OPTALYSE PE Study

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 centers)

Objectives

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

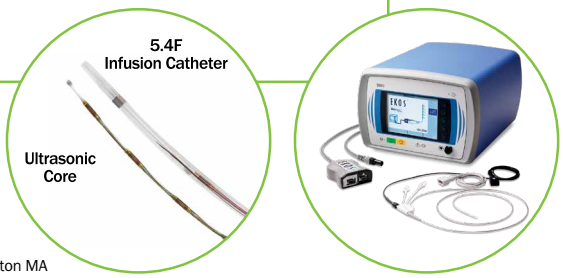
- **Efficacy - Change in RV/LV ratio on CTA at 48hrs**
- **Safety – As measured by major bleeding within 72hrs**

Randomization

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



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

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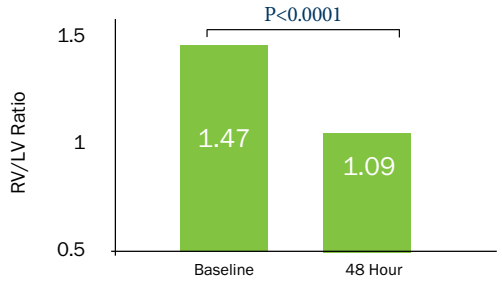
Key Results

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

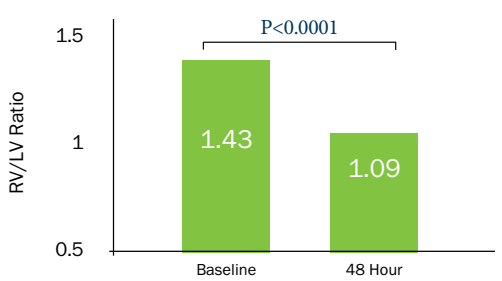
- Significant reduction in RV/LV ratios in all cohorts at 48 hours post initiation of procedure.
- RV/LV ratio reduced by 24% (P<0.0001) for the two-hour cohort using only 4mg of r-tPA per catheter.
- All cohorts had zero to very low bleeding rates.[6]

Cohort 1
24% Reduction in RV/LV Ratio



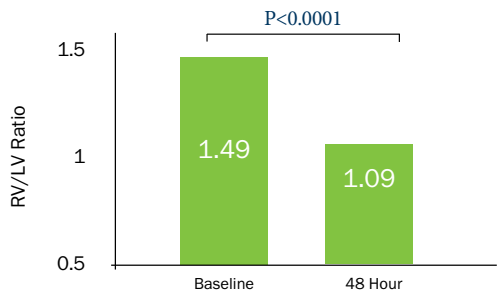
2 (h) EKOS™ Duration
4/8 mg r-tPA*

Cohort 2
23% Reduction in RV/LV Ratio



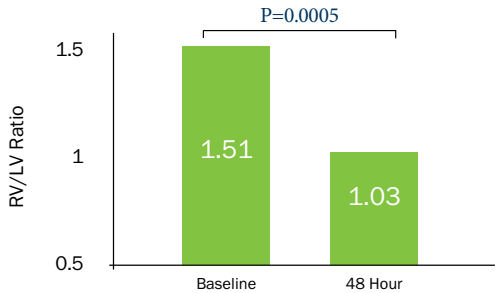
4 (h) EKOS™ Duration
4/8 mg r-tPA*

Cohort 3
26% Reduction in RV/LV Ratio



6 (h) EKOS™ Duration
6/12 mg r-tPA*

Cohort 4
26% Reduction in RV/LV Ratio



6 (h) EKOS™ Duration
12/24 mg r-tPA*

6 - 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**

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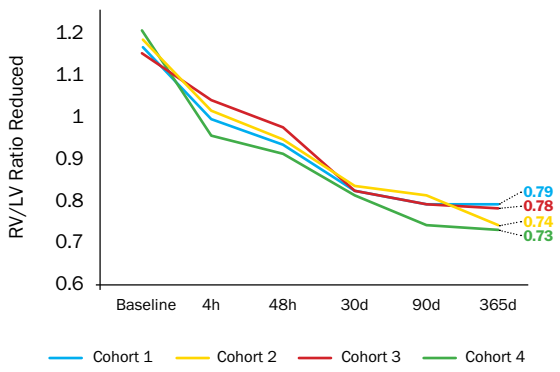
Key Results: Long Term

Patients continued to improve through 365d[7] follow up:

- RV/LV ratio improved significantly across all four cohorts long-term.[7]
- Multiple Quality of Life (QOL) metrics showed valuable improvements from 30d following EKOS™ treatment to 365d post-treatment.
- Very low all-cause mortality and recurrent PE rates of 2% each for all cohorts.

RV/LV ratio continued to reduce after 48h
P value <0.0001 @ 365d



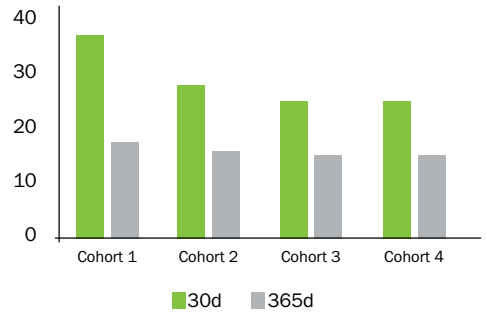
Long-term OPTALYSE safety & efficacy at 365d

	Mortality	Recurrent PE
OPTALYSE PE	2%	2%
PEITHO-AC[8]	8%	N/A
PEITHO-TNK[8]	10%	N/A
Baglin - AC[9]	N/A	3.7%

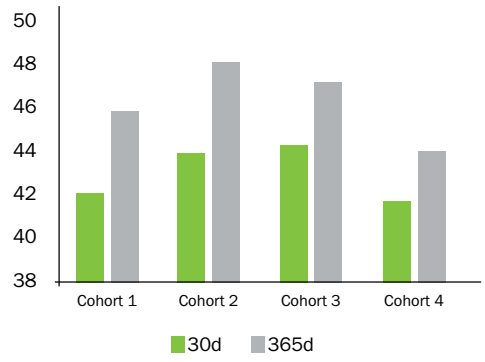
Quality of Life

Two unique measurements of quality of life show significant improvements from 30d to 365d following EKOS™ therapy.

PEmb-QOL score decreased for all cohorts



PROMIS-PF score increased for all cohorts



7 - Sterling, K. "Long-term Results of the OPTALYSE PE trial" as presented at the International Symposium on Endovascular Therapy (ISET) meeting, Hollywood, FL Feb 2018.
8 - Konstantinides, MD, et al, "Impact of Thrombolytic Therapy on the Long-Term Outcome of Intermediate-Risk Pulmonary Embolism" Journal of the American College of Cardiology; vol 69, pp.1536-1544, 2017.
9 - Baglin, et al., "Does the clinical presentation and extent of venous thrombosis predict likelihood and type of recurrence? A patient-level meta-analysis," Journal of Thrombosis and Haemostasis, vol. 8, no. 11, pp. 2436–2442, 2010. 3.

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ACUTE RESULTS:

The EKOS™ system's very low dose and short-duration regimens, in the OPTALYSE PE trial, prove to be as acutely effective as the regimens in previous EKOS™ studies (ULTIMA & SEATTLE II), pointing to a paradigm-changing approach for PE treatment.

LONG-TERM RESULTS:

The EKOS™ System's very low dose and short duration regimens, in the OPTALYSE PE trial, resulted in rapidly improved measures of right-heart function that were maintained for one year. Additionally, the favorable mortality rates, recurrent PE rates, and quality of life results demonstrate long-term benefits of EKOS™ therapy. This data further proves the PE clinical efficacy and safety of the OPTALYSE PE treatment protocols.

About EKOS™

EKOS Corporation, a BTG International group company, pioneered the development and clinical application of ultrasound infusion technologies in medicine, introducing its first system for the treatment of vascular thrombosis in 2005. Today, interventional radiologists, cardiologists, and cardiothoracic and vascular surgeons at leading institutions around the world use the EKOS™ EkoSonic™ Endovascular System to provide faster, safer and more complete dissolution of thrombus. To find out more about the EKOS™ EkoSonic™ Endovascular System, visit www.ekoscorp.com.

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