Hemostatic Medical Devices for Trauma Use Workshop 2014

More Data or the Right Data?

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The Right Data

- Continuously learning health system in trauma care...

Americans would be better served by a more nimble health care system that is consistently reliable and that constantly, systematically, and seamlessly improves.
The Right Data

US Defense Center of Excellence Joint Trauma System

JTS

Clinical Questions

JTS

Clinical Guidance
The Right Data

• Application of *focused empiricism*

emp·ir·i·cism
*Noun Philosophy*
noun: *empiricism*
theory that all knowledge is derived from sense-experience

The Right Data

Application of *focused empiricism*

“identifying what works & what does not work, refining it over time & embracing a culture of continuous process improvement..”
The Right Data

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

Abstract

Objectives To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.

Design Systematic review of randomised controlled trials.

“although the costly use of parachutes appears to reduce the risk of injury, their effectiveness has not been proven…”
The Right Data

Joint Theater Trauma System Clinical Practice Guideline

DAMAGE CONTROL RESUSCITATION AT LEVEL IIb/III TREATMENT FACILITIES

<table>
<thead>
<tr>
<th>Original Release/Approval</th>
<th>18 Dec 2004</th>
<th>Note: This CPG requires an annual review.</th>
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<tr>
<td>Reviewed:</td>
<td>Jan 2013</td>
<td>Approved: 1 Feb 2013</td>
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<tr>
<td>Supersedes:</td>
<td>Damage Control Resuscitation at Level IIb / III Treatment Facilities, 11 Oct 2012</td>
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<td>☑ Changes are substantial and require a thorough reading of this CPG (or)</td>
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http://www.usaisr.amedd.army.mil/clinical_practice_guidelines

- While aiming for highest levels of evidence to support clinical practice, JTS has demonstrated the value of integrating the best available observations & findings from trauma care & combat casualty care research into its system of continuous PI
The Right Data Driving Advances

- Advances come in three categories:
  1. Systems or processes of care
  2. Knowledge products
  3. Material or device solutions

- Each advance integrally related to & spurred by “requirements driven”, programmed trauma research

- Investigator-initiated research is of interest to general scientific community without priority or urgency, but military trauma research is...

- ..gap-driven, programmed or “top-down” with urgency for solutions (material or knowledge) to the warfighter
The Right Data Driving Advances

- Development and implementation of a coordinated military trauma system
- Systematization of point of injury care, including methods of hemorrhage control, to reduce preventable death
- Understanding of blood and blood component-based resuscitation from shock
- Identification of life-saving value of enhanced en-route care capabilities during the movement of severely injured patients
Systems of Care

- Defense Center of Excellence Joint Trauma System
  - Coordinated movement of injured from the battlefield with the simultaneous performance of life preserving maneuvers

  “Right patient to the right place, for the right treatment at the right time”
Systems of Care

Military trauma system in Afghanistan: lessons for civil systems?

Col. Jeffrey A. Bailey\textsuperscript{a,b,c}, Maj. Jonathan J. Morrison\textsuperscript{d,e}, and Col Todd E. Rasmussen\textsuperscript{a,c}

*Curr Opin Crit Care 2013;19:569-577

- Evidence-based Performance Improvement (PI)
- Deployed JTS Surgeon (current & future scenarios)
- Deployed Injury & injury management information on more than 50,000 combat injured*
- Dynamic, evidence-based clinical practice guidelines
Eliminating Preventable Death on the Battlefield

Conclusions: A command-directed casualty response system that trains all personnel in Tactical Combat Casualty Care and receives continuous feedback from prehospital trauma registry data facilitated Tactical Combat Casualty Care performance improvements centered on clinical outcomes that resulted in unprecedented reduction of killed-in-action deaths, casualties who died of wounds, and preventable combat death. This data-driven approach is the model for improving prehospital trauma care and casualty outcomes on the battlefield and has considerable implications for civilian trauma systems.
Knowledge Products

- Understanding of blood component-based resuscitation
- Reduced use or elimination of crystalloids
Resuscitation strategies (blood component based)

Mortality FFP: pRBC ratio

Fig. 1. Percentage mortality associated with low, medium, and high plasma to RBC ratios transfused at admission. Ratios are median ratios per group and include units of fresh whole blood counted both as plasma and RBCs.
The Prospective, Observational, Multicenter, Major Trauma Transfusion (PROMMTT) Study

Comparative Effectiveness of a Time-Varying Treatment With Competing Risks

John B. Holcomb, MD; Deborah J. del Junco, PhD; Erin E. Fox, PhD; Charles E. Wade, PhD; Mitchell J. Cohen, MD; Martin A. Schreiber, MD; Louis H. Alarcon, MD; Yu Bai, MD, PhD; Karen J. Brasel, MD, MPH; Eileen M. Bulger, MD; Bryan A. Cotton, MD, MPH; Nena Matijevic, PhD; Peter Muskat, MD; John G. Myers, MD; Herb A. Phelan, MD, MSCS; Christopher E. White, MD; Jiajie Zhang, PhD; Mohammad H. Rahbar, PhD; for the PROMMTT Study Group

Conclusions: Higher plasma and platelet ratios early in resuscitation were associated with decreased mortality in patients who received transfusions of at least 3 units of blood products during the first 24 hours after admission. Among survivors at 24 hours, the subsequent risk of death by day 30 was not associated with plasma or platelet ratios.

Conclusion

PROPPR is the largest randomized study to enrol severely bleeding patients. This study showed that rapidly enrolling and successfully providing randomized blood products to severely injured patients in an EFIC study is feasible. PROPPR was able to achieve these goals by utilizing a collaborative structure and developing successful procedures and design elements that can be part of future trauma studies.
Knowledge Products

Knowledge products vetted by and feed into JTS CPGs

Joint Theater Trauma System Clinical Practice Guideline

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  - Tranexamic acid added as another drug to consider when treating patients with significant hemorrhage
Processes of Care

**Pre-Hospital Clinical Research**

Impact of critical care–trained flight paramedics on casualty survival during helicopter evacuation in the current war in Afghanistan

Robert L. Mabry, MD, MC, Amy Apodaca, MS, Jason Penrod, PharmD, Jean A. Orman, ScD, MPH, Robert T. Gerhardt, MD, MPH, and Warren C. Dorlac, MD, Fort Sam Houston, Texas

- 671 patients (CCFP: 202 / Standard MEDEVAC: 469)
- Mortality (CCFP: 8% / Standard MEDEVAC 15%)
- CCFP system associated with 66% lower risk of mortality

These findings demonstrate that using an air ambulance system based on modern civilian helicopter EMS practice was associated with a lower estimated risk of 48-hour mortality among severely injured patients in a combat setting. (J Trauma Acute Care Surg. 2012;73: S32–S37. Copyright © 2012 by Lippincott Williams & Wilkins)
Conventional platforms are effective in most casualties with low ISS
An ISS exists for which advanced POI en route care improves survival
Implications of Combat Casualty Care for Mass Casualty Events

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Violence from explosives and firearms results in mass casualty events in which the injured have multiple penetrating and soft tissue injuries. Events such as those in Boston, Massachusetts; Newtown, Connecticut; and Aurora, Colorado, as well as those in other locations, such as Europe and the Middle East, demonstrate that civilian trauma may at times resemble that seen in a combat setting. As the civilian sector prepares for and responds to these casualty scenarios, research and trauma practices that have emerged from the wars in Afghanistan and Iraq provide a valuable foundation for responding to civilian mass casualty events. Several lessons learned by the US military were implemented during the response to the bombings in Boston in April of this year.

Military research has found that approximately 25% of persons who die as a result of explosive or gunshot wounds have potentially survivable wounds. These individuals have injuries that are not immediately or necessarily lethal and have a chance to survive if appropriate care is rendered in a timely fashion. The military has learned that implementation of evidence-based, clinical practice guidelines can reduce potentially preventable death. Certain aspects of these lessons also apply to multiple casualty scenarios in civilian settings.

Care During Transport
Evacuation is the next step in the continuum. Findings from military research have shown improved survival associated with the use of more advanced en route care capability. Mabry et al demonstrated a 66% reduction in mortality among patients evacuated by critical care flight paramedic teams (16 deaths among 202 patients) compared with casualties transported by basic emergency medical technicians (71 deaths among 469 patients). The survival benefit was attributed to higher levels of training and experience among flight paramedics. Morrison et al extended these observations in a study of injured military personnel evacuated by the United Kingdom’s physician-led platform (aircraft or airframe used to transport patients) referred to as the medical emergency response team-extended (MERT-E). In this report, there was a 33% reduction in mortality in the...
Conclusion

• Advances from military’s clinical experience & programmed research come as systems of care, knowledge products & material solutions

• Process integrates the “right data” from combat care into requirements driven, programmed research & represents a military continuously learning system for trauma

• All these advances have important implications for civilian trauma care