

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

Victor Tapson<sup>1</sup>, Gregory Piazza<sup>2</sup>, Keith Sterling<sup>3</sup>, Kenneth Ouriel<sup>4</sup>, Ping-Yu Liu<sup>5</sup>; Samuel Z. Goldhaber<sup>2</sup> as presented at the American Thoracic Society (ATS) meeting, Washington, DC, May 2017.

### Patients

Acute PE with RV/LV ratio  $\geq 0.9$   
(n= 101; 17 centers)

### 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

### Randomization

Cohort 1	Cohort 2	Cohort 3	Cohort 4
26 Patients	26 Patients	27 Patients	18 Patients
2 (h) EKOS®	4 (h) EKOS®	6 (h) EKOS®	6 (h) EKOS®
4/8 mg r-tPA*	4/8 mg r-tPA*	6/12 mg r-tPA*	12/24 mg 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



1 - Victor Tapson<sup>1</sup> Pulmonary / Critical Care Division, Cedars-Sinai Medical Center, Los Angeles, CA  
2 - Gregory Piazza<sup>2</sup>, Samuel Z. Goldhaber<sup>2</sup> Cardiovascular Division, Brigham and Women's Hospital, Harvard University, Boston MA  
3 - Keith Sterling<sup>3</sup> Cardiovascular & Interventional Radiology, Inova Alexandria Hospital, Alexandria, VA  
4 - Kenneth Ouriel<sup>4</sup> Syntactx, NY, NY  
5 - Ping-Yu Liu<sup>5</sup> Fred Hutchinson Cancer Center, Seattle, WA

\* Total mg r-tPA: one/two catheters

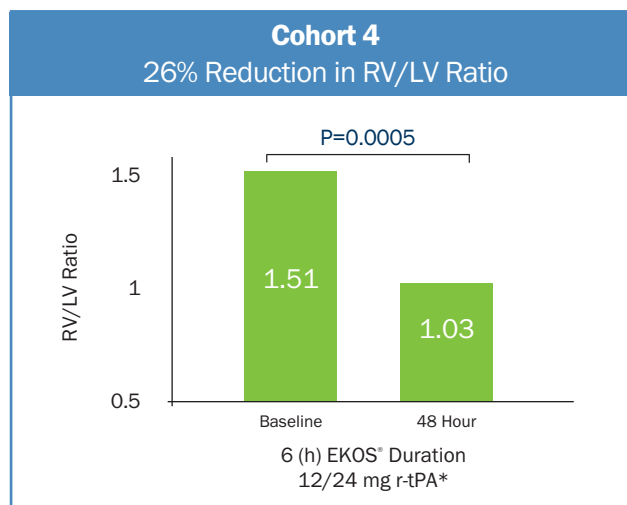
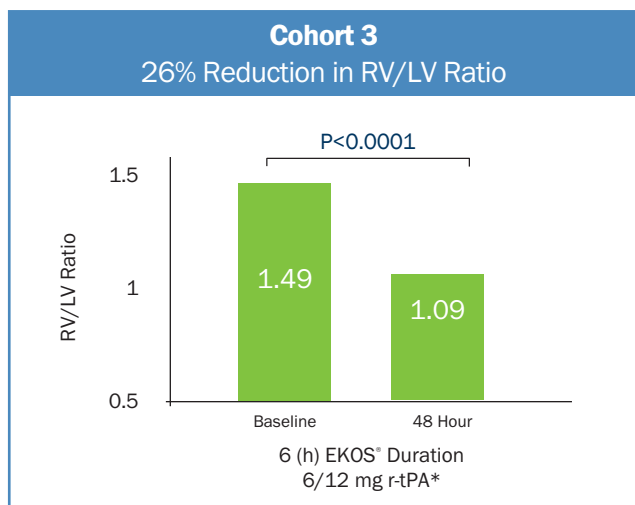
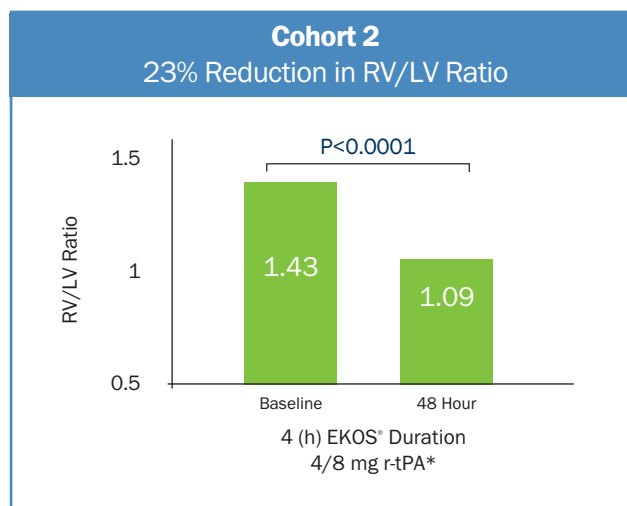
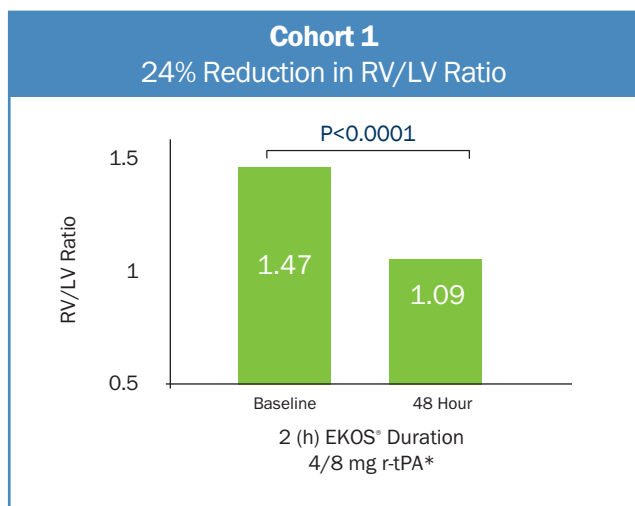
Imagine where we can go.



## 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.<sup>1</sup>



## 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.

<sup>1</sup>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