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Ancrod for the Treatment of Acute CVA

ABSTRACT & COMMENTARY

Source: Sherman DG, et al for the STAT participants. Intravenous ancrod for treatment of acute ischemic stroke — the STAT study: A randomized controlled trial. *JAMA* 2000;283:2395-2403.

Extracted from malaysian pit viper venom, ancrod has been used outside the United States for thrombosis treatment because of its ability to accelerate fibrinogen cleavage and induce rapid defibrinogenation. Because elevated fibrinogen has been associated with poor outcomes in stroke, some have suggested ancrod for emergent treatment. Possible mechanisms include depletion of fibrinogen for thrombosis, accelerated spontaneous fibrinolysis, decreased blood viscosity, and improved circulation.

This study reports the findings of the Stroke Treatment with Ancrod Trial (STAT), a four-year multicenter, double-blind, controlled trial in which 500 ischemic stroke patients were randomized to receive either ancrod or placebo. Eligible patients included those presenting within three hours of symptom onset who did not meet exclusion criteria (e.g., intracranial hemorrhage [ICH], mass lesion, bleeding disorder, elevated blood pressure). Ancrod was administered as a 72-hour initial infusion (doses of 0.167, 0.125, or 0.082 IU/kg/hr based on initial fibrinogen levels), followed by one-hour infusions on days four and five, with target fibrinogen levels of 1.18-2.03 µmol/L.

Patients were followed for 90 days with a primary outcome measure of favorable functional status, defined as a Barthel Index (BI) score of 95 (indicating little or no need for help with activities of daily living or return to at least baseline prestroke status). Safety monitors included patient mortality, adverse events, and ICH incidence.

The ancrod group had a higher rate of favorable outcomes vs. placebo (41.1% vs 35.3%, respectively) and a higher rate of complete recovery (a BI score of 100) or return to baseline prestroke status (36.1% vs 26.4%, respectively). This better outcome was consistent regardless of age, prestroke disability, or time to treatment (within the 3-hour treatment period, though some patients were outside

INSIDE

this window). Mortality and adverse event rates were similar for both groups. There was a trend toward more symptomatic ICHs for ancrod (5.2% vs 2.0%, P = 0.06), all occurring within 72 hours of treatment onset.

Rapid initial defibrinogenation was associated with treatment success (favorable outcome of 45.8% vs 34.6% when 6-hour levels were within therapeutic range) and with less risk for adverse events. Conversely, subsequent serial low fibrinogen levels appeared associated with greater risk for ICH and less treatment success. The investigators concluded that ancrod has a favorable risk/benefit profile in the setting of acute ischemic stroke.

COMMENT BY THEODORE C. CHAN, MD, FACEP

The STAT study adds to the growing literature supporting acute stroke therapy, along with the National Institute of Neurological Disorders and Stroke (NINDS) trial assessing tPA and the second Prolyse in Acute Cerebral Thromboembolism (PROACT II) trial assessing intra-arterial thrombolysis.[1,2]

This study is remarkable from a number of standpoints. First, the study was conducted primarily in community hospitals, indicating that both research on stroke and actual acute treatment of it are feasible and applicable in this setting, where the large majority of stroke patients receive care. Second, while only 500 of 2613 patients screened were eligible, only a small number (383) were excluded because they presented outside the three-hour window. Third, rapid initial defibrinogenation was associated with favorable outcome, whereas subsequent levels were related to increased ICH risk, suggesting that control of fibrinogen levels may improve outcome without necessarily increasing risk.

The results of STAT must be interpreted cautiously. The investigators used only the BI as their measure of functional status. Other studies, such as NINDS, used multiple measurements to assess neurologic status. Also, tPA had a much easier dosing regimen in NINDS, and results were as favorable as the STAT findings for ancrod. Third, a recent European Stroke Treatment with Ancrod Trial (ESTAT) has been prematurely terminated because of increased 90-day mortality. Assessment of ancrod for acute ischemic stroke should await the analysis of this trial. ❖

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Emergency Medicine Alert, ISSN 1075-6914, is published monthly by American Health Consultants, 3525 Piedmont Rd., NE, Bldg. 6, Suite 400, Atlanta, GA 30305.

Vice President/Group Publisher: Brenda Mooney.
Editorial Group Head: Valerie Loner.
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Marketing Manager: Schandale Kornegay.

GST Registration Number: R128870672.

Periodical postage paid at Atlanta GA 30304. **POSTMASTER:** Send address changes to ***Emergency Medicine Alert***, P.O. Box 740059, Atlanta, GA 30374.

Back issues: $37. One to nine additional copies, $175 each; 10 or more additional copies, $131 each.

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Subscription Prices

United States: $219 per year (Resident rate: $110)
Canada: $239 per year plus GST (Resident rate: $120)
Elsewhere: $239 per year (Resident rate: $120)

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Statement of Financial Disclosure

In order to reveal any potential bias in this publication, and in accordance with Accreditation Council for Continuing Medical Education guidelines, we disclose that Dr. Brady is on the speaker's bureau for Genentech; Dr. Gibbs is a consultant and advisory board member and is involved in research for LMA North America; and Dr. Karras is involved with research for Bayer Pharmaceuticals. Drs. Abbuhl, Chan, Grauer, Harrigan, Hamilton, and Ufberg report no financial relationships with companies having ties to this field of study.

Hemolytic-Uremic Syndrome in Children Receiving Antibiotics for *E. coli* Infection

ABSTRACT & COMMENTARY

Source: Wong CS, et al. The risk of hemolytic-uremic syndrome after antibiotic treatment of *E. coli* O157:H7 infections. *N Engl J Med* 2000;342:1930-1936.

The authors of this prospective, multicenter study observed the course of illness in 73 children younger than 10 years old with confirmed *Escherichia coli* O157:H7 enteric infections. The authors gathered data on administration of antibiotics and antimotility agents, other prescribed and nonprescription drugs taken, initial laboratory values, and clinical outcomes. Daily blood counts and renal function tests were obtained to assess for the development of hemolytic-uremic syndrome (HUS), which was defined as the

presence of hemolysis, thrombocytopenia, and any renal insufficiency.

Ten of the 71 children developed HUS; it was seen in five of the nine children given antibiotics (56%) and in five of the 62 children not given antibiotics (8%). The relative risk of developing HUS in children receiving antibiotics was 14.3. The authors also noted that HUS was more likely to develop in children with higher white blood cell counts and those undergoing earlier stool cultures—markers of more severe disease. In a multivariate analysis adjusted for white blood cell count and the day on which cultures were obtained, the relative risk of HUS in antibiotic-treated patients rose to 17.3. The authors conclude that there is a strong association between development of HUS and antibiotic therapy for *E. coli* O157:H7 infection, and they caution against giving antimicrobial agents to children with such illness.

COMMENT BY DAVID J. KARRAS, MD, FAAEM, FACEP

This is an exceptionally strong epidemiologic study that confirms the potential danger of indiscriminate antibiotic utilization for serious diarrheal illness. *E. coli* O157:H7 is a notorious pathogen that accounts for 5% of laboratory-confirmed cases of bacterial enteritis.[1] While the effects of *E. coli* are usually limited to severe diarrheal illness and volume depletion, between 5% and 15% of cases will develop HUS. *E. coli* O157:H7 is the most common known cause of HUS, and HUS is the most common cause of renal failure in children.

The pathogenicity of *E. coli* O157:H7 is related to its production of Shiga-like toxins. It is suspected that antibiotic administration may accelerate the release of these toxins in the intestine, thus increasing toxin absorption and toxin-related systemic illnesses such as renal failure and hemolysis. While antibiotic therapy is generally safe and often effective in reducing the severity and duration of some diarrheal illnesses in adults, antimicrobials must be avoided in individuals (particularly children) suspected of having *E. coli* O157:H7 infections. Such patients are likely to present with grossly bloody diarrhea and may be part of a disease epidemic. In any case, empiric antibiotic therapy is not recommended for young children with acute diarrheal illnesses of any suspected etiology. ❖

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Ventilator Use in Acute Lung Injury and Acute Respiratory Distress Syndrome

ABSTRACT & COMMENTARY

Source: The Acute Respiratory Distress Syndrome Network. Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. *N Engl J Med* 2000;342:1301-1308.

The mortality rate associated with acute lung injury and the acute respiratory distress syndrome (ARDS) has been estimated to be between 40% and 50%. During the last decade, researchers have pinpointed some of the mechanisms of acute lung injury. However, little if any progress has been made in treating its effects. This multicenter, randomized trial from the 10 university hospitals comprising the Acute Respiratory Distress Syndrome Network attempted to determine the effects of decreased ventilator tidal volumes in patients with acute lung injury and ARDS. Patients were randomized to one of two treatment arms. The first was "traditional" ventilation using an initial tidal volume of 12 mL/kg of predicted body weight, maintaining plateau pressures below 50 cm water. The "low tidal volume ventilation" arm used an initial tidal volume of 6 mL/kg of predicted body weight, keeping plateau pressures below 30 cm water. Bicarbonate and increased respiratory rates were used as necessary to help control acidosis. The primary study end points included patient death prior to discharge home with unassisted breathing and the number of ventilator-free days between study days one and 28. Secondary end points included days of nonpulmonary organ or organ system failure between days one and day 28 and plasma interleukin-6 concentrations (a marker of inflammatory response).

This trial was stopped after interim analysis of the first 861 patients because of significantly lower mortality in the low tidal volume group than in the traditional tidal volume group (31.0% vs 39.8%, P = 0.007). The number of ventilator-free days was significantly increased using the low tidal volume strategy (12 + 11 vs 10 + 11, P = 0.007). The number of days with nonpulmonary organ or organ system failure was less in the low tidal volume group, and interleukin-6 levels decreased more in the low tidal volume group.

COMMENT BY JACOB W. UFBERG, MD

Following traditional guidelines for mechanical ventilation, we use tidal volumes that are larger than the tidal volumes of normal humans at rest (7-8 mL/kg). We do

this in order to normalize the arterial blood gas values of pH and pCO_2. However, the last decade of research has demonstrated that decreasing tidal volumes in order to reduce "lung stretch" and lower end-inspiratory pressures may reduce mortality, despite the resultant hypercapnia and respiratory acidosis.

This large, randomized study from the Acute Respiratory Distress Syndrome Network showed that lowering tidal volumes reduced mortality by 22% and increased the number of ventilator-free days in patients with acute lung injury and ARDS. These benefits occurred despite the need for higher PEEP and FIO_2 levels during the first several days of care. This well-done study should cause us to re-evaluate our approach to mechanical ventilation in these patients, keeping an eye on preventing lung stretch injury. ❖

Special Feature

ED Management of the Unstable Patient with Pelvic Ring Trauma

By Michael A. Gibbs, MD, FACEP

Pelvic ring fractures are the third most common cause of death from blunt trauma, behind head injury and aortic disruption. Despite advances in trauma care, the mortality associated with these injuries remains at least 10%. Because of the high risk of hemorrhage and associated injury, the ED management of pelvic trauma requires a sound understanding of the biomechanics of injury, clinical presentation, and essentials of early resuscitation. A reasoned diagnostic and therapeutic plan and the involvement of a multidisciplinary team are pivotal in the initial care of these complex injuries.

The pelvic ring has impressive inherent strength and stability. Because major forces are required to disrupt this ring, fractures must always be considered a red flag for major multisystem trauma. This is not just another broken bone. The presence of a pelvic ring fracture may alter the sequence and/or technique of the initial diagnostic evaluation and will mandate that associated injuries be rapidly identified, prioritized, and managed either sequentially or in tandem. This article outlines an approach to the initial evaluation of the unstable patient with pelvic ring trauma, focusing on the key decision points shown in Table 1.

Table 1
Key Issues in the Evaluation of Pelvic Ring Trauma

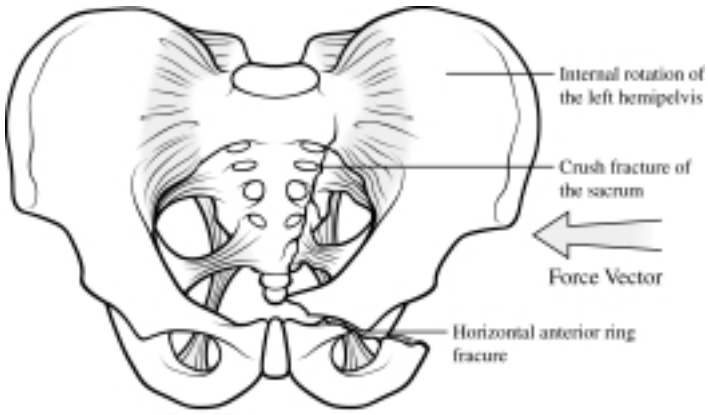
- ☐ Is pelvic radiography indicated?
- ☐ Is the pelvic ring open?
- ☐ Is hemoperitoneum present?
- ☐ What are the essentials of early management?
- ☐ Where should the patient go from here?

Question No. 1: Is Pelvic Radiography Indicated?

Detection of the injury is an obvious first step. Pelvic radiography should be routine in all severely injured, blunt trauma patients who are either hemodynamically unstable or obtunded, and in those with clinical evidence of pelvic injury (e.g., bruising, tenderness, instability). Conversely, several studies suggest that pelvic radiography can be deferred safely in the stable, alert patient without these high-risk criteria.[1-3]

The anteroposterior (AP) radiograph will identify most pelvic fractures and in the majority of cases is sufficient to guide early management.[3] This view should include the iliac crests, fifth lumbar vertebra, both hip joints, and the proximal portion of each femur. Examination of the anterior ring for pubic ramus fractures, symphysis disruption, or combined lesions should follow. Posterior pathology can present as iliac wing fractures, sacral fractures, or sacroiliac fracture/dislocations. While it is important to recognize that radiographs at right angles to each other (inlet and outlet views) provide a more accurate view of pelvic displacement than a

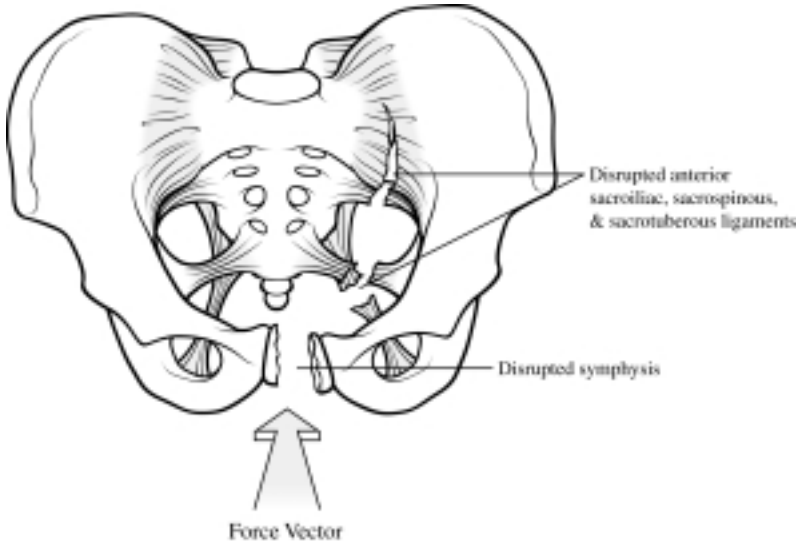
Figure 1
Pelvic Fracture: Lateral Compression



Source: Anne Olson, Carolinas Medical Center, Charlotte, NC.

Figure 2

Pelvic Fracture: Anteroposterior Compression



Source: Anne Olson, Carolinas Medical Center, Charlotte, NC.

single AP image, these should only be obtained if the patient has been stabilized. In the persistently hypotensive patient, do not delay or interrupt resuscitative efforts to obtain these additional views, especially when there is an indication for immediate laparotomy, pelvic angiography, or interfacility transport.

Question No. 2:
Is the Pelvic Ring Open?

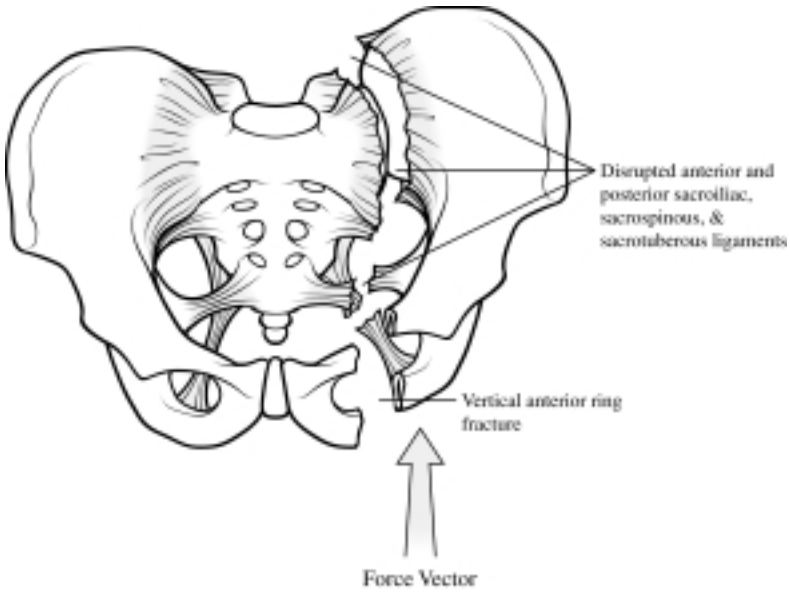
Injuries that open the pelvic ring, either in the lateral or vertical plane, increase pelvic volume, creating a potential space for ongoing hemorrhage. The classification system for pelvic ring fractures is based on the direction of the causative force vector and indirectly on whether the pelvic ring is open or closed.[4] This schema describes three fracture types: lateral compression, AP compression, and vertical shear *(see Figures 1-3)*. Lateral compression fractures are the most common injury type, accounting for roughly half of all cases. As the name suggests, the force is delivered to the pelvis from the side, as might occur in a "T-bone" motor vehicle collision (MVC) or when a pedestrian is struck from the side. The affected hemipelvis is crushed inward, the pelvic ring remains closed, and pelvic volume may actually decrease. Lateral compression injuries typically are not associated with major bleeding.

AP compression may occur following a head-on MVC or when a pedestrian is struck head-on by an oncoming vehicle. Anterior forces disrupt the ring at the symphysis or at vertically oriented pubic rami fractures. Posterior disruption follows at the sacroiliac joint or posterior bony pelvis. This causes the pelvis to open like a book, dramatically increasing pelvic volume and the risk of uncontrolled hemorrhage. Open-book pelvic fractures are major killers, and detection should trigger immediate vigorous resuscitation, pelvic stabilization, and rapid transfer to a trauma center.

Vertical shear injuries occur when the causative force vector is delivered to the pelvis from above or below. This usually is the result of a fall from a height or following a head-on motor vehicle crash in which the occupant has the leg fully extended. Alternatively, a downward force delivered to the pelvis via the spine, as may occur when a heavy object falls on the back or shoulders, may produce this injury pattern. One hemipelvis migrates vertically in relation to the other, causing complete ligamentous disruption and instability. As with AP compression fractures, the risk for hemorrhage is great, and the initial treatment paradigm should be the same.

Figure 3

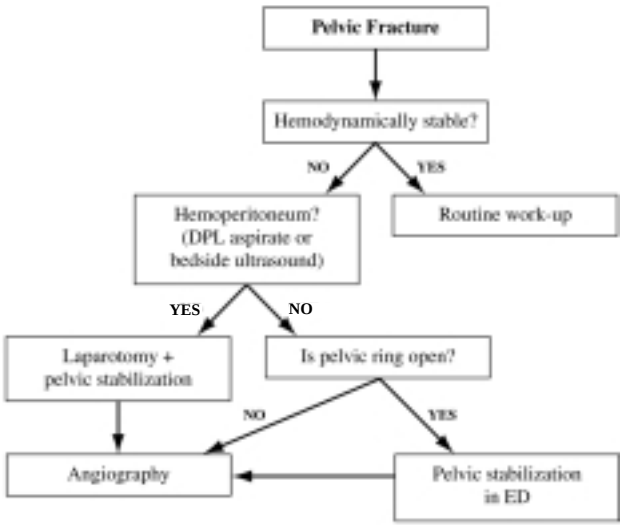
Pelvic Fracture: Vertical Shear



Source: Anne Olson, Carolinas Medical Center, Charlotte, NC.

Figure 3

Initial Management of the Patient with Pelvic Fracture



Source: Michael A. Gibbs, MD, FACEP, Anne Olson, Carolinas Medical Center, Charlotte, NC.

Question No. 3: Is Hemoperitoneum Present?

During the resuscitation of the hemodynamically unstable patient with pelvic trauma, it is critical to rapidly identify the predominant site of hemorrhage. Should pelvic bleeding pose the primary life-threat, angiography and skeletal stabilization is indicated. Conversely, if clinical instability is primarily the result of intra-abdominal hemorrhage, laparotomy should be performed first. *(See algorithm in Figure 4.)* Taking a patient down the wrong branch of this algorithm can have devastating consequences: either uncontrolled pelvic hemorrhage in the operating room or intra-abdominal exsanguination in the angiography suite. By using diagnostic peritoneal lavage (DPL) or ultrasonography (US), the emergency physician can make the appropriate decision at the bedside.

The objective of DPL in this situation is to detect life-threatening abdominal hemorrhage and not just the presence of intraperitoneal blood. The DPL aspirate, not the cell count, should be used to guide decision making.[5] The aspiration of 5-10 cc of gross blood following the introduction of the catheter is considered "positive" and indicative of life-threatening abdominal hemorrhage. In the unstable patient, a positive peritoneal aspirate mandates immediate laparotomy, while a negative aspirate should be followed by pelvic angiography and vascular embolization. The open supraumbilical technique is preferred when performing the DPL in this setting.[6] This avoids the risk of blindly entering an anterior abdominal wall hematoma dissecting cephalad from the pelvis and obtaining a false-positive aspirate. Bedside US also can be used to perform a rapid assessment for hemoperitoneum. An unequivocally positive US in the unstable patient with a pelvic fracture is an indication for immediate laparotomy.

Question No. 4:
What are the Essentials of Early Management?

- **Anticipate and treat instability.**

A common pitfall in the initial management of the patient with significant pelvic trauma is the failure to anticipate hypotension and initiate early, aggressive resuscitation. In the setting of major blunt trauma, a pelvic fracture is an ominous finding and should immediately heighten the concern of the treating clinician. Adequate intravenous access with at least two large-bore intravenous catheters should be secured, and blood should be sent for type and cross-match. In the unstable patient, aggressive resuscitation with warmed crystalloid

and early transfusion are essential. These patients have the potential to deteriorate rapidly. Monitor the patient carefully and pay close attention to the airway. This is especially important before long trips to the radiology suite and certainly before interfacility transport.

• **Stabilize the pelvis.**

Injuries that increase pelvic volume (i.e., AP compression and vertical shear injuries) create a potential space for unabated hemorrhage. Rubash described a normal pelvic volume of 1.5 L. This increased to 3 L and 6 L with diastasis of the pubic symphysis of 3 cm and 6 cm, respectively.[6] Pelvic stabilization provides benefit by reducing pelvic volume, stabilizing displaced fracture segments, and providing a tamponade effect on venous bleeding. This can be accomplished by several simple measures in the ED prior to the application of an external fixator or definitive operative repair. Internally rotating the lower extremities and wrapping a sheet tightly around the pelvis will close the pelvic ring to some degree. Application of MAST or a vacuum splint will help maintain reduction, limit pelvic motion, and tamponade venous bleeding. If the pelvic ring is open, this should be done before patient transfer.

Question No. 5: Where Should the Patient Go from Here?

The answer to this seemingly trivial question may be the difference between life and death for the patient. A few recommendations:

• Patients with significant pelvic ring trauma should be treated at a trauma center with a multidisciplinary team and immediate availability of an operating room and angiography suite. Transfer should be initiated without delay once the primary and secondary surveys have been completed, resuscitation has been initiated, and appropriate screening radiographs have been taken.

• Avoid the CT scanner trap. In the unstable patient, hemoperitoneum should be ruled out at the bedside, not in the radiology suite. Pelvic CT imaging is inappropriate in this setting, as it wastes valuable time.

• In the patient with a positive DPL aspirate or US, the next destination should be the OR. If these are negative, pelvic stabilization and angiography become the priority. ❖

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CME questions

13. Ancrod, from Malaysian pit vipor venom, may have utility in the emergent treatment of acute ischemic stroke because of its ability to:

a. increase endogenous serum thrombin levels.
b. induce platelet dysfunction and binding to fibrin substrate.
c. cause cerebral vasodilation at sites of thrombus formation.
d. reduce endogenous fibrinogen levels.
e. activate Factor V of the intrinsic clotting cascade.

14. What is the tidal volume of a normal, resting human subject?

a. 5-7 mL/kg
b. 7-8 mL/kg
c. 9-12 mL/kg
d. 12-15 mL/kg

15. Which of the following pelvic fractures is *not* associated with an increased risk of significant hemorrhage?

a. Lateral compression
b. Anteroposterior compression
c. Vertical shear
d. Tangential inverse shear

16. Which of the following pelvic fractures is most commonly encountered?

a. Lateral compression
b. Anteroposterior compression
c. Vertical shear
d. Tangential inverse shear

17. While caring for the patient with major blunt trauma from a high-speed motor vehicle collision, which of the following is *not* a reasonable choice of tests if the patient is hemodynamically unstable in the ED trauma bay?

a. Bedside ultrasonography of the abdomen
b. Bedside diagnostic peritoneal lavage
c. Bedside single-view radiograph of the pelvis
d. Spiral CT with contrast of the abdomen and pelvis

18. Enteric infections with *E. coli* O157:H7:

a. should be treated with antibiotics.
b. are associated with significant mortality.
c. are only seen in epidemics.
d. are associated with grossly bloody stool.

Confirming Dextrocardia: Technician Error

By Ken Grauer, MD

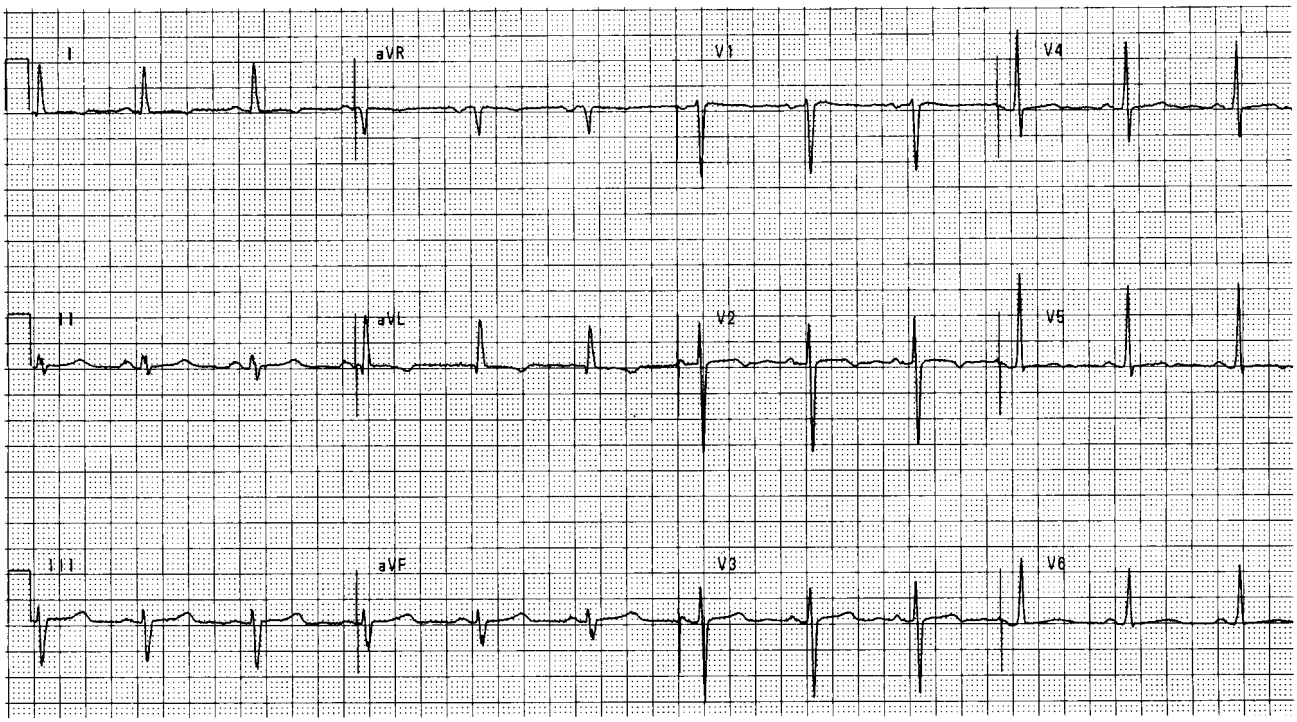

Figure. ECG obtained from a patient with dextrocardia after "reversing the leads." What did the tech do wrong?

Clinical Scenario: The ECG shown in the Figure was obtained from a 60-year-old woman with dextrocardia (it is the follow-up tracing to the ECG shown in last month's ECG Review). In an attempt to confirm the diagnosis of dextrocardia, the tech had been asked to "repeat the ECG with the leads reversed." How should the tech have been instructed to repeat this ECG? What simpler approach could have been used to confirm dextrocardia?

Interpretation: The finding of complete (or almost complete) negativity of the QRS complex in lead I in association with an upright QRS complex in lead aVR is distinctly abnormal and should always prompt consideration of two clinical entities: 1) dextrocardia; and 2) limb lead misplacement. Practically speaking, the latter is much more common. Assessment of R wave progression in the precordial leads will usually distinguish between these two entities: R wave progression should be normal when there is limb lead reversal, whereas R wave progression is *reversed* when there is dextrocardia (as it was in last month's ECG Review). Verifying correct placement of limb lead electrodes and then repeating the ECG with precordial leads reversed should confirm what the true diagnosis is, in that R wave progression will normalize for a patient with dextrocardia when precordial leads are placed on the right side of the chest (as they do in the Figure). The error the tech made in this case was to also reverse the limb lead electrodes, which is why the QRS complex is now upright in lead I. The simplest way to confirm dextrocardia is to listen for heart sounds on the right side of the chest. ❖

In Future Issues: Fenoldopam for Hypertensive Emergency