment and therefore increase dependence on neurophysiologic parameters, particularly SSEP. Although this is a small study with a bias toward identification of false positive results, it suggests that absent N20 may not be as reliable early in the course of TH and that meaningful recovery of cortical responses may occur later than previously expected in these patients. Further prospective studies designed to establish false-positive rates and appropriate timing of evoked potential testing are needed to guide decision-making in patients treated with induced hypothermia. Until then, bilateral absence of the N20 response in these patients should be interpreted cautiously. ■

Silent Pulmonary Emboli in Patients with DVT: Time to Screen?

ABSTRACT & COMMENTARY

By Joseph Varon, MD, FACP, FCCP, FCCM

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Dr. Varon receives grant/research support from and serves on the speakers bureaus for The Medicines Group and EKR Pharma.

This article originally appeared in the May 29, 2010 issue of Internal Medicine Alert. *t was edited by Stephen A. Brunton, MD, and peer reviewed by Gerald Roberts, MD. Dr. Brunton is Adjunct Clinical Professor, University of North Carolina, Chapel Hill, and Dr. Roberts is Assistant Clinical Professor of Medicine, Albert Einstein College of Medicine, New York, NY. Dr. Brunton serves on the advisory boards of Amylin, Kowa, Novo Nordisk, and serves as a speaker for Boehringer Ingelheim and Novo Nordisk. Dr. Roberts reports no financial relationships relevant to this field of study.*

Synopsis: *Asymptomatic pulmonary embolism is quite common among patients with deep venous thrombosis. In many instances in these patients, the pulmonary emboli are located within the central pulmonary arteries.*

Source: Stein PD, et al. Silent pulmonary embolism in patients with deep venous thrombosis: A systematic review. *Am J Med* 2010;123:426-431.

THIS STUDY WAS AIMED AT EVALUATING THE INCIDENCE OF UNsuspected or undiagnosed pulmonary embolism (PE) among patients with deep venous thrombosis (DVT). The primary question that the investigators were addressing was whether or not routine PE screening was necessary for those patients with documented DVT. To accomplish this task, the investigators conducted a systematic review of 28 published studies in PubMed through July 2009. These 28 studies were the result of a literature search that included more than 950 citations. The 28 studies contained specific raw data and detailed description of the methodology utilized to diagnose PE, and documented the absence of symptoms of PE. Criteria for diagnosis of a "silent" PE included the interpretation of a high-probability ventilation-perfusion lung scan, computed tomography (CT), pulmonary arteriography on the basis of either the prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED) or non-PIOPED criteria and the absence of pulmonary symptoms and/or signs.

Of 5233 patients with DVT evaluated, 1655 (32%) had evidence of silent PE. Those patients with proximal DVT had a higher incidence of PE. Larger perfusion defects were noted in those patients that had DVT in the pelvic veins or thighs as compared with those with distal thrombi. Moreover, the incidence of recurrent PE was higher in those patients with silent PE (5.1%) as compared to those patients without silent PE (0.6%). A trend for an increased prevalence of silent PE was noted with aging. Those patients younger than age 40 years had silent PE in 14% of the cases as compared to 22% in those aged 40-70 years, and 40% in those older than 70 years of age.

■ **COMMENTARY**

For decades, we have known that PE is commonly found in patients postmortem, in whom this clinical entity was undiagnosed or not suspected antemortem.[1] The main question has been: Should we look for PE in every patient with DVT even if they have no pulmonary signs or symptoms?[2] The fact is that the treatment of both DVT and PE is the same, and conducting additional studies has cost and potential side-effect issues.

This well-conducted systematic review is interesting because it shows a high prevalence of silent PE in patients with DVT. With this in mind, the rationale for conducting "additional" pulmonary work-up in patients with documented venous thrombosis (i.e., ventilation-perfusion lung scans, CT, or angiogram) is the fact that patients with DVT tend to have more recurrent PEs when the patients have a "silent" PE (as noted in this study) when compared to those with a first episode of non-silent PE.

That almost one-third of all patients with DVT have a silent PE moves forward the concept of considering pulmonary screening in this patient population. In addition, the decision to admit a patient with a documented DVT to a hospital instead of treating at home may be modified on the basis of these findings. ■

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2. Monreal M, et al. Prospective study on the usefulness of lung scan in patients with deep vein thrombosis of the lower limbs. *Thromb Haemost.* 2001;85:771-774.

Daily Reminders and Earlier Removal of Central Venous and Urinary Catheters

ABSTRACT & COMMENTARY

By David J. Pierson, MD

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

This article originally appeared in the June 2010 issue of Critical Care Alert. *It was peer reviewed by William Thompson, MD.*

Synopsis: *In this before-after study in a surgical ICU, addition to the daily physician worksheet of a red box requiring the checking of "yes" or "no" to continued need for central venous and urinary catheters was associated with a significant reduction in the duration of catheterization.*

Source: Seguin P, et al. Effectiveness of simple daily sensitization of physicians to the duration of central venous and urinary tract catheterization. *Intensive Care Med*. 2010; Epub ahead of print; doi: 10.1007/s00134-010-1829-1831.

This study from a surgical ICU in a French university hospital sought to determine the effect on catheterization duration of a daily reminder notifying physicians that the patient had a central venous catheter (CVC) or urinary tract catheter (UTC) and asking whether there was continued need for that catheter. The authors used a before-and-after study design. In the "before" period, the number and duration of CVCs and UTCs in the unit were tracked for a 10-month period, along with the incidence of catheter-associated infections and clinical patient data. For 10 months, starting two months after the "before" phase ended, a red box questioning the continued utility of the catheter was added to every daily physician worksheet for all patients with CVCs or UTCs. As part of the routine charting and ordering for each patient every day, the physician was required to check "yes" or "no" to the continued utility of the catheter. If "no" was checked, the nurses in the unit removed the catheter that day.

There were 676 patients in the "before" period and 595 in the "after" period. Duration of catheterization (median [interquartile range]) was significantly less in the "after" period: for CVC, from 5 (3-9) to 4 (3-7) days ($p < 0.001$), and for UTC, from 5 (3-11) to 4 (3-8) days ($p = 0.010$). For CVCs, the incidence of catheter-related infections fell from 1.8% to 0.3% ($p = 0.029$ unadjusted, and 0.010 when adjusted for age, diagnosis, and SAPS II score) in the second study period, although the difference in incidence per 1000 device-days (2.8 vs. 0.7) was not different after adjustment as mentioned ($p = 0.051$). For UTCs, the incidence of catheter-related infections was not different (4.3% vs. 3.0%; $p = 0.23$ after adjustment), and the same was true for the rate per 1,000 device-days (5.0 vs. 4.9; $p = 0.938$). The authors conclude that, "This study showed that a simple reminder on the patient's daily care sheet significantly decreased the duration of central venous and urinary tract catheterization."

■ **COMMENTARY**

This study has a number of potentially important design problems, the paper omits aspects of the methods and potential discussion points that could have bearing on its validity, and the causality imputed in the authors' concluding statement is assumed rather than demonstrated by the results.

In the methods section, the historical baseline durations of CVCs and UTCs in the authors' unit are given as 8 ± 6 and 9 ± 7 days, respectively, yet the observed median "before" rates preceding the intervention described were 5 days in each case. This substantial discrepancy and its relationship to the 1-day average reduction in duration for both catheters following the intervention are not discussed. A concern is that the daily reminder may not have been the only thing different with respect to physicians' tendency to remove catheters sooner than in the past. It is not possible from the information in the paper to assess this or several other questions about the methods, or about other aspects of care in this particular ICU that might have affected the study's findings.

These design and interpretation difficulties notwithstanding, though, the association between the physician reminder and a shorter duration of catheterization supports the notion that changing clinician behavior is an important step in improving outcomes in the ICU. For catheters in ICU patients, time is money. That is, the longer patients have them, the more it costs in terms of the devices and their care, and also in terms of complications. When patients no longer need CVCs and/or UTCs, getting them out as quickly as possible is not only cost-effective but — more importantly — is also better for the patients in several ways. ■

CME / Objectives

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

- discuss pertinent safety, infection control and quality improvement practices;
- explain diagnosis and treatment of acute illness in the hospital setting; and
- discuss current data on diagnostic and therapeutic modalities for common inpatient problems. ■

CME Questions

33. In the randomized, controlled trial by De Backer and colleagues that compared dopamine to norepinephrine in patients with shock, which of the following outcomes was more common in patients managed with dopamine?

a. Survival to ICU discharge
b. Fewer days of shock
c. Arrhythmias
d. Distal limb ischemia

34. According to the retrospective study by Leithner, et al, when therapeutic hypothermia was used to treat patients who were comatose after cardiac arrest, the use of somatosensory evoked potentials (SSEP) to predict neurological recovery were:

a. Equally predictive regardless of the use of therapeutic hypothermia
b. Less predictive after therapeutic hypothermia
c. More predictive after therapeutic hypothermia
d. Technically difficult to perform after therapeutic hypothermia

35. Based on the recent review by Stein and co-authors on pulmonary emboli in the setting of DVT, which of the following statements is true?

a. The prevalence of asymptomatic PE is common in patients with proximal DVT
b. The detection of asymptomatic PE alters the treatment of patients with proximal DVT
c. Patients with proximal DVT found to have asymptomatic PE had a higher mortality
d. None of the above

Answers: 33. (c); 34. (b); 35. (a)