OPTALYSE PE Study

EKOS™

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:

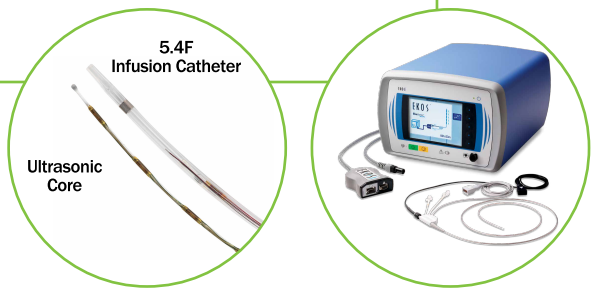
- **Efficacy – Change in RV/LV ratio on CTA at 48hrs**
- **Safety – As measured by major bleeding within 72hrs**

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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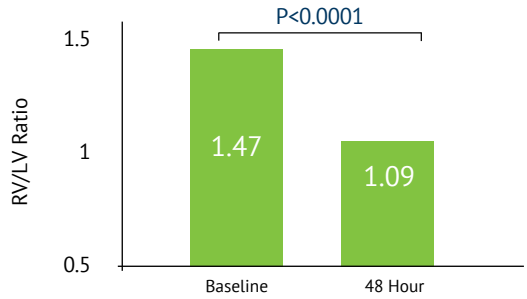
Key Results

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

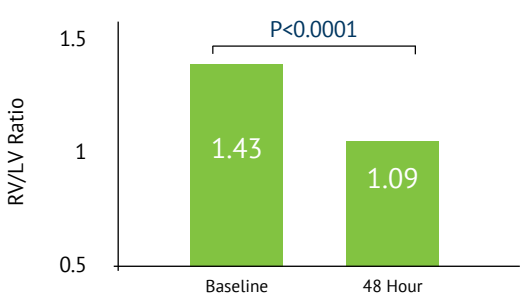
- **Significant reduction in RV/LV ratios in all cohorts at 48 hours post initiation of procedure**
- **RV/LV ratio reduced by 24% (P<0.0001) for the two-hour cohort using only 4mg of r-tPA per catheter**
- **All cohorts had zero to very low bleeding rates[1]**

Cohort 1
24% Reduction in RV/LV Ratio



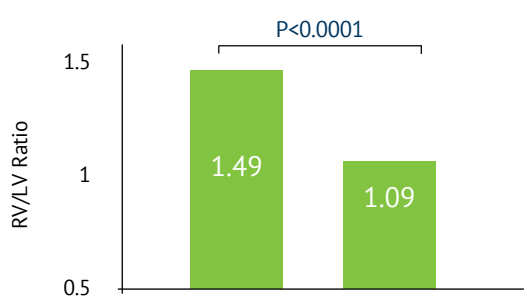
2hrs EKOS™ Duration
4/8mg r-tPA*

Cohort 2
23% Reduction in RV/LV Ratio



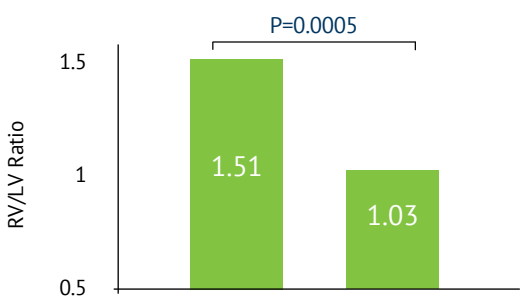
4hrs EKOS™ Duration
4/8mg r-tPA*

Cohort 3
26% Reduction in RV/LV Ratio



6hrs EKOS™ Duration
6/12mg r-tPA*

Cohort 4
26% Reduction in RV/LV Ratio



6hrs EKOS™ Duration
12/24mg r-tPA*

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**

Imagine where we can go.

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