THE SEATTLE II TRIAL

A Prospective, Single-Arm, Multicentre Trial of Ultrasound-Facilitated, Low-Dose Fibrinolysis for Acute Massive and Submassive Pulmonary Embolism


Patients

Acute Massive and Submassive PE with RV/LV ratio ≥ 0.9
(n = 150; 22 centers)

Objectives

Evaluate ultrasound-facilitated, catheter-directed low-dose fibrinolysis:

- **Efficacy** – as measured by reduction in RV/LV ratio
- **Safety** – as measured by major bleeding within 72 hours

Method

- Ultrasound-facilitated fibrinolysis using EKOS®
  - If unilateral PE
    - tPA 1 mg/hr using one device for 24 hours
  - If bilateral PE
    - tPA 1 mg/hr per device (using two simultaneously) for 12 hours
- Follow up at 48 +/- 6 hours
  - CT measurement of RV/LV ratio
  - Echocardiogram to estimate PA systolic pressure

Indications for use: The EkoSonic® Endovascular System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. The EkoSonic® Endovascular System is intended for the infusion of solutions into the pulmonary arteries. The EkoSonic® Endovascular System is indicated for the ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism. Contraindications: This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient’s condition. See device instructions for use for complete prescribing information.
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Key Results

Acute massive and submassive PE patients treated with EKOS® showed:

25% decrease in RV/LV ratio over 48 hours

Minimized risk of intracranial hemorrhage

<table>
<thead>
<tr>
<th>Study</th>
<th>Intracranial Hemorrhage (Fibrinolysis Group)</th>
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<tbody>
<tr>
<td>ICOPER (Goldhaber SZ, et al. 1999)</td>
<td>9/304 (3%)</td>
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<tr>
<td>PEITHO (Meyer G, et al. 2014)</td>
<td>10/506 (2%)</td>
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<tr>
<td>SEATTLE II (Piazza G, et al. 2015)</td>
<td>0/150 (0%)</td>
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</tbody>
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Rapidly relieved pulmonary artery obstruction

Reduced pulmonary hypertension

CONCLUSION

Ultrasound-facilitated, catheter-directed, low-dose fibrinolysis for acute PE improves RV function and decreases pulmonary hypertension and angiographic obstruction. By minimizing the risk of intracranial bleed, it represents a potential “game-changer” in the treatment of high-risk PE patients.