



Ultrasound-Facilitated, Catheter-Directed Fibrinolysis (USCDT) for Acute Pulmonary Embolism (HI-PEITHO trial) » randomized, controlled, multi-center study

Population	Intervention and Comparison	Outcomes	Results
<p>544 patients with intermediate-high risk PE.</p> <p>Key inclusion criteria:</p> <ul style="list-style-type: none"> • Age 18-80 years • PE in at least one main or proximal lobar pulmonary artery confirmed by CTPA • Elevated risk of early death/hemodynamic collapse, at least two criteria: <ul style="list-style-type: none"> ◦ HR \geq 100 bpm ◦ SBP \leq 110 mmHg ◦ Respiratory rate $>$ 20 or SO₂ $<$ 90% or PaO₂ $<$ 60mmHg on room air • RV/LV diameter \geq 1 • Serum troponin I/T $>$ ULN 	<p><u>USCDT + Anticoagulation</u></p> <ul style="list-style-type: none"> • Device: EkoSonic Endovascular System (Boston Scientific). • Procedure: US assisted thrombolysis, using 2mg/h alteplase per catheter for 7 hours (total 9-18 mg). • Initiation of therapy within 2 hours <p><u>Anticoagulation Alone</u> vs</p> <ul style="list-style-type: none"> • Protocol: Standard heparin-based anticoagulation alone 	<p><u>Primary outcome:</u> A composite of PE related death, cardiorespiratory decompensation or collapse, or non-fatal symptomatic recurrence of PE within 7 days</p> <p><u>Secondary outcomes:</u></p> <ul style="list-style-type: none"> • Individual components of primary outcome • Change in RV/LV ratio • GUSTO major bleeding within 7 days, 30 days and 6 months • Ischemic/ hemorrhagic stroke • WHO functional class • 6-minute walking distance at 30 days 	<p>Primary Outcome: An event occurred in 11 patients (4.0%) in the intervention group and 28 (10.3%) in the control group (relative risk, 0.39; 95% CI, 0.20 to 0.77; P=0.005).</p> <p>Benefit: driven primarily by a reduction in cardiorespiratory decompensation or collapse.</p> <p>Safety: While overall major bleeding was not statistically significantly higher in the treatment arm (4.1% vs 2.2%), there was a numerically higher incidence of bleeding, though no intracranial hemorrhages occurred.</p> <p>Mortality: No significant difference in 30 days.</p>