Recommendations for using the ROTEM® in the management of perioperative bleeding in Cardiac Surgery

• The following recommendations were drafted at three consecutive ROTEM® Expert Meetings from 2005-2007 in the working group dedicated to cardiac surgery. Participants of these meetings were ROTEM® users from 16 mainly European countries, their ROTEM® experience ranging from several months to greater than 6 years. Most of the participants were anaesthetists working as front line clinicians at institutions covering a wide range of adult and paediatric cardiovascular surgery.

• The objectives of the working groups were to define indications, timing and selection of tests and their cutoff values for therapeutic interventions when using the ROTEM®. It was acknowledged that inter-institutional differences and differences between countries existed (resources, availability of blood products and therapeutics, national guidelines, etc.). Our aim also was to balance the cost and benefits of incorporating ROTEM® use in patient management.

• The recommendations represent a common base compromise and not an optimized protocol. They are intended to assist new ROTEM® users in establishing their own protocols according to their specific background and needs.

• Please note that the recommendations given cannot replace thorough familiarization with ROTEM® use and interpretation. The decision about any therapy has to be made in accordance with the clinical findings of the patient and is reserved exclusively to the physician in charge. Suggestions made here are non-binding.

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Indications for using ROTEM monitoring

1. HIGH RISK Patients
   - Pre-op bleeding risk (screening questionnaire)
   - Combined or complex procedures
     - re-operations
     - valve+CABG, multiple valves
     - aortic, etc.
   - Emergency surgery
   - Circulatory arrest

2. PROLONGED CARDIOPULMONARY BYPASS (CPB)
   - Prolonged CPB >180 min

3. POST CPB AND POSTOPERATIVE BLEEDING
   - Excessive bleeding any time after reversal of heparin
Sample times

1. **Anaesthesia**
   - Optional¹
   - EXTEM

2. **CPB**
   - Optional²
   - HEPTEM
   - FIBTEM
   - 30 min before coming off bypass

3. **Protamine**
   - INTEM
   - EXTEM
   - 10 min after protamine

4. **ICU**

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1. Baseline testing left to clinician preference - may be helpful for comparison with subsequent tests
2. EXTEM useful to guide PCC or FFP use in some centres. Monitor EXTEM if using aprotinin which prolongs CTINTEM
**Result and Action**

1. Only TREAT if the patient is BLEEDING
2. Abnormal results + NOT bleeding: Observe patient; repeat tests
3. Some institutions advise a higher FIBTEM target in the bleeding patient (e.g. MCF>12 mm) and especially in presence of dual anti-platelet therapy
4. Some clinicians give DDAVP (0.3µg/kg) in patients on aspirin - there are mixed reports of efficacy (and complications) in the literature
5. Indications for Factor rVIIa are not established: but efficacy relies on first optimizing pH, temperature, Ca++, fibrinogen (FIBTEM >8), platelet number (>20,000), and haematocrit (Hct)
6. Aprotinin therapy may increase CT$_{INTEM}$: therefore use EXTEM instead in these cases
Anaesthesia

CPB

Protamine

ICU

Markedly abnormal results during CPB may suggest a high risk of bleeding post bypass. Consider requesting blood products:

- **HEPTEM MCF < 35 & FIBTEM MCF > 8**: request PLATELETS
- **FIBTEM MCF < 5**: request FIBRINOGEN (Cryoppt/FFP)

Only TREAT if the patient is BLEEDING

- **CT_{INTEM} >> CT_{HEPTEM} (> 25% difference)**: circulation has excess heparin - PROTAMINE
- **FIBTEM MCF < 8**: low fibrinogen, likely < 1g/L - FIBRINOGEN (or Cryoppt or FFP)
- **HEPTEM MCF < 45**: assuming FIBTEM MCF > 8 - give PLATELETS
  - Some institutions advise aiming for FIBTEM MCF > 12 before considering platelets
- **CT_{HEPTEM} > 300 s or CT_{EXTEM} > 100 s**: FFP or PCC
  (Aprotinin therapy may increase CT_{INTEM/HEPTEM}; therefore use EXTEM instead in these cases)
  - But correct FIBTEM first; low fibrinogen prolongs CT

Near-normal result: consider platelet function tests or give platelets if recent anti-platelet therapy. High bleeding rate: unlikely to be coagulopathy – consider RESTERNOTOMY
EXPLANATORY NOTES: Indications

1. In adult cardiac surgery, ROTEM® monitoring is not necessary in every case
   - Cost-benefit considerations

2. ROTEM® monitoring may be recommended in most pediatric/neonatal cases
   - Complex pathologies
   - Immature coagulation systems
   - Less hemostatic reserve
   - Greater impact of fluid shifts and blood loss
   - Insufficient clinical experience of TEM in this age group
EXPLANATORY NOTES: Baseline samples


2. Baseline test not necessary in most patients with no prior hemostatic abnormalities
   - Default recommendation is to not do a baseline sample routinely
   - unlikely that baseline result would substantially alter subsequent clinical management

3. Baseline test may be recommended in some situations
   - Pre-existing hemostatic abnormalities; situations that may give rise to such conditions (e.g. infection), certain drug therapies, as part of a formal evaluation process (research)

4. Baseline test may be INTEM or EXTEM
   - No data to support the use of one, in preference to the other. Choose EXTEM if using aprotinin which may prolong CT of INTEM
1. Purpose of ROTEM® monitoring before weaning of CPB is to highlight the potentially coagulopathic patient early.
   - most institutions experience variable time lag between requesting and obtaining blood products
   - In pediatrics, the impact of haemodilution during CPB, which is reversed by ultrafiltration, on the ROTEM® parameters obtained during CPB is unknown.
   - CT values for HEPTEM and FIBTEM performed during CPB may be influenced by heparin. But any effect is probably minor and does not devalue the information that can be obtained from this ‘early warning’ test.

2. Thresholds of the different parameters and their predictive value for excessive bleeding - such as to require treatment - have not been established
   - Further research is needed here
EXPLANATORY NOTES: Samples after protamine

1. INTEM, HEPTEM and FIBTEM should be tested simultaneously at this stage

   - note that aprotinin therapy may increase CT of INTEM: therefore use EXTEM in these cases.

2. Additionally, EXTEM may be tested

   - in centers where PCC is given in preference to FFP (see later)
EXPLANATORY NOTES:
Treatment in bleeding complications after protamine

1. Exclude the possibility of excess heparin: compare CT of INTEM with HEPTEM.

2. If HEPTEM, INTEM or EXTEM MCF is less than 45 (A10† is less than 35-40) and FIBTEM MCF is less than 8 (A10† is less than 6), treat with fibrinogen (Cryo/FFP).

3. DDAVP could be given if significant aspirin-effect is likely (0.3 µg/kg).

4. In the presence of dual antiplatelet therapy, aiming for a higher FIBTEM threshold of MCF>12 (A10†>10) may compensate for the platelet inhibition (see # 7 below).

5. Platelets may be required if FIBTEM MCF>8 (A10†>6) but HEPTEM, INTEM or EXTEM MCF is less than 45 (A10† is less than 35-40).

6. Check the INTEM/HEPTEM CT (threshold of 300s) for the need to replace clotting factors (FFP, PCC). Note that aprotinin therapy may increase CT of INTEM. Therefore use EXTEM (threshold 100s) in these cases.

7. ‘Near normal’ ROTEM® results should lead clinicians to ask, in the context of very recent antiplatelet therapy (e.g. < 5 days) and FIBTEM MCF>8, whether platelet tx is required. Some institutions report less platelet use by aiming for higher FIBTEM MCF (>12).

8. Excessive bleeding rate (>300ml/h) is more likely to be secondary to a surgical than a medical cause; even if ROTEM® results are abnormal, clinicians should consider RESTERNOTOMY.

† A10 values are correlated to MCF and therefore can be used to give an earlier indication of the likely MCF that would be achieved. Using A10 instead of MCF allows the clinician to have a earlier - but only by several minutes - appreciation of the clot dynamics.