

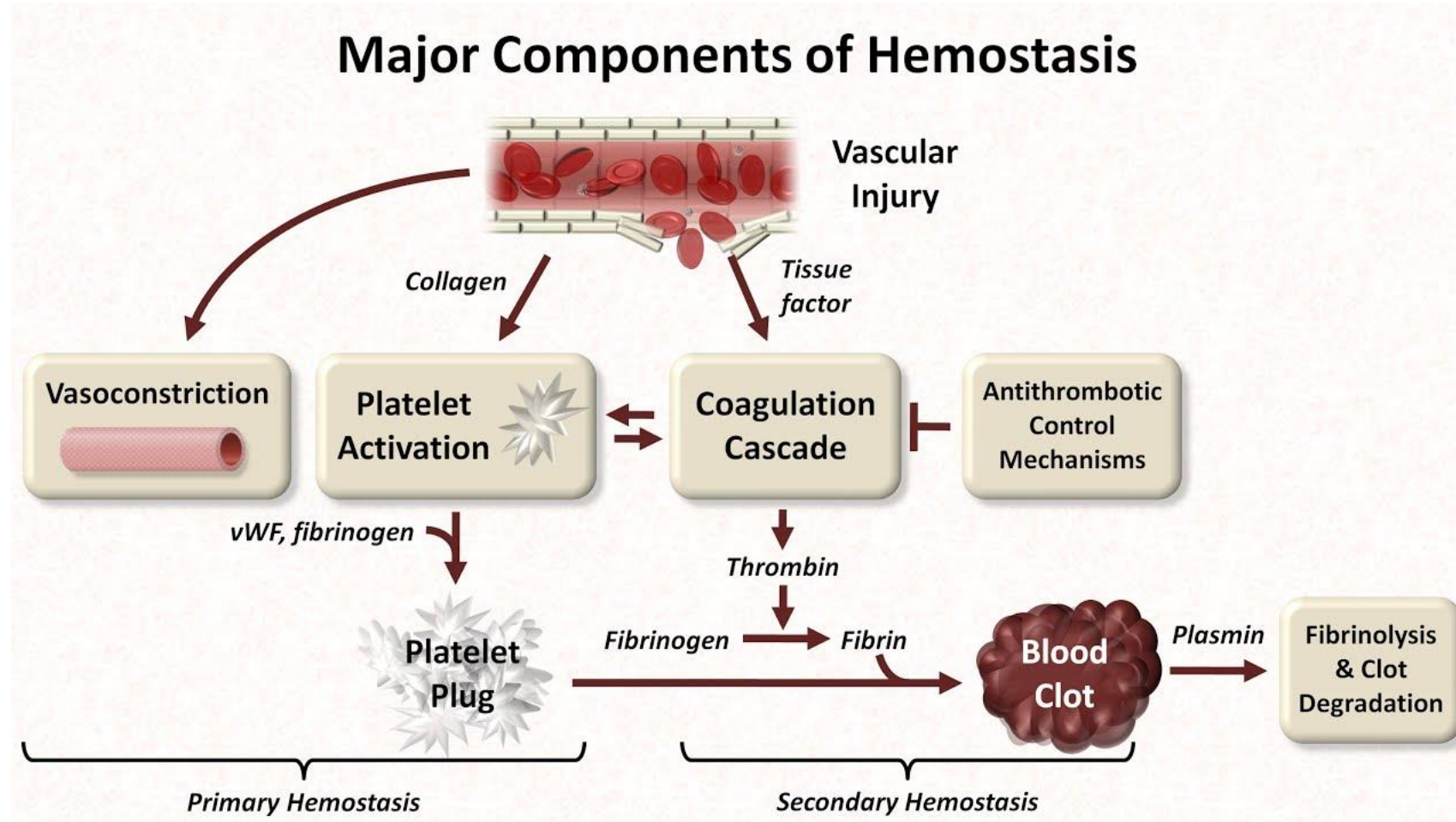


# TXA in Modern Trauma Practice

Sqn.Ldr. Sittichai Kawachakul, MD, FRCST

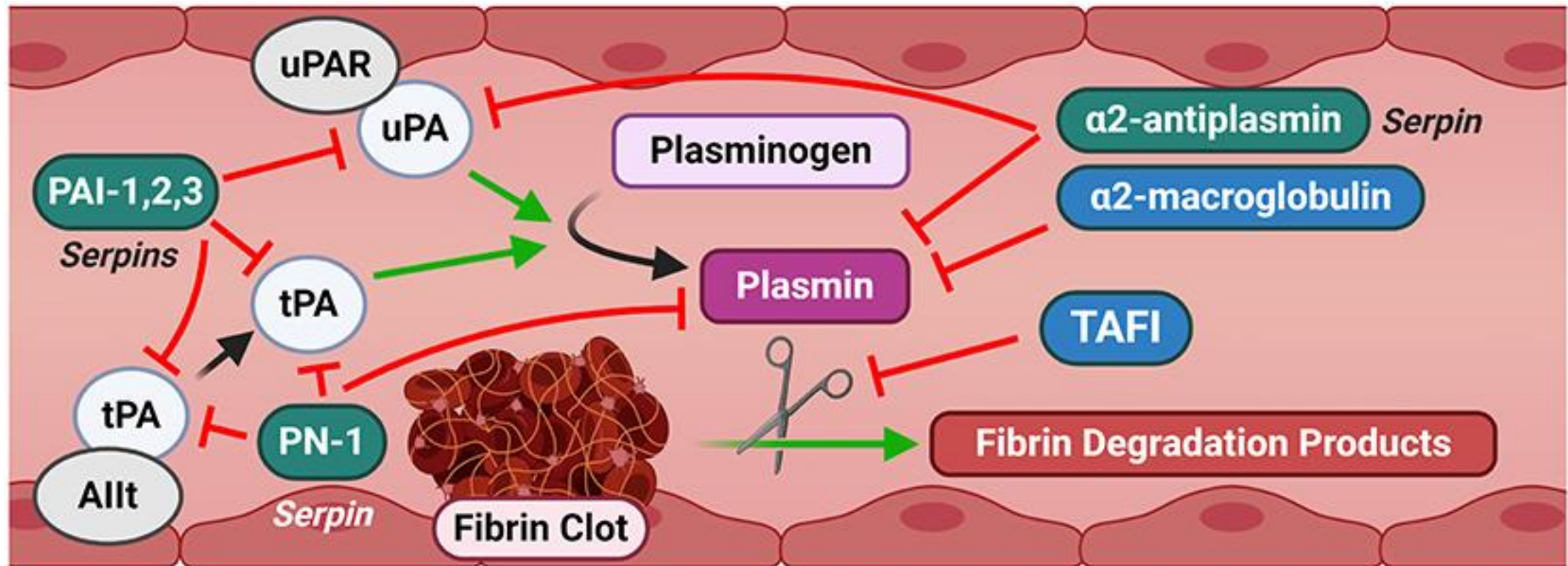
Trauma unit, Department of Surgery, Bhumibol Adulyadej hospital, RTAF

# Overview of Hemostasis



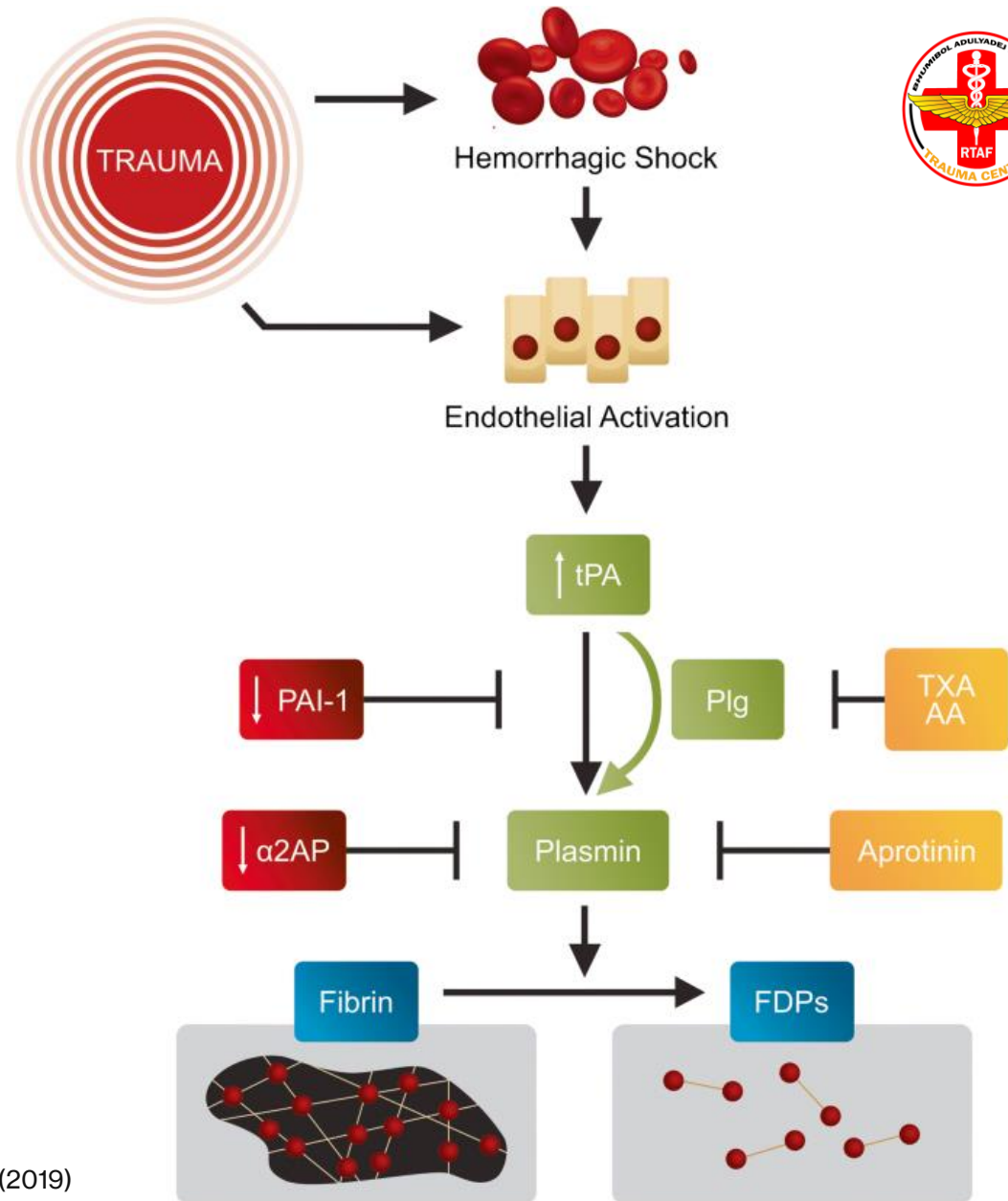


# Fibrinolysis pathway



# Hyperfibrinolysis in Trauma

- TIC and hyperfibrinolysis
  - Plasmin overactivity → Fibrin breakdown

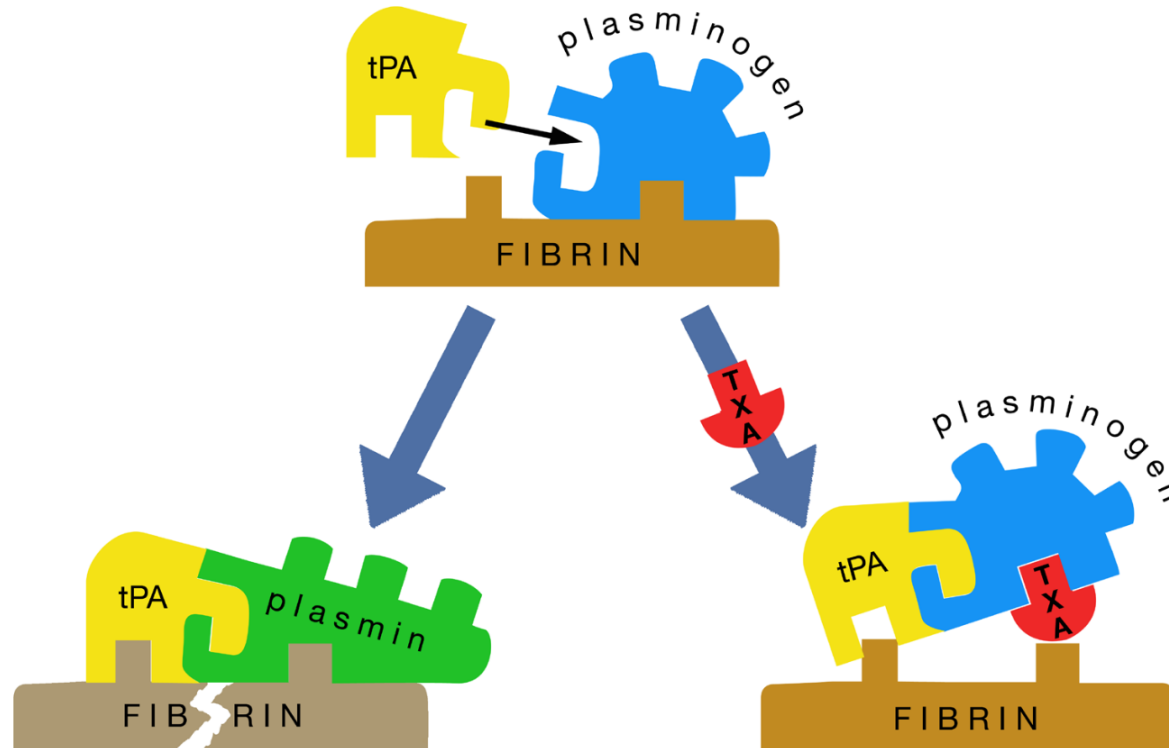


# TXA mechanism of action



## ■ Figure 6-11: TXA Mechanism of Action.

Pathologic hyperfibrinolysis may occur following trauma. This process will disrupt clot formation and contribute to uncontrolled hemorrhage. As illustrated on the left of the diagram, fibrinolysis is initiated when tissue plasminogen activator (tPA) binds to plasminogen, creating activated plasmin. Illustrated on the right of the diagram, tranexamic acid (TXA) binds to plasminogen, blocking its binding to fibrin and inhibiting fibrinolysis.



# TXA Pharmacokinetics



## ONSET OF ACTION

IV (ฉีดเข้าหลอดเลือดดำ) : 10-15 นาที

**ABSORPTION/DISTRIBUTION** ดูดซึมได้ดีและ  
กระจายตัวได้ดี

แบบรับประทาน ดูดซึมได้ 30-50% ในระบบทางเดินอาหาร

**METABOLISM** ผ่านตับ

## DURATION OF ACTION

IV/Oral : 6-8 ชั่วโมง

HALF-LIFE 80 นาที

PROTEIN BINDING <1%

## EXCRETION

**EXCRETION** ทางปัสสาวะในรูปแบบเดิม >95%

Oral route ยาจะถูกขจัดออกทางปัสสาวะในรูปแบบเดิม 40-70% ใน 24 ชั่วโมง

IV route ยาจะถูกขับออกทางปัสสาวะประมาณ 30% ในชั่วโมงแรก, 45% ใน 3 ชั่วโมง และ 90% ใน 24 ชั่วโมง

# TXA

## Pharmacokinetics

---

Rapidly absorbed from the GI tract

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Proportion entering the circulation ranges from 30-50%

---

T<sub>max</sub> 3 hours

---

Plasma protein binding is negligible

---

Distributed widely throughout the body

---

Plasma elimination half-life ~ 80 minutes

---

Over 95% being excreted unchanged in the urine



# การบริหาร **Tranexamic acid Injection**

- กรณีฉีดเข้าเส้นเลือดดำ (IV) ต้องฉีดยาช้า ๆ 10 ml. ในเวลา 1-2 นาที การให้ยาเร็วเกินไป อาจเกิดอาการไม่พึงประสงค์แบบเฉียบพลันได้ เช่น คลื่นไส้ ใจสั่น ไม่สบายในหน้าอกหรือความดันโลหิตลดลง
- กรณีฉีดเข้ากล้ามเนื้อ ให้หลีกเลี่ยงการฉีดยาใกล้แนวประสาท ถ้าต้องฉีดยาช้าให้ย้ายตำแหน่งฉีดยา

## ข้อมูลการเตรียมยา รวมถึงความเข้ากันได้ของยาและสารละลาย

### (Compatibility Profile)

Tranexamic acid Injection สามารถผสมเข้ากับสารละลายได้หลายชนิด

- สารน้ำที่เข้ากันได้: D5W, DSS, D5S/2, D5S/3, D10W, NSS, NSS/2, LRS
- ไม่ควรผสมลงในสารเลือดหรือสารละลายที่ประกอบด้วยตัวยากลุ่ม Penicillin



# Penetration Percentages of TXA (of plasma concentration)



Plasma	100%
Joints	90-100 %
Umbilical cord blood	40-100 %
Seminal fluid	10-100%
Cerebrospinal fluid	10-30 %
Aqueous humour	10%
Breast milk	1-2%

# Therapeutically Adequate Antifibrinolytic Activity



Serum

7- 8 hours

Tissues

up to 17 hours

Urine

up to 48 hours

# Adverse Effects and Contraindication

## ***Adverse Reactions:*** (uncommon)

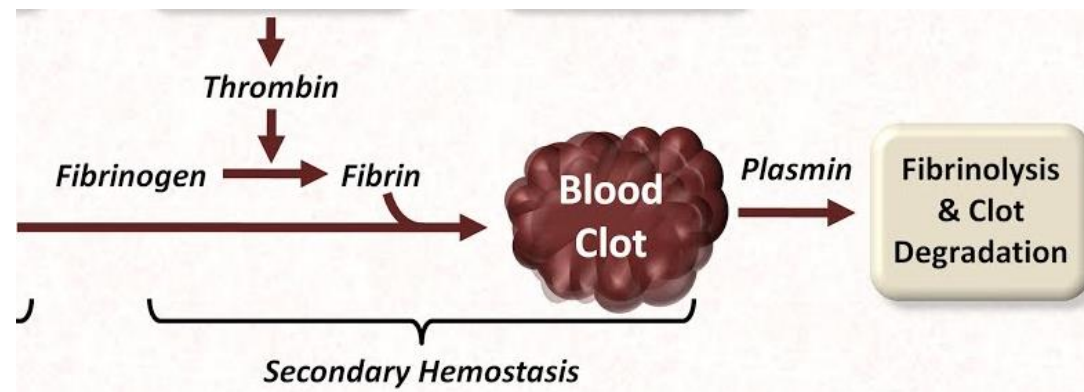
- Anorexia, nausea, vomiting, diarrhea and heartburn

## ***Precautions:***

- Patients with a history of **thromboembolic disease**
- Dosage reductions are recommended in patients with **renal insufficiency**

## ***Contraindication:***

- Patients with a history of hypersensitivity to any of the ingredients of the product.
- Patients receiving **thrombin** (increased Thrombotic events)



# Doses Recommended for Patients with Renal Impairment



Creatine clearance (ml/min)	Dose (mg/kg) Intravenous	Dose (mg/kg) oral	Frequency
50 – 80	10	15	Twice daily
10 - 50	10	15	Every 24 hour
< 10	10	15	Every 48 hour





Clinical use

# 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

*I Roberts, H Shakur, T Coats, B Hunt, E Balogun, L Barnettson, L Cook, T Kawahara, P Perel, D Prieto-Merino, M Ramos, J Cairns and C Guerriero*

**Design:** RCT, 20,211 adult trauma patients, 274 hospitals, 40 countries

**Intervention:** TXA 1 g IV bolus (10 min) + 1 g IV over 8 h vs placebo

**Population:** Significant bleeding (SBP < 90 or HR > 110) or at risk, ≤8 h post-injury

**Primary Outcome:** All-cause mortality at 28 days

# CRASH-2 Trial



- **Results**
- ↓ **All-cause mortality:** 14.5% vs 16.0% (RR 0.91;  $p=0.0035$ )
- ↓ **Death from bleeding:** 4.9% vs 5.7% (RR 0.85;  $p=0.0077$ )
- **Time-critical effect:**
  - $\leq 1$  h: RR 0.68 (**32%↓ risk**)
  - 1–3 h: RR 0.79 (**21%↓ risk**)
  - $> 3$  h: ↑ **risk** (RR 1.44)
- No ↑ vascular occlusive events

**TXA 1 gm iv within 3 hrs after injury then 1 gm over 8 hr**

# STAAMP Trial

JAMA Surgery | **Original Investigation**

## Tranexamic Acid During Prehospital Transport in Patients at Risk for Hemorrhage After Injury

A Double-blind, Placebo-Controlled, Randomized Clinical Trial



### Objective

- To determine whether **prehospital TXA** administration improves **30-day mortality** in trauma patients at risk of hemorrhage.

### Study Design

- **Multicenter, randomized, double-blind, placebo-controlled trial**
- **20 EMS systems, 12 trauma centers (USA)**
- **Population (n=927):** Trauma patients  $\geq 15$  yrs, high risk of bleeding (SBP  $\leq 90$  mmHg, HR  $\geq 110$  bpm, or prehospital transfusion).
- **Arms:**
  - TXA Bolus only** – 1 g IV over 10 min
  - TXA Bolus + Infusion** – 1 g IV bolus + 1 g over 8 hr (hospital)
  - Placebo**



# STAAMP Trial



## Results

- **Primary outcome (30-day mortality):**
  - TXA: **8.1%** vs Placebo: **9.9%** → NS ( $p=0.16$ )
- **Secondary/subgroup analyses:**
  - **TXA < 1 hr after injury:** Lower mortality (4.6% vs 7.6%)
  - **Severe shock (SBP  $\leq 70$  mmHg):** Significant mortality reduction (18.5% vs 35.5%)
  - **Safety:** No increase in thromboembolic events or seizures

## Conclusion

- **TXA in prehospital trauma is safe**
- **No overall mortality benefit, but clear signal of benefit in severe shock and when given within 1 hour post-injury**
- Supports principle: **“The earlier, the better”** for TXA.



ORIGINAL ARTICLE

# Prehospital Tranexamic Acid for Severe Trauma

The PATCH-Trauma Investigators and the ANZICS Clinical Trials Group\*

## Objective

- To assess whether **prehospital TXA** improves outcomes in patients with **severe trauma and risk of coagulopathy**.

## Study Design

- **Multicenter, randomized, double-blind, placebo-controlled trial**
- **15 ambulance services & 21 trauma centers (Australia, NZ, Germany)**
- **Population (n=1,310):** Adults with severe trauma (risk of trauma-induced coagulopathy, high prehospital mortality risk score  $\geq 15$ )
- **Intervention:** 1 g IV TXA prehospital + 1 g IV over 8 hr in-hospital
- **Control:** Placebo

# PATCH Trial



## Results

- **Primary Outcome (Favorable Functional Survival at 6 mo, GOS-E  $\geq 5$ ):**
  - TXA: **53.7%** vs Placebo: **53.5%**  $\rightarrow$  NS (RR 1.00, 95% CI 0.90–1.12)
- **Mortality**
  - **at 24 hr:** TXA: **9.7%** vs Placebo: **14.1%** (RR 0.69, 95% CI 0.51–0.94)  $\rightarrow$   $\downarrow$  Deaths
  - **at 28 days:** TXA: **17.3%** vs Placebo: **21.8%** (RR 0.79, 95% CI 0.63–0.99)  $\rightarrow$   $\downarrow$  Deaths
- **Safety:** No increase in vascular occlusive events (PE, DVT, MI, stroke)

## Conclusion

- **TXA did not improve functional neurological outcome at 6 months**
- **Did reduce early mortality (24 hr and 28 day)**
- Safe, with no increase in thromboembolic complications
- Clinical implication: TXA may save lives but **survivors often have severe disability.**



# Effects of tranexamic acid on death, disability, vascular occlusive events and other morbidities in patients with acute traumatic brain injury (CRASH-3): a randomised, placebo-controlled trial

*The CRASH-3 trial collaborators\**

## Design & Methods

**Type:** Randomized, double-blind, placebo-controlled trial

**Sample:** 12,737 patients, 175 hospitals, 29 countries

**Inclusion:** TBI with GCS  $\leq 12$  or any intracranial bleeding on CT, within  $\leq 3$  h of injury

**Intervention:** TXA 1 g IV bolus (10 min) + 1 g IV over 8 h vs placebo

**Primary outcome:** Head injury-related death within 28 days in hospital



# CRASH-3 Trial



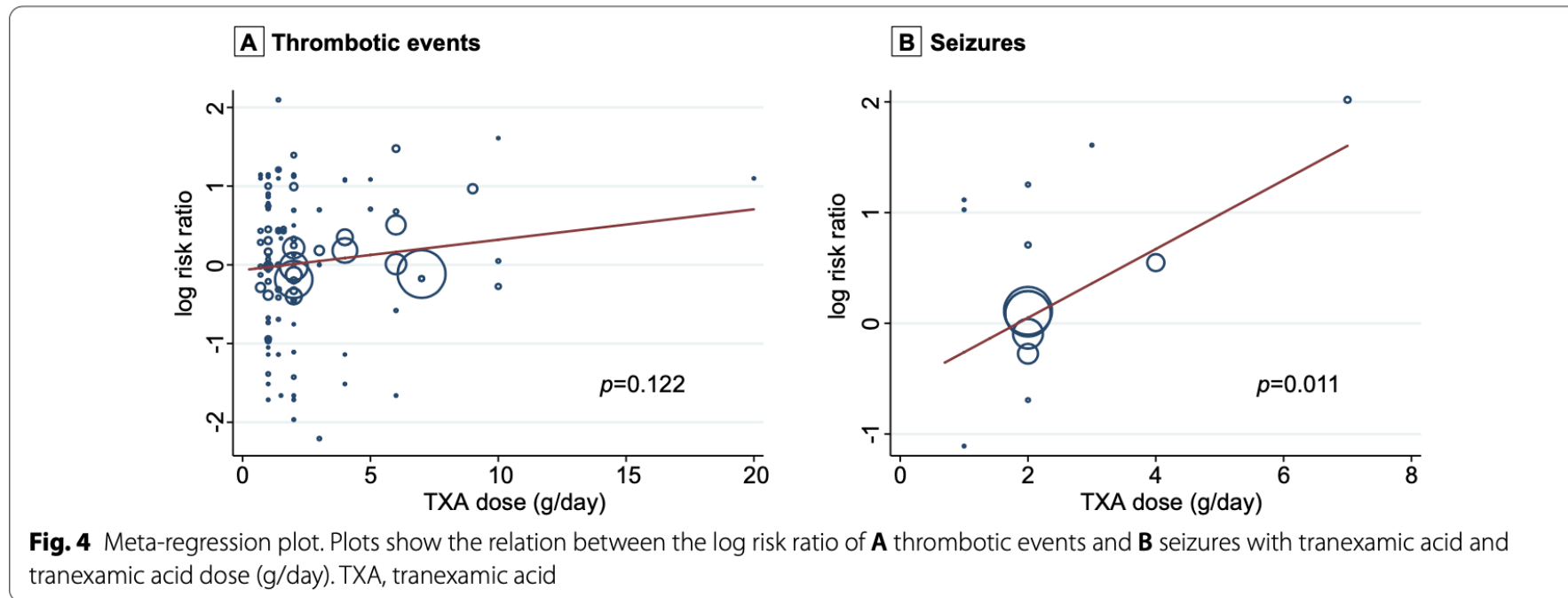
## Results

- **Overall:** No significant reduction in head injury–related mortality (18.5% vs 19.8%, RR 0.94; 95% CI 0.86–1.02)
- **Early treatment effect:**
  - **Mild–moderate TBI (GCS 9–15):** 5.8% vs 7.5% (RR 0.78; 95% CI 0.64–0.95) – *benefit*
  - **Severe TBI (GCS 3–8) :** No significant benefit
  - Treatment **>3 h:** no benefit
- **Safety:** No increase in vascular occlusive events or seizures

For TBI without major extracranial bleeding, give **TXA 1 gm in 10 min then 1 gm over 8 hr** ( $\leq 3$  h, ideally  $< 1$  h after injury), especially in mild–moderate cases, to reduce TBI–related mortality.

# Safety and meta analysis of TXA

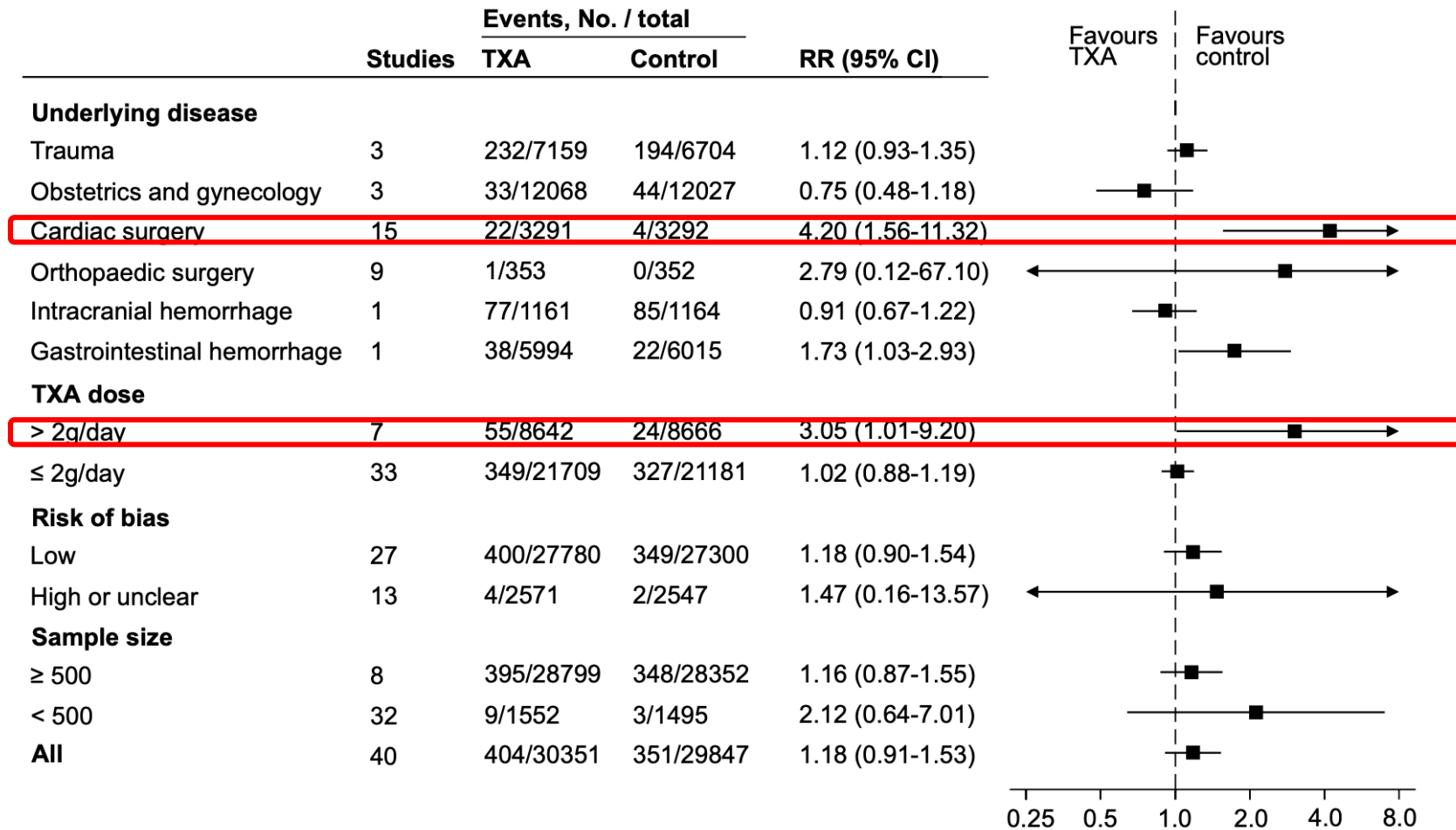
- No increased risk of Thrombotic event.
- Risk of seizure with high dose of TXA in Cardiac surgery more than Trauma.
- Becareful in high dose and renal impairment.



# Safety and meta analysis



## B Seizures





# Dosing

- CRASH-2 :
  - 1 gm iv in 10 min + 1 gm iv over 8 hours
  - within 3 hours of injury
- *Tranexamic acid (TXA) 2gm bolus is now favored over the traditional 1gm prehospital bolus followed by 1gm infusion over 8 hours.*
- *The 2gm TXA bolus should be given as close to the time of injury as possible and not outside of the 3 hours window.*



# Optimal dose of tranexamic acid in traumatic brain injury: Systematic review and network meta-analysis of randomized controlled trials

**Shu Utsumi, MD, Akiko Kawakami, MD, and Yu Amemiya, MD, Hiroshima, Japan**

## **Background**

- Tranexamic acid (TXA) used to reduce hyperfibrinolysis in TBI.
- Optimal dosage remains unclear.

## **Methods**

- Network meta-analysis of 10 randomized controlled trials (to May 2024).
- Primary outcomes: mortality, poor neurological outcome.
- Secondary outcome: vascular occlusive events.



## Results

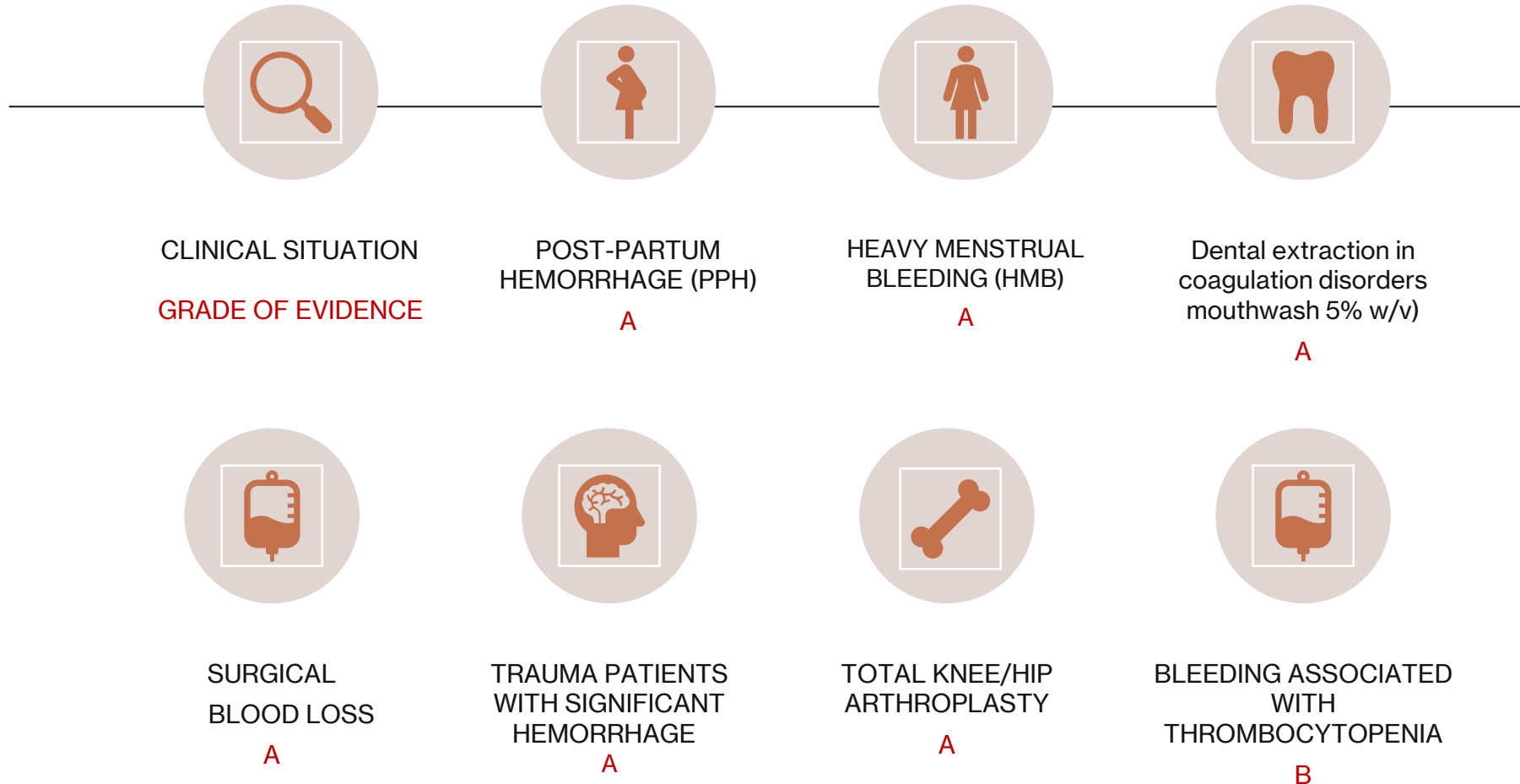
- **Placebo vs 2 g TXA bolus** → Higher mortality (RR 1.53, 95% CI 1.08–2.17).
- **1 g bolus + 1 g maintenance vs 2 g bolus** → Higher mortality (RR 1.43, 95% CI 1.02–2.03).
- **Neurological outcome** → No significant differences.
- **Vascular occlusive events** → No significant differences.

## Conclusion

- **2 g IV bolus TXA reduces mortality** vs placebo and 1 g + 1 g regimen.
- No increased risk of vascular occlusion.
- Evidence limited (only one RCT with 2 g bolus) → further studies required.

# Indications for Tranexamic acid in the Treatment of Excessive Bleeding

Tranexamic acid is recommended in multiple guidelines and classified as an essential medicine by the World Health Organization (WHO)





# Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial



*WOMAN Trial Collaborators\**

## **Design & Methods**

**Type:** Randomized, double-blind, placebo-controlled trial

**Sample:** 20,060 women with clinically diagnosed PPH after vaginal birth or cesarean, 193 hospitals, 21 countries

**Intervention:** TXA 1 g IV (10 min); 2nd dose if bleeding continued/recurred after 30 min or restarted within 24 h

**Primary outcome:** Death from any cause within 42 days of giving birth

**Key secondary outcome:** Death due to bleeding

# WOMAN Trial



## Results

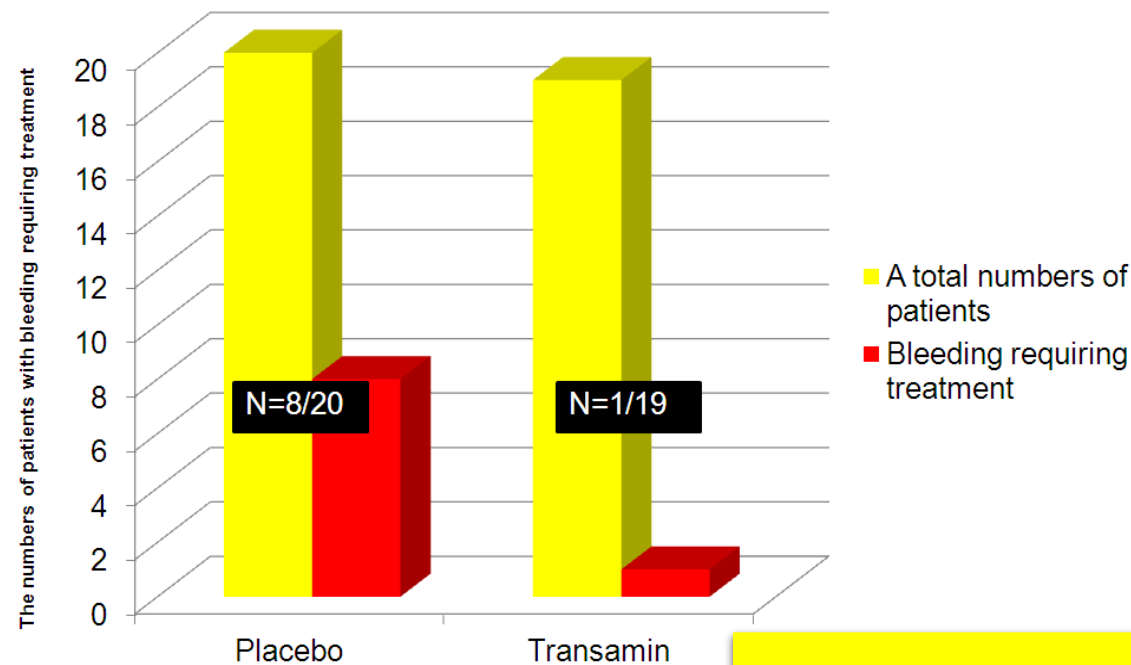
- **All-cause mortality:** No significant reduction (2.3% TXA vs 2.6% placebo; RR 0.88, 95% CI 0.74–1.05)
- **Death due to bleeding: Significantly reduced** – 1.5% vs 1.9% (RR 0.81, 95% CI 0.65–1.00;  $p=0.045$ )
- **Time to treatment:** Critical
  - **≤3 h:** 1.2% vs 1.7% (RR 0.69, 95% CI 0.52–0.91) → **31% ↓ risk**
  - **>3 h:** No benefit
- **Safety:** No increase in thromboembolic events

Give **TXA 1 g IV** in women with postpartum hemorrhage, ideally **within 3 h after birth**; repeat once if bleeding continues.

# Tranexamic acid for Dental Procedure Bleeding

- A significant hemostatic effect of 4.8% Tranexamic acid mouthwash after oral surgery

An alternative method to discontinuing anticoagulant therapy : A placebo-controlled, double-blind, randomized study



- Compared with placebo in 39 patients receiving oral anticoagulants
- The difference between the two group in the numbers of patients with bleeding requiring treatment was statistically significant ( $P=0.01$ )
- No systemic side effect

**Tranexamic acid 500 mg + น้ำ 10 mL**

ใช้บ้วนปากครั้งละ 2 นาที วันละ 4 ครั้ง เป็นเวลานาน 7 วัน

# 5% Tranexamic acid mouthwash after oral surgery



- วิธีการผสมยา Tranexamic acid Capsule ให้เป็นยาน้ำบ้วนปาก 5% TXA mouthwash
- มี 2 วิธีหลักๆ
  - แกะ Transamin capsule (250mg x 2 เม็ด) ผสม Tranexamic acid 500 mg ในน้ำ 10 mL ให้อมกลั้วให้ทั่วปาก 2 นาที แล้วบ้วนทิ้ง **หรือ**
  - ใช้แบบ solution for injection (ampoule) ก็ dilute Tranexamic Injection 250mg/5ml Solution for Injection 2 amps (10 mL) ให้อมกลั้วให้ทั่วปาก 2 นาทีแล้วบ้วนทิ้ง

**Tranexamic acid 500 mg + น้ำ 10 mL**

**ใช้บ้วนปากครั้งละ 2 นาที วันละ 4 ครั้ง เป็นเวลานาน 7 วัน**

\*\*Tranexamic acid 250 mg/5 mL/amp

\*\*Tranexamic acid 250 mg/capsule



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American Journal of Emergency Medicine

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## Topical tranexamic acid for the treatment of acute epistaxis in the emergency department☆

Asha R. Birmingham, PharmD<sup>a</sup>, Nathan D. Mah, PharmD<sup>a,\*</sup>, Ran Ran, MD<sup>b</sup>, Matthew Hansen, MD<sup>b</sup>

<sup>a</sup> Department of Pharmacy, Oregon Health & Science University, United States

<sup>b</sup> Department of Emergency Medicine, Oregon Health & Science University, United States

- Among 122 patients, 30 received topical TXA (500 mg injectable solution soaked onto packing material and applied to the affected nostril) and 92 were managed with standard care.
- TXA was associated with a significant reduction in otolaryngologist consults (30.0% vs 65.2%,  $p = 0.002$ ) and nasal packing (16.7% vs 23.9%,  $p = 0.003$ ). No significant difference was observed in the ED LOS (272 vs 232 min in TXA and standard care arms, respectively,  $p = 0.26$ ).



Indications	Tranexamic Acid Dosage Regimens		References
	Intravenous (250 mg/ 5mL)	Oral (250 mg Capsule)	
Trauma	Loading 1 g (4 amps) over 10 min then 1 g (4 amps) over 8 hr *Several studies have used a standardized dose of 1 g*		WHO Model List of Essential Medicines (EML) 2011 CRASH-2 trail, Lancet 2010;376:23-32 The European guideline on management of major bleeding and coagulopathy following trauma: 5 <sup>th</sup> edition 2019
Aneurysmal Subarachnoid Hemorrhage (SAH)	IV 1 g (4 amps) of TXA was immediately given intravenously, before the patients were transported to the regional neurosurgical center. The initial dose was followed by a second dose of 1 g (4 amps) after 2 hours, and therapy was then continued with doses of 1 g (4 amps) every 6th hour until the aneurysm was occluded, up to 72 hours of treatment post-SAH.		J Neurosurg 2002;97:771-8
Cardiac Surgery	IV Bolus 1 g (4 amps) 10-15 mins before incision then 400mg/h until the completion of surgery		Anesth Analg 2012;115(2):239-43
Upper GI Bleeding	IV 1 g (4 amps) q 6 hr for 2-3 day (3-6 g/day)	Followed by oral 3-6 g/day for 3-5 days	Br Med J 1998;298:1142-6
Prostatectomy Surgery	Loading 500 mg (2 amps) 20 mins before surgery followed by continuous IV 250 mg/hr during surgery		BMJ 2011;343:d5701
Total Knee Arthroplasty (TKA)	IV TXA : Loading 10-20 mg/kg before beginning procedure, with at least one additional iv dose administered postoperatively (several studies have used a standardized dose of 1 g (4 amps)) Topical TXA doses >2g appear to be more efficacious than lower dose	Followed by 500 mg (2 capsules) 3 times daily for 5 days	the American Academy of Orthopaedic Surgeons (AAOS) Guidelines 2015 (Recommendation : Strong Evidence) Charoencholvani K et al 2011
Total Hip Arthroplasty (THA)	TXA, a 1 g (4 amps) bolus was administered IV at the beginning of surgery. At the end of surgery another 1 g (4 amps) bolus was given by either IV or IA route, according to the surgeon's preference		Medicine (2018) 97:21
Spine Surgery	Loading 2 g (8 amps) followed by 100 mg/hr (for adult) or 30 mg/kg (for children) followed by 1 mg/kg/hr (for children) during surgery and for 5 hours after the operation		SPINE 2008;33:2577-80
Postpartum Hemorrhage (PPH)	Administered at a fixed dose of 1 g (4 amps) IV at 1 mL per minute (over 10 minutes), with a second dose of 1 g IV if bleeding continues after 30 minutes, TXA for PPH treatment should not be initiated more than 3 hours after birth		WHO Global Recommendation 2017 WOMEN trial, Lancet 2017; 389: 2105–16
Elective Cesarean Section (CS)	IV 1 g (4 amps) diluted with 20 mL of 5%glucose before incision 10 mins		Am J Perinatol 2011;28(3):233-40
Heavy Menstrual Bleeding (HMB)		1 g (4 capsules) 3 times daily for 5 days in each cycle for 3 cycles, starting on the first day of period	UK RCOG NICE guideline 44;2007
Epistaxis		500 mg (2 capsules) 3 times daily for 3 days	B-ENT 2005;1(1):27-43
Traumatic Hyphaema		500 mg (2 capsules) 3 times daily for 5 days	Can J Ophthalmol 1992;27(4):181-83
Pulmonary Tuberculosis (Blood sputum or Haemoptysis)	Inhalation : Administered through a jet nebulizer with a flow rate of 5 L of oxygen per minute, and doses of 2.5 or 5 mL were prescribed according to clinical decision, using a concentration of 500 mg/5 mL (โพแทสเซียม 500 mg/10 mL)	500 mg (2 capsules) 3 times daily for 7 days (1.5 g/day)	Chest. 2016;149(2):604 J Med Assoc Thai 2002;85(4):399-404





# Integration into MTP in BAH experience

## Massive Transfusion Protocol for Trauma

Evidence of internal or external bleeding by PE or e-FAST



### Indication for MTP activation

Initial resuscitation 1-2 L. of warm isotonic crystalloid and

- one of followings :
- |                  |                      |
|------------------|----------------------|
| 1. SBP < 90 mmHg | 2. HR > 120 bpm      |
| 3. pH < 7.2      | 4. Base deficit > 10 |

Trauma team **activates "MTP"** to Blood bank (Tel : 27833,27834)

- Lab
1. G/M
  2. CBC, PT PTT INR, BUN Cr Electrolyte
  3. ABG

- Drugs
1. Tranexamic acid 1 gm. iv if bleeding occurs within 3 hrs
  2. Vit K 10 mg. iv if on Anticoagulants

### Hypothermia prevention

Warm blanket and/or Radiant warmer



Call for **"MTP box 1"**

( 1<sup>st</sup> MTP box = PRC 4 u, FFP 4 u, SDP 1 u in 20 min)

Hemorrhage control and resuscitation

(Hemorrhage control = pressure dressing, tourniquet, splint, or surgery)

### MTP version 1

Administer 1 gm of TXA intravenously within 3 hours  
PRC 4 units – FFP 4 units – SDP 1 unit

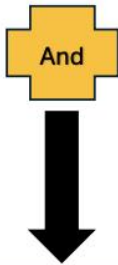




## BAH Massive Transfusion Protocol for Trauma

Evidence of internal or external bleeding

- FAST positive more than 1 quadrant
- Massive hemothorax
- Unstable Pelvic fracture
- Long bone fracture with vascular injury
- Evidence of massive external bleeding required intervention
- Penetrating injury at Torso, Neck



Initial resuscitation 1 L of warm isotonic crystalloid and  
One of following: SBP < 90 mmHg  
HR > 120 bpm  
pH < 7.2  
Base deficit > 10

Trauma team **"Activated MTP"** to blood bank (Tel: 27833, 27834)

- Lab: 1. G/M blood tube 2 tubes      2. CBC, PT, PTT, INR, BUN, Cr, Electrolyte  
3. ABG      4. Serum ionized calcium

Tel 27060 ICU CVT เปิดเครื่อง ROTEM

Drug: Tranexamic acid 2 gm iv if onset of injury < 3 hours  
10% Calcium gluconate 20 ml iv slowly push (2gm)

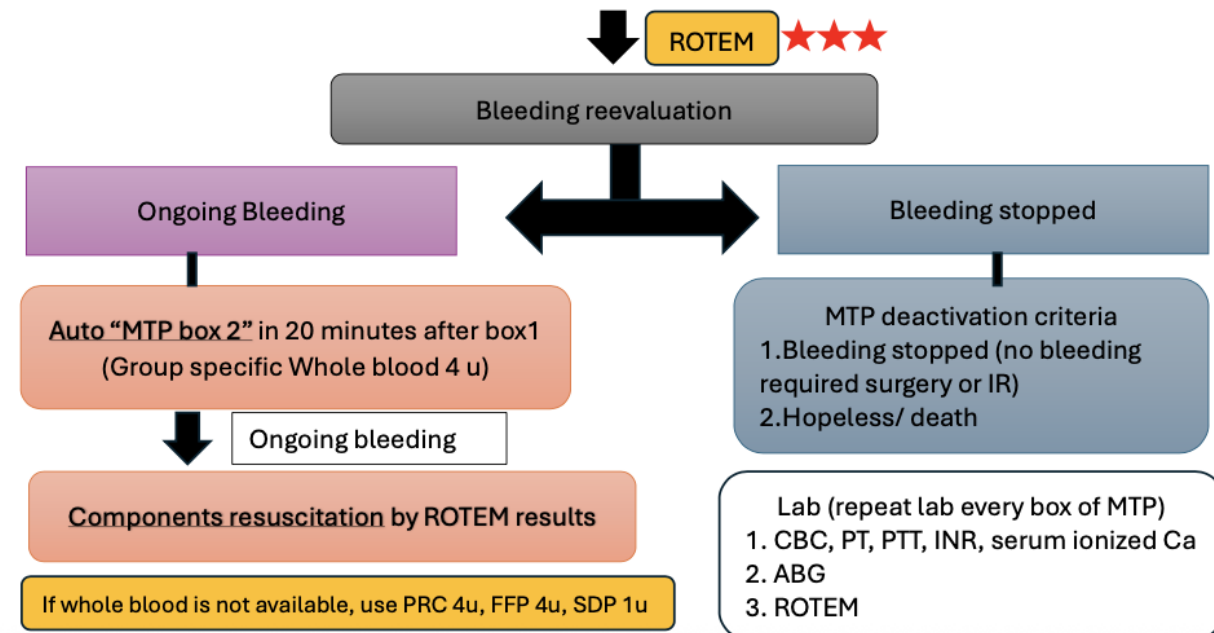
Hypothermia prevention: Warm blanket and/or Radiant warmer

**"MTP box 1"**

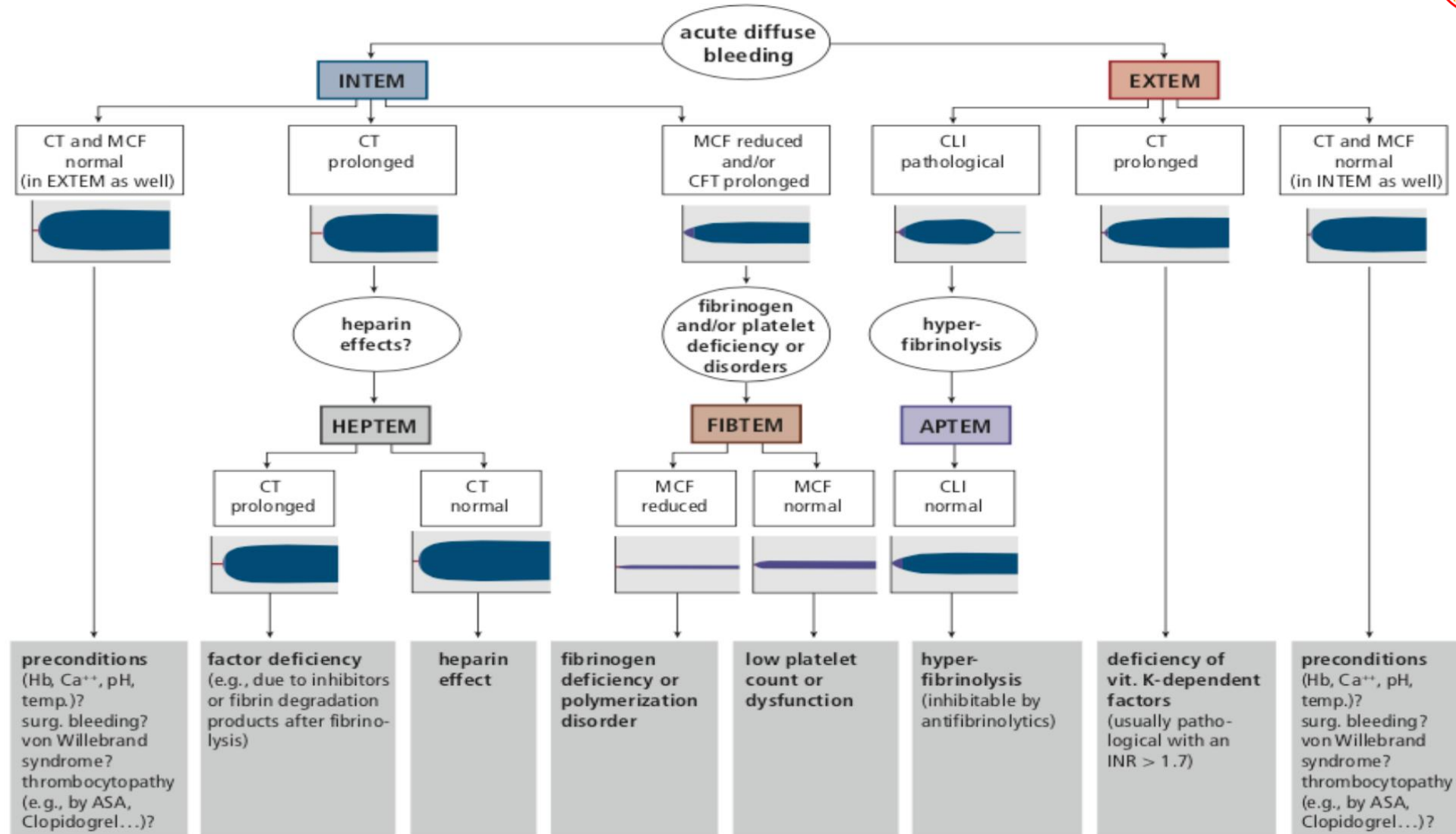
(1<sup>st</sup> MTP box = group O low titer PRC 2 u, group specific Whole blood 4 u)  
Hemorrhagic control = Pressure dressing, Tourniquet, Splint, or Surgery

## MTP version 3

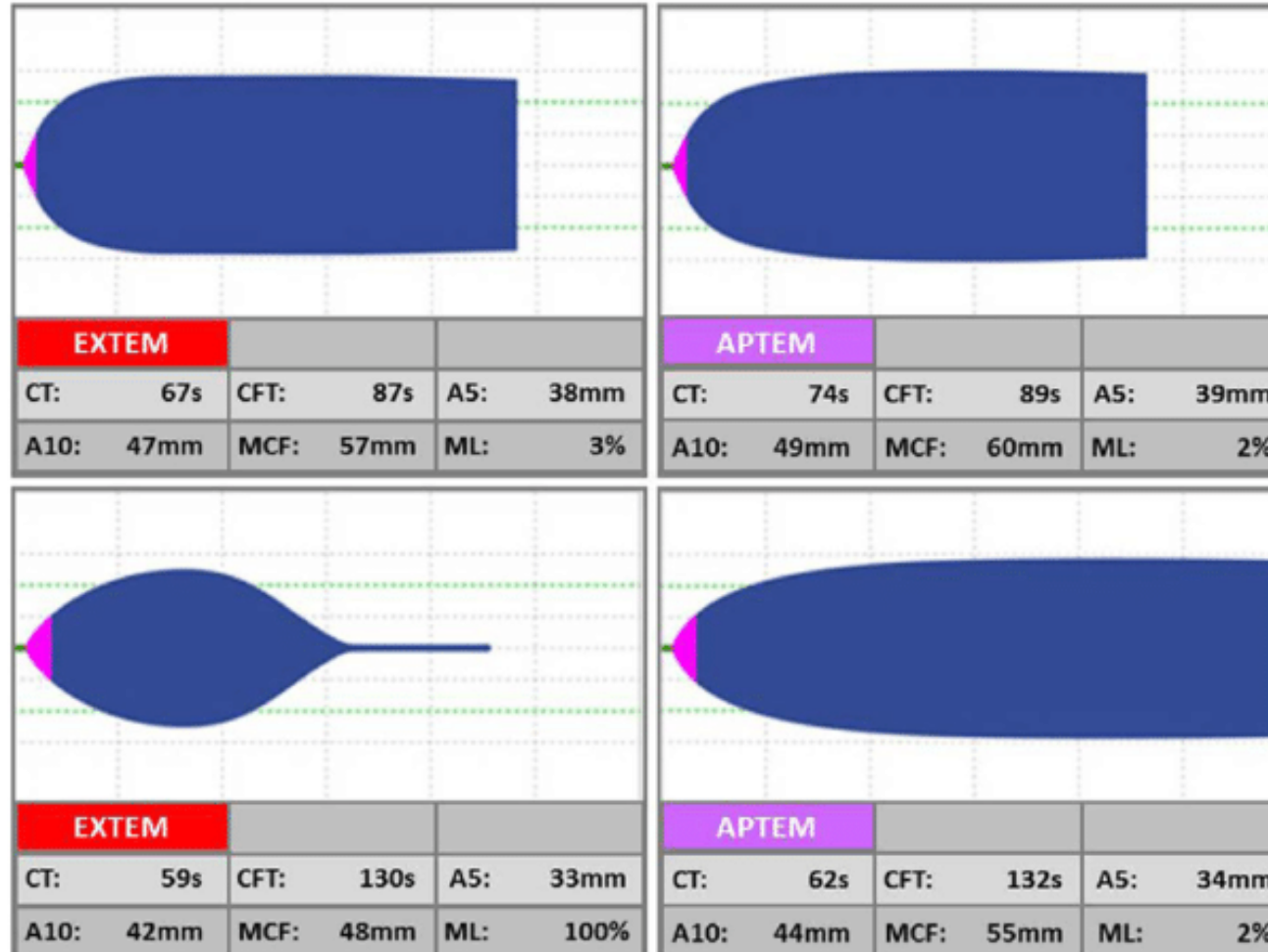
- Administer TXA 2 gm intravenously within 3 hours
- Provide 10% calcium gluconate 20 ml (2 gm of calcium)
- Transfuse 4 units of whole blood



# ROTEM-Guided TXA Use



# Example of hyperfibrinolysis in ROTEM





# Take home message

- **Time is critical** – Administer TXA **as early as possible, within 3 hours** after injury → maximum benefit.
- **Dosing options** –
  - **CRASH-2:** 1 g IV bolus → 1 g infusion over 8 h
  - **JTS 2023:** 2 g IV/IO bolus (simple, suitable for military/prehospital)
- **Patient selection** – Trauma patients with bleeding or at risk, shock, penetrating torso injuries, and moderate TBI within 3 h.
- **Safety** – No significant increase in thrombotic events in trauma; watch for seizures with high doses or renal impairment.
- **Integration** – TXA is part of **Damage Control Resuscitation (DCR)**: MTP activation, balanced transfusion/whole blood, calcium, and fibrinogen support.
- **Avoid late use** – TXA given **>3 hours after injury** shows no benefit and may cause harm but indicate as ROTEM/TEG guided



# THANK YOU

