Step-By-Step Technical Tips for Pharmaco – Mechanical Intervention for PE

Gary M Ansel MD
System Medical Chief: Vascular
OhioHealth/Riverside Methodist Hospital
Columbus, Ohio

When To Utilize Pharmaco-Mechanical Thrombolysis?

- Massive PE that has contraindication to full dose lytic
- Sub-massive Elevated risk

Don’t Be Frozen by Indecision

- Majority of patients eligible for thrombolysis do not receive it
  - Hypotension
  - Abnormal RV and + biomarkers

Gary M Ansel MD
Conflicts of Interest

- Consultant
  - Abbott Vascular
  - Boston Scientific
  - Cordis Corporation
  - Boston Scientific
  - WL Gore
  - CR Bard
  - Primacea
  - Varian
  - Volcano/Philips
  - Venarum
  - Novartis
  - ReFlow Medical

- Equity
  - Embolitech
  - Primacea
  - ReFlow Medical

November 2018

ESC 2014 Guidelines: PE Categories

Utilization of Thrombolysis

EUR Heart J 2014:35;3033-69

In-hospital Mortality

Echo Measurement of subannular RV/LV ratio

1. Obtain an end-diastolic image defined as last available image prior to the onset tricuspid valve closure
2. Obtain center line through interventricular septum
3. Obtain tricuspid annular line at septal insertion point of tricuspid valve, perpendicular to interventricular septum line
4. Obtain subannular line 1 cm above and parallel to annular line
5. Obtain RV and LV dimensions on the subannular line using endocardial borders
6. Calculate the RV/LV ratio: RVEDD divided by LVEDD

Why Treat Sub Massive Elevated Risk PE
- PE and unresolved RV dysfunction at discharge
- 8-times more recurrent PE
- 4-times the mortality rate

Treatment of Higher Risk PE
What else can be done for Massive and sub-massive PE’s?
- IVC filters
- Embolectomy
- Surgery

Step by Step
- Make the diagnosis and clinical decision consistently
- PERT team or other consistent mechanism
- Hospital Environment may dictate options ie Tertiary vs community
- Have a STEMI like protocol to get patients to the angio suite
- Catheter vs EKOS institutional preference since we lack randomized data

OHVI App
- PE Algorithm
  - Quick access to clinical pathways and easy to navigate
The OhioHealth Vascular Institute

PE’s to be Treated are Algorithm Based

Massive PE
- SBP < 90
- Systolic contraindications to thrombolysis
- Full dose t-PA (100mg over 2 hours) started in ER
- Admit to Intensive Care Unit (ICU) within 1 hour if possible, fully monitored
- Cardiac surgery involvement on a case-by-case basis
- Intra-aortic balloon pump
- Anticoagulation is contraindicated, call consultant for consideration of VNC filter
- This pathway should not supplant the clinician’s best bedside judgement. This document presents an evidence-based standard that is appropriate for most patients. Clinical judgement and patient choice may occasionally require deviation from this standard.

- Must have one or more of the following:
  - Young women (LG)
  - Male (MG)
  - Severe cardiogenic shock
  - DM

- SBP < 90
- High risk for HTN
- Need pressor support
- Need for intubation
- Need for inotropes

- TCC
- VNC
- FAST

Submassive Increased Risk
- Must have evidence of RV dysfunction on echocardiogram or CT scan
- SBP < 90
- RV dysfunction
- Hypotension
- Syncope

- Assess contraindications to thrombolysis
- Call consultant for consideration of endovascular therapy vs IV thrombolysis or mechanical thrombolysis Type/dose of thrombolytic per consultant and consider to be started in ER
- If endovascular therapy, rapid transport to angiography suite
- admit to Intensive Care Unit
- Cardiothoracic surgery involvement on a case by case basis
- If anticoagulation is contraindicated, call consultant for consideration of IVC filter.

Special Considerations
For Thrombolytic Therapy

- Tolerance of Thrombolysis
- Underlying Tolerance of Pulmonary Hypertension
- Socked in pulmonary artery no perfusion may want to quicken therapy ie EKOS to theoretically decrease amount of pulmonary infarction

Get the Patient Back from the Edge

We Primarily Use Low dose TNK (Tenectaplaste) which is off label though most use TPA

PEITHO Trial: TNK (Tenectaplaste)

- n = 1,066 patients
- mean age 70 years
- 13 countries in Europe and Israel
- included patients with confirmed PE, an abnormal RV on echocardiography or CT, and a positive troponin I or T test result
- randomized blinded to heparin plus placebo or heparin plus full dose weight-adapted bolus of tenectaplaste
- combined primary end point: death from any cause or hemodynamic collapse after seven days

- Results:
  - primary and post RRR of 56% if treated with tenecaplaste and heparin, compared with the heparin only group (1.8% in the tenecaplaste group vs 5.6% in the placebo group, p = 0.015)
  - substantial reduction in the combined endpoint of early mortality or hemodynamic collapse in patients with RV dysfunction (25.5% in the tenecaplaste group vs 34.1% in the placebo group, p = 0.015)
  - significant increase in major hemorrhage (including intracranial hemorrhagic) particularly evident among elderly patients aged >75
  - major bleeding was significantly increased in the tenecaplaste group (6.3% vs 1.5% in the placebo group, p = 0.001)

- subgroup analysis by age, in the >75y group RRR was 37% and the risk of stroke almost 2%

Typical On Table PE result

Catheter mechanico - lysis
- No uniform dosing in literature
- Typically reduced dose
- Spin catheter during dosing
- Local recommendation is 20-30% of typical dose over 5 minutes and observe for 25-30 minutes to see if pulmonary pressures improve
- If significant improvement no continued dose
- If not improved continue infusion at 0.5 to 1 mg/hour

Ultrasound accelerated thrombolysis

EKOS EkoSonic® Mach 4e Endovascular System
- Infusion side-hole catheter with a multi-element ultrasound core wire
- 12 cm nominal treatment zone length typically used for PE therapy

Bilateral EKOS 12 CM in Place

SEATTLE 2
- 150 Patients
  - sub-massive (79%)
  - massive pulmonary embolism (21%)
  - Right ventricular LV per CT defined ratio of at least 0.9
- Patients underwent ultrasound-facilitated fibrinolysis (EKOS) for either unilateral or bilateral pulmonary embolism
- Mean total dose 24 mg tPA (1mg/hour/catheter)
- At 48 hours Evaluation
- CT Scan: Change in RV:LV diameter ratio measured
- Echocardiography pulmonary artery systolic pressures

JACC Cardiovasc Interv. 2015;8:1382-92

SEATTLE 2 Results
- Procedure completed successfully 98%
- 86% of patients had bilateral disease.
- 48 hour results:
  - RV:LV ratio decreased by 30%
  - Pulmonary artery systolic pressures decreased by 30%
- Sub-massive and massive pulmonary embolism patients showed no difference in response.
Ultima Trial: Faster RV Recovery

Kucher et al. Circ 2014;129:479-86