

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

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### Patients

**Acute Massive and Submassive PE with RV/LV ratio  $\geq 0.9$   
(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

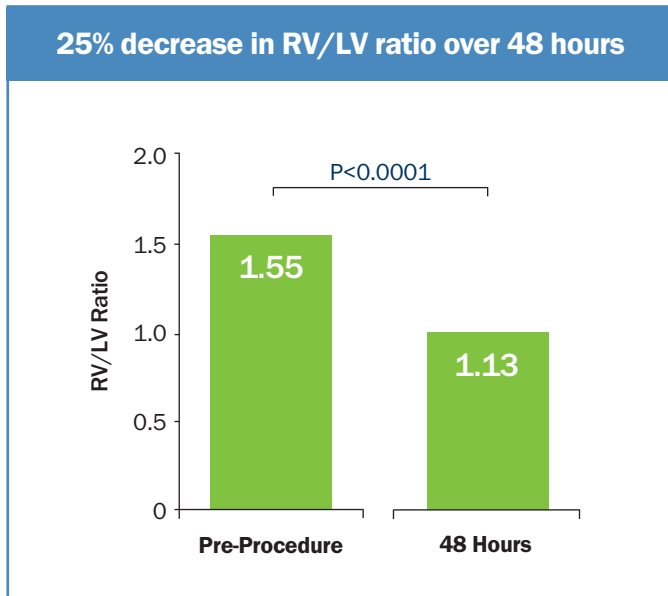
### Method

- **Ultrasound-facilitated fibrinolysis using EKOS<sup>®</sup>**
  - 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



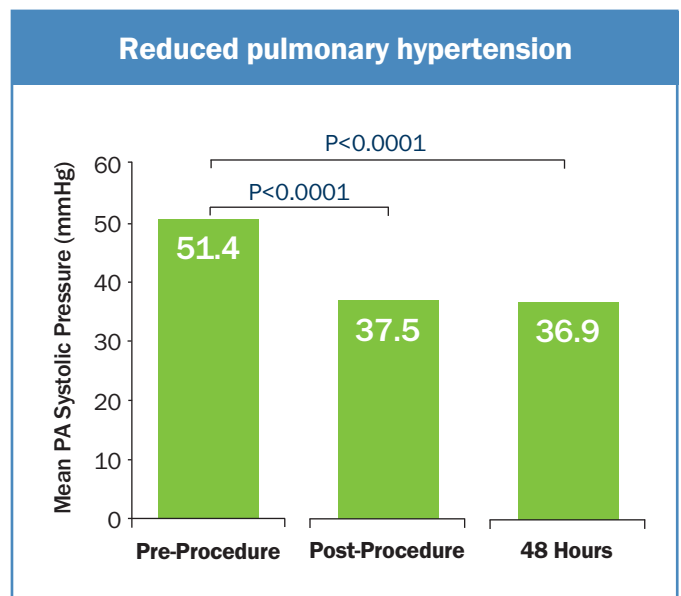
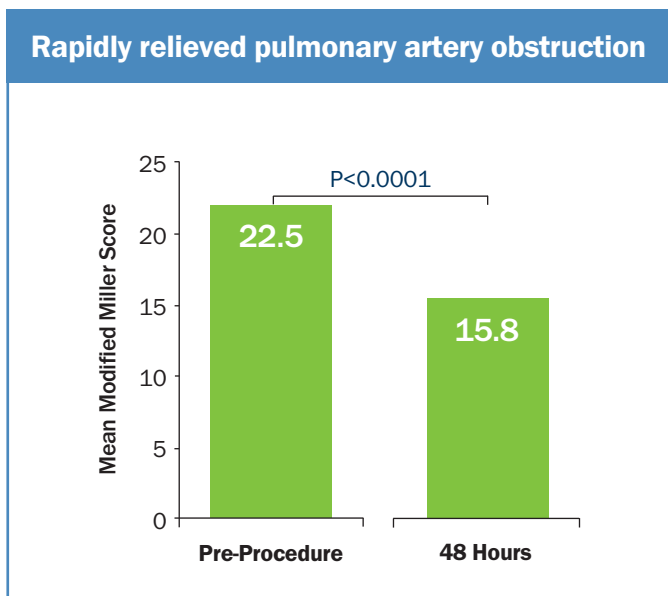
## Key Results

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



### Minimized risk of intracranial hemorrhage

Study	Intracranial Hemorrhage (Fibrinolysis Group)
<b>ICOPER</b> (Goldhaber SZ, et al. 1999)	<b>9/304 (3%)</b>
<b>PEITHO</b> (Meyer G, et al. 2014)	<b>10/506 (2%)</b>
<b>SEATTLE II</b> (Piazza G, et al. 2014)	<b>0/150 (0%)</b>



## 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.