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TIC Tock: Pharmacologic Management of Trauma Induced Coagulopathy

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August 24, 2021

Conflicts of Interest

- The following individual has nothing to disclose concerning possible conflicts of interests related to this presentation
- The unapproved/investigational use of commercial products will be discussed during the educational activity

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Objectives

- Review the pathophysiology of **trauma induced coagulopathy (TIC)**
- Discuss the pharmacologic management of TIC
- Apply principles of TIC management to a patient case

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TIC Overview

- Injury is the fourth leading cause of mortality worldwide
- Trauma induced coagulopathy (TIC): abnormal coagulation capacity attributable to trauma
- Manifests as a spectrum of phenotypes from hypocoagulation to hypercoagulation
- 25-35% trauma patients
- 4-fold increase in mortality rate

Mortality
*(**early** < 6 h injury)*
Uncontrolled hemorrhage

Mortality
*(**late** > 24 h injury)*
Hypercoagulability

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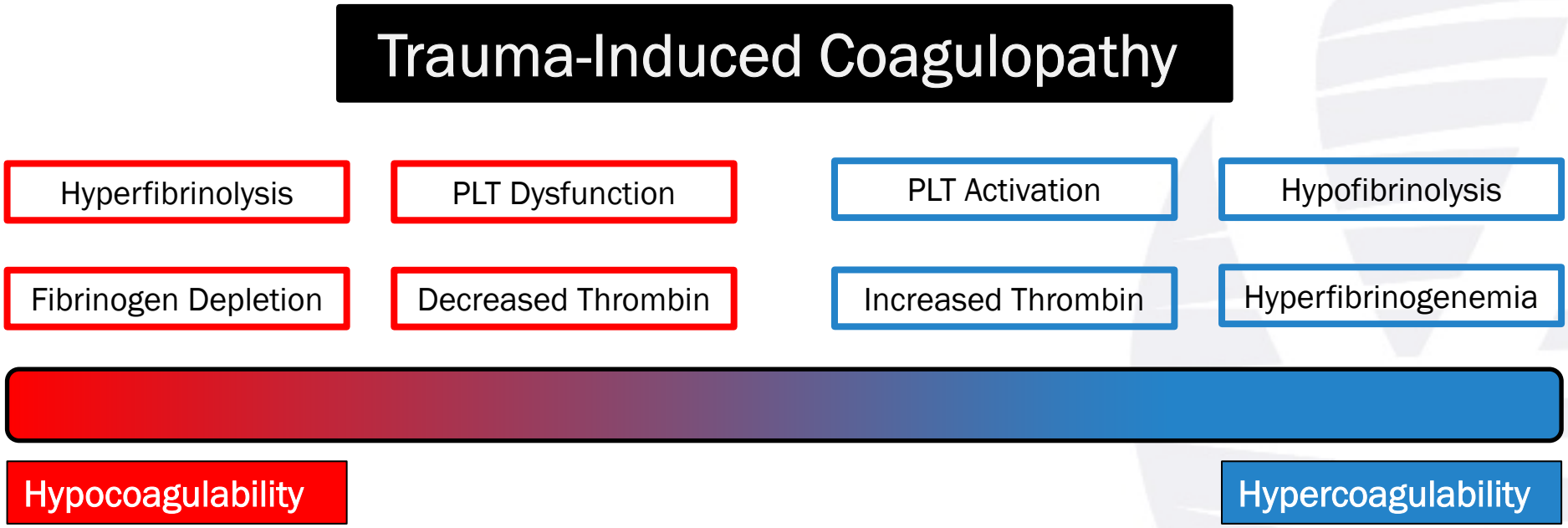
Moore, EE, et al. Nat Rev Dis Primers 7, 30 (2021).

Phenotypes of TIC



PLT: platelet

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Moore, EE, et al. Nat Rev Dis Primers 7, 30 (2021).
Gonzalez E, et al. Ann Surg. 2016;263(6):1051-1059.

0022-5282/82/2208-0672$02.00/0
THE JOURNAL OF TRAUMA
Vol. 22, No. 8

Major Abdominal Vascular Trauma—A Unified Approach

JEFFRY L. KASHUK, M.D., ERNEST E. MOORE, M.D., J. SCOTT MILLIKAN, M.D., AND JOHN B. MOORE, M.D.

- Retrospective review of major abdominal vascular injuries (N = 123)
- Average time from field notification to ED: 22 min
- Average time from ED to incision: 45 min
- Mortality from hemorrhage: 89%
  - **Mortality after vascular control of hemorrhage: 49%**
    - Average arterial pH: 7.21
    - Average core temperature: 31.2°C

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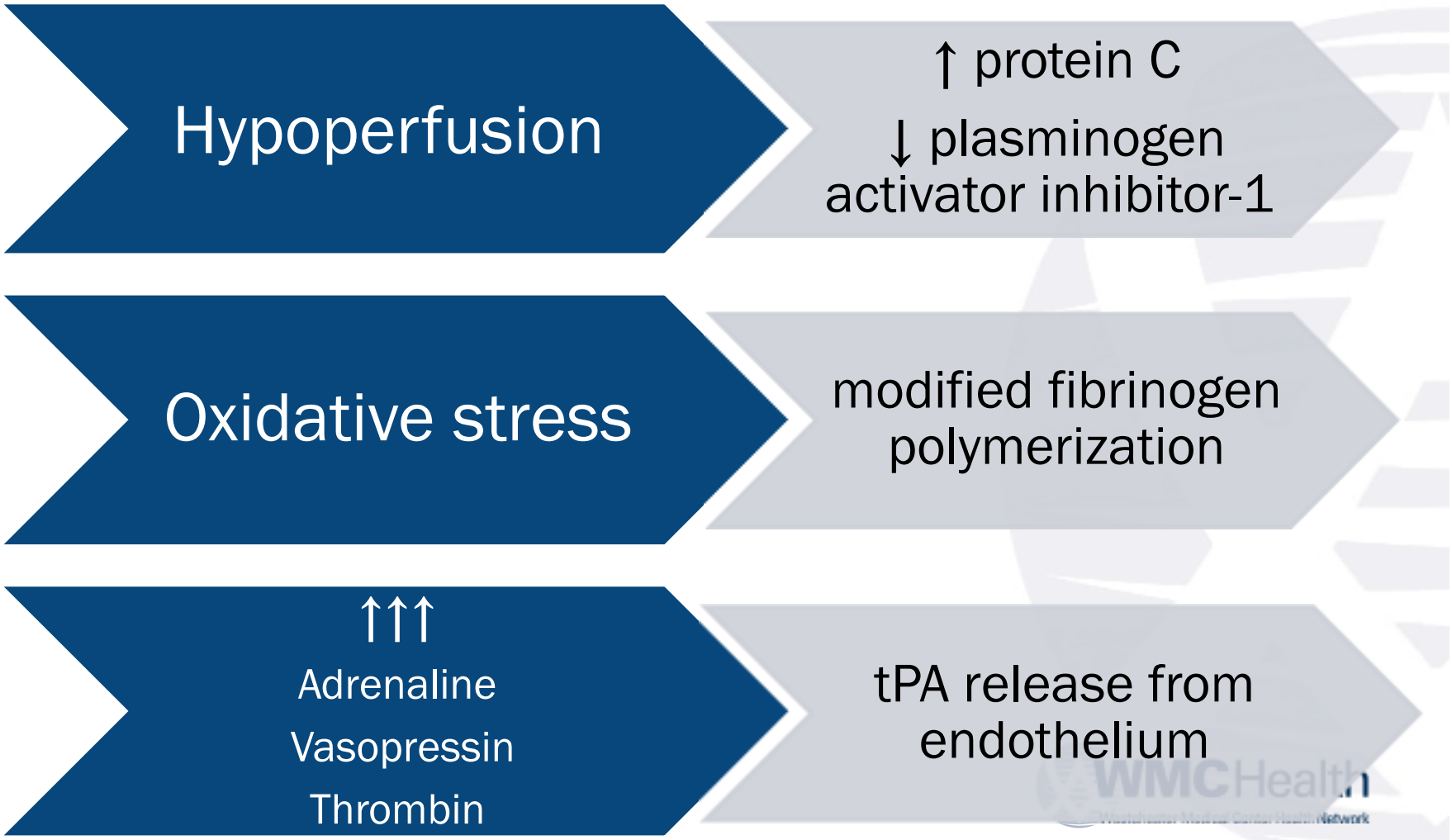
Kashuk JL, et al. J Trauma. 1982;22(8):672-679.

Mechanisms of TIC

- Trauma-induced hypoperfusion
- Tissue injury
- Endothelial dysfunction
- Platelet dysfunction
- Inappropriate thrombin generation
- Fibrinogen depletion
- Trauma's vicious triad

Mechanisms of TIC: Hypoperfusion



Moore, EE, et al. Nat Rev Dis Primers 7, 30 (2021).

Mechanisms of TIC: Tissue Injury

- Initially activates coagulation system via tissue factor
- Initial thrombin surge activates endogenous anticoagulation pathways
- Release of damage-associated molecular patterns (DAMPs)
  - Stimulates inflammatory pathways
  - Decreased platelet responsiveness

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Moore, EE, et al. Nat Rev Dis Primers 7, 30 (2021).

TIC Related to TBI

- Systematic manifestation of a local injury

BBB: blood brain barrier; BDMV: brain-derived cellular microvesicles

- #Clot: cerebral microthrombi = hyperactive platelets
- #Bleed: Platelets shown to be poorly responsive to ADP or AA

ADP: adenosine diphosphate
AA: arachidonic acid

Savioli, G, et al. Medicines. 2021;8(4):16.
Zhang J, et al. Blood. 2018;131(18):2001-2006.

Mechanisms of TIC: Endothelial Dysfunction

- Essential for regulation of coagulation, inflammation, microcirculation, and barrier function
- Endotheliopathy of trauma
  - Loss of barrier function
  - Endothelial activation
  - Micro/macro-thrombosis

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Moore, EE, et al. Nat Rev Dis Primers 7, 30 (2021).
Hunt BJ, et al. BMJ. 1998;316(7141):1328-1329.

Mechanism of TIC: Platelets and Thrombin

- Platelet exhaustion – impaired aggregation responses
  - Initial injury activates platelets beyond primary hemostasis requirements
  - Pool of activated and "exhausted" platelets formed, unable to contribute to hemostasis
- Inappropriate thrombin generation
  - Initial phase: insufficient → clots with diminished stability
  - Late phase: excessive 2/2 depletion of endogenous inhibitors
    - Antithrombin III, protein C inhibitor, nexin I

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Moore, EE, et al. Nat Rev Dis Primers 7, 30 (2021).
Huntington JA. Thromb Haemost. 2014;111(4):583-589.

Mechanism of TIC: Fibrinogen

- Low fibrinogen hemodilution, blood loss, consumption, hypothermia, acidosis, excessive release of tPA from endothelium
- Surge of PAI-1 suppresses fibrinolysis starting 2 hours from injury
- Early fibrinolysis shutdown (within 1 hour) associated with 2-6x increase in mortality

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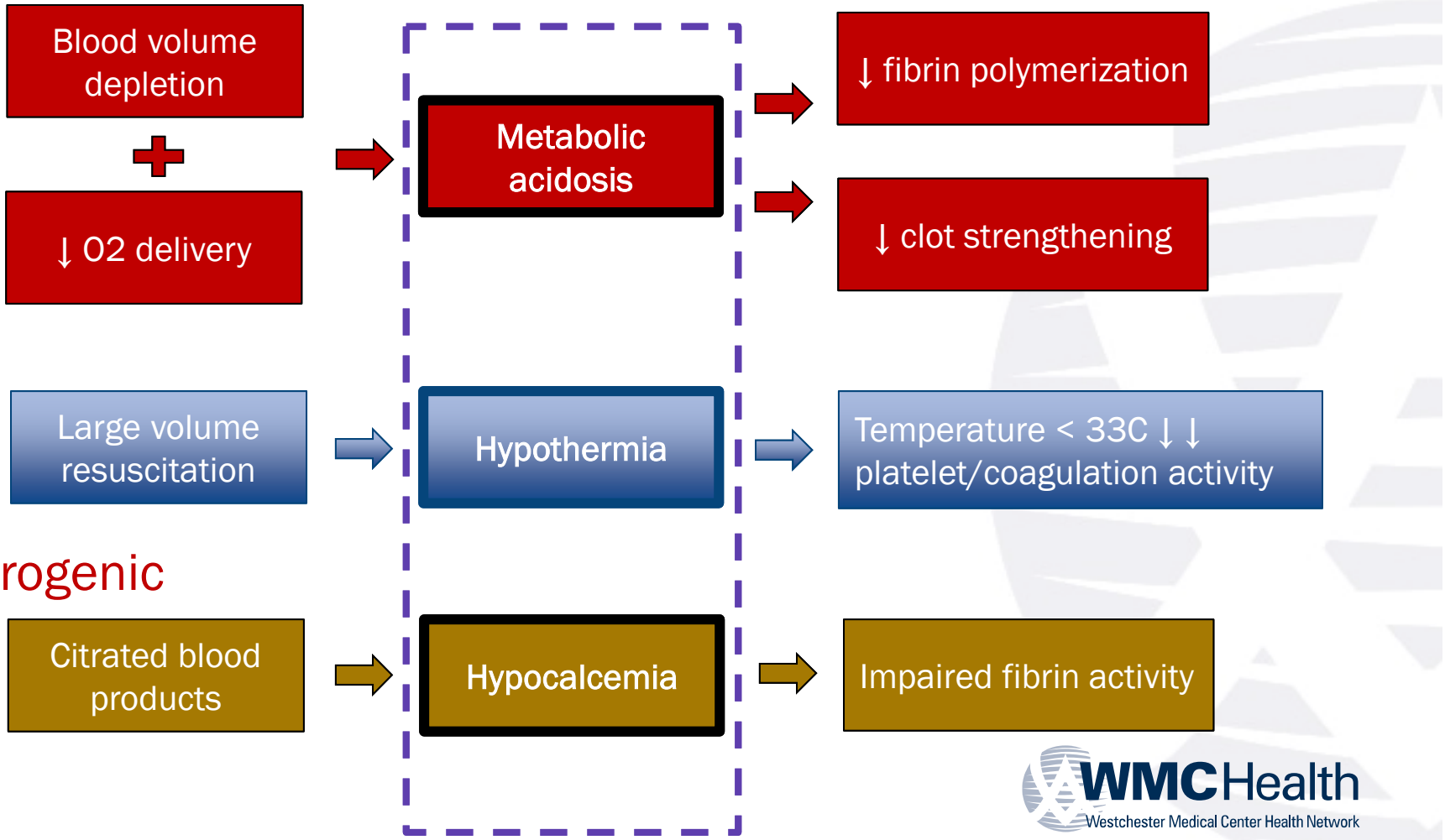
Moore, EE, et al. Nat Rev Dis Primers 7, 30 (2021).
Gall LS, et al. Ann Surg. 2019;269(6):1184-1191.

Trauma's Vicious Triad



#Iatrogenic

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Engstrom M, et al. J Trauma. 2006 Sep;61(3):624-8.
Weisel JW, et al. Blood. 2013;121(10):1712-1719.

Diagnosis

- Controversial: PT, aPTT, INR
  - Prolongation associated with increased mortality
  - Does **NOT** reflect abnormal clotting factor activity
  - May be normal value despite endothelial cell and glycocalyx damage
  - Unclear thresholds for diagnosis of TIC

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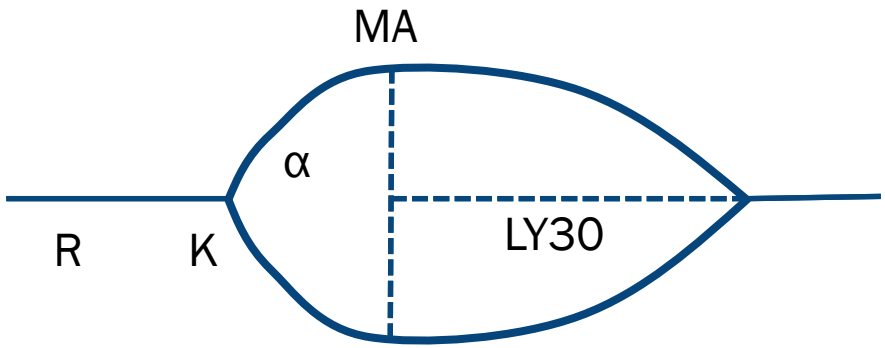
Moore, EE, et al. Nat Rev Dis Primers 7, 30 (2021).
Stettler GR, et al. J Trauma Acute Care Surg. 2019;87(3):582-589.
Johansson PI, et al. Crit Care. 2011;15(6):R272.

Diagnosis

- Viscoelastic assays: thromboelastography, rotational thromboelastometry
  - Assessment of whole-blood clot formation and degradation
  - Results available within 10 minutes
  - Decreased clot strength independent predictor of massive transfusion and mortality
  - Unclear thresholds for diagnosis of TIC



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Pezold M, et al. Surgery. 2012;151(1):48-54.
Moore, EE, et al. Nat Rev Dis Primers 7, 30 (2021).

Prioritize the clinical status of the patient

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Screening of Late TIC

- Hypercoagulable state following hypocoagulable state within 24 hours
- Viscoelastic assays: increased clot strength and fibrinolysis shutdown
  - mA >= 65 mm independent predictor of VTE
  - Increased alpha angle 2.97 times more likely for acute ischemic stroke
- Optimal duration to start VTE prophylaxis?

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Gary JL, et al. J Orthop Trauma. 2016;30(6):294-298.
Sumislawski JJ, et al. J Trauma Acute Care Surg. 2019;87(5):1082-1087.

Management

- Massive transfusion protocol
- Tranexamic acid
- Factor replacement
- Desmopressin
- VTE prophylaxis

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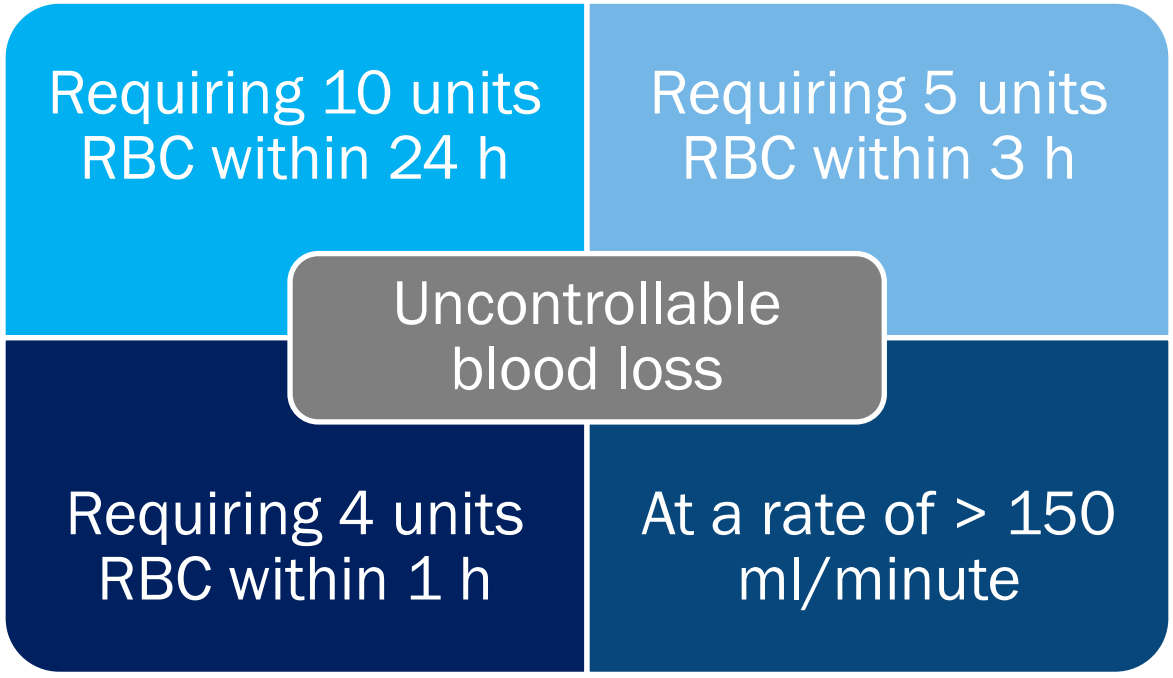
Massive Transfusion Protocol

- Rapid administration of large amounts of blood products in fixed ratios for the management of hemorrhagic shock



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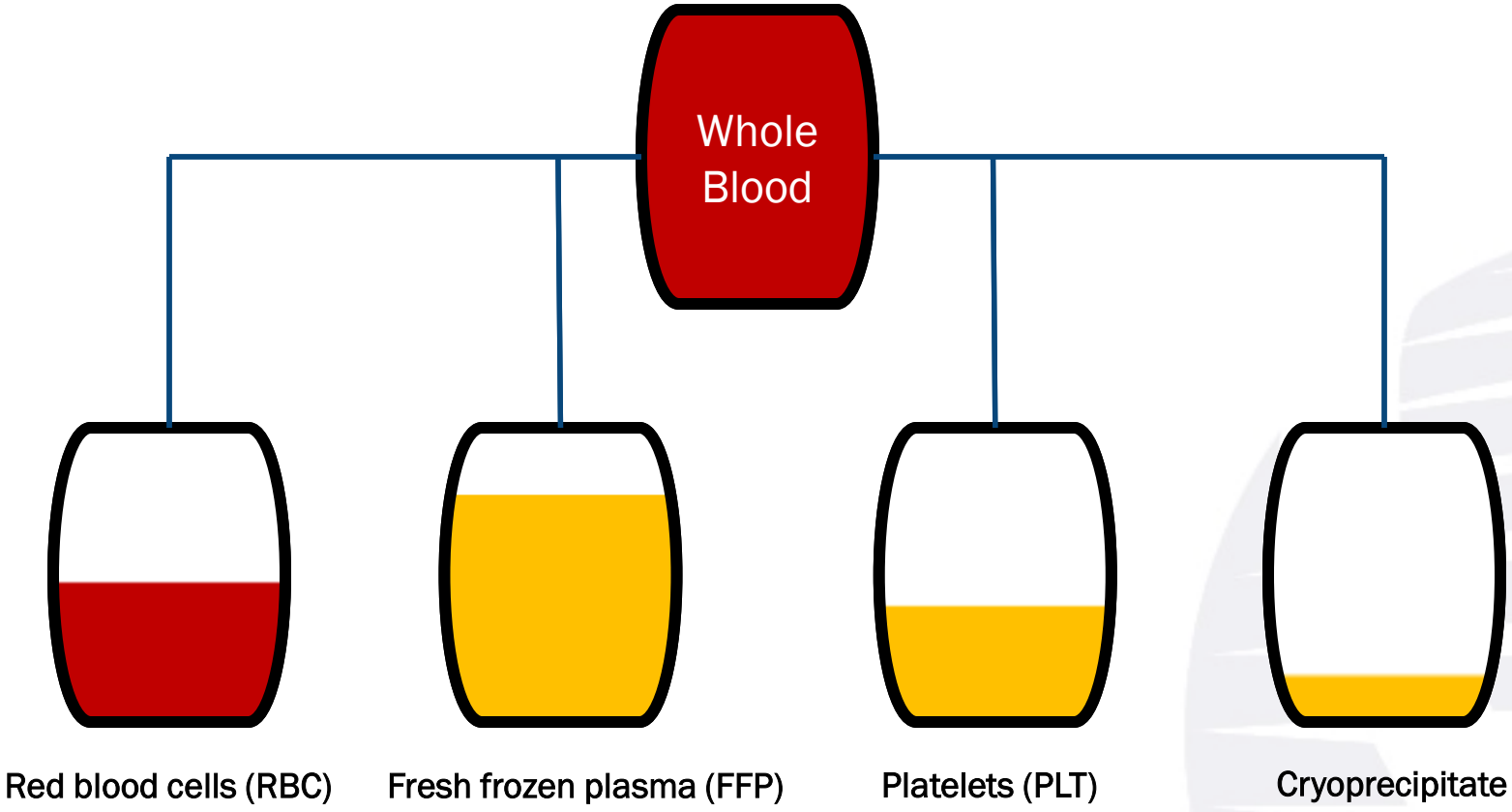

	RBC	FFP	PLT	Cryoprecipitate
Volume	300 mL	250 mL	200-300 mL	10 mL
Effect/unit	Hgb ~ 1.0 g/dL HCT ~ 3%	↑ coagulation factors	PLT ~ 30,000/uL	10 mg/dL

Transfusion of Plasma, Platelets, and Red Blood Cells in a 1:1:1 vs a 1:1:2 Ratio and Mortality in Patients With Severe Trauma

The PROPPR Randomized Clinical Trial

- Pragmatic, phase III, multisite, randomized trial of trauma patients requiring massive transfusion (N = 680)

Intervention: 1:1:1 (plasma:platelet:RBC)

6 units plasma | 1 apheresis unit platelet | 6 units RBC

Intervention Transfusion Order

PLT first, then 1 RBC alternating with 1 plasma

Control: 1:1:2 (plasma:platelet:RBC)

1. 3 units plasma | 0 apheresis unit platelet | 6 units RBC
2. 3 units plasma | 1 apheresis unit platelet | 6 units RBC

Alternating

Control Transfusion Order

1) Alternating 2 RBC and 1 plasma
2) PLT first, then 2 RBC and 1 plasma

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Holcomb JB, et al. JAMA. 2015;313(5):471-482.

PROPPR Trial

- Results (1:1:1 vs. 1:1:2)
  - No difference in pre-randomization blood product administration
  - No difference in 24-h mortality (12.7% vs. 17.0%, P = 0.12)
  - No difference in 30-d mortality (22.4% vs. 26.1 %, P = 0.26)
  - Higher rate of hemostasis (86.1% vs. 78.1%, P = 0.006)
  - No difference in time to hemostasis (105 min vs. 100 min, P = 0.44)
  - No difference in prespecified complications
  - Post-hoc: less death by exsanguination (9.2% vs. 14.6%, P = 0.03)

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Holcomb JB, et al. JAMA. 2015;313(5):471-482.

Sample MTP Protocol

MTP Packs	PRBCs	Plasma	Platelets	Cryoprecipitate	
Pack 1	6	6	1		If less than 3 hours from injury event administer one dose of tranexamic acid 1000mg IVPB AFTER the 4th unit of PRBC
Pack 2	6	6	1		*10 units of cryo should be requested with every third pack if MTP is expected to be continued.
Pack 3*	6	6	1	10	
Pack 4	6	6	1		
Pack 5	6	6	1		

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Calcium

- Involved in activation of platelets and Factor VIII
- Citrate in blood products binds to endogenous calcium
- Typically metabolized by liver when blood given gradually
- ~ 3g/unit RBC vs. liver metabolism 3 g citrate in 5 min
- Dosing: 1 g IV calcium chloride or 3 g IV calcium gluconate per round of MTP (e.g. every 6 PRBC)

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Singh S, et al. Sci Rep 9,11324 (2019).
Li K, et al. Int J Clin Exp Med. 2015;8(4):6578-6584.

Tranexamic Acid (TXA)

- Synthetic derivative of amino acid lysine
- MOA: inhibits fibrinolysis by blocking interaction of plasminogen with lysine residues of fibrin
- Potential benefit: antifibrinolytic effect to mitigate surge of tPA during TIC
- Potential risk: thrombotic events during the fibrinolytic shutdown phase of TIC

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Nishida T, et al. J Intensive Care. 2017;5:5.

The CRASH-2 trial: a randomised controlled trial and economic evaluation of the effects of tranexamic acid on death, vascular occlusive events and transfusion requirement in bleeding trauma patients

- Randomized placebo-controlled trial in adult trauma patients with or at risk of significant bleeding within 8 hours of injury (N = 20,211)
- TXA 1 g over 10 min then infusion of 1 g over 8 hr

Inclusion	Exclusion
Significant hemorrhage • SBP < 90 mmHg • HR > 110 BPM	Contraindication to TXA • Hypersensitivity • Active intravascular clotting
Within 8 hr injury	
Treating provider uncertain about use of TXA	

CRASH-2 Trial

Results (TXA vs. Placebo)

- All-cause mortality: 14.5% vs. 16.0%, RR 0.91 (0.85 to 0.97)
- Mortality from bleeding: 4.9% vs. 5.7%, RR 0.85 (0.76 to 0.96)
- Mortality from vascular occlusion: 0.3% vs. 0.5%, RR 0.69 (0.44 to 1.07)
- Blood product transfusions: 50.4% vs. 51.3%, P = 0.21
- Received surgical intervention: 47.9% vs. 48.0%, P = 0.79

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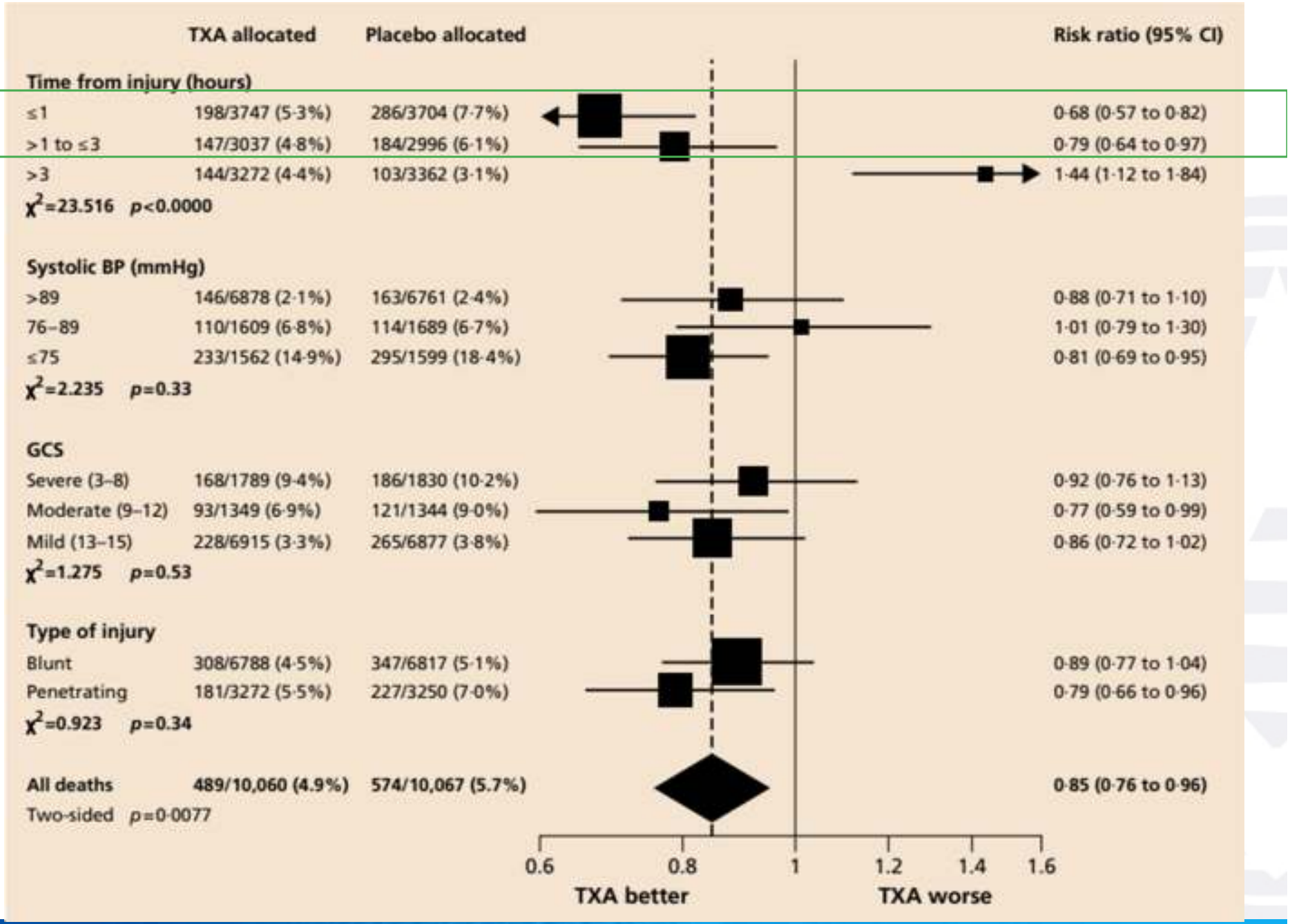
Roberts I, Health Technol Assess. 2013;17(10):1-79.



Roberts I, Health Technol Assess. 2013;17(10):1-79.

CRASH-2 Trial

- Randomization subjective based on treating physician (selection bias)
  - "Patients were included if the responsible doctor was substantially uncertain about whether or not treat with TXA…when the responsible doctor was substantially uncertain whether or not to treat with this agent, these patients were eligible"
- Small sample size of hypotensive (SBP < 90): 31.5% vs. 32.7%
- Small effect size on mortality
- TXA did not reduce transfusion rates

Roberts I, Health Technol Assess. 2013;17(10):1-79.

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

- Retrospective observational study in combat-related injury receiving at least 1 unit of RBC (N = 896)
- TXA 1 g bolus with repeat bolus as determined by provider
- TXA group higher injury severity score
  - 25.2 vs. 22.5, P < 0.001
- TXA group required more transfusions within 24 hrs
  - RBC, FFP, platelets, cryoprecipitate
- Increased venous thromboembolism
  - Pulmonary embolism (2.7% vs. 0.3%, P = 0.001)
  - Deep vein thrombosis (2.4% vs. 0.2%, P = 0.001)

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Morrison JJ, et al. Arch Surg. 2012;147(2):113-119.

MATTERs Study

All-Cause Mortality

End Point	TXA	No TXA	P Value
Overall			
< 24 h	293 (9.6)	603 (12.4)	0.20
< 48 h	264 (11.3)	507 (18.9)	0.004
In-hospital	264 (17.4)	603 (23.9)	0.03
Massive Transfusion			
< 24 h	125 (9.6)	196 (14.8)	0.17
< 48 h	112 (10.4)	160 (23.5)	0.003
In-hospital	125 (14.4)	196 (28.1)	0.004

Independent predictors for mortality

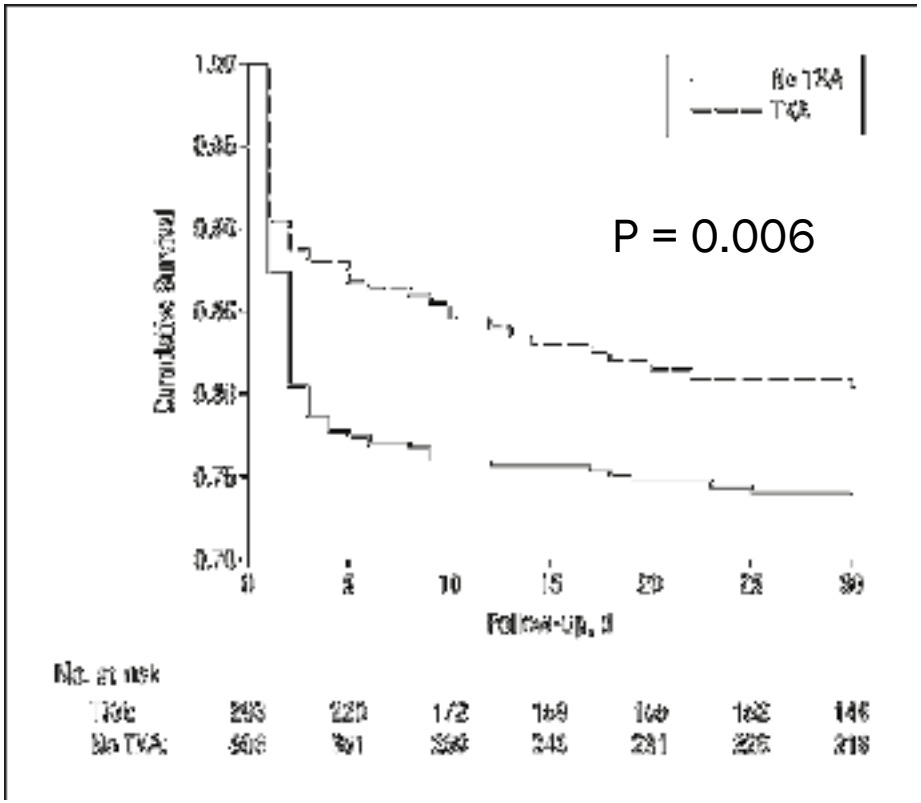
- GCS <= 8 (P = 0.02)
- SBP <= 90 mmHg (P = 0.02)
- Evidence of hypocoagulopathy (P = 0.01)

TXA Odds Ratio for Survival
7.228 (3.016 – 17.322, P < 0.001)
MT group

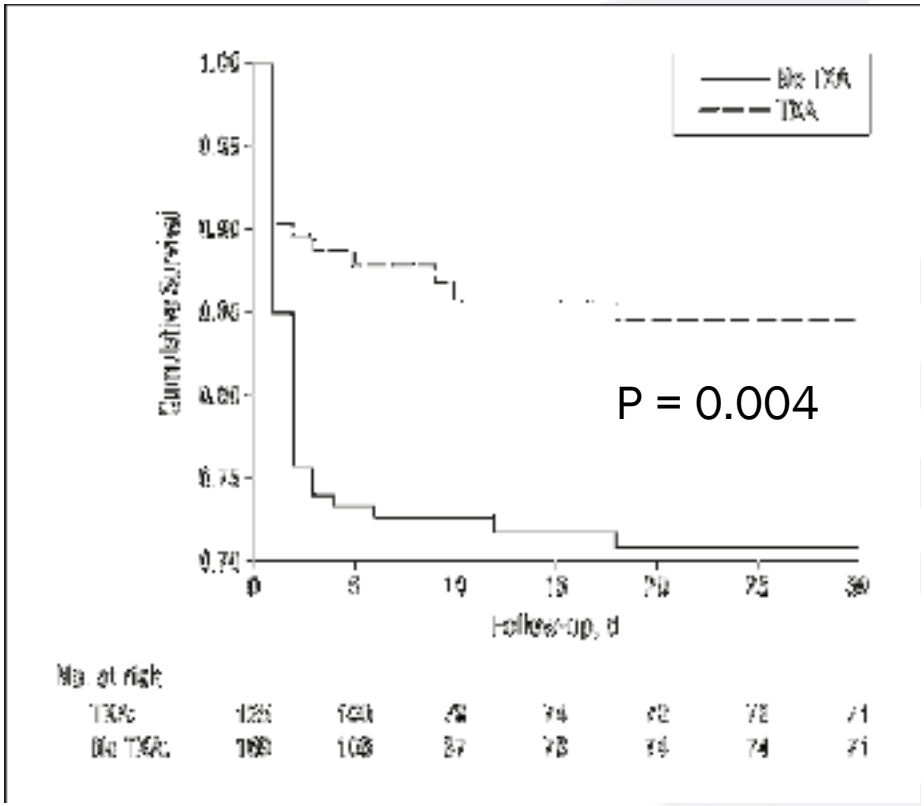
Morrison JJ, et al. Arch Surg. 2012;147(2):113-119.

MATTERs Study

30-day survival: overall



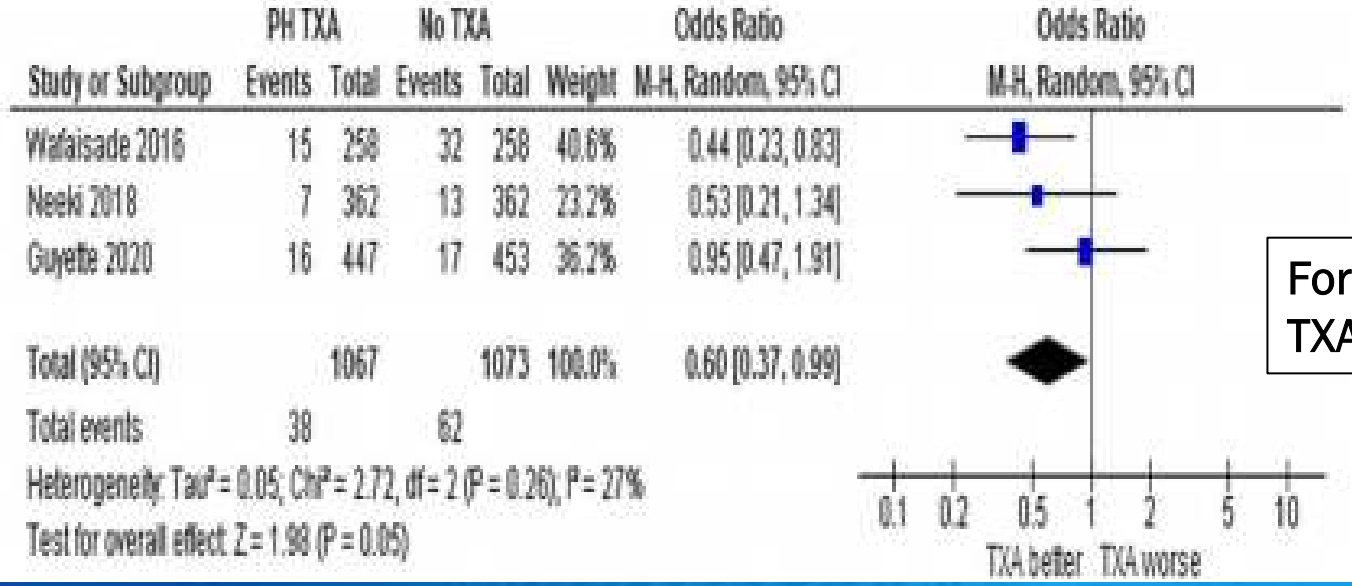
30-day survival: massive transfusion



Morrison JJ, et al. Arch Surg. 2012;147(2):113-119.

The impact of prehospital TXA on mortality among bleeding trauma patients: A systematic review and meta-analysis

- 797 publications identified, 4 included in review (N = 2,347)
- Decreased 24-hour mortality with pre-hospital TXA (P = 0.05)
- No difference in late mortality (28 to 30 days)
- No difference in VTE (P = 0.12)



Forest plot prehospital TXA on 24-h mortality

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Almuwallad A, et al. J Trauma Acute Care Surg. 2021;90(5):901-907.

4-F PCC (Kcentra)

- Complex concentrate of factors II, VII, IX, X, protein C, protein S
- Can be considered as adjunct to FFP for management of TIC
- Retrospective single center study (N = 516) adult trauma patients with INR > 1.5
- **25 units/kg 4-F PCC + FFP vs. FFP alone in TIC**
  - Time to INR correction: 373 min vs. 955 min, P < 0.001
  - PRBC units transfused: 7 units vs. 9 units, P = 0.04
  - Thromboembolic complications: 2.5% vs. 1.2%, P = 0.5
  - Mortality: 25% vs. 33%, P = 0.04

Average Wholesale Price: ~$3.14/unit
Cost for 70 kg patient: $6,000

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Jehan F, et al. J Trauma Acute Care Surg. 2018;85(1):18-24.

Recombinant Factor VII (Novoseven)

- Hemostatic agent for hemophilia, congenital deficiency of factor VII, Glanzmann's thrombasthenia
- Associated with reduction in RBC in severe blunt/penetrating traumas
- No demonstrated mortality benefit
- Higher rates of venous and arterial thromboembolic events
- 200 mcg/kg x 1, then 100 mcg/kg at 1 hour and 3 hours

Average Wholesale Price: ~$2.88/mcg
Cost for 70 kg patient: ~$80,000

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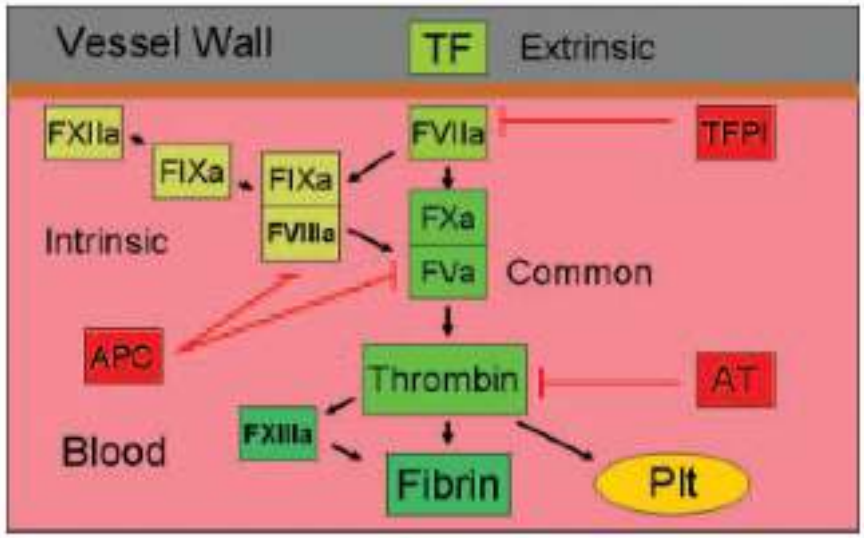
Mamtani R, et al. World J Emerg Surg. 2012;7 Suppl 1(Suppl 1):S7.
Hauser CJ, et al. J Trauma. 2010;69(3):489-500.
Levi M, et al. N Engl J Med. 2010;363(19):1791-1800.

Predictors of Response to Factor VIIa

- Factor assay analysis via spectrophotometry in-vitro
- <u>Reduction in pH from 7.4 to 7.0</u>
  - Reduced FVIIa activity (90% reduction)
  - Reduced FVIIa/TF complex (55% reduction)
  - Reduced FVa/Xa complex
- Temperature does not reduce TF-independent activity of FVIIa



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Meng ZH, et al. J Trauma. 2003;55(5):886-891.
Mackman N, et al. Anesth Analg. 2009;108(5):1447-1452.

The utility of recombinant factor VIIa as a last resort in trauma

Rishi Mamtani[1], Bartolomeu Nascimento[2], Sandro Rizoli[3], Ruxandra Pinto[4], Yulia Lin[5], Homer Tien[6*]

- Retrospective review of MTP patients that received rFVIIa (N = 71)
- Compared outcomes between last resort (N = 11) vs. all others (N = 60)
  - Last resort defined as **pH <= 7.02** (100% specific for mortality)
- Dosing
  - **Median dose administered 85.7 mcg/kg**
  - 72% received 1 dose (median time to dose 4.5 h)
  - 24% received 2 doses (median time interval for repeat 2.3 h)
  - 4% received 3 doses

Table 2 pH & In-hospital Mortality

	Alive	Dead	Hospital Mortality
pH > 7.02 (n=60)	34	26	43%
pH ≤ 7.02 (n=11)	0	11	100%
Sensitivity	**Specificity**	**(PPV)**	**(NPV)**
100% (34/34)	30% (11/37)	57% (34/60)	100% (11/11)

PPV, positive predictive value; NPV, negative predictive value

Mamtani R, et al. World J Emerg Surg. 2012;7 Suppl 1(Suppl 1):S7.

Desmopressin (DDAVP)

- Indicated for diabetes insipidus, von Willebrand's disease, hemophilia, uremic bleeding
- Dose: 0.3 to 0.4 mcg/kg x 1
- Increases release of VWF and factor VIII from storage sites
- Onset of action: 30 minutes
- Duration of hemostatic effect: 24 hr

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Hedges S, et al. Nat Rev Nephrol. 2007;3(3):138-153

Desmopressin in Trauma

- No high-quality evidence to suggest benefit for TIC
- Reasonable in renal failure or after antiplatelet therapy
- Meta-analysis demonstrates trend towards decreased perioperative transfusion requirements
- Reduced blood loss during cardiac surgery
- ?Extrapolate to trauma patients

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Crescenzi G, et al. Anesthesiology. 2008;109(6):1063-1076.
Salzman EW, et al. N Engl J Med. 1986;314(22):1402-1406.

Timing of VTE Prophylaxis

- Incidence of VTE in trauma highest during first few days
- 8.7% incidence of VTE without prophylaxis
- American Association for Surgery of Trauma guidelines 2021
  - As soon as possible after TBI (24-72 hours following admission)
  - Isolated SAH/IVH/SDH <= 8 mm + stable head CT: within 24 hours
  - Prophylaxis within 48 hours for blunt solid organ injury

SAH: subarachnoid hemorrhage
IVH: intraventricular hemorrhage
SDH: subdural hematoma

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Rappold JF, et al. Trauma Surg Acute Care Open 2021;6:e000643.
Barrera LM, et al. Cochrane Database Syst Rev. 2013;(3):CD008303.

LMWH vs. UFH

- DVT: 31% vs. 44%, P = 0.014
- Major bleed: P = 0.12

A COMPARISON OF LOW-DOSE HEPARIN WITH LOW-MOLECULAR-WEIGHT HEPARIN AS PROPHYLAXIS AGAINST VENOUS THROMBOEMBOLISM AFTER MAJOR TRAUMA

WILLIAM H. GEERTS, M.D., RICHARD M. JAY, M.D., KAREN I. CODE, R.N., ERLUO CHEN, M.B., M.P.H., JOHN PAUL SZALAI, PH.D., ERIC A. SAIBIL, M.D., AND PAUL A. HAMILTON, M.D.

Effectiveness of low-molecular-weight heparin versus unfractionated heparin to prevent pulmonary embolism following major trauma: A propensity-matched analysis

James P. Byrne, MD, William Geerts, MD, Stephanie A. Mason, MD, David Gomez, MD, PhD, Christopher Hoeft, MA, Ryan Murphy, MPH, Melanie Neal, MS, and Avery B. Nathens, MD, PhD, *Toronto, Ontario, Canada*

LMWH vs. UFH

- ↓ rates of PE (OR, 0.56, 95% CI 0.50 – 0.63)
- ↓ rates of DVT (OR 0.61; 95% CI, 0.56 – 0.66)

LMWH vs. UFH

- LMWH independent predictor of survival
- LMWH independent protective factor against thromboembolic complications
- No difference in unplanned return trips to the OR

Pharmacological Thromboembolic Prophylaxis in Traumatic Brain Injuries

Low Molecular Weight Heparin Is Superior to Unfractionated Heparin

Elizabeth Benjamin, MD, PhD, FACS, Gustavo Recinos, MD, Alberto Aiolfi, MD, Kenji Inaba, MD, FACS, and Demetrios Demetriades, MD, PhD, FACS

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Rappold JF, et al. Trauma Surg Acute Care Open 2021;6:e000643.
Geerts WH, et al. N Engl J Med 1996;335:701-707.
Byrne JP, et al. J Trauma Acute Care Surg 2017;8:252-62.
Benjamin E, et al. Ann Surg 2017;266:463-9.

Either UFH or LMWH may be used for VTE prophylaxis although LMWH may be better

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Assessment Questions

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Bob is a 35 YO M unknown PMH presented to your trauma unit as a pedestrian struck by MV at 50 MPH 15 minutes ago. Bob was intubated in the field with a GCS of 3T. Bob was hypotensive and given a 2L bolus of normal saline by EMS.

Injuries: extensive maxillofacial fractures, extensive acute TBI with multi-compartmental ICH, right PTX, right pelvic fx

Data

BP: 60/30 (40), HR: 120, RR: 18, T: 35.6 C

Which of the following is the most appropriate resuscitative intervention?

a) 30 ml/kg plasmalyte IV bolus

b) Plasma:PLT:RBC in a 1:1:1 ratio, RBC first

c) Plasma:PLT:RBC in a 1:1:2 ratio, RBC first

d) Plamsa:PLT:RBC in a 1:1:1 ratio, PLT first

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Bob responded to the initial resuscitative measure. A left subclavian triple lumen catheter is placed along with an arterial line in the right radial artery. Bob continues to have diffuse bleeding at the insertion sites. Someone on the team asks about the role of TXA for Bob.

Data

BP: 90/50 (63), HR: 105, RR: 18, T: 35.3 C

Which of the following best describes the role of TXA in this case?

a) TXA is not indicated since Bob is outside of the time window for benefit

b) TXA is not indicated since Bob responded to the initial resuscitative measure

c) TXA is a reasonable option in acute trauma that may have mortality benefit

d) TXA is a reasonable option in acute trauma that decreases transfusion requirements

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Repeat head CT for Bob demonstrated expansion of ICH with no mass effect. The team is concerned of ongoing coagulopathy despite resuscitative measures and inquires about Factor VII.

Data

BP: 95/50 (65), HR: 105, RR: 18, T: 35.3 C

Hgb: 6.8 g/dL, HCT: 34%, PLT: 80 K/mm^3, Fibrinogen: 210 mg/dL

ABG: pH: 7.02, pCO2: 30, HCO3: 8, PO2: 100

Which of the following best describes the role of Factor VII?

a) Factor VII is indicated in the setting of ICH expansion

b) Factor VII is indicated due to coagulopathy refractory to massive transfusion

c) Factor VII is not indicated as there will likely be no benefit given the pH

d) Factor VII is not indicated for Hgb > 6.5 g/dL

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After initial resuscitative measures, the following are Bob's vitals and lab values 24 hours after admission.

Data

BP: 110/60 (77), HR: 90, RR: 18, T: 37.3 C
Hgb: 8.5 g/dL, HCT: 38%, PLT: 100 K/mm^3, Fibrinogen: 210 mg/dL
SCr: 0.8 mg/dL, CrCl: > 120 ml/min

Imaging: Repeat head CT stable

Which of the following is true regarding chemical VTE prophylaxis?

a) VTE prophylaxis should be held until no further operative procedures are planned
b) VTE prophylaxis should be held until after 72 hours from initial trauma
c) Initiate UFH 5000 units Q8H
d) Initiate LMWH 30 mg Q12H

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Conclusion

- TIC is a phenomenon characterized by coagulopathy followed by hypercoagulability secondary to various mechanisms
- Diagnosis of TIC should be made through a combination of patient assessment and coagulation studies
- Management of TIC involves adequate resuscitation with blood products and other adjunctive therapies

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TIC Tock: Pharmacologic Management of Trauma Induced Coagulopathy

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