



Defense Health Board

Filling in the Gaps:

Proposed Updates to the Tactical Combat Casualty Care Guidelines

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Chair, Trauma and Injury Subcommittee

**Defense Health Board Meeting
August 8, 2011**



Overview

- Scope of the Problem: Preventable Deaths in Theater
- Proposed Solutions
 - Junctional Hemorrhage Pressure Control/Combat Ready Clamp™
 - Tranexamic Acid
 - Needle Decompression?



Preventable Deaths

Study data has historically shown that **15 to 25 percent** of combat deaths in Iraq and Afghanistan resulted from potentially survivable injuries

Over 80 percent are due to hemorrhage.

Of those, 70 percent had nontourniquetable or noncompressible wounds.



Preventable Deaths (cont'd.)

Table 4 Causes of Death Among Potentially Survivable Casualties

Cause of Death*	Group 1 (n = 93) (% Total of PS)	Group 2 (n = 139) (% Total of PS)
CNS	12 (13)	8 (6)
Head	11 (12)	6 (4) ($p < 0.04$)
Neck	1 (1)	0 (0)
Spinal cord	1 (1)	3 (2)
Hemorrhage	81 (87)	116 (83)
Tourniquetable (ext)	31 (33)	46 (33)
Noncompressible (torso)	47 (51)	68 (49)
Nontourniquetable (ax/neck/groin)	19 (20)	29 (21)
Airway	14 (15)	14 (10)
Sepsis/MSOF	2 (2)	9 (6)
Total causes of death identified	219	299

* Casualties could have 1 or more cause of death. MSOF indicates multisystem organ failure.



Recent Findings

Preliminary findings of an ongoing analysis of the causes of death in U.S. fatalities from Iraq and Afghanistan indicate that among those Killed in Action (KIA), the most common cause of death is **junctional** hemorrhage.

*-COL Brian Eastridge, M.D., Trauma
Consultant, U.S. Army Surgeon General,
August 3, 2011*



Junctional (truncal) Hemorrhage

Junctional/truncal=

- Groin proximal to inguinal ligament
- Buttocks
- Gluteal and pelvic areas
- Perineum
- Axilla and shoulder girdle
- Base of the neck



Recent Injury Patterns

- **Recently, the incidence of dismounted complex blast injury (DCBI) has increased significantly**
 - Dr. John Holcomb's presentation to the DHB, March 2011
 - U.S. Army Surgeon General appointed Task Force on DCBI

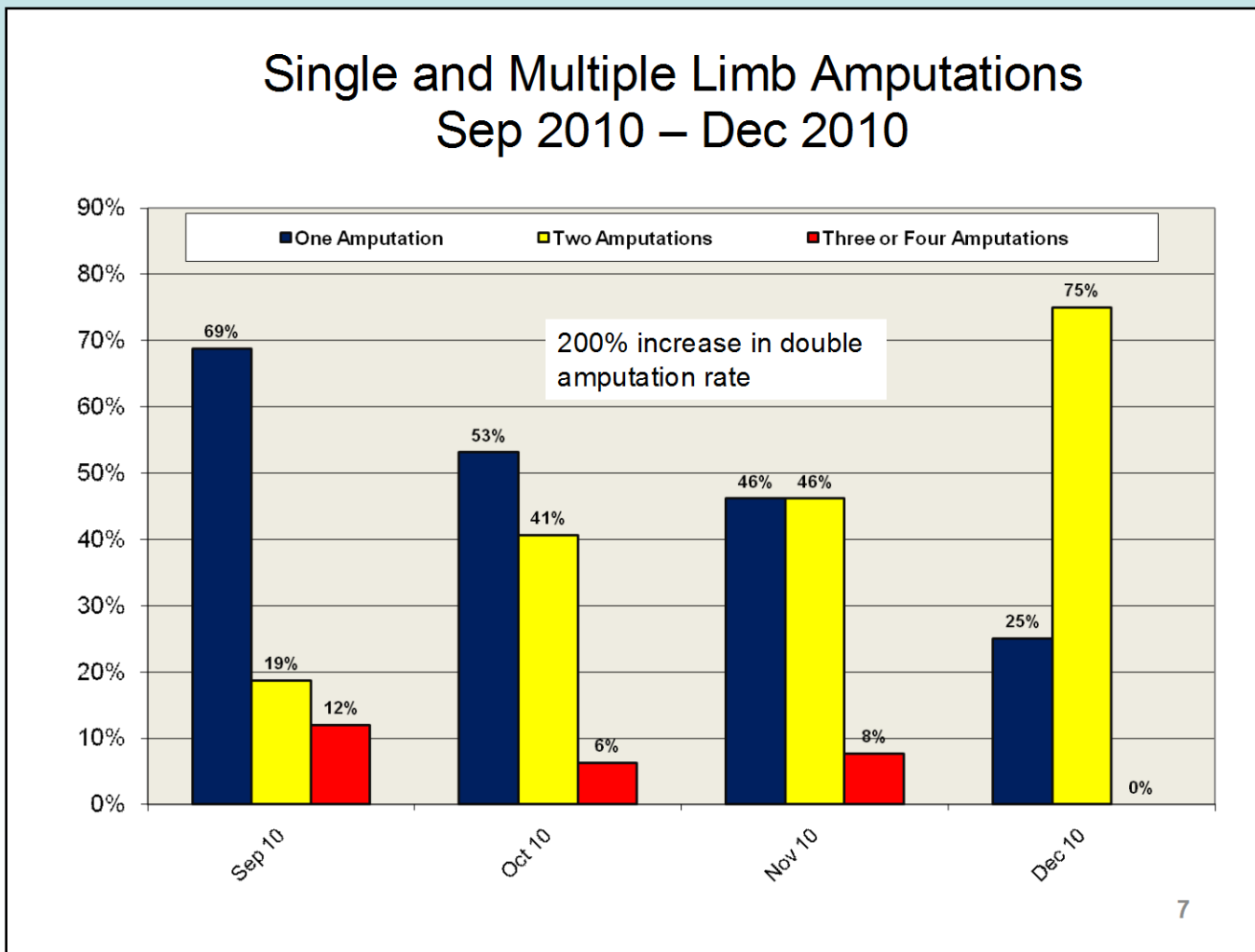


Recent Injury Patterns (Cont'd.)

- Urogenital injuries
- Multiple amputations
- High, extremely proximal amputations that are **not amenable to traditional tourniquet application**



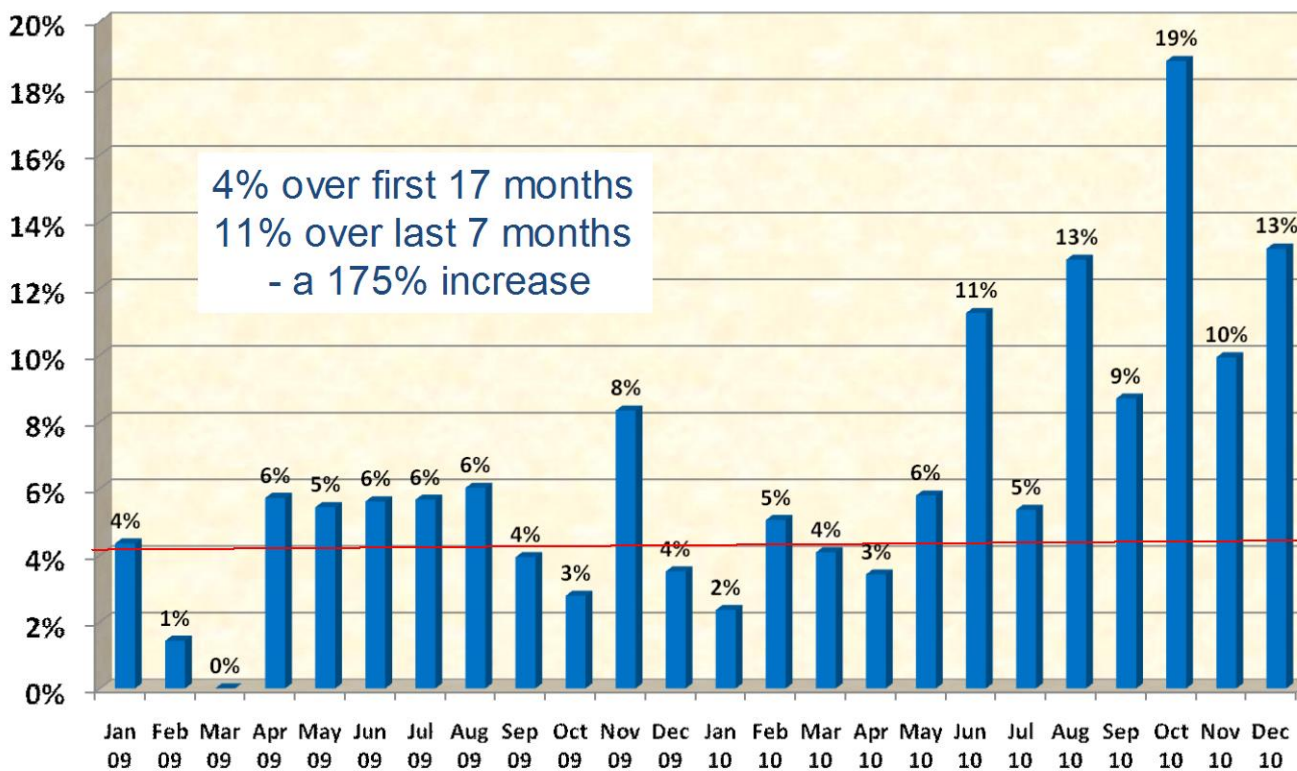
Recent Injury Patterns (Cont'd.)





Recent Injury Patterns (Cont'd.)

Percent of LRMC Trauma Admissions with GU Injuries 2009-2010





DHB RDT&E Recommendation Memorandum, June 14, 2011

- The DHB called for **further study of hemorrhage control mechanisms, particularly non-compressible hemorrhage**
- Specifically, the memo stated:
 - Follow-up studies should be conducted to determine the benefits and risks of using tranexamic acid for trauma patients with non-compressible hemorrhage.
 - Studies documenting the efficacy of truncal tourniquets as well as the ability of users to apply it effectively are needed. Case series describing outcomes from using this device in pre-hospital trauma management would also be useful.



In the Interim...

There is a substantial gap in Tactical Combat Casualty Care that will result in further fatalities due to exsanguination on the battlefield.

We now have options to address this gap.



Treatment Options for Non-Compressible & Junctional Hemorrhage

- Combat Gauze™ is the only TCCC-endorsed tool for treating non-compressible hemorrhage
- Studies suggest that it is safe and efficacious
- However, fatality data suggest that it is unable to stop all significant hemorrhages

Particularly given recent DCBI patterns, medics need an alternative/additional option



Proposed Solutions

1. Mechanical pressure devices to control hemorrhage (i.e. Combat Ready Clamp™)
2. Use of an Antifibrinolytic, Tranexamic Acid, to reduce bleeding by preventing activation of anti-clotting factor



Junctional Hemorrhage Control

MSG Harold Montgomery

Regimental Senior Medic

U.S. Army 75th Ranger Regiment



Discussion/Vote

Mechanical Pressure Devices for
Junctional Hemorrhage Control
(i.e. Combat Ready Clamp™)



Proposed Addition to TCCC Guidelines:

Tranexamic Acid



Review of Evidence

- **CRASH-2 Study:**
 - Large prospective RCT of TXA use in trauma patients
 - Concluded: TXA reduces mortality in trauma patients
 - CoTCCC and JTTS Directors reviewed thoroughly and were not convinced that this was enough evidence to field TXA.
 - Cochrane Review, 2011, concluded that TXA is inexpensive and easy to administer; should be added to normal management of hemorrhaging trauma patients worldwide.
- **MATTERS Study:**
 - Retrospective study analyzing U.K. experience with TXA in Afghanistan
 - Patients admitted to Bastion (busiest MTF in theater)
 - 28-Day mortality was significantly lower in group administered TXA, overall, and in a subset of patients that were massively transfused



CRASH-2 Study

Lancet, Online Article, 2010

Effects of tranexamic acid on death, vascular occlusive events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised, placebo-controlled trial



CRASH-2 trial collaborators*

- Prospective, randomized controlled trial
- 20,211 patients
- TXA significantly reduced all cause mortality from 16.0% to 14.5%
- TXA significantly reduced death due to bleeding from 5.7% to 4.9%



CRASH-2: Timing of TXA Dosing – *Lancet*, 2011

Ⓜ The importance of early treatment with tranexamic acid in bleeding trauma patients: an exploratory analysis of the CRASH-2 randomised controlled trial

The CRASH-2 collaborators*

- Subgroup analysis of 20,211 trauma patients based on time of administration of TXA
- Timing; only deaths due to bleeding
- 3076 overall deaths; 1063 due to bleeding
- **Risk of death due to bleeding was significantly reduced (5.3% vs 7.7%) if TXA given within 1 hour of injury. At 1-3 hrs after injury, also significant (4.8 vs 6.1%)**



The MATTERS Study



U.S. AIR FORCE



The MATTERS Study

Retrospective Study Analysing UK Experience of TXA in CCC

MATTERS Inclusion Criteria

- Combat Injury
- Admitted to Bastion
- Jan 09 to Dec 10 inclusive
- Received ≥ 1 unit PRBC

Received TXA

Did Not Received TXA

•End Points

- Mortality (<24hr and 28-day)
- Blood product use within 24hrs of wounding
- (Coagulation, arterial and venous thrombosis)

Team Aerospace Begins Here!



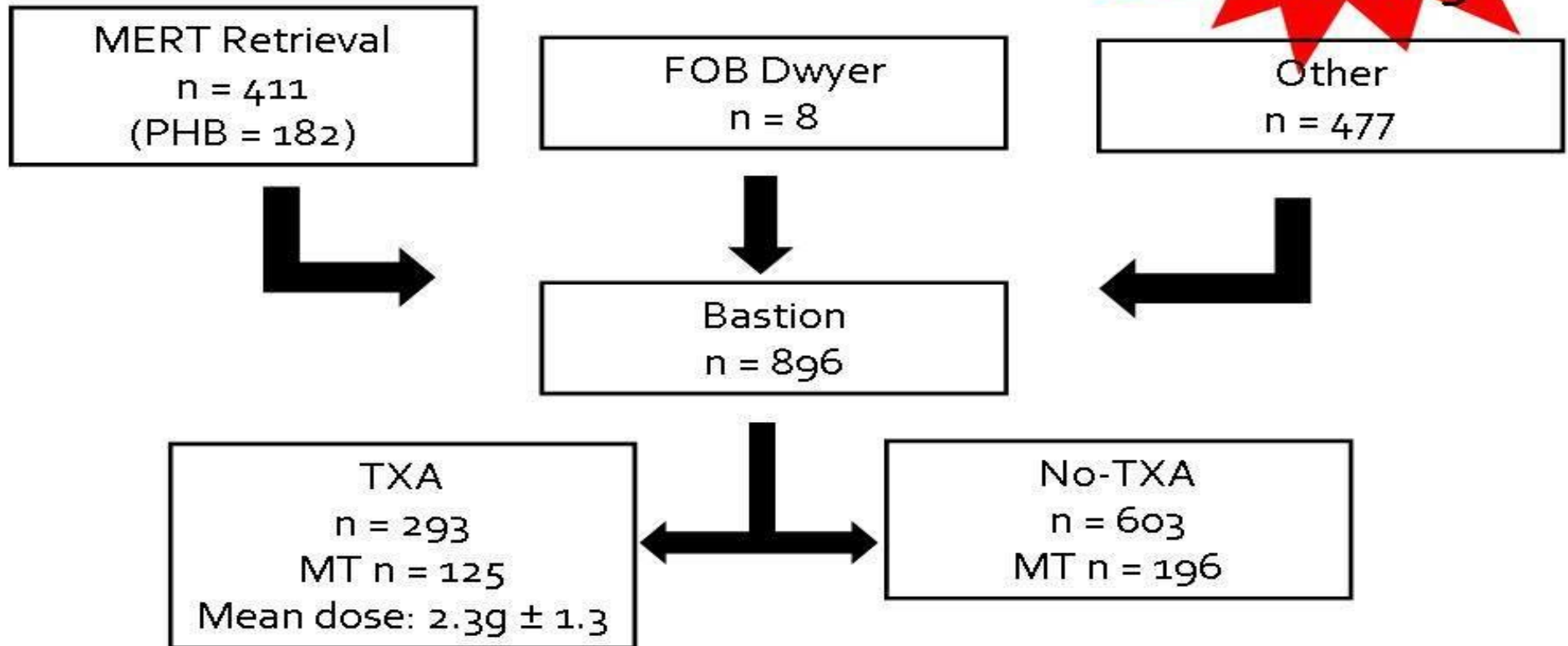
Patients



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Patients



Team Aerospace Begins Here!



Mortality Analysis



Mortality Analysis



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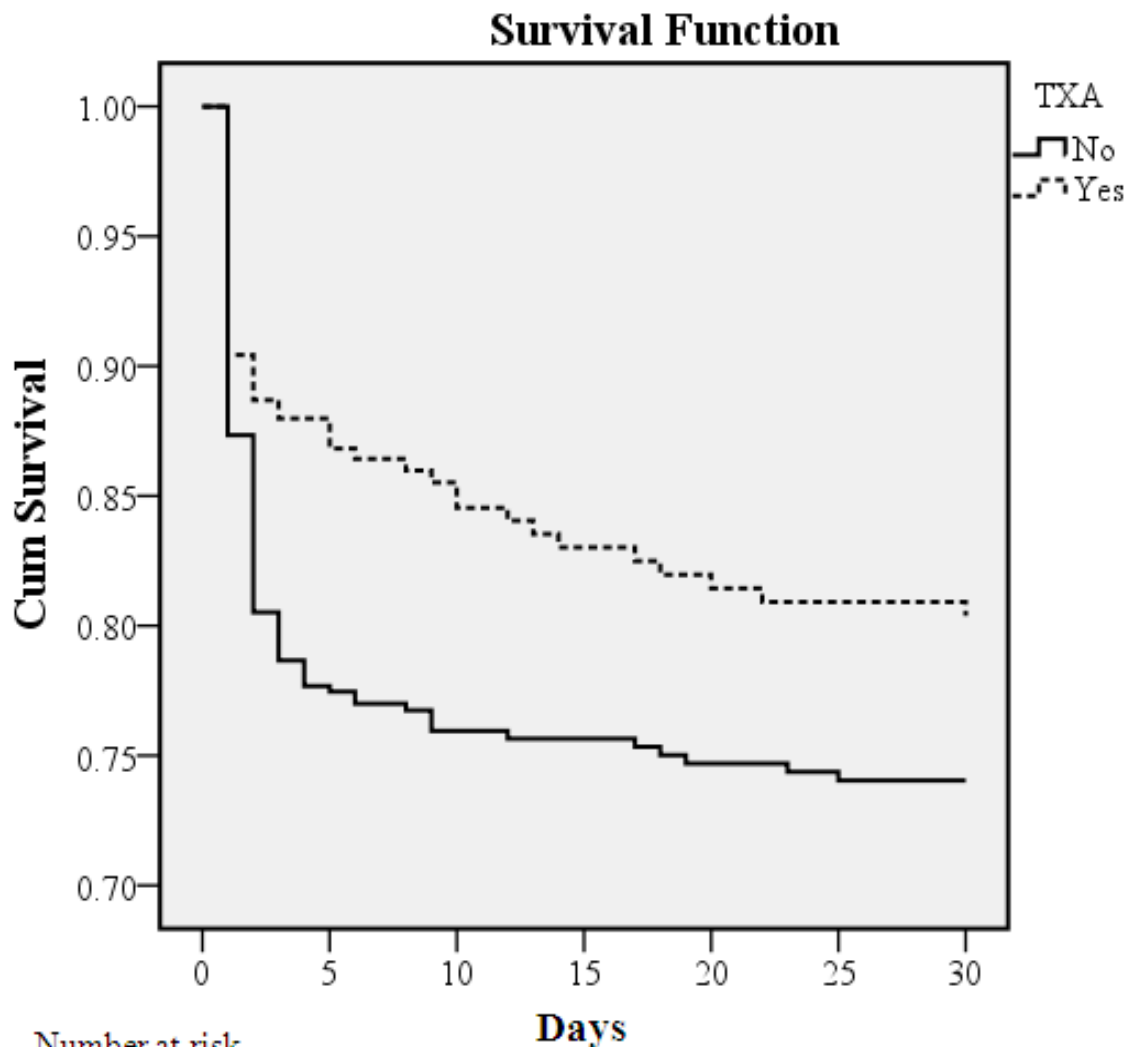
Overall	TXA	No-TXA	p Value
< 24 Hr	8.2%	8.5%	0.892
28 Day	16.4%	23.2%	0.018

MT	TXA	No-TXA	p Value
<24 Hr	8.8%	9.2%	0.907
28 Day	13.6%	27.6%	0.003

Team Aerospace Begins Here!



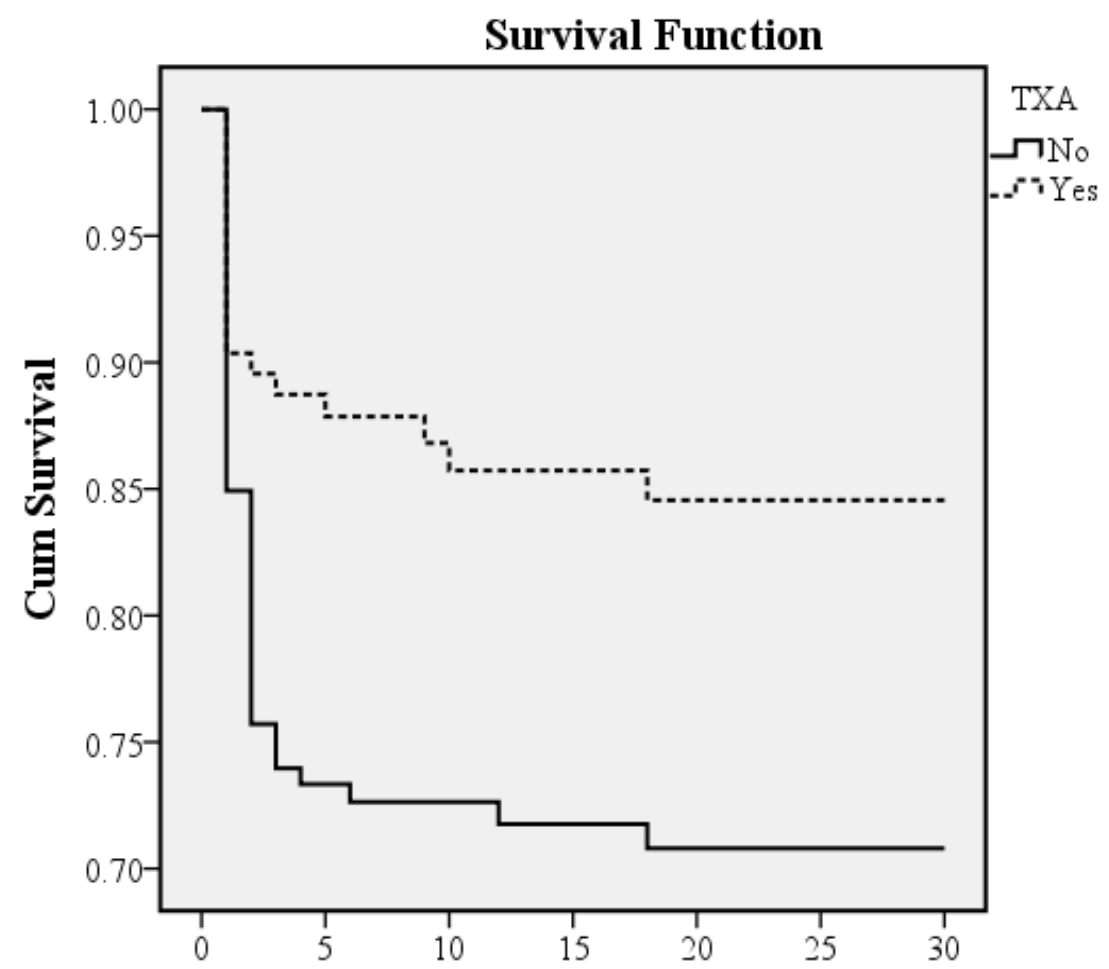
MATTERS: Kaplan-Meier survival curve of the overall cohort



$p = 0.006$
(Wilcoxon
Statistic)



MATTERS: Kaplan-Meier survival curve of the massive transfusion group receiving TXA



	0	5	10	15	20	25	30
TXA:	125	100	78	74	72	72	71
No-TXA:	169	106	87	78	74	74	71

p = 0.004
 (Wilcoxon
 Statistic)



Conclusions

- Tranexamic acid is the only drug to have a demonstrated benefit in treating significant trauma induced hemorrhage.
- Timing of administration appears to be critical in trauma
- Use only within 3 hours of injury; earlier is better.
- Overall safety profile is very reassuring.
- Only available dosing guidance provided by CRASH-2 (1gm load over 10 minutes, then 1gm over 8 hours).
- Bastion experience includes 1 gm dose intravenous push followed by 1 to 2 additional grams within the next few hours.



Proposed Changes

Tactical Field Care and Tactical Evacuation Care sections:

(Add in both sections before Intravenous Fluids section)

- If a casualty is anticipated to need significant blood transfusion (for example: presents with hemorrhagic shock, one or more major amputations, penetrating torso trauma, or evidence of severe bleeding)
 - Administer 1 gram of tranexamic acid in 100 cc in Normal Saline or Lactated Ringer's as soon as possible but not later than 3 hours after injury.
 - Begin second infusion of 1 gm TXA after Hextend or other fluid treatment.



Proposed Recommendation

- That the Board approve the proposed addition to the TCCC Guidelines
- That the Board note in its recommendation memorandum that ongoing analysis of the use of TXA in theater be a critical element in Performance Improvement Measures by the Services



Discussion/Vote