2018 AmSECT pediatric
October 4-6, 2018 | Miami, FL

AmSECT experience

Anticoagulation Management During ECLS
Past-Present-Future

Jorge W. Ojito, CCP, FPP
Chief Perfusionist
Nicklaus Children's Hospital
Miami, FL

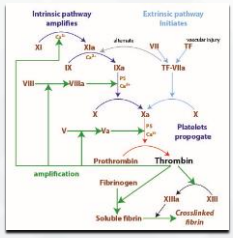
Nicklaus Children's Hospital
Heart Program

2018 AmSECT pediatric
October 4-6, 2018 | Miami, FL
AmSECT experience

Anticoagulation Management During ECLS

Heparin

- Discovered 1916
- Current management therapy
  - Imperfect Science
  - Not Standardized
- Past
- Our current practice
- Future



2018 AmSECT pediatric
October 4-6, 2018 | Miami, FL
AmSECT experience

Past Heparin Management Techniques

- 1948 WBCT
  - Takes to long
- APTT
  - Not practical or reliable
- 1966 ACT
  - Standard of care 1979
  - 300, 400, 480 Sec. for CPB
- Heparin Dose Response Curve
  - Dosing & reversal

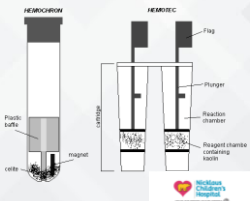
Nicklaus Children's Hospital
Heart Program

2018 AmSECT pediatric
October 4-6, 2018 | Miami, FL
AmSECT experience

Activated Clotting Time (ACT)

Advantages

- Quick
- POC
- Low cost
- Simple
  - Whole blood
  - Some dirt
  - Mixed with a stick

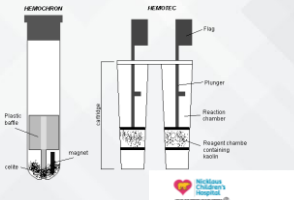


Nicklaus Children's Hospital
Heart Program

Activated Clotting Time (ACT)

ACT Disadvantages

- Operator variability
- Testing system
- Factor deficiencies
- Coagulopathies
- Hemodilution
- Platelet dysfunction
- Sample quality

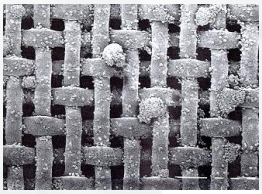


Microemboli Production During ECLS

CPB blood filters 1970's

- Decreased cerebral injury

- Microembolic encephalopathy
  - Gaseous
  - Particulate/Solid
  - Thrombi
- ALF Standard of care



Microemboli Production During ECLS

ECMO Blood filter use

- Unnecessary
  - Closed circuit
  - Less emboli potential
- Dangerous
  - Blood cell damage
  - Frequent filter replacement

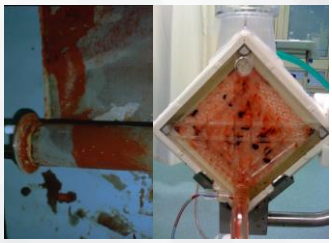
Microemboli Production During ECLS

ECMO Heparin Management

- ACT based
- 180 - 200 sec
- Weeks at a time

Complications (ELSO)

- 26% are neurologic
- Clots most common
  - 52.3% Neonates

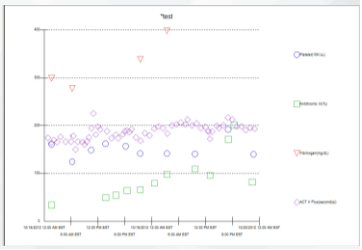


Microemboli Production During ECLS

ECLS safer today

- Advances technology
- Bio-coatings
- Oxygenators / pumps
- ELSO clinical guides

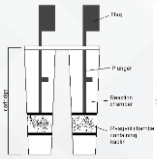
- Heparin management
  - Center-specific
  - Mostly ACT based

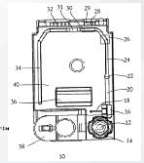


Microemboli Production During ECLS

What is an ACT?

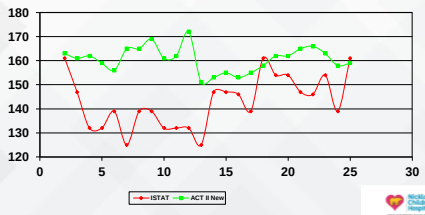
- Depends on who you ask
- No standardization
- Mechanical detection
- I-STAT electrochemical sensor
  - Thrombin substrate conversion





Heart Program

ACT Validation at NCH



Heart Program

ACT Comparison Study Two Stations 4 Systems Each

Hemocron Cath-Lab

ACT Plus CPS

Hepcon CPB

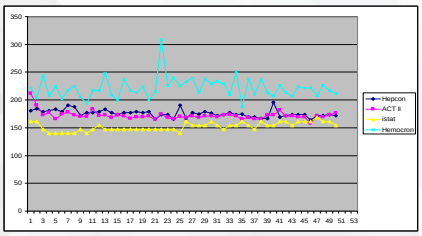
iSTAT ECMO

Heart Program

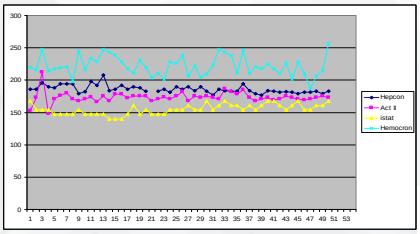
Fresh Heparinized Whole Blood

- 100 simultaneous samples
- 600 ACT tests run
- 800 Data points generated

Test Station I



Test Station II



ECLS Neurologic Complications

Highest in cardiac Patients.

- Worst in neonates
- Seizures 7.2%
- Infarction 3.5%
- CNS Hemorrhage 11.1%
- Most Underreported

World Journal of Critical Care Medicine

Neurologic complications and neurodevelopmental outcome with extracorporeal life support

Exclusive Anti-Xa Titration Anticoagulation Protocol

Anti-Xa based heparin management

- Is feasible
- Decreased blood sampling
- Less Heparin adjustments
- 50% (11/22) Survival


Anti-Xa Directed Protocol for Anticoagulation Management in Children Supported With Extracorporeal Membrane Oxygenation

Exclusive Anti-Xa Titration Anticoagulation Protocol

Bleeding & transfusions associated with

- Thrombotic complications
- Circuit/Oxygenator change-out

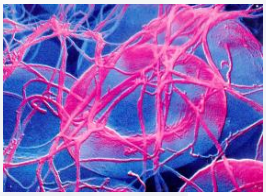
- 32% (7/22) Required 1 Oxy/Circuit change
  - 11 total occurring at median 93 hours
- 54% (7/13) Postcardiotomy Oxy/Circuit change
  - 100% Mortality (7/7) Oxy/Circuit change
  - 27% Mortality No Oxy/Circuit change


Anti-Xa Directed Protocol for Anticoagulation Management in Children Supported With Extracorporeal Membrane Oxygenation

NCH Current Practice Microemboli Prevention

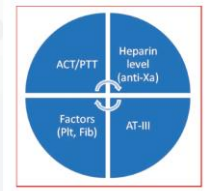
Strategies

- Maximized hemostasis management
- Prevent stagnant flow fields
- Maintain laminar blood flow
- Reduce foreign surfaces
- Limited circuit port access
- MicroClave IV connector
- All fluids given IV & Filtered
- Integrated ALF

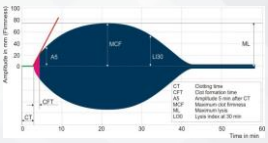


Nicklaus Children's Hospital
Heart Program

NCH Coagulation Management



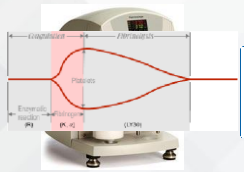
Quantitative



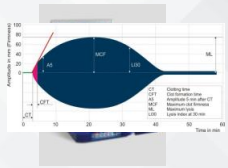
Qualitative

Viscoelastic Testing Systems

TEG



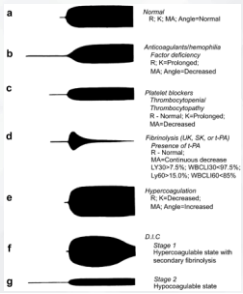
ROTEM



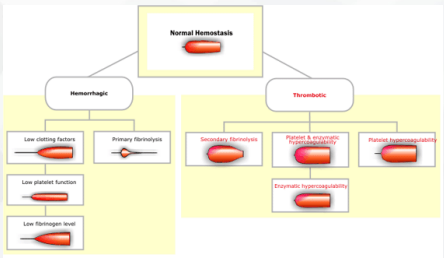
Viscoelastic Testing

TEG / ROTEM

- Graphs are similar
- Only POC that evaluates clot strength
- Time to fibrin formation
- Clot stability
- Clot lysis
- Platelet function
- Fibrinogen function



Viscoelastic Testing Decision Tree



Thromboelastography (TEG)

- Global hemostatic function
  - Platelet function
  - Fibrinogen function
  - Clotting factors
  - Heparin effect
- Disadvantage
  - Training needed
  - Manual pipetting
  - Liquid QC every 8hrs
  - Mechanical shock
  - Two channels
  - Difference normal ranges
    - Infants & adults

Nicklaus Children's Hospital
Heart Program

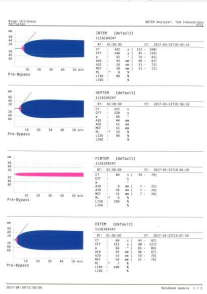
ROTEM (Thromboelastometry)

- Advantage
  - Auto-pipetting / touch screen
  - Liquid QC weekly < cost
  - Mechanical shock resistant
  - 4 channels
  - Requires less blood

ROTEM (Thromboelastometry)

INTEM

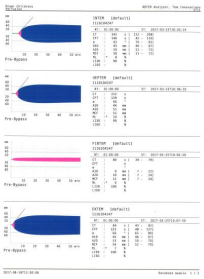
- Coagulation is activated via the contact phase (as in the aPTT and ACT). The INTEM is therefore sensitive for factor deficiencies of the intrinsic system (e.g. FVIII) and for the presence of heparin in the sample.



ROTEM (Thromboelastometry)

HEPTEM

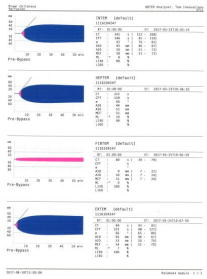
- Coagulation is activated as in INTEM. The addition of heparinase in the reagent degrades heparin present in the sample and therefore allows the ROTEM® analysis in heparinised samples.



ROTEM (Thromboelastometry)

FIBTEM

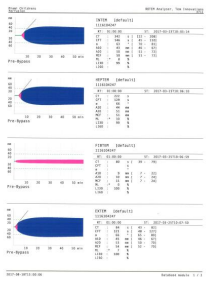
- Coagulation is activated as in EXTEM. By the addition of cytochalasin D, the thrombocytes are blocked. The resulting clot is therefore only depending on fibrin formation and fibrin polymerisation.



ROTEM (Thromboelastometry)

EXTEM

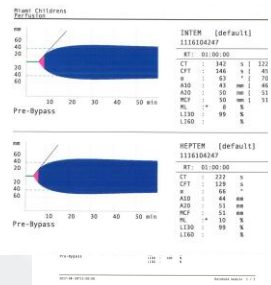
- Coagulation is activated by a small amount of tissue thromboplastin (tissue factor). This typically leads to the initiation of clot formation within 70 seconds. Thus, clot formation can be assessed within 10 minutes.



Case revue

ROTEM Pre-CPB

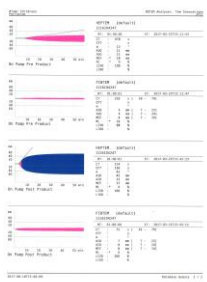
- ACT 186 sec
- INTEM CT prolonged
- HEPTEM CT shorter prolonged
- ATIII level 49
- HMS 3.8 mg/kg
- FFP (1 quad) added to prime



Case revue

On CPB only HEPTEM / FIBTEM

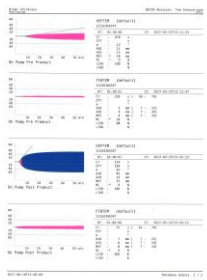
- On CPB case end
  - After maximum hemofiltration
- On CPB after addition of required factors
  - Platelet apheresis (1 Unit) added
  - FFP (1 quad) added



Case revue

During switchover

- Protamine 30mg given
  - HMS patient dose
- CPB blood used in support circuit
- Once at full flows
  - Fibrinogen (RiaSTAP) 800mg given



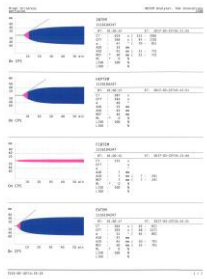
Case revue

In CICU 1 hour post-Op

- ACT 200
- CT time prolonged
- FFP (1 quad)
- Platelet apheresis (60cc) added

Heparin is withheld until

- ROTEM results are normal
- ACT is 160
- Bleeding minimal



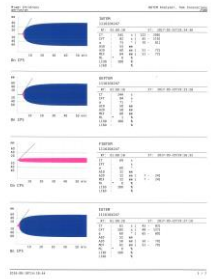
Case revue

In CICU 4 hour post-Op

- ACT 162
- CT time prolonged
- No products given

Heparin is withheld until

- ROTEM results are normal
- ACT is 160
- Bleeding minimal



Case revue

In CICU 7 hour post-Op

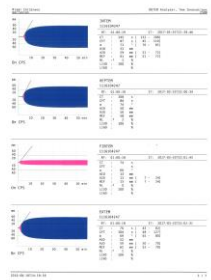
- ACT 150
- Bleeding minimal
- Heparin started 10 unit/Kg/hr

Nicklaus Children's Hospital
Heart Program

Case revue

In CICU 8 hour post-Op

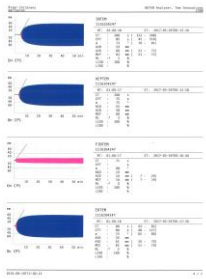
- INTEM CT prolonged
- HEPTEM CT normal
- ACT 152
- ATIII 52
- AT3 given (Thrombate)
- Heparin10 unit/Kg/hr



Case revue

In CICU 15 hour post-Op

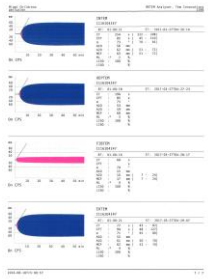
- INTEM CT time prolonged
- HEPTEM normal
- ACT 163
- ATIII 91
- Heparin 20 unit/Kg/hr



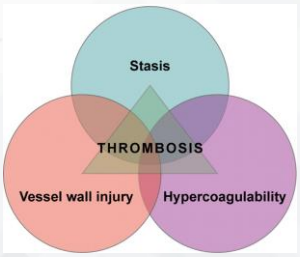
Case revue

In CICU 42 hour post-Op

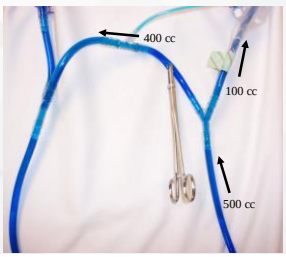
- INTEM CT time prolonged
- HEPTEM normal
- ACT 161
- ATIII 62
- Heparin 20 unit/Kg/hr
- Off support 44 hours post-op



NCH Microemboli Prevention Strategies



NCH Microemboli Prevention Strategies



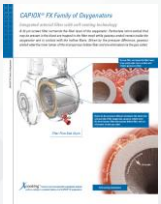
Heart Program

Gaseous Micro-Emboli Prevention

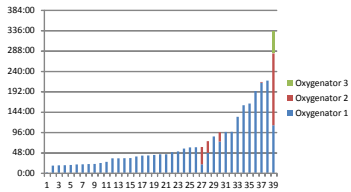
- Intravenous filter

- MicroClave IV connector

NCH Microemboli Prevention Strategies

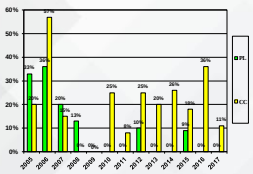


Baby FX Oxygenator Longevity



Nicklaus Children's Hospital
Heart Program

NCH FX / Affinity Longevity & Outcomes (2011-2017)



- 79 CPS using FX Oxy (48% SHD)
- 55 Postcardiotomy (44% SHD)
- 24% (13/55) required oxy/circuit changes
  - 9 increased sweep requirement
  - 3 decreased Blood flow
    - All 3 on in OR using Baby RX
  - 1 Affinity pump (noise)
- 26 Post from CPB in OR (50% SHD)
  - 21% (5/26) required oxy/circuit changes

Future POC Hemostasis Management Systems

TEG 6s

- Fully automated
- Sample vial fits into cartridge
- Avoids sample manipulation
- Automated functional test

ROTEM Sigma

Anticoagulation Management During ECLS

Conclusion

- Coagulation Management is complicated and imperfect
- POC Viscoelastic Testing is beneficial
- Postcardiotomy patients at highest risk
- Arterial blood filters during ECLS should be considered