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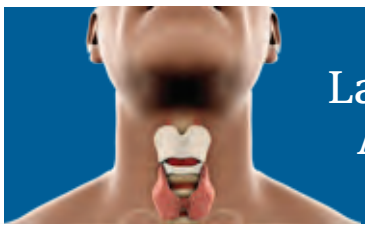

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PLUS

SKEPTICS' GUIDE TO EM
Implementing goal-oriented, bundled care
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PEARLS FROM EM LIT
Are opiates futile in low back pain?
SEE PAGE 19

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For more clinical stories and practice trends, plus commentary and opinion pieces, go to:
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SONJA EAGLE

Traumatizing Patients with Trauma Activations

by KATIE LEBOLD, MD, PHD; AND SONJA EAGLE, MD

Each time she moved her hand it caught my eye: the glint of her bejeweled fingers sharply contrasting with the spare gurney and paper-thin blanket. The fat heaviness of her rings seemed startling against her bony fingers, as if they should have shrunk in parallel with her collagen and fat. She fought against the technician removing her belongings while her protestations melded with my trauma survey.

"GCS14."

"Leave me alone."

"Front scalp hematoma."

CONTINUED *on page 15*

Brain Trauma Guidelines for Emergency Medicine

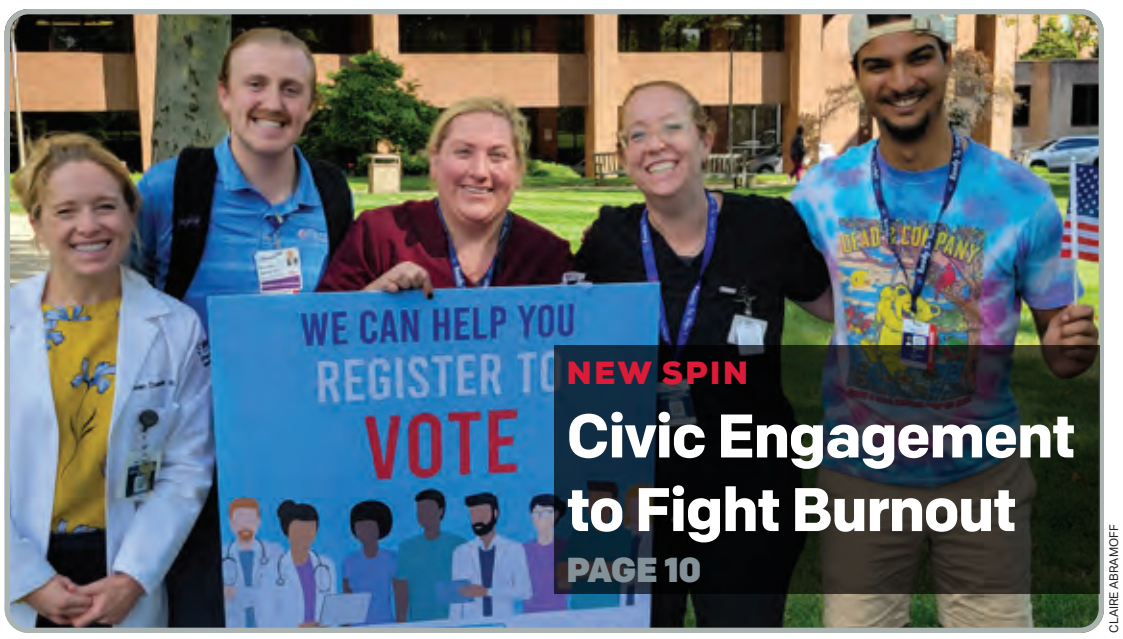
Guidelines for the pre-hospital management of traumatic brain injury

by ANDY JAGODA, MD; BEN BOBROW, MD; AL LULLA, MD; JAMSHID GHAJAR, MD; GREG HAWRYLUK, MD

In April 2023, the third edition of the Brain Trauma Foundation's evidence-based guidelines for the prehospital management of traumatic brain injury (TBI) was published in *Prehospital Emergency Care*.[1] The practice guidelines were written by a multi-disciplinary group of experts and went through an extensive peer review process. This document is an update of guidelines first published in 2000, and then updated in 2007. These guidelines present the best available evidence to support clinical decision making in the prehospital setting when TBI care may have the most significant impact on outcomes; they also establish a research agenda for future investigations.

TBI is a major public health concern and

CONTINUED *on page 13*



CLAIRE ABRAMOFF

NEW SPIN
Civic Engagement to Fight Burnout
PAGE 10

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1. Beal S, et al. JCM. Jan 2018, 56 (1): JCM. 01457-17. 2. Cybulski et al. CID. Nov 2018, 13;67(11):1688-1696
3. Axelrad JE, et al. J of Clin. Microbiology. 2019; 27;57(3). e01775-18. 4. Moon RC, et al. J Clin Microbiol. 2023 Feb 22;61(2):e0162822.

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NEWS FROM THE COLLEGE

UPDATES AND ALERTS FROM ACEP

Urge Your Legislators to Support New Bill to Combat Boarding, Support Mental Health Access from the ED

The bipartisan *Improving Mental Health Access from the Emergency Department Act* was recently reintroduced in the House for the 118th Congress by Reps. Raul Ruiz, MD (D-CA) and Brian Fitzpatrick (R-PA). The legislation is the House companion to identical Senate legislation (S. 1346) that was one of ACEP's emergency department boarding priorities at the 2023 Leadership and Advocacy Conference in May.

ACEP helped inform and develop this legislation, which establishes a grant program to help enable emergency departments to improve coordination of care for patients experiencing acute psychiatric episodes as part of broader efforts to reduce the impact of the ongoing emergency department (ED) boarding crisis. Rather than a one-size-fits-all approach, the bill is designed to equip EDs with the ability to implement innovative models to ensure efficient, coordinated transition for patients from the ED to the longer-term mental health supports and resources they need and deserve.

Your voice and your stories are critical in bringing Congress' attention to ED boarding crisis and making it a priority. Send a letter to your legislators at acep.org/actioncenter.

ACEP's *SAVE Act* Introduced in Senate

On Sept. 12, the ACEP-supported "Safety from Violence for Healthcare Employees (SAVE) Act" was introduced in the Senate by Senators Marco Rubio (R-FL) and Joe Manchin (D-WV). This legislation establishes federal criminal penalties for individuals who assault health care workers and is modeled after existing protections for airline employees. It serves as the Senate companion to the House version that ACEP advocated for during the Leadership & Advocacy Conference in May. The Senate version is essentially identical in terms of the federal penalties language and who would be covered, but there are two key differences from the House version—the Senate bill does not include provisions regarding grants for hospitals that are in the House bill, and the Senate bill includes a new section requiring a GAO report on the effectiveness of criminal penalties and prosecutions for violence against health care workers.

ACEP President Christopher S. Kang, MD, FACEP, was quoted in the senators' press release: "Violence in the emergency department is escalating, threatening the health and safety of physicians, nurses, health care workers, and our patients. ED violence exacerbates the severe burnout affecting emergency care teams and can lead health care workers to leave an already strained workforce."

ACEP Details Devastating Impact of Corporatization for FTC

On Sept. 14, during an open meeting of the Federal Trade Commission (FTC), ACEP Executive Director Sue Sedory delivered candid remarks about emergency physicians' challenges from the fallout of increasing acquisitions in health care and the collapse of APP. In ACEP's comment letter responding to the FTC and Department of Justice's proposed updates to health care merger guidelines, ACEP urged the Agencies to finalize changes that would bring more scrutiny to health care mergers and slow down consolidation.

New Member Benefit: Laurel Road

Student loan payments are back and Laurel Road is here to help! Schedule a free consultation with a student loan specialist to understand all your repayment and forgiveness options and get a personalized plan. ACEP members receive a discount on an annual membership. Learn more at LaurelRoad.com/ACEP.

Member Benefit Spotlight: Visual Dx

Improve emergency care with VisualDx. Make better decisions with our comprehensive differential builder. Our platform saves time by minimizing resource search time. Engage patients with medical imagery and patient handouts, boosting satisfaction. Trusted by colleagues. Try for free today at www.visualdx.com/ACEP.

Rely on **the only antidote** for the reversal of Eliquis® or Xarelto® in patients with acute major bleeding[1]

SHUT OFF FXa INHIBITOR ACTIVITY WITH ANDEXXA[1]*

IMPORTANT SAFETY INFORMATION FOR ANDEXXA® (coagulation factor Xa [recombinant], inactivated-zhzo)

WARNING: THROMBOEMBOLIC RISKS, ISCHEMIC RISKS, CARDIAC ARREST, AND SUDDEN DEATHS

Treatment with ANDEXXA has been associated with serious and life-threatening adverse events, including:

- **Arterial and venous thromboembolic events**
- **Ischemic events, including myocardial infarction and ischemic stroke**
- **Cardiac arrest**
- **Sudden deaths**

Monitor for thromboembolic events and initiate anticoagulation when medically appropriate. Monitor for symptoms and signs that precede cardiac arrest and provide treatment as needed.

WARNINGS AND PRECAUTIONS

- Arterial and venous thromboembolic events, ischemic events, and cardiac events, including sudden death, have occurred during treatment with ANDEXXA. To reduce thromboembolic risk, resume anticoagulant therapy as soon as medically appropriate following treatment with ANDEXXA. The safety of ANDEXXA has not been evaluated in subjects who experienced thromboembolic events or disseminated intravascular coagulation within two weeks prior to the life-threatening bleeding event requiring treatment with ANDEXXA. Safety of ANDEXXA also has not been evaluated in subjects who received prothrombin complex concentrates, recombinant factor VIIa, or whole blood products within seven days prior to the bleeding event.
- Re-elevation or incomplete reversal of anticoagulant activity can occur.
- ANDEXXA may interfere with the anticoagulant effect of heparin. If anticoagulation is needed, use an alternative anticoagulant to heparin.

ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) in bleeding subjects receiving ANDEXXA were urinary tract infections and pneumonia. The most common adverse reactions (≥ 3%) in healthy volunteers treated with ANDEXXA were infusion-related reactions.

INDICATION

ANDEXXA® (coagulation factor Xa [recombinant], inactivated-zhzo) is a recombinant modified human factor Xa (FXa) protein indicated for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

ANDEXXA is the only reversal agent for Eliquis and Xarelto patients with acute major bleeds with **prospective data** and confirmatory **real-world evidence**[1-7]

Andexxa®
Coagulation Factor Xa (Recombinant), Inactivated-zhzo

Change in FXa-inhibitor activity and thrombin generation[1,2]

Hemostatic efficacy[1,5†]

In-hospital and 30-day mortality[4,7‡§]

55% PRICE REDUCTION[8‖]

Learn more about **ANDEXXA**

An improvement in hemostasis has not been established[1]

*In ANNEXA-A (N=31) and ANNEXA-R (N=39), randomized, double-blind, placebo-controlled studies in healthy volunteers, ANDEXXA bolus followed by continuous infusion reduced the primary endpoint of mean percent change in anti-FXa activity from baseline to nadir by 92% in Eliquis-treated subjects and 97% in Xarelto-treated subjects receiving low and high dose, respectively (P<0.0001).[1,2]

†ANNEXA-4 was a phase 3b/4, multicenter, prospective, single-arm, open-label study evaluating ANDEXXA in patients with acute major bleeding within 18 hours of FXa inhibitor administration (N=352). ANDEXXA was administered as a bolus dose followed by a 2-hour infusion as a low- or high-dose regimen depending on the identity, timing, and dose of the last FXa inhibitor received. The low-dose regimen consisted of a bolus dose of 400 mg at a target rate of 30 mg/minute, and an infusion dose of 480 mg at 4 mg/minute for 2 hours. The high-dose regimen consisted of a bolus dose of 800 mg at a target rate of 30 mg/minute, and an infusion dose of 960 mg at 8 mg/minute for 2 hours. Co-primary efficacy endpoints: percent change in anti-FXa activity from baseline to the nadir between 5 minutes after the end of the bolus up until the end of the infusion, and rate of effective hemostasis within 12 hours after infusion.[1,5,9]

‡Coleman et al 2020 was a multicenter, retrospective analysis that captured electronic medical records for adult patients hospitalized for FXa inhibitor-related bleeding between January 2016 and September 2019. Records from the 45 US-based hospitals that agreed to participate included 3030 FXa inhibitor-related hospitalizations for major bleeds. At baseline, 49% of patients had been treated with Xarelto and 45% of patients had been treated with Eliquis.[4]

§Cohen et al 2022 was a retrospective, indirect, comparative analysis of results from the ANNEXA-4 and ORANGE studies that used propensity score matching to compare all-cause 30-day mortality by overall cohort and by type of bleed: ICH, GI bleed, and other major bleeds as the primary analysis. ORANGE was an observational prospective registry study that collected information from 32 UK hospitals on the presentation and clinical outcomes of patients who were admitted for a FXa inhibitor-related major bleed (N=2192). Only patients on apixaban or rivaroxaban from both studies were included in this analysis.[7]

‖Wholesale Acquisition Cost (WAC) as of April 1, 2022.[8]

FXa, factor Xa; GI, gastrointestinal; ICH, intracranial hemorrhage.

IMPORTANT SAFETY INFORMATION (cont'd)

INDICATION (cont'd)

This indication is approved under accelerated approval based on the change from baseline in anti-FXa activity in healthy volunteers. An improvement in hemostasis has not been established. Continued approval for this indication may be contingent upon the results of studies that demonstrate an improvement in hemostasis in patients.

Limitations of Use

ANDEXXA has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban or rivaroxaban.

You are encouraged to report the negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

Please see additional Important Safety Information throughout and brief summary, including Boxed WARNING, on the following page.

References: 1. ANDEXXA® (coagulation factor Xa [recombinant], inactivated-zhzo) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023. **2**. Siegal DM, Curnutte JT, Connolly SJ, et al. Andexanet alfa for the reversal of factor Xa inhibitor activity. *N Engl J Med.* 2015;373(25):2413-2424. **3**. Lu G, Lin J, Bui K, Curnutte JT, Conley PB. Andexanet versus prothrombin complex concentrates: differences in reversal of factor Xa inhibitors in in vitro thrombin generation. *Res Pract Thromb Haemost.* 2020;4(8):1282-1294. **4**. Coleman CI, Dobesh PP, Danese S, Ulloa J, Lovelace B. Real-world management of oral factor Xa inhibitor-related bleeds with reversal or replacement agents including andexanet alfa and four-factor prothrombin complex concentrate: a multicenter study. *Future Cardiol.* 2021;17(1):127-135. **5**. Connolly SJ, Crowther M, Eikelboom JW, et al. Full study report of andexanet alfa for bleeding associated with factor Xa inhibitors. *N Engl J Med.* 2019;380(14):1326-1335. **6**. Milling TJ Jr, Middeldorp S, Xu L, et al. Final study report of andexanet alfa for major bleeding with factor Xa inhibitors. *Circulation.* 2023;147(13):1026-1038. **7**. Cohen AT, Lewis M, Connor A, et al. Thirty-day mortality with andexanet alfa compared with prothrombin complex concentrate therapy for life-threatening direct oral anticoagulant-related bleeding. *J Am Coll Emerg Physicians Open.* 2022;3(2):e12655. **8**. Data on File. US-61922. AstraZeneca Pharmaceuticals LP; 2022. **9**. Connolly SJ, Crowther M, Eikelboom JW, et al. Full study report of andexanet alfa for bleeding associated with factor Xa inhibitors. *N Engl J Med.* 2019;380(suppl1):1326-1335.

AstraZeneca

ANDEXXA® (coagulation factor Xa (recombinant), inactivated-zhzo)
Lyophilized powder for solution for intravenous injection
Initial U.S. Approval: 2018

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

WARNING: THROMBOEMBOLIC RISKS, ISCHEMIC RISKS, CARDIAC ARREST, AND SUDDEN DEATHS

Treatment with ANDEXXA has been associated with serious and life-threatening adverse events, including: (5.1)

- **Arterial and venous thromboembolic events**
- **Ischemic events, including myocardial infarction and ischemic stroke**
- **Cardiac arrest**
- **Sudden deaths**

Monitor for thromboembolic events and initiate anticoagulation when medically appropriate. Monitor for symptoms and signs that precede cardiac arrest and provide treatment as needed.

INDICATIONS AND USAGE

ANDEXXA is indicated for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

This indication is approved under accelerated approval based on the change from baseline in anti-FXa activity in healthy volunteers *[see Clinical Studies (14) in the full Prescribing Information]*. An improvement in hemostasis has not been established. Continued approval for this indication may be contingent upon the results of studies that demonstrate an improvement in hemostasis in patients.

Limitations of Use

ANDEXXA has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban or rivaroxaban.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Thromboembolic and Ischemic Risks

The thromboembolic and ischemic risks were assessed in 352 bleeding subjects who received ANDEXXA. Of the 63 subjects who experienced a thrombotic event, the median time to first event was 7 days, and 21 subjects experienced the event within the first three days. A total of 63 (18%) experienced 88 thromboembolic or ischemic events. Of the 352 subjects who received ANDEXXA, 223 received at least one anticoagulation dose within 30 days after treatment. Of these 223, 18 subjects (8%) had a thrombotic event and/or ischemic event after resumption.

Monitor subjects treated with ANDEXXA for signs and symptoms of arterial and venous thromboembolic events, ischemic events, and cardiac arrest. To reduce thromboembolic risk, resume anticoagulant therapy as soon as medically appropriate following treatment with ANDEXXA.

The safety of ANDEXXA has not been evaluated in subjects who experienced thromboembolic events or disseminated intravascular coagulation within two weeks prior to the life-threatening bleeding event requiring treatment with ANDEXXA. Safety of ANDEXXA also has not been evaluated in subjects who received prothrombin complex concentrates, recombinant factor VIIa, or whole blood products within seven days prior to the bleeding event.

Re-elevation or Incomplete Reversal of Anti-FXa Activity

The time course of anti-FXa activity following ANDEXXA administration was consistent among the healthy volunteer studies and the ANNEXA-4 study in bleeding subjects *[see Clinical Studies (14) in the full Prescribing Information]*. Compared to baseline, there was a rapid and substantial decrease in anti-FXa activity corresponding to the ANDEXXA bolus. This decrease was sustained through the end of the ANDEXXA continuous infusion. The anti-FXa activity returned to the placebo levels approximately two hours after completion of a bolus or continuous infusion. Subsequently, the anti-FXa activity decreased at a rate similar to the clearance of the FXa inhibitors.

Seventy-one subjects were anticoagulated with apixaban and had baseline levels of anti-FXa activity > 150 ng/mL. Nineteen subjects who were anticoagulated with rivaroxaban had elevated baseline anti-FXa activity levels >300 ng/mL. Forty-eight of the 71 apixaban-treated subjects (68%) experienced a > 90% decrease from baseline anti-FXa activity after administration of ANDEXXA. Ten of the 19 rivaroxaban subjects (53%) experienced a > 90% decrease from baseline anti-FXa activity after administration of ANDEXXA.

Use of Heparin Following Administration of ANDEXXA

ANDEXXA may interfere with the anticoagulant effect of heparin.

Use of ANDEXXA as an antidote for heparin has not been established. Avoid use of ANDEXXA for the reversal of direct FXa inhibitors (apixaban and rivaroxaban) prior to heparinization as ANDEXXA may cause unresponsiveness to heparin. If anticoagulation is needed, use an alternative anticoagulant to heparin.

ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) in bleeding subjects receiving ANDEXXA were urinary tract infections and pneumonia.

The most common adverse reactions (≥ 3%) in healthy subjects treated with ANDEXXA were infusion-related reactions.

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 compared directly to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In the pooled safety analysis of clinical trials of ANDEXXA, 223 healthy volunteers received FXa inhibitors, followed by treatment with ANDEXXA. The frequency of adverse reactions was similar in the ANDEXXA-treated group (120/223; 54%) and in the placebo-treated group (54/94; 57%). Infusion-related adverse reactions occurred in 18% (39/223) of the ANDEXXA-treated group and were the only type of adverse reaction that occurred more frequently than in the placebo group. No serious or severe adverse reactions were reported.

The ANNEXA-4 study is an ongoing multinational, prospective, open-label study using ANDEXXA in subjects presenting with acute major bleeding and who have recently received an FXa inhibitor. To date, safety data are available for 352 subjects. Sixty-three percent of the 352 subjects were 75 years or older. Subjects had received either apixaban (194/352; 55%) or rivaroxaban (128/352; 36%) as anticoagulation treatment for atrial fibrillation (286/352; 81%) or venous thromboembolism (87/352; 25%). In the majority of subjects, ANDEXXA was used to reverse anticoagulant therapy following either an intracranial hemorrhage (227; 64%) or a gastrointestinal bleed (90; 26%), with the remaining 35 subjects (10%) experiencing bleeding at other sites. Subjects were assessed at a Day 30 follow-up visit following infusion with ANDEXXA.

Deaths

In the ongoing ANNEXA-4 study, of the 352 subjects completing 30-day safety follow-up, there were 54 deaths (15%) occurring prior to the Day 30 visit. The number of cardiovascular deaths, including three with unknown causes and two that were unadjudicated, was 42 of 352 (12%), and the number of non-cardiovascular deaths was 12 (3%). Twenty (37%) subjects died within ten days after the ANDEXXA infusion. All subjects died prior to Day 45. Of the 54 subjects who died, the bleeding type was intracranial bleeding in 37 (69%), gastrointestinal bleeding in 12 (22%), and other bleeding types in 5 (9%) subjects.

Thromboembolic and Ischemic Events

In the ANNEXA-4 study, 63/352 (18%) subjects experienced one or more of the following overall thromboembolic events: cerebrovascular accident (CVA) (16/63; 25%), deep venous thrombosis (16/63; 25%), acute myocardial infarction (10/63; 16%), pulmonary embolism (5/63;8%), and transient ischemic attack (1/63; 2%). The median time to event was seven days. A total of 33% of subjects with thromboembolic events (21/63) experienced the thromboembolic event during the first three days. Of the 352 subjects who received ANDEXXA, 223 received at least one anticoagulation dose within 30 days after treatment. Of these 223, 18 subjects (8%) had a thrombotic event and/or ischemic event after resumption *[see Warnings and Precautions (5.1) in the full Prescribing Information]*.

No thromboembolic events were observed in 223 healthy volunteers who received FXa inhibitors and were treated with ANDEXXA.

Infusion-Related Reactions

Infusion-related reactions occurred in 18% (39/223) of ANDEXXA-treated healthy volunteers vs. 6% (6/94) of placebo-treated subjects. These reactions were characterized by a range of symptoms, including flushing, feeling hot, cough, dysgeusia, and dyspnea. Symptoms were mild to moderate in severity, and 90% (35/39) did not require treatment. One subject with a history of hives prematurely discontinued ANDEXXA after developing mild hives. Two of 352 (0.6%) subjects in the ANNEXA-4 study experienced an infusion-related reaction.

Immunogenicity

As with all therapeutic proteins, there is the potential for immunogenicity. Using an electrochemiluminescence (ECL)-based assay, 145 ANDEXXA-treated healthy subjects were tested for antibodies to ANDEXXA as well as for antibodies cross-reacting with factor X (FX) and FXa. Low titers of anti-ANDEXXA antibodies were observed in 26/145 healthy subjects (17%); 6% (9/145) were first observed at Day 30, with 20 subjects (14%) still having titers at the last time point (Days 44 to 48). To date, the pattern of antibody response in subjects in the ongoing ANNEXA-4 study has been similar to that observed in healthy volunteers. Of the 236 subjects with available samples, 6.8% (16/236) had antibodies against ANDEXXA. None of these anti-ANDEXXA antibodies were neutralizing. No neutralizing antibodies cross-reacting with FX or FXa were detected in healthy subjects (0/145) or in bleeding subjects (0/209) to date.

Detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to ANDEXXA with the incidence of antibodies to other products may be misleading.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate and well-controlled studies of ANDEXXA in pregnant women to inform patients of associated risks. Animal reproductive and developmental studies have not been conducted with ANDEXXA.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Labor or Delivery

The safety and effectiveness of ANDEXXA during labor and delivery have not been evaluated.

Lactation

Risk Summary

There is no information regarding the presence of ANDEXXA in human milk, the effects on the breastfed child, or the effects on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ANDEXXA and any potential adverse effects on the breastfed child from ANDEXXA or from the underlying maternal condition.

Pediatric Use

The safety and efficacy of ANDEXXA in the pediatric population have not been studied.

Geriatric Use

Of the 352 subjects in the ANNEXA-4 study of ANDEXXA, 314 were 65 years of age or older, and 231 were 75 years of age or older. No overall differences in safety or efficacy were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between elderly and younger subjects; however, greater sensitivity of some older individuals cannot be ruled out.

The pharmacokinetics of ANDEXXA in healthy older (≥ 65 years; n=10) subjects were not different compared to younger (18-45 years; n=10) subjects.

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RESIDENCY SPOTLIGHT

COREWELL HEALTH–GRAND RAPIDS/MICHIGAN STATE UNIVERSITY EMERGENCY MEDICINE RESIDENCY

MATT SINGH

In 2022, Spectrum Health and Beaumont Health integrated to create one system, Corewell Health. We continue to provide the same educational excellence that fosters innovation to always remain at the forefront of medicine.

What does your program offer that residents can't get anywhere else?

Our residency program is dedicated to producing safe, competent and qualified individuals in emergency medicine. As the seventh oldest emergency medicine program in the United States, we have spent decades fine-tuning our program into a compassionate, comprehensive training experience for our residents. The emergency medicine residency program at Corewell Health in West Michigan provides a well-developed foundation of skills integral in our residents' journeys. Additionally, our vast network of program alumni allows residents ample opportunity to secure jobs throughout the country.

With approximately 180,000 patient visits annually, we have one of the busiest single-site emergency department systems in the country. We are a level I adult and pediatric trauma center and the highest volume trauma center in Michigan. Residents gain valuable experience in numerous aspects of emergency medicine, including longitudinal exposure in pediatric emergency medicine at a nationally recognized children's hospital. The program works to maximize the time spent in emergency department rotations and minimize off-service rotations.

What are some fun activities residents like to partake in or recently participated in?

Our program is primarily based at the heart of West Michigan in the city of Grand Rapids, the second largest city in the state. For those who enjoy exploring, West Michigan is home to countless attractions; from scenic trails and the beaches of Lake Michigan to a variety of museums and festivals, there is something of interest for people of all ages, identities, and interests. In fact, not only is Grand Rapids well known for its food and arts scenes, but the city has recently been declared the second-best place to live in Michigan and the 20th in the entire country by *U.S. News* and *World Report*.

How should potential applicants learn more about your program?

Learn more about the program by visiting spectrumhealth.org.

—Katie Stallard; Jilaine Snoeyink; Matt Singh, MD; Jason Seamon, DO

TOXICOLOGY Q&A

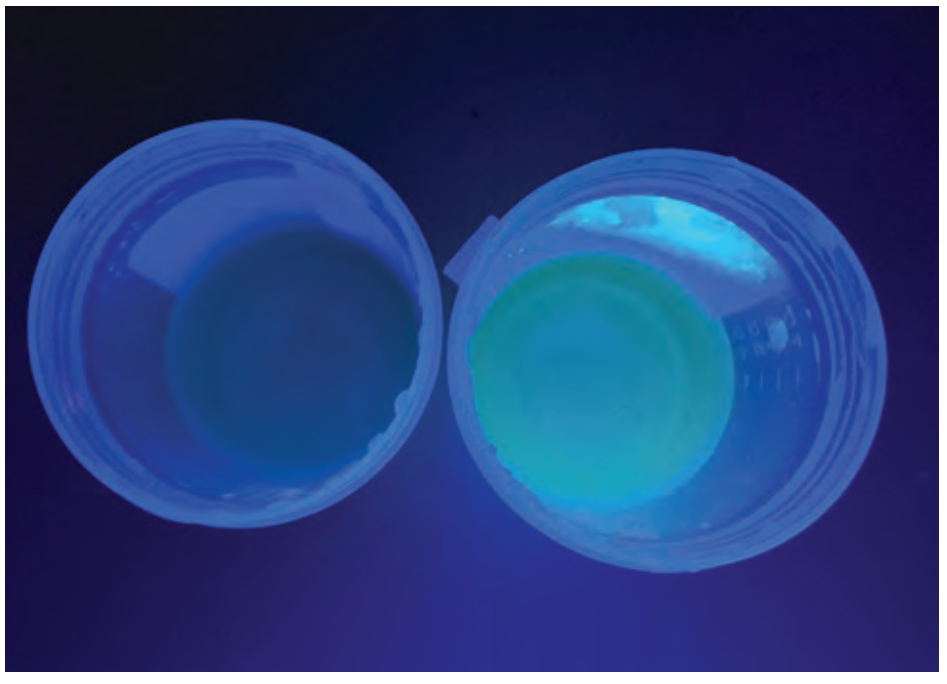

PHOTO: JASON HACK (OLEANDER PHOTOGRAPHY)

QUESTION: Can coming into contact with this chemical compound result in mortality?

SEE THE ANSWER *on page 20*

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ACEP4U: Your Employer Should Be an Open Book

BOOSTING THE EMERGENCY MEDICINE MARKET THROUGH TRANSPARENCY

The last few years have been a tumultuous time for the emergency medicine (EM) specialty, especially as it pertains to our workforce. Per Medscape, emergency physicians have the highest burnout rate—65 percent—among all surveyed specialties.[1] Attrition rates within the profession are high and rising, especially for female physicians and those working in rural settings.[2–5]

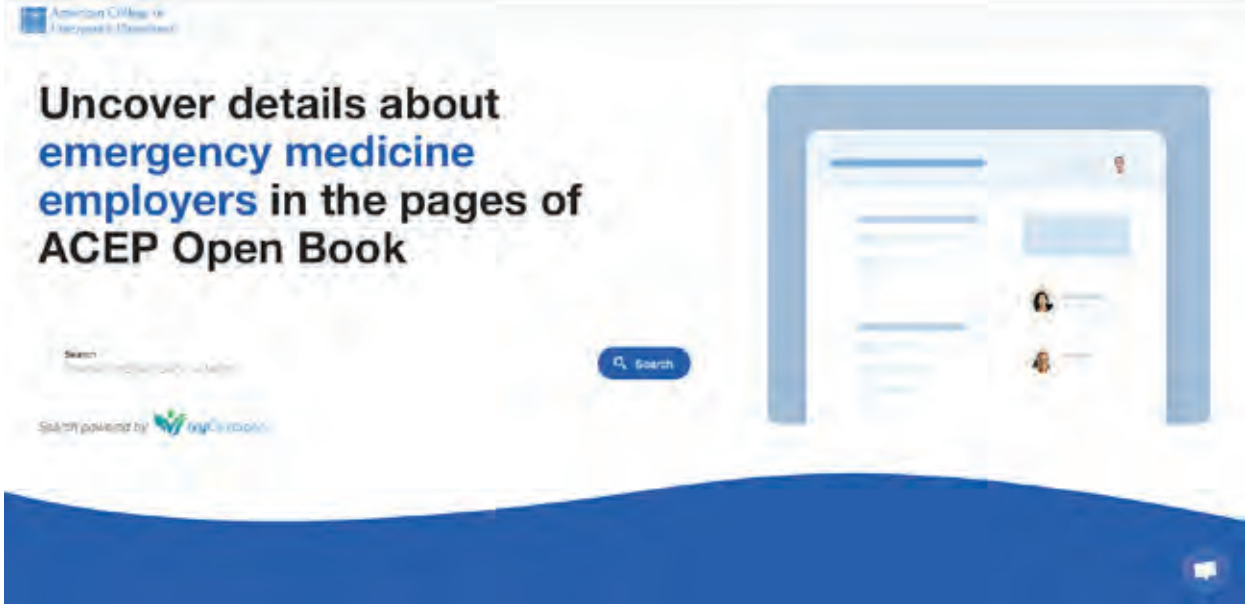
If many emergency physicians are unsatisfied with their jobs, what prevents more emergency physicians from finding a better workplace? ACEP is identifying and addressing the factors harming the EM job marketplace through advocacy work while also developing new resources.

At the most fundamental level, emergency physicians cannot change jobs if they are legally prevented from doing so by non-compete agreements. In March 2023, ACEP sent a letter to the Federal Trade Commission strongly supporting the FTC's proposal to ban non-compete agreements from employment contracts.[6] Per ACEP President Christopher S. Kang, MD, FACEP, "ACEP supports the Commission's proposal to categorically ban non-compete clauses, and we urge it to finalize the regulation as proposed to help address the current anti-competitive conditions faced by many emergency physicians that limit their right to freely practice medicine in their communities."[7]

Other core elements of a well-functioning job market are supply, safety, transparency, and simplicity. The EM job market could be improved in all four of those dimensions. The EM job market's lack of transparency is especially striking. Even figuring out which medical practice staffs a particular emergency department is challenging. As job boards post only about one-fifth of emergency department jobs at any given time, the emergency-physician application process often still relies heavily on word of mouth. In an era when we can do almost anything online, the EM marketplace still functions much like it did in the last century.

The EM job market's opacity and inefficiency have led to the growth of expensive intermediaries. EM practices spend up to $50,000 per hire in recruitment costs, while locum tenens companies charge up to 30 percent commissions.

ACEP is actively addressing the safety, transparency, and simplicity of the EM job market. ACEP has recently partnered with Ivy Clinicians to create ACEP Open Book, the core of which is a survey of employers about their practices and characteristics. The survey results will be easily searchable through ACEP's Career Center.



Visit the newly available openbook.acep.org today!

For those looking to find more information about specific emergency departments, Open Book will grant all ACEP members free access to Ivy Clinicians' platform. Ivy has connected every emergency department with its employer group, as well as site-level demographics, quality, and efficiency. Searching for potential employers through Open Book will be as simple as searching for houses on Zillow.

Because ACEP strongly values its members' data privacy, Open Book and its partners will share physician information only with employers specifically chosen by that physician. Using the platform will not lead to unsolicited spam.

The EM job market has significantly changed over the past decade. ACEP's advocacy and technology have evolved along with those market changes. One of ACEP's primary goals is to improve how the EM job market functions so every emergency physician can find work in a setting that gives them meaning and satisfaction. Explore this new resource by visiting openbook.acep.org.

References

1. Kane L. Physician burnout & depression report 2023: Medscape website. https://www.medscape.com/slideshow/2023-lifestyle-burnout-6016058 Published January 27, 2023. Accessed September 20, 2023.
2. Gettel CJ, Courtney DM, Janke AT, et al. The 2013 to 2019 emergency medicine workforce: Clinician entry and attrition across the US geography. *Ann Emerg Med.* 2022;80(3):260-271.
3. Gettel CJ, Courtney DM, Bennett CL, et al. Attrition from the US emergency medicine workforce during early stages of the COVID-19 pandemic. *Ann Emerg Med. 2023;82(2):234-236.*
4. Gettel CJ, Courtney DM, Agrawal P. Emergency medicine physician workforce attrition differences by age and gender. *Acad Emerg Med.* 2023; online preprint. Available at: https://pubmed.ncbi.nlm.nih.gov/37313983/. Published June 14, 2023. Accessed September 20, 2023.
5. Arnoff S. Press release: New analysis reveals worsening shortage of emergency physicians in rural areas. ACEP website. https://www.emergencyphysicians.org/press-releases/2020/8-12-20-new-analysis-reveals-worsening-shortage-of-emergency-physicians-in-rural-areas. Published August 12, 2020. Accessed September 20, 2023.
6. Kaplan P. Press release: FTC proposes rule to ban noncompete clauses, which hurt workers and harm competition. Federal Trade Commission website. https://www.ftc.gov/news-events/news/press-releases/2023/01/ftc-proposes-rule-ban-noncompete-clauses-which-hurt-workers-harm-competition. Published January 5, 2023. Accessed September 20, 2023.
7. Kang, CS. Re: Non-compete clause rulemaking, Matter No. P201200 (letter). ACEP website. https://www.acep.org/siteassets/new-pdfs/advocacy/acep-letter-on--ftc-noncompete-clause-03.07.23.pdf. Published March 7, 2023. Accessed September 20, 2023.

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A NEW SPIN

Using Civic Engagement and Voter Registration to Fight My Burnout

Are you intentionally missing the elephant in the trauma bay?

by CLAIRE ABRAMOFF, MD

At times, I want to give up this crazy, broken career as an emergency physician. We all recognize that our jobs have become more challenging since COVID-19 broke down our health care system and destroyed many of our social safety nets. COVID-19, vaccines, and health care in general have become more and more politicized, and I think that anyone who continues to deny the role politics and policy play in the health of our patients is intentionally missing the elephant in the trauma bay.

Observations on Shift and on the Street

I see the consequences of political decisions and policies. The elderly woman about to lose a foot due to complications of her diabetes? She is unable to afford the monthly cost of her prescription medications, despite having insurance and having been employed her entire adult life, and so rations her insulin. Teen pregnancies, recurrent sexually transmitted disease exposures and infections, injuries due to intimate partner violence? Data clearly suggest that abstinence-only sexual education in our public school systems has resulted in astonishing rates of teen pregnancy, abortions, and sexually transmitted disease infections.[1,2]

The most dramatic example of the interplay between politics and medicine is the ever-increasing gun violence in my home city, Philadelphia. 2021 was a remarkably violent year in the city—there were more than 550 homicides, 85 percent of which were due to shootings.[3,4] There was a total of more than 2,300 shootings in the city in 2021—that shows up in the trauma bays and resuscitation rooms in our emergency departments.

A resident once said to me that in emergency medicine, "we carry our graveyards with us." Well, unfortunately my graveyard is bursting at the seams. Eventually, they chip away at our ability to work in this field.

Doing Something Different

In a moment of burnout, desperate to continue as an emergency physician, and needing to change something, I signed up for a civic health fellowship through Vot-ER.[5] Vot-ER is a nonpartisan organization that works to bring voter registration into health care settings, with the goal of giving patients a voice in the policies that directly impact them. This fellowship has reinvigorated me and given me a way to funnel my anger into action.

There are 51 million unregistered voters in the United States, the vast majority of whom are young, low-income people of color—a huge chunk of the patient population that we serve on a daily basis.[6] When patients do not vote, political campaigns are less likely to address their needs. In Philadelphia specifically, neighborhoods with higher voter turnouts have higher life expectancies in comparison with areas with lower voter activity.[7]

Our patients desperately need their voices heard by those in political power: they need political action and policy that will address gun violence, crime, education, access to health care, and countless other challenges that negatively impact their health. Using the tools learned in my fellowship, we have had tremendous success registering our patients to vote. We have run educational sessions for our emergency medicine faculty and residents to present the concept of voting as a social determinant of health, and teach methods and strategies for registering patients in an emergency department setting. Vot-ER has provided us with badges printed with QR codes, which patients can scan and check their voter registration in real time. We have worked with our registration staff, and have successfully integrated a voter registration prompt into the emergency department registration process. We have also added a voter registration QR code to all discharge instructions printed from the emergency department.

In the fall of 2022, we organized and ran a city-wide voter registration day in health care centers across Philadelphia. Working with colleagues in other hospitals to set up a unified event was an incredibly energizing and satisfying project that helped reinvigorate and inspire me as a physician. The health care field can often feel very competitive, especially in academia. This event, though, was a true collaboration to help the underrepresented patients of Philadelphia. We worked across five major academic institutions to co-run voter registration drives at our hospitals and clinics for National Voter Registration Day in September. At my hospital alone, we registered nearly 50 new voters in this single event.

We have expanded our project from last year, and plan to include more clinics, hospitals, and medical schools. Please consider planning an event at your hospital–you may be surprised at the amount of support and satisfaction you receive.

Impactful Work . . . Everywhere

In some ways, this feels more impactful than a lot of my clinical work. I can fix the electrolyte derangements and acidosis of my patient presenting in diabetic ketoacidosis, but I cannot fix the social issues that led to their near-monthly hospital presentations for the same issue. However, by empowering the community to participate in our democratic process, hopefully systemic change can occur and help make our country a healthier place to live. This has re-inspired me as a physician, and has helped me find meaning and purpose in the often heartbreaking reality of our profession.

References

1. Stanger-Hall KF, Hall DW. Abstinence-only education and teen pregnancy rates: why we need comprehensive sex education in the U.S. *PLoS One*. 2011;6(10).
2. Kohler PK, Manhart LE, Lafferty WE. Abstinence-only and comprehensive sex education and the initiation of sexual activity and teen pregnancy. *J Adolesc Health*. 2008;42(4):344-51.
3. Beatrice Forman. A hard look at the numbers behind 2021's record gun violence in Philly, and an overview of what's being done. BillyPenn newsletter website. https://billypenn.com/2022/01/10/philadelphia-gun-violence-statistics-2021/. Published January 10, 2022. Accessed August 10, 2023.
4. American Academy of Family Physicians. Gun violence, prevention of (position paper). AAFP website. https://www.aafp.org/about/policies/all/gun-violence.html. Published 2018. Accessed August 10, 2023.
5. Healthy communities powered by a healthy democracy. Vot-ER website. https://vot-er.org/. Accessed August 10, 2023.
6. How does gun violence impact the communities you care about? Everytown for Gun Safety website. https://everystat.org/#Pennsylvania. Updated February 2023. Accessed August 10, 2023.
7. Pittel H. Elections: voter turnout varies between wealthy and impoverished neighborhoods. Philadelphia Neighborhoods website. https://philadelphianeighborhoods.com/2019/07/03/elections-voter-turnout-varies-between-wealthy-and-impoverished-neighborhoods/. Published July 3, 2019. Accessed August 10, 2023.

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"A New Spin" is the personal perspective of the author and does not represent an official position of *ACEP Now* or ACEP.

Creative CAREERS

Exploring unique career options for emergency physicians

LIZ CLAYBORNE, MD, FACEP

Founder and CEO of NasaClip

Dr. Liz Clayborne didn't set out to become an entrepreneur. She had her mind set on academic emergency medicine (EM), with specific interests in health policy, medical ethics, and health disparities. The spark that ignited her entrepreneurial journey was a common problem when she was an EM resident at George Washington University (GW): nosebleeds. So many nosebleeds.

She was taping together some tongue depressors for yet another nosebleed when she thought, "We have inventions for everything. There is a device for everything. I cannot believe there is nothing truly in the market that helped deal with nosebleeds." She had an idea for a device inspired by kayak nose clips that she thought might work, and one of her attendings encouraged her to pursue her idea further by applying for the GW business plan competition. She worked on her patents and intellectual property for what would become NasaClip, but she put it all on hold because life got busy with marriage, parenthood, and an active academic career.

Dr. Clayborne knew she would have to dedicate herself to pursuing her product idea or it would never make it off the backburner. She made the bold decision to enroll in the TEDCO accelerator program during her maternity leave in 2020 because that specific program required full-time enrollment, and the only way she could pull it off was during leave. Somehow, she made it work, finishing that 12-week program with the capital and executive support she needed to get her company off the ground.

Fast-forward to July 2023, the official launch of her nosebleed management device. It came after two rounds of funding during which Dr. Clayborne raised $1.1 million. She's been relentlessly persistent in pursuit of her dream to join the very small club of Black woman entrepreneurs, learning a lot along the way. "I really have honed my skills of being able to clearly communicate my problem, what my solution is, why my business is going to be successful, and why I am the type of founder my investors want to get behind and back financially," she said.

LIZ CLAYBORNE

It hasn't been easy, but she said it has been exciting. "That three-year period between 2020 and 2023 when I launched was still the most challenging because you are always juggling still doing clinical work, and I also think you have an internal battle—am I going to give up this profession that I spent so much time and effort to become?"

For Dr. Clayborne, she stepped down her clinical work gradually until deciding to go PRN in April 2023. Now she dedicates most of her time to growing her company and is in the middle of a $4 million seed raise to grow NasaClip into new territory, perhaps as an intranasal medication delivery platform. Her goal for the next 12 months is to grow product awareness in the clinician and consumer markets while building an internal infrastructure to sustain growth on NasaClip.com.

How does Dr. Clayborne "do it all" as a business owner and mother of two kids under four? It can be exhausting, she admits, but she protects her Mondays as rest days, and she makes a point to celebrate her little wins along the way. One little win coming up that she's looking forward to? Debuting her product as an exhibitor at ACEP23!

Though she's focused on growing her company for now, she is already thinking about her exit strategy. Dr. Clayborne wants to use her entrepreneurial success to inspire others, both as a keynote speaker and as an angel investor.

"I'd love to be able to have that capital to reinvest in other women and people of color," she said. "I truly think this is a way to build true generational wealth within these communities that have historically not had good access to capital historically in this country."

She has two pieces of advice for fellow emergency physicians who have a business idea they want to pursue. "You have to believe in yourself first. If you don't truly believe in your idea and you don't believe in yourself, you aren't going to get anyone else to back. You have to have that enthusiasm first. That fire has to come from you," she said. "The second one is just take one step forward instead of thinking about the 20 steps that you need to accomplish in order to make this idea come to fruition. Think about what are the three most immediate steps I need to take to get to the next level and work on those."

Visit acepnow.com to read the full article.

BRIDGING THE LANGUAGE GAP

Tips for working with medical interpreters

by MARC CASSONE, DO

Clinical Case

Your next patient is a Spanish-speaking 24-year-old female who begins by telling you that she is *embarazada*. Despite her bashfulness, you debate whether or not to call in the interpreter, since the waiting room is overflowing and between her broken English and your high-school Spanish you think you can get by without formal interpretation.

Medical Interpreting

According to the U.S. Census Bureau, 60.6 million Americans (approximately 20.8 percent) do not speak English as a primary language, and 25 million of those speak English less than well (known as "limited English proficiency" or LEP); many indicators show this number will only continue to grow. This demographic is higher risk of adverse events during hospital encounters, often due to communication issues, leading to tragic outcomes and malpractice suits including cases of missed intracerebral hemorrhages, unnecessary or incorrect surgeries, misused medical devices, and fatal medication dosing.[1,2] Medical interpreters (as opposed to *translators* who work with the written word), are essential to bridging the language gap.

Regulations

Section 1557 of the *Affordable Care Act* focuses on services available to limited-English-proficiency patients and builds on anti-discriminatory precedents set by Title VI of the *Civil Rights Act*. Current rules mandate that covered entities must communicate availability of interpreter services and are, "obligated to take reasonable steps to ensure access to services." It also limits the use of *ad hoc* (or nonqualified) interpreters such as family, friends, or untrained staff to certain situations (e.g., emergencies, patient's request).[3] A new 2022 proposed change to Section 1557 hopes to expand its scope to other HHS activities (including Medicare Part B) and telehealth services, require staff training on availability of services, and further define the roles of qualified versus nonqualified interpreters.[4] The Joint Commission's standards follow similar requirements. However, actual increases in available services in emergency departments based on prior state-level requirements have been mixed.[5]

Many medical interpreters are certified by organizations such as the National Board of Certification for Medical Interpreters, or the Certification Commission for Healthcare Interpreters, which require both written and oral testing and documented experience, as well as additional training in medical ethics, terminology, and patient privacy regulations. These include ASL interpreters. However, it has not been feasible to develop and validate certifications for all of the over 350 different languages spoken in the U.S., let alone find qualified interpreters for each language. Some certifying bodies may provide provisional interpreters in cases where they cannot certify an interpreter for a certain language or dialect. In other cases, medical staff may have to rely on *ad hoc* interpreters.

Tips for Working with Medical Interpreters

Prepare ahead before entering the patient's room. Have an initial plan for the conversation including what information you want to convey and specific questions you want to ask. If possible, discuss these ahead with the interpreter. Being patient, using clear language, and a respectful tone will go a long way to establishing trust with the patient and their families. Beware of possible prejudices and assuming cultural values of the patient and others who speak that language. Physicians should document the interpreter's name and identification number if available in the patient's chart.

Telephone-Based Services

Remote tele-interpreter services have certainly improved access to certified and qualified interpreters with extended availability and a wide range of spoken languages. Users must ensure a reliable connection speed and good audiovisual capabilities (especially for the elderly and hearing- or sight-impaired), and consider the of lack visual cues such as body language and facial expressions that can be a source of misunderstandings when compared to in-person services.[6]

Using Ad Hoc Interpreters

In emergency cases, ad hoc interpreters (friends, family, community members, or untrained staff) will need to be used because of extenuating circumstances. Ideally, medical staff should attempt some vetting of the ad hoc interpreters and confirm the patient agrees with using this person to interpret.[7] Unfortunately, non-adult children are often used as ad hoc interpreters, which can be fraught with issues. Ad hoc interpreters have a higher rate of potentially consequential errors compared to professional interpreters (22 percent versus 12 percent) and outcomes significantly are improved for individuals with over 100 hours of training (2 percent).[8]

Although there are no current standards forbidding it, multilingual physicians may be tempted to use their own language backgrounds to forgo an interpreter.[9] Being bilingual is often not enough to be a medical interpreter, which requires precision, experience, and knowledge of medical jargon, as well as culturally specific idioms and phrases. For example, the French-Canadian patient who claims to have *chair blesseé* has a flesh wound and not a holy seat and the Spanish-speaking patient who is *constipado* may just need a nasal decongestant and not a stool softener. A physician once attemtpted to use his limited Diné, which is notably hard to pronounce, to ask a Navajo patient for their *ch'ah* (stool sample) and just ended up getting a chuckle and her *chąą'* (hat) instead.

Documentation

Providing patient-facing documentation such as procedural consent forms, discharge instructions, and medication prescriptions in the appropriate language can provide a distinct challenge. Some electronic-health-record packages provide discharge instructions for common diagnoses in common languages; however, these are certainly not extensive and can lack individualized information. Although tempting to use, current online language translation programs can be inconsistent, worse than human translators, and possibly even lead to dangerous mistranslations.[10-11]

Clinical Case Resolution

You decide to call in the interpreter and find out the patient was actually telling you that she was *pregnant* (and not embarrassed) and had heavy first-trimester bleeding. After the appropriate work-up, you are glad to have had the medical interpreter present to appropriately communicate the nuances of a threatened abortion and address your patient's concerns in her primary language. ⊕

DR. CASSONE is an attending physician based in northern New York and has worked in several multicultural contexts, including Native American reservations and with Médecins Sans Frontières.

References

1. Divi C, Koss R, Schmaltz S, Loeb J. *Int J Qual Health Care*. 2007;19(2):60-7.
2. Surinder S. Medical translation gone wrong: 7 devastating medical translation errors. K-International/The Language Blog website. https://www.k-international.com/blog/medical-translation-gone-wrong-4-devastating-examples/. Published Feb 8, 2018. Accessed August 11, 2023.
3. Office of Civil Rights. U.S. Department of Health and Human Services website. https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html. Last reviewed February 3, 2023.
4. Centers for Medicare and Medicaid Services, et al. Nondiscrimination in health programs and activities: a proposed rule by the centers for medicare & medicaid services on 08/04/2022. Federal Register website. https://www.federalregister.gov/documents/2022/08/04/2022-16217/nondiscrimination-in-health-programs-and-activities. Published August 4, 2022. Accessed August 11, 2023.
5. Ginde A, Sullivan A, Corel B, at al. Reevaluation of the effect of mandatory interpreter legislation on use of professional interpreters for ED patients with language barriers. *Patient Educ Couns*. 2010;1(2):204-6.
6. Benda NC, Bisantz AM, Butler R, et al. The active role of interpreters in medical discourse - An observational study in emergency medicine. *Patient Education and Counseling*. 2022;105(1):62-73.
7. Balch, B. The United States needs more Spanish-speaking physicians. American Association of Medical Colleges website. https://www.aamc.org/news/united-states-needs-more-spanish-speaking-physicians. Published July 18, 2023. Accessed July 18, 2023.
8. Flores G, Abreu M, Barrone CP, et al. Errors of medical interpretation and their potential clinical consequences: a comparison of professional versus ad hoc versus no interpreters. *Annals of EM*. 2012; 60(5): 545-553.
9. Regenstein M, Anders E, Wynia MK. Promoting appropriate use of physicians' non-English language skills in clinical care: A white paper of the Commission to End Health Care Disparities with recommendations for policymakers, organizations and clinicians. American Medical Association, Chicago IL 2013.
10. Kreger V, Aintablian H, Diamond L, et al. Google translate as a tool for emergency department discharge instructions? Not so fast! *Annals of EM*. 2019;74(4):S5-6.
11. Taira RB, Kreger V, Orue A, Diamond L. A pragmatic assessment of Google Translate for emergency department instructions. *J Gen Intern Med*. 2021;36:3361-3365.

a leading cause of morbidity and mortality for both children and adults. There are at least 600 TBI-related hospitalizations and 175 TBI-related deaths per day.[2,3] TBI outcomes are profoundly linked to the timing and quality of care provided before patients reach the hospital. Continuous cerebral blood flow is paramount and brief episodes of systemic hypotension, hypoxia, or inadvertent iatrogenic hyperventilation have been strongly associated with worse outcomes in both children and adults.[4] Similar to out-of-hospital cardiac arrest, the actions of prehospital providers have enormous impact on survival and the degree of any long-term disability. Prehospital providers must be competent and proficient in both the recognition and the seamless management of TBI, as well as facile in determining the most appropriate receiving facility for the acutely brain injured patient.

Prognosis from brain injury results not only from the initial or primary injury, but also from secondary injury that occurs after the event, mainly, hypoxic/ischemic brain injury from under resuscitation or cerebral edema from the release of neurotoxic inflammatory mediators. These guidelines are designed to minimize secondary injury and thus maximize survival by addressing the actions that take place during that critical time from the primary event to arrival at the hospital.

This guideline revision is particularly timely as EMS systems have shown their abilities to dramatically improve survival and neurologic outcome after cardiac arrest, STEMI, acute stroke, and other time-sensitive conditions.

In creating these guidelines, the author team utilized a rigorous grading of the published evidence and provided detailed evidentiary tables that support the recommendations. Terminology used include *Strength* (rating of *strong* vs. *weak)* and *Quality of Evidence* (*high*, *moderate*, or *low)*. These designations take into account not only the class of the evidence based on study design but also design flaws that weaken a study's internal or external validity.

The recommendations in the first two editions of these guidelines were all graded as "weak" due to the lack of high-quality evidence. Since the last edition, evidence has grown supporting an outcome benefit of interventions; specifically, the statewide Excellence in Prehospital Injury Care (EPIC) initiative from Arizona which documented an outcome benefit for patients with moderate and severe TBI when prehospital treatment guidelines were followed.[4] In addition, a number of meta-analyses have produced a higher level of evidence that consequently support a "strong" recommendation in several areas where the recommendation was rated "weak" in prior guideline editions.

The recommendations in the guidelines are divided into sections pertaining to "Assessment", "Treatment" and "Decision Making": Chapters within these sections are uniformly structured to include Recommendations, Evidence Tables, Scientific Foundations, and Key Issues for Future Investigation, and References. The following

CONTINUED *on page 14*

ASSESSMENT

Oxygenation, Blood Pressure, Ventilation

- Patients with suspected traumatic brain injury (TBI) should be carefully monitored in the prehospital setting for hypoxemia (<90% arterial hemoglobin saturation), hypotension (<100 mmHg systolic blood pressure [SBP]), hypertension (150 mmHg SBP or higher), hyperventilation (end tidal CO_2 reading less than 35) and hypo- or hyperthermia.
- Blood oxygen saturation should be continuously measured in the prehospital setting with a pulse oximeter and supplemental oxygen administered to maintain blood oxygen saturation above 90%.
- Systolic and diastolic blood pressure should be measured in the prehospital setting using the most accurate method available and should be measured frequently (every 5-10 min) or monitored continuously if possible.
- Ventilation should be assessed in the prehospital setting for all patients with an altered level of consciousness with continuous capnography to maintain end tidal CO_2 values between 35 and 45 mmHg.
- Temperature should be measured in the prehospital setting and efforts should be undertaken to maintain euthermia in the patient equating to temperatures of 36-37 degrees Celsius.
- In non-resource-limited settings, appropriately sized equipment to measure oxygenation, blood pressure, and temperature in children and adults should be maintained and available for routine use by trained prehospital professionals.

Glasgow Coma Scale Score

- The adult protocol for standard GCS measurement should be followed in children over 2 years of age. In pre-verbal children, the P-GCS should be employed.
- The GCS score should be reported every 30 minutes in the prehospital setting and whenever there is a change in mental status to identify improvement or deterioration over time. Confounders to the GCS such as seizure and post-ictal phase, ingestions and drug overdose, as well as medications administered in the prehospital setting that impact GCS score should be documented.
- The GCS must be obtained through interaction with the patient (i.e., by giving verbal directions or, for patients unable to follow commands, by applying a painful stimulus such as nail bed pressure or axillary pinch).
- The GCS should be measured after airway, breathing, and circulation are assessed, after a clear airway is established, and after necessary ventilatory or circulatory resuscitation has been performed.
- The GCS should be measured prior to administering sedative or paralytic agents when possible and when not delaying airway stabilization, or after these drugs have been metabolized as they may obscure correct scoring.
- The GCS should be measured by prehospital professionals who are appropriately trained in how to administer the GCS to both adults and children.
- The GCS of the prehospital patient, including any changes in score, should be communicated to receiving facilities during all communications and upon arrival.
- Prehospital assessment of neurologic status using the Simplified Motor Score (SMS), or the isolated motor component of the GCS may provide similar diagnostic and prognostic utility to the complete GCS in adults and may be used in trauma systems organized to incorporate these measures.

Pupil Examination

Pupils should be assessed in the prehospital setting after the patient has been resuscitated and stabilized, with the examination recorded and relayed to the receiving facility. When assessing pupils, the following should be examined for and documented:

- » Evidence of orbital and ocular trauma
- » Comparison of left and right pupillary findings. Clinically significant asymmetry is defined as > 1mm difference in diameter
- » Presence of unilateral or bilateral dilated pupil(s)
- » Presence of fixed and dilated pupil(s). A fixed pupil is defined as < 1mm response to bright light
- » Confounders to pupil exam

TREATMENT

Airway, Ventilation, and Oxygenation

- All patients with suspected severe TBI should be placed on continuous oxygen supplementation via nasal cannula or face mask in the prehospital setting in order to minimize secondary insults related to hypoxia.
- Hypoxemia (oxygen saturation [SpO_2] < 90%) should be monitored using continuous pulse oximetry and corrected immediately upon identification by 1) ensuring appropriate airway positioning and 2) administering continuous, supplemental oxygen.
- If signs of hypoxia persist (central cyanosis and/or hypoxemia on pulse oximetry) despite increasing the flow and concentration of continuous supplemental oxygen, the following stepwise strategies should be undertaken with re-evaluation of oxygen saturation and respiratory effort following each strategy:
  - » airway re-positioning,
  - » positive pressure ventilation as with bag-valve-mask ventilation in conjunction with appropriate airway adjuncts (e.g., oropharyngeal airway), and/or
  - » supraglottic airway or endotracheal intubation by a trained health care professional.
- An airway should be established, by the most appropriate means available, in patients who have signs of severe TBI, GCS < 9, or 9 and decompensating, the inability to maintain an adequate airway, or if hypoxemia is not corrected by supplemental oxygen.
- Emergency Medical Service (EMS) systems implementing endotracheal intubation protocols including the use of rapid sequence intubation (RSI) protocols should confirm endotracheal tube placement in the trachea by the presence of bilateral breath sounds on auscultation, $ETCO_2$ detection and/or capnography. Intubated patients in the prehospital setting require continuously monitored oxygenation, $ETCO_2$, and frequent blood pressure monitoring.
- Patients requiring respiratory support with positive pressure ventilation should be maintained with normal breathing rates (approximately 10 breaths per minute with $ETCO_2$ 35-45 mmHg), and hyperventilation ($ETCO_2$ < 35 mmHg) should be avoided. Ventilatory adjuncts such as pressure-controlled bags, ventilation-rate timers, $ETCO_2$ monitoring, and ventilators should be used to support appropriate ventilation and minimize the risk of secondary insults by avoiding hypo- and hyperventilation.

Fluid Resuscitation

- Intravenous fluids should be administered in the prehospital setting to treat hypotension and/or limit hypotension to the shortest duration possible.
- Hypotensive patients should be treated with blood products and/or isotonic fluids in the prehospital setting.
- Hypertonic fluid resuscitation may be administered to patients with a Glasgow Coma Scale Score (GCS) < 8 in whom increased ICP is suspected in the prehospital setting.

Hyperventilation and Hyperosmolar Therapy for Suspected Increased Intracranial Pressure (ICP)

- Hyperventilation should be avoided in the prehospital care of children and adults with TBI in the absence of signs of active cerebral herniation.
- Ventilation strategies should target eucapnia and avoid hypocapnia (i.e., $ETCO_2$ of 35- 40) and be monitored using capnography.
- When used to address signs of active and imminent herniation, hyperventilation should target an $ETCO_2$ of 30-35 using capnography.
- Hyperosmolar therapy should not be administered for the prophylactic treatment of suspected elevated ICP, with or without signs of cerebral herniation, in the prehospital setting at this time.
- Prehospital administration of TXA therapy is not generally and widely indicated for the prophylactic treatment of suspected ICH or elevated ICP at this time.

is a summary of the guidelines; An algorithm that synthesizes best practice recommendations based on the guidelines is available at https://doi.org/10.1080/10903127.2023.2187905 and from the Brain Trauma Foundation at www.braintrauma.org.

SUMMARY

The Brain Trauma Foundation's guidelines for prehospital management of traumatic brain injury patients provide evidence-based recommendations for assessment, treatment, and transport decisions. The guidelines emphasize the importance of monitoring and treatment of airway, oxygenation, and ventilation, with caution against hyperventilation and recommendations for the use of $ETCO_2$ to ensure appropriate ventilation. Close monitoring of oxygenation and blood pressure is also stressed, with interventions recommended based on the results of this monitoring. The guidelines also address issues related to EMS provider skill level, transportation modality, and destination for the patient. The recommendations are applicable to all types of EMS systems.

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DECISION-MAKING WITHIN THE EMS SYSTEM

Dispatch and Destination, On-scene, and Transportation

- All regions should have an organized trauma care system with comprehensive documentation of each encounter including time, assessment, and care provided.
- Emergency Medical Services (EMS) should establish specific protocols directing destination decisions for patients with suspected traumatic brain injury (TBI).
  - » Pediatric patients with suspected TBI should be treated in a pediatric trauma center or in an adult trauma center with added qualifications to treat children in preference to a Level I or II adult trauma center without added qualifications for pediatric treatment.
- Patients with suspected moderate-severe TBI should be transported directly to a facility with immediately available computed tomography (CT) neuroimaging capabilities, prompt neurosurgical care, and the ability to monitor intracranial pressure and treat intracranial hypertension.
  - » While direct transport to a trauma center is preferable for most patients, in the event that this transport is not possible, stabilization at a non-trauma center with subsequent transfer within an established trauma system may occur.
  - » In a metropolitan area, pediatric patients with severe TBI should be transported directly to a pediatric trauma center if available.
  - » The mode of transport should be selected to minimize the time to definitive interventions for the patient with TBI.

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REFERENCES

1. Lulla A, et al. Prehospital Guidelines for the management of traumatic brain injury – 3rd edition. *Prehosp Emerg Care*. 2023; https://doi.org/10.1080/10903127.2023.2187905
2. Centers for Disease Control and Prevention. National Center for Health Statistics: Mortality Data on CDC WONDER. Accessed 2022, https://wonder.cdc.gov/mcd.html.
3. Bell JM, Breiding MJ, DePadilla L. CDC's efforts to improve traumatic brain injury surveillance. *J Safety Res*. 2017;62:253 -256.
4. Spaite DW, Bobrow BJ, Keim SM, et al. Association of Statewide Implementation of the Prehospital Traumatic Brain Injury Treatment Guidelines With Patient Survival Following Traumatic Brain Injury: The Excellence in Prehospital Injury Care (EPIC) Study. *JAMA Surg*. 2019;154(7):e191152.

TRAUMATIZING PATIENTS | CONTINUED FROM PAGE 1

"What are you doing?"

"Pupils equal and reactive."

"Those are mine!"

She was an elderly woman with head trauma after a fall. We thought we were saving her life with a trauma activation. She thought we were robbing her of precious life possessions.

For years I have stripped trauma patients, probing their painful wounds for elusive injuries and examining them with a level of detail usually reserved for mothers studying their newborn babes. Patient after patient, trauma activation after activation, my trauma surveys became rote and depersonalized by necessity. Yet, I could never shake the nagging feeling that I was performing exams without patients' explicit consent. Or even worse, against their verbal objection. I couldn't escape that I was traumatizing my patients with a trauma activation.

Consent to a trauma evaluation is presumed when a patient presents as a trauma activation; implied consent applies to all life-threatening emergencies and is not unique to trauma activations. However, patients are neither knowledgeable about our opaque trauma protocols nor informed about trauma activations. The concept of rapid assessment for heart attacks and strokes is not foreign to the general public, but these emergencies do not include rapid destruction of clothing, private examinations performed in front of audiences, or a quick succession of invasive procedures. Trauma is unique.

Throughout the Advanced Trauma Life Support manual, a mere three sentences relate to the murky ethics of trauma consent: "Consent is sought before treatment, if possible. In life-threatening emergencies, it is often not possible to obtain such consent. In these cases, provide treatment first, and obtain formal consent later."[1] The time pressure of trauma resuscitations and the variable severity of injury make obtaining informed consent before a trauma exam difficult. Thus, a full disclosure of the process and alternatives seldom happens. Too many times we offer, in place of full disclosure, a simple statement—"I'm going to examine you head to toe for injuries"—and accept fearful silence as voluntary agreement. This process is worse for systemically marginalized populations, including people with mental-health comorbidities, primary languages other than English, minorities, and those who have experienced assault.

The salvage of life and limb is the purpose of trauma activations and surveys, but it assumes that moral injury is an appropriate sacrifice in pursuit of that goal. Many of my colleagues fear personally experiencing a trauma activation—not due to personal injury, but because they know about the *process*. Interviews with patients who experienced trauma resuscitations reveal themes similar to our unspoken professional fears. The violation of personal space and dignity and removal of valued objects without explanation or consent are common frustrations.[2] The same patients are reassured by our competence, yet we must address the times when acuity, standardized protocols and patient values are misaligned. During one of our recent surges, I rushed through discharging a man without serious injuries after a fall, my mind distracted by the burgeoning waiting room. I asked what questions he had and the only one was about his sweatshirt. His wife had died six months earlier and I had destroyed her last remaining possession, one that he kept with him.

These days, I attempt to balance a less morally injurious trauma resuscitation with the need for rapid stabilization and treatment. The other night I stood in the trauma bay, listening to rain patter against the automatic doors, awaiting an ambulance. The doors slid open and above the rain I heard a woman yelling repeatedly in mixed English and Dari, "No, I do not consent," while paramedics relayed their concern for a spinal injury after she fell down concrete steps. We found an interpreter, took her vitals, and did one of the harder things to do in a trauma bay—we paused. It took time, but we learned how we could perform a trauma survey aligned with her values and she understood the process. Wearing a cut-up trauma sheet as a hijab, she walked out of our emergency department several hours later, intact and not traumatized.

References

1. American College of Surgeons Committee on Trauma. *Advanced Trauma Life Support: Student Course Manual.* 10th ed. Chicago, IL: American College of Surgeons; 2018.
2. Kaufman EJ, Richmond TS, Wiebe DJ, et al. Patient experiences of trauma resuscitation. *JAMA Surg.* 2017;152(9):843.

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Acknowledgement: Luz Silverio, MD, who provided content review and editing assistance.

DOGMA FEELS RIGHT UNTIL YOU STEP IN IT

SKEPTICS' GUIDE TO EMERGENCY MEDICINE

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INTERACT-3

Implementing goal-oriented, bundled care for intracerebral hemorrhage improve outcomes

by KEN MILNE, MD

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Case

A 76-year-old female presents to the emergency department obtunded with left hemiplegia. Symptoms began just prior to presentation. Her blood pressure (BP) is 195/104 mmHg. The CT scan reveals a hemorrhage in the right internal capsule, suggestive of acute hypertensive hemorrhagic stroke. Should the BP be treated aggressively, what is the target, and how quickly should we achieve that target?

Background

There have been a couple of large and influential trials published on BP management after an intracranial hemorrhage (ICH). Both INTERACT-2 and ATACH-2 showed no statistical difference in their primary outcome between intensively lowering the BP and a less-intensive strategy.[1,2]

The 2022 AHA/ASA Guidelines give several recommendations on this topic.[3] The class (strength) of their recommendation is 2a/2b based upon Level B and Level C quality of evidence. The language used in the guidelines is important. The specific language used in the AHA/ASA guidelines is as follows:

- "In patients with spontaneous ICH in whom acute BP lowering is considered, initiating treatment within 2 hours and reaching target within 1 hour can be beneficial to reduce the risk of HE [hematoma expansion] and improve functional outcome"
  - » Class 2a recommendation, "Moderate": is reasonable, can be beneficial; level of evidence C-LD (limited data)
- "In patients with spontaneous ICH of mild to moderate severity presenting with SBP [systolic BP] between 150 and 220 mmHg, acute lowering of SBP to a target of 140 mmHg with the goal of maintaining in the range of 130 to 150 mmHg is safe and may be reasonable for improving functional outcomes."
  - » Class 2b recommendation, "Weak": may be reasonable, may be beneficial, effectiveness not well established; level of evidence B-R (randomized; moderate quality evidence from 1 or more randomized controlled trials or meta-analyses of moderate-quality randomized controlled trials)
- "In patients with spontaneous ICH presenting with large or severe ICH or those requiring surgical decompression, the safety and efficacy of intensive BP lowering are not well established."
  - » Class 2b recommendation, "Weak": may be reasonable, may be beneficial, effectiveness not well established; level of evidence C-LD (limited data)

Clinical Question

Can the implementation of a goal-directed care bundle, incorporating protocols for early, intensive BP lowering in addition to management algorithms for hyperglycemia, pyrexia, and abnormal anticoagulation, implemented in a hospital setting, improve outcomes for patients with acute spontaneous intracerebral hemorrhage?

Reference

Ma LM, Hu X, Song L, et. al. The third intensive care bundle with blood pressure reduction in acute cerebral haemorrhage trial (INTERACT3): an international, stepped wedge cluster randomised controlled trial. *Lancet.* 2023;402(10395):27-40.

- **Population:** Patients 18 years of age and older, presenting within six hours after the onset of ICH
  - » **Exclusions:**
    - Definite evidence that the ICH is secondary to either a structural abnormality in the brain or previous thrombolysis
    - Attending clinician felt there was a high likelihood that the patient would not adhere to the study treatment and follow-up regimen
- **Intervention:** Bundled care per a goal-directed intensive care protocol to correct hypertension, hyperglycemia, pyrexia, and hypercoagulability, with the goal of achieving treatment targets within one hour of initiating treatment and maintaining them for seven days (or until discharge or death, whichever came first)
- **Comparison:** Usual care at the discretion of the treating physician
- **Outcome:**
  - » **Primary Outcome:** Functional recovery measured at six months according to the modified Rankin Scale (mRS) score and analyzed as an ordinal outcome (shift across all categories)
  - » **Secondary Outcomes:**
    - Functional recovery according to a shift analysis of scores on the National Institutes of Health Stroke Scale at seven days
    - Dichotomous mRS outcomes at six months (0-2 versus 3-6, and 0-2 versus 3-5)
    - Death at six months
    - Death or neurological deterioration at seven days
    - Health-related quality of life using the EuroQoL Group 5-Dimension self-report questionnaire
    - Residence at six months (own home versus other)
    - Time to hospital discharge
  - » **Safety Outcomes:** All-cause and cause-specific serious adverse events, recorded for the duration of follow-up
- **Type of Study:** A pragmatic, international (10 countries), multicenter (121 hospitals), unmasked, stepped-wedge, cluster randomized, controlled trial

Authors' Conclusions

"Implementation of a care bundle protocol for intensive blood pressure lowering and other management algorithms for physiological control within several hours of the onset of symptoms resulted in improved functional outcome for patients with acute intracerebral haemorrhage. Hospitals should incorporate this approach into clinical practice as part of active management for this serious condition.**"**

Results

A total of 7,036 patients were recruited from 121 hospitals that could be included in the modified intention-to-treat analysis. The mean age of patients was 62 years with 36 percent female. Most of the patients (over 90 percent) were Chinese.

Key Results

The odds of a poor functional outcome were lower in the care bundle group compared to usual care.

- **Primary Outcome:** mRS favored the care bundle group (OR, 0.86; 95 percent confidence interval, 0.76-0.97; P = 0.015), consistent across all adjustments and calculations.
- **Secondary Outcomes:** Most secondary outcomes did not show a statistically significant difference. Some showed trends in a positive direction. Patients who received the intervention were statistically more likely to be discharged by day seven. The EuroQoL Group 5-Dimension self-report questionnaire quality of life assessment was a mixed bag, but the effects on this scale diminished when they made the various statistical adjustments in their post-hoc analysis.
- **Safety Outcomes:** There were significantly fewer serious adverse events in the bundled care group.

EBM Commentary

1. **External Validity:** It is unclear if this data

applies to patient you see in your emergency department. One reason is where these patients were recruited to be included in the trial. The cohort came from nine low- and middle-income countries and one high-income country. Most of the patients were recruited from China (90 percent) with only 3 percent coming from Chile (the only one classified as a high-income country).

2. **Medications** used to lower BP are also important. The majority of patients' BP was lowered with urapidil (61 percent) with a minority being treated with nicardipine (8 percent). How would this data extrapolate to North America, where nicardipine is a commonly used medication, while urapidil is not available in the United States or Canada?
3. **Bundle:** The bundle treatment included addressing hypertension, hyperglycemia, pyrexia, and hypercoagulability. Which part of the intervention caused the benefit? We have seen other bundles, in conditions like sepsis, that did not ultimately turn out to be better than usual care (ARISE, ProMISe and ProCESS).[4] There could also be a Hawthorne Effect because this was unmasked trial and participants and clinicians knew whether they were receiving bundled care or usual care.
4. **Outcome Assessment:** The primary outcome in this trial was an ordinal analysis of the mRS score. Concerns have been raised about ordinal analyses. Dr. Rory Spiegel, who does the podcast for Annals of Emergency Medicine with Dr. Ryan Radecki, has written about this issue of ordinal analyses.[5,6]

Table: Method of assessment of 6-month outcomes

ASSESSMENT TYPE	CARE BUNDLE (N=3221)	USUAL CARE (N=3815)
Phone to caregiver	2470/3121 (79.1)	2913/3683 (79.1)
Phone to patient	247/3121 (7.9)	255/3683 (6.9)
Phone to patient's doctor or medical practitioner	115/3121 (3. 7)	110/3683 (3.0)
Face to face	32/3121 (l.0)	6/3683 (0.2)
Other	33/3121 (l.l)	23/3683 (0.6)
Refused to receive follow-up assessment	11/3121 (0.4)	39/3683 (l.l)
Lost to follow-up	213/3121 (6.8)	337/3683 (9.2)

Data are n/N (%)

There are also the issues with the mRS score itself for inter-rater reliability. Scoring of mRS, even by a neurologist, is only moderately reliable at best when done face-to-face.[7] Similar issues with the mRS have been reported by others.[7]

In INTERACT-3 the outcome assessment is done via caregiver over the phone (79 percent of the time) or with the patient over the phone (7 percent of the time) and not face-to-face (less than 1 percent of the time). (See table) This should decrease our confidence in the primary outcome of mRS at six months.

Bottom Line

Intense blood pressure lowering in patients with ICHs continues to seem safe if we do not overshoot our target BP and cause hypotension, but we are still uncertain if it provides a patient-oriented outcome of benefit.

Case Resolution

The patient has severe disease with a poor prognosis. There is no definitive evidence to inform our management. You have a conversation with the neurological critical-care team and discuss what will be a mutually agreeable treatment plan.

Thank you to Dr. Mike Pallaci who is both a professor of emergency medicine for the Northeast Ohio Medical University, and an adjunct clinical professor of emergency medicine for the Ohio University Heritage College of Osteopathic Medicine, for his help with this critical appraisal.

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

References

1. Anderson CS, Heeley E, Huang Y et al. Rapid blood-pressure lowering in patients with acute intracerebral hemorrhage. *N Engl J Med*. 2013;368(25):2355-65.
2. Qureshi AI, Palesch YY, Barsan WG, et al. Intensive blood-pressure lowering in patients with acute cerebral hemorrhage. *N Engl J Med*. 2016;375(11):1033-43.
3. Greenberg SM, Ziai WC, Cordonnier C, et al. 2022 guideline for the management of patients with spontaneous intracerebral hemorrhage: a guideline from the American Heart Association/American Stroke Association. *Stroke*. 2022;53(7):e282-e361.
4. ARISE Investigators; ANZICS Clinical Trials Group; Peake SL, et al. Goal-directed resuscitation for patients with early septic shock. *N Engl J Med*. 2014;371(16):1496-506.
5. Spiegel R. The adventure of the cardboard box. EMCrit website. http://emcrit.org/emnerd/the-adventure-of-the-cardboard-box/. Published June 30, 2013. Accessed September 17, 2023.
6. Spiegel R. A Secondary Examination of The Adventure of the Cardboard Box. http://emcrit.org/emnerd/secondary-examination-adventure-cardboard-box/. Published November 10, 2014. Accessed September 17, 2023.
7. Quinn TJ, Dawson J, Walters MR, et al. Reliability of the modified Rankin Scale: a systematic review. *Stroke*. 2009;40(10):3393-5.

PUTTING RESEARCH TO WORK FOR YOU

PRACTICE CHANGERS

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SubQ, Yes Please

Needing a little less sweetness in your life

by LAUREN WESTAFER, DO, MPH, MS

The treatment of diabetic ketoacidosis (DKA) is, in many ways, unchanged: intravenous fluids, electrolyte repletion, insulin, and treatment of any precipitating factors. However, as with many treatments, there has been substantial de-escalation in intensity of therapy over time. Historically, patients were given a bolus of intravenous insulin followed by an insulin infusion. In 2009, a consensus statement from the American Diabetes Association (ADA) discussed using a low-dose infusion (0.1 to 0.14 units/kg/hour) rather than a bolus.[1] Additionally, the consensus statement discussed the emerging use of subcutaneous insulin to treat DKA. More recently, evidence has mounted demonstrating that DKA can be managed with subcutaneous insulin in many patients, which is endorsed in the most recent iteration of the Standards of Care in Diabetes from the ADA.[2,3] In fact, traditional insulin infusions do not result in quicker closure of the anion gap or lowering of the serum glucose below 250 mg/dL.[3,4]

Logistics of Subcutaneous Insulin Pathways

The eligibility criteria for entry into a subcutaneous insulin pathway for DKA varies. All pathways exclude those who are obtunded (Glasgow Coma Scale below 8) or have another critical illness necessitating intensive care. In some studies, individuals with mild to moderate DKA are eligible (pH at least 7.0, bicarbonate at least 10 mEq/L) whereas some studies have included any non-critically ill patient otherwise eligible, regardless of DKA severity.[4,5] Notably, patients weighing 166 kg or more may have altered absorption of insulin and were eventually excluded from one hospital system's protocol.

In subcutaneous insulin protocols, patients receive the same supportive care as in infusion pathways—a couple of liters of intravenous fluids (depending on comorbidities) and electrolyte repletion. In addition, patients receive a hefty dose of a short-acting insulin every four hours, as long as the glucose is above 250 mg/dL (e.g., lispro 0.3 units/kg subcutaneously). In a recent protocol that included noncritically ill patients across the spectrum of DKA severity (that is, inclusive of severe DKA), patients also received a dose of long-acting insulin (e.g., glargine 0.3 units/kg subcutaneously or the patient's usual home dosage) alongside the short-acting insulin. Point-of-care glucose monitoring can be conducted less frequently than in infusion pathways, every two hours until four hours after the last "big" dose of short-acting insulin.

What's the Advantage?

Intravenous insulin infusions typically require treatment in highly monitored settings, such as an intensive care unit (ICU) or step-down unit for safety and due to the frequency and intensity of monitoring. ICU and step-down beds are a limited resource and generate higher hospital charges. One study found a 57 percent reduction in ICU admissions among patients with DKA at a site that implemented a subcutaneous insulin protocol compared with 21 control sites. However, this profound reduction has not been seen in all studies, possibly due to differences in protocols or, more likely, local comfort and adjusting to a different process of care. Additionally, in the current era of ubiquitous emergency department (ED) boarding, ED length of stay is of critical importance. A single-institution study found an approximately three-hour reduction in ED length of stay after implementation of a subcutaneous protocol.

Management of DKA using insulin exclusively through the subcutaneous route is safe, acceptable, and can have system-level benefits. As protocolized care has improved the quality of care of patients with DKA, it is critical to adapt institutional protocols to ensure safe implementation of subcutaneous pathways.

References

1. Kitabchi AE, Umpierrez GE, Miles JM, et al. Hyperglycemic crises in adult patients with diabetes. *Diabetes Care*. 2009;32(7):1335-1343.
2. ElSayed NA, Aleppo G, Aroda VR, et al. Diabetes care in the hospital: standards of care in diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1):S267-S278.
3. Andrade-Castellanos CA, Colunga-Lozano LE, Delgado-Figueroa N, et al. Subcutaneous rapid-acting insulin analogues for diabetic ketoacidosis. *Cochrane Libr*. 2016;2016(1).
4. Rao P, Jiang SF, Kipnis P, et al. Evaluation of outcomes following hospital-wide implementation of a subcutaneous insulin protocol for diabetic ketoacidosis. *JAMA Netw Open*. 2022;5(4):e226417.
5. Griffey RT, Schneider RM, Girardi M, et al. The SQuID protocol (subcutaneous insulin in diabetic ketoacidosis): Impacts on ED operational metrics. *Acad Emerg Med*. 2023;30(8):800-808.

EM LITERATURE OF NOTE

PEARLS FROM THE MEDICAL LITERATURE

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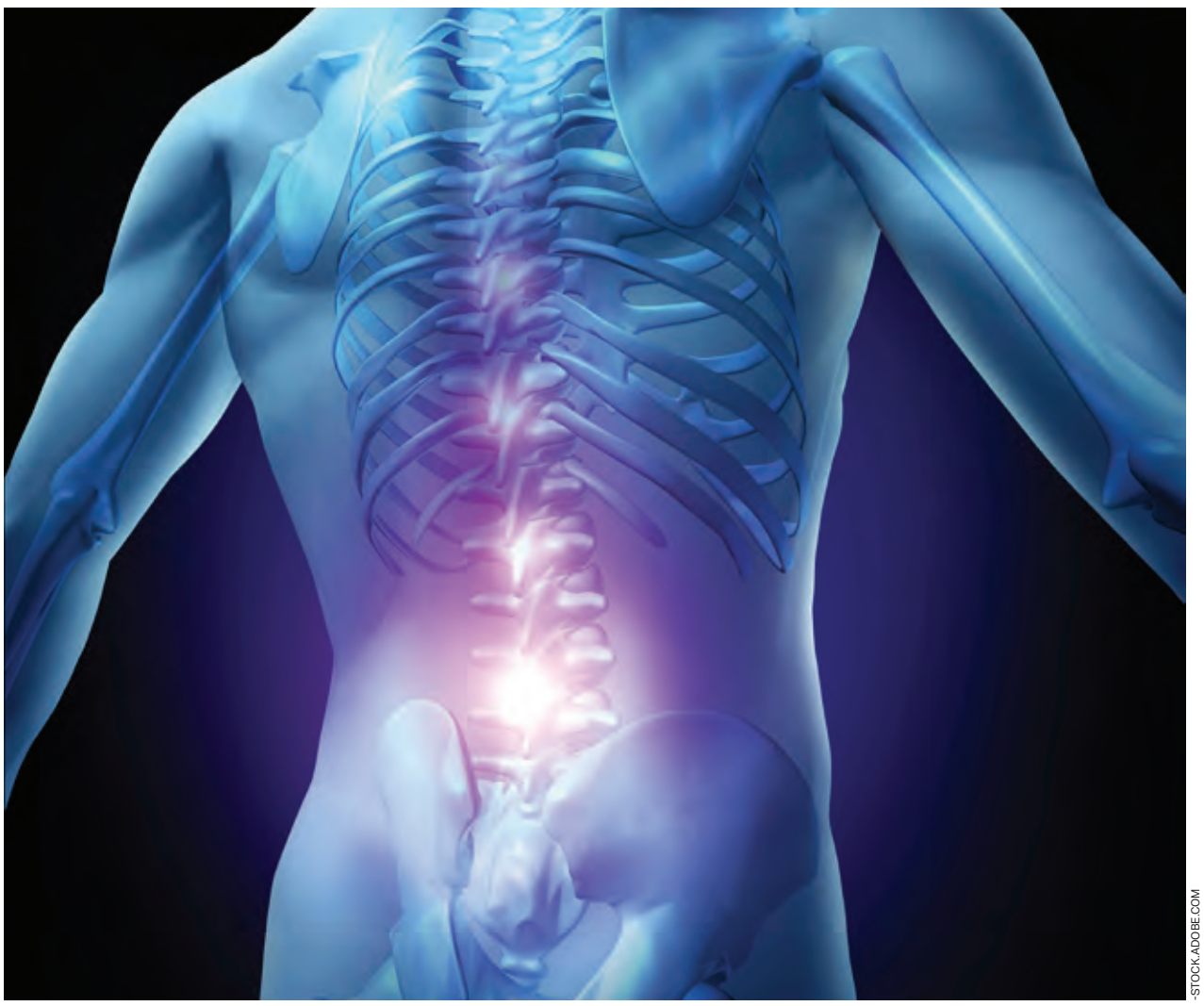
Pearls from EM Literature

Are opiates futile in low back pain?

by RYAN RADECKI, MD, MS



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There is no shortage of evidence regarding the harms of opiate use and misuse. With this in mind, prescriptions for opiates have been dropping in the United States, but were still dispensed at a rate of 43.4 prescriptions annually per 100 persons in 2020.[1] The emergency department remains an important frontier for work in judicious prescribing, but opiate analgesia remains a valuable tool for the initial treatment of a variety of presentations.

Which brings us to acute back pain, a frustrating and challenging condition to manage for patients and physicians alike.

Recently, substantial media coverage summarized the OPAL trial published in *The Lancet*, concerning the use of opiates for acute "spinal" pain—inclusive of both back and neck pain.[2] The lay media spin on the article fell onto side of universally negative against the use of opiates. While this reporting is superficially true, it tells only part of the story, and little regarding its relevance to emergency-department practice.

Patients included in this Australian trial were recruited in both the emergency department and in general practice, and were eligible if the current episode of pain began within the past 12 weeks. The authors define this as "acute" pain, and while we certainly see a share of patients in the emergency department suffering from months of pain, we consider these patients as a distinct presentation from those whose pain has rapidly escalated in the preceding 24 to 48 hours. In fact, the original trial protocol required patients to have had pain for at least two weeks prior to recruitment, further limiting generalizability to the scope of patients presenting to the emergency department.

After enrollment, patients were randomized either to a modified-release oxycodone-naloxone combination opiate, starting with an initial dose containing 5 mg of oxycodone, or placebo. Patients were prescribed a schedule of twice-daily analgesia, and were allowed to increase the dose from 5 mg to 10 mg if pain was not initially well-controlled. This may contrast from typical practice using immediate-release preparations to manage severe pain, or from use of oxycodone-acetaminophen or hydrocodone-acetaminophen combination products. The addition of naloxone to the tablets may also provide a confounder in terms of the analgesia provided.

The trial analgesia protocol also differs from typical prescribing in which acute pain is managed by starting from a maximal dose, determined by the clinically necessary analgesic effect, then rapidly decreased as pain improves. Rather, the research protocol describes a prolonged six-week program of follow-up and repeated prescribing. From an emergency-department perspective, the scope of initial treatment is rarely, if ever, intended to involve a six-week period of treatment. The treatment response for any six-week program is of limited relevance to the acute treatment provided in the emergency department.

Regardless, the reason this study became widely discussed is because the primary outcome of the trial was negative, concluding there was "no evidence that opioids should be prescribed for people with acute non-specific low back or neck pain." It is worth parsing this statement semantically, noting the authors do not conclude opioids should not be prescribed, only that evidence is lacking in support. In this respect, the conclusion is absolutely true.

Only one other study of reasonable quality informs practice with respect to opiate analgesia for low back pain in the emergency department. Published in JAMA in 2015, the authors conducted a three-arm trial comparing cyclobenzaprine, oxycodone-acetaminophen, and placebo.[3] In contrast to the OPAL study, this trial specifically excluded patients whose pain had persisted for more than two weeks. Patients were all prescribed naproxen in addition to the study medication, and were able to take one or two tablets of these immediate-release preparations up to every eight hours, as needed.

The primary outcome was a more relevant seven-day outcome, rather than six-week follow-up. Like OPAL, this was a "negative" trial, in which there was no "statistically significant" difference between functional outcomes between any groups. It is worth noting, however, that the group with the least pain, the greatest improvement, and the fewest days off work was the group taking oxycodone-acetaminophen. A frequentist approach to this trial would conclude, if the trial were to be repeated many times, nearly all the trials would replicate the favorable effects seen for oxycodone-acetaminophen. A Bayesian approach to interpretation would depend on your prior assumptions regarding the efficacy of opiates for treating acutely painful conditions, and may also support the differences favoring oxycodone-acetaminophen, as well.

Finally, even though a seven-day outcome is more relevant, successful acute treatment in emergency medicine may be better measured by time frames of 72 hours or less. In that respect, these trials, particularly OPAL, provide very little insight into whether opiate analgesia supports this early recovery. Only exploratory outcomes provide some supporting evidence that opiate analgesia may improve return to activities and work, but these observations are weak enough they are best represented as equipoise for future research.

After much ado, we may finally arrive back where we started, with little relevant evidence on this specific topic capable of informing our practice in the emergency department. The analgesic options available to us in the emergency department remain limited, as are the options readily prescribed in oral form for discharge. Attempts to discern an advantage associated with skeletal muscle relaxants were unable to find benefit relating to metaxalone, tizanadine, or baclofen.[4] In a similar fashion, even the addition of acetaminophen, or the addition of diazepam, to a non-steroidal anti-inflammatory did not show an advantage in function or analgesia.[5,6]

Frankly, the only reliable option for improving low back pain appears simply to be time, an unsatisfying situation for both patient and practitioner. Opiate analgesia lacks evidence of both efficacy and inefficacy. However, what has been clearly and repeatedly proven are adverse effects and downstream harms from opiate prescribing. Better evidence directly informing the immediate post-encounter period is sorely needed to either confirm or refute what likely remains widespread and common use in the acute setting.

References

1. Centers for Disease Control and Prevention. US opioid dispensing rate map. CDC website. https://www.cdc.gov/drugoverdose/rxrate-maps/index.html. Last updated November 10, 2021. Accessed September 17, 2023.
2. Jones CMP, Day RO, Koes BW, et al. Opioid analgesia for acute low back pain and neck pain (The OPAL trial): a randomised placebo-controlled trial. *The Lancet*. 2023;402(10398):304-312.
3. Friedman BW, Dym AA, Davitt M, et al. Naproxen with cyclobenzaprine, oxycodone/acetaminophen, or placebo for treating acute low back pain: a randomized clinical trial. *JAMA*. 2015;314(15):1572.
4. Friedman BW, Irizarry E, Solorzano C, et al. A randomized, placebo-controlled trial of ibuprofen plus metaxalone, tizanidine, or baclofen for acute low back pain. *Ann Emerg Med*. 2019;74(4):512-520.
5. Friedman BW, Irizarry E, Chertoff A, et al. Ibuprofen plus acetaminophen versus ibuprofen alone for acute low back pain: an emergency department-based randomized study. *Acad Emerg Med*. 2020;27(3):229-235.
6. Friedman BW, Irizarry E, Solorzano C, et al. Diazepam is no better than placebo when added to naproxen for acute low back pain. *Ann Emerg Med*. 2017;70(2):169-176.e1

QUESTION ON PAGE 7

An Illustrated Case of Ethylene Glycol, Direct and Indirect

Clues and discussion

by JASON HACK, MD

Ethylene glycol (EG), also known as ethane-1,2-diol, with the molecular formula CH_2OHCH_2OH, is a colorless, odorless, water-soluble liquid commonly used as antifreeze fluid in automobile radiators, and remains an important cause of significant and sometimes fatal toxicity in the United States, with approximately 6,000 exposures and 20 deaths reported to poison centers in 2021.[1] After possible exposures, early diagnosis and treatment are critical for preventing morbidity and mortality. However, the diagnosis of EG exposures continues to be problematic due to inconsistent history, restricted availability of EG-specific testing, and inconsistent time-sensitive indirect clues in laboratory analysis.

Case

A young adult male with a prior history of self-harm presented 30 minutes after stating he "might have drunk half a gallon of antifreeze." Physical examination revealed an awake, anxious-appearing, tachycardic man with no other abnormalities. Laboratory data were notable for normal renal function, osmol gap 24 (normal range, -14 to +10), anion gap 10 (normal range, 3 to 13), and normal urine without crystals. He was empirically loaded with fomepizole (15 mg/kg). The patient's urine was obtained and compared with the urine of his emergency physician using a Wood's lamp, and the patient's was found to be brightly fluorescent, supporting the presumptive diagnosis of EG poisoning. After 12 hours, his initial EG level returned 130 mg/dL. After resolution of EG poisoning, he was transferred to psychiatry and ultimately discharged home without complication.

Discussion

The diagnosis of EG ingestion is problematic, often made on suggestive indirect information, and must be made quickly because time represents renal injury. The bedside physician must gather as many direct and indirect, classically suggestive data as possible and decide which are "bad" (they probably drank it), or "good" (they probably didn't). The presence of urine fluorescence might be additive to this data collection.

History

Someone saw them drink the EG. This is bad (direct evidence). Their experience drinking the liquid. For example: Doctor: I bet it was terrible when you drank it, huh? Patient: You know Doc, it wasn't so bad, actually sort of sweet. This is bad (indirect evidence).

Laboratory Results

Osmol gap: If the gap is large—this is bad (indirect evidence). However, it is the parent alcohol that causes the gap, and with a typical half-life of three to six hours (peaking at 30 to 60 minutes) once it has been metabolized, *the gap goes away*.[2] Additionally, there are large variations in the range of osmol gaps depending on the equation used to calculate osmolarity and the fact that some people naturally have negative osmol gaps. Because of this large range of values, small osmol gaps cannot be used to eliminate the possibility of toxic alcohol ingestion.[3,4]

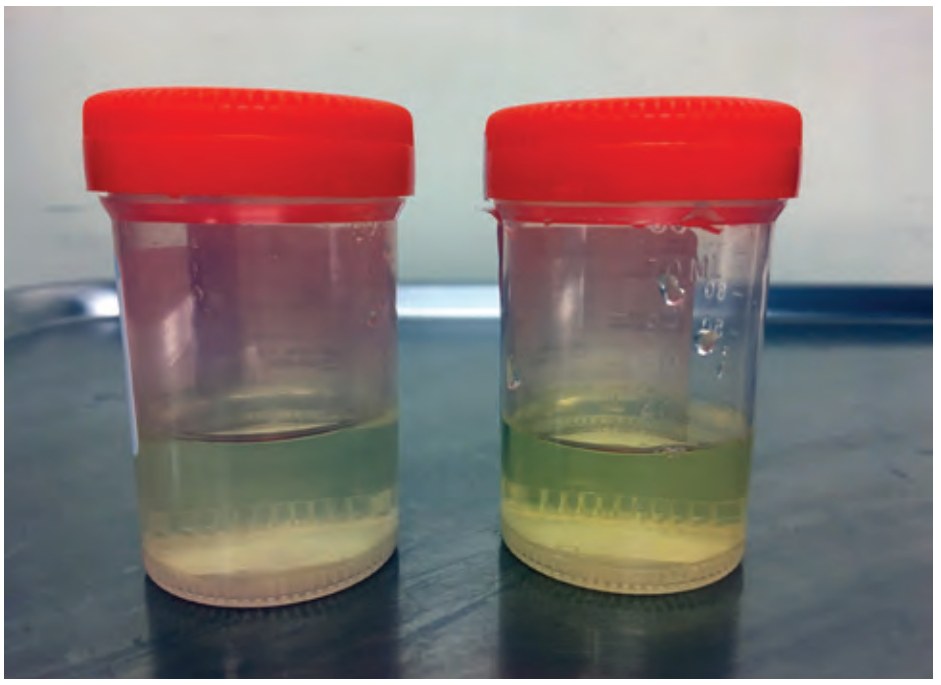
Anion gap metabolic acidosis: if this is large—very bad (indirect evidence). The toxic metabolites of EG ingestions are what cause the acidosis (glycolic, glyoxylic, and oxalic acids as well as lactate) and present later in the ingestion after EG is metabolized to these bad actors. Once there is an anion gap, the horse has left the barn and the remaining definitive treatment is hemodialysis. Additionally, anion gap acidoses occur for other reasons (recall the mnemonic MUDPILES: methanol, uremia, diabetic or alcoholic ketoacidosis, paraldehyde, isoniazid, lactic acidosis, ethanol/ethylene glycol, or salicylates).

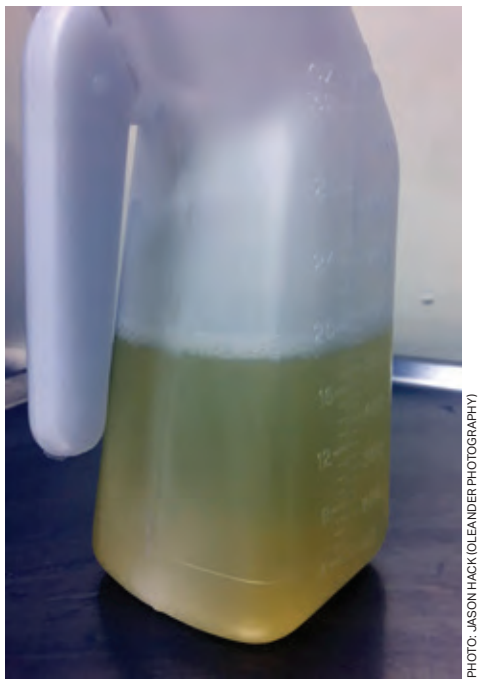
Urine crystals: presence of octahedral or needle-shaped calcium oxalate crystals in the urine—very bad (direct finding). The precipitation of oxalate crystals in the renal tubular lumen resulting in blockage is the primary cause of renal injury. Unfortunately, urinary crystal absence does not rule out EG ingestion.[5]

Urine fluorescence: if the urine is fluorescent—very bad (direct finding). Sodium fluorescein (uranine yellow), is a fluorescent dye that is added to some commercial antifreeze preparations to assist in the location of engine coolant leaks. It is found in concentrations typically between 15 and 20 µg/mL.[6] It causes a yellowish-green fluorescence that is visually detectable to a lower limit of 20 ng/mL in liquid when exposed to ultraviolet light.[7]

In medicine, the application of Wood's lamp produces light photons in the ultraviolet light wavelength spectrum, in a range between 320 nm and 400 nm with a peak at 365 nm. When a substance absorbs light or energy (photons) from one source, its own photons get excited; when these excited photons relax they produce (emit) light of a different color. The re-emitted photons, or fluorescence, have no heat, a longer wavelength, lower energy, and a different color that disappears when the exciting light is removed. This light reaction is used in medicine for many purposes, including detection of dermatologic abnormalities in skin and nails by making them glow, such as dermatophytes (*Tinea versicolor*, etc.), bacterial infections (*Pseudomonas*, etc.) and porphyria (porphyria cutanea tarda, etc.). It is also used in ophthalmologic diagnostics of retinal vasculature imaging and corneal insult assessment. Other uses include detection of scorpions and semen. Urine may also fluoresce under this "blacklight" after ingestion of riboflavin and niacin, amoxicillin, and carbamazepine.[8]

Research into urine fluorescence to help EG diagnosis has been both supportive and dismissive. Winter, et al., in 1990 showed nearly 100 percent detection after volunteer ingestion of fluoresceine at zero to two hours and





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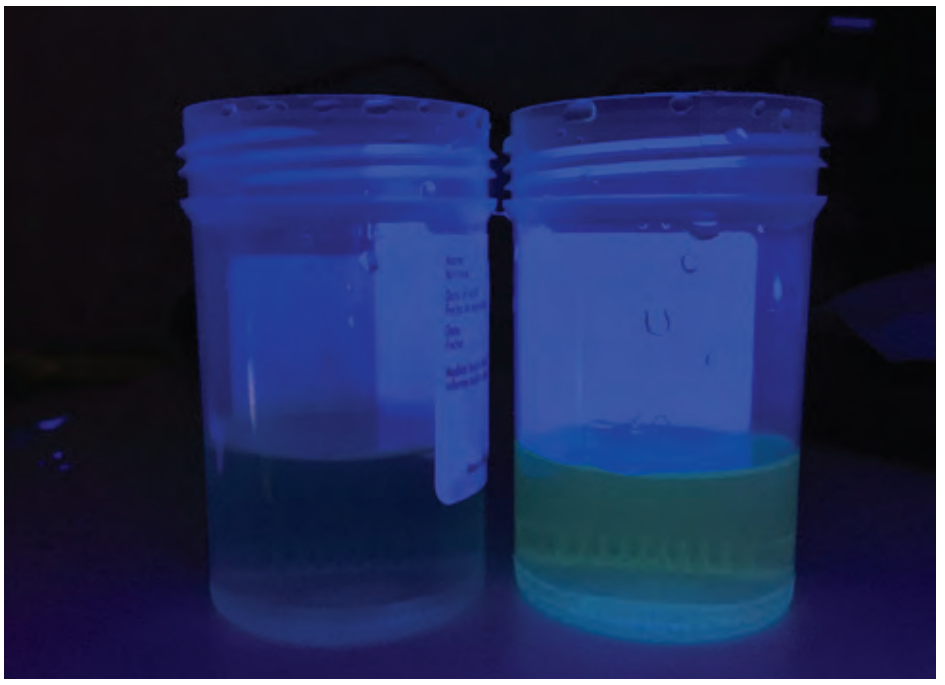

FIGURES 1A and 1B: Comparison of physician's (**LEFT**) and patient's urine (**RIGHT**) under normal light (**TOP**) and under Wood's lamp (**ABOVE**) in urine cups.

FIGURES 2A and 2B: Patient's urine under normal light (**TOP**) and under Wood's lamp (**ABOVE**), demonstrating bright fluorescence in urinal.

60 percent at four hours in volunteers.[6] Other studies have shown poor detection and sensitivity of fluorescent presence in urine, false positives in children, and complication by fluorescence of the containers (some glass and plastic test tubes can glow), all of which may limit clinical use.[9–11]

In our case, despite having a markedly elevated EG level (130 mg/dL), the patient's ED examination was normal; while his laboratory results were notable for elevated osmol gap (with no prior for comparison), he had normal renal function, no anion gap, urine that had no visual abnormality and no crystals. What he did have was brightly fluorescent urine—on its own and when compared with the bedside physician's urine held in various identical containers (a urine cup, a urinal) and exposed to a Wood's lamp. This information was considered in real time as supporting the presumptive diagnosis of EG ingestion and need for treatment.

Conclusion

Diagnosis of EG poisoned patients may be confounded by historical uncertainty, delayed return of definitive toxic alcohol levels, unreliable osmol gaps, and delayed development of other abnormalities. Although experimentally doubted, the detection of strongly positive fluorescent urine in the setting of a suspected recent ingestion of a fluorescein-containing EG product may bring additional support to initiation of therapy (before development of urinary crystals or an anion gap metabolic acidosis). The addition of a concurrent comparison with a control (even if your own) may also be useful. It may also be useful in resource-poor environments where laboratory testing is limited.

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References

1. Gummin DD, Mowry JB, Beuhler MC, et al. 2021 annual report of the National Poison Data System© (NPDS) from America's poison centers: 39th annual report. *Clin Toxicol (Phila).* 60(12):1381-1643.
2. Gessner PK, Parke DV, Williams RT. Studies in detoxication. 86. The metabolism of 14C-labelled ethylene glycol. *Biochem J.* 1961;79:482-489.
3. Hoffman RS, Smilkstein MJ, Howland MA, et al. Osmol gaps revisited: normal values and limitations. *J Toxicol Clin Toxicol.* 1993;31(1):81-93.
4. Takayesu JK, Bazari H, Linshaw MD. Case 7-2006: A 47-Year-Old Man with Altered Mental Status and Acute Renal Failure. *N Engl J Med.* 2006;354:1065-72.
5. Boyer EW, Mejia M, Woolf A, et al. Severe ethylene glycol ingestion treated without hemodialysis. *Pediatrics.* 2001;107(1):172-3.
6. Winter ML, et al. Urine fluorescence using a Woods lamp to detect the antifreeze additive sodium fluorescein: A qualitative adjunctive test in suspected ethylene glycol ingestions. *Ann Emerg Med.* 1990;19:663-667.
7. O'Neil MJ. *Merck Index.* 13th ed. Whitehouse Station (NJ):Merck & Co;2001:736.
8. Sharma S, Sharma, A. Robert Williams Wood: pioneer of invisible light. *Photodermatol Photoimmunol Photomed.* 2016;32:60-65.
9. Wallace KL, Suchard JR, Curry SC, et al. Diagnostic use of physicians' detection of urine fluorescence in a simulated ingestion of sodium fluorescein–containing antifreeze. *Ann Emerg Med.* 2001;38:49-54.
10. Parsa T, Cunningham SJ, Wall SP, et al. The usefulness of urine fluorescence for suspected antifreeze ingestion in children. *Am J Emerg Med.* 2005;23:787–792.
11. Casavant MJ, Shah MN, Battels R. Does fluorescent urine indicate antifreeze ingestion by children? *Pediatrics.* 2001;107(1):113-114.

AIRWAY

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AIRWAY ESSENTIALS FOR TODAY'S EMERGENCY PHYSICIAN

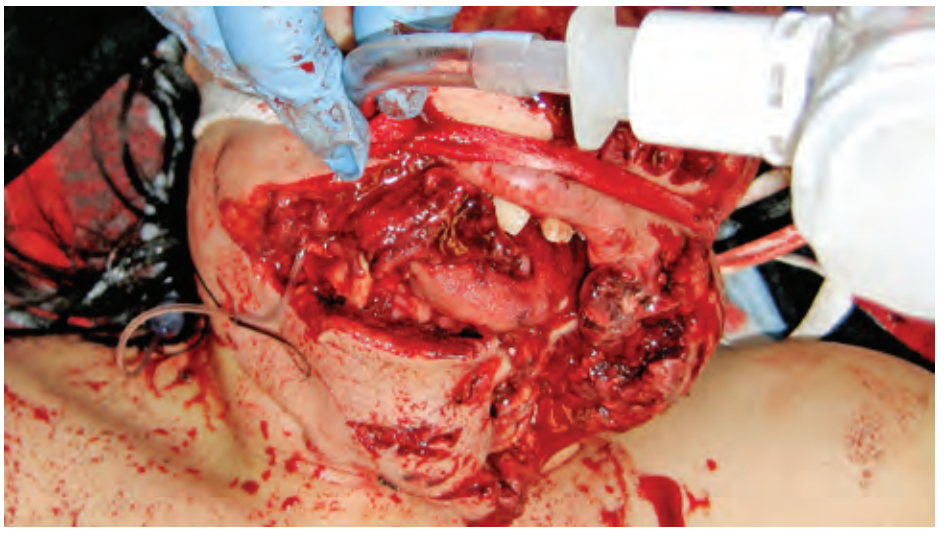
Laryngeal Injuries: An Introduction

by JONATHAN GLAUSER MD, MBA, FACEP; DAVID EFFRON MD, MBA, FACEP

Case

A 37-year-old female was walking home from grocery shopping when she had an encounter with a stray pit bull. For obvious reasons, all history was obtained via emergency medical services and Cleveland police. They were called to the scene to find her with a blood pressure of 135/85, pulse of 110 beats per minute, and respiratory rate of 26 per minute. The major injury was to her face and neck, with lacerations and bites to her legs.

On arrival to the emergency department (ED) she was awake and breathing with stridor. A tracheostomy was considered, but her trachea appeared to be grossly intact and her vocal cords were visible through her wounds. She was intubated with the assistance of bougie and ketamine, and her appearance after intubation is pictured above.



The patient was intubated successfully as the vocal cords were visible through the wound and the trachea appeared to be intact.

Overview

Laryngotracheal wounds occur rarely, whether blunt or penetrating. The larynx is generally protected from blunt injury by the mandible and sternum. These injuries' significance lies, of course, in their high mortality rate. While they constitute less than one percent of all traumatic injuries, laryngeal injury is the second most common cause of death (after intracranial injuries) in patients with head and neck injuries.[1] Missing a significant laryngotracheal injury can lead to airway obstruction and death. Injuries involving the cricoid cartilage are particularly lethal because of asphyxia from airway obstruction, edema, or hematoma. Patients with small lacerations or abrasions of the larynx or trachea may be managed conservatively with close observation, steroids, and serial endoscopy.

Laryngeal trauma occurs in one in 14,000 to one in 30,000 ED visits. Laryngotracheal trauma has been cited as accounting for less than one in 100,000 hospital admissions.[2] As noted above, one major reason for its rarity is that the larynx is protected by the mandible, sternum, and cervical spine.

In children, the larynx is at the level of C_4, and protected by the mandible. Fracturing the larynx requires considerable force, and the great majority of fractures are from blunt high-velocity trauma. These include motor vehicle crashes, sports injury, and penetrating neck injuries.[3]

The most severe occurrence is generally the "clothesline" injury, in which a motorcyclist, dirt biker, or snowmobiler hits a fixed

CONTINUED *on page 22*

item such as barbed wire, fencing net, or a tree branch, thus striking the front of the neck below the helmet. This mechanism may cause crumbling injury to the cartilage or a laryngotracheal separation. It is noteworthy that trauma to the trachea and larynx may be accompanied by vascular damage to the carotid arteries, jugular veins, or esophagus. The example in this case notwithstanding, motor vehicle crashes are the most common cause of laryngeal injuries.[1]

Blunt laryngeal injuries may occur from blunt trauma during fights or sports. Airway obstruction may be immediate or delayed. Unstable patients should have an airway established, generally by tracheostomy or cricothyrotomy. Devascularization and scarring of tissue might result in long-term obstruction. Any intralaryngeal mucosal injury is likely to produce some degree of granulation tissue, which may lead to scarring or obstruction. Prompt repair of the mucosa and avoidance of exposed cartilage is critical. Even with optimal care, patients may become dependent on a tracheostomy and/or gastrostomy in the long term.[4]

Laryngeal injuries may also be classified based on the anatomical site and the structures involved:

- **Type 1:** Supraglottic: epiglottic hematoma or avulsion; hyoid bone fracture; thyroid cartilage fracture; arytenoid dislocation or degloving; endolaryngeal edema; airway obstruction
- **Type 2:** Glottic injuries: hoarseness (generally associated with thyroid-cartilage fracture); vocal-cord edema; endolaryngeal lacerations; or avulsion of vocal cords from the anterior commissure
- **Type 3:** Subglottic injuries: involvement of the cricoid cartilage and trachea with airway compromise; complete cricotracheal disruption with airway obstruction that may be rapidly fatal.[7]

For completeness, four varieties of laryngeal fracture have been described:

1. Supraglottic laryngeal fracture with posterior displacement of the epiglottis and laryngeal inlet
2. Cricotracheal separation
3. Vertical midline fracture, damaging the anterior commissure and separating the thyroid alae
4. Comminuted fracture: more commonly encountered in the older, rigid, and calcified larynx.[8]

Initial evaluation starts with the history: blunt or penetrating, polytrauma or other injuries, and whether the patient is coherent and cooperative or has an altered voice. Does the patient have difficulty breathing or swallowing? The primary management of laryngeal injuries is to evaluate and establish an airway.

The physical examination, as always, follows airway, breathing, circulation, evaluation of cervical spine. Is the patient stridorous or hoarse? The thyroid cartilage should be checked for prominence or loss thereof. The neck should be palpated for subcutaneous air. Is there respiratory distress or a neck hematoma? Is there an open neck wound or palpable cartilage fracture? The patient should be evaluated for hemoptysis, cough, sternal retractions, thrill, or bruit.

Flexible laryngoscopy, CT scan, direct laryngoscopy under general anesthesia, esophagoscopy, ultrasound, or chest X-ray may all be requested by the surgical consultant. If the airway is deemed to be stable, flexible fiber-optic laryngoscopy and computed tomography of the neck may be appropriate initial studies. Flexible laryngoscopy is used to evaluate mucosal tissues of the larynx and upper digestive tract after the primary and secondary trauma surveys are completed. Edema, laryngeal lacerations, mucosal tears, hematomas, exposed muscle, and vocal-cord paralysis or paresis may be diagnosed in such fashion.

Reconstructive computed tomography can assess the laryngeal framework to avoid missing laryngeal fracture and, hopefully, long-term comorbidities. Non-contrast CT can evaluate the cartilaginous and bony components of the hyoid and larynx. Depending on availability and local expertise, videostroboscopy of the larynx and electromyography of the larynx may be performed by the appropriate consultants.

For Schaefer type 1 and 2 injuries, close monitoring is recommended, along with intravenous dexamethasone and nebulized steroids. Conservative management entails observation, elevation of the head of the bed, steam inhalation, voice rest, and IV corticosteroids.

If the patient needs surgical exploration, tracheostomy is the recommended intervention to secure the airway. Early exploration and reconstruction of the laryngeal framework is generally recommended to preserve laryngeal function and to restore normal phonation. Surgical exploration and correction of fractures may utilize mini-plates, 3-D plates, bioresorbable plates, Montgomery intralaryngeal stent, thread, steel wires, titanium mesh to fix fractured laryngeal cartilage, or titanium plates.[3]

The patient was intubated successfully, in

SCHAEFER SYSTEM

One commonly cited classification system for laryngeal injury is the Schaefer (or Schaefer-Fuhrman) system. This was based on a literature review from 90 years of publications regarding acute laryngeal injuries:[2]

- **TYPE 1:** Minor laceration of the endolarynx or fracture without laceration
- **TYPE 2:** A fracture which is not dislocated; a break in the mucosa without exposure of cartilage, extreme edema, or hematoma
- **TYPE 3:** Extensive edema, extensive break in the mucosa, dislocated fractures, exposed cartilage, immobility of vocal cord(s)
- **TYPE 4:** Serious interruption of the anterior larynx, unstable fractures or fracture lines, severe trauma of mucosa
- **TYPE 5:** Total isolation of the trachea and larynx (laryngotracheal separation)[5,6]

the ED under direct vision, as the vocal cords were visible through the wound and the trachea appeared to be intact. An endotracheal tube (ETT) was placed over a bougie. She was transported to the operating suite where a tracheostomy was performed. Significant mucosal lacerations were encountered. The mucosa was repaired to ensure coverage and to prevent scarring. Reduction of laryngeal fractures with fixation was accomplished. A minor esophageal injury was repaired. Soft tissue and skin were repaired last. She was given tube feedings for approximately one week. Major vessels were unharmed per neck CT with contrast. The tracheostomy was kept in place until the larynx was fully healed. She is currently undergoing therapy with a speech pathologist.

While her long-term result is still evolving, it is important to note that complications of laryngeal injuries may be both acute and chronic. Acute complications are upper-airway obstruction and asphyxia. Recurrent nerve injury, hematoma, infection, and death are possible. Chronic complications may cause problems which may cause patients to present to the ED: vocal-cord paralysis; chronic aspiration; recurrent granulation formation; hoarseness; supraglottic, glottic, subglottic, or tracheal stenosis; and recurrent laryngeal nerve dysfunction.

The Difficult Airway: A Brief Overview of the Airway Disruption Algorithm

The American Society of Anesthesiologists (ASA) in 2005 modified the ASA Difficult Airway Algorithm.[9] A surgical airway may be the best choice in patients with oromaxillofacial trauma. In this particular case, a tracheostomy could be performed in the operating suite under somewhat controlled circumstances. More recent ASA guidelines suggest awake intubation for airway disruption if there is a major laryngeal, tracheal, or bronchial tear, provided that the patient is awake, cooperative, hemodynamically stable, and able to maintain adequate oxygen saturation.[10] For infralaryngeal and tracheal injury, recommendations include rapid sequence intubation or direct laryngoscopy (perhaps video-assisted) with a flexible intubation scope with an appropriately sized ETT already loaded over it. The ETT is then introduced over the flexible intubation scope with the cuff positioned over the airway. Positive-pressure ventilation and transtracheal jet ventilation should be avoided proximal to an infralaryngeal tear.[10]

References

1. Malvi A, Jain S. Laryngeal trauma, its types and management. *Cereus*. 2022;14(10): e29877.
2. Schaeffer SD. The acute management of external laryngeal trauma. A 27-year experience. *Arch Otolaryngol Head Neck Surg*. 1992;118(6):598-604.
3. Rai S, Anjum F. *Laryngeal fracture*. Treasure Island, FL: StatPearls Publishing 2023. Available at https://www.ncbi.nlm.nih.gov/books/NBK562276/. Accessed September 16, 2023.
4. Shaker K, Winters R. *Laryngeal Injury*. Treasure Island, FL: StatPearls Publishing 2023. Available at https://www.ncbi.nlm.nih.gov/books/NBK556150/. Accessed September 16, 2023.
5. Schaefer SD. Management of acute blunt and penetrating external laryngeal trauma. *The Laryngoscope*. 2014;124(1):233-44.
6. Moonsamy P, Sachdeva UM, Morse CR. Management of laryngotracheal trauma. *Ann Cardiothorac Surg*. 2018;7:210-216.
7. Bell RB, Verschueren DS, Dierks EJ. Management of laryngeal trauma. *Oral Maxillofac Surg Clin North Am*. 2008;20(3):415-30.
8. Flood LM, Astley B. Anesthetic management of acute laryngeal trauma. *Br J Anesth*. 1982;54(12):1339-43
9. Wilson WC. Trauma airway management. *ASA Newsl*. 2005;69(11):9-16
10. Hagberg CA, Kaslow O. Difficult airway management algorithm in trauma updated by COTEP. *American Society of Anesthesiologists*. 2014;78(9):56-60

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