New ways to manage massive haemorrhage - using ROTEM and fibrinogen concentrate

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Haemorrhage is the second commonest cause of death in major trauma patients

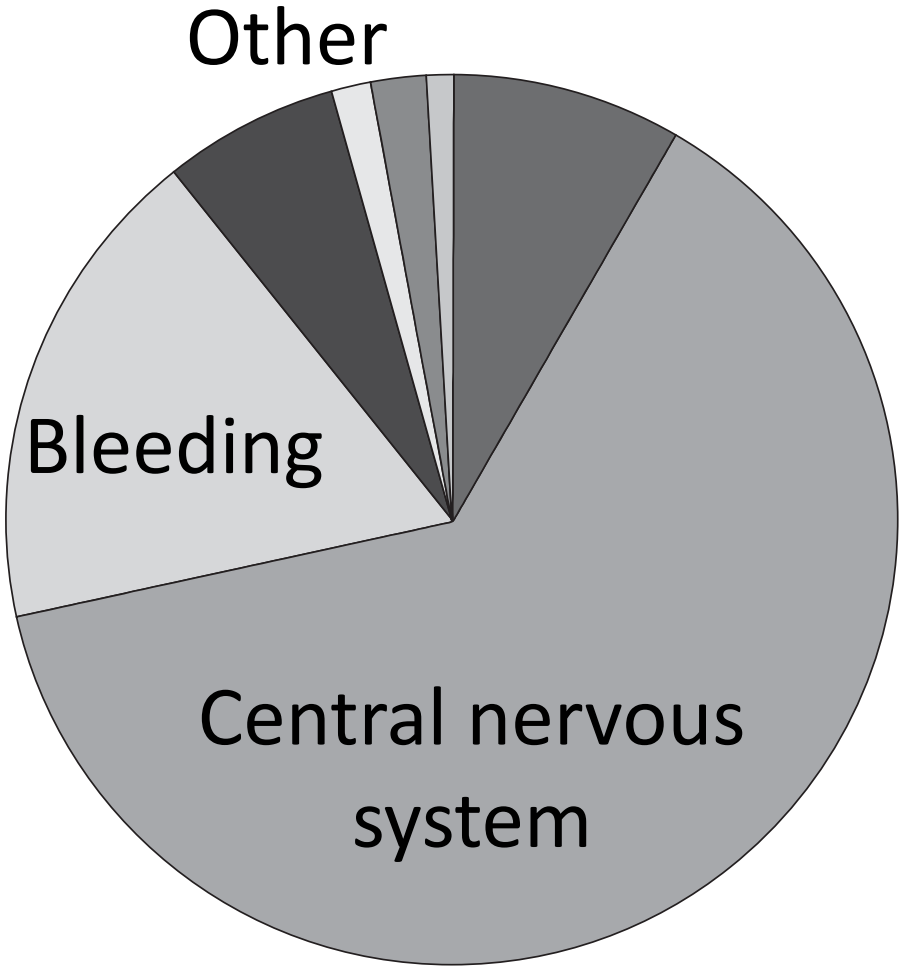
Incidence and etiology of mortality in polytrauma patients in a Dutch level I trauma center

Zainab El Mestoui, Hamid Jalalzadeh, Georgios F. Giannakopoulos and Wietse P. Zuidema

European Journal of Emergency Medicine 2015, Vol 00 No 00

95% blunt injuries

18% die of exsanguination

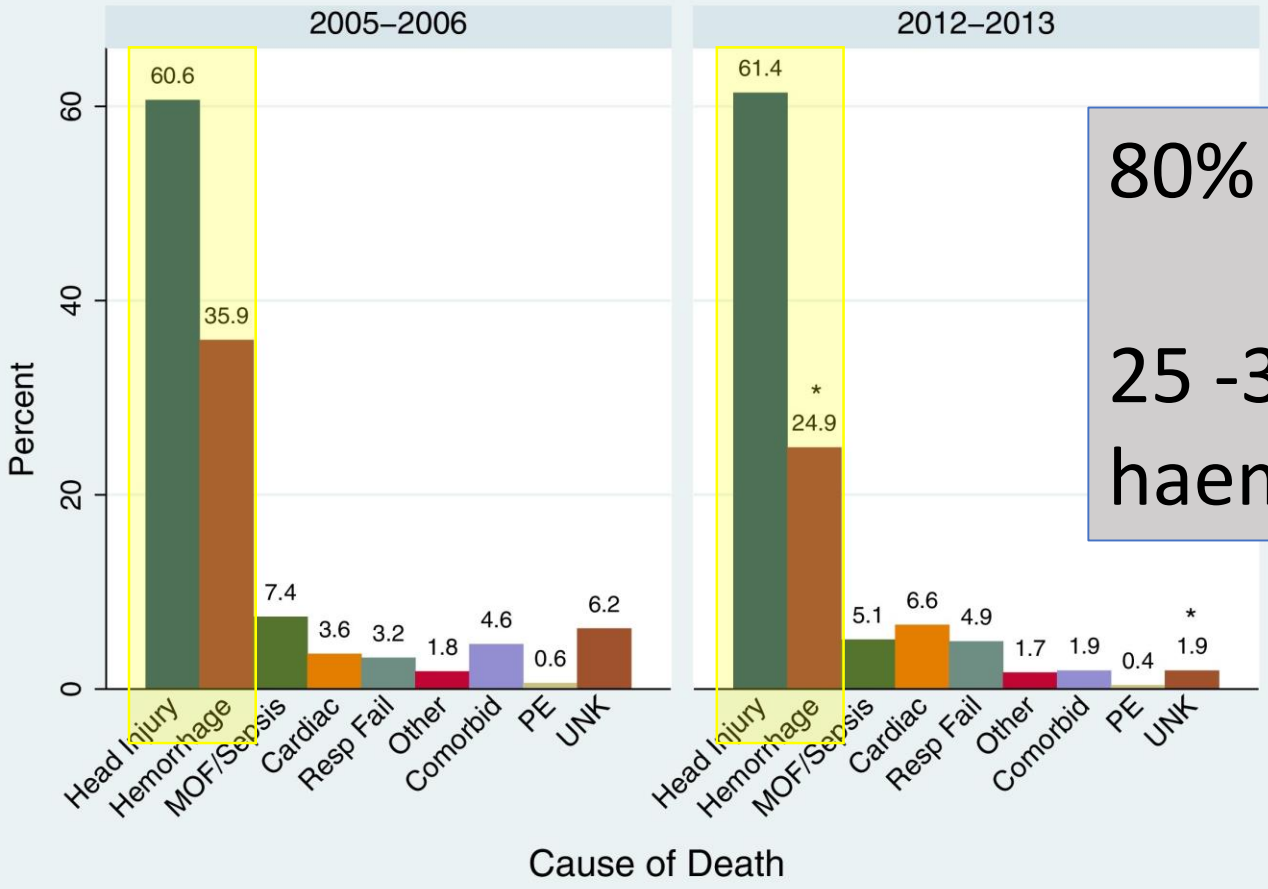


Trends in 1029 trauma deaths at a level 1 trauma center: Impact of a bleeding control bundle of care

Blessing T. Oyeniyi, Erin E. Fox, Michelle Scerbo, Jeffrey S. Tomasek, Charles E. Wade, John B. Holcomb*

Center for Translational Injury Research, Division of Acute Care Surgery, Department of Surgery, Medical School, The University of Texas Health Science Center at Houston, Houston, TX, USA

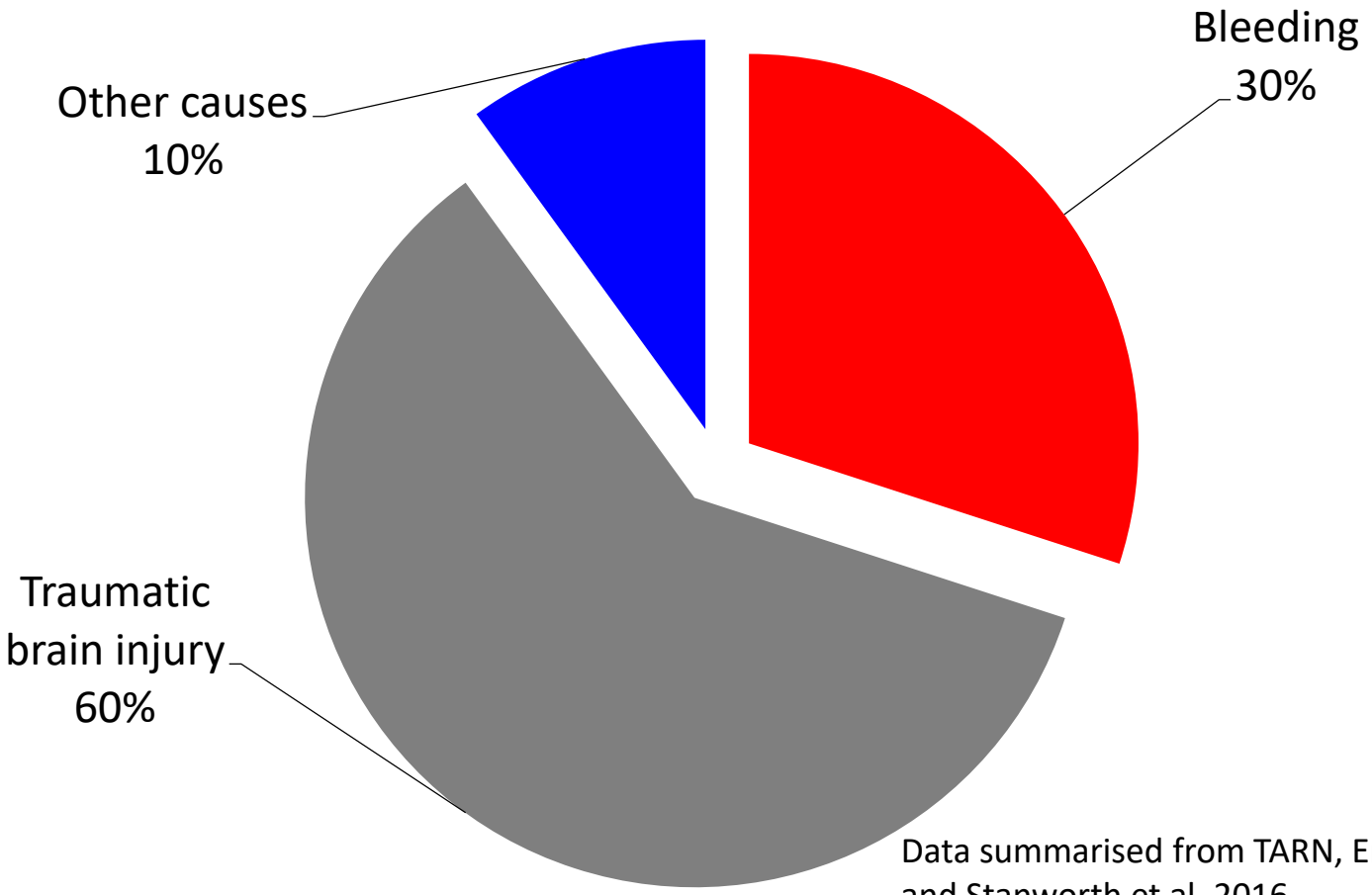
Injury, Int. J. Care Injured 48 (2017) 5–12



80% blunt injuries

25 -35 % die from haemorrhage

Causes of death after major trauma in England & Wales



Data summarised from TARN, England & Wales and Stanworth et al. 2016

95% of deaths due to blunt trauma

Trauma-associated haemorrhage

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1. Tissue Injury
2. Coagulopathy
   a. Trauma-induced coagulopathy.
   b. Secondary coagulopathy from consumption, dilution and/or metabolic factors (acidosis, hypothermia).
3. Sometimes all of the above

Major haemorrhage in trauma

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- Clinical indicators are poor predictors of which major trauma patients will have major haemorrhage (from Code Red activation research).
- < 5-10% of major trauma patients (varies with definition of major trauma) present with major haemorrhage.
- Major haemorrhage in the trauma patient is uncommon and unpredictable but potentially deadly.

Bleeding control bundle of care.

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1 Identify the bleeding patient

2 Prehospital and hospital damage control resuscitation

3
- Prehospital and hospital extremity and junctional tourniquets
- Prehospital and hospital pelvic binders
- Prehospital and hospital hemostatic dressings
- Resuscitative endovascular balloon occlusion of the aorta

Physical methods

4 Coagulation monitoring

Assessment of haemostasis

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Laboratory

- PT, APTT, fibrinogen, platelet count.
- Turn around time too slow to make immediate diagnosis of coagulopathy or guide on-going resuscitation.
- Limited appreciation of dynamics of clot formation and unable to diagnose hyperfibrinolysis.
- Most trauma patients who receive a blood products (Code Red) have normal PT and APTT on admission.

Viscoelastic tests

- TEG® -predominantly USA but also UK.
- ROTEM® - predominantly Europe and Canada.

Platelet function

“Thromboelastographie” - Hartert 1948

KLINISCHE WOCHENSCHRIFT

26. JAHRGANG, HEFT 37/38 1. OKTOBER 1948

ORIGINALIEN.

BLUTGERINNUNGSSTUDIEN MIT DER THROMBELASTOGRAPHIE, EINEM NEUEN UNTERSUCHUNGSVERFAHREN*.

Von

HELLMUT HARTERT.

Medizinische Universitätsklinik Heidelberg (Direktor: Prof. Dr. R. SIEBECK).

Die Blutgerinnung ist einer der kompliziertesten Gerinnsels und unter gewissen Bedingung

die Fibrinolyse in meist wiederholt schubartigen Thrombocytenzahl ab (s. unten). Über die m

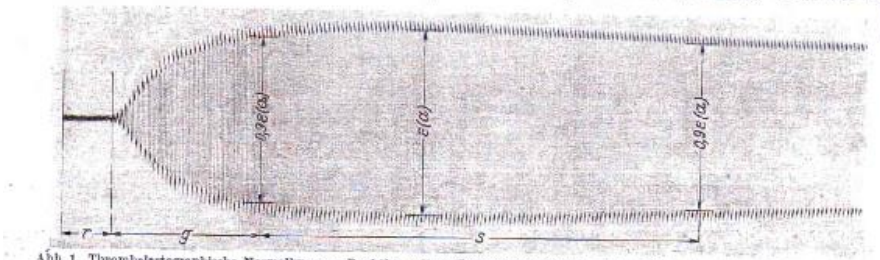
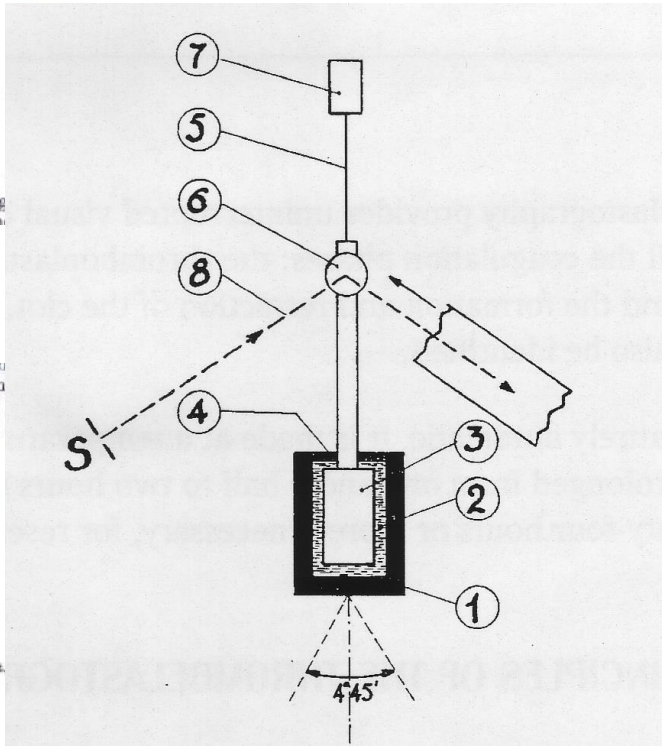
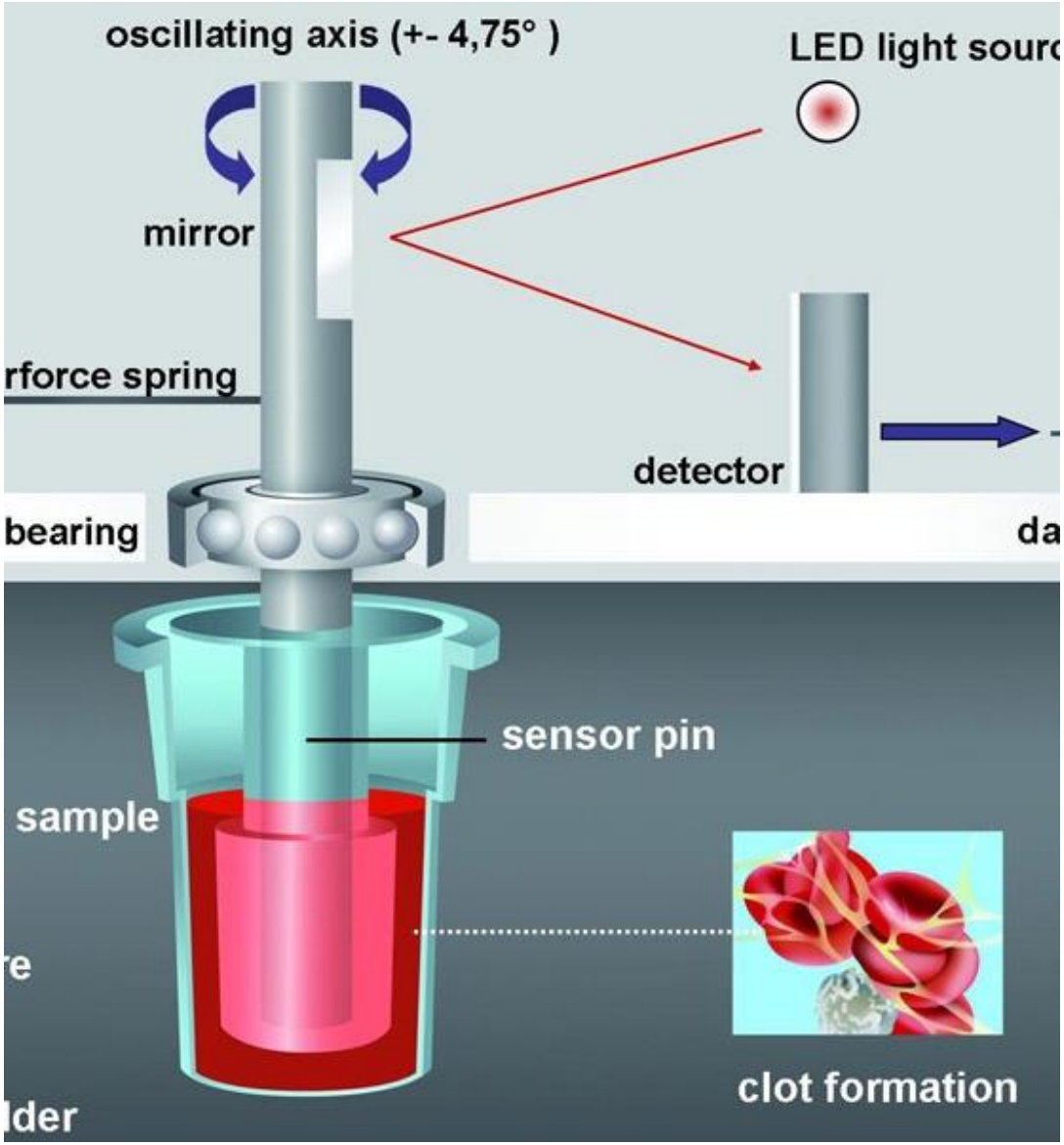


Abb. 1. Thrombelastographische Normalkurve. r Reaktionszeit, g Gerinnselbildungszeit, s Retraktionszeit, s lineare Gesamtelastizität.

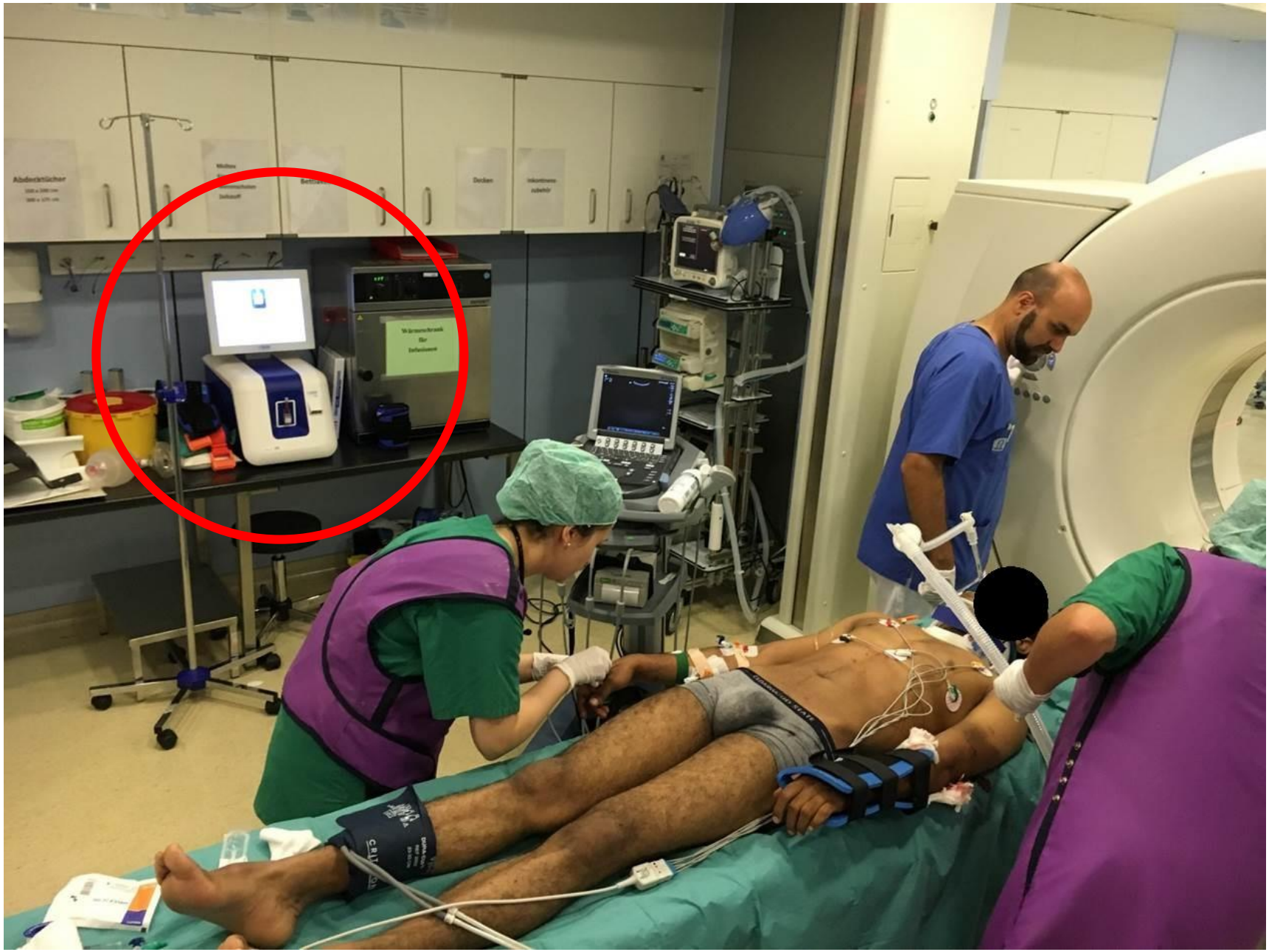
Senkungen der Elastizität anschließt. Aus den Rück



ROTEM® - Rotational thromboelastometry



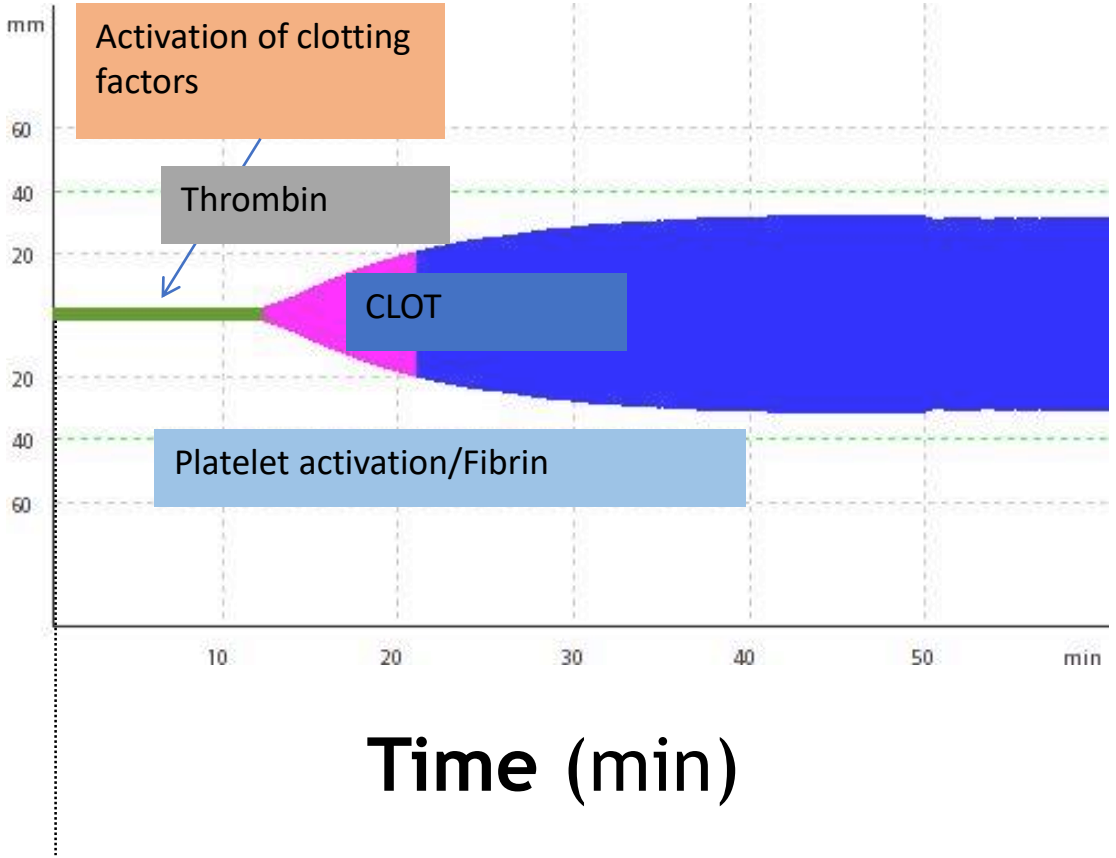
Cartridge-based ROTEM Sigma



Courtesy of Dr. Christian F. Weber, Univ Klinik Frankfurt

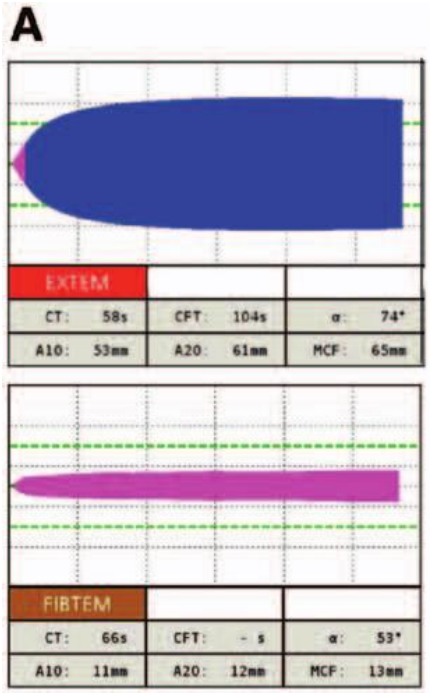
ROTEM

Amplitude (mm)



Time (min)

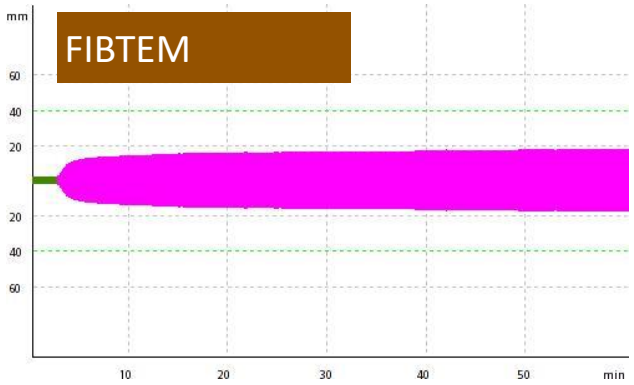
Normal



Trauma Bleeding Management: The Concept of Goal-Directed Primary Care

Herbert Schöchl, MD,*† and Christoph J. Schlimp, MD†

Anesth Analg 2014;119:1064-73



Fibrinogen/fibrin polymerisation

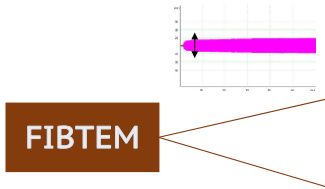
Normal - MCF 9-25 mm

Revised 10.01.2018

v. A_5

1. Check FIBTEM A_5 first

If active or suspected bleeding: correct low FIBTEM (low fibrinogen) **first**

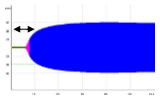


FIBTEM

- A_5 <10
  - A_5 <5 → 4 CRYO or Fibrinogen 6g
  - A_5 5-9 → 3 CRYO or Fibrinogen 4g
- A_5 ≥10 → Check EXTEM

2. Look at EXTEM CT and A_5

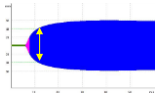
Repeat FIBTEM and EXTEM after blood product transfusion or every 30 mins if actively bleeding



CT

- CT <85 → Check EXTEM A_5
- CT ≥85
  - FIBTEM A_5 ≥10 → Check EXTEM A_5
  - FIBTEM A_5 <10 → 3-4 CRYO or Fibrinogen 4 - 6g

EXTEM



A_5

- A_5 <35
  - FIBTEM A_5 <10 → 3-4 CRYO or Fibrinogen 4 - 6g
  - FIBTEM A_5 ≥10 → Platelets
- A_5 ≥35
  - CT ≥85
    - FIBTEM A_5 >10 → FFP
    - FIBTEM A_5 <10 → 3-4 CRYO or Fibrinogen 4 - 6g
  - CT <85 → ? platelet function if FIBTEM A_5 >10 EXTEM CT<80 and EXTEM A_5>35

STOP the cause of bleeding!
- Physical
- Surgical

Tranexamic acid

Targets
- Hb 90-100 g/L if bleeding
- Platelets > 50 x 10^9/L
- Systolic BP 80-100 mmHg
- Mean BP ≥ 80 if brain injury
- Temperature 35 - 37* C
- pH > 7.2

Doses

Cryoprecipitate (5u/bag)
- 4 bags ~ 6g Fibrinogen
- 3 bags ~ 4.5g
- 2 bags ~ 3g

Fibrinogen 25-50 mg/kg

FFP 20 ml/kg

Platelets – 1 pool

Tranexamic acid 2g (10-30 mg/kg)

Dual anti-platelet drugs or DOAC – ask specialist help

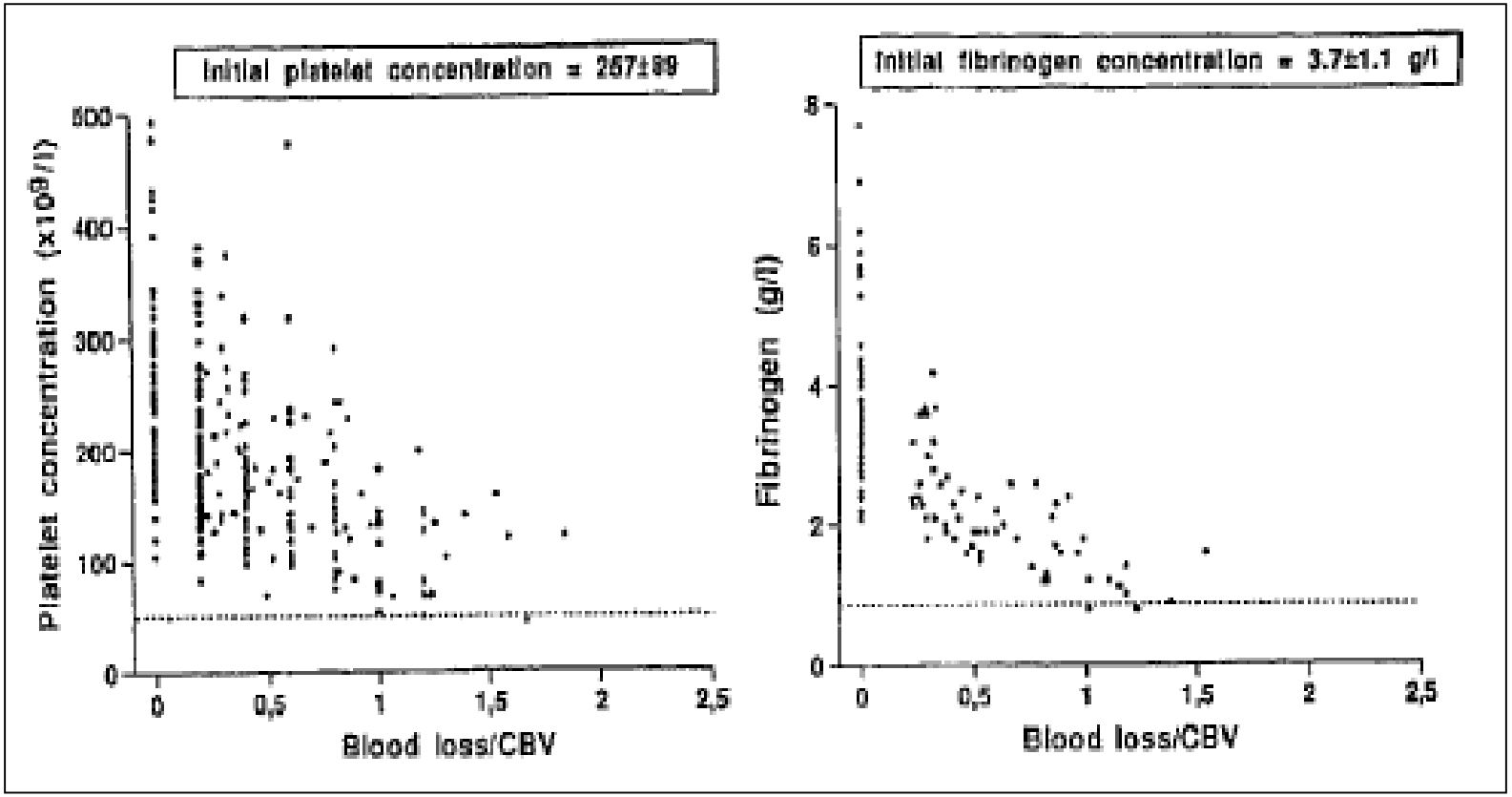
Brighton and Sussex University Hospitals NHS Trust

ROTEM® - guided intervention in critical bleeding

The key role of Factor I

Fibrinogen & major surgical blood loss

Hiippala ST et al., Anesth Analg. 1995 Aug;81(2):360-5



Fibrinogen is a major coagulation protein and deficiency develops earlier than other coagulation factors

What happens to Fibrinogen in trauma?

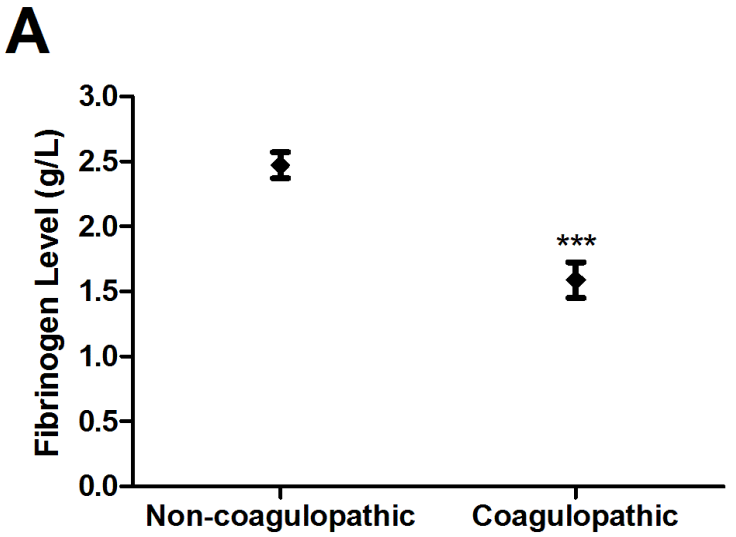
ACIT-2 data (n = 517)

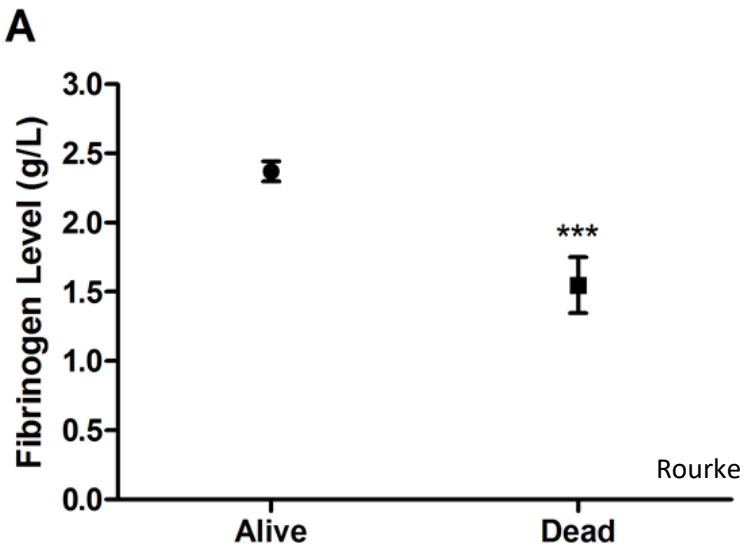
Fibrinogen levels on admission

- Non-coagulopathic: 2.5g/L
- Coagulopathic: 1.6g/L

Admission Fibrinogen

- Independent predictor of 24h & 28 day mortality (p<0.001)





Rourke et al, 2012 JTH

BSUH Massive Transfusion Protocol March 2011

- **➔Is blood needed immediately?**
  - **Arrange collection of PACK A**
    (4 units of red cells & 4 units cryoprecipitate)
- **➔Blood samples**
  - **FBC; G&S; Clotting; Fibrinogen**
  - **Blood gas and/or Haemocue**
  - **Send a separate second G&S sample**
- **➔Arrange collection of PACK B**
  (6 units of type specific red cells; 2 units cryo; 4 units FFP)

2018

Adult Massive Transfusion Protocol

	Trauma Emergency Department		Non-trauma Other locations
	Suspected critical bleeding requiring emergency blood transfusion		
Indications for activating Code Red	Major trauma and **2 or more of** 1. Penetrating injury 2. FAST scan - abdominal fluid+ 3. HR > 120/min 4. SBP < 90 mmHg	**Or** Major trauma and • Senior clinician's suspicion of ongoing bleeding	• Bleeding > 150 ml/min • Blood loss > 1500ml • Loss of half the circulating blood volume in less than 2 hours • Rapid blood loss leading to circulatory failure despite ongoing volume resuscitation

Activate CODE RED

TRAUMA	or	non-trauma
Request Pack A Send baseline bloods		**Request Pack A** Send baseline bloods
Prepare Pack A		Prepare Pack A
Send Red cells and Fibrinogen		Send Red cells and Fibrinogen
Perform ROTEM		Perform ROTEM

Pack A

4 units red cell concentrate (RED Cell)
+
Fibrinogen concentrate 6g

Give RED Cells and Fibrinogen	Give RED Cells and Fibrinogen
If > 4 units RED Cells required: **Request Pack A again**	If > 4 units RED Cells required: **Request Pack A again**

Request PLATELETS if patient still bleeding after 6-8 units RED cells

Give additional products according to ROTEM

BSUH Massive Transfusion Protocol March 2018

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1. **Pack A**
- Four units of Packed Red Cells
- Fibrinogen Concentrate 6g
2. **Pack B**
- Four units of Packed Red Cells
- Fibrinogen Concentrate 6g
3. **Additional blood products guided by ROTEM**
4. **Packs C & D**

Bleeding control bundle of care.

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1 Identify the bleeding patient
2 Prehospital and hospital damage control resuscitation
3 Prehospital and hospital extremity and junctional tourniquets
Prehospital and hospital pelvic binders
Prehospital and hospital hemostatic dressings
Resuscitative endovascular balloon occlusion of the aorta
4 Coagulation monitoring with ROTEM
5 TXA for patients with significant fibrinolysis
Decreased time to operating room
Decreased time to interventional radiology
6 Goal directed resuscitation with blood products as bleeding slows

Physical methods

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6 Months On – ROTEM in Blood Transfusion

Changes in MHP

Case Studies

Impacts of Change

MTP – previous and current

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	2011 - 2018	2018 - current
Pack A	4 RBC 4 Cryo	4 RBC 6g Fibrinogen conc **ROTEM after 30 min**
Pack B	4 RBC 2 Cryo 4FFP 1 Platelets	4 RBC 6g Fibrinogen conc **ROTEM after 30 min**
Pack C	**Repeat pack B until lab results available**	1 Platelets **ROTEM after 30 min**
Pack D		4 RBC 4FFP 3 Cryo **ROTEM after 30 min**

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AIM IS TO ESTABLISH ROTEM GUIDED ISSUE OF BLOOD PRODUCTS AS EARLY AS POSSIBLE

Case 1

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Polytrauma Code Red

Pack A Issued and given in Resus

- Rotem performed post Pack A

Pack A - 4 RBC + 6g Fibrinogen

- Fibtem – A5 14 mm

- Extem – A5 37 mm
- Extem – CT 74 secs

Patient taken to Theatre

- No further products required.

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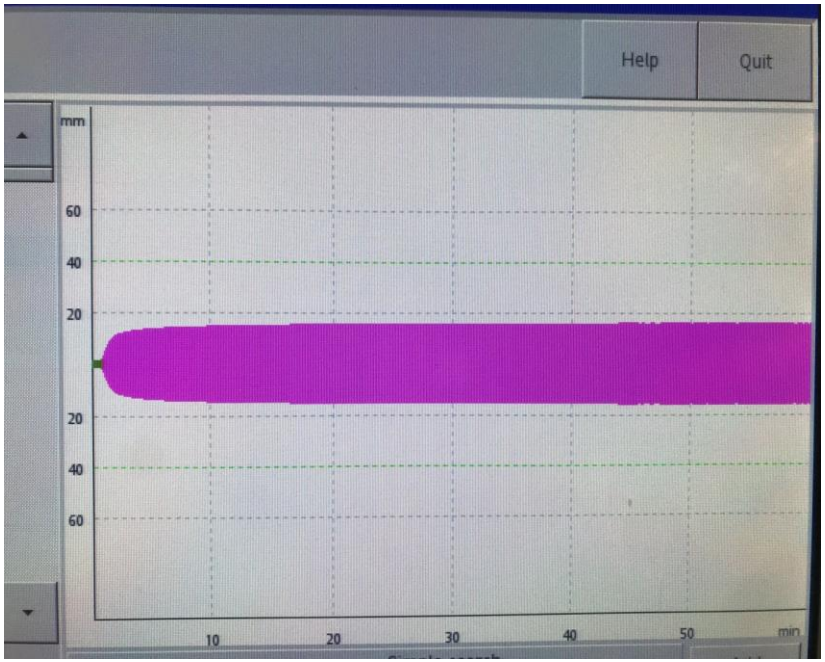

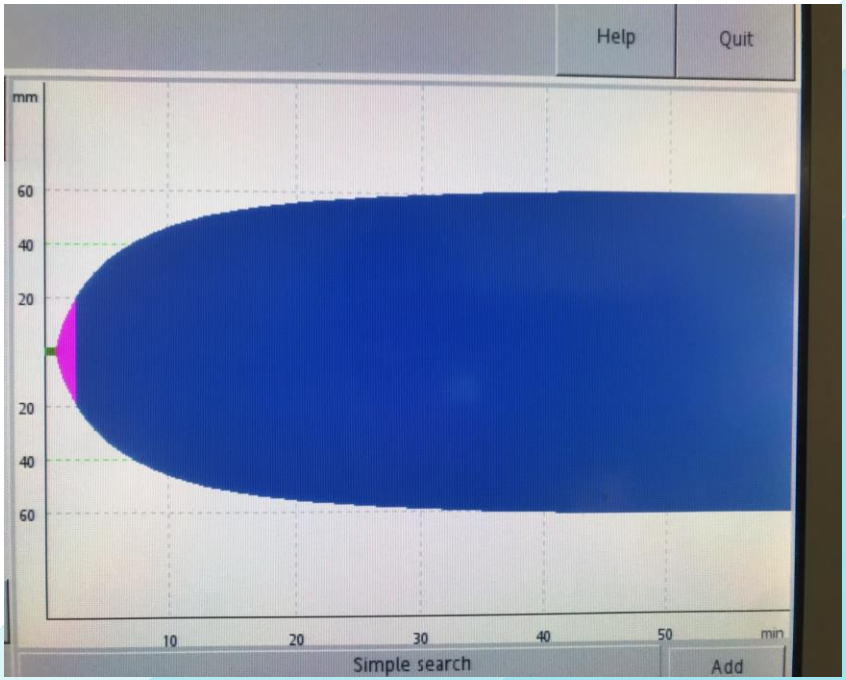

Case 2

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Polytrauma Code Red

Pack A Issued and given in Resus

Baseline ROTEM showed the need for Fibrinogen

ROTEM repeated

1 Pool Platelets given.

ROTEM repeated

No further products required.

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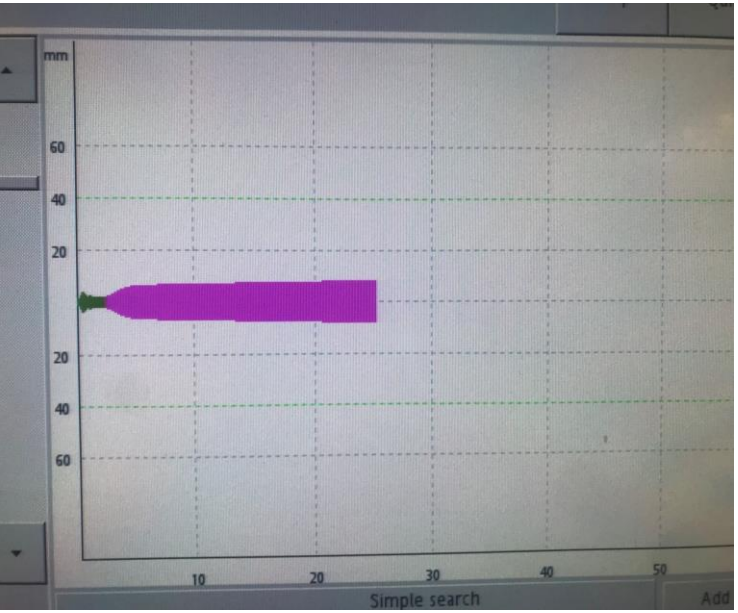

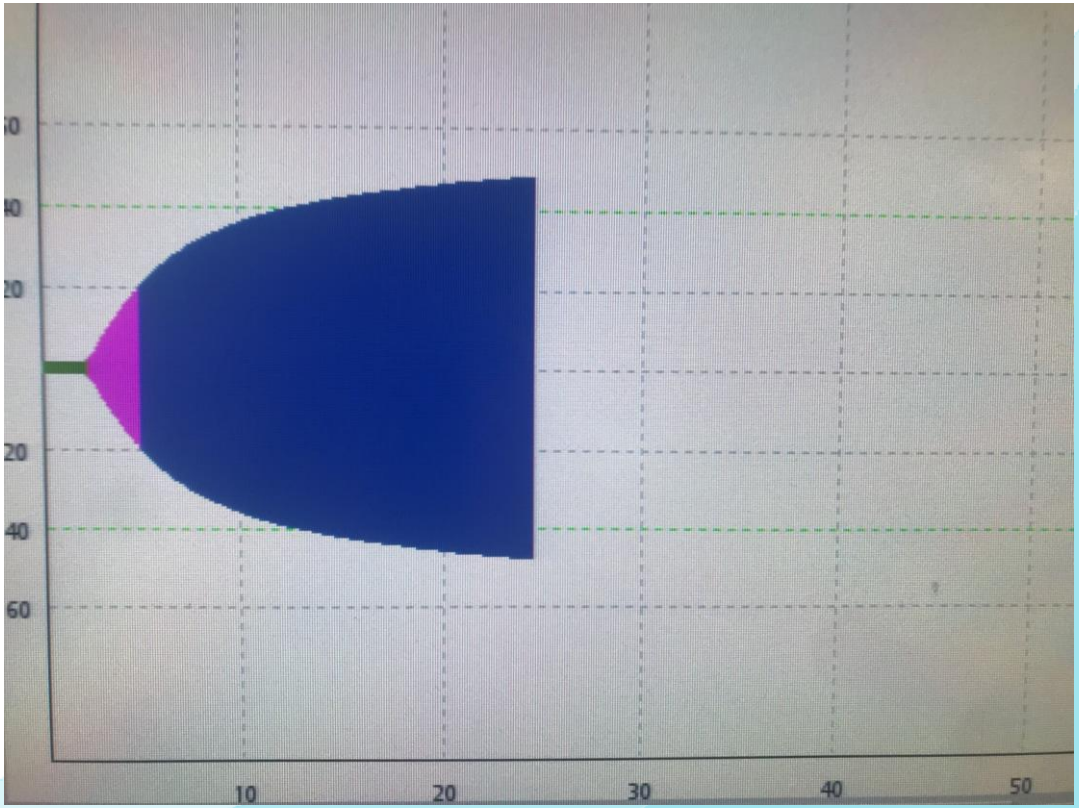

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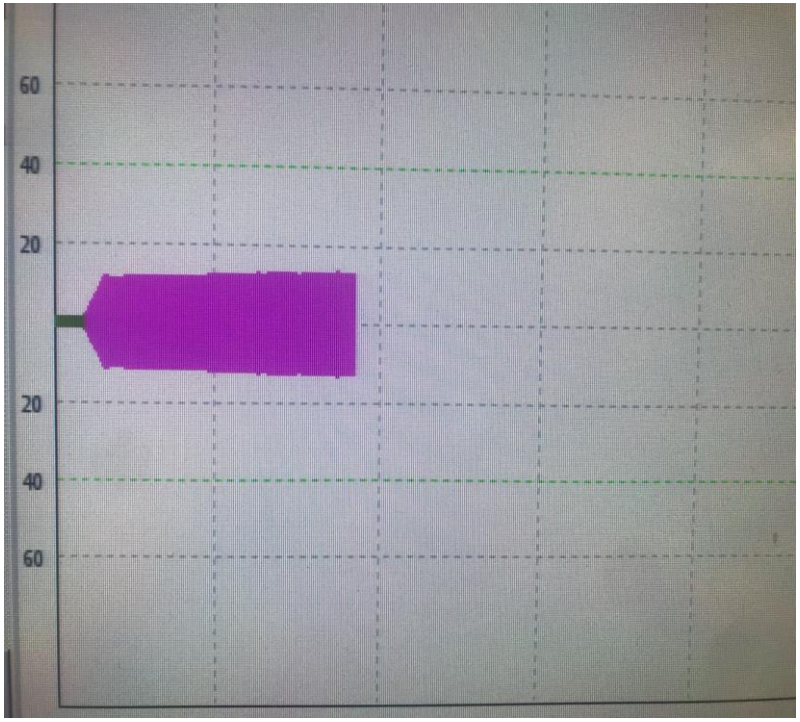

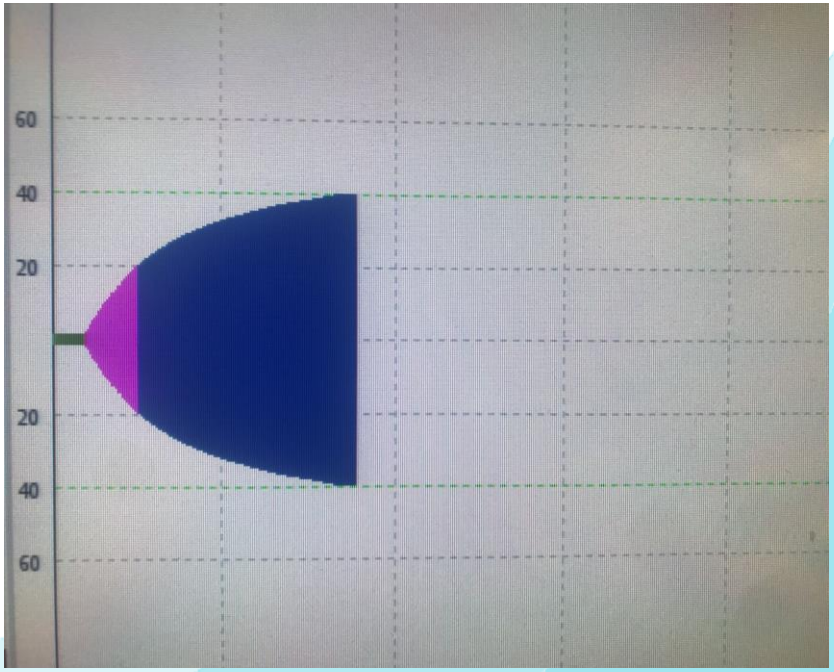

Case 3

Code Red Trauma

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Given in Resus;

Pack A – 4 RBC + 6g Fibrinogen

Pack B – 4 RBC + 6g Fibrinogen

Pack C – Platelets

Then ROTEM guidance used

- ROTEM 1 – Give 3 Cryo or 6g Fibrinogen
- ROTEM 2 – Give 3 Cryo or 6g Fibrinogen
- ROTEM 3 – Give 3 Cryo or 6g Fibrinogen
- ROTEM 4 – Give FFP
- ROTEM 5 – No result – gave platelets, cryo and rVIIa.

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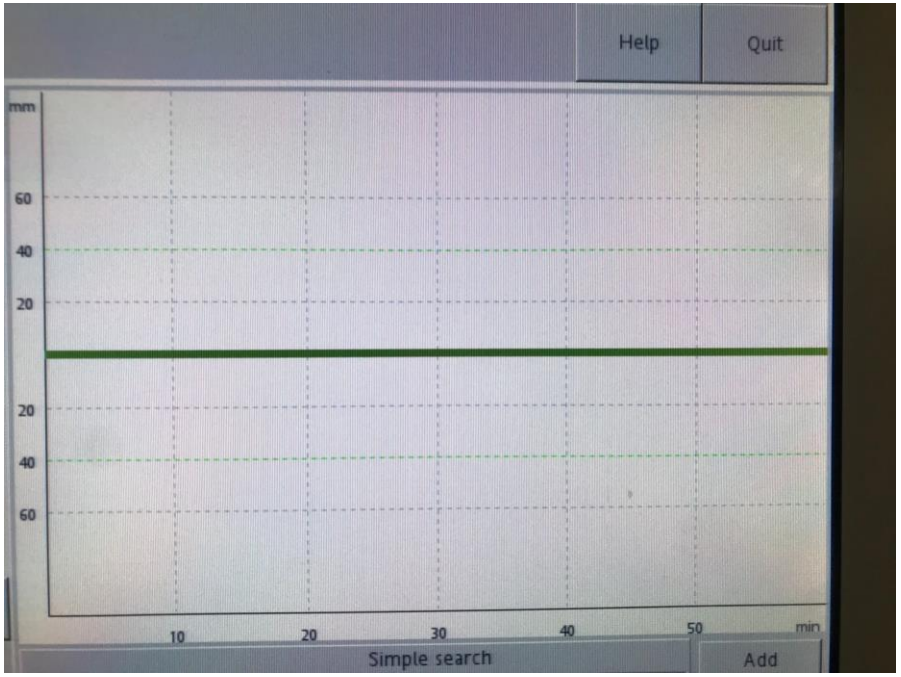

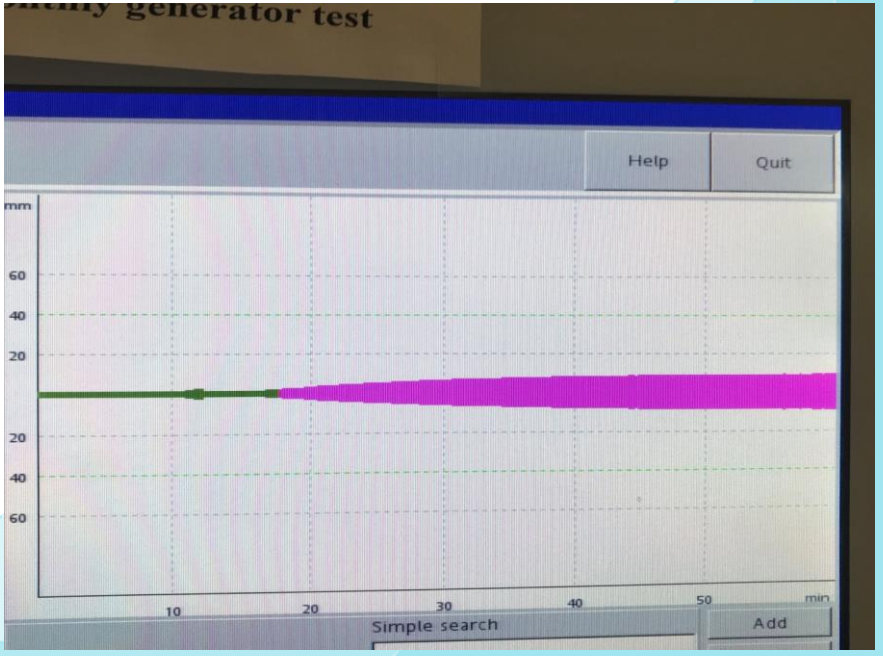

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ROTEM Interpretation;

Check FIBTEM A5 first if active or suspected bleeding –

Correct low fibrinogen first.

FIBTEM	**A5 < 5**	**Give 3 Cryo or 6g Fibrinogen**
	A5 5-9	**Give 2 Cryo or 4g Fibrinogen**
	A5 >10	**Check EXTEM**

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ROTEM STATISTICS SO FAR

Aug, Sept, Oct – 31 tests

November – 25 tests

December – 43 tests

January – 47 tests

Evaluation of results

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	No products	1 product	2 products
November 2018	9	15	1
December 2018	17	22	4
January 2019	25	19	3

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MOVING FORWARD

Helipad open in 2019 - ? More complex cases

Increased theatre/ITU capacity

Will the ROTEM decrease our blood product usage?

Does it improve patient outcome?