

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

Piazza G et al. JACC: Cardiovascular Interventions 2015; 8(10): 1382-1392.

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

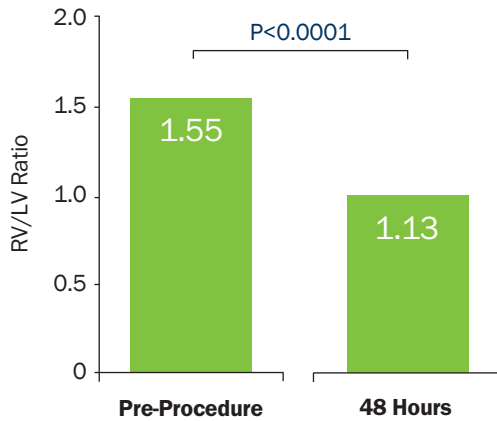
- Ultrasound-facilitated fibrinolysis using EKOS®
 - If unilateral PE
 - tPA 1 mg/hr using one device for 24 hours
 - If bilateral PE
 - tPA 1 mg/hr per device (using two simultaneously) for 12 hours
- Follow up at 48 +/- 6 hours
 - CT measurement of RV/LV ratio
 - Echocardiogram to estimate PA systolic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



Key Results

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

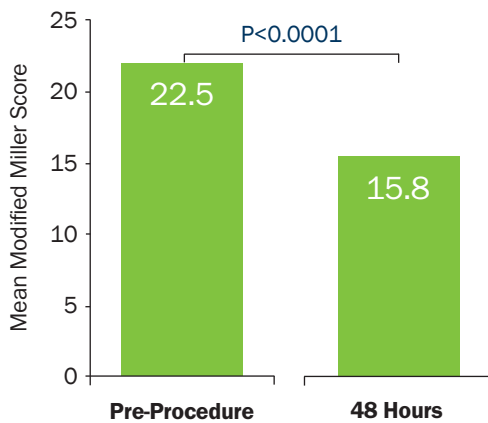
25% decrease in RV/LV ratio over 48 hours



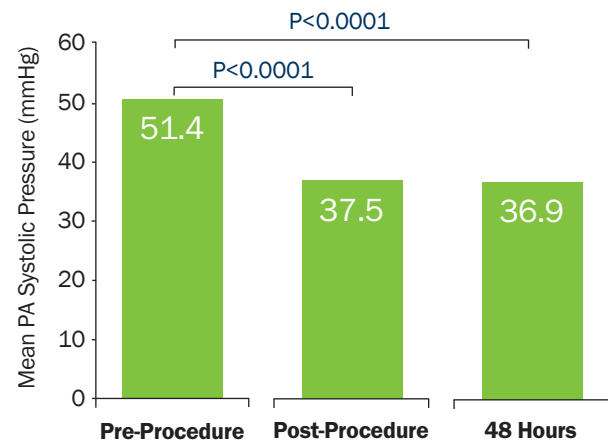
Minimized risk of intracranial hemorrhage

Study	Intracranial Hemorrhage (Fibrinolysis Group)
ICOPER (Goldhaber SZ, et al. 1999)	9/304 (3%)
PEITHO (Meyer G, et al. 2014)	10/506 (2%)
SEATTLE II (Piazza G, et al. 2015)	0/150 (0%)

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.