Deep Vein Thrombosis
And
Pulmonary Embolism
Deep Vein Thrombosis

– Very common disorder

– Third most common cause of cardiovascular morbidity and mortality
  • After coronary artery disease and stroke

– Approximately 600,000
  • Inpatient/outpatient visits each year in US
Acute Lower Extremity DVT

• Proximal Lower extremity DVT
  – 80% of these cases
  – Any DVT above the popliteal vein
    • Femoropopliteal
    • Iliofemoral
    • Caval

• Calf DVT – Distal DVT
Anticoagulation

- Prevents - Clot propagation
- Reduces - Risk of pulmonary embolism

- **DOES NOT** prevent development of Post Thrombotic Syndrome (PTS)
Recanalization Rates

Elkof and Rutherford Vascular surgery
20 - 50% - Proximal LE DVT
Post Thrombotic Syndrome (PTS)

- Pain/heaviness
- Swelling and edema
- Itching/paresthesia
- Hyperpigmentation and stasis dermatitis
- Lipodermatosclerosis
- Ulcers

Schreiber, D. Deep venous thrombosis and thrombophlebitis. www.emedicine.com
Post Thrombotic Syndrome

- Marked impairment in Quality of life
  - Which parallels that of COPD or CHF

- Huge Economic Burden
  - 2.4 billion dollars annually in US
  - 200 million workdays lost annually in US

Vedantham S; Semin Respir Crit Care Med 2008;29:56–65
Question

• What additional treatments can be considered to reduce her risk of post thrombotic syndrome?
  
  – *Knee high Compression stockings (30-40 mmHg)*
  
  – *Catheter-based thrombus removal*
Surgical Thrombectomy

P < 0.005

NNT – 3

Venous symptoms
Venous Obstruction
Valvular reflux

Surgical Thrombectomy

- Lack of surgical expertise
- Risks of general anesthesia
- Slightly increased risk of PE
Systemic Thrombolysis - PTS

Cochrane Analysis of trials that reported PTS
PTS – RR 0.7 (95% CI 0.5 – 0.9)
Systemic Thrombolysis - Safety

Turpie et al Chest 1990: 172S - 175S

Bar chart showing major bleeding rates:
- Intravenous tPA: 14%
- Heparin: 4%

Significance: $P=0.04$
Catheter-directed Thrombolysis (CDT)

- Place a infusion catheter (Multiple sideholes)
- Infuse thrombolytic - 24 to 96 hrs
CDT and PTS – 5 year

78%

p < 0.001

NNT 2

0 – 2 CEAP Score

AbuRahma et al Ann Surgery 2001:233; 752-760
Pharmacomechanical Thrombolysis

- Reduce the procedure time
- Reduce the dose of thrombolytics
- Even allow single session treatments
40 Year-old female

• Left Leg swelling and pain

• ER – Extensive left lower extremity DVT from iliac to popliteal veins

• Discharged on LMWH and warfarin from ER
Ultrasound guided transpopliteal vein access
May Thurner syndrome

Pre-stent

Post Stent
Pre-Pharmacomechanical thrombectomy  Post Pharmacomechanical thrombectomy
Intravenous lesions (ridges/webs/chords)

Eliahou R et al. Radiographics 2012;32:E33-E49
Diagnosis

CT Scan

MRA

Rt. Iliac Artery

Lt. Common Iliac Vein
Intravascular Ultrasound

Proximal Iliac Vein

Iliac Vein Compression
Acute Pulmonary Embolism

• Estimated 530,000 cases of symptomatic PE annually

• 1% - Cardiopulmonary arrest

• Approximately 300,000 people die every year from acute PE

High Risk Acute Pulmonary Embolism

• Shock or hemodynamic compromise
• 5%
• Mortality:
  – Cardiopulmonary arrest - ~ 70%
  – Hypotension requiring pressors - 30%
• Treatment
  – Systemic thrombolysis
  – Catheter-based or surgical thrombectomy

Intermediate Risk (Sub Massive) Acute Pulmonary Embolism

• Signs of Right Ventricular dysfunction with or without elevations in Troponin or BNP.

• 30%
A Spectrum of Short Term Risks

32% In-Hospital Mortality

3.4% In-Hospital Mortality

Unstable

Stable

Becattini C, et al. CHEST 2013;144: 1539
Long Term Risk - Chronic Thromboembolic Pulmonary Hypertension
Intermediate Risk (Sub Massive) Acute Pulmonary Embolism

- Advanced Treatment Options
  - Systemic thrombolysis
  - Catheter-based Thrombus Removal
  - Surgical thrombectomy
Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism

Guy Meyer, M.D., Eric Vicaut, M.D., Thierry Danays, M.D., Giancarlo Agnelli, M.D., Cecilia Becattini, M.D., Jan Beyer-Westendorf, M.D., Erich Bluhmki, M.D., Ph.D., Helene Bouvaist, M.D., Benjamin Brenner, M.D., Francis Couturaud, M.D., Ph.D., Claudia Dellas, M.D., Klaus Empen, M.D., Ana Franca, M.D., Nazzareno Galiè, M.D., Annette Geibel, M.D., Samuel Z. Goldhaber, M.D., David Jimenez, M.D., Ph.D., Matija Kozak, M.D., Christian Kupatt, M.D., Nils Kucher, M.D., Irene M. Lang, M.D., Mareike Lankeit, M.D., Nicolas Meneveau, M.D., Ph.D., Gerard Pacouret, M.D., Massimiliano Palazzini, M.D., Antoniu Petris, M.D., Ph.D., Piotr Pruszczyk, M.D., Matteo Rugolotto, M.D., Aldo Salvi, M.D., Sebastian Schellong, M.D., Mustapha Sebbane, M.D., Bozena Sobkowicz, M.D., Branislav S. Stefanovic, M.D., Ph.D., Holger Thiele, M.D., Adam Torbicki, M.D., Franck Verschuren, M.D., Ph.D., and Stavros V. Konstantinides, M.D., for the PEITHO Investigators*
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Tenecteplase (N = 506)</th>
<th>Placebo (N = 499)</th>
<th>Odds Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome — no. (%)</td>
<td>13 (2.6)</td>
<td>28 (5.6)</td>
<td>0.44 (0.23–0.87)</td>
<td>0.02</td>
</tr>
<tr>
<td>Death from any cause</td>
<td>6 (1.2)</td>
<td>9 (1.8)</td>
<td>0.65 (0.23–1.85)</td>
<td>0.42</td>
</tr>
<tr>
<td>Hemodynamic decompensation</td>
<td>8 (1.6)</td>
<td>25 (5.0)</td>
<td>0.30 (0.14–0.68)</td>
<td>0.002</td>
</tr>
<tr>
<td>Time between randomization and primary efficacy outcome — days</td>
<td>1.54±1.71</td>
<td>1.79±1.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrent pulmonary embolism between randomization and day 7 — no. (%)</td>
<td>1 (0.2)</td>
<td>5 (1.0)</td>
<td>0.20 (0.02–1.68)</td>
<td>0.12</td>
</tr>
<tr>
<td>Fatal</td>
<td>0</td>
<td>3 (0.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonfatal</td>
<td>1 (0.2)</td>
<td>2 (0.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other in-hospital complications and procedures — no. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>8 (1.6)</td>
<td>15 (3.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical embolectomy</td>
<td>1 (0.2)</td>
<td>2 (0.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter thrombus fragmentation</td>
<td>1 (0.2)</td>
<td>0 (0.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vena cava interruption</td>
<td>5 (1.0)</td>
<td>1 (0.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombolytic treatment other than study medication</td>
<td>4 (0.8)</td>
<td>23 (4.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death from any cause between randomization and day 30 — no. (%)</td>
<td>12 (2.4)</td>
<td>16 (3.2)</td>
<td>0.73 (0.34–1.57)</td>
<td>0.42</td>
</tr>
<tr>
<td>Patient still hospitalized at day 30 — no. (%)</td>
<td>59 (11.7)</td>
<td>50 (10.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rehospitalization between randomization and day 30 — no. (%)</td>
<td>22 (4.4)</td>
<td>15 (3.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Table 4. Safety Outcomes in the Intention-to-Treat Population.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Tenecteplase (N = 506)</th>
<th>Placebo (N = 499)</th>
<th>Odds Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bleeding between randomization and day 7</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major extracranial bleeding</td>
<td>32 (6.3)</td>
<td>6 (1.2)</td>
<td>5.55 (2.3–13.39)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Minor bleeding</td>
<td>165 (32.6)</td>
<td>43 (8.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Major bleeding†</strong></td>
<td>58 (11.5)</td>
<td>12 (2.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke between randomization and day 7</td>
<td>12 (2.4)</td>
<td>1 (0.2)</td>
<td>12.10 (1.57–93.39)</td>
<td>0.003</td>
</tr>
<tr>
<td>Ischemic stroke</td>
<td>2 (0.4)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hemorrhagic stroke‡</strong></td>
<td>10 (2.0)</td>
<td>1 (0.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious adverse events between randomization and day 30</td>
<td>55 (10.9)</td>
<td>59 (11.8)</td>
<td>0.91 (0.62–1.34)</td>
<td>0.63</td>
</tr>
</tbody>
</table>
Original Investigation

Thrombolysis for Pulmonary Embolism and Risk of All-Cause Mortality, Major Bleeding, and Intracranial Hemorrhage: A Meta-analysis

Saurav Chatterjee, MD; Anasua Chakraborty, MD; Ido Weinberg, MD; Mitul Kadakia, MD; Robert L. Wilensky, MD; Partha Sardar, MD; Dharam J. Kumbhani, MD, SM, MRCP; Debabrata Mukherjee, MD, MS; Michael R. Jaff, DO; Jay Giri, MD, MPH

JAMA June 18, 2014 Volume 311, Number 23
### Mortality - Thrombolysis vs Anticoagulation

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Events</th>
<th>No. of Patients</th>
<th>No. of Events</th>
<th>No. of Patients</th>
<th>OR (95% CI)</th>
<th>Favors</th>
<th>Favors</th>
<th>Weight, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPETSG, 31 1970</td>
<td>6</td>
<td>82</td>
<td>7</td>
<td>78</td>
<td>0.80 (0.26-2.49)</td>
<td></td>
<td></td>
<td>20.2</td>
</tr>
<tr>
<td>Tibbutt et al, 28 1974</td>
<td>0</td>
<td>13</td>
<td>1</td>
<td>17</td>
<td>0.17 (0.00-8.94)</td>
<td></td>
<td></td>
<td>1.6</td>
</tr>
<tr>
<td>Ly et al, 25 1978</td>
<td>1</td>
<td>14</td>
<td>2</td>
<td>11</td>
<td>0.37 (0.03-3.96)</td>
<td></td>
<td></td>
<td>4.5</td>
</tr>
<tr>
<td>Marini et al, 26 1988</td>
<td>0</td>
<td>20</td>
<td>0</td>
<td>10</td>
<td>Not estimable</td>
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<td></td>
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<tr>
<td>Levine et al, 22 1990</td>
<td>1</td>
<td>33</td>
<td>0</td>
<td>25</td>
<td>5.80 (0.11-303.49)</td>
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<tr>
<td>PIOPED, 27 1990</td>
<td>1</td>
<td>9</td>
<td>0</td>
<td>4</td>
<td>4.24 (0.06-296.20)</td>
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<td>1.4</td>
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<tr>
<td>Dalla-Volta et al, 23 1992</td>
<td>2</td>
<td>20</td>
<td>1</td>
<td>16</td>
<td>1.61 (0.15-16.82)</td>
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<td>4.7</td>
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<tr>
<td>Goldhaber et al, 2 1993</td>
<td>0</td>
<td>46</td>
<td>2</td>
<td>55</td>
<td>0.16 (0.01-2.57)</td>
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<td></td>
<td>3.3</td>
</tr>
<tr>
<td>Jerges-Sanchez et al, 24 1995</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>0.03 (0.00-0.40)</td>
<td></td>
<td></td>
<td>3.8</td>
</tr>
<tr>
<td>Konstantinides et al, 3 2002</td>
<td>4</td>
<td>118</td>
<td>3</td>
<td>138</td>
<td>1.58 (0.35-7.09)</td>
<td></td>
<td></td>
<td>11.4</td>
</tr>
<tr>
<td>TIPES, 29 2010</td>
<td>0</td>
<td>28</td>
<td>1</td>
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<td></td>
<td></td>
<td>9.3</td>
</tr>
<tr>
<td>MOPETT, 10 2012</td>
<td>1</td>
<td>61</td>
<td>3</td>
<td>60</td>
<td>0.35 (0.05-2.57)</td>
<td></td>
<td></td>
<td>6.5</td>
</tr>
<tr>
<td>ULTIMA, 30 2013</td>
<td>0</td>
<td>30</td>
<td>1</td>
<td>29</td>
<td>0.13 (0.00-6.59)</td>
<td></td>
<td></td>
<td>1.7</td>
</tr>
<tr>
<td>TOPCOAT, 9 2014</td>
<td>1</td>
<td>40</td>
<td>1</td>
<td>43</td>
<td>1.08 (0.07-17.53)</td>
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<td>3.3</td>
</tr>
<tr>
<td>PEITHO, 8 2014</td>
<td>6</td>
<td>506</td>
<td>9</td>
<td>499</td>
<td>0.66 (0.24-1.82)</td>
<td></td>
<td></td>
<td>24.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>23</td>
<td>1061</td>
<td>41</td>
<td>1054</td>
<td><strong>0.53 (0.32-0.88)</strong></td>
<td></td>
<td></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

Heterogeneity: $\chi^2_{14}=16.51; P = .28; I^2 = 15\%$
Overall effect: $z = 2.45; P = .01$
Mortality
Thrombolysis vs Anticoagulation

<table>
<thead>
<tr>
<th>Source</th>
<th>No. of Events Thrombolitics</th>
<th>No. of Patients Thrombolitics</th>
<th>No. of Events Anticoagulants</th>
<th>No. of Patients Anticoagulants</th>
<th>OR (95% CI)</th>
<th>Favors Thrombolitics</th>
<th>Favors Anticoagulants</th>
<th>Weight, %</th>
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<tr>
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<td>Fasullo et al,¹¹ 2011</td>
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<td>—</td>
<td>10.5</td>
</tr>
<tr>
<td>ULTIMA,³⁰ 2013</td>
<td>0</td>
<td>30</td>
<td>1</td>
<td>29</td>
<td>0.13 (0.00-6.59)</td>
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<td>9</td>
<td>499</td>
<td>0.66 (0.24-1.82)</td>
<td>—</td>
<td>—</td>
<td>40.0</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>866</td>
<td>26</td>
<td>889</td>
<td>0.48 (0.25-0.92)</td>
<td>—</td>
<td>—</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Heterogeneity: χ² = 7.63; P = .37; I² = 8%
Overall effect: z = 2.22; P = .03
Outcomes
Thrombolysis vs Anticoagulation

<table>
<thead>
<tr>
<th>Outcome of Interest</th>
<th>No. of Events/No. of Patients, Absolute Event Rate (%)</th>
<th>No. Needed to Treat or Harm</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Thrombolytic Group</td>
<td>Anticoagulant Group</td>
<td></td>
</tr>
<tr>
<td>All-cause mortality (16)</td>
<td>23/1061 (2.17)</td>
<td>41/1054 (3.89)</td>
<td>NNT = 59</td>
</tr>
<tr>
<td>Major bleeding (16)</td>
<td>98/1061 (9.24)</td>
<td>36/1054 (3.42)</td>
<td>NNH = 18</td>
</tr>
<tr>
<td>ICH (15)</td>
<td>15/1024 (1.46)</td>
<td>2/1019 (0.19)</td>
<td>NNH = 78</td>
</tr>
<tr>
<td>Recurrent PE (15)</td>
<td>12/1024 (1.17)</td>
<td>31/1019 (3.04)</td>
<td>NNT = 54</td>
</tr>
<tr>
<td>Age &gt;65 y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All-cause mortality (5)</td>
<td>14/673 (2.08)</td>
<td>24/658 (3.65)</td>
<td>NNT = 64</td>
</tr>
<tr>
<td>Major bleeding (5)</td>
<td>87/673 (12.93)</td>
<td>27/658 (4.10)</td>
<td>NNH = 11</td>
</tr>
<tr>
<td>Age ≤65 y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All-cause mortality (11)</td>
<td>9/388 (2.32)</td>
<td>17/396 (4.29)</td>
<td>NNT = 51</td>
</tr>
<tr>
<td>Major bleeding (11)</td>
<td>11/388 (2.84)</td>
<td>9/396 (2.27)</td>
<td>NNH = 176</td>
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<tr>
<td>Intermediate-risk PE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All-cause mortality (8)</td>
<td>12/866 (1.39)</td>
<td>26/889 (2.92)</td>
<td>NNT = 65</td>
</tr>
<tr>
<td>Major bleeding (8)</td>
<td>67/866 (7.74)</td>
<td>20/889 (2.25)</td>
<td>NNH = 18</td>
</tr>
</tbody>
</table>
Rationale for Endovascular Thrombus Removal

• 20 – 30% patients
  • Contraindications for systemic thrombolysis

• Major bleeding rates – 22%
  – Even after using it in low bleeding risk patients

• Failure of systemic thrombolysis
SEATLE II Study

CT-confirmed PE
- Symptoms ≤ 14 days
- Massive or submassive
- Meets all inclusion and no exclusion criteria

RV enlargement as documented by initial CT
- RV:LV ratio ≥ 0.9

Ultrasound-facilitated fibrinolysis
- t-PA 1 mg/hr for 24 hours (1 device)
- t-PA 1 mg/hr for 12 hours (2 devices)
- TOTAL t-PA Dose = 24 mg

Follow-up at 48 ±6 hours after start of the procedure
- CT measurement of RV:LV ratio
- Echocardiogram to estimate PA systolic pressure

Study Sites = 21
Total Trial Population = 150
<table>
<thead>
<tr>
<th>Clinical outcomes*</th>
<th>N = 150</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean length of stay ± SD, days</td>
<td>8.8 ± 5</td>
</tr>
<tr>
<td>In-hospital death, n (%)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>30-day mortality**, n (%)</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Serious adverse events due to t-PA, n (%)</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>IVC filter placed, n (%)</td>
<td>24 (16)</td>
</tr>
<tr>
<td>Intracranial hemorrhage, n (%)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

*All death, serious adverse, and bleeding events were adjudicated by an independent safety monitor.

**N = 149 (1 patient lost to follow-up)
The ULTIMA Trial

A Prospective, Randomized, Controlled Study of Ultrasound Accelerated Thrombolysis for the Treatment of Acute Pulmonary Embolism

Nils Kucher, M.D.

Clinics for Angiology & Cardiology

University Hospital Bern

Bern, Switzerland
Primary endpoint: Reduction in RV/LV ratio (echo)

Reduction in RV/LV Ratio

Baseline to 24 hrs  Baseline to 90 days

EKOS+Heparin  Heparin

Baseline to 24 hrs  Baseline to 90 days

0.30  0.03

P<0.0001
Primary endpoint: Reduction in RV/LV ratio (echo)

- EKOS+Heparin:
  - Baseline to 24 hrs: 0.30
  - Baseline to 90 days: 0.38
  - P<0.0001

- Heparin:
  - Baseline to 24 hrs: 0.03
  - Baseline to 90 days: 0.22

P=0.03
## Overcoming Intracranial Hemorrhage

<table>
<thead>
<tr>
<th>Study</th>
<th>Intracranial Hemorrhage (Fibrinolysis Group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICOPER (IV Fibrinolysis)</td>
<td>9/304 (3%)</td>
</tr>
<tr>
<td>(Goldhaber SZ, et al. 1999)</td>
<td></td>
</tr>
<tr>
<td>PEITHO (IV Fibrinolysis)</td>
<td>10/506 (2%)</td>
</tr>
<tr>
<td>(Meyer G, et al. 2014)</td>
<td></td>
</tr>
<tr>
<td>SEATTLE II (CDT-EKOS)</td>
<td>0/150 (0%)</td>
</tr>
<tr>
<td>ULTIMA (CDT – EKOS)</td>
<td>0/30 (0%)</td>
</tr>
<tr>
<td>Kucher, et al 2014</td>
<td></td>
</tr>
</tbody>
</table>
PE-TRACT Study

- Randomized Multicenter nationwide Study of Sub-massive Pulmonary Embolism randomizing to Catheter-based Thrombus Removal versus Anticoagulation Alone.
69 Year old man with sudden onset Shortness of Breath

- Normotensive
- Enlarged Right Ventricle with Hypokinesis
- Elevated Troponin
Bilateral EKOS catheter placement
Repeat CTA – 72 hours

- Pulmonary Obstruction index: 100 to 46
- Cardiac Index: 2.6 to 3.6
- PA systolic pressure: 60 – 50
- RV/LV Ratio: 1.1 to 0.9
CTA – 3 Months
Cardiac Effects

Pre EKOS CDT

Post EKOS CDT
Saddle Embolus

Pre EKOS CDT

Post EKOS CDT
Conclusions (I)

• In massive PE - Thrombolysis first line treatment

  – Patients who have a contraindication for fibrinolysis or are unstable despite fibrinolysis.

  • Catheter embolectomy/fragmentation or
  
  • Surgical embolectomy should be considered
Conclusions

• *In submassive PE patients*

  – *consider catheter-directed thrombolysis*

    *particularly ultrasound enhanced thrombolysis.*
Temple Venous Thromboembolism Program