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50 YEARS OF EMERGENCY MEDICAL CARE

Celebrating ACEP's golden anniversary with a look back at milestones and accomplishments

by KEVIN M. KLAUER, DO, EJD, FACEP

What we've accomplished in the first 50 years begs the question, how will emergency medical care look 50 years from now? A bright future is illuminated by knowledge of the past. As part of the celebration of our specialty's 50th anniversary, *ACEP Now* will provide a series of articles discussing the timeline of many critical aspects of emergency medicine.

Turn to page 18 for a few historical snapshots of emergency medicine.

TWO ACCOUNTS OF VEGAS MASS SHOOTING

Experiences of an emergency physician filtered through the lens of the victim

On Oct. 1, 2017, attendees of the Route 91 Harvest country music festival in Las Vegas were enjoying the event's closing performance by Jason Aldean when tragedy struck. A single gunman opened fire on the crowd from a room in the nearby Mandalay Bay Resort and Casino, injuring 851 people and killing 58. The victims were transported by private vehicle, taxi, and ambulance to nearby hospitals, including Sunrise Hospital & Medical Center, where Scott Scherr, MD, medical director of the emergency department, and his colleagues prepared to treat the injured.

ACEP Now Medical Editor-in-Chief Kevin Klauer, DO, EJD, FACEP, recently sat down with Dr. Scherr and Jeannine Ruggeiro, a 28-year-old social work graduate student from Sonoma County, California, who was one of the shooting victims that night, to discuss their experiences in the aftermath of the mass shooting. Here is Part 1 of their

CONTINUED *on page 12*

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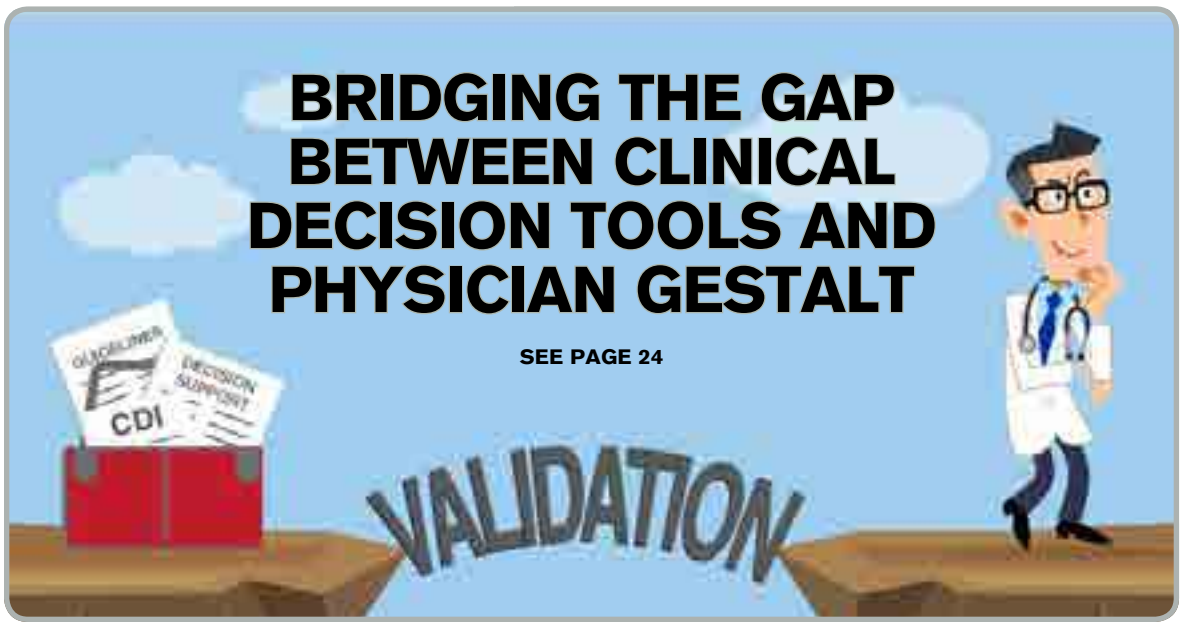
BRIDGING THE GAP BETWEEN CLINICAL DECISION TOOLS AND PHYSICIAN GESTALT



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Xarelto®
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10 mg NOW APPROVED:

For the reduction in the risk of recurrence of DVT/PE in patients at continued risk of DVT/PE*

*After 6 months initial treatment.

The ONLY NOAC to demonstrate a major bleeding rate as low as aspirin with superior efficacy

Convenient 30-day Starter Pack
for the initial treatment of DVT and/or PE

INDICATIONS

XARELTO® is indicated for the treatment of deep vein thrombosis (DVT). XARELTO® is indicated for the treatment of pulmonary embolism (PE). XARELTO® is indicated for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months.

IMPORTANT SAFETY INFORMATION

WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO® INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

A. Premature discontinuation of XARELTO® increases the risk of thrombotic events

Premature discontinuation of any oral anticoagulant, including XARELTO®, increases the risk of thrombotic events. If anticoagulation with XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

B. Spinal/epidural hematoma

Epidural or spinal hematomas have occurred in patients treated with XARELTO® who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- **Use of indwelling epidural catheters**
- **Concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants, *see* Drug Interactions**
- **A history of traumatic or repeated epidural or spinal punctures**
- **A history of spinal deformity or spinal surgery**
- **Optimal timing between the administration of XARELTO® and neuraxial procedures is not known**

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

NOAC = non-vitamin K antagonist oral anticoagulant.

Please see accompanying Brief Summary of full Prescribing Information, including Boxed WARNINGS, or visit www.XareltoHCP.com/PI.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- Active pathological bleeding
- Severe hypersensitivity reaction to XARELTO® (eg, anaphylactic reactions)

WARNINGS AND PRECAUTIONS

- **Increased Risk of Thrombotic Events After Premature Discontinuation:** Premature discontinuation of any oral anticoagulant, including XARELTO®, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO® to warfarin in clinical trials in atrial fibrillation patients. If XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- **Risk of Bleeding:** XARELTO® increases the risk of bleeding and can cause serious or fatal bleeding. Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue XARELTO® in patients with active pathological hemorrhage.
  - A specific antidote for rivaroxaban is not available. Because of high plasma protein binding, rivaroxaban is not expected to be dialyzable.
  - Concomitant use of other drugs that impair hemostasis increases the risk of bleeding. These include aspirin, $P2Y_{12}$ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, NSAIDs, selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs).
- **Spinal/Epidural Anesthesia or Puncture:** When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma, which can result in long-term or permanent paralysis. To reduce the potential risk of bleeding associated with the concurrent use of XARELTO® and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of XARELTO®. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of XARELTO® is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known. An indwelling epidural or intrathecal catheter should not be removed before at least 2 half-lives have elapsed (ie, 18 hours in young patients aged 20 to 45 years and 26 hours in elderly patients aged 60 to 76 years), after the last administration of XARELTO®. The next XARELTO® dose should not be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of XARELTO® for 24 hours. Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), or bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.
- **Use in Patients With Renal Impairment:**
  - **Nonvalvular Atrial Fibrillation:** Periodically assess renal function as clinically indicated (ie, more frequently in situations in which renal function may decline) and adjust therapy accordingly. Consider dose adjustment or discontinuation of XARELTO® in patients who develop acute renal failure while on XARELTO®.
  - **Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population.
  - **Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO® should discontinue the treatment.
- **Use in Patients With Hepatic Impairment:** No clinical data are available for patients with severe hepatic impairment. Avoid use of XARELTO® in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy, since drug exposure and bleeding risk may be increased.
- **Use With P-gp and Strong CYP3A4 Inhibitors or Inducers:** Avoid concomitant use of XARELTO® with known combined P-gp and strong CYP3A4 inhibitors. Avoid concomitant use of XARELTO® with drugs that are known combined P-gp and strong CYP3A4 inducers.
- **Risk of Pregnancy-Related Hemorrhage:** In pregnant women, XARELTO® should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO® dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO® cannot be monitored with standard laboratory testing nor readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (eg, a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).
- **Patients With Prosthetic Heart Valves:** The safety and efficacy of XARELTO® have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO® is not recommended in these patients.
- **Acute PE in Hemodynamically Unstable Patients/Patients Who Require Thrombolysis or Pulmonary Embolectomy:** Initiation of XARELTO® is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

DRUG INTERACTIONS

- Combined P-gp and strong CYP3A4 inhibitors increase exposure to rivaroxaban and may increase the risk of bleeding.
- Combined P-gp and strong CYP3A4 inducers decrease exposure to rivaroxaban and may increase the risk of thromboembolic events.
- XARELTO® should not be used in patients with CrCl 15 to <80 mL/min who are receiving concomitant combined P-gp and moderate CYP3A4 inhibitors (eg, erythromycin) unless the potential benefit justifies the potential risk.
- Coadministration of enoxaparin, warfarin, aspirin, clopidogrel, and chronic NSAID use may increase the risk of bleeding.
- Avoid concurrent use of XARELTO® with other anticoagulants due to increased bleeding risk, unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** The limited available data on XARELTO® in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. Use XARELTO® with caution in pregnant patients because of the potential for pregnancy-related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible. The anticoagulant effect of XARELTO® cannot be reliably monitored with standard laboratory testing. Consider the benefits and risks of XARELTO® for the mother and possible risks to the fetus when prescribing XARELTO® to a pregnant woman.
  - Fetal/Neonatal adverse reactions: Based on the pharmacologic activity of Factor Xa inhibitors and the potential to cross the placenta, bleeding may occur at any site in the fetus and/or neonate.
  - Labor or delivery: The risk of bleeding should be balanced with the risk of thrombotic events when considering the use of XARELTO® in this setting.
  - There are no adequate or well-controlled studies of XARELTO® in pregnant women, and dosing for pregnant women has not been established. Post-marketing experience is currently insufficient to determine a rivaroxaban-associated risk for major birth defects or miscarriage.
- **Lactation:** Rivaroxaban has been detected in human milk. There are insufficient data to determine the effects of rivaroxaban on the breastfed child or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XARELTO® and any potential adverse effects on the breastfed infant from XARELTO® or from the underlying maternal condition.
- **Females and Males of Reproductive Potential:** Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.
- **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

OVERDOSAGE

- Discontinue XARELTO® and initiate appropriate therapy if bleeding complications associated with overdosage occur. A specific antidote for rivaroxaban is not available. The use of activated charcoal to reduce absorption in case of XARELTO® overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not dialyzable.

ADVERSE REACTIONS IN CLINICAL STUDIES

- The most common adverse reactions with XARELTO® were bleeding complications.

083074-171026

Please see accompanying Brief Summary of full Prescribing Information, including Boxed WARNINGS, or visit www.XareltoHCP.com/PI.

Xarelto® rivaroxaban tablets

Janssen Pharmaceuticals, Inc.

janssen | PHARMACEUTICAL COMPANIES OF Johnson&Johnson

Brief Summary of Prescribing Information for XARELTO® (rivaroxaban)

XARELTO® (rivaroxaban) tablets, for oral use

See package insert for full Prescribing Information

WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

A. Premature discontinuation of XARELTO increases the risk of thrombotic events

Premature discontinuation of any oral anticoagulant, including XARELTO, increases the risk of thrombotic events. If anticoagulation with XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant *[see Dosage and Administration (2.3, 2.8), in full Prescribing Information, Warnings and Precautions, and Clinical Studies (14.1) in full Prescribing Information]*.

B. Spinal/epidural hematoma

Epidural or spinal hematomas have occurred in patients treated with XARELTO who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- **use of indwelling epidural catheters**
- **concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants**
- **a history of traumatic or repeated epidural or spinal punctures**
- **a history of spinal deformity or spinal surgery**
- **optimal timing between the administration of XARELTO and neuraxial procedures is not known**

***[see Warnings and Precautions and Adverse Reactions]*.**

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary *[see Warnings and Precautions]*.

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis *[see Warnings and Precautions]*.

INDICATIONS AND USAGE

Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation: XARELTO is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

There are limited data on the relative effectiveness of XARELTO and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well-controlled *[see Clinical Studies (14.1) in full Prescribing Information]*.

Treatment of Deep Vein Thrombosis: XARELTO is indicated for the treatment of deep vein thrombosis (DVT).

Treatment of Pulmonary Embolism: XARELTO is indicated for the treatment of pulmonary embolism (PE).

Reduction in the Risk of Recurrence of Deep Vein Thrombosis and/or Pulmonary Embolism: XARELTO is indicated for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: XARELTO is indicated for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

CONTRAINDICATIONS

XARELTO is contraindicated in patients with:

- active pathological bleeding *[see Warnings and Precautions]*
- severe hypersensitivity reaction to XARELTO (e.g., anaphylactic reactions) *[see Adverse Reactions]*

WARNINGS AND PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation: Premature discontinuation of any oral anticoagulant, including XARELTO, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO to warfarin in clinical trials in atrial fibrillation patients. If XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant *[see Dosage and Administration (2.3, 2.8) and Clinical Studies (14.1) in full Prescribing Information]*.

Risk of Bleeding: XARELTO increases the risk of bleeding and can cause serious or fatal bleeding. In deciding whether to prescribe XARELTO to patients at increased risk of bleeding, the risk of thrombotic events should be weighed against the risk of bleeding.

Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue XARELTO in patients with active pathological hemorrhage. The terminal elimination half-life of rivaroxaban is 5 to 9 hours in healthy subjects aged 20 to 45 years.

Concomitant use of other drugs that impair hemostasis increases the risk of bleeding. These include aspirin, $P2Y_{12}$ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) *[see Drug Interactions]*, selective serotonin reuptake inhibitors, and serotonin norepinephrine reuptake inhibitors.

Concomitant use of drugs that are known combined P-gp and strong CYP3A4 inhibitors increases rivaroxaban exposure and may increase bleeding risk *[see Drug Interactions]*.

Reversal of Anticoagulant Effect: A specific antidote for rivaroxaban is not available. Because of high plasma protein binding, rivaroxaban is not expected to be dialyzable *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of rivaroxaban. Partial reversal of prothrombin time prolongation has been seen after administration of prothrombin complex concentrates (PCCs) in healthy volunteers. The use of other procoagulant reversal agents like activated prothrombin complex concentrate (APCC) or recombinant factor VIIa (rFVIIa) has not been evaluated.

Spinal/Epidural Anesthesia or Puncture: When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis *[see Boxed Warning]*.

To reduce the potential risk of bleeding associated with the concurrent use of XARELTO and epidural or spinal anesthesia/analgesia or spinal puncture, consider the pharmacokinetic profile of XARELTO *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of XARELTO is low; however, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known.

An indwelling epidural or intrathecal catheter should not be removed before at least 2 half-lives have elapsed (i.e., 18 hours in young patients aged 20 to 45 years and 26 hours in elderly patients aged 60 to 76 years), after the last administration of XARELTO *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. The next XARELTO dose should not be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of XARELTO for 24 hours.

Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.

Use in Patients with Renal Impairment: Nonvalvular Atrial Fibrillation: Periodically assess renal function as clinically indicated (i.e., more frequently in situations in which renal function may decline) and adjust therapy accordingly *[see Dosage and Administration (2.4) in full Prescribing Information]*. Consider dose adjustment or discontinuation of XARELTO in patients who develop acute renal failure while on XARELTO *[see Use in Specific Populations]*.

Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE: Avoid the use of XARELTO in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population *[see Use in Specific Populations]*.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: Avoid the use of XARELTO in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO should discontinue the treatment *[see Use in Specific Populations]*.

Use in Patients with Hepatic Impairment: No clinical data are available for patients with severe hepatic impairment.

Avoid use of XARELTO in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy since drug exposure and bleeding risk may be increased *[see Use in Specific Populations]*.

Use with P-gp and Strong CYP3A4 Inhibitors or Inducers: Avoid concomitant use of XARELTO with known combined P-gp and strong CYP3A4 inhibitors *[see Drug Interactions]*.

Avoid concomitant use of XARELTO with drugs that are known combined P-gp and strong CYP3A4 inducers *[see Drug Interactions]*.

Risk of Pregnancy-Related Hemorrhage: In pregnant women, XARELTO should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO cannot be monitored with standard laboratory testing nor readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (e.g., a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).

Patients with Prosthetic Heart Valves: The safety and efficacy of XARELTO have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO is not recommended in these patients.

Acute PE in Hemodynamically Unstable Patients or Patients Who Require Thrombolysis or Pulmonary Embolectomy: Initiation of XARELTO is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

ADVERSE REACTIONS

The following adverse reactions are also discussed in other sections of the labeling:

- Increased risk of stroke after discontinuation in nonvalvular atrial fibrillation *[see Boxed Warning and Warnings and Precautions]*
- Bleeding risk *[see Warnings and Precautions]*
- Spinal/epidural hematoma *[see Boxed Warning and Warnings and Precautions]*

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

During clinical development for the approved indications, 18560 patients were exposed to XARELTO. These included 7111 patients who received XARELTO 15 mg or 20 mg orally once daily for a mean of 19 months (5558 for 12 months and 2512 for 24 months) to reduce the risk of stroke and systemic embolism in nonvalvular atrial fibrillation (ROCKET AF); 6962 patients who received XARELTO 15 mg orally twice daily for three weeks followed by 20 mg orally once daily to treat DVT or PE (EINSTEIN DVT, EINSTEIN PE), 10 mg or 20 mg orally once daily (EINSTEIN Extension, EINSTEIN CHOICE) to reduce the risk of recurrence of DVT and/or PE; and 4487 patients who received XARELTO 10 mg orally once daily for prophylaxis of DVT following hip or knee replacement surgery (RECORD 1-3).

Hemorrhage: The most common adverse reactions with XARELTO were bleeding complications *[see Warnings and Precautions]*.

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 4.3% for XARELTO vs. 3.1% for warfarin. The incidence of discontinuations for non-bleeding adverse events was similar in both treatment groups.

Table 1 shows the number of patients experiencing various types of bleeding events in the ROCKET AF trial.

Table 1: Bleeding Events in ROCKET AF*- On Treatment Plus 2 Days

Parameter	XARELTO N=7111 n (%/year)	Warfarin N=7125 n (%/year)	XARELTO vs. Warfarin HR (95% CI)
Major Bleeding†	395 (3.6)	386 (3.5)	1.04 (0.90, 1.20)
Intracranial Hemorrhage (ICH)‡	55 (0.5)	84 (0.7)	0.67 (0.47, 0.93)
Hemorrhagic Stroke§	36 (0.3)	58 (0.5)	0.63 (0.42, 0.96)
Other ICH	19 (0.2)	26 (0.2)	0.74 (0.41, 1.34)
Gastrointestinal (GI)¶	221 (2.0)	140 (1.2)	1.61 (1.30, 1.99)
Fatal Bleeding#	27 (0.2)	55 (0.5)	0.50 (0.31, 0.79)
ICH	24 (0.2)	42 (0.4)	0.58 (0.35, 0.96)
Non-intracranial	3 (0.0)	13 (0.1)	0.23 (0.07, 0.82)

Abbreviations: HR = Hazard Ratio, CI = Confidence interval, CRNM = Clinically Relevant Non-Major.

* Major bleeding events within each subcategory were counted once per patient, but patients may have contributed events to multiple subcategories. These events occurred during treatment or within 2 days of stopping treatment.

† Defined as clinically overt bleeding associated with a decrease in hemoglobin of ≥2 g/dL, a transfusion of ≥2 units of packed red blood cells or whole blood, bleeding at a critical site, or with a fatal outcome.

‡ Intracranial bleeding events included intraparenchymal, intraventricular, subdural, subarachnoid and/or epidural hematoma.

XARELTO® (rivaroxaban) tablets

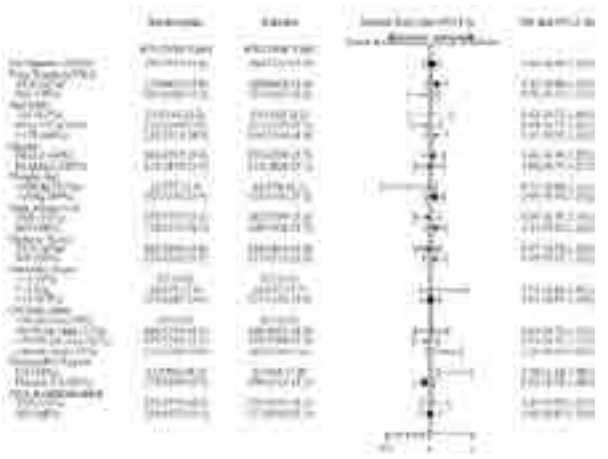
§ Hemorrhagic stroke in this table specifically refers to non-traumatic intraparenchymal and/or intraventricular hematoma in patients on treatment plus 2 days.

¶ Gastrointestinal bleeding events included upper GI, lower GI, and rectal bleeding.

Fatal bleeding is adjudicated death with the primary cause of death from bleeding.

Figure 1 shows the risk of major bleeding events across major subgroups.

Figure 1: Risk of Major Bleeding Events by Baseline Characteristics in ROCKET AF – On Treatment Plus 2 Days



Note: The figure above presents effects in various subgroups all of which are baseline characteristics and all of which were pre-specified (diabetic status was not pre-specified in the subgroup, but was a criterion for the CHADS2 score). The 95% confidence limits that are shown do not take into account how many comparisons were made, nor do they reflect the effect of a particular factor after adjustment for all other factors. Apparent homogeneity or heterogeneity among groups should not be over-interpreted.

Treatment of Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE): EINSTEIN DVT and EINSTEIN PE Studies: In the pooled analysis of the EINSTEIN DVT and EINSTEIN PE clinical studies, the most frequent adverse reactions leading to permanent drug discontinuation were bleeding events, with XARELTO vs. enoxaparin/Vitamin K antagonist (VKA) incidence rates of 1.7% vs. 1.5%, respectively. The mean duration of treatment was 208 days for XARELTO-treated patients and 204 days for enoxaparin/VKA-treated patients.

Table 2 shows the number of patients experiencing major bleeding events in the pooled analysis of the EINSTEIN DVT and EINSTEIN PE studies.

Table 2: Bleeding Events* in the Pooled Analysis of EINSTEIN DVT and EINSTEIN PE Studies

Parameter	XARELTO† N=4130 n (%)	Enoxaparin/ VKA† N=4116 n (%)
Major bleeding event	40 (1.0)	72 (1.7)
Fatal bleeding	3 (<0.1)	8 (0.2)
Intracranial	2 (<0.1)	4 (<0.1)
Non-fatal critical organ bleeding	10 (0.2)	29 (0.7)
Intracranial‡	3 (<0.1)	10 (0.2)
Retroperitoneal‡	1 (<0.1)	8 (0.2)
Intraocular‡	3 (<0.1)	2 (<0.1)
Intra-articular‡	0	4 (<0.1)
Non-fatal non-critical organ bleeding§	27 (0.7)	37 (0.9)
Decrease in Hb ≥ 2 g/dL	28 (0.7)	42 (1.0)
Transfusion of ≥2 units of whole blood or packed red blood cells	18 (0.4)	25 (0.6)
Clinically relevant non-major bleeding	357 (8.6)	357 (8.7)
Any bleeding	1169 (28.3)	1153 (28.0)

* Bleeding event occurred after randomization and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.

† Treatment schedule in EINSTEIN DVT and EINSTEIN PE studies: XARELTO 15 mg twice daily for 3 weeks followed by 20 mg once daily; enoxaparin/VKA [enoxaparin: 1 mg/kg twice daily, VKA: individually titrated doses to achieve a target INR of 2.5 (range: 2.0-3.0)]

‡ Treatment-emergent major bleeding events with at least >2 subjects in any pooled treatment group

§ Major bleeding which is not fatal or in a critical organ, but resulting in a decrease in Hb ≥ 2 g/dL and/or transfusion of ≥2 units of whole blood or packed red blood cells

Reduction in the Risk of Recurrence of DVT and/or PE: EINSTEIN CHOICE Study: In the EINSTEIN CHOICE clinical study, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 1% for XARELTO 10 mg, 2% for XARELTO 20 mg, and 1% for acetylsalicylic acid (aspirin) 100 mg. The mean duration of treatment was 293 days for XARELTO 10 mg-treated patients and 286 days for aspirin 100 mg-treated patients.

Table 3 shows the number of patients experiencing bleeding events in the EINSTEIN CHOICE study.

Table 3: Bleeding Events* in EINSTEIN CHOICE

Parameter	XARELTO† 10 mg N=1127 n (%)	Acetylsalicylic Acid (aspirin)† 100 mg N=1131 n (%)
Major bleeding event	5 (0.4)	3 (0.3)
Fatal bleeding	0	1 (<0.1)
Non-fatal critical organ bleeding	2 (0.2)	1 (<0.1)
Non-fatal non-critical organ bleeding§	3 (0.3)	1 (<0.1)
Clinically relevant non-major (CRNM) bleeding¶	22 (2.0)	20 (1.8)
Any bleeding	151 (13.4)	138 (12.2)

* Bleeding event occurred after the first dose and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.

† Treatment schedule: XARELTO 10 mg once daily or aspirin 100 mg once daily.

§ Major bleeding which is not fatal or in a critical organ, but resulting in a decrease in Hb ≥ 2 g/dL and/or transfusion of ≥ 2 units of whole blood or packed red blood cells.

¶ Bleeding which was clinically overt, did not meet the criteria for major bleeding, but was associated with medical intervention, unscheduled contact with a physician, temporary cessation of treatment, discomfort for the patient, or impairment of activities of daily life.

In the EINSTEIN CHOICE study, there was an increased incidence of bleeding, including major and CRNM bleeding in the XARELTO 20 mg group compared to the XARELTO 10 mg or aspirin 100 mg groups.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: In the RECORD clinical trials, the overall incidence rate of adverse reactions leading to permanent treatment discontinuation was 3.7% with XARELTO.

The rates of major bleeding events and any bleeding events observed in patients in the RECORD clinical trials are shown in Table 4.

Table 4: Bleeding Events* in Patients Undergoing Hip or Knee Replacement Surgeries (RECORD 1-3)

	XARELTO 10 mg	Enoxaparin†
Total treated patients	**N=4487 n (%)**	**N=4524 n (%)**
Major bleeding event	14 (0.3)	9 (0.2)
Fatal bleeding	1 (<0.1)	0
Bleeding into a critical organ	2 (<0.1)	3 (0.1)
Bleeding that required re-operation	7 (0.2)	5 (0.1)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	4 (0.1)	1 (<0.1)
Any bleeding event‡	261 (5.8)	251 (5.6)
Hip Surgery Studies	**N=3281 n (%)**	**N=3298 n (%)**
Major bleeding event	7 (0.2)	3 (0.1)
Fatal bleeding	1 (<0.1)	0
Bleeding into a critical organ	1 (<0.1)	1 (<0.1)
Bleeding that required re-operation	2 (0.1)	1 (<0.1)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	3 (0.1)	1 (<0.1)
Any bleeding event‡	201 (6.1)	191 (5.8)
Knee Surgery Study	**N=1206 n (%)**	**N=1226 n (%)**
Major bleeding event	7 (0.6)	6 (0.5)
Fatal bleeding	0	0
Bleeding into a critical organ	1 (0.1)	2 (0.2)
Bleeding that required re-operation	5 (0.4)	4 (0.3)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	1 (0.1)	0
Any bleeding event‡	60 (5.0)	60 (4.9)

* Bleeding events occurring any time following the first dose of double-blind study medication (which may have been prior to administration of active drug) until two days after the last dose of double-blind study medication. Patients may have more than one event.

† Includes the placebo-controlled period for RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)

‡ Includes major bleeding events

Following XARELTO treatment, the majority of major bleeding complications (≥60%) occurred during the first week after surgery.

Other Adverse Reactions: Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in the EINSTEIN DVT and EINSTEIN PE studies are shown in Table 5.

Table 5: Other Adverse Reactions* Reported by ≥1% of XARELTO-Treated Patients in EINSTEIN DVT and EINSTEIN PE Studies

Body System Adverse Reaction		
EINSTEIN DVT Study	**XARELTO 20 mg N=1718 n (%)**	**Enoxaparin/VKA N=1711 n (%)**
Gastrointestinal disorders		
Abdominal pain	46 (2.7)	25 (1.5)
General disorders and administration site conditions		
Fatigue	24 (1.4)	15 (0.9)
Musculoskeletal and connective tissue disorders		
Back pain	50 (2.9)	31 (1.8)
Muscle spasm	23 (1.3)	13 (0.8)
Nervous system disorders		
Dizziness	38 (2.2)	22 (1.3)
Psychiatric disorders		
Anxiety	24 (1.4)	11 (0.6)
Depression	20 (1.2)	10 (0.6)
Insomnia	28 (1.6)	18 (1.1)
EINSTEIN PE Study	**XARELTO 20 mg N=2412 n (%)**	**Enoxaparin/VKA N=2405 n (%)**
Skin and subcutaneous tissue disorders		
Pruritus	53 (2.2)	27 (1.1)

* Adverse reaction with Relative Risk >1.5 for XARELTO versus comparator

Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in RECORD 1-3 studies are shown in Table 6.

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Table 6: Other Adverse Drug Reactions* Reported by ≥1% of XARELTO-Treated Patients in RECORD 1-3 Studies

Body System Adverse Reaction	XARELTO 10 mg N=4487 n (%)	Enoxaparin† N=4524 n (%)
Injury, poisoning and procedural complications		
Wound secretion	125 (2.8)	89 (2.0)
Musculoskeletal and connective tissue disorders		
Pain in extremity	74 (1.7)	55 (1.2)
Muscle spasm	52 (1.2)	32 (0.7)
Nervous system disorders		
Syncope	55 (1.2)	32 (0.7)
Skin and subcutaneous tissue disorders		
Pruritus	96 (2.1)	79 (1.8)
Blister	63 (1.4)	40 (0.9)

* Adverse reaction occurring any time following the first dose of double-blind medication, which may have been prior to administration of active drug, until two days after the last dose of double-blind study medication

† Includes the placebo-controlled period of RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)

Other clinical trial experience: In an investigational study of acute medically ill patients being treated with XARELTO 10 mg tablets, cases of pulmonary hemorrhage and pulmonary hemorrhage with bronchiectasis were observed.

Postmarketing Experience: The following adverse reactions have been identified during post-approval use of XARELTO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and lymphatic system disorders: agranulocytosis, thrombocytopenia

Gastrointestinal disorders: retroperitoneal hemorrhage

Hepatobiliary disorders: jaundice, cholestasis, hepatitis (including hepatocellular injury)

Immune system disorders: hypersensitivity, anaphylactic reaction, anaphylactic shock, angioedema

Nervous system disorders: cerebral hemorrhage, subdural hematoma, epidural hematoma, hemiparesis

Skin and subcutaneous tissue disorders: Stevens-Johnson syndrome

DRUG INTERACTIONS

General Inhibition and Induction Properties: Rivaroxaban is a substrate of CYP3A4/5, CYP2J2, and the P-gp and ATP-binding cassette G2 (ABCG2) transporters. Combined P-gp and strong CYP3A4 inhibitors increase exposure to rivaroxaban and may increase the risk of bleeding. Combined P-gp and strong CYP3A4 inducers decrease exposure to rivaroxaban and may increase the risk of thromboembolic events.

Drugs that Inhibit Cytochrome P450 3A4 Enzymes and Drug Transport Systems: Interaction with Combined P-gp and Strong CYP3A4 Inhibitors: Avoid concomitant administration of XARELTO with known combined P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole and ritonavir) *[see Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information].*

Although clarithromycin is a combined P-gp and strong CYP3A4 inhibitor, pharmacokinetic data suggests that no precautions are necessary with concomitant administration with XARELTO as the change in exposure is unlikely to affect the bleeding risk *[see Clinical Pharmacology (12.3) in full Prescribing Information].*

Interaction with Combined P-gp and Moderate CYP3A4 Inhibitors in Patients with Renal Impairment: XARELTO should not be used in patients with CrCl 15 to <80 mL/min who are receiving concomitant combined P-gp and moderate CYP3A4 inhibitors (e.g., erythromycin) unless the potential benefit justifies the potential risk *[see Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information].*

Drugs that Induce Cytochrome P450 3A4 Enzymes and Drug Transport Systems: Avoid concomitant use of XARELTO with drugs that are combined P-gp and strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin, St. John's wort) *[see Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information].*

Anticoagulants and NSAIDs/Aspirin: Coadministration of enoxaparin, warfarin, aspirin, clopidogrel and chronic NSAID use may increase the risk of bleeding *[see Clinical Pharmacology (12.3) in full Prescribing Information].*

Avoid concurrent use of XARELTO with other anticoagulants due to increased bleeding risk unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs *[see Warnings and Precautions].*

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary: The limited available data on XARELTO in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. Use XARELTO with caution in pregnant patients because of the potential for pregnancy related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible. The anticoagulant effect of XARELTO cannot be reliably monitored with standard laboratory testing. Consider the benefits and risks of XARELTO for the mother and possible risks to the fetus when prescribing XARELTO to a pregnant woman *[see Warnings and Precautions].*

Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

Clinical Considerations: *Disease-Associated Maternal and/or Embryo/Fetal Risk:* Pregnancy is a risk factor for venous thromboembolism and that risk is increased in women with inherited or acquired thrombophilias. Pregnant women with thromboembolic disease have an increased risk of maternal complications including pre-eclampsia. Maternal thromboembolic disease increases the risk for intrauterine growth restriction, placental abruption and early and late pregnancy loss.

Fetal/Neonatal Adverse Reactions: Based on the pharmacologic activity of Factor Xa inhibitors and the potential to cross the placenta, bleeding may occur at any site in the fetus and/or neonate.

Labor or Delivery: All patients receiving anticoagulants, including pregnant women, are at risk for bleeding and this risk may be increased during labor or delivery *[see Warnings and Precautions].* The risk of bleeding should be balanced with the risk of thrombotic events when considering the use of XARELTO in this setting.

Data: *Human Data:* There are no adequate or well-controlled studies of XARELTO in pregnant women, and dosing for pregnant women has not been established. Post-marketing experience is currently insufficient to determine a rivaroxaban-associated risk for major birth defects or miscarriage. In an *in vitro* placenta perfusion model, unbound rivaroxaban was rapidly transferred across the human placenta.

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Animal Data: Rivaroxaban crosses the placenta in animals. Rivaroxaban increased fetal toxicity (increased resorptions, decreased number of live fetuses, and decreased fetal body weight) when pregnant rabbits were given oral doses of ≥10 mg/kg rivaroxaban during the period of organogenesis. This dose corresponds to about 4 times the human exposure of unbound drug, based on AUC comparisons at the highest recommended human dose of 20 mg/day. Fetal body weights decreased when pregnant rats were given oral doses of 120 mg/kg during the period of organogenesis. This dose corresponds to about 14 times the human exposure of unbound drug. In rats, peripartal maternal bleeding and maternal and fetal death occurred at the rivaroxaban dose of 40 mg/kg (about 6 times maximum human exposure of the unbound drug at the human dose of 20 mg/day).

Lactation: Risk Summary: Rivaroxaban has been detected in human milk. There are insufficient data to determine the effects of rivaroxaban on the breastfed child or on milk production. Rivaroxaban and/or its metabolites were present in the milk of rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XARELTO and any potential adverse effects on the breastfed infant from XARELTO or from the underlying maternal condition *(see Data).*

Data: *Animal data:* Following a single oral administration of 3 mg/kg of radioactive [^{14}C]-rivaroxaban to lactating rats between Day 8 to 10 postpartum, the concentration of total radioactivity was determined in milk samples collected up to 32 hours post-dose. The estimated amount of radioactivity excreted with milk within 32 hours after administration was 2.1% of the maternal dose.

Females and Males of Reproductive Potential: Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Of the total number of patients in the RECORD 1-3 clinical studies evaluating XARELTO, about 54% were 65 years and over, while about 15% were >75 years. In ROCKET AF, approximately 77% were 65 years and over and about 38% were >75 years. In the EINSTEIN DVT, PE and Extension clinical studies approximately 37% were 65 years and over and about 16% were >75 years. In EINSTEIN CHOICE, approximately 39% were 65 years and over and about 12% were >75 years. In clinical trials the efficacy of XARELTO in the elderly (65 years or older) was similar to that seen in patients younger than 65 years. Both thrombotic and bleeding event rates were higher in these older patients, but the risk-benefit profile was favorable in all age groups *[see Clinical Pharmacology (12.3) and Clinical Studies (14) in full Prescribing Information].*

Renal Impairment: In pharmacokinetic studies, compared to healthy subjects with normal creatinine clearance, rivaroxaban exposure increased by approximately 44 to 64% in subjects with renal impairment. Increases in pharmacodynamic effects were also observed *[see Clinical Pharmacology (12.3) in full Prescribing Information].*

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, patients with CrCl 30 to 50 mL/min were administered XARELTO 15 mg once daily resulting in serum concentrations of rivaroxaban and clinical outcomes similar to those in patients with better renal function administered XARELTO 20 mg once daily. Patients with CrCl 15 to 30 mL/min were not studied, but administration of XARELTO 15 mg once daily is also expected to result in serum concentrations of rivaroxaban similar to those in patients with normal renal function *[see Dosage and Administration (2.4) and Clinical Pharmacology (12.3) in full Prescribing Information].*

Patients with End-Stage Renal Disease on Dialysis: Clinical efficacy and safety studies with XARELTO did not enroll patients with end-stage renal disease (ESRD) on dialysis. In patients with ESRD maintained on intermittent hemodialysis, administration of XARELTO 15 mg once daily will result in concentrations of rivaroxaban and pharmacodynamic activity similar to those observed in the ROCKET AF study *[see Clinical Pharmacology (12.2, 12.3) in full Prescribing Information].* It is not known whether these concentrations will lead to similar stroke reduction and bleeding risk in patients with ESRD on dialysis as was seen in ROCKET AF.

Treatment of DVT and/or PE and Reduction in the Risk of Recurrence of DVT and/or PE : In the EINSTEIN trials, patients with CrCl values <30 mL/min at screening were excluded from the studies. Avoid the use of XARELTO in patients with CrCl <30 mL/min.

Prophylaxis of DVT Following Hip or Knee Replacement Surgery: The combined analysis of the RECORD 1-3 clinical efficacy studies did not show an increase in bleeding risk for patients with CrCl 30 to 50 mL/min and reported a possible increase in total venous thromboemboli in this population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Avoid the use of XARELTO in patients with CrCl <30 mL/min.

Hepatic Impairment: In a pharmacokinetic study, compared to healthy subjects with normal liver function, AUC increases of 127% were observed in subjects with moderate hepatic impairment (Child-Pugh B).

The safety or PK of XARELTO in patients with severe hepatic impairment (Child-Pugh C) has not been evaluated *[see Clinical Pharmacology (12.3) in full Prescribing Information].*

Avoid the use of XARELTO in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy.

OVERDOSAGE

Overdose of XARELTO may lead to hemorrhage. Discontinue XARELTO and initiate appropriate therapy if bleeding complications associated with overdosage occur. A specific antidote for rivaroxaban is not available. Rivaroxaban systemic exposure is not further increased at single doses >50 mg due to limited absorption. The use of activated charcoal to reduce absorption in case of XARELTO overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not dialyzable *[see Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information].* Partial reversal of laboratory anticoagulation parameters may be achieved with use of plasma products.

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NEWS FROM THE COLLEGE

UPDATES AND ALERTS FROM ACEP

Awards and Board of Directors Nominations Now Open

Know someone who deserves to be recognized for their emergency medicine achievements? The ACEP awards program has been developed for one reason: to recognize leadership and excellence. The program provides an opportunity to recognize our members for significant professional contributions as well as service to the College. All entries must be submitted by April 2, 2018, to be considered by the Awards Committee. Visit **acep.org/awardnomination** to nominate today.

The ACEP Nominating Committee is now accepting individual, chapter, and section recommendations for Board of Directors candidates. Board candidates must be highly motivated, their membership in good standing, and involved in ACEP national and chapter activities. For complete requirements and submission information, visit **acep.org/leadershipnominations**.

Tips on MIPS

Want to know more about reporting under the Merit-Based Incentive Payment System (MIPS)? This is for you: an in-depth review of the steps and process involved using the Clinical Emergency Data Registry (CEDR) for group or individual 2018 MIPS reporting. Topics for this webinar will include selection of reportable measures, advancing care information data entry, and improvement activity reporting through CEDR. The webinar will be March 13, 2018 at 1 p.m. CDT. Register now at **acep.org/CEDR**.

ACEP Leaders Work for You

ACEP President Paul Kivela, MD, MBA, FACEP, President-Elect John Rogers, MD, FACEP, and ACEP staff met with leaders of the American Society of Anesthesiologists to discuss their sedation polices and potential impact on emergency medicine practice. They also discussed collaboration and strategies to ensure reasonable out-of-network reimbursement.

In late December, Dr. Rogers and ACEP Associate Executive Director for Public Affairs Laura Wooster met with representatives of Anthem to discuss Anthem's policy to deny payment for patient visits to the emergency department in several states, which ACEP contends is in violation of federal and state law protecting patients, according to the prudent layperson standard.

In December, ACEP's Board held its annual strategic planning meeting. The Board discussed many issues that impact the specialty, including ways to overcome challenges to fair reimbursement, how to enhance ACEP's engagement with members on social media, quality measures and CEDR, the care of patients with mental health disorders, and how to seek improved relations with other emergency medicine organizations.

For a monthly rundown of what the ACEP leadership is doing to affect emergency medicine for you and your patients, visit **acep.org/leadershipreport**.

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- ACS – The First Hours of Care
- Acute Heart Failure: Diagnostic Pearls
- Acute Heart Failure: Therapeutic Pearls
- Role of the ED in Non-Heart-Beating Donors
- Skin and Soft Tissue Infection Pearls
- Unusual But Important Cardiac Syndromes - Part 1
- Unusual But Important Cardiac Syndromes - Part 2
- Pneumonia Care Controversies
- New ED Gizmos and Gadgets
- Low-Risk Chest Pain – Who Goes Home?
- Pearls from *ED Leadership Monthly* - Part 1
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- Syncope 2018: Is Anything New?
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- Acute Ischemic Conditioning for MIs and Stroke
- Pediatric Severe Asthma in the ED
- Ear, Nose and Throat Potpourri
- Endovascular Stroke Treatment Issues
- Integration of PAs and NPs into the ED
- Adverse Effects of Biologics Marketed on TV
- Adult Severe Asthma in the ED
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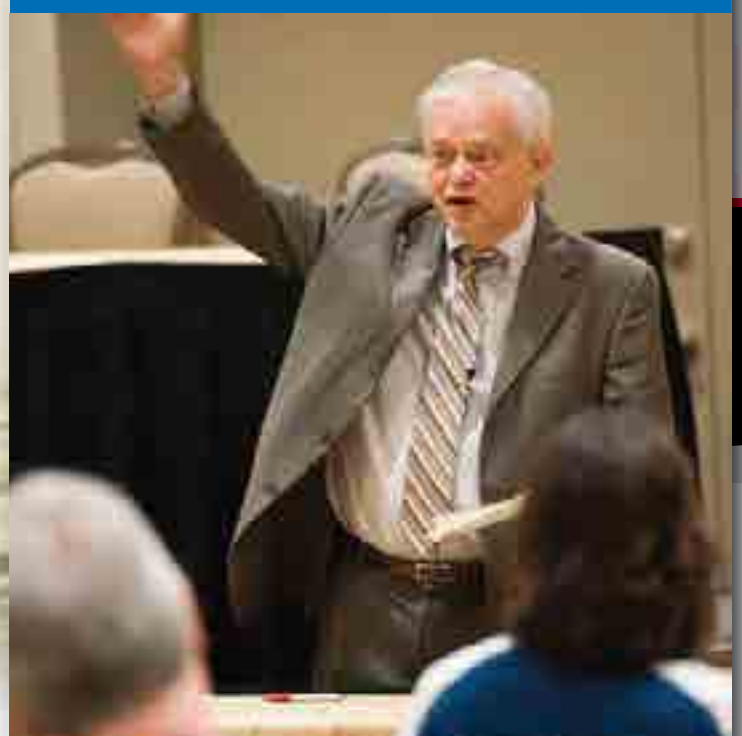

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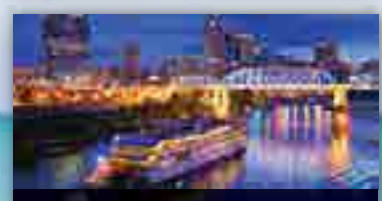

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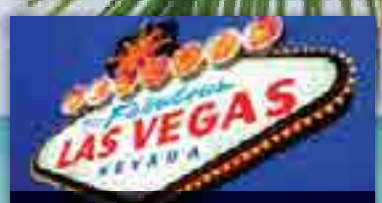

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NEW SERIES

Why Addiction Is Not Just a "Tox" Problem

Shifting the perspective on the disease of addiction might improve care of these patients in the emergency department

by R. COREY WALLER MD, MS FACEP, DFASAM; AND EVAN SCHWARZ, MD FACEP, FACMT

Editor's Note: This is the first part of an ongoing series on what emergency physicians can do to combat the opioid epidemic. The series will continue in the April issue.

During emergency medicine residency, all of us were "pimped" regularly on the toxidrome du jour. Each attending had their favorite, and by the end of training, you could predict which answer to blurt out before they even started the question. We had the intoxication syndromes, the withdrawal syndromes, the encephalopathies, the psychoses, etc. However, the word "addiction" was never associated with the explanations given for any toxidromes.

Addiction is a chronic neurobiological disorder that causes a derangement of the reward system, creating characteristic behaviors that stem from the drug replacing all other natural rewards. In fact, the behaviors are so characteristic that they are how the DSM-5 diagnoses the disease. Yet, we tend to perceive these behaviors in our emergency departments as frustrations rather than symptoms of the disease that is the number-one cause of injury-related death in our country.

What drives these behaviors? All addictions have a final common pathway that causes a decrease in the dopamine produced in the nucleus accumbens (NAc) and the ventral tegmental area (VTA). This decrease in dopamine leads to a baseline anhedonia (flat affect with lack of inherent motivation) that is, in the patient's mind, only reversed with their drug of choice. When a patient says that they are using so that they can feel "normal," this matches the neurobiological truth.

So how does this happen? We're glad you asked!

Biology of Addiction

Generally, our reward center produces a stable amount of dopamine on a daily basis that lets us get out of bed, migrate to the coffee maker, and, despite the inner voice begging for the beach, go to work. With a natural stimulus like winning the lottery (or the scheduler forgetting to put you on the holiday schedule), we produce about 100 ng/dL of dopamine in the reward system. On the worst day—you know, the day you pull the backup call ripcord—our NAc produces about 40 ng/dL. This is the "normal" range of dopamine (aka motivation).

When a patient (or one of us) uses an addictive substance, dopamine goes up 10 times higher than the normal range. As with other systems in the body, the brain fights back with aggressive movement toward homeostasis. It decreases the amount of dopamine released. If the patient continues to use, then the body decreases the amount of dopamine produced, which then atrophies the neurons. Finally, with continued use, the brain may kill the dopamine-producing neurons via apoptosis. This neurobiology may make you think back to college and wonder if you could blame alcohol and subsequent low dopamine for lack of motivation to finish charts. So far, we've found that compliance officers are not buying it. Hopefully, this is starting to explain why addiction is much more complicated than, "The patient is just making poor decisions," and you better understand why telling them, "You could have died!" is generally ineffective. Additionally, it explains why attempting basic reasoning with the patient doesn't work and just frustrates you, and the patient, further.

What do we do with this information? If dopamine is subtherapeutic and we need it to survive, then these patients are in survival mode. People in survival mode do crazy things. Again, this is why trying to have a general conversation about quitting with these patients is likely not going to work, much like trying to have an in-depth conversation with an asthmatic who is tripoding and struggling to breathe. The next time your addicted patient is screaming for "vitamin D," flailing on the floor, or ripping the hand sanitizer dispenser off the wall, remember that these are symptoms of a severe form of addiction.

This may sound crazy, and some of you are coming up with 50 reasons to call BS on this, but think about it. When a person is serotonin-depleted, they are depressed and may lose their job, stop eating, and, in severe cases, even commit suicide. If a patient's dopamine is deranged in other parts of the brain, it causes Parkinson's disease or schizophrenia. A new-onset Parkinson's patient came in a couple of shifts ago, and she was having delusions to the point where she pulled a gun on her daughter. Is it so hard to believe that a dopamine derangement in the reward center of the brain could cause these behaviors?

What Does this Mean for Emergency Care?

What can we do about it since our current approach doesn't seem to be working? This one is an easy technical fix but a hard adaptive (hearts and minds) fix. We treat it like any other chronic disorder. We admit it to the hospitalist, and let them figure it out.

Ha, not so fast. The 90-day mortality rate for a post–opioid overdose patient is between 9 percent and 20 percent, depending on geography (mainly due to presence or absence of synthetics). This is higher than a missed non–ST-elevation myocardial infarction. If we miss a troponin of 0.01, the world comes down on us the next morning. However, we discharge the overdose patient without a second thought, despite having treatments that are 55 percent to 75 percent effective at one year well within our scope of practice and sitting in our pharmacies. Now, we aren't advocating for admitting every one of these patients; we know hospitals would not allow this. However, starting them on bridging medication, such as buprenorphine, so that their withdrawal stabilizes and their craving dissipates is not a bad start. Making a meaningful attempt at care coordination is something else we can do right now. You do not need a special license to use buprenorphine to treat opioid withdrawal, only for maintenance treatment.

We will leave you with this. The next time you see a patient with an addiction who is in survival mode, see the behaviors as a symptom, document them in the chart, and give the patient a diagnosis of addiction and not just the toxicological syndrome of intoxication or withdrawal. Once you see the behaviors as a symptom rather than a frustration, you will be less angry at the patient and more likely to go at them with a bucket of evidence-based medicine rather than security.

DR. WALLER is a fellow at the National Center for Complex Health and Social Needs and managing partner at Complex Care Consulting LLC. **DR. SCHWARZ** is assistant professor of emergency medicine and medical toxicology section chief at Washington University School of Medicine in St. Louis.

SEND US YOUR QUESTIONS!

In future articles in this series, we will delineate the best practices for treatment and approach in the emergency department. If you have questions or ideas, feel free to send them our way at schwarze@wustl.edu. Until then, let data, science, and math rule the day!

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- Serves as a medicolegal consultant for numerous physician groups and hospitals
- Editor of the ACEP book *Emergency Medicine Risk Management: A Comprehensive Review*

W. Richard Bukata, MD

- As Founder of *Emergency Medical Abstracts,* has edited over 15,000 abstracts and written over 200 essays on EM-related topics
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BEAM–ED

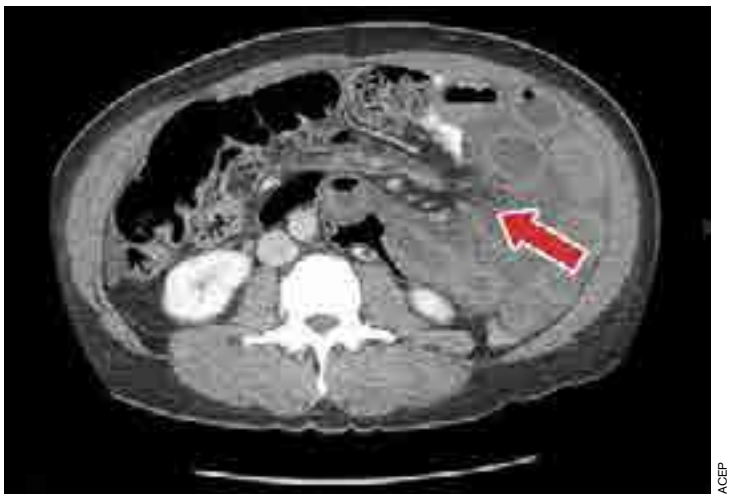
A clinical tool for bariatric examination, assessment, and management

by ALAN S. MILLER, MD, MBA, FACEP, CPE

Members of ACEP's Emergency Medicine Practice Committee, along with the American Society for Metabolic and Bariatric Surgery, created a tool for quick reference and application to aid the emergency medicine provider caring for a post–bariatric surgery patient.

The BEAM-ED tool, which can be found on the ACEP website at **www.acep.org/beam**, was designed for easy access and is structured in a history, physical exam, diagnostic, and treatment format.

The first step centers on the patient's history. The design of the information facilitates an understanding of several possible conditions following the most common bariatric surgical procedures. Since the practicing emergency physician often acquires, reviews, and processes data while performing tasks simultaneously, this format allows for a targeted yet comprehensive survey of the evaluation of the post–bariatric surgery patient. By opening each of these sections (eg, who, what, where, and how), one can ascertain pertinent information that will establish a framework to initiate the diagnostic evaluation. I particularly like the "what" section (see Figure 1), as it gives the user a visual overview and a brief description of the procedure performed on the patient. This allows one to comprehend the most common anatomical modifications performed, from the more traditional gastric bypass (GB) to the more common sleeve gastrectomy (SG).

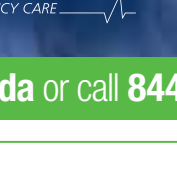


ACEP

LEFT, Figure 1: The BEAM-ED tool.
ABOVE, Figure 2: Internal hernia with small bowel obstruction.

The other significant historical component centers on determining when the surgery occurred. Patients who present fewer than 30 days from the onset of their surgery are more likely to have bleeding complications, wound infections, or an anastomotic leak. Those patients who present after 30 days are more likely to have an abscess, intestinal obstruction, internal hernia (see Figure 2), or nutritional concerns. What remains constant in our approach are the ABCs and the need to determine which patients are stable and which need emergent intervention. The diagnostic study of choice remains CT scan with oral and IV contrast. For post-bariatric surgery patients, an immediate CT scan after drinking one or two cups of contrast will suffice.

Once the etiology of the patient's symptoms has been elucidated, the diagnostic findings are further subdivided into what to anticipate after the various surgical procedures. Furthermore, there is an instructional video showing how to deflate a gastric band. In addition to being an efficient clinical reference for the practitioner in the emergency department, the information could be used to generate bariatric order sets for an electronic medical record. The information on this site will be updated periodically to provide the emergency department clinician easy access to the most current recommendations for the post–bariatric surgery patient.



DR. MILLER is a member of ACEP's Emergency Medicine Practice Committee.

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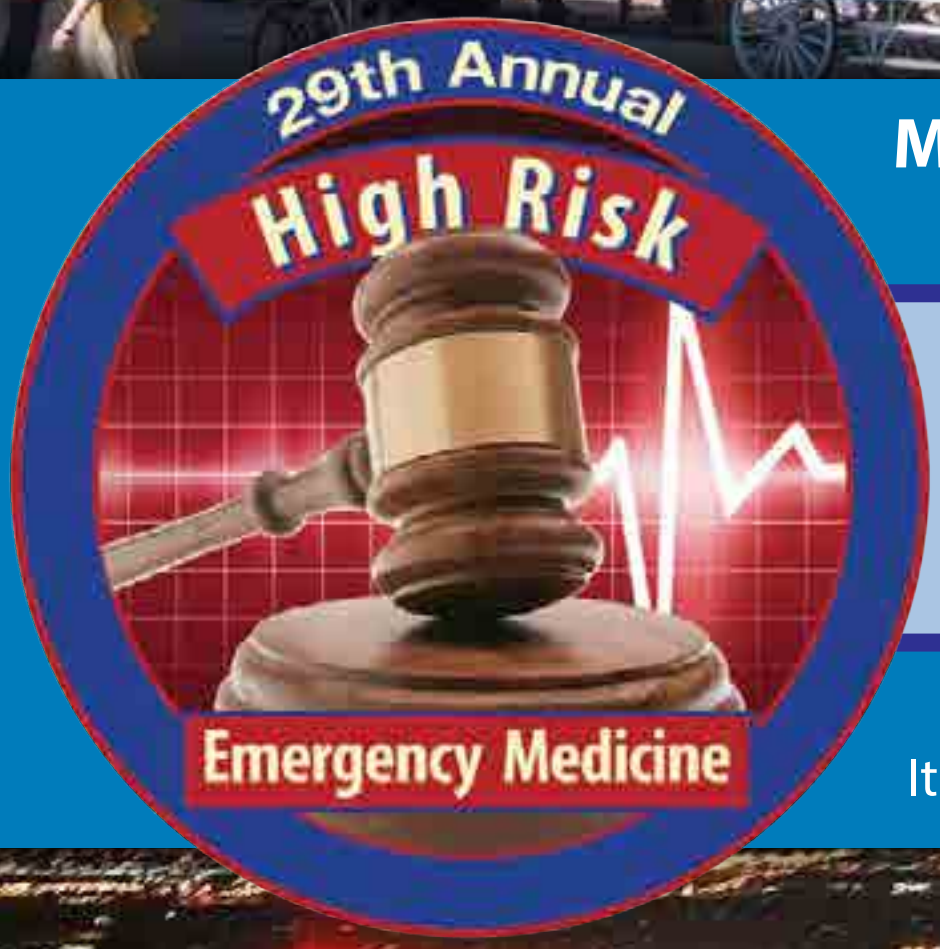

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conversation. Part 2 will appear in the March issue.

KK: Scott, we'll just touch base about this event Oct. 1 at the Harvest music festival in Las Vegas. You're the medical director at Sunrise. How many patients did you receive that night?

SS: We saw 215 patients, and all 215 patients were seen within about 90 minutes. The first patient arrived by private vehicle 20 minutes after the incident started.

KK: Did you have the sense what the volume of patients would be or that there was even an event going on?

SS: I was at home getting ready for bed when I got the calls and the text messages, so I just hurried up and got dressed. I was listening to the radio on the way in and heard a report of an active shooter on the Strip with two known fatalities and multiple injuries. I wasn't expecting this type of magnitude when I showed up 45 minutes after the incident started and saw the ambulance bay full of private vehicles, trucks, Ubers, and taxis.

Dr. Scherr

Jeannine Ruggeiro

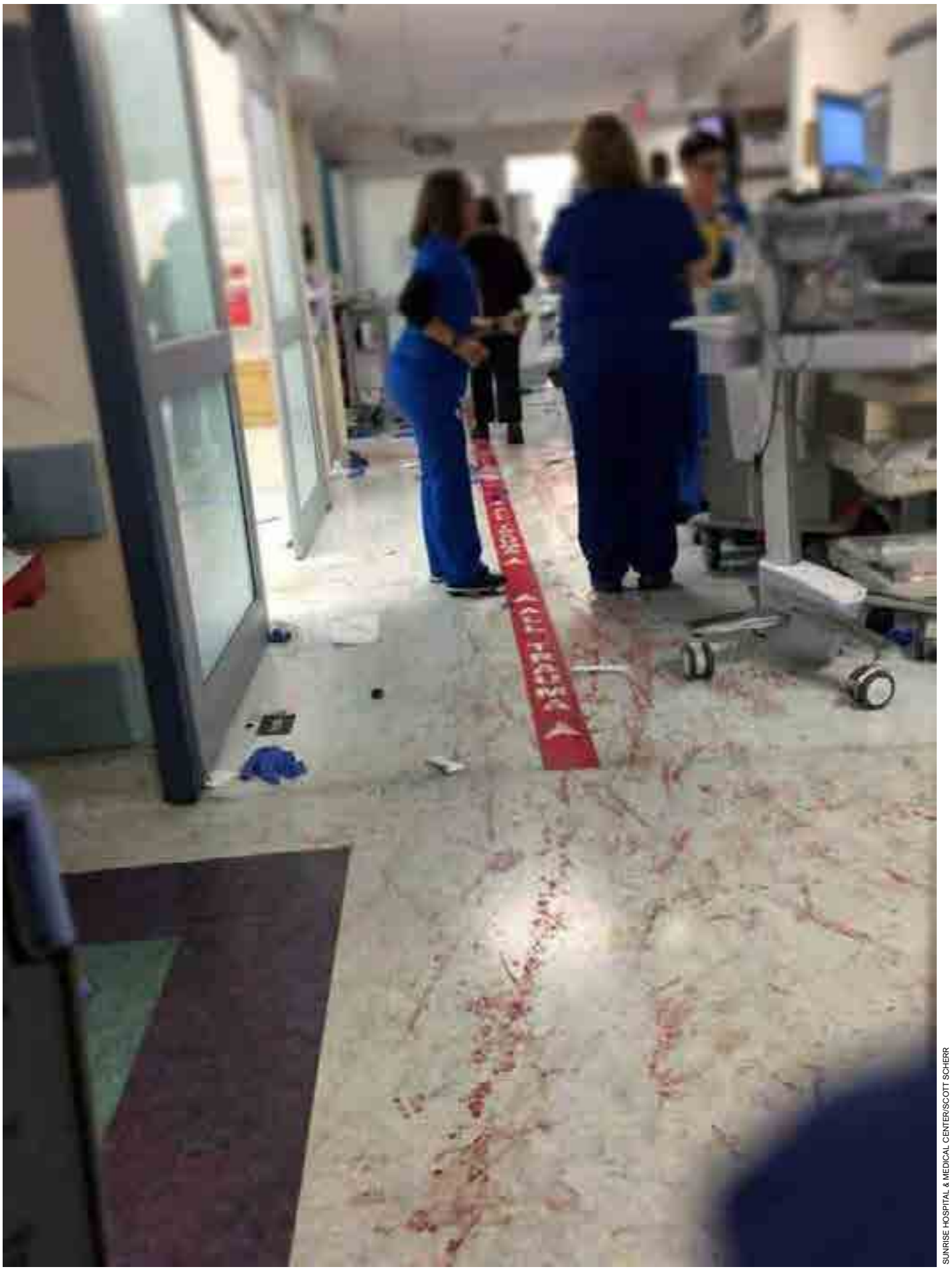
KK: How were you able to coordinate all of that traffic in the ambulance bay?

SS: Fortunately, Dr. Kevin Menes is a SWAT medic. He was able to go to his car, get his radio, and listen to the police chatter. By the time I got there, he had all the gurneys, wheelchairs, and frontline staff actually sitting and waiting in the ambulance bay for the first patients to arrive.

KK: Did you do any initial triage outside of the emergency department, or did you bring everybody inside to do that?

SS: Everybody was brought inside. We were fortunate that this was a Sunday night in Las Vegas. The ED volume was not like it would be on a Monday or Tuesday night, so we were able to put our active patients in certain areas to make room for the patients that were coming in. Initially, the MCI [mass casualty incident] triage was done by a physician. However, we needed physicians in the back to take care of the sicker patients, so we passed that on to one of the nurses out there to coordinate the MCI triage. A lot of things that I'm going to learn, I'm going to learn from Jeannine, from the patient's perspective.

Station 1 was the area where we took care of all our "red" patients. Those were our most unstable patients with the most life-threatening injuries. Station 2 and Station 4 were for what we call our "yellow" or our "immediate" patients to resuscitate them and stabilize them there. Then we utilized our ambulatory care areas, our pediatric emergency department, and our PAC-U [post-anesthesia care unit] space [as Station 3] for what we call our "green" patients, which is kind of our "walking wounded." We had that pretty well dialed in when the first patients started to arrive.



SUNRISE HOSPITAL & MEDICAL CENTER/SCOTT SCHERR

The Sunrise Hospital & Medical Center emergency department after caring for the victims of the Oct. 1 mass shooting in Las Vegas.

KK: Can you give us a sense of the spectrum of injuries that you saw?

SS: Most severe were gunshot wounds to the chest, abdomen, and also to the head.

KK: I have to credit you and others for your disaster preparedness plan and making sure everybody was ready to go. Do you think that plan was adequate?

SS: It was from an organizational standpoint, but there were a lot of lessons learned. We've practiced MCIs and even had a few MCIs, but nothing to this scale, so there are certain things that we ran out of. We ran out chest tubes and laryngoscopes. We ran out of ventilators at one point. We ended up having to put two patients on the same ventilator at one point. Sunrise is part of a three-hospital system, so we were able to commandeer level 1 transfusers, chest tubes, laryngoscopes, and blood products from our area hospitals in a matter of minutes.

KK: What did you do in those cases where you realized you were ready to put the chest tube in and you didn't have any more chest tubes? What do you do?

SS: We utilized endotracheal tubes to substitute as a chest tube until we could get more chest tubes.

KK: That's impressive. And two patients on one ventilator?

SS: There's data out there from case studies. If they're like-sized, you just double the tidal volume and separate the ventilator by an H-tube or a T-tube. Luckily, we only had to do that one time, and it was only for a matter of minutes until we got another ventilator.

KK: Wow, but what a great solution. Who came up with that idea?

SS: Actually, Dr. Menez did. That was one of his patients. We've read about it, and the respiratory therapist knew exactly what equipment to provide.

KK: You mentioned earlier that you are really trying to get your arms around the data of this whole event. Can you tell us a little bit about what you know already from that assessment?

SS: A lot of things, very simple stuff. Registration got completely overwhelmed, and you can't do anything treatment-wise on the patient or order any medications on the patient without proper identification of the patient. When you see 215 patients in 90 minutes, to get them into the computer in an accurate fashion, that was really difficult. We're working on ways to have a more rapid intake model when it comes to patient identification.

Communication with incident command is really good, but the footprint of the ER grew from a 45-bed ER and multiplied by roughly four times as we took over the PAC-U space and the pediatric ER space and various other spaces on the ground floor of the hospital. It made my job difficult to communicate with the physicians in each station on what they needed and the status of the patients in those stations.

Another issue was obtaining radiology interpretations. When an X-ray is taken, it's taken electronically and needs to be verified by the technologist before the radiologist could interpret it. We actually had the radiologist follow the portable X-ray machine around and provide preliminary reads to us verbally, or they would write them on the patient's gurney or on the patients themselves. We had real-time reads.

KK: Did you get anything documented on these patients in a formal fashion at all?

SS: We did initially, but the documentation was sparse. We had 18 of our scribes show up that night, so we were able to do a pretty good job documenting later once the patients were verified and put in the proper treatment areas.

KK: I would think that's one of the first things that is going to go by the wayside. Take care of the patients and document what you can, if you can. With 200-plus patients, how much time did it take to process and take care of all of them?

SS: By probably six o'clock in the morning, everybody had been seen and taken care of. By eight or nine o'clock in the morning, we had pretty much the entire emergency department cleared of anybody that was involved in the incident.

KK: That's an impressive piece of work, Scott, and I can't thank you enough for the service you provided to prepare your team and, most important, to care for those 215 victims. What a great demonstration of the impact that emergency physicians and emergency medicine can provide for a community.

SS: The response that we got, not only our ER team but from so many others, was amazing. We had 20 physicians and nurse practitioners show up to the emergency department that night. We had pediatric emergency department doctors and nurses taking care of adult patients on their side [of the emergency department] and then over 100 physicians, including pediatric surgeons, handling the sickest patients. Over 200 surgeons and additional staff responded as well.

STAR MAX/IPX

First responders to the mass shooting on the Las Vegas Strip.

KK: What your team, hospital, and community did in such short order is nothing less than heroic. As unfortunate as this was, I'm sure lessons can be learned from this horrific event. What we don't hear much about is the patient's perspective. From a humanistic perspective, what are their experiences like? So Jeannine is with us, and she's been kind enough to share her thoughts with us. Scott, did you take care of Jeannine?

SS: I didn't directly take care of her. She was in Station 2. The reason I know that is I had a call from one of my high school friends stating that the fiancée of one of the guys that he works with in the police department was shot and was injured, so I asked the age of the patient and the injuries and I said, "Well, that sounds like somebody who was in Station 2 that one of my docs, Dr. English, took care of," and it ended up being Jeannine. About two days later, I was able to visit Jeannine in the hospital.

KK: Jeannine, could you tell us a little bit about your evening before this whole thing happened?

JR: It was the third day of the music festival and the last performer of the night, Jason Aldean. I was toward the front of the stage on the right-hand side, on the Mandalay Bay side, with two of my girlfriends. We were dancing, laughing, singing, had drinks, just like pretty much everyone else in the crowd, when the shooting started. When it first started, none of us knew what was going on. Everybody in the crowd said, "Oh, maybe it's fireworks. Maybe it's a blown amp." Jason Aldean was still performing at that point, and then the shooting began again at a faster pace. Everyone dropped to the ground. Jason Aldean went off the stage. People were screaming. I immediately just had this feeling like, "How do I get out of here?" Then there was a break in the shooting for a couple moments. We got up to run, and it was at that time I was shot in my back and collapsed to the ground.

Be sure to look for Part 2 of this interview in the March issue.

EMF RESEARCH EXPLORES METHYLENE BLUE FOR CALCIUM CHANNEL BLOCKER TOXICITY

Is there a better way to counteract overdoses than traditional vasopressor therapy with norepinephrine?

by JENNA M. LEROY, MD

Editor's Note: *This is the first installment of a continuing series highlighting researchers sponsored by the Emergency Medicine Foundation (EMF) and illustrating the impact EMF-funded research is having on emergency medicine.*

Study Title:

Effect of methylene blue on mortality in a porcine model of amlodipine toxicity

Authors

Jenna M. LeRoy, MD; Sean Boley, MD; K.M. Engebretsen, PharmD; Jackie Kelly, MD; Samuel J. Stellpflug, MD, FACEP

Researcher Bios

Dr. LeRoy is an attending emergency physician and clinical toxicologist at Regions Hospital in St. Paul, Minnesota, and assistant professor of emergency medicine at the University of Minnesota Medical School.

Dr. Boley is an emergency physician at United Hospital in St. Paul, Minnesota.

Dr. Engebretsen is a clinical pharmacist and toxicologist at Regions Hospital.

Dr. Kelly is a quality fellow at HealthPartners Institute for Education and Research and an emergency physician at Regions Hospital.

Dr. Stellpflug is an attending emergency physician and clinical toxicologist at Regions Hospital and associate professor of emergency medicine at the University of Minnesota Medical School.

Study Background

Cardiovascular medication overdose causes significant morbidity and mortality in the United States. In 2015, the National Poison Data System (NPDS) responded to more than 2.1 million exposures, with 103,339 related to cardiovascular drugs. Cardiovascular drugs were the seventh most frequently involved substance and are now rated as the NPDS top fourth category with the greatest rate of increase in exposure. Despite maximal supportive pharmacologic therapy, including vasopressor administration, high-dose insulin therapy, lipid emulsion therapy, and extracorporeal life support, there are still cases of refractory shock leading to death. In vitro studies on canine arteries exposed to amlodipine have shown that it stimulates release of nitric oxide (NO), leading to peripheral vasodilation. Amlodipine overdose could, therefore, be managed by scavenging NO. Methylene blue (MB) inhibits NO directly but also inhibits NO production by inhibiting guanylyl cyclase and endothelial NO synthase activity. We developed a porcine model of amlodipine toxicity and compared the effects of MB to traditional vasopressor therapy with norepinephrine (NE). Time to death was the primary outcome.

Study Design

The pigs were anesthetized and instrumented with monitoring devices according to previous protocols in our institution, and a pilot study was first completed to establish a lethal model of amlodipine toxicity. Each of the two groups of animals received a toxic dose of amlodipine. A continuous infusion of amlodipine with accelerating doses was given to mimic overdose and continuing gastrointestinal absorption. After 70 minutes of amlodipine infusion, each group was resuscitated with 20 mL/kg of normal saline. Animals in each group were then randomized to receive either MB or NE therapy. Hemodynamic parameters, including mean arterial pressure and cardiac output, were measured every 10 minutes.

Results

The primary outcome was time to death. Survival times were compared using a Kaplan-Meier analysis, and the two groups were compared with the log-rank test. The study was powered at 80 percent to detect a hazard ratio of 0.2 (MB versus NE), assuming a two-sided log-rank test with alpha=0.05. Nine animals per group were required for adequate power.

An interim analysis was conducted after 15 of the initially planned 18 animal protocols were completed (seven MB and eight NE). This revealed that, for the primary outcome, MB was clearly not superior to NE. Furthermore, it would be impossible to achieve a statistically significant effect for the MB hazard ratio with the addition of three pigs, regardless of the outcome. Therefore, the study was terminated early. Overall, one of seven animals (14 percent) in the MB group survived to 300 minutes compared to two of eight animals (25 percent) in the NE group. Median survival time was 100 minutes for the MB group and 177 minutes for the NE group. Survival time did not differ by group (log-rank test P=0.29), but there was a nonsignificant trend toward longer survival in the NE group.

Projected Impact

Our data contribute to a growing body of literature on usage of methylene blue in toxin-induced shock. We hope that this will encourage more research in the field as it is still unclear where this antidote fits in the management of patients.

DR. LEROY is an attending emergency physician and clinical toxicologist at Regions Hospital in St. Paul, Minnesota, and assistant professor of emergency medicine at the University of Minnesota Medical School.

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From left: Dr. Tirado, Dr. Novello, Dr. Kotler, and Dr. Trivino arriving at Jayuya, Puerto Rico.

EM Residency May Not Prepare You for Everything

A resident's journey through the devastation of Hurricane Maria

by JULIAN TRIVINO, DO, MS

There I was, landing in a town cut off from the outside world by Mother Nature. The distinct sound of the Black Hawk's four rotors broke through the thin air while horses ran freely and stunned children watched, amazed by the sight of a 12,000-pound machine slowly hovering and touching down on a wet field. For their mothers and fathers, this was a glimmer of hope. Despite all this, it was difficult to ignore the degree of destruction that surrounded us.

HOW MY JOURNEY BEGAN

On Sept. 21, 2017, I was sitting in conference at Florida Hospital when I got a text from one of my attendings: "Would you be interested in going to Puerto Rico [PR] next week?" The worst natural disaster on record had just struck the island of PR, and there were people in need of immediate medical attention. "YES!" I replied. I wanted to be on that island at all costs.

Many of my attendings at Florida Hospital had trained in PR, and although they had lived in the continental United States for many years, their hearts still remained on the island. Following Hurricane Maria, it was evident to them that there were discrepancies between the reports from the media and from physicians whom they had trained with on the ground. While the media reported improvements following the aftermath, the limited communication received by our team portrayed a picture of an island with incredible need for medical relief, supplies, and support. Due to power outages on more than 95 percent of the island, there was limited communication between hospitals, physicians, citizens, and the outside world, leaving the overall health of the Puerto Rican people in question.

As I boarded that flight, I left behind the mainland and any doubt regarding the reason I had chosen this specialty. I was born to do this. My heart filled with joy; my body, with excitement. As my colleagues—Katia Lugo, MD; Alfredo Tirado, MD, FAAEM; and Jorge Lopez, MD, FACEP, from the Florida Hospital emergency department and my fellow resident William Kotler, MD—and I arrived in PR with a plane full of supplies, we began to appreciate the challenges the island faced. From the plane looking down, a stream of lights stretching approximately two to three miles shone brightly, surrounded by darkness—a line of cars waiting to fill up with gas. Some cars had been there for more than 48 hours. The streets were otherwise empty due to a 7 p.m. curfew. Tons of rental cars were available due to the mass exodus from the island, but there was no gas. We caught a ride from an airport employee to our hotel, having to leave all of our supplies behind for the time being. At the hotel, we were met by locked doors and security, as the concern for looting became more prevalent with each passing day. In the hotel, we were greeted by staff ecstatic to see US physicians arriving.

PHOTOS: JULIAN TRIVINO

LEFT: Dr. Trivino assisting in the resuscitation of a patient in cardiac arrest.

ABOVE(from left): Dr. Lugo, Dr. Tirado, Dr. Kotler, and Dr. Lopez inside the US Customs and Border Patrol plane that transported the team to Puerto Rico.

The next day, we spent much of our time establishing provisional medical licenses to practice in PR. The PR Department of Health (DOH) had moved its headquarters to the convention center in San Juan; it had become a military fortress. Military personnel with automatic weapons surrounded the building. There we made contact with Norma Torres, the assistant to the secretary of the DOH. Through her, we were granted provisional licenses #001–004. She informed us that a nearby hospital in Aguadilla, which supported the entire northwest corner of the island, was on the brink of closing, and the PR DOH needed personnel to assess the current situation of the hospital and likely stay to work for a few days. Communication lines were down, so updates were being relayed to the DOH by townspeople making their way to San Juan in search of assistance.

AT THE HOSPITAL

We arrived in Aguadilla the next morning as the sun was rising. The hospital sits adjacent to the ocean, and despite the level of surrounding destruction, it remained a beautiful sight. We were shown to the office of the medical director where hospital leaders were discussing shutting down the hospital within two hours. They were concerned about the lack of diesel fuel and potable water as well as their overworked staff.

As the medical director took us into the emergency department, one of the patients being held there went into cardiac arrest. There was only one physician for 30 beds, and she was busy tending to another critically ill patient. The medical director immediately sprung into action and started CPR. Our team and the remaining staff worked for more than 15 minutes to successfully resuscitate the patient. Within a matter of 10 minutes, we had walked into the emergency department, resuscitated a patient, and established rapport with the staff. Although the emergency department was hemorrhaging morale, our arrival lifted the spirits of nurses, techs, and other physicians who had been praying for help.

The emergency department in Aguadilla had no air-conditioning, and temperatures were 91–97°F at all times. The air was humid and smelled of disease. After just one hour in the emergency department, my scrubs were soaked and sticking to my body. We faced challenges I had never experienced in the United States. The first was managing septic patients with fevers of 103–106°F in a room that was only a few degrees cooler. We were short on antibiotics, normal saline, ice to pack axillas, central lines, and IV tubing. There were no imaging capabilities, only plain radiographs, without a radiologist to read images. To transfer a patient to a trauma center, we had to use our satellite phones and attempt to establish a connection while pointing the antenna to the clearest spot in the sky. With the help of Florida Hospital, within two days, we had a shipment sent on a private plane with many of the needed supplies. In addition to the Florida Hospital shipment, we received aid from the Federal Emergency Management Agency and continued support from PR DOH. After spending three days in Aguadilla, Ms. Torres asked us to return to San Juan for our next mission. They had heard via people coming from Aguadilla that the hospital had been stabilized.

JULIAN TRIVINO

Dr. Trivino reads a C-spine X-ray while outside the Aguadilla hospital in Puerto Rico.

HELPING IN OTHER AREAS

The PR DOH began to hear of other towns in dire need of supplies, personnel, and acute care. Many of those with chronic illnesses were decompensating. Many had been out of medications since the hurricane began, and those with limited medications had no place to refill them. For many who lived on insulin, the lack of power and the heat and humidity had ruined their remaining insulin. Many pharmacies were having problems issuing medicines, as power outages limited their ability to contact insurers to verify and authorize prescriptions. We reached out to Florida Hospital for a temporary solution. They sent insulin and several commonly prescribed medications. Ms. Torres asked us to try to reach as many towns as we could, assess their needs, deliver medications, and treat anyone we could. Our travel was limited, as the road conditions were poor; driving at night was treacherous.

The solution to that problem arrived. Antonia Novello, MD, surgeon general during President George H.W. Bush's administration, was a friend of one of the leaders of our group, Dr. Lopez. She came to join our team efforts. With her collaboration with the PR DOH and the U.S. Army, we were granted access to the 101st Airborne Division, who flew us to several hospitals throughout PR. We found needs similar to those seen in Aguadilla. On more than one occasion, care providers were forced to place acutely sick patients in ambulances and transfer them, without any notification, through harsh terrain and dangerous roads. Dr. Lugo and Dr. Novello came across an orphanage where kids were out of food and water. By the next day, with the help of the 101st Airborne, they had crates full of water and food.

After three weeks in PR, our team had been able to reach 28 towns and deliver medications, supplies, food, and water and provide medical care to thousands of patients. However, we did more than that. We lifted the spirits of the people of PR. The sight of joy and hope as we landed in desolate towns is now permanently embedded in my memory. It is a tribute to the simple truth that what we do as emergency physicians matters. I am grateful and honored to be part of this family and would never choose a different specialty.

DR. TRIVINO is chief resident in the emergency medicine residency at Florida Hospital in Orlando.

THEN & NOW

CONTINUED FROM PAGE 1

What seems commonplace today may not have been so clear back then, and many stops along the way have proved ineffective or even harmful, but it's all part of the evolution of emergency medicine. What milestones were reached? Who was involved? Dead ends? Plenty of those. Today's emergency physician has to ask, how could they practice back then? Many from that era might say the same about today's emergency medicine.

We intend to cover topics such as stroke, acute coronary syndrome, trauma care, resuscitation, toxicology, infectious disease, airway management, and many more. Illustrating the issues of the times is a compilation of covers and advertisements from the *Journal of the American College of Emergency Physicians* (*JACEP*), now known as the *Annals of Emergency Medicine*.

Stroke: In the 1960s, hypertension was identified as a risk factor for stroke, and in the 1970s, aspirin made a big splash along with the advent of the CT scanner.

Trauma: Although the concept of pneumatic anti-shock garments was introduced in 1903, NASA claimed credit for the development of medical anti-shock trousers (MAST) in the 1960s. MAST entered the medical scene during the Vietnam War and were deemed essential for all ambulances to carry by the American College of Surgeons Committee on Trauma in 1977.

Sepsis: Lactate was first introduced in 1964? What took knowledge translation so long? In 1954, corticosteroids emerged as a treatment option for severe infections, and it took the next 50-plus years to prove that they didn't work.

Toxicology: In the late 1970s and early 1980s, ipecac was all the rage! Home? Hospital? It didn't matter—give it! It's hard to imagine the sheer volume of emesis that must have been produced until this approach to gastric decontamination fell out of favor due to aspiration, Mallory-Weiss tears, bronchospasm, pneumomediastinum, and other complications.

Acute Coronary Syndrome: In the early 1970s, the World Health Organization defined a myocardial infarction as any two of the following three: 1) chest pain, 2) development of Q waves on an ECG, and 3) increase in cardiac enzymes (combination of total creatine phosphokinase, creatine phosphokinase-MB, aspartate aminotransferase, and lactate dehydrogenase).

Public Policy: In 1966, the National Academy of Sciences published a white paper, "Accidental Death and Disability, the Neglected Disease of Modern Society," which seems to coincide with the early recognition of the need for the specialty of emergency medicine.

It is truly amazing to consider how far we've come in a relatively short period. Although emergency medicine is young compared to many other specialties, our roots are well established, and we have earned our place in the history of the house of medicine through evidence-based contributions, public health advancements, and public policy initiatives. We look forward to helping illustrate emergency medicine's wonderful history in the coming months.

DR. KLAUER is an ACEP Board member; chief medical officer–hospital-based services, chief risk officer, and executive director–patient safety organization at TeamHealth; *ACEP Now* medical Editor-in-Chief; and clinical assistant professor, University of Tennessee and Michigan State University College of Osteopathic Medicine.

DOGMA FEELS RIGHT UNTIL YOU STEP IN IT

SKEPTICS' GUIDE TO EMERGENCY MEDICINE

DR. MILNE is chief of emergency medicine and chief of staff at South Huron Hospital, Ontario, Canada. He is on the Best Evidence in Emergency Medicine faculty and is creator of the knowledge translation project the Skeptics' Guide to Emergency Medicine (www.TheSGEM.com).

Dexy's Midnight Wheezers

Prednisolone or dexamethasone for pediatric asthma exacerbations?

by **KEN MILNE, MD, MSC, CCFP-EM, FCFP, FRRMS**

The Case

A 6-year-old girl presents to the emergency department after waking up at midnight with another asthma exacerbation. She had been getting worse despite using her albuterol correctly. After receiving three treatments with albuterol and Atrovent, she is doing much better. You prepare to discharge her on a three-day course of prednisolone (PRED). Her parents ask if there is something else that tastes better because it is a real struggle to get her to take the medicine.

Background

PRED has been the oral steroid used in the treatment of pediatric asthma exacerbations for decades. However, it has a bitter taste that can make it very hard to administer to a young child. PRED is also associated with a significant amount of vomiting; this is one of the leading reasons for treatment failure for outpatient asthma.[1]

Dexamethasone (DEX) has a longer half-life than PRED, is much better tolerated, and has been used for a variety of pediatric conditions, including croup.[2,3] A number of recent studies have compared PRED to DEX for the outpatient treatment of asthma. A systematic review and meta-analysis showed that a single- or two-dose regimen of DEX was as effective as a five-day course of prednisone/PRED, with less vomiting in the DEX group.[4]

All the studies have shown that DEX was as good as PRED for the treatment of asthma. Of the seven randomized control trials, all have issues with methodology and utilized different doses.

Clinical Question

In children presenting to the emergency department with an acute exacerbation of asthma, is a single oral dose of DEX noninferior to three days of PRED?

Reference

Cronin JJ, McCoy S, Kennedy U, et al. A randomized trial of single-dose oral dexamethasone versus multidose prednisolone for acute exacerbations of asthma in children who attend the emergency department. *Ann Emerg Med*. 2016;67(5):593-601.e3.

- **Population:** Patients between 2 and 16 years of age with a prior history of asthma presenting to the emergency department with an acute asthma exacerbation.
  - **Excluded:** Anyone with a critical or life-threatening exacerbation, varicella or herpes simplex virus infection, tuberculosis exposure, fevers higher than 39.5°C, steroid use within the last four weeks, metabolic disease, or any comorbid condition.
- **Intervention:** DEX 0.3 mg/kg (maximum 12 mg) orally once.
- **Comparison:** PRED 1 mg/kg per day (maximum 40 mg/day) orally for three days.
- **Outcomes:**
  - **Primary:** Pediatric Respiratory Assessment Measure (PRAM; range 0 to 12) at day four of treatment (see Table 1).
  - **Secondary:** Change in PRAM score, PRAM score at emergency department discharge, hospital admission on day one, emergency department length of stay, unscheduled visits to health care providers for respiratory symptoms, readmission to the hospital or additional systemic corticosteroids within 14 days of study enrollment, vomiting within 30 minutes of administration of the study medication, school days and parental workdays missed, and days of restricted activity.

TABLE 1. The Pediatric Respiratory Assessment Measure (PRAM)

SIGNS	SCORE 0	1	2	3
Suprasternal muscle contraction	Absent		Present	
Scalene muscle contraction	Absent		Present	
Air entry*	Normal	Decreased at bases	Widespread decrease	Absent/minimal
Wheezing*	Absent	Expiratory only	Inspiratory and expiratory	Audible without stethoscope/silent chest with minimal air entry
SaO_2, %	≥95	92–94	<92	

***In case of asymmetry, the worst lung is rated. Mild exacerbation=1 to 3; moderate, 4 to 7; and severe, 8 to 12.**

SOURCE: CRONIN JJ, MCCOY S, KENNEDY U, ET AL. A RANDOMIZED TRIAL OF SINGLE-DOSE DEXAMETHASONE VERSUS MULTIDOSE PREDNISOLONE FOR ACUTE EXACERBATIONS OF ASTHMA IN CHILDREN WHO ATTEND THE EMERGENCY DEPARTMENT. ANN EMERG MED. 2016;67(5):593-601.E3.

Authors' Conclusion

"In children with acute exacerbations of asthma, a single dose of oral dexamethasone (0.3 mg/kg) is noninferior to a 3-day course of oral prednisolone (1 mg/kg per day) as measured by the mean PRAM score on day 4."

Key Results

There were 226 children included in this study, with more boys than girls. The mean age was around 6 years.

- **Primary Outcome:** There was no difference in mean PRAM scores at day four between the DEX and PRED groups.
  - Mean PRAM 0.91 DEX versus 0.91 PRED (95% CI, -0.35 to 0.34)
- **Secondary Outcomes:**
  - There was no difference between groups for any of the secondary outcomes except for further systemic steroids (13.1 percent DEX versus 4.2 percent PRED).
  - Fourteen patients in the PRED group vomited, while no patients in the DEX group vomited.

Evidence-Based Medicine Commentary

1. **Blinding:** This was not a blinded study, which could have introduced bias. It would have been better if the participants and providers did not know what treatment was being received.
2. **Selection Bias:** Some of the exclusion criteria were subjective in nature. This could have introduced bias into the study.
3. **Prognostic Factors:** In the DEX group, there were higher rates of atopic dermatitis, stronger family histories for both atopic dermatitis and asthma, and higher rates of daily usage of salbutamol. This might indicate that the DEX group was sicker than the PRED group. This imbalance of prognostic factors could have skewed the data to make them less significant when compared with the PRED group.
4. **Side Effects:** Vomiting was the most common side effect but was not observed in the DEX group. A common reason to fail outpatient management is not being able to tolerate oral medications (vomiting). The lack of vomiting in the DEX group would bias the results away from oral PRED.
5. **Treatment Failure:** The DEX group had a higher number of treatment failures that required a second course of steroids. However, these patients were older and, based on their PRAM scores, were actually sicker than the other patients in the study. This observation also held true for the PRED group. A possible reason for treatment failure is that providers in the United Kingdom and Ireland use a lower dose of DEX (0.3 mg/kg) than those in the United States (0.6 mg/kg). However, similar failure rates have been observed in other studies done in the United States using the higher-dosing regimen. What some clinicians do is provide a second dose of DEX for the sicker child to take 48 hours postdischarge.

Bottom Line: In children presenting to the emergency department with an acute exacerbation of asthma, a single dose of DEX is noninferior to a three-day course of oral PRED.

Case Resolution

The 6-year-old girl who did not like the taste of PRED was given oral DEX 0.6 mg/kg. A second dose was provided to be given if needed at 48 hours.

Thank you to Dr. Michael Falk, a pediatric emergency medicine provider working at Harlem Hospital Center in New York and Children's National Medical Center in Washington, D.C. He is also a Best Evidence in Emergency Medicine (BEEM) presenter and author.

Remember to be skeptical of anything you learn, even if you heard it on the Skeptics' Guide to Emergency Medicine.

References

1. Lucas-Bouwman ME, Roorda RJ, Jansman FG, et al. Crushed prednisolone tablets or oral solution for acute asthma? *Arch Dis Child*. 2001;84(4):347-348.
2. Schimmer BP, Parker KL. Adrenocorticotropic hormone; adrenocortical steroids and their synthetic analogs; inhibitors of the synthesis and actions of adrenocortical hormones. In: Brunton LL, Lazo JS, Parker KL, eds. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*. 11th ed. New York: McGraw-Hill; 2007:1587-1612.
3. Russell KF, Liang Y, O'Gorman K, et al. Glucocorticoids for croup. *Cochrane Database Syst Rev*. 2011;(1):CD001955.
4. Keeney GE, Gray MP, Morrison AK, et al. Dexamethasone for acute asthma exacerbations in children: a meta-analysis. *Pediatrics*. 2014;133(3):493-499.

RESOURCES FOR FURTHER READING

- **St. Emlyn's: Why don't we use dexamethasone for children's asthma?** Available at: stemlynsblog.org/dexamethasone-asthma-children/

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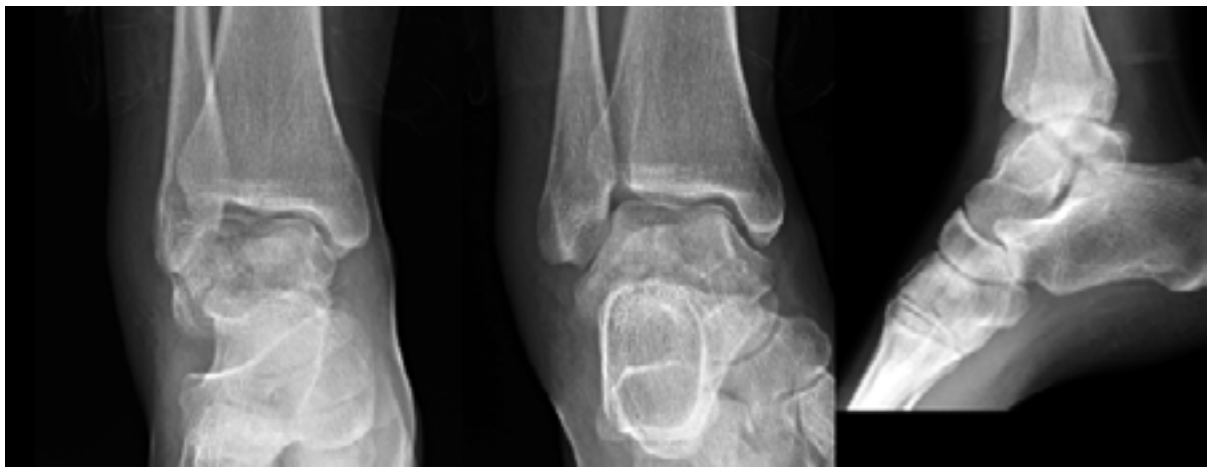
"Up Front" About Commonly Missed Ankle Injuries

Consider your ED plans for each of these patients with isolated ankle injuries

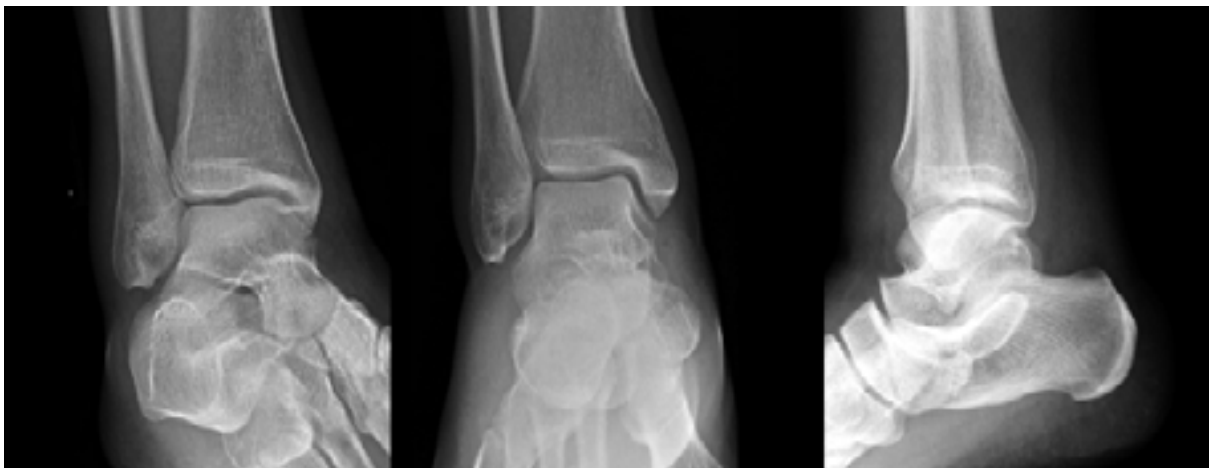
by ARUN SAYAL, MD, CCFP(EM)

Written from the perspective of an emergency physician who also runs a weekly minor fracture clinic, this column is intended to highlight a few key ED teaching points for commonly missed and commonly mismanaged ED orthopedic cases.



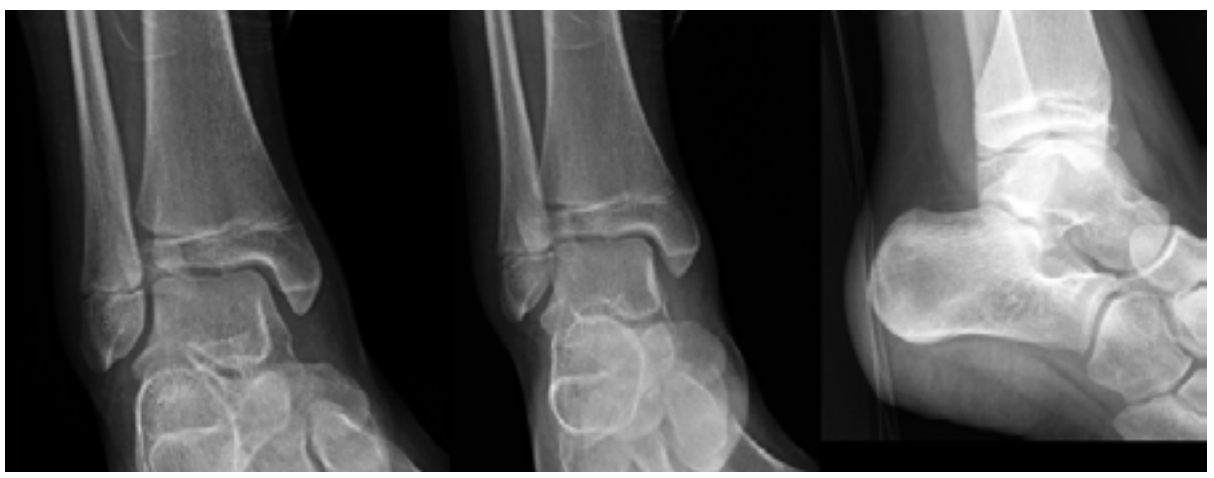
CASE 1

A 22-year-old female falls, injures her ankle, and is non-weight-bearing. Lateral ankle pain is noted. The Ottawa ankle rules (OAR) indicated X-rays, and the emergency department images are above (**Case 1, Figure 1**).



CASE 2

A 45-year-old male slips on a sidewalk. He has mild lateral pain, his medial malleolus is non-tender, and he is non-weight-bearing. The OAR indicated X-rays, and the emergency department images are above (**Case 2, Figure 1**).



PHOTOS: ARUN SAYAL, MD, CCFP(EM)

CASE 3

A 13-year-old female slips playing soccer. She has mild lateral pain but is non-weight-bearing. The OAR indicated X-rays, and the emergency department images are above (**Case 3, Figure 1**).

What Happened in the Emergency Department?

- **Case 1:** The 22-year-old female was diagnosed with a severe lateral ankle sprain. She was treated with a walking boot, crutches, and follow-up in the minor fracture clinic.
- **Case 2:** The 45-year-old male was diagnosed with a soft tissue injury (STI) of the ankle. He was treated with an air-stirrup, crutches, and follow-up in the minor fracture clinic.
- **Case 3:** The 13-year-old female was diagnosed with a Salter-Harris I fracture in the distal fibula. She was treated with an air-stirrup, crutches, and follow-up in the minor fracture clinic

What happened in the end? Well, all three cases were surgical (see **Case 1, Figure 2; Case 2, Figure 2; and Case 3, Figure 2,** opposite page).

The details of each case are below, but in the bigger picture, it's worth discussing reasons the OAR can be "bad to the bone." The OAR ask us to palpate the posterior aspects of the medial and lateral malleoli. However, there also are important structures to examine in the front and back of the ankle. This article will focus on commonly missed injuries at the front of the ankle joint.

Ankle injuries are frequently seen in emergency departments. The majority of ankle injuries are sprains; fewer than 15 percent of ED X-rays reveal fractures. To reduce the number of X-rays ordered, the OAR were proposed more than 25 years ago. They have subsequently been validated and implemented with reasonable success and acceptance.[1–7]

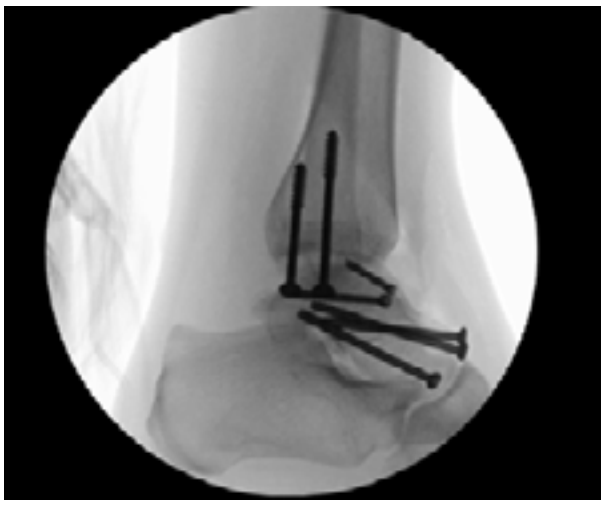
The OAR are a very good clinical decision instrument when used properly. They are designed to simply help decide which emergency department patients with ankle injuries require an X-ray. They should only be used after a proper assessment has been completed.

Over time, the OAR seem to have transformed from an emergency department X-ray utilization tool to an emergency department ankle examination tool. This is not what the OAR were intended for. While this observation is anecdotal from my experiences teaching in the emergency department, during courses, and following up with ED patients with acute ankle injuries in the minor fracture clinic, you may find this pattern sounds familiar.

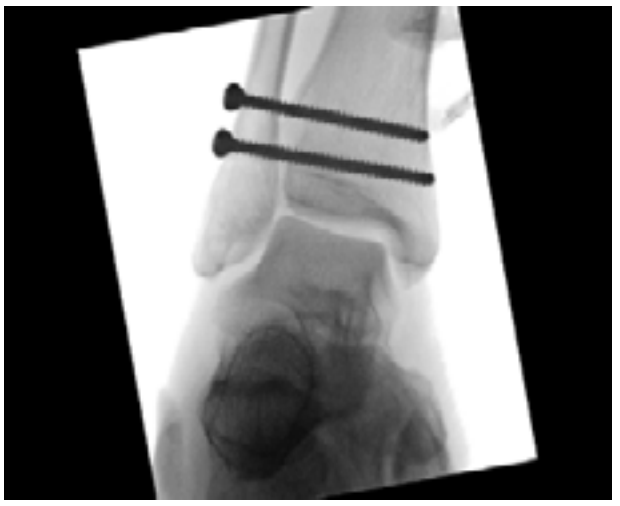
For some practitioners, the ED ankle assessment has been condensed to the application of the OAR. If a patient twisted an ankle, one asks about weight-bearing, then palpates the four sites of tenderness for the OAR (the posterior 6 cm of the lateral malleolus, the posterior 6 cm of the medial malleolus, the navicular, and the base of the 5th metatarsal). After checking the distal neurovascular status, the ankle exam is done! When indicated, the X-ray is ordered and interpreted, and if negative, the patient is diagnosed with STI of the ankle. Next patient! Well, not so fast.

While the OAR have some value, they are only a small part of the emergency department ankle assessment. Beyond the OAR, there are other vital aspects of the ankle/foot assessment. A proper emergency department ankle assessment requires understanding:

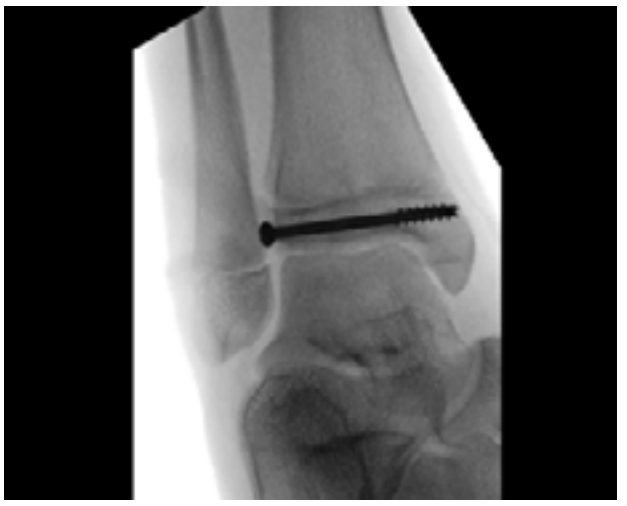
- The mechanism of injury, the forces involved, and the events after injury
- Previous injuries to the ankle (and to the opposite, comparison ankle)
- Relevant past medical history (neuropathy, long-term steroids, etc.)
- An efficient and complete exam of the lower leg, ankle, and foot (Look, Feel, Move—inspect, palpate, range of motion)
- The specific differential diagnosis based on the patient's injury and evaluation



Case 1, Figure 2: 22-year-old female



Case 2, Figure 2: 45-year-old male



Case 3, Figure 2: 13-year-old female

With all of this, one can then interpret the X-rays in the context of the patient's differential diagnosis. Radiologists are often asked to interpret X-rays without clinical information. As emergency physicians, we obviously have access to the clinical side. Interpreting X-rays without that clinical information is unnecessarily stacking the deck against us.

These three cases highlight the importance of the history and examination of the anterior aspect of the ankle. All three were seen by excellent emergency physicians. Despite that, all three were subtle misdiagnoses. All three were operative cases. All three had worrisome histories and were tender over the anterior aspect of the ankle, but these findings were not discovered in the emergency department. Two of the three had abnormal X-rays. In retrospect, some may call them fairly obvious radiologic abnormalities. However, the concerning mechanisms were not identified by history, and focal tenderness was not identified on exam. As a result, these uncommon injuries were not part of the differential and were not sought on X-ray interpretation. Just as a pneumothorax can be hard to see if you don't look for it, these injuries can easily be overlooked if they are not considered. The clues to consider them are often found in the patient's history and physical exam.

Case 1

The emergency physician noted the patient fell and injured her ankle. The ankle was swollen and tender laterally, but there was no emergency department assessment of her anterior ankle. Diagnosis: severe lateral ankle sprain. She was given a walking boot and crutches, with follow-up in a week.

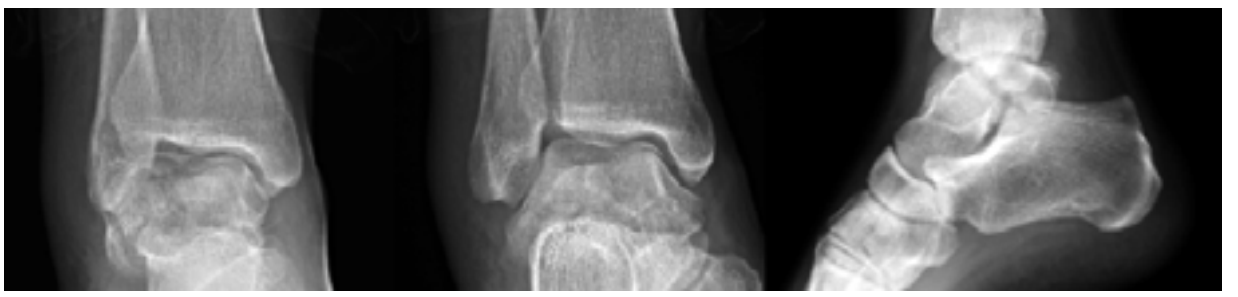
A few extra details: In fact, she jumped from a wall about six to seven feet high, landed on her feet, then fell over. Unable to walk, she presented to the emergency department the same evening. No anterior joint/talar pain was documented in the emergency department note on the initial visit. However, she was noted to be quite tender there when she returned the next day (after she was called back to the emergency department for an X-ray discrepancy). The original emergency department X-rays (cropped) are in **Case 1, Figure 3**.

Case 1, Figure 4 includes arrows to show some of the fracture lines visible throughout the talus.

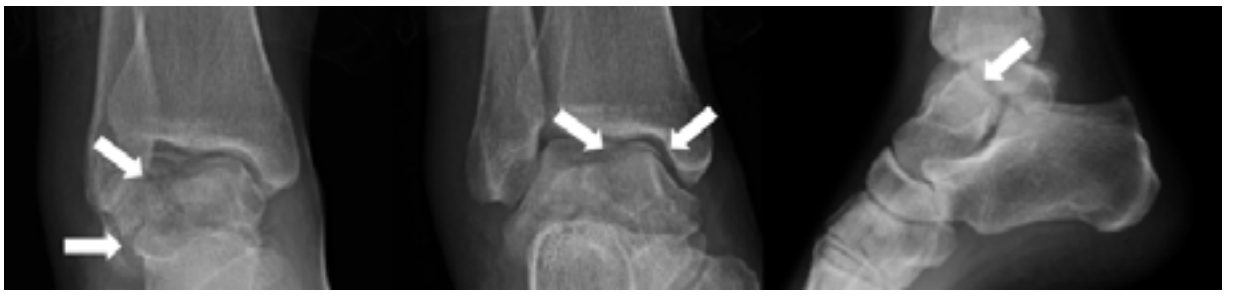
The X-ray study was read as "no fracture" by the emergency physician. The radiologist identified the fractured talus. The patient returned to the emergency department the next day, and a CT scan in **Case 1, Figure 5** showed the shattered talus.

The patient was admitted for surgical management, as shown in Case 1, Figure 2.

Case 1 highlights the importance of the history (eg, mechanism, force, and events after) and physical examination (eg, examining the anterior aspect of the ankle). Once the patient's story is understood, the physician will then look at the X-rays with more focus and should also search for known associated injuries (eg, calcaneus, other foot, knees, hips, and the thoracolumbar spine).



Case 1, Figure 3



Case 1, Figure 4

Case 1, Figure 5

Case 2, Figure 3A

Case 2, Figure 3B

Case 2, Figure 3C

Case 2

The emergency department report showed the patient had mild tenderness laterally and no tenderness over the medial malleolus. He was diagnosed with a STI of the ankle, placed in an air-stirrup, given crutches, and provided with follow-up in the clinic in a week.

He came back on day 10. He was quite specific about the mechanism. He caught the instep of his right foot, and as his left foot went forward, his injured right foot clearly turned out. The mechanism was external rotation, a red flag mechanism. He was unable to bear weight up. At the patient's follow-up exam, the emergency physician stated, "The patient had very mild tenderness laterally, and he was non-tender over the medial malleolus." However, as images **Case 2, Figure 3A–C** show, he also had pain at three other points (points the OAR do not ask us to examine).

Case 2, Figure 3A: The deltoid ligament, below the medial malleolus.

Case 2, Figure 3B: Above the ankle joint, over the syndesmosis.

Case 2, Figure 3C: The proximal fibula.

In the clinic on day 10, X-rays were taken of the tibia and fibula (**Case 2, Figures 4A and 4B**). The proximal fibula shows the oblique fracture of the fibula. The fracture is only seen on the lateral view (**Case 2, Figure 4B**), a re-

CONTINUED *on page 22*

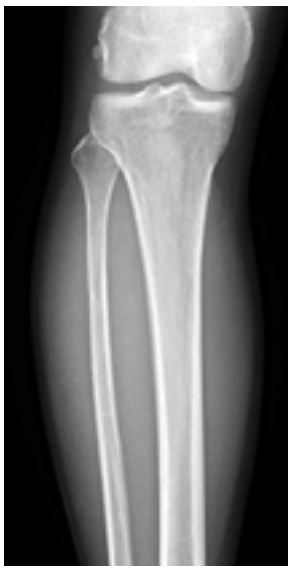
minder of the orthopedic mantra, "One view is one view too few." He had the classic Maisonneuve fracture, an external rotation mechanism resulting in injuries to the medial ankle (deltoid ligament or medial malleolus), syndesmosis, and interosseous membrane exiting out the proximal third of the fibula with an oblique fracture.

The patient was referred to an orthopedic surgeon and had surgery the following day, as shown in **Case 2, Figure 2**.

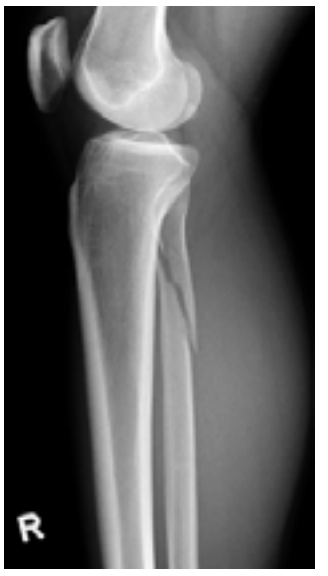
The OAR ask us to examine the posterior 6 cm of the medial and lateral malleoli, which was done. However, that is not a complete emergency department ankle exam. One needs to palpate many structures to localize the pain and discover the pathology. In this case, the ankle exam also revealed pain over both the deltoid ligament and the syndesmosis. Neither of these are part of the OAR. Either one can be a red flag on physical, and the combination certainly is concerning for a higher fibular fracture, which on palpation can be quite subtle. So in cases of twisting ankle injuries with significant medial ankle pain and little or no lateral ankle pain, it is best to X-ray the ankle and add the tibia/fibula views as a separate X-ray study.

This case again highlights that the OAR are not a complete emergency department ankle exam; they are simply a tool to use after a proper ankle assessment to decide if an X-ray is indicated.

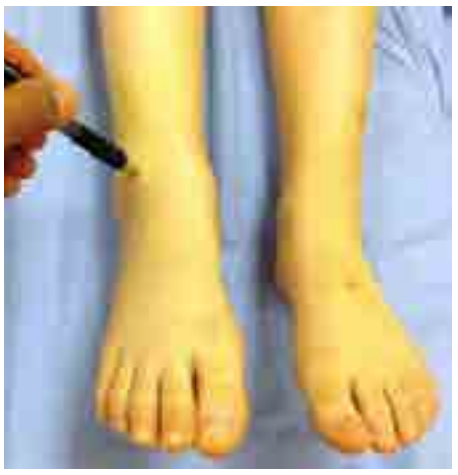
It can be a bit daunting to see the "normal" X-rays and then the intraoperative films. This case was a missed Maisonneuve fracture, a classic fracture that will often show up on board certification examinations. More important than nailing the exam question, we should make sure we know how to recognize it the next time we see an emergency department patient with an ankle injury. This was a very subtle case without medial malleolus fracture (he had the deltoid ligament equivalent) and without shift of the ankle mortise. If we mistakenly put all of our focus on the X-ray, we are more likely to miss uncommon injuries. Again, the importance of history, appreciating that external rotation is a red flag, and physical tenderness over the deltoid ligament and the syndesmosis cannot be overemphasized. Then interpret the X-ray in the proper clinical context.



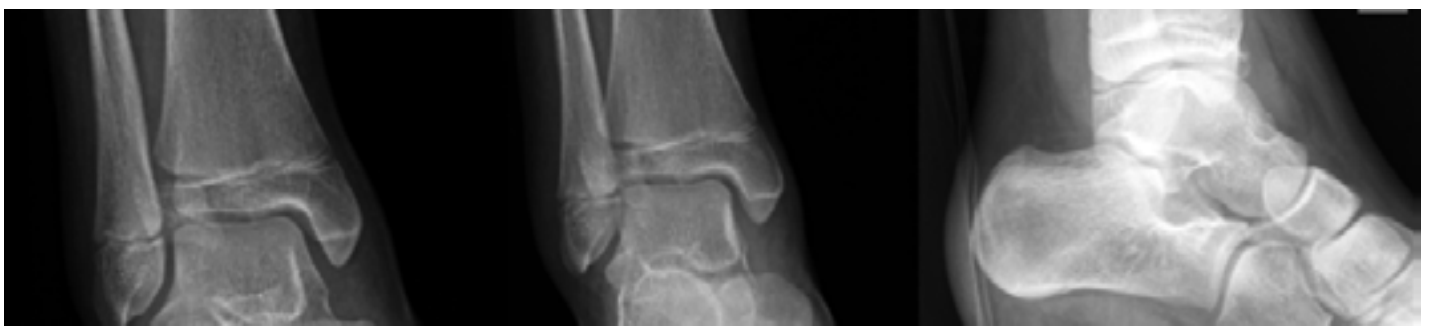
Case 2, Figure 4A



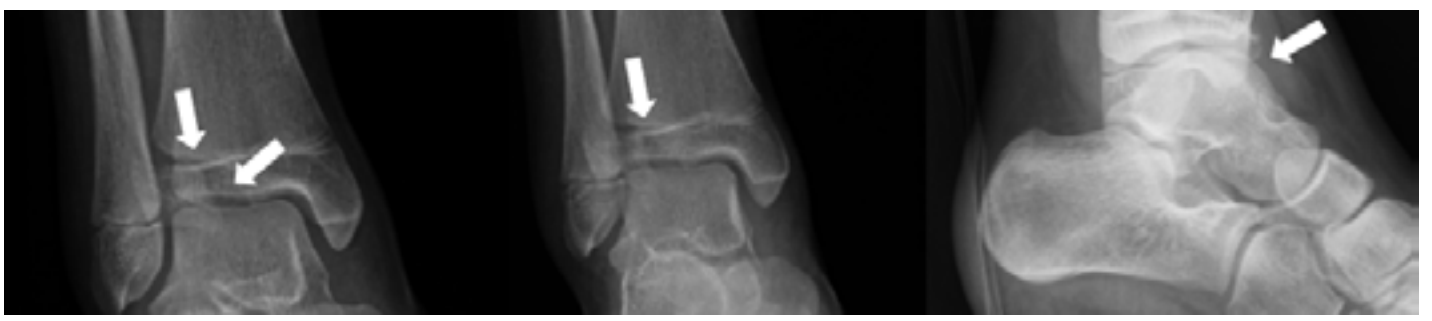
Case 2, Figure 4B



Case 3, Figure 3



Case 3, Figure 4



Case 3, Figure 5

Case 3

The patient was diagnosed with a Salter-Harris I fracture, placed in an air-stirrup, given crutches, and followed up in the minor fracture clinic on day eight. She had not been walking on it due to the pain.

At follow-up, a little more detail on the mechanism of injury was obtained. She stated she was playing soccer on a muddy field and was wearing cleats. As she turned her body in to get away from another player, her foot remained stuck in the mud. In terms of mechanism, she was quite clear: Her body turned in with her foot stuck. This is external rotation of her ankle. Of note, the emergency physician had found her mildly sore at the distal fibular area and made the diagnosis of a Salter-Harris I fracture. Emergency department examination of the anterior joint line was not documented. When she came to the clinic, her pain was localized to the anterior joint line, as pictured in **Case 3, Figure 3**. Note the impressive swelling (better recognized when compared to the opposite side).

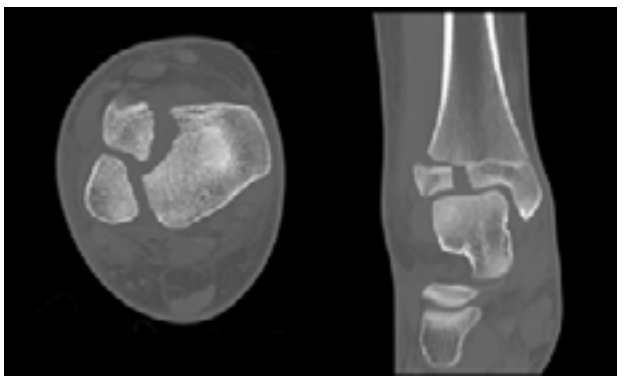
She was tender over the antero-lateral aspect of the distal tibia. She was non-tender over the lateral side along the fibula.

In reviewing the X-rays (**Case 3, Figure 4, cropped**) and now knowing where her pain localizes, it may be easier to detect the abnormality: a Salter-Harris III fracture of the distal tibial epiphysis, a Tillaux fracture.

On the anterior-posterior and mortise views, a displaced intra-articular fracture is seen (**Case 3, Figure 5, arrows**). On the lateral view, it is subtle, but the fragment is mildly anteriorly displaced (Case 3, Figure 5, arrow).

This is a displaced intra-articular fracture. A CT scan confirmed the position. The patient underwent surgery the following day (see CT in **Case 3, Figure 6**, and intraoperative picture in **Case 3, Figure 2**).

A Tillaux fracture occurs in girls about 11–14 years old and boys about 12–15 years old because the distal tibial growth plate starts to fuse around these ages. It fuses from the medial half across to the lateral side. With external rotation, the syndesmosis (anterior distal tibiofibular ligament) is stressed, and the force separates the open (lateral) part of growth plate. When the force hits the closed part of the growth plate, the force exits down into the joint.[8] The result is a Salter-Harris III fracture. This is the Tillaux fracture. Of note, a related injury exists, a Salter-Harris IV fracture. This has the same mechanism and involves the same age groups, but a triplane fracture can be seen on the lateral view to extend posteriorly up the distal tibial metaphysis.



Case 3, Figure 6

Summary

These three injuries are uncommon but commonly missed. They serve to highlight the importance of mechanism and anterior joint line tenderness of the ankle. The clinical clues to these uncommon diagnoses are often present, but they can easily escape detection.

The cornerstones of the assessment are the mechanism plus the physical exam. A host of uncommon ankle injuries should be considered. The above three cases plus syndesmosis injury, Achilles tendon rupture, calcaneal fracture, and lateral process of the talus fracture are all diagnoses worthy of consideration. The list can be confidently narrowed by focusing on the mechanism of the injury (amount and direction of force) and the physical examination. When tenderness is found along the anterior joint line, consideration should be given to structures such as the syndesmosis, distal tibia, and talus. We can then interpret the X-rays within the proper clinical context and give proper attention to the areas of clinical concern.

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EM PICS WORTH A THOUSAND WORD

IMAGES IN EM

DR. THOMAS is an emergency medicine resident at Highland Hospital in Oakland, California.

BENJAMIN THOMAS

Ode to County

Training that extends beyond textbooks

by BENJAMIN THOMAS, MD

My time as an emergency medicine resident will be coming to an end in less than six months. I have mixed feelings about this upcoming transition. Don't get me wrong—I cannot wait to apply what I've learned in residency and work on my own. Yet, with that said, I do have trepidation in leaving a place that has been so familiar to me. Some call it the "knife-and-gun club." Some call it county.

For the last four years, I've simply called it home.

Working at a county hospital has taught me much more beyond clinical medicine. It has opened my eyes to the imperfections of our society, the beauty of human perseverance, and, most important, to the bigger picture of how we should treat each other as human beings.

Some say that emergency physicians should not be taking on the role of social workers. At the beginning of my training, I would have agreed. I soon realized that my way of thinking was absolutely naive to the conditions that my patients face. It's hard to follow doctor's orders when you don't have reliable transportation, when you don't know when your next meal will be, or even when you don't have a safe place to sleep at night. It's easy to ignore the problem or punt these issues to a social worker, but in my experience, this often leads to increased cost, bounce backs, and worse outcomes.

I have the privilege of learning about the joys and struggles that patients face in their lives when they seek care. It's in those intimate interactions where I have come to appreciate and respect what patients have to overcome on a daily basis, in addition to whatever their chief complaint is for that day in the emergency department. With that said, I often receive the question, "What's the craziest thing you have seen?" I would often tell a funny or shocking anecdote of a recent case that I had seen in the emergency department. Nowadays, when I receive that question, I speak about the awe I have for a community that has remained resilient despite the social, economic, and geopolitical impediments that may restrict access to health care.

My time in residency has by no means been glamorous. There were many times that I felt disheartened by the dysfunction of our health care system. Sometimes I questioned whether I had the fortitude to do this work. Despite it all, the dysfunction, chaos, and toil of it all have pushed me to be a better doctor and person. As I transition to the next phase of my career, all I can say is thank you to the place that I've called home. Thank you for helping me preserve the ideals that initially drew me to medicine. I won't forget what you have done for me.

DR. RADECKI is assistant professor of emergency medicine at The University of Texas Medical School at Houston. He blogs at Emergency Medicine Literature of Note (emlitofnote.com) and can be found on Twitter @emlitofnote.

Published Clinical Decision Aids May Lack Validation

Bridging the gap between clinical decision tools and physician gestalt

by RYAN PATRICK RADECKI, MD, MS

ILLUSTRATION: CHRIS WHISSEN & SHUTTERSTOCK.COM

The physician life has never been "easier." We live in a fortunate future, replete with information technology at our fingertips, along with the decision support to suit our every clinical need. What tremendous satisfaction we all must take with the various epiphanies and pearls presented to us by our electronic health records. Independent thought, along with clinical judgment, is being rendered obsolete.

A steady diet of academic research inflates our fulsome girth of clinical calculators, shortcuts, and acronyms. NEXUS! PERC! HEART! HAS-BLED! The siren's call of simplicity and cognitive unburdening is insidiously appealing. With progress, unfortunately, also comes folly. Are these tools actually smarter than the average bear? Does this ever-expanding cornucopia of "decision support" actually outperform a trained clinician?

Perhaps a better question is, is anyone even *asking* that question?

It's troublingly that this does not appear to be the case. A recent historical review in *Annals of Emergency Medicine* looked back at 171 research articles evaluating the performance of decision aids.[1] For a decision aid intended to be incorporated into routine practice, it should seem reasonable not only to simply statistically validate a prediction but to also ensure it outperforms current clinical practice.

Of the 171 decision aids included in their survey, the authors were only able to identify 21 publications either in *Annals* or another journal in which the aid was compared directly to clinician judgment. In the remainder, no comparison was made or could be identified in the external literature. Of the handful for which a comparison was identified, the results are, unfortunately, discouraging. In these 21 comparisons, the decision aid was clearly superior to clinician judgment in only two. The two comparisons favoring the decision aid were a prognostic neural network for outcomes in patients presenting with chest pain—effective but too unwieldy for widespread use—and the useful and well-studied Canadian C-Spine Rule. Conversely, six decision aids clearly underperformed as compared to clinician judgment, and the remainder were a wash. Examples of popular decision instruments either inferior to or no different than clinician judgment included the Alvarado score for appendicitis, a general evaluation of pediatric head injury rules, risk-stratification rules for pulmonary embolism, and the San Francisco Syncope Rule.

A mere 21 publications hardly represent more than a tenth of their survey substrate, and it would be erroneous to assume those left untested are equally unreliable. It is also reasonable to suggest the decision aids for which the comparisons showed no difference may have suffered from flawed comparator study design rather than a failing of the decision aid itself. Regardless, it should certainly not instill any disproportionate confidence in clinical decision aids as a replacement for thoughtful clinical judgment and experience.

A salient contemporary example of a decision aid of questionable value versus clinical judgment is the Ottawa Subarachnoid Hemorrhage Rule.[2] This rule, derived and described originally in *JAMA*, then recently validated prospectively in the *Canadian Medical Association Journal*, targets an important clinical question: Which patients with acute headache should be evaluated for subarachnoid hemorrhage (SAH)?[2,3] Patients for whom an initial SAH or sentinel bleed is missed tend to have poor and potentially avoidable outcomes. However, the flip side is excessive resource use either by CT scanning or invasive procedures, such as lumbar puncture. A decision aid superior to clinician judgment could add a great deal of value for this clinical scenario.

The good news first: Sensitivity for SAH was the same in the validation as it was in the derivation, effectively 100 percent. Applying the Ottawa SAH Rule, as constructed, would virtually never miss a serious outcome in an acute headache matching the inclusion criteria for the study. That said, in their pursuit of absolute sensitivity, these authors have also followed the breadcrumbs laid out by their statistical analysis to their somewhat inane conclusion: The only path to zero-miss involves evaluating virtually everyone. The specificity of their rule was 13.6 percent, capturing almost all comers in pursuit of their small handful of true positives.

This is an example of a decision aid that, after seven years and thousands of patients, likely cannot be shown to be superior to physician judgment when explicitly studied. No direct comparison was performed, but the underlying physician practice in these various studies was to investigate by either CT or lumbar puncture in between 85 percent and 90 percent of cases; the impact of this rule would be negligible. More concerning is the impact of a rule with such low specificity when used outside the narrow inclusion criteria and high prevalence of specific academic referral settings. It is possible or even likely that misuse of these criteria could lead to many more patient evaluations than by current clinical judgment without detectable advantage in patient-oriented outcomes.

A rule such as this is a prime example of why all decision aids should be tested in practice against physician judgment before their widespread use is encouraged. Given the past history of underwhelming performance of decision aids in direct comparison, this and countless other substitutions for clinician judgment should be viewed with skepticism rather than idolatry.

This should not suggest that decision aids can't inform clinical judgment prior to formal testing, only that their limitations ought be considered at the time of utilization. Decision aids are derived and tested in unavoidably limited populations, outcomes are measured with flawed or incomplete gold standards, and the prioritization and weighting of different elements in the statistical analysis may have profound effects on the final model. Then, even in those ultimately tested against physician judgment, the same generalizability considerations persist, along with the confounding question of practice culture/environment and similarity to the clinicians involved.

The future of digital cognitive enhancement is bright, and computers may yet replace substantial portions of clinical decision making—but not today!

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MYTHS IN EMERGENCY MEDICINE

Rooted in culture, based on tradition

by KEVIN M. KLAUER, DO, EJD, FACEP

Kidney Stones, Beyond the Pain

The momentum of kidney stone patient "expulsion" from the emergency department has never been greater. Big stone? No problem. Obstruction? No problem. Infection? That's the problem. Some of these patients may require admission.

A recent interesting malpractice claims trend has prompted a reassessment of outpatient management of nephrolithiasis. Females with an active ureteral stone with obstruction and, most important, possible urinary tract infection (UTI) have returned with pyelonephritis and sepsis, suffering horrific outcomes. Urinary symptoms, other than those associated with acute ureterolithiasis, are often absent in these patients.

Although few recommendations deserve inclusion of an "always" or a "never," this trend at least deserves some consideration in our approach to certain cases.

In England and Wales, 91 percent of deaths from nephrolithiasis were associated with kidney and ureteral stones, compared to lower tract stones, which accounted for 7.9 percent of deaths. Although the raw numbers aren't alarming—mean 9.4 deaths per year from ureteric stones (141 deaths total) and 130.3 deaths per year from urolithiasis (1,954 deaths total) identified between 1999 and 2013—their report of increasing trends in developed nations is concerning. Although men had a higher incidence (1.3:1) of stones compared to women, mortality was significantly higher in females (1.5:1). Equally worrisome, urosepsis accounts for 25 percent of adult sepsis cases.[1]

"This too shall pass," a quote dating back to 1839, fits well with regard to stone size.[2]

It has been taught that stones ≥5 mm are unlikely to pass spontaneously. That's a reasonable guideline, but what difference does it really make? If patients are pain-free or their pain can be controlled with oral analgesics, there are no indications for admission (eg, pyelonephritis, solitary kidney, etc.), and follow-up is available, then size isn't critical for the disposition decision. Jendeberg et al reported multiple CT-related variables that may predict stone passage.[3] Although limited by the study's retrospective design and nonstandardized follow-up, their conclusion suggests our 5 mm line in the sand is less than clear. "The spontaneous passage rate in 20 weeks was 312 out of 392 stones, 98% in 0–2 mm, 98% in 3 mm, 81% in 4 mm, 65% in 5 mm, 33% in 6 mm and 9% in ≥6.5 mm wide stones."[3] Stone size appears to be relegated to an academic discussion with limited relevance to emergency medicine.

Hydronephrosis is practically synonymous with obstruction and is expected with active ureteral stones. However, an active stone that is unlikely to pass may prolong the duration of associated ureteral obstruction.[3] In the context of possible infection, obstruction is important.

Uncomplicated UTIs can almost universally be treated without hospitalization. UTIs in the context of nephrolithiasis with obstruction, however, are complicated. Appropriate diagnosis is critical.

Although admission may be unnecessary, noting the potential for poor outcomes, even with a seemingly benign presentation, mandates something more than the standard approach for those without possible UTI. Thus, initiation of antimicrobials, phone consultation, confirmed close follow-up, and, in some cases, admission, are all reasonable considerations.

The limitations of nitrite, leukocyte esterase, and the presence white blood cells (>5/hpf) via dipstick or formal urinalysis may lead to dismissing positive findings. In asymptomatic patients without a stone, a wait-and-see approach is appropriate for nondefinitive findings. However, with an obstructive stone, any one being positive should prompt recognition in the medical record, the ordering of a culture, and consideration of the above strategies.

Watch the pH. Some organisms are urease-producing, reducing urea, which has an antibacterial effect, and will increase ammonia levels.[4] This effect has been found in more than 200 bacterial species, including *Ureaplasma urealyticum*, *Proteus*, *Klebsiella*, and *Pseudomonas*.[4] The alkaline environment prompts formation of struvite-magnesium ammonium phosphate (infected stones) and apatite-calcium phosphate stones.[5,6] Also, staghorn calculi are frequently composed of these two types.[7] UTI may be causative, not an incidental finding, with nephrolithiasis.[5,6,7] Further, some suggest greater mortality from struvite and staghorn stones, as they cannot be treated with antimicrobials alone.[6]

Being mindful of possible infection associated with acute nephrolithiasis may improve outcomes and will definitely reduce your professional liability risk.

Editor's Note: *Visit ACEPNow.com to view the references for this article.*

DR. KLAUER is an ACEP Board member; chief medical officer–hospital-based services, chief risk officer, and executive director–patient safety organization at TeamHealth; *ACEP Now* medical Editor-in-Chief; and clinical assistant professor, University of Tennessee and Michigan State University College of Osteopathic Medicine.

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THE END OF THE RAINBOW

DR. DAHLE is the author of *The White Coat Investor: A Doctor's Guide to Personal Finance and Investing* and blogs at http://whitecoatinvestor.com. He is not a licensed financial adviser, accountant, or attorney and recommends you consult with your own advisers prior to acting on any information you read here.

Emergency Physicians Come Out Ahead with Tax Reform

What you need to know about the Tax Cuts and Jobs Act of 2017

by JAMES M. DAHLE, MD, FACEP

Q. I know there are a bunch of changes to the tax system this year, but I get confused when I read about them. Can you break it down to just the stuff I need to know as an emergency physician?

A. I'll discuss the major changes in the tax code that will affect you and try to explain how it was before and why it is different now. We don't have the space to be comprehensive, but I'll try to hit the major points in a simple, easy-to-understand way. Bear in mind that the largest changes to the tax code are on the corporate side, but I'll only be outlining changes to the individual tax code.

A quick aside: basic financial literacy must include at least the basics of the tax code (eg, how tax brackets work; the difference between gross income, adjusted gross income, and taxable income; and the difference between an above-the-line deduction, a below-the-line deduction, an exemption, and a credit). There is no better way to learn the tax code than to do your own taxes by hand, although that is admittedly a rather painful process. At a minimum, try to look over your tax forms (Form 1040 and Schedule A if nothing else) when they are returned to you by your tax preparer.

ILLUSTRATION: CHRIS WHISSEN PHOTOS: SHUTTERSTOCK.COM

Lower Tax Rates

The most significant change to the tax code is that the tax rates applied to your income have gone down. The 15 percent bracket is now the 12 percent bracket, the 25 percent bracket is now the 22 percent bracket, the 39.6 percent bracket is now the 37 percent bracket, and so forth. This single change will cause most people, in all brackets, to have a lower overall tax bill.

Higher Standard Deduction

The standard deduction has been nearly doubled, from $6,350 ($12,700 if married) to $12,000 ($24,000 if married). This will result in many more people taking the standard deduction who used to itemize their below-the-line deductions (like state taxes, mortgage interest, and charity) on Schedule A (itemized deductions). Estimates are that 70 percent of Americans used to take the standard deduction and that 90 percent of Americans will do so now. Even many physicians will now choose to take the standard deduction at least some of the time.

State and Property Tax Deduction Limits

The amount of state income and property tax that can be deducted on Schedule A will be limited to just $10,000 total. Combined with the higher standard deduction, this will push

more physicians to take the standard deduction. A very small percentage of Americans will see their tax bill actually go up in 2018, and it is primarily due to this change. These folks, some of whom will be physicians, mostly live in high-tax states with a high cost of living, such as California and "blue" states in the Northeast.

Changes to Dependents

Exemptions (a $4,050 reduction in taxable income in 2017 for you, your spouse, and each of your children) are now gone, but many emergency physicians were phased out of those previously anyway. However, the child tax credit ($2,000 per child) phaseout was increased significantly, from $75,000 ($110,000 married) to $200,000 ($400,000). So many emergency physicians who could not take this credit before will now be able to. There is also a new, smaller credit ($500) for college-age children and adult dependents that you may qualify for.

Alternative Minimum Tax

Many emergency physicians in the past have been caught up in the alternative minimum tax (AMT) system. The AMT is actually a completely separate tax system, not an additional tax. You are required by law to calculate your tax due under both the regular system and the AMT and pay the higher of the two amounts. Three changes went into place that make you less likely to have to pay under the AMT system on your 2018 taxes. The first is that the state income tax deduction has been severely limited, as discussed above, and this was a major reason some people owed more under the AMT, where this deduction is not allowed. The second is that the exemption amount under the AMT was increased from $55,400 ($86,200 if married) to $70,300 ($109,400 if married). The third, and perhaps most significant, is that the phaseout of the exemption was increased from $123,100 ($164,100 if married) to $500,000 ($1 million if married). When you look at all three of these changes, the bottom line effect is that many emergency physicians who used to pay under the AMT no longer will.

Pease Phaseout

The Pease phaseout of your itemized deductions is now gone. This had the effect of adding an extra 1 percent to 1.2 percent tax on the tax bill of anyone with a taxable income of more than $261,500 ($313,800 if married). If your marginal tax rate (tax bracket) used to be 39.6 percent, it was really 40.6 percent, and now it will be reduced to 37 percent.

Marriage Penalty

The so-called "marriage penalty" still exists in the tax code, but it has been reduced.

CONTINUED *on page 28*

CLASSIFIEDS

529 Accounts

529 accounts can now be used to pay for K–12 education tax-free.

Estate Tax Exemption Doubled

Few emergency physicians ever accumulated enough wealth so that their estates would owe federal estate tax. That is even more unlikely now as the exemption amount has been doubled to $11 million ($22 million if married).

Deferred Compensation Changes

If you use a 457(b) plan or other similar retirement plan, you will want to pay attention to any changes your plan may make this year in response to this law. If your distribution options become less favorable, you may wish to invest in a simple taxable nonqualified account instead. It won't affect 401(k)s or 403(b)s.

Alimony Tax Treatment Reversed

In what is basically a new tax on divorce, alimony will no longer be deductible to those who pay it and taxable to those who receive it. The reverse will apply: Alimony payments will not be deductible, and they will not be taxable income for the recipient. Previous divorce agreements are grandfathered in under the old rules, however.

Pass-Through Entity Deduction

There is a new deduction for pass-through businesses such as sole proprietorships, LLCs, and S corporations. However, this deduction is specifically limited for physicians and similar professionals who have a taxable income of more than $157,500 ($315,000 if married). Some self-employed emergency physicians will be able to get their taxable income below this amount by maxing out retirement accounts and thus receive this deduction, but many will not. Employed physicians are not eligible. If you own a non-professional service business on the side, this may be a significant deduction for you going forward.

Overall, most emergency physicians will see their tax bill decrease in 2018, but as with any change to the tax code, some people will benefit more than others. As you learn more about the tax code, you will be able to make changes in your financial life that will allow you to minimize your tax burden going forward.

CLASSIFIEDS

CODING WIZARD

NAVIGATE THE CPT MAZE, OPTIMIZING YOUR REIMBURSEMENT

Editor's Note: *Cutting through the red tape to make certain that you get paid for every dollar you earn has become more difficult than ever, particularly in our current climate of health care reform and ICD-10 transition. The ACEP Coding and Nomenclature Committee has partnered with ACEP Now to provide you with practical, impactful tips to help you navigate through this coding and reimbursement maze.*

BILLING FOR NERVE BLOCKS

by **HAMILTON LEMPERT, MD, FACEP, CEDC**

Question: Can I bill for a nerve block?

Answer: Trying to reduce opioid use? Nerve blocks are a safe alternative for pain control, but can you bill for them? Yes and no. If you are performing the nerve block as part of a surgical procedure, then no. The nerve block is included (bundled) in the procedure code. However, if you are performing the nerve block without a surgical procedure, you can bill for it. A real-life example is if you perform a digital block to repair a laceration, then the digital block cannot be billed separately. If you do a digital block to alleviate the pain of a crushed finger, however, then you can bill separately for the digital block.

How much is the reimbursement for a digital block? The Medicare Physician Fee Schedule for CPT code 64450 is $81, so document your digital block well. There is also a code for trigeminal nerve block for dental pain (CPT code 64400, $130 on the Medicare Physician Fee Schedule). This includes blocks for the infraorbital and inferior alveolar nerves.

Want to read more about nerve block reimbursement? Go to http://bit.ly/2AfqGoo.

Brought to you by the ACEP Coding and Nomenclature Committee.

DR. LEMPERT is chief medical officer, coding policy, at TeamHealth, based in Knoxville, Tennessee.

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