

Optimum Duration and Dose of r-tPA with the Acoustic Pulse Thrombolysis Procedure for Submassive Pulmonary Embolism: OPTALYSE PE

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as presented at the American Thoracic Society (ATS) meeting, Washington, DC, May 2017.

Patients

Acute PE with RV/LV ratio ≥ 0.9
(n = 101; 17 centres)

Objectives

Evaluate the optimal duration and dose of Acoustic Pulse Thrombolysis™ (APT) treatment using r-tPA administered via the EKOS™ system:

- Efficacy – Change in RV/LV ratio on CTA at 48hrs
- Safety – As measured by major bleeding within 72hrs

Randomisation

Cohort 1	Cohort 2	Cohort 3	Cohort 4
26 Patients 2hrs EKOS™ 4/8mg r-tPA*	26 Patients 4hrs EKOS™ 4/8mg r-tPA*	27 Patients 6hrs EKOS™ 6/12mg r-tPA*	18 Patients 6hrs EKOS™ 12/24mg r-tPA*

Methods

- Anticoagulation therapy using heparin
- Acoustic Pulse Thrombolysis™ treatment using EKOS™ – following duration and dosage of randomly assigned study cohort
- Follow up at 48hrs post treatment start with CTA



* Total mg r-tPA: one/two catheters

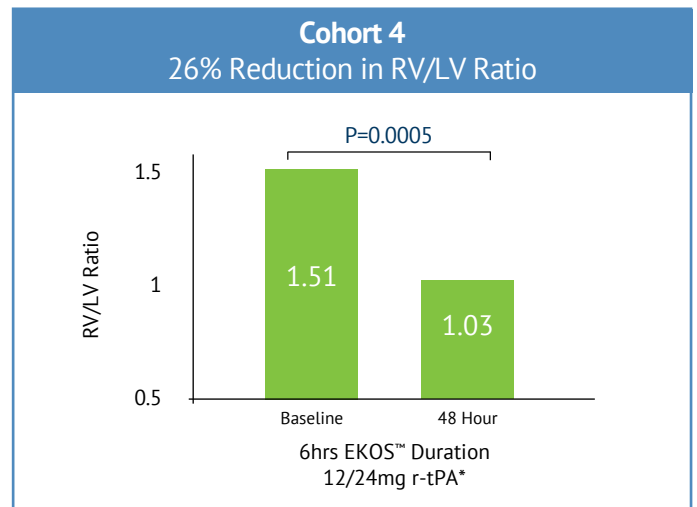
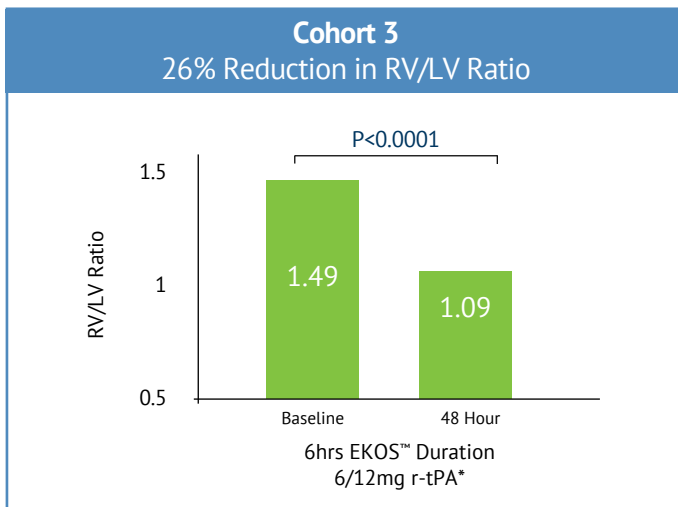
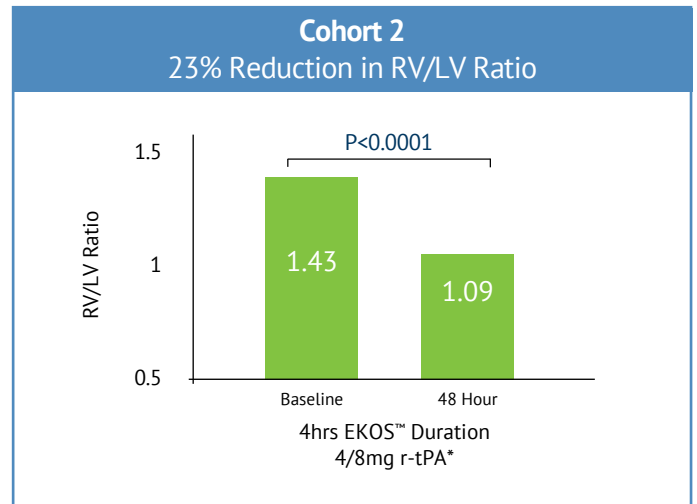
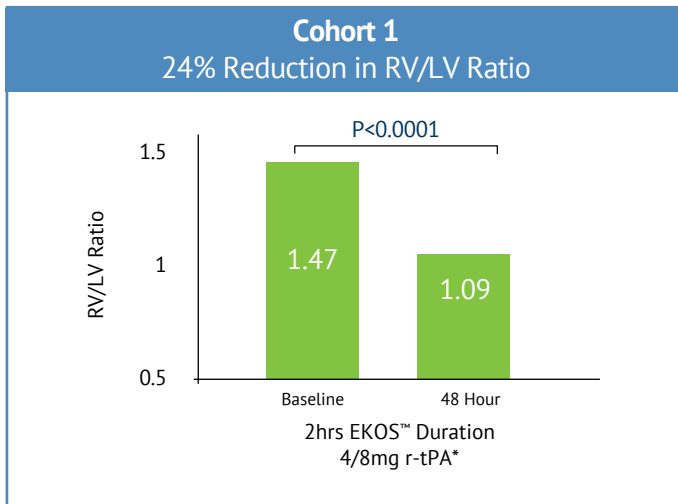
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INDICATIONS FOR USE: The EkoSonic™ Endovascular System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. The EkoSonic™ Endovascular System is CE Marked for the treatment of pulmonary embolism with a $\geq 50\%$ clot burden in one or both main pulmonary arteries or lobar pulmonary arteries, and evidence of right heart dysfunction based on right heart pressures (mean pulmonary artery pressure ≥ 25 mmHg) or echocardiographic evaluation. **Contraindications:** Not designed for peripheral vasculature dilation purposes. This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise that patient's condition. Such conditions include but are not limited to: • Tortuous vascular anatomy compromising safe introduction of endovascular equipment • Conditions associated with increased risk of bleeding. See device instructions for use for complete prescribing information http://ekoscorp.com/international_enter.htm#Resources

Key Results

Acute PE patients treated with EKOS™ showed the following improvements:

- Significant reduction in RV/LV ratios in all cohorts at 48 hours post initiation of procedure
- RV/LV ratio reduced by 24% (P<0.0001) for the two-hour cohort using only 4mg of r-tPA per catheter
- All cohorts had zero to very low bleeding rates¹



CONCLUSION

The EKOS™ system's very-low-dose and short-duration regimens in the OPTALYSE PE trial appear to be as acutely effective as the regimens in other EKOS™ studies (ULTIMA & SEATTLE II), pointing to a paradigm-changing approach for PE treatment. These results offer physicians a new treatment standard for proven PE clinical efficacy and safety.

¹ Cohorts 1 and 3 had zero major bleeding incidents, cohort 2 had one incident and cohort 4 had two incidents (including one ICH)

* Total mg r-tPA: one/two catheters