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EKOS™ Endovascular System
KNOCOUT PE

Prospective Multicenter International Registry of Ultrasound-Facilitated Catheter-Directed Thrombolysis in Intermediate-High and High-Risk Pulmonary Embolism (KNOCOUT PE)

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TRIAL OBJECTIVE

To understand the impact of the OPTALYSE PE study on various ultrasound-accelerated thrombolysis (USAT) protocols being used as the standard of care in the treatment of acute PE and associated long-term outcomes.

PATIENTS

489 prospective patients

CENTERS

64 international sites

Registry Design | Prospective Cohort

PATIENTS

489 patients
with intermediate-high risk and high-risk PE

Treated with EKOS from March 2018-June 2020

INCLUSION CRITERIA

- Male or female > 18 years of age and < 80 years of age
- Intermediate High-Risk or High-Risk PE
- RV/LV > 1.0 from diagnostic CTA or echocardiogram
- Symptom duration < 14 days
- Troponin elevation
- Investigator has selected the EKOS device to treat patient
- Infusion dose/duration per investigator's SOC

EXCLUSION CRITERIA

- Clinician deems subject high-risk for catastrophic bleeding
- Life expectancy < 1y

End Points

EFFICACY

- Thrombolytic dosing
- Thrombolytic infusion duration
- Adjuvant therapy
- Healthcare utilization: ICU and hospital length of stay (LOS)
- Quality of life as measured by PEmb-QoL and EQ-5D-5L VAS–365 days
- Echocardiogram
  - Change in RV:LV ratio from baseline
  - Tricuspid annular plane systolic excursion (TAPSE)
  - IVC collapse
  - Estimated right ventricular systolic pressure (RVSP)

SAFETY

- Recurrent VTE
- Major bleeding
- Mortality
- Diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH)

Key Results
Safety (Within 30 Days)

0 ICH*
(0/489)

1.6% ISTH Major Bleeding
(8/489)

RECURRENT VTE
PE: 0.4%
(2/489)

Major Bleeding at 72 hours	8 (1.6%)
Gastrointestinal Hemorrhage	2 (0.4%)
Head Laceration	1 (0.2)
Vascular Access Site Hematoma	4 (0.8%)
Subdural Hematoma (pre-existing)	1 (0.2)

Recurrent VTE within 30 days	
Pulmonary Embolism	2 (0.4%)

*1 preexisting subdural hematoma (SDH)

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Key Results | Procedural

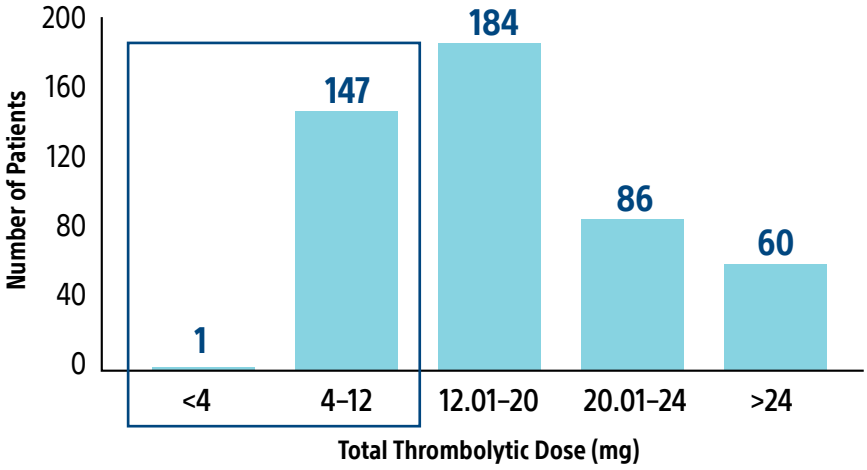
PROCEDURAL

- Mean dose of r-tPA: 18.1mg (SD 7.4)
- Mean infusion time: 10.5 hrs (SD 5.37)

31.0% of patients received < 12mg r-tPA

69.5% of patients received < 20mg r-tPA

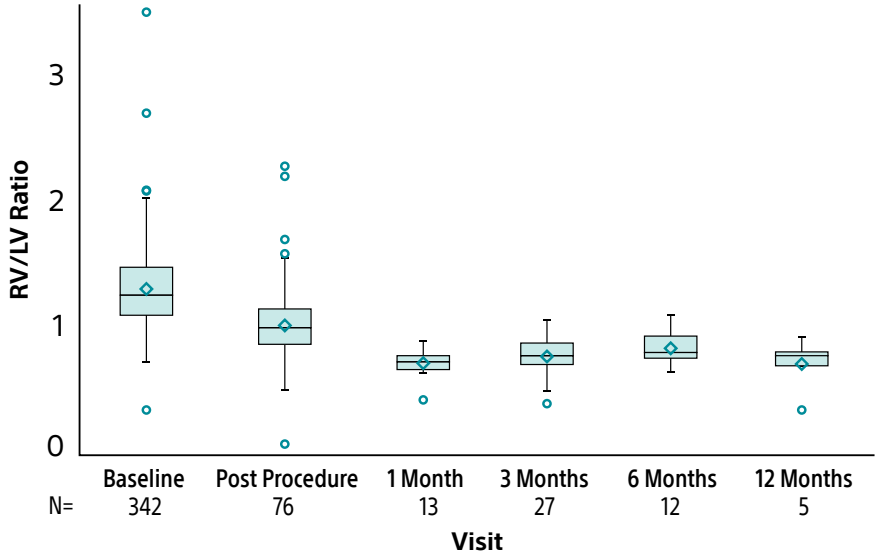
TOTAL THROMBOLYTIC DOSE



Key Results | Efficacy

RV/LV RATIO BY VISIT ON ECHO

Efficacy population in prospective patients



Key Results | Quality Of Life

QUALITY OF LIFE

- PEmb-QOL reduction at 3-months: 41%

QoL Measure	Post-Procedure Mean (SD)	3-Months Mean (SD)	Percent Change Mean (SD)	2-sided P-value
PEmb-QOL	38.5 (22.1)	16.0 (17.7)	41.1 (114.1)	<0.0001
VAS	63.1 (23.0)	75.5 (19.8)	56 (255.0)	0.0001

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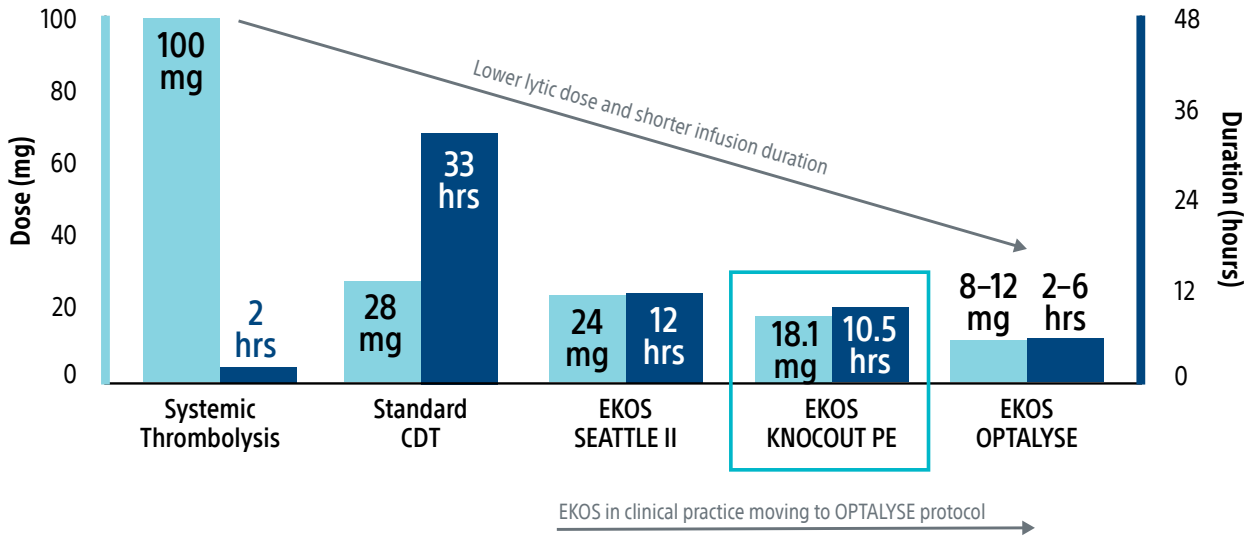
KNOCOUT PE CONCLUSIONS:

Results from this prospective multicenter registry reflect contemporary practice and demonstrate the performance of EKOS in the management of PE with lower total r-TPA dose and shorter infusion duration, marked clinical improvement in RV/LV ratio and low rates of major hemorrhagic complications with no intracerebral hemorrhagic events.

THROMBOLYTIC THERAPIES:

KNOCOUT PE shows that contemporary clinical practices are moving to low-dose, short duration OPTALYSE protocols. It adds to the growing evidence that EKOS is effective at treating intermediate risk and high risk PE with lower lytic doses and shorter infusion durations compared to other thrombolytic therapies.

DURATION AND DOSE BY THERAPY



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