

Hemostatic Medical Devices for Trauma Use

FDA Public Workshop

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The REBOA Company™



Session III - Assessing Safety and Effectiveness:

Gain an understanding of the types of novel products being developed and their challenges with target patient populations, regulatory strategies and human factors consideration.



ORIGINAL ARTICLE

Death on the battlefield (2001–2011): Implications for the future of combat casualty care

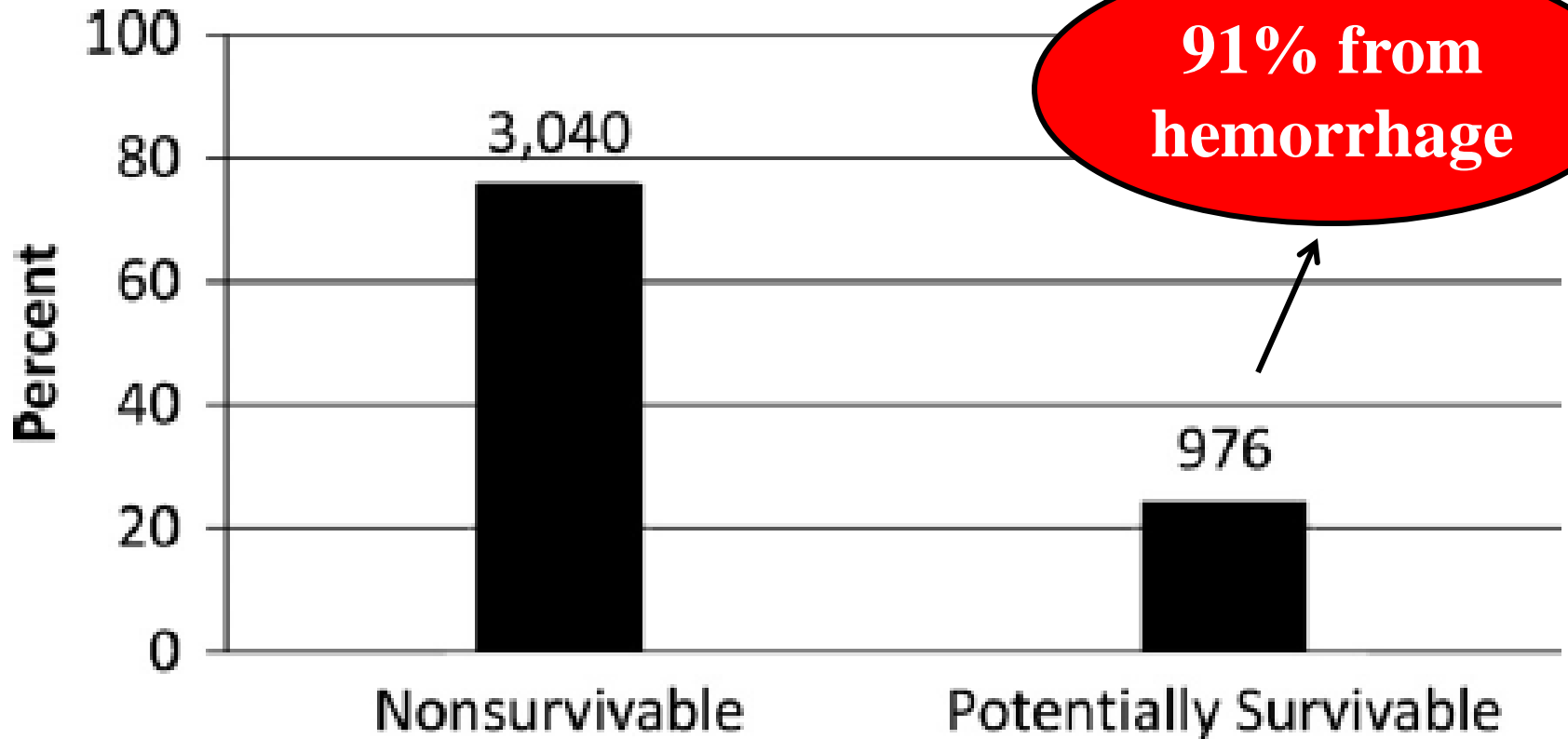
Brian J. Eastridge, MD, Robert L. Mabry, MD, Peter Seguin, MD, Joyce Cantrell, MD, Terrill Tops, MD, Paul Uribe, MD, Olga Mallett, Tamara Zubko, Lynne Oetjen-Gerdes, Todd E. Rasmussen, MD, Frank K. Butler, MD, Russell S. Kotwal, MD, John B. Holcomb, MD, Charles Wade, PhD, Howard Champion, MD, Mimi Lawnick, Leon Moores, MD, and Lorne H. Blackbourne, MD

J Trauma Acute Care Surg 2012;73(Suppl1):S431-S437

Potentially Survivable Death

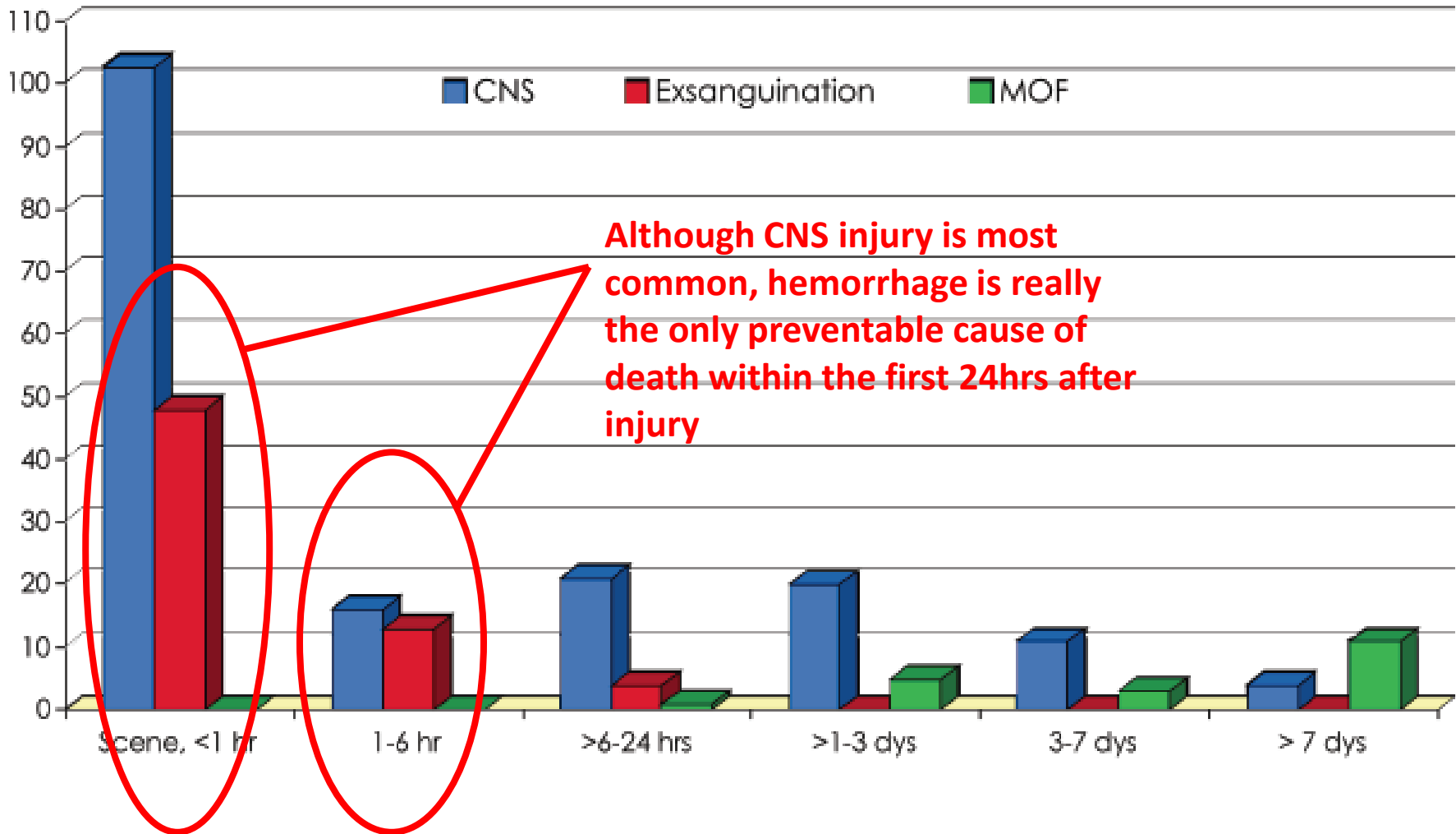


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Civilian Data – Trauma Related Death



Demetriades D, et al. Trauma deaths in a mature urban trauma system: is "trimodal" distribution a valid concept? *J Am Coll Surg* 2005; 201: 343-8

Needed: A 'Trauma Specific' REBOA Catheter



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Selected Features:

- <7 Fr
- Fluoroscopy Free
- One Pass
- Compliant Balloon
- Built in arterial pressure monitoring



Not FDA Cleared
for Human Use

Our Answer – The ER-REBOA™ Catheter



Target Patient Populations: Civilian vs Military

- Trauma is Trauma?
- Patient Demographics
- Co-Morbidities
- Vascular Access
- Remote/ Far Forward Treatment
- Risk / Benefit
- Availability of Funding

Human Factors

- Simplicity and Ease of Use
- Durable, Easy Open Package
- Low Weight and Cube

Regulatory Strategies

- Trauma is Trauma?

Identified Clinical Need

- Top thought leaders – increasing and relentless focus on the “mission”
- Military, FDA, Industry

Availability of Data

Design of Clinical Studies for Trauma

- What gold standard? (Ex: Open Thoracotomy vs REBOA)
- Risk/Benefit
- Informed consent
- Relatively low number of trauma related clinical trials
 - Need trauma trial experienced research nurses, IRBs, CROs, pre hospital providers

Business Questions

- Funding problems
- Are we sufficiently engaged with the commercial innovation ecosystem?

National Research Priorities

- Will there be a Trauma ‘Ice Bucket Challenge’?