ROTEM based coagulation management
The B-O-F-Sign
The B-O-F-Sign

BLOOD ON FLOOR
Diffuse bleeding from cathether insertion
Diffuse bleeding from cathether insertion
The B-O-S-Sign
BLOOD ON SURGEON
intravaskuläres System

Kontaktaktivierung durch geschädigtes Gefäßendothel

extravaskuläres System

Gewebsverletzung

Gewebsthromboplastin

Faktor

I  Fibrinogen
II  Prothrombin
III  Gewebsthamboplastin
IV  Ca++
V  Accelerin
VI  kein selbstständiger Faktor
VII  Proconvertin
VIII  Antihämophiles Globulin A
IX  Antihämophiles Globulin B
   Christmas-Faktor
X  Stuart-Power-Faktor
XI  Plasma-Thromboplastin
XII  Hageman-Faktor
XIII  Plasmatransglutaminase
PL  Phospholipide

Prothrombinaktivatorkomplex

Xa, XIa .... aktive Faktoren
X, XI .... inaktive Faktoren

Fibrinogen

Prothrombin

Thrombin

Fibrinmonomere

Fibrinpolymere (instabil)

Plasmin

Aktivator aus Gefäßendothel, Streptokinase

Gewebsaktivatoren

XIIIa

Fibrinolyse
而形成红色凝血块，至此凝血过程全部完成（图 5-3-2）。
• What is my problem?

- Problems in primary hemostasis
  - thrombocytopenia
  - acquired platelet disorders (CBP, APD)
What is my problem?

→ hyperfibrinolysis

→ plasmatic disorders (e.g. dilution ?)
Aim of our therapy ...
• What is my problem?
  - Lack of time
  - What kind of diagnostics?
  - What kind of therapy?
  - Dynamic process
Time to get lab results?
(Interactive Conference FK333; DAC 2007)
ROTEM – Coagulation monitoring

- Whole blood
- Fast point of care method
- Different tests
ROTEM

Mechanism

Adsorption of fibrinogen

surface
ROTEM

Activated platelets

Mechanism
Obstructed torsion of the pin

soluble fibrin
unsoluble fibrin
Further clot stabilization by FXIII
Dissolution of the clot by (hyper)fibrinolysis
ROTEM

ROTEM-parameter

Maximalamplitude [mm] (MA) = Maximum Clot Firmness (MCF)

Fibrinolyse [%]:
Clot Lysis Index (CLI-30; CLI-60)
Maximum Lysis (ML)

Gerinnungszeit [sec] = Reaktionszeit (r) = Coagulation Time (CT)
Gerinnelbildungszeit [sec] = Koagulationszeit (k)
= Clot Formation Time (CFT)
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ROTEM

Tests
Tests

EXTEM : CaCl$_2$ + extrinsically activation
Tests

INTEM : CaCl$_2$ + intrinsically activation
ROTEM

Tests

FIBTEM : EXTEM + Cytochalasin D
Tests

APTEM : EXTEM + Aprotinin
General conditions

Hypothermia (Temp < 34 °C)

Acidosis (pH < 7.2)

Anemia (Hb < 10 g/dl)

Hypocalcemia (Ca$_i$ < 1 mmol/l)
Patients history

*Intake of coagulation inhibiting drugs*

*Inheriditary deseases*

...
Hyperfibrinolysis

Underestimated problem ???
<table>
<thead>
<tr>
<th>EXTEM</th>
<th>2010-09-23 12:10</th>
<th>2: Polytrauma</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT: 87s</td>
<td>CFT: 233s</td>
<td>α: 53°</td>
</tr>
<tr>
<td>A10: 1mm</td>
<td>A20: 1mm</td>
<td>MCF: 20mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FIBTEM</th>
<th>2010-09-23 12:10</th>
<th>2: Polytrauma</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT: 109s</td>
<td>CFT: -s</td>
<td>α: -°</td>
</tr>
<tr>
<td>A10: 0mm</td>
<td>A20: 0mm</td>
<td>MCF: 4mm</td>
</tr>
</tbody>
</table>
Hyperfibrinolysis depending on ISS

Schöchl H: J. Trauma  2009
Outcome

35 patients with hyperfibrinolyis in ER

- **Complete lysis < 30min**
  - ER: 8
  - ICU: 4
  - *survived*: 0

- **Complete lysis 30 – 60 min**
  - ER: 5
  - ICU: 6
  - *survived*: 1

- **Complete lysis > 60 min**
  - ER: 1
  - ICU: 7
  - *survived*: 3

**Non-Survivors 31 - Survivors 4**
Mortality: 88%

Schöchl H: J. Trauma 2009
Antifibrinolytics

Why or why not?
Antifibrinolytics

Clinical Randomisation of an Antifibrinolytic in Significant Haemorrhage

CRASH 2 - Study

• prospective randomised multicenter-study

• 274 trauma-centers in 40 countries (≠Germany 😞 Netherlands ???)

• n = 20211 trauma patients

• Administration of TXA vs. Placebo

• Primary endpoint: In-hospital death within 4 weeks

CRASH 2 - Study

Figure 2: Mortality by days from randomisation

CRASH 2 - Study

<table>
<thead>
<tr>
<th></th>
<th>Tranexamic acid (n=10060)</th>
<th>Placebo (n=10067)</th>
<th>RR (95% CI)</th>
<th>p value (two-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any cause of death</td>
<td>1463 (14.5%)</td>
<td>1613 (16.0%)</td>
<td>0.91 (0.85–0.97)</td>
<td>0.0035</td>
</tr>
<tr>
<td>Bleeding</td>
<td>489 (4.9%)</td>
<td>574 (5.7%)</td>
<td>0.85 (0.76–0.96)</td>
<td>0.0077</td>
</tr>
<tr>
<td>Vascular occlusion*</td>
<td>33 (0.3%)</td>
<td>48 (0.5%)</td>
<td>0.69 (0.44–1.07)</td>
<td>0.096</td>
</tr>
<tr>
<td>Multiorgan failure</td>
<td>209 (2.1%)</td>
<td>233 (2.3%)</td>
<td>0.90 (0.75–1.08)</td>
<td>0.25</td>
</tr>
<tr>
<td>Head injury</td>
<td>603 (6.0%)</td>
<td>621 (6.2%)</td>
<td>0.97 (0.87–1.08)</td>
<td>0.60</td>
</tr>
<tr>
<td>Other causes</td>
<td>129 (1.3%)</td>
<td>137 (1.4%)</td>
<td>0.94 (0.74–1.20)</td>
<td>0.63</td>
</tr>
</tbody>
</table>

Data are number (%), unless otherwise indicated. RR = relative risk. *Includes myocardial infarction, stroke, and pulmonary embolism.

Table 2: Death by cause

*Lancet. 2010 Jul 3;376(9734):23-32.*
# CRASH 2 - Study

<table>
<thead>
<tr>
<th>Time from injury (h)</th>
<th>Tranexamic acid allocated</th>
<th>Placebo allocated</th>
<th>Risk ratio (99% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤1</td>
<td>509/3747 (13.6%)</td>
<td>581/3704 (15.7%)</td>
<td>0.87 (0.75-1.00)</td>
</tr>
<tr>
<td>&gt;1–≤3</td>
<td>463/3937 (15.2%)</td>
<td>528/2996 (17.6%)</td>
<td>0.87 (0.75-1.00)</td>
</tr>
<tr>
<td>&gt;3</td>
<td>491/3272 (15.0%)</td>
<td>502/3352 (14.9%)</td>
<td>1.00 (0.86-1.17)</td>
</tr>
</tbody>
</table>

χ² = 4.411; p = 0.11

<table>
<thead>
<tr>
<th>Systolic blood pressure (mm Hg)</th>
<th>Tranexamic acid allocated</th>
<th>Placebo allocated</th>
<th>Risk ratio (99% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥90</td>
<td>702/6878 (10.2%)</td>
<td>736/6651 (10.9%)</td>
<td>0.94 (0.82-1.07)</td>
</tr>
<tr>
<td>76–89</td>
<td>280/1699 (17.5%)</td>
<td>313/1689 (18.5%)</td>
<td>0.94 (0.78-1.14)</td>
</tr>
<tr>
<td>&lt;75</td>
<td>478/1562 (30.6%)</td>
<td>562/1599 (35.1%)</td>
<td>0.87 (0.76-0.99)</td>
</tr>
</tbody>
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χ² = 1.345; p = 0.51

<table>
<thead>
<tr>
<th>GCS</th>
<th>Tranexamic acid allocated</th>
<th>Placebo allocated</th>
<th>Risk ratio (99% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe (3–8)</td>
<td>796/1789 (44.5%)</td>
<td>860/1830 (47.0%)</td>
<td>0.95 (0.86-1.04)</td>
</tr>
<tr>
<td>Moderate (9–12)</td>
<td>219/1349 (16.2%)</td>
<td>249/1344 (18.5%)</td>
<td>0.88 (0.70-1.09)</td>
</tr>
<tr>
<td>Mild (13–15)</td>
<td>447/6915 (6.5%)</td>
<td>502/6877 (7.3%)</td>
<td>0.88 (0.75-1.04)</td>
</tr>
</tbody>
</table>

χ² = 1.387; p = 0.50

<table>
<thead>
<tr>
<th>Injury type</th>
<th>Tranexamic acid allocated</th>
<th>Placebo allocated</th>
<th>Risk ratio (99% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blunt</td>
<td>1134/6788 (16.7%)</td>
<td>1233/6817 (18.1%)</td>
<td>0.92 (0.83-1.02)</td>
</tr>
<tr>
<td>Penetrating</td>
<td>329/3272 (10.1%)</td>
<td>380/3250 (11.7%)</td>
<td>0.86 (0.72-1.03)</td>
</tr>
</tbody>
</table>

χ² = 0.791; p = 0.37

<table>
<thead>
<tr>
<th>All patients</th>
<th>Tranexamic acid allocated</th>
<th>Placebo allocated</th>
<th>Risk ratio (99% CI)</th>
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Two-sided p = 0.0035

---

*Lancet. 2010 Jul 3;376(9734):23-32.*
Fibrinogen

*Essential substrate of coagulation*
Critical concentration of coagulation factors after blood loss

- 20 multiple trauma patients; ISS 37 +/- 9,
- cristalloid 1,5l (0,4-3,5l), colloid 1,25l (0,25-4,7l)

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<th>Scene of trauma</th>
<th>ER</th>
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<td>91 (70/112)</td>
<td>64 * (34/80)</td>
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<td>aPTT (30-45 sec)</td>
<td>31 (27/34)</td>
<td>38 * (33/64)</td>
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- Lampl L. et al. AINS 1992; 27: 31
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Fibrinogen at admission to ER
n = 256

Fibrinogen in
mg/dl

<table>
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<tr>
<th>ISS</th>
<th>0 - 14</th>
<th>15 - 29</th>
<th>30 - 44</th>
<th>45 - 59</th>
<th>60 - 75</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>180</td>
<td>140</td>
<td>100</td>
<td>80</td>
<td>60</td>
</tr>
</tbody>
</table>
| H. Schöchl

Medizinische Hochschule Hannover
Substitutionstrigger

Universal trigger for fibrinogen substitution?

1 g/L
1.5 g/L
2 g/L
3.8 g/L


German BÄK guideline DÄV, 2008.


Karlson: Cardiosurgery Transfusion, 2008.
Administration of 3 g Fibrinogen

Quick 55 %
Fib 64 mg/dl
Plt 63/nl
PTT 66 s
AT 34 %

Quick 62 %
Fib 138 mg/dl
Plt 52/nl
PTT 61 s
AT 37 %

180 cm / 96 kg

3 g Fibrinogen
Dosing FFP

- 22 ICU-patients
- acute bleeding or before intervention
- 10 ml/kg and 30 ml/kg FFP

<table>
<thead>
<tr>
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<td>69</td>
<td>&lt;0.05</td>
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<tr>
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<td>85</td>
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</tr>
<tr>
<td>F VIII</td>
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<td>17</td>
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</tr>
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<td>F X</td>
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<td>37</td>
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</tr>
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<td>9</td>
<td>23</td>
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</tr>
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- Chowdhury P; Br J Haematolol 2004, 125:69
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• Chowdhury P; Br J Haematolol 2004, 125:69
Fibrinogen concentrate versus FFP: ingredients FFP

FFP: Plasma healthy donators $\rightarrow$ ca. 100% FA

Preparation and storage $\rightarrow$ ca. 70% FA

6 g fibrinogen 2000 ml FFP vs. 300 ml concentrate
Fibrinogen concentrate versus FFP: example

Female trauma patient 48 kg
At admission fibrinogen 1,34 g/l
\(\rightarrow\) Blood volume 3,84 l \(\rightarrow\) total fibrinogen 5,15 g

+ 6 g fibrinogen concentrate (300ml)
\(\rightarrow\) Blood volume 4,14 l \(\rightarrow\) total fibrinogen 11,15 g
\(\rightarrow\) LEVEL: 2,69 g/l
Fibrinogen concentrate versus FFP: example

Female trauma patient 48 kg
At admission fibrinogen 1.34 g/l

→ Blood volume 3.84 l → total fibrinogen 5.15 g

+ 6 g fibrinogen concentrate (300ml)

→ Blood volume 4.14 l → total fibrinogen 11.15 g
→ LEVEL: 2.69 g/l

+ 6 g fibrinogen in 2000 ml FFP

→ blood volume 5.84 l → total fibrinogen 11.15 g
→ LEVEL: 1.9 g/l
Coagulation factor substitution

Speed booster
## Indication for PCC

### Example

30 year old female

Car accident

*vs. tree*

<table>
<thead>
<tr>
<th>Gerinnung</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quick-Test</td>
<td>53-%</td>
</tr>
<tr>
<td>INR (Ratio)</td>
<td>1.44+</td>
</tr>
<tr>
<td>APTT</td>
<td>47+</td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>1.20-</td>
</tr>
</tbody>
</table>
Indication for PCC

Motorbike accident with open leg fracture and severe bleeding: goal-directed therapy with Prothrombin Complex Concentrate

19 min

175 cm, 110 kg
INR 2.6 → 1.7
Quick (PT in %) 27% → 44%

2000 IU PCC
A Pilot Observation Study on Faktor XIII in the Trauma Patient

*ASA New Orleans Okt. 2009*

Alexander A. Hanke, Tim Lögters, Martin Jetzek-Zader, Klaus Görlinger, Peter Kienbaum

Graph showing FXIII Activity after Trauma with data points and standard deviations. The graph indicates a decline in FXIII activity post-trauma with a subsequent increase over time.
Platelets

*Stones in the wall of coagulation*
Administration of 1 pooled platelet concentrate

180 cm / 96 kg

Plt 52/nl

1 pooled PltC

Plt 85/nl

FUNCTION ???
Magic bullet in coagulation?
rFVIIa
rF VIIa
Mechanism
rF VIIa
Effectivity

Review of literature: Use of rFVIIa in therapy resistant trauma patients with exclusion of hemophilia

- 117 patienten in 8 series and 24 single reports
- in 85% bleeding stopped
- in 77% survival
- only 4% thromboembolic complications

Barletta J et al, J Trauma 2005, 58:646
rF VIIa

Effectivity

Randomised, placebo controlled double blinded study

• Blunt or penetrating abdominal trauma (n=301)
• Placebo vs rFVIIa
• Significant reduction of 2.6 pRBC in blunt and 1 pRBC in penetrating trauma
• CAVE: costs for rFXIIa 25.000 Euro / patient

Boffard KD et al,
J Trauma 2005, 59:8
ROTEM based therapy
POC Algorithm for Coagulation Management in Trauma Surgery

**Multicenter**

**POC**

**Experience**

**Exchange**

3 Level 1 Trauma Center
- University Hospital Essen
- University Hospital Frankfurt
- Hannover Medical School
Goal-directed coagulation management of major trauma patients using thromboelastometry (ROTEM®)-guided administration of fibrinogen concentrate and prothrombin complex concentrate

Herbert Schöchl1,2, Ulrike Nienaber3, Georg Hofer1, Wolfgang Voelckel1, Csilla Jambor4, Gisela Scharbert5, Sibylle Kozek-Langenecker5 and Cristina Solomon*6
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January 2005 – April 2009
149 patients; age 46 ± 18; ISS 38 ± 15
Goal-directed coagulation management of major trauma patients using thromboelastometry (ROTEM®)-guided administration of fibrinogen concentrate and prothrombin complex concentrate

- Coagulation factor concentrates can be used successfully in trauma patients with severe bleeding
- Thromboelastometry (ROTEM) allowed rapid and reliable diagnosis of the underlying coagulopathy and guided the haemostatic therapy.
- Observed mortality appeared lower than the mortality predicted by the TRISS and by the RISC score.
Heir apparent.

Fully functional Mac OS X 10.5 Leopard.
3G compatibility. Stately hard drive capacity.
Ready to ascend the throne as your all-in-one multimedia device.

The new iPhone. Long live the king.
First-line Therapy with Coagulation Factor Concentrates Combined with Point-of-Care Coagulation Testing Is Associated with Decreased Allogeneic Blood Transfusion in Cardiovascular Surgery

A Retrospective, Single-center Cohort Study

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Conclusions: First-line administration of coagulation factor concentrates combined with point-of-care testing was associated with decreased incidence of blood transfusion and thrombotic/thromboembolic events.
Efficacy and Safety of Fibrinogen Concentrate in the Treatment of Major Bleeding During Cardiac Surgery: Results of a Randomized, Placebo-Controlled Trial

Niels Rahe-Meyer, M.D., Cristina Solomon, M.D., Alexander Hanke, M.D., Dirk S. Schmidt, M.D., Maximilian Pichlmaier, M.D.

60 patients were included (n=29; placebo, n=31)
FIBTEM guided fibrinogen administration
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**blood products**

- fibrinogen concentrate group median: 2.0 U (range 0-31)
- placebo group median: 13.0 U (range 4-42)
- p<0.0001
Total avoidance of transfusion in 45% (n=13) of fibrinogen group while all patients from placebo group required transfusion (p<0.0001, Chi square test).
Traditional transfusion practices are changing

John B Holcomb*

See related research by Schochl et al., http://ccforum.com/content/14/2/R55

„It will be nice to only transfuse what is needed,…“
What are the advantages of ROTEM monitoring

- visualization of coagulation
- qualitative analysis of the end product of coagulation: the clot
- fast and near patient (POC)
- possibility of targeted therapy
- ... and finally reduction of costs
ROTEM

ROTEM limitations???
- primary hemostasis
- Von Willebrand syndrome
- Anti platelet drug therapy
POC-BASED THERAPY
- LIFE -
Thanks for listening !!!

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