Hemostatic Medical Devices for Trauma Use Workshop 2014

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Hemorrhage

- Late 17th century (as a noun): alteration of obsolete hemorrhagy, via Latin haemorrhagia from Greek haimorrhagia, from haima ‘blood’ + the stem of rhēgnunai ‘burst.’
Hemorrhage

- noun: hemorrhage; escape of blood from a ruptured blood vessel, especially when profuse
What’s New?

Hemorrhage is not new….

So why are we here?
Sacrifices of Generation
(2001 – Current; 156 months)

• Burden of wartime injury combined with requirements-driven, programmed research investment has resulted in extraordinary occasion to improve trauma care

Wounded: 52,201
Deaths: 6,833
defense.gov/news/casualty
September 2nd 2014
Understanding Combat Casualty Care Statistics

John B. Holcomb, MD, Lynn G. Stansbury, MD, Howard R. Champion, FRCS, Charles Wade, PhD, and Ronald F. Bellamy, MD

“...if efforts are successful, current war will be the first from which detailed analyses of epidemiology, severity of injury, trauma care and outcomes can be used to, guide research resources for CCC..”
Where Does it Come From?

- Extremities
Where Does it Come From?

- Extremities
- Head & cervical region
Where Does it Come From?

- Extremities
- Head & cervical region
- Torso (thorax, abdomen & pelvis)
Where Does it Come From?

- Extremities
- Head & cervical region
- Torso (thorax, abdomen & pelvis)
- “Junctional” regions
Historical Context

**Chart 1.**—Incidence of arterial wounds among battle casualties in various wars.
Contemporary Rate


Limitations of Initial Studies

- Initial studies on vascular injury focused exclusively on named axial vessels amenable to repair or ligation.
- Thus initial studies on vascular injury did not account for breadth of the whole burden of hemorrhage (i.e. other sites of vascular disruption).
“...majority of deaths on modern battlefield are non-survivable. Improved methods of intracavitary, noncompressible hemostasis may increase survival...”

Joseph F. Kelly, MD, Amber E. Ritenour, MD, Daniel F. McLaughlin, MD, Karen A. Bagg, MS, Amy N. Apodaca, MS, Craig T. Mallak, MD, Lisa Pearse, MD, Mary M. Lawnick, RN, BSN, Howard R. Champion, MD, Charles E. Wade, PhD, and COL John B. Holcomb, MC

**Background:** The opinion that injuries sustained in Iraq and Afghanistan have increased in severity is widely held by clinicians who have deployed multiple times. To continuously improve combat casualty care, the Department of Defense has enacted numerous evidence-based policies and clinical practice guidelines. We hypothesized that the severity of wounds has increased over time. Furthermore, we examined cause of death looking for opportunities of improvement for research and training.

**Methods:** Autopsies of the earliest combat deaths from Iraq and Afghanistan and the latest deaths of 2006 were analyzed to assess changes in injury severity and causes of death. Fatalities were classified as nonsurvivable (NS) or potentially survivable (PS). PS deaths were then reviewed in depth to analyze mechanism and cause.

**Results:** There were 486 cases from March 2003 to April 2004 (group 1) and 496 from June 2006 to December 2006 (group 2) that met inclusion criteria. Of the PS fatalities (group 1: 93 and group 2: 139), the injury severity score was lower in the first group (27 ± 14 vs. 37 ± 16, p < 0.001), and had a lower number of abbreviated injury scores ≥4 (1.1 ± 0.79 vs. 1.5 ± 0.83 per person, p < 0.001). The main cause of death in the PS fatalities was truncal hemorrhage (51% vs. 49%, p = NS). Deaths per month between groups doubled (35 vs. 71), whereas the case fatality rates between the two time periods were equivalent (11.0 vs. 9.8, p = NS).

**Discussion:** In the time periods of the war studied, deaths per month has doubled, with increases in both injury severity and number of wounds per casualty. Truncal hemorrhage is the leading cause of potentially survivable deaths. Arguably, the success of the medical improvements during this war has served to maintain the lowest case fatality rate on record.

**Key Words:** Injury severity score, Autopsy, Combat, Iraq, Afghanistan.
Noncompressible Torso Hemorrhage
A Review with Contemporary Definitions and Management Strategies


Jonathan J. Morrison, MB, ChB, MRCSc, MD
Todd E. Rasmussen, MD

Table 1
Noncompressible torso hemorrhage (NCTH)

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<thead>
<tr>
<th>Anatomic Criteria</th>
<th>Hemodynamic/Procedural Criteria</th>
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<tr>
<td>1. Thoracic cavity (including lung)</td>
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<tr>
<td>2. Solid organ injury ≥ grade 4 (liver, kidney, spleen)</td>
<td>Hemorrhagic shock&lt;sup&gt;a&lt;/sup&gt;; or need for immediate operation</td>
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<td>3. Named axial torso vessel</td>
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<td>4. Pelvic fracture with ring disruption</td>
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**Broader Definition**

**ORIGINAL ARTICLE**

**Military Application of Tranexamic Acid in Trauma Emergency Resuscitation (MATTERs) Study**

Jonathan J. Morrison, MB ChB, MRCS; Joseph J. Dubose, MD; Todd E. Rasmussen, MD; Mark J. Midwinter, BMEdSci, MD, FRCS

**Objectives:** To characterize contemporary use of tranexamic acid (TXA) in combat injury and to assess the effect of its administration on total blood product use, thromboembolic complications, and mortality.

**Design:** Retrospective observational study comparing TXA administration with no-TXA in patients receiving at least 1 unit of packed red blood cells. A subgroup of patients receiving massive transfusion (≥10 units of packed red blood cells) was also examined. Univariate and multivariate regression analyses were used to identify parameters associated with survival. Kaplan-Meier life tables were used to report survival.

**Setting:** A Role 3 Echelon surgical hospital in southern Afghanistan.

**Patients:** A total of 896 consecutive admissions with combat injury, of which 293 received TXA, were identified from prospectively collected UK and US trauma registries.

**Main Outcome Measures:** Mortality at 24 hours, 48 hours, and 30 days as well as the influence of TXA administration on postoperative coagulopathy and the rate of thromboembolic complications.

**Results:** The TXA group had lower unadjusted mortality than the no-TXA group (17.4% vs 23.9%, respectively; P = .03) despite being more severely injured (mean [SD] Injury Severity Score, 25.2 [16.6] vs 22.5 [18.3], respectively; P < .001). This benefit was greatest in the group of patients who received massive transfusion (14.4% vs 28.1%, respectively; P = .004), where TXA was also independently associated with survival (odds ratio = 7.22; 95% CI, 3.016-17.622) and less coagulopathy (P = .003).

**Conclusions:** Use of TXA with blood component-based resuscitation following combat injury results in improved measures of coagulopathy and survival, a benefit that is most prominent in patients requiring massive transfusion. Treatment with TXA should be implemented into clinical practice as part of a resuscitation strategy following severe wartime injury and hemorrhage.


**VASCULAR DISRUPTION with concomitant hemorrhage is a leading cause of death in civilian and military trauma.**

Experience from the wars in Iraq and Afghanistan has led to advances in resuscitation for hemorrhagic shock, with identification of optimum ratios of blood components to be used in this setting. These new strategies are based on early and balanced administration of packed...
The epidemiology of noncompressible torso hemorrhage in the wars in Iraq and Afghanistan

Adam Stannard, MRCS, Jonathan J. Morrison, MRCS, Daniel J. Scott, MD, Rebecca A. Ivatury, RN, James D. Ross, PhD, and Todd E. Rasmussen, MD, San Antonio, Texas

J Trauma Acute Care Surg 2013;74(3):830-834

- Pattern of noncompressible torso injury pattern 13% of patients in JTTR/DoDTR
- Noncompressible torso hemorrhage in 2.2% of patients in JTTR/DoDTR
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
AFME Epidemiologic Study

91% from hemorrhage

J Trauma Acute Care Surg 2012;73(Suppl1):S431-S437
Focus of Lethal Hemorrhage

- **Truncal**: 67.3%, n = 598
- **Junctional**: 19.2%, n = 171
- **Extremity**: 13.5%, n = 119

*J Trauma Acute Care Surg 2012;73(Suppl1):S431-S437*
Modern Device Categories

• **Exovascular**
  - With or without adjunct devices (tourniquets, clamps, compressive bladders or topical hemostatic agents)
  - Basic, non-invasive
  - Provide no inherent circulatory support*

• **Endovascular**
  - More complex & invasive (vascular access)
  - Adjuncts of covered stents & balloons
  - Ability to provide circulatory support
Exovascular

Combat Medical Systems

North American Rescue
“A new era for surgery would become, if we will be able to stop the blood flow in a major artery without exploration, external compression and ligation…”

Professor Nicolay Pirogov  
Russian surgeon – founder of field surgery (circa 1864)
Endovascular

- Zone III neck wound with carotid to jugular arteriovenous fistula treated with covered stent
• Penetrating right axillary artery injury reconstructed with covered stent graft
Endovascular

- Unlike external compression, endovascular occlusion can provide immediate circulatory support proximal to balloon.
- Inflow control distal to balloon occlusion.
- Particularly appealing as less invasive, remote access to sites of torso hemorrhage.
Endovascular Resuscitation Techniques for Severe Hemorrhagic Shock and Traumatic Arrest in the Presurgical Setting

Nicholas A. True, MD; Sean Siler, DO, MBA; James E. Manning, MD

Endovascular

- Balloon technology aimed at reducing catheter size, facilitating arterial access, eliminating need for fluoroscopy & x-ray
How Are We Doing?

• Progress in resolving GDF gaps including hemorrhage control

Military Trauma Research: Answering the Call

Top Priorities in Combat Casualty Care

Gap in Care

2008
9%

Gap Resolved

2014
39%

• Job far from complete..
Conclusion

• Vascular disruption & hemorrhage result in shock & challenge care of the injured patient…

• Burden of injury & requirements-driven, programmed research have defined hemorrhage & honed devices like never before…

• Devices should be categorized, considered & studied in as exovascular or endovascular…

• Devices are complementary, contributing to toolbox for a spectrum of providers