Advancing the Science in PE Treatment – What do We Need to Know, and How Will We Learn

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Massive PE

Prospective Registry Randomized Controlled Trial

Massive
Submassive

25-85% mortality (ICOPER, MAPPET)
3% mortality (Jaff Circ 2011)
5% decompensation (PEITHO)
<1% mortality (Jaff, Circ 2011)

Massive
Submassive
Low-risk

Rescue
Prevent mortality and hemodynamic decompensation (?)
Prevent progression to above (AC)
A massive PE case

- 54 y.o. male who has a past medical history of L craniotomy for resection of glioma (12/11/2018), complex plastics closure on 3/21
- Scheduled for repeat complex closure on 4/2/19, had pre-op DVT with IVC filter placement. Post op c/b hypotension, hypoxia found to have bilateral PE with R heart strain.
Pre vs post hemodynamics

- Pre: 55/22 (35) mmHg (systolic/diastolic (mean))
- Post Right sided thrombectomy: 40/16 (26) mmHg
- Post Left sided thrombectomy: 38/14 (24) mmHg
- Oxygen saturation: 91–96%
- Weaned off pressors
- Extubated that evening

Best analysis done so far – Kuo et al. 2009

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<tr>
<th>Major Complications</th>
<th>Clinical Success</th>
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<td>2.4% (CI: 1.9%, 4.3%)</td>
<td>86.5% (CI: 82.2%, 90.2%)</td>
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What does the data (not) tell us?

- Techniques are available to remove thrombus or create a channel through occluded pulmonary arteries
- Can be used if systemic lysis is contraindicated
- (not): which catheter-based techniques are most effective (and safe)?
- (not): whether catheter-based therapy is better than the other therapies or should be used in combination

Massive 5% incidence
Submassive 25-40% incidence
Low-risk 60% incidence
Back of the envelope calculation: RCT not feasible for Massive PE

- 800 bed hospital
- 200 PE's per year
- 5% Massive = 10 per year
- Assume 40% enrollment
- 4 massive PE's per year/institution
- Randomize them to what? IV lytics vs surgery vs interventional therapy? 3 arm study? What is the effect size, and how would you power it?

What does a Massive PE Prospective Registry look like?

- Detailed baseline characteristics
- Every patient is included
- Detailed intervention (device, fibrinolytic drug, surgical intervention, ECMO)
- 7 and 30 day outcomes, followed for 1 year

Submassive PE

Systemic thrombolysis has a questionable risk-benefit profile in patients with submassive PE
Main PA systolic pressure = 60 mmHg.

Prospective CDT trials

ULTIMA – CDT reduced RV/LV ratio to a greater extent than heparin at 24 hours*

Kucher et al., Circulation 2014
What does the data (not) tell us?

- CDT probably reduces RV strain faster than AC alone
- Major bleeding is seen with CDT (SEATTLE 2, OPTALYSE)
- (not): what the short and long-term clinical outcomes are following CDT for submassive PE
- (not): what the optimal dose/duration of thrombolytic drug is
- (not): whether non-lytic techniques are efficacious and safe

>1600 patients have been randomized in systemic lytic trials. 59 have been randomized in a single, non-US, CDT trial
Thank you!
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