Interventional Management of Acute Pulmonary Embolism

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DECLARATION OF CONFLICT OF INTEREST

- Consultant to EKOS Corp.
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Pulmonary embolism: clinical risk stratification (Grade IC)

*Initial treatment*

Unfractionated heparin, low molecular weight heparin, or fondaparinux for at least 5 days

Grade IC guidelines

No IVC filter placement except contraindication to anticoagulation

Hemodynamic status

- **Low-risk PE**
  - (BP > 90 mm Hg, biomarkers –, ECHO –)
  - Grade IB guidelines
  - No thrombolysis, catheter intervention, surgery, or staged procedures
  - Grade IA guidelines

- **Intermediate-risk (submassive) PE**
  - (BP > 90 mm Hg, biomarker +, ECHO +)
  - Systemic thrombolysis (Grade IIB)
  - Catheter-directed thrombolysis (Grade IIB) (if bleeding risk ↓)
  - Grade IA guidelines

- **High-risk (massive) PE**
  - (BP < 90 mm Hg, shock, CPR)
  - Systemic thrombolysis (Grade IB)
  - Catheter-directed thrombolysis (Grade IB)
  - Catheter interventions (Grade IIC)
  - Surgical embolectomy (Grade IIC)
  - Grade IA guidelines

*Long-term treatment*

Vitamin K antagonist for ≥ 3 months
Goals of Catheter Embolectomy in Massive Pulmonary Embolism

- Decrease in pulmonary vascular resistance and pulmonary artery pressure
- Recovery of right ventricular dysfunction
- Increase in systemic arterial pressure
- Improvement of symptoms and survival

Kucher N, Goldhaber SZ. Circulation 2006;112:e28-32
Combined Mechanical Techniques: Fragmentation and Thrombectomy

Eidt-Lid et al. Chest 2008; 134:54
Pharmacomechanical Interventions

AngioJet  Power Pulse thrombolysis + thrombectomy (Venturi effect)

EKOS  Ultrasound-assisted thrombolysis
## Meta-analysis on PE catheter interventions (35 studies)

<table>
<thead>
<tr>
<th></th>
<th>Clinical success*</th>
<th>Clinical success in studies with &gt;80% patients receiving thrombolysis</th>
<th>Clinical success in studies with &lt;80% patients receiving thrombolysis</th>
<th>Major complications</th>
<th>Minor complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 594</td>
<td>86%</td>
<td>91%</td>
<td>83%</td>
<td>2%</td>
<td>8%</td>
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*defined as stabilization of hemodynamic parameters, resolution of hypoxia, and survival of massive PE

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Complications of Catheter Embolectomy

• Pulmonary hemorrhage/ hemoptysis

• Right ventricular failure from distal embolization

• Bleeding from anticoagulation or thrombolysis

• Hemolysis, hemoglobinuria

• Arrhythmia

• Contrast-induced anaphylaxis and contrast-induced nephropathy

• Vascular access complications

Kucher N, Goldhaber SZ. Circulation 2006;112:e28-32
Ultrasound-Assisted Thrombolysis
Effect of Ultrasound

Without Ultrasound
Fibrin strands prevent drug from penetrating thrombus and binding to plasminogen receptor sites

With Ultrasound
Destabilization of fibrin strands, enabling penetration of drug into thrombus

Ultrasound + Thrombolysis
Ultrasound pressure waves force drug into thrombus, resulting in rapid removal of thrombus even at low drug dose
The Ekosonic Endovascular System

Ekosonic Control Unit

Ekosonic Mach4 Endovascular Device

5 fr Intelligent side-hole drug delivery catheter

Ultrasound MicroSonic™ Core
Ultrasound-Assisted Thrombolysis
Rapid Improvement in Right Ventricular Enlargement

Subannular RV/LV ratio

Hemodynamically stable patients with acute symptomatic PE
UFH 80 U/kg Bolus IV, UFH continuous infusion of 18 U/kg/min IV (max 1800 U/h)
(N =50)

Contrast-Enhanced Chest CT:
Filling defect in at least one main or proximal lower lobe pulmonary artery

Baseline ECHO: RV/LV ratio >1.0

Open Label Randomization \( \leq 4 \) hours

UFH IV alone (N=25)

UFH IV + EkoSonic procedure:
Ultrasound-assisted tPA of 10 mg over 15 hours if one lung is treated and 20 mg over 15 hours if both lungs are treated (N=25)

Primary endpoint assessed by blinded core-lab:
RV/LV ratio from baseline to 24h

Secondary endpoints: Mortality, recurrent PE, major & minor bleeding at 90 days

ULTIMA
Recorded Massive PE Case

• 70 yo woman with history of prior PE developed dyspnea NYHA II for two weeks
• On Aug 15 2011, she suffered syncope and sudden severe dyspnea at rest
• On admission, she had ongoing hypotension (BP 80 mm Hg) requiring catecholamine support und ongoing hypoxia (O2 sat 80%) while receiving 10 liters of oxygen via face mask
Massive PE: Ultrasound-Assisted Thrombolysis
Take Home

• Catheter interventions are promising alternatives for PE patients who cannot receive full-dose systemic thrombolysis
• Mechanical techniques are often combined
• Pharmacomechanical interventions are more effective than mechanical interventions
• There is a need for clinical trials to establish the role for catheter interventions in patients with submassive PE