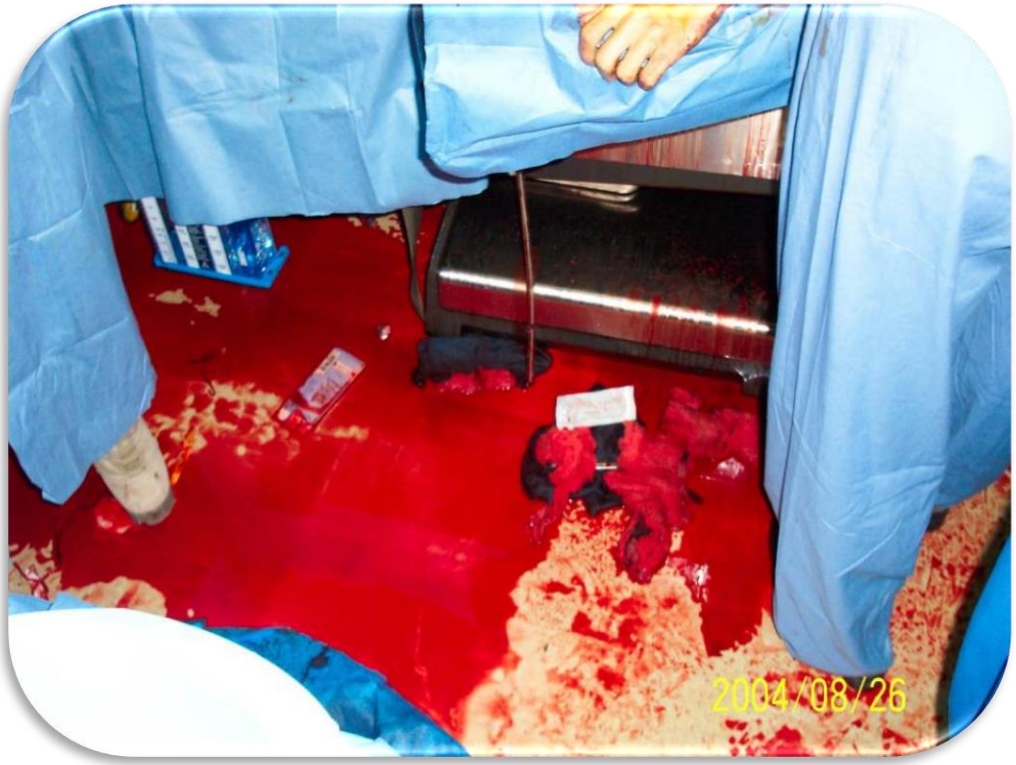
THOR and The Rationale for Whole Blood



Phil Spinella, MD, FCCM
Professor, Pediatrics
Washington University in St Louis
15 Nov 2018

The THOR Network

- An international multidisciplinary network of civilian and military providers ranging from first responders and medics to critical care physicians and from basic scientists to clinical trialists.

- VISION: To improve outcomes from traumatic hemorrhagic shock by optimizing the acute phase of resuscitation.

The THOR Network

- MISSION: To develop and implement best practices for prehospital care through to the completion of the acute phase of hemorrhagic shock resuscitation.

- The THOR Network will execute this mission through a multidisciplinary collaborative approach to research, education, training, and advocacy.

THOR Network Origin

- 2010 email: Strandenes to Spinella to Chair Scientific Steering Committee
- 2011 meeting in Innsbruck Austria
  - Epiphany at Limerick Bill's Irish bar.
  - Start yearly conference with international experts on trauma resuscitation to expedite knowledge transfer and change practice.
- June 2011 first meeting in Bergen
- June 2012-present meetings at Solstrand

Strength in Balance

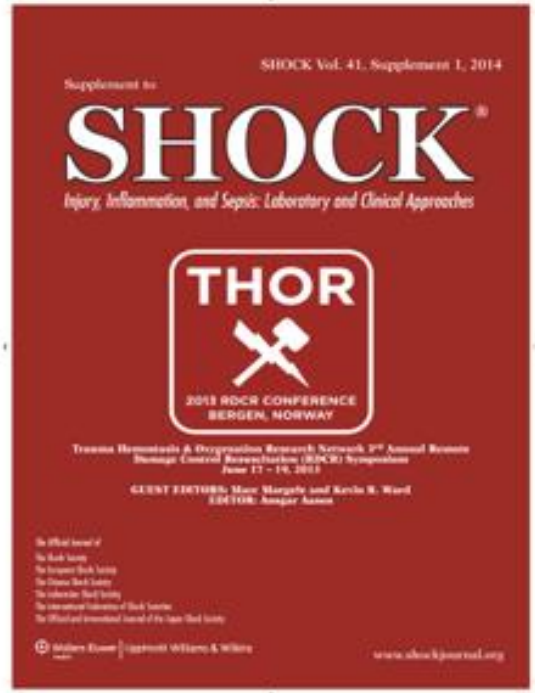
- Civilian and Military
- North American and Europe
  - Australia, South America, Asia
- Prehospital and in hospital providers
- Medics to basic scientists
- Multi-disciplinary

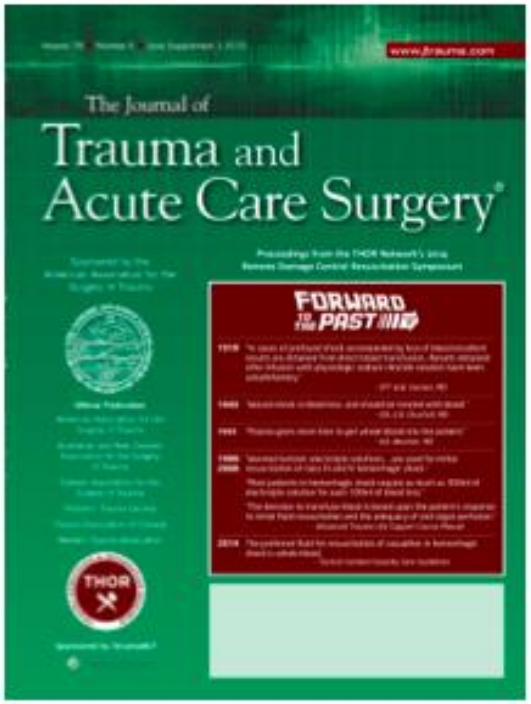
- Major key to success of Network

THOR Activities

- Annual meeting in Norway
  - Annual supplement
  - Position papers
- Satellite meetings
  - Italy, Switzerland, Brazil
  - AABB (Boston, San Diego)
- RDCR Training manual (in production)
- DCR Textbook (in production)


TRANSFUSION
Viking Laws
A Supplement to TRANSFUSION
The THOR Network 2012 Remote Damage Control Resuscitation Symposium
Guest Editor: Philip C. Spinella, MD, FCCM
Assistant Guest Editor: Shibani Pati, MD, PhD


SHOCK Vol. 41, Supplement 1, 2014
Supplement to
SHOCK
Injury, Inflammation, and Sepsis: Laboratory and Clinical Approaches
THOR
2013 RDCR CONFERENCE
BERGEN, NORWAY
Trauma Hemostasis & Oxygenation Research Network 3rd Annual Remote Damage Control Resuscitation (RDCR) Symposium
June 17 – 19, 2013
GUEST EDITORS: Marc Maegele and Kevin R. Ward
EDITOR: Ansgar Asmus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FORWARD TO THE PAST III
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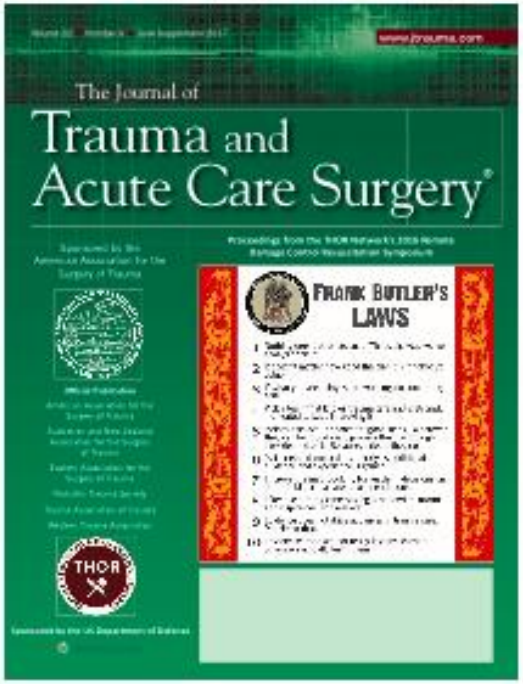
TRANSFUSION
GLOBAL PREHOSPITAL CARE ROOTED IN A HISTORY OF MILITARY INNOVATION
BATTLEFRONT TRANSFUSION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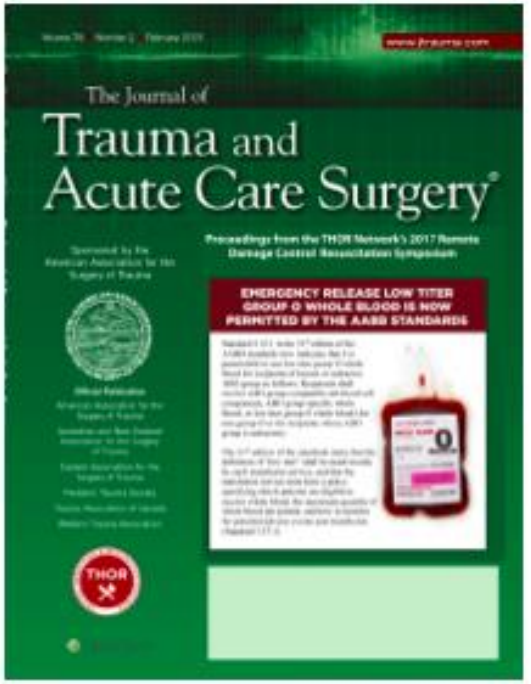
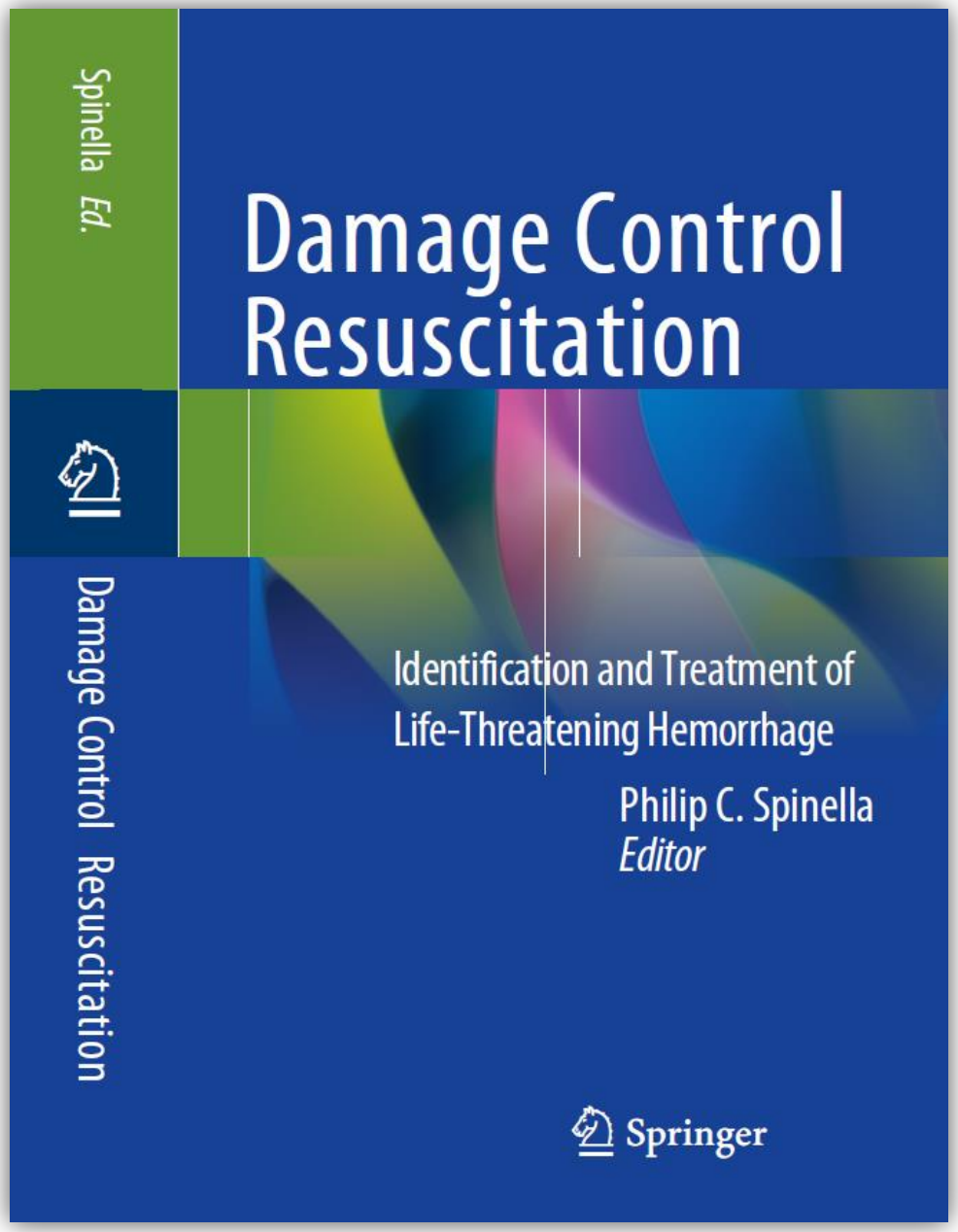
FRANK BUTLER'S LAWS
THOR


www.jtrauma.com
The Journal of
Trauma and
Acute Care Surgery
Proceedings from the THOR Network's 2017 Remote Damage Control Resuscitation Symposium
EMERGENCY RELEASE LOW TITER GROUP O WHOLE BLOOD IS NOW PERMITTED BY THE AABB STANDARDS
THOR

Trauma Hemostasis and Oxygenation Research Network position paper on the role of hypotensive resuscitation as part of remote damage control resuscitation

Thomas Woolley, MD, Patrick Thompson, Emrys Kirkman, PhD, Richard Reed, Sylvain Ausset, MD, Andrew Beckett, MD, Christopher Bjerkvig, MD, Andrew P. Cap, MD, PhD, Tim Coats, MD, Mitchell Cohen, MD, Marc Despasquale, Warren Dorlac, MD, Heidi Doughty, Richard Dutton, MD, Brian Eastridge, Elon Glassberg, MD, Anthony Hudson, Donald Jenkins, MD, Sean Keenan, MD, Christophe Martinaud, PhD, Ethan Miles, Ernest Moore, MD, Giles Nordmann, Nicolas Prat, PhD, Joseph Rappold, MD, Michael C. Reade, MBBD D Phil, Paul Rees, MD, Rory Rickard, PhD, Martin Schreiber, MD, Stacy Shackelford, MD, Håkon Skogran Eliassen, Jason Smith, MD, Mike Smith, PhD, Philip Spinella, MD, Geir Strandenes, MD, Kevin Ward, MD, Sarah Watts, PhD, Nathan White, MD, *and* **Steve Williams**, *Birmingham, United Kingdom*

ABSTRACT: The Trauma Hemostasis and Oxygenation Research (THOR) Network has developed a consensus statement on the role of permissive hypotension in remote damage control resuscitation (RDCR). A summary of the evidence on permissive hypotension follows the THOR Network position on the topic. In RDCR, the burden of time in the care of the patients suffering from noncompressible hemorrhage affects outcomes. Despite the lack of published evidence, and based on clinical experience and expertise, it is the THOR Network's opinion that the increase in prehospital time leads to an increased burden of shock, which poses a greater risk to the patient than the risk of rebleeding due to slightly increased blood pressure, especially when blood products are available as part of prehospital resuscitation. The THOR Network's consensus statement is, "In a casualty with life-threatening hemorrhage, shock should be reversed as soon as possible using a blood-based HR fluid. Whole blood is preferred to blood components. As a part of this HR, the initial systolic blood pressure target should be 100 mm Hg. In RDCR, it is vital for higher echelon care providers to receive a casualty with sufficient physiologic reserve to survive definitive surgical hemostasis and aggressive resuscitation. The combined use of blood-based resuscitation and limiting systolic blood pressure is believed to be effective in promoting hemostasis and reversing shock" (*J Trauma Acute Care Surg.* 2018;84: S3–S13.


Spinella Ed.
Damage Control Resuscitation
Damage Control Resuscitation
Identification and Treatment of Life-Threatening Hemorrhage
Philip C. Spinella
Editor
Springer

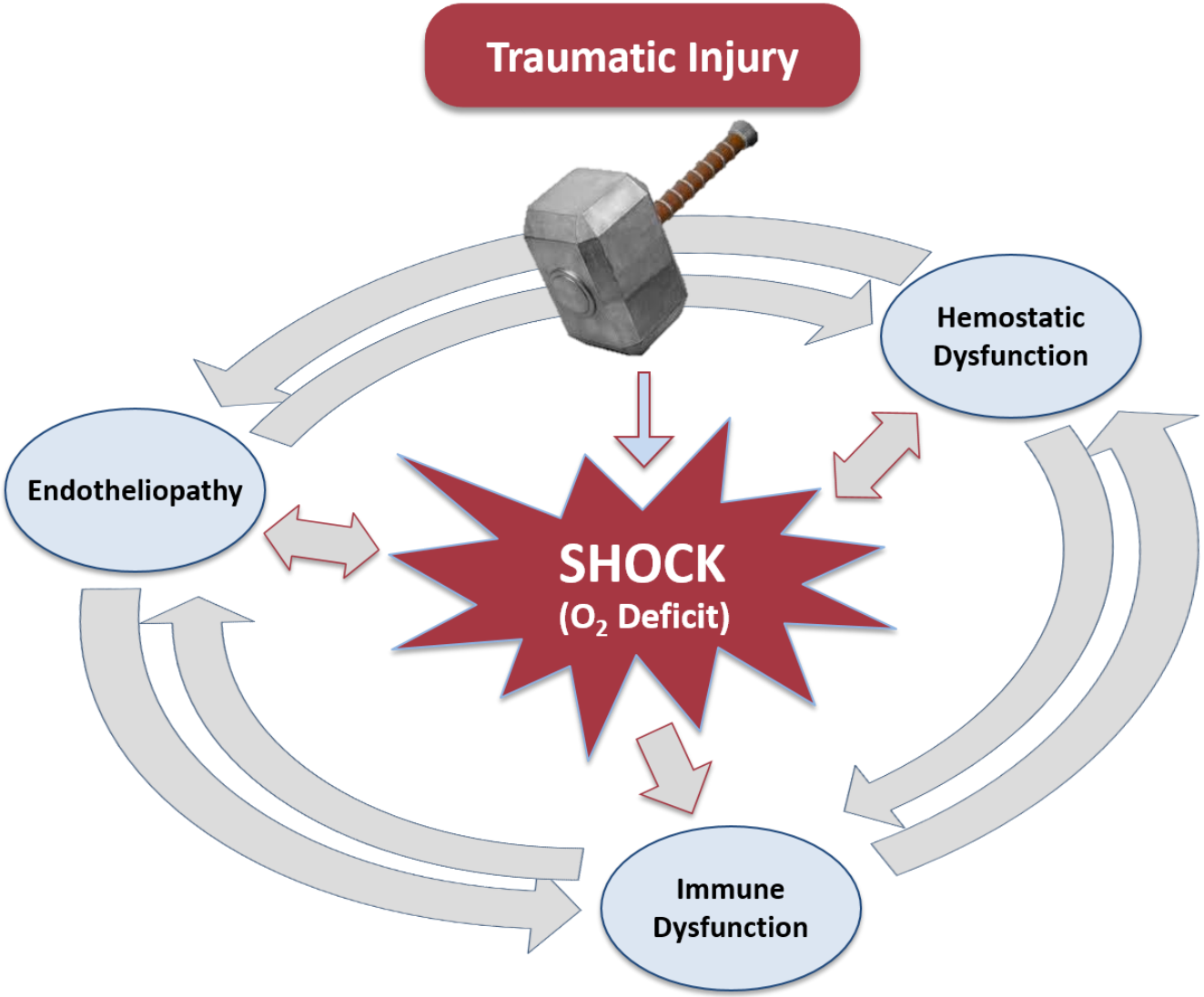
Remote Damage Control Resuscitation

- Prehospital/Presurgical application of Damage Control Resuscitation (DCR) principles
- Goals are the same RDCR and DCR
- How achieved differs between RDCR and DCR
  - Austere environment
  - Airway management
  - Monitoring capabilities
  - Therapeutic options

RDCR Principles – Blood Failure

- Blood is an organ and can fail like any other organ
- Term emphasizes the interaction between blood systems
  - Promote a balanced approach to resuscitation
- Balanced/simultaneous treatment
  - Shock, hemostatic and endothelial dysfunction
  - Prevents the exacerbation of another system

RDCR Principles – Trauma Induced Blood Failure



Trauma Induced Blood Failure: Frequent at Admission

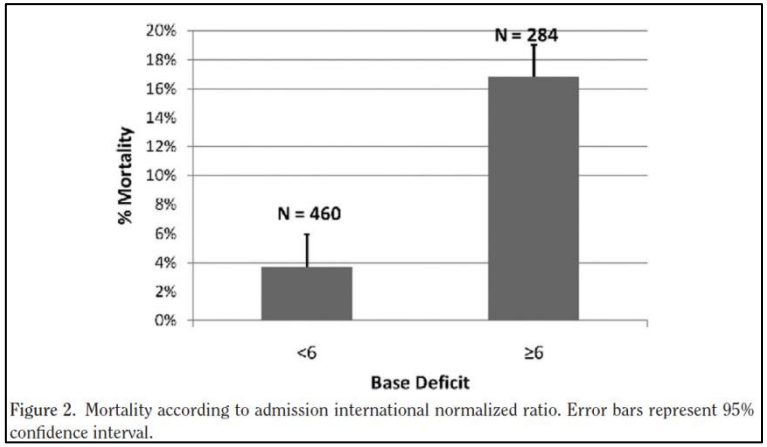


Figure 2. Mortality according to admission international normalized ratio. Error bars represent 95% confidence interval.

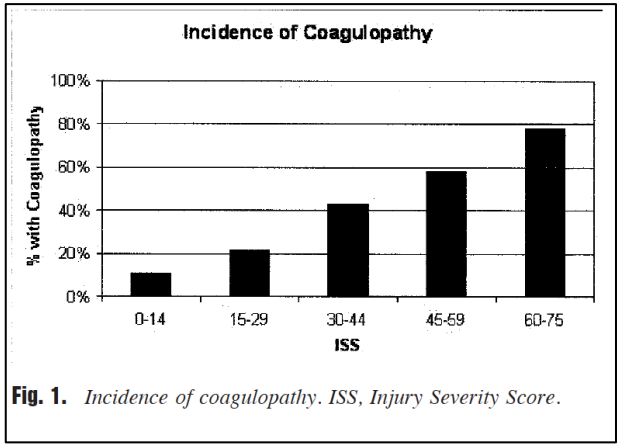
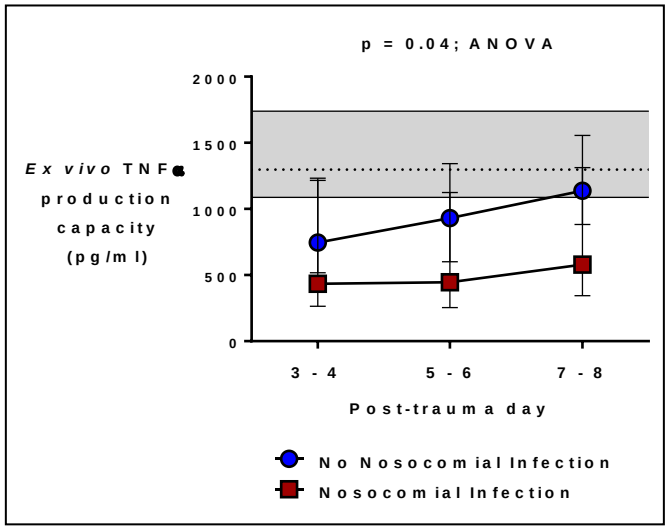
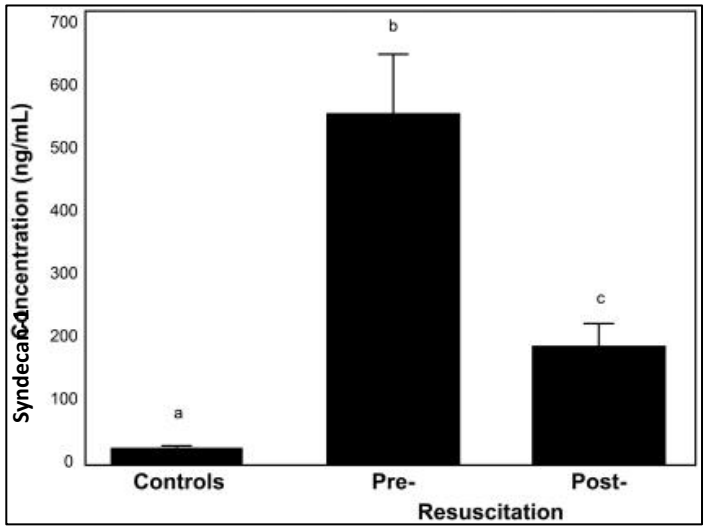


Fig. 1. *Incidence of coagulopathy. ISS, Injury Severity Score.*





Rodriguez EG. Jam Coll Surg. 2017
Brohi. J Trauma. 2003

Patregnani J. Ped Crit Care Med.2012
Muszynski J. Shock. 2014

Trauma Induced Blood Failure: Correlates with Mortality

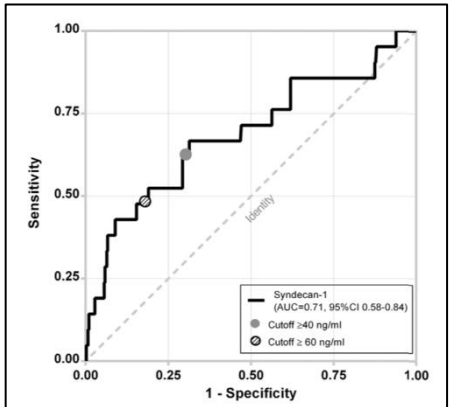


Figure 2. Receiver operating characteristic curve analysis and identification of the optimal cutoff with the Youden index (J) for syndecan-1 as predictor of 24-hour in-hospital mortality in 410 trauma patients. Patients were defined as having the endotheliopathy of trauma (EoT+) based on a syndecan-1 level ≥40 ng/mL selected with the Youden index (J = 0.35) as the cutoff value that maximized the sum of sensitivity and specificity in predicting 24-hour in-hospital mortality. The point that corresponds to the cutoff for the upper quartile of syndecan-1 levels (≥60 ng/mL) is also represented here. AUC, area under the curve.

Table 2. Logistic regression results for inhospital mortality

Variable	Odds Ratio (95% confidence interval)	*p*
Injury Severity Score	1.1 (1.1–1.1)	<.001
Coagulopathy	2.2 (1.1–4.5)	.025
Shock	3.0 (1.1–7.5)	.019
Glasgow Coma Score	0.85 (0.80–0.91)	<.001

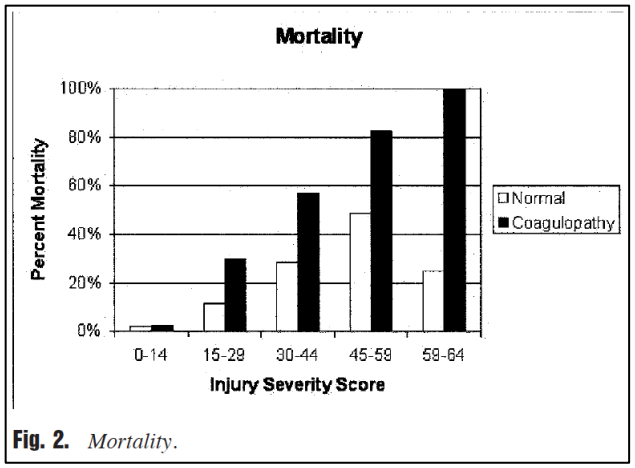
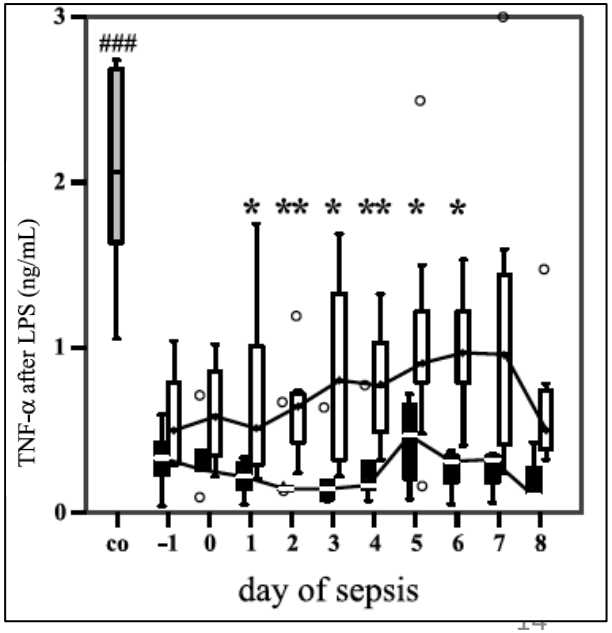


Fig. 2. *Mortality.*



Rodriguez EG. Jam Coll Surg. 2017
Brohi. J Trauma. 2003

Patregnani J. Ped Crit Care Med.2012
Muszynski J. Shock. 2014

Epidemiology and Outcomes

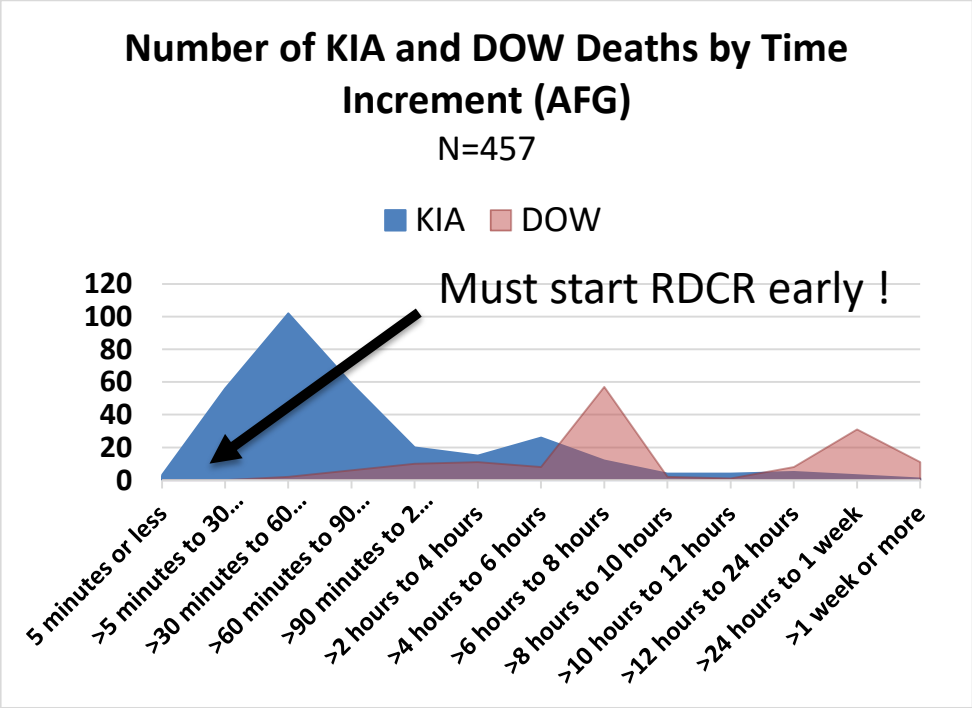
- Trauma most common cause of death
  - 1-46 years of age in US
- Hemorrhage most common cause of medically preventable death
- Hemorrhagic death occurs fast
  - 85% of hemorrhagic deaths occur within 6 hours
  - Median time to death is between 1 to 3 hours
- **Rapid treatment of traumatic hemorrhage**
  - **Greatest impact on survival**

Eastridge et al. *J Trauma* 2013.
Kotwal et al. *Arch Surg* 2011.
Spinella et al. Blood Reviews 2009

Fox, E.E. Shock 2017. 2.
Holcomb, J.B., Jama, 2015. 3.
Sauaia, A. Journal of Trauma and Acute Care Surgery, 1995.
Demetriades, D. J Am Coll Surg, 2004.

Why focus on prehospital ?

- Where vast majority of deaths occur
  - Preventable deaths
  - Military and Civilian
- Hemorrhagic deaths occur fast



Shackelford, et al.
JTS 2016.

Preventable Deaths from Hemorrhage After Trauma

- 148,000 US civilian traumatic deaths
- **30,000 potentially preventable** trauma deaths due to **hemorrhage** per year in the US
  - 25,000 of these deaths occur in prehospital phase of resuscitation

National Academy Sciences Report: National Trauma System, 2016
Spinella PC, Cap AP, Current opinion in Hematology. 2017

Blood transfusion management in the severely bleeding military patient

Curr Opin Anesthesiol 2018, 31:000–000
DOI:10.1097/ACO.0000000000000574

Jennifer M. Gurney[a,b] *and Philip C. Spinella*[b,c]

Table 1. Damage control resuscitation principles

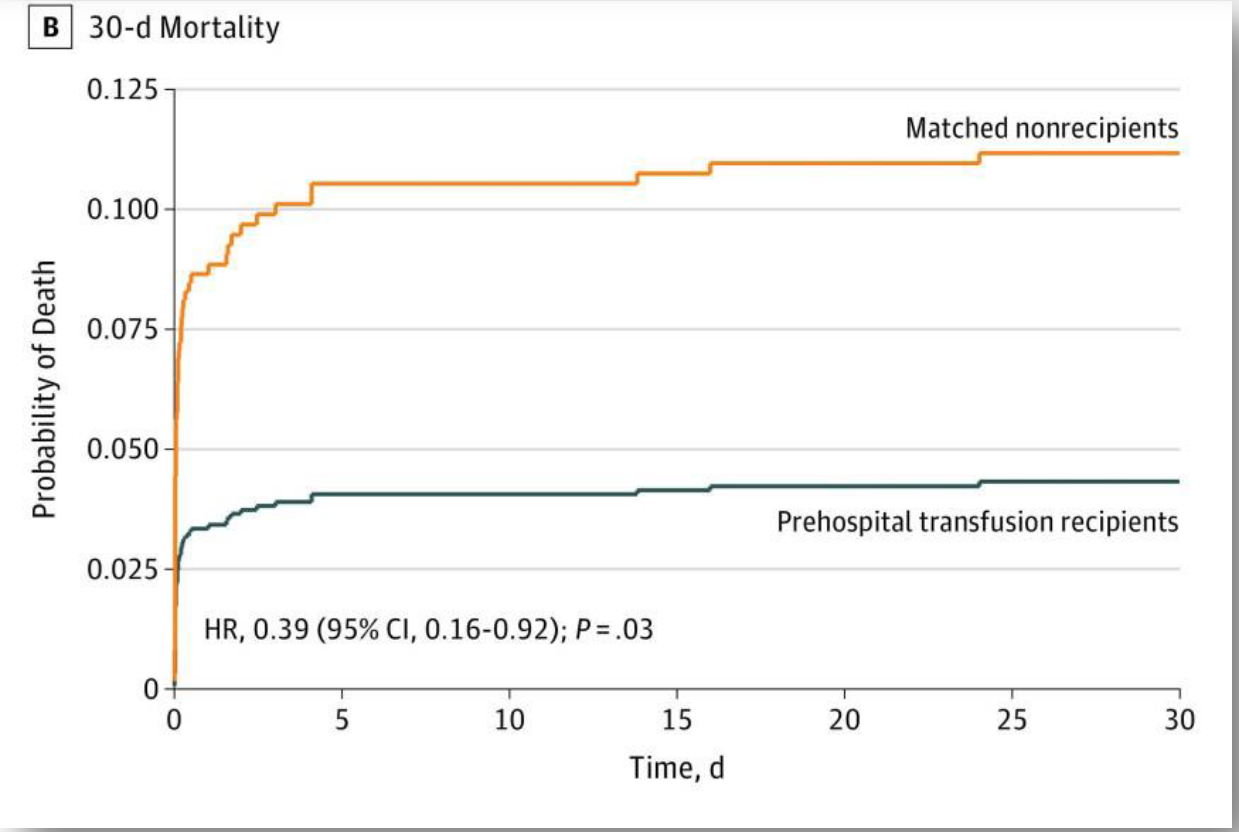
Pre-hospital
Rapid recognition of life-threatening hemorrhagic shock
Point-of-care devices: near infrared spectroscopy; INR; lactate level may be of value
Prevent hypothermia
Hemorrhage control with mechanical hemostatic adjuncts:
Tourniquet/junctional tourniquet
Pressure dressings/thrombin and fibrin-impregnated gauze
REBOA
Intraabdominal foams (investigational)
Hemostatic resuscitation
Whole blood is optimal
Component therapy with plasma (dried, liquid, or thawed), RBCs, and platelets in 1 : 1 : 1 ratio
Permissive hypotension for patients without traumatic brain injury[a]
Avoid crystalloid resuscitation
Consider TXA administration if less than 3 h from time of injury[b]
Consider source of fibrinogen (fibrinogen concentrate or cryoprecipitate)
Avoid hypocalcemia
In prolonged evacuations, empiric calcium administration for every 4–6 units of RBCs or WB

JAMA | Original Investigation

Association of Prehospital Blood Product Transfusion During Medical Evacuation of Combat Casualties in Afghanistan With Acute and 30-Day Survival

JAMA. 2017;318(16):1581-1591.

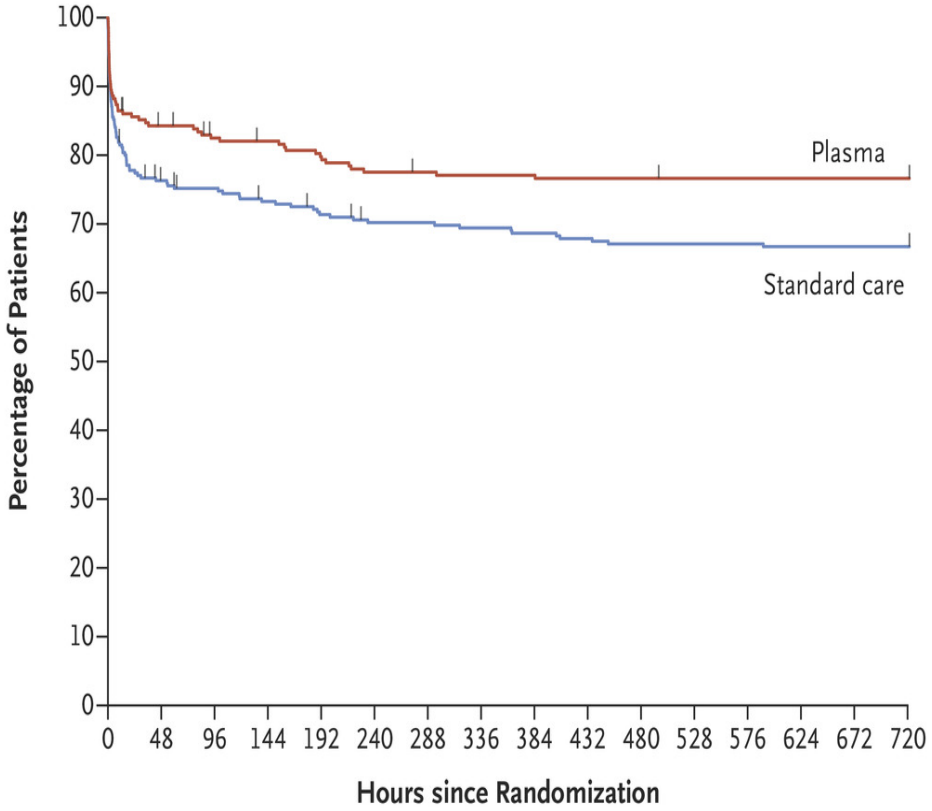
Stacy A. Shackelford, MD; Deborah J. del Junco, PhD; Nicole Powell-Dunford, MD; Edward L. Mazuchowski, MD, PhD; Jeffrey T. Howard, PhD; Russ S. Kotwal, MD, MPH; Jennifer Gurney, MD; Frank K. Butler Jr, MD; Kirby Gross, MD; Zsolt T. Stockinger, MD



Prehospital Plasma during Air Medical Transport in Trauma Patients at Risk for Hemorrhagic Shock

Jason L. Sperry, M.D., M.P.H., Francis X. Guyette, M.D., M.P.H., Joshua B. Brown, M.D., Mark H. Yazer, M.D., Darrell J. Triulzi, M.D., Barbara J. Early-Young, B.S.N., Peter W. Adams, B.S., Brian J. Daley, M.D., Richard S. Miller, M.D., Brian G. Harbrecht, M.D., Jeffrey A. Claridge, M.D., Herb A. Phelan, M.D., M.S.C.S., et al., for the PAMPer Study Group*

NEJM.2018;379(4):315-326.



No. at Risk							
Plasma	230	183	172	170	169	168	168
Standard care	271	194	181	179	173	172	172

REGULAR ARTICLE

blood advances

Platelet transfusions improve hemostasis and survival in a substudy of the prospective, randomized PROPPR trial

Jessica C. Cardenas,[1,2] Xu Zhang,[3] Erin E. Fox,[1-3] Bryan A. Cotton,[1-3] John R. Hess,[4] Martin A. Schreiber,[5] Charles E. Wade,[1-3] and John B. Holcomb,[1-3] on behalf of the PROPPR Study Group

[1]Division of Acute Care Surgery, Department of Surgery, McGovern School of Medicine, [2]Center for Translational Injury Research, and [3]Center for Translational and Clinical Studies, University of Texas Health Science Center, Houston, TX; [4]Department of Laboratory Medicine, Harborview Medical Center, University of Washington, Seattle, WA; and [5]Division of Trauma, Critical Care and Acute Care Surgery, Department of Surgery, Oregon Health and Science University, Portland, OR

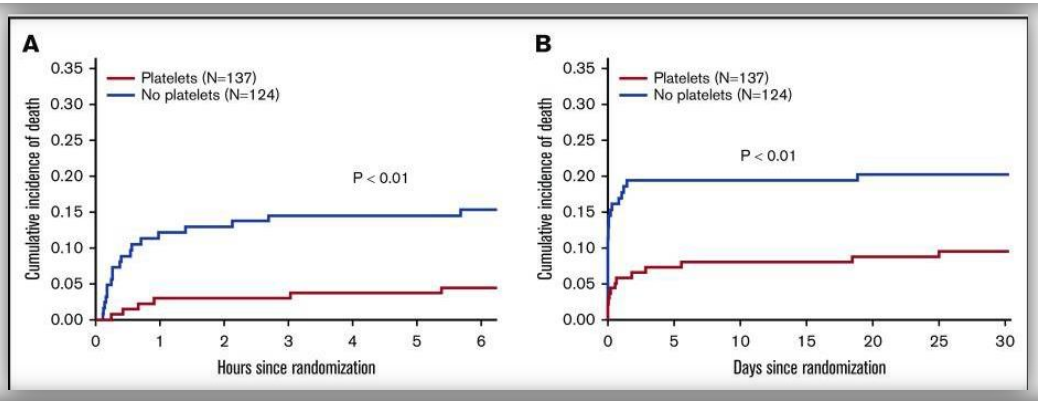


Table 4. Cause of death by treatment group

	First 24 hours			30 days		
	Platelets (n = 137)	No platelets (n = 124)	P*	Platelets (n = 137)	No platelets (n = 124)	P*
Total number of deaths	8	21		13	25	
Cause of death, n (%)†						
Exsanguination	2 (1.5)	16 (12.9)	<.01	2 (1.5)	16 (12.9)	<.01
Traumatic brain injury	4 (2.9)	5 (4.0)	.63	8 (5.8)	9 (7.3)	.64
Respiratory, pulmonary contusion, or tension pneumothorax	0 (0)	0 (0)	—	1 (0.7)	0 (0)	.32
Multiple organ failure	0 (0)	0 (0)	—	0 (0)	1 (0.8)	.32
Myocardial infarction	1 (0.7)	1 (0.8)	.94	1 (0.7)	1 (0.8)	.94
Pulmonary embolism	0 (0)	1 (0.8)	.32	0 (0)	1 (0.8)	.32

*P value was based on the Wald test for comparing 2 proportions.
†Patients may have had >1 cause of death.

Every minute counts: Time to delivery of initial massive transfusion cooler and its impact on mortality

J Trauma Acute Care Surg
Volume 83, Number 1

David E. Meyer, MD, Laura E. Vincent, RN, Erin E. Fox, PhD, Terence O'Keeffe, MBChB, Kenji Inaba, MD, Eileen Bulger, MD, John B. Holcomb, MD, *and* **Bryan A. Cotton, MD**, *Houston, Texas*

TABLE 3. Multivariate Regression Predicting 30-d Mortality

	OR	95% CI	*p*
Time to receipt of first cooler, min	1.05	1.01–1.09	0.016
Anatomic injury severity (ISS)	1.05	1.03–1.06	<0.001
Disturbed arrival physiology (w-RTS)	0.61	0.53–0.69	<0.001
Randomization group (1:1:2)	1.46	0.92–2.29	0.102
RI, units	1.03	0.60–1.44	0.184

Median (IQR) time from arrival to MTP activation was 9 (3-20) min
Median (IQR) time from MTP activation to delivery of blood products was 8 (5-11) min

Options for Trauma Induced Blood Failure

- If agree hemostatic resuscitation is needed
  - Shock
  - Endothelial, Hemostatic, Immune Dysfunction
- Resuscitation strategy is either
  - Whole Blood
  - RBCs, plasma, platelets
- Prehospital and in hospital scenarios

Types of Whole Blood

- Warm and Fresh
  - Room temp (22C)
  - Transfused within 8 hours
  - Most military data
- Cold and Stored
  - 2-6 C
  - Stored for 14-35 days
  - Civilian data

Types of Whole Blood

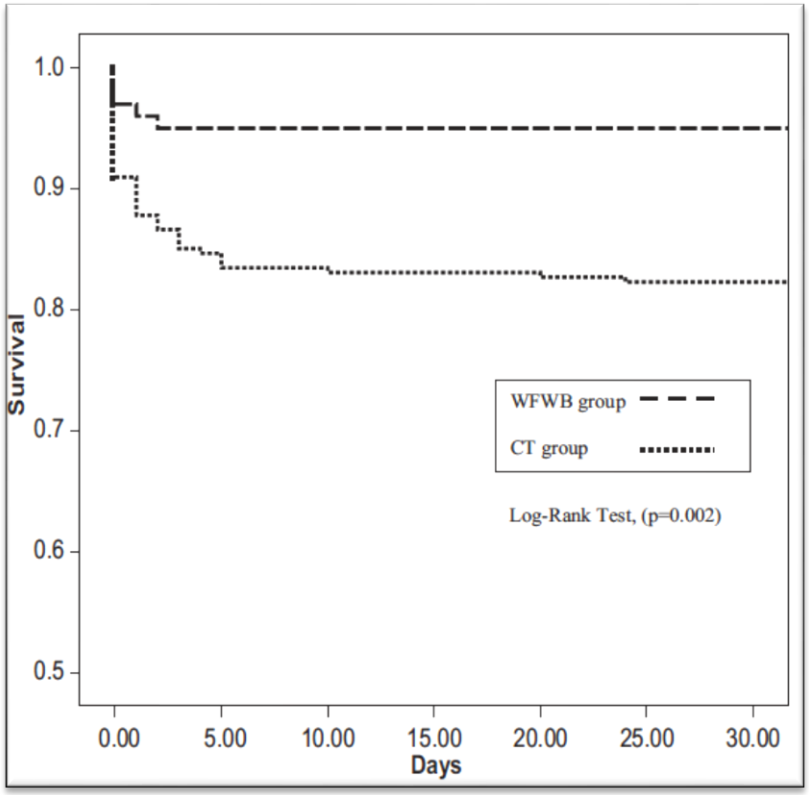
- ABO specific
  - Military data with warm fresh whole blood
- Group O Whole Blood
  - Low titer (Anti A and B < 256)
  - Civilian data with cold whole blood

The Journal of TRAUMA® Injury, Infection, and Critical Care

Warm Fresh Whole Blood Is Independently Associated With Improved Survival for Patients With Combat-Related Traumatic Injuries

J Trauma. 2009;66:S69–S76.

Philip C. Spinella, MD, Jeremy G. Perkins, MD, Kurt W. Grathwohl, MD, Alec C. Beekley, MD, and John B. Holcomb, MD



Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets

Volume 53, January 2013 Supplement **TRANSFUSION** 107S

Shawn C. Nessen, Brian J. Eastridge, Daniel Cronk, Robert M. Craig, Olle Berséus, Richard Ellison, Kyle Remick, Jason Seery, Avani Shah, and Philip C. Spinella

TABLE 6. Propensity score used as continuous variable in logistic regression predicting effect of FWB on death

	Odds ratio	95% CI	p Value
FWB use	0.096	0.02,0.53	0.008
Injury Severity Score	1.07	1.03,1.11	<0.001
Glasgow Coma Score	0.72	0.65,0.79	<0.001
Propensity score	9.72	1.45,64.97	0.019

Arrival systolic blood pressure, arrival temperature, use of factor VIIa, total red blood cells, and total plasma administered were used to calculate propensity score.
CI = confidence interval; FWB = fresh whole blood.

TABLE 7. Stratified propensity score analysis predicting the effect of the use of FWB on death

	Odds ratio	95% CI	p Value
FWB use	0.11	0.02, 0.78	0.03
Injury Severity Score	1.06	1.01, 1.11	0.01
Glasgow Coma Score	0.71	0.63, 0.79	<0.001

CI = confidence interval; FWB = fresh whole blood.

blood 1991 77: 930-936

Comparison of the hemostatic effects of fresh whole blood, stored whole blood, and components after open heart surgery in children

CS Manno, KW Hedberg, HC Kim, GR Bunin, S Nicolson, D Jobes, E Schwartz and WI Norwood

	Cold FWB	Blood (1:1:1)	P value
24 hr blood loss (ml/kg)	44.8 (±6)	74.2 (±9)	0.03
24 hr blood loss (ml/kg) < 2 yrs	51.7 (±7.4)	96.2 (±11)	0.001
PTT (30 min)	39.7(±3.4)	43.3 (±1.8)	0.06
Fibrinogen (mg/dl)	195 (±5.6)	184 (±4.8)	0.07
PLT aggregation (30 min)		most reduced ADP, epinephrine, collagen	0.02

Risk/Benefit Assessment
LTOWB compared to blood components

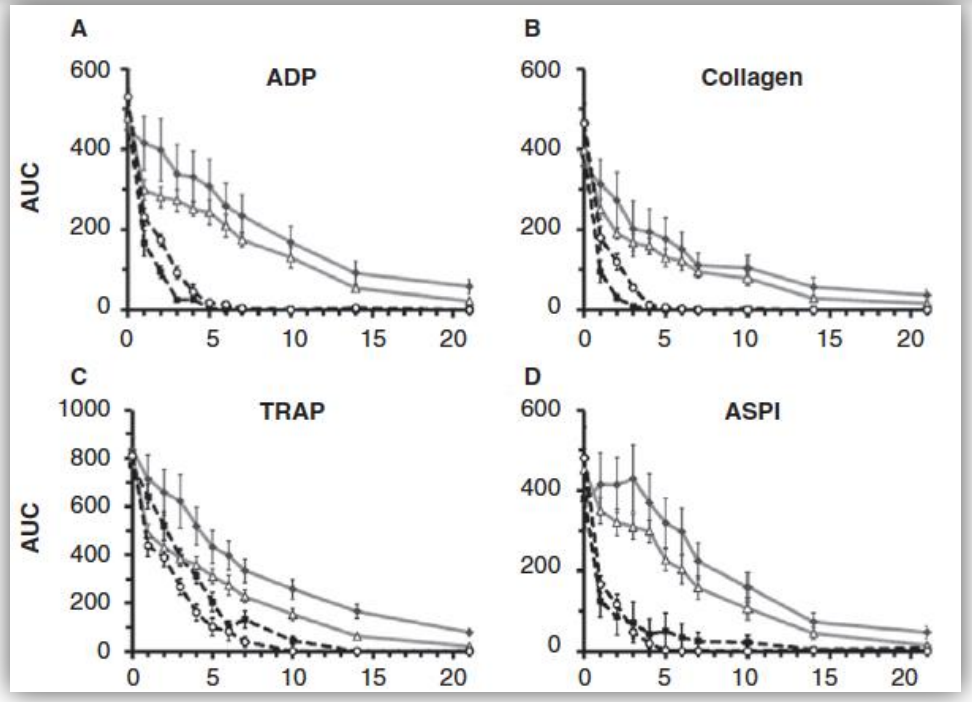
Advantages of LTOWB	Risks of LTOWB
More potent product Higher Hb, plasma, platelets per volume	Incompatible plasma/immune complexes? Theoretical risk.
Cold platelets – improved hemostasis (RCT data)	Waste? Reduced/eliminated if used in non trauma massive bleeding
Increased storage duration of platelet product	
Less risk of ABO incompatible transfusion reactions than ABO compatible components	
Less bacterial contamination risk	
Logistical advantages Quicker transfusion of balanced product One product vs four products	

ORIGINAL ARTICLE

Primary hemostatic capacity of whole blood: a comprehensive analysis of pathogen reduction and refrigeration effects over time

TRANSFUSION 2013 Jan;53 Suppl 1:137S-149S.

Heather F. Pidcoke, Steve J. McFaul, Anand K. Ramasubramanian, Bijaya K. Parida, Alex G. Mora, Chriselda G. Fedyk, Krystal K. Valdez-Delgado, Robbie K. Montgomery, Kristin M. Reddoch, Armando C. Rodriguez, James K. Aden, John A. Jones, Ron S. Bryant, Michael R. Scherer, Heather L. Reddy, Raymond P. Goodrich, and Andrew P. Cap



■ = CON 22; ● = CON 4; ○ = PRT 22; △ = PRT 4.

Volume and Concentrations Between Component Therapy vs. Warm Whole Blood

VS

Component Therapy: *680 mL*
RBC unit + PLT unit + FFP unit + Cryo unit

- *Red blood cell concentration: 29%*
- *Platelets: 80,000*
- *Coagulation factors: 65%*

Whole Blood: 500 mL
A single WB unit

- *Red blood cell concentration: 38-50%*
- *Platelets: 150,000-400,000*
- *Coagulation factor concentration: 100%*

Standard Amounts of Anti-coagulants and Additives in Reconstituted Whole Blood vs Whole Blood

Component Therapy per Unit:

6 x RBC (AS-5)	6 x 120 ml = 720ml
6 x FFP	6 x 50 ml = 300ml
1 x aPLT	1 x 35 ml = 35ml
	Total =1055ml

Whole Blood per Unit:

6 x 63ml = 378ml

Total= 378ml

There is 3 times the volume of anticoagulant and additives with reconstituted whole blood from components compared to whole blood

Spinella PC, J Trauma. 2009;66:S69-76

SHOCK, Vol. 41, Supplement 1, pp. 70–75, 2014

LOW TITER GROUP O WHOLE BLOOD IN EMERGENCY SITUATIONS

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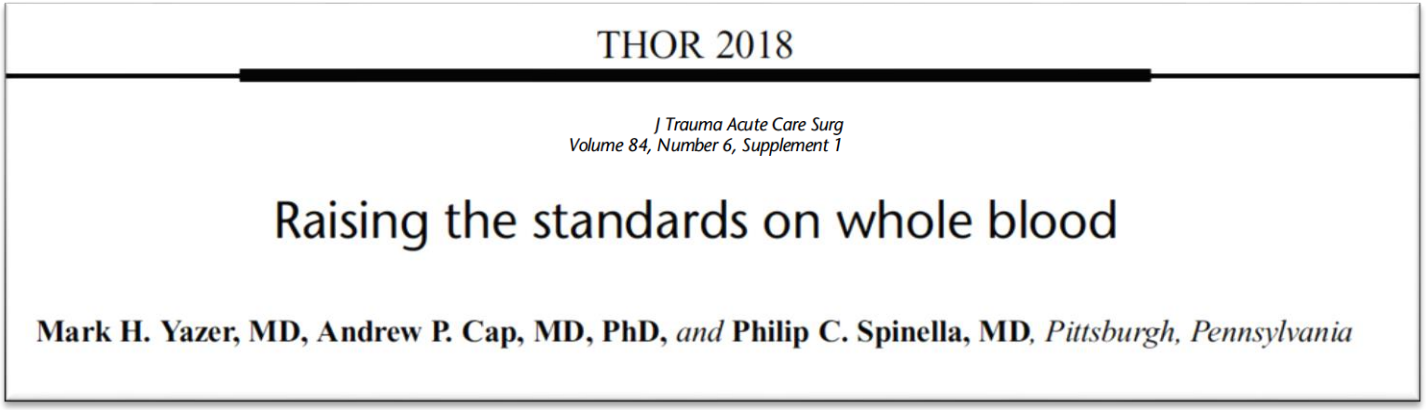
ABO compatible - 1:80,000 risk of fatal hemolytic reaction

Incompatible plasma – 1: 120,000 risk of mild to moderate reaction



- 5.15 Selection of Compatible Blood and Blood Components for Transfusion
  - 5.15.1 Recipients shall receive
    - ABO group-compatible Red Blood Cell components
    - ABO group-specific Whole Blood
    - **Low titer group O Whole Blood (for non group O or for recipients whose ABO group is unknown)**

Survey – LTOWB In-hospital

- 22 US Hospitals & 2 countries

Brooke Army Medical Center, San Antonio, TX

Cincinnati University, Cincinnati, OH

Cooper University, Camden, NJ

Emory University, Atlanta, GA

Medical College of Wisconsin, Milwaukee, WI

Haukeland University Hospital, Bergen, Norway

Intermountain Medical Center, Salt Lake City, Utah

Johns Hopkins University, Baltimore, MD

Magen David Adom in Israel, Israel

Mayo Clinic, Rochester, MN

Ohio State University, Columbus, OH

Penn Presbyterian Med Center, Philadelphia, PA

St. Louis University hospital, St. Louis, MO

University California Los Angeles, Los Angeles, CA

University of Oregon, Portland, OR

University of Phoenix, Phoenix, AZ

University of Pittsburgh, Pittsburgh, PA

University of Pittsburgh, Susquehanna, PA

University of Texas, Houston, TX

University of Texas, San Antonio, TX

University of Washington St Louis, St Louis, MO

Wake Forest University, NC

Yazer M. Transfusion. 2018

LTOWB Use

- Max # of units
  - No limit at 25% of hospitals
  - Mean of 4 (range 2-8) at 75%
- Who can get it?
  - Trauma only, 75% of hospitals
  - Any patient with massive bleeding, 25%
  - Children w Trauma, 21%

Yazer M. Transfusion. 2018

LTOWB Use

- What D type of the LTOWB supplied to females?
  - D- if she is of reproductive age, D+ if she is not, 33%
  - D+ LTOWB is only provided to females older than reproductive age (defined locally), 25%
  - D- only regardless of her age, 21%
  - D+ only regardless of her age, 8%
  - LTOWB is not provided to females of any age, 13%

Yazer M. Transfusion. 2018

LTOWB Use

- Maximum storage duration, LTOWB
  - 21 days, 42%
  - 14 days, 42%
  - 10 days, 8%
  - 35 days, 4%
  - Other, 4%
- Do you produce an RBC unit upon expiration?
  - Yes, 38%

LTOWB Use

- Max titer of A and B antibodies
  - < 200, 54%
  - < 50, 17%
  - < 256, 13%
  - < 100, 8%
  - <128, 4%
  - Other, 4%

LTOWB Use

- Is the LTOWB leukocyte reduced
  - Yes, 58%
  - No, 42%

Unpublished Data

- Effect of leukoreduction treatment on hemostatic measures in whole blood stored at 4C for 21 days
  - 8 samples in each study group

LR with PLT sparing filter vs No LR

- No differences for 21 days
  - PLT count
  - Platelet activating factors
  - Thrombin generation
- Differences
  - Fibrinogen and platelet function

Conclusions

- Whole blood based resuscitation optimal for Trauma Induced Blood Failure
- Whole blood optimal compared to blood components in 1:1:1 ratio
  - Logistics, Efficacy, Safety
- Prehospital benefit higher than in-hospital use

THOR-STORE

rdcr.org/shop

Blood is for bleeding
Saltwater is for cooking pasta!
-Spinella 2017


QUESTIONS
ANSWERED
HERE
EVEN THE
SILLY ONES