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EKOS™ Endovascular System
EKOS-PE Study

Evaluation of Long-Term Key Outcomes and Safety in Pulmonary Embolism

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Objective

Evaluate the long-term clinical outcomes – including RV function and quality of life (QoL) – in patients with massive and submassive PE treated with the EKOS Endovascular System.

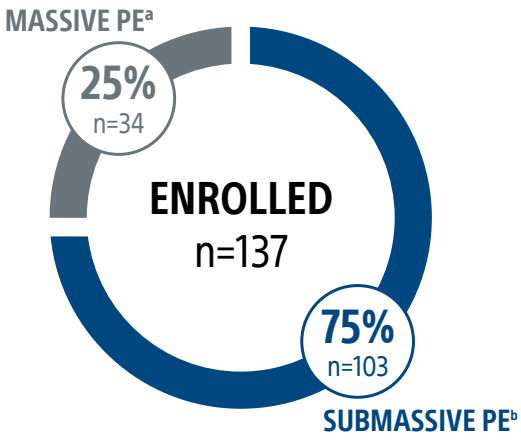
Centers

All patients were treated with the EKOS Endovascular System within the Baylor Scott & White Health System from March 2020 to March 2024.

Endpoints

- All-cause & PE-related mortality
- All-cause & PE-related readmission
- RV/LV ratio reduction
- Residual RV dysfunction
- Pulmonary embolism quality of life (PEmb-QoL) questionnaire

Patients



Results – Key Takeaways

EKOS therapy is associated with significant long-term improvement in RV function, low mortality, and favorable perceived QoL post-procedure.

7.2%
ALL-CAUSE MORTALITY
(at 26.5 Months)

0.7%
ADVERSE EVENTS

5.1%
ALL CAUSE READMISSION
(at 30 Days)

26.7%
RV/LV RATIO REDUCTION
(at 5.2 months)

Results — Full

Mortality		Follow Up
All-Cause	7.3%	26.5 ± 17.2 months
PE-Related	0.7%	
Readmission		**Follow Up**
All-Cause	5.0%	30 Days
PE-Related	0.7%	
Residual RV Dysfunction		**Follow Up**
None	79%	5.2 ± 7.8 months
Mild	8%	
Moderate	8%	
Severe	5%	
RV/LV Ratio Reduction	**26.7%**	**5.2 ± 7.8 months**

PEmb-QoL Results — 37 month follow-up

SUBSTANTIAL SYMPTOM IMPROVEMENT
Most patients reported minimal or no pulmonary complaints post-procedure

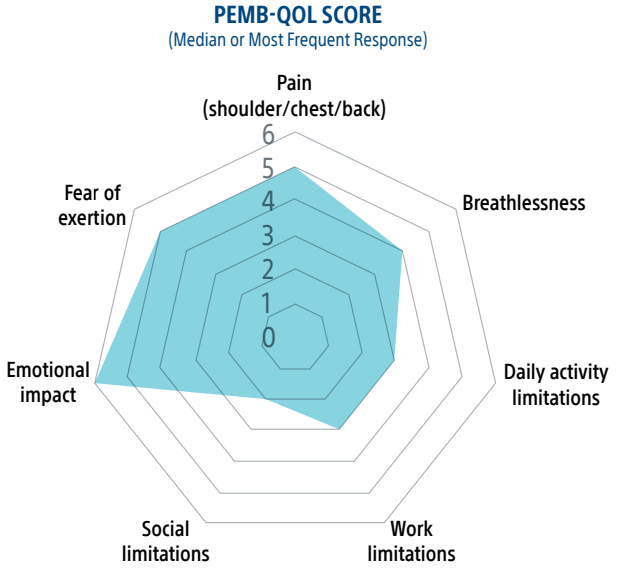
ENHANCED FUNCTIONAL CAPACITY
61.5% felt their lungs were "much better" compared to pre-procedure

RESIDUAL RESTRICTIONS & SOCIAL IMPACT
65.4% had no interference with normal social activities

a) Documented PE with subsequent syncope, systemic hypotension (SBP < 90 mmHg) cardiogenic shock, or resuscitated cardiac arrest
b) Presence of RV dysfunction (RV/LV ratio > 0.9 on echocardiography or troponin I > 0.4 ng/mL) without hemodynamic shock

PEmb-QoL Results — Full

52 Patients* – Mean Follow Up of 37.2 ± 12 months



Pain/Breathlessness (0-5)
1-Everyday, 2-Several times a week, 3-About once a week, 4-Less than once a week, 5-Never

Activity limitations (0-3)
0-I do not work; 1-Yes, limited a lot; 2-Yes, limited a little; 3-No, not limited at all

Emotional impact (1-6)
1-All of the time, 2-Most of the time, 3-A good bit of the time, 4-Some of the time, 5-A little of the time, 6-None of the time

Substantial Symptom Improvement:

- Most patients reported minimal or no pulmonary complaints post-procedure
- Median scores for various lung-related pain or nagging sensations were at "never" levels
- Mild chest pain and breathlessness were infrequent or absent for most

Enhanced Functional Capacity:

- 61.5% felt their lungs were "much better" compared to pre-procedure; 7.7% felt "somewhat better"
- Routine home tasks, social activities, and moderate exertion showed "no limitation at all"
- More strenuous activities (e.g., running) had mild-to-moderate limitations in a subset

Residual Restrictions & Social Impact:

- 19.2% reduced work/activity time, 25% achieved less, and 26.9% felt limited in task variety
- Nonetheless, 65.4% had no interference with normal social activities

Current Pain and Breathlessness:

- 69.2% reported no shoulder-blade or chest pain; 53.8% had no breathlessness.
- A small proportion did experience more severe shortness of breath

Lingering Concerns:

- Ongoing worries about recurrent PE (median score 4 [3–6]) and stopping anticoagulation (4.5 [2–6]) persisted

Conclusion

The EKOS-PE study found that EKOS therapy for massive and submassive PE significantly reduced the RV/LV diameter ratio, improved long-term RV function, and was associated with a low all-cause mortality rate and minimal residual symptoms.

*remaining patients declined participation or were unavailable for follow up

EkoSonic™ Endovascular Device

Indications, Safety and Warnings CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE / INDICATIONS FOR USE** The EkoSonic Endovascular Device is intended to be used with EKOS-branded control systems to employ high frequency (2 MHz to 3 MHz), low-power ultrasound to facilitate the infusion of physician-specified fluids, including procedural fluids and thrombolytics, into the pulmonary and/or peripheral vasculature of adults. It is intended to be used by physicians experienced in endovascular interventional procedures. The EkoSonic Endovascular System is not intended for use in the neurovasculature. Refer to the product insert supplied with the physician-specified fluid for fluid-specific preparation, contraindications, side effects, warnings, and precautions. The EkoSonic Endovascular System, consisting of the Infusion Catheter and the Ultrasonic Core, is indicated for the: • Ultrasound facilitated, controlled and selective intravascular infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism and/or deep vein thrombosis. • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries and/or peripheral vasculature. **CONTRAINDICATIONS** The EkoSonic Endovascular Device is contraindicated for use in: • Patients in whom thrombolytic and/or anticoagulation therapy is contraindicated. • Any situation in which the medical judgment of the physician determines such a procedure may compromise the patient's condition. **WARNINGS** • Never aspirate blood back into the drug lumens as perfusion pores and/or drug lumens may become occluded. • Never activate ultrasound energy with the Infusion Catheter or Ultrasonic Core's working length exposed to the air. The device should be placed within the patient anatomy, with physician-specified fluids running through the drug lumen and coolant flowing through the coolant lumen. Otherwise, overheating may occur, potentially causing burns, damage to the Ultrasonic Core, and/or interrupting therapy. • Never attempt to use the Ultrasonic Core with any catheter except the compatible EKOS Infusion Catheter. • Do not attempt to use non-compatible working lengths (i.e., 135 cm Infusion Catheter and 106 cm Ultrasonic Core and vice-versa). Incorrect size matching may be harmful to the patient and require additional intervention or surgery. • The EkoSonic Endovascular System is not intended for use in the neurovasculature. **PRECAUTIONS** Carefully read all Instructions for Use prior to use. • The EkoSonic device is designed to provide optimum acoustic output during the first 24 hours of operation. • The EkoSonic device should only be used to infuse physician-specified fluids, including thrombolytics. Other types of fluids, outside of thrombolytics and procedural fluids (heparinized saline, saline, contrast media, etc.), have not been evaluated for use with the EkoSonic Endovascular Device. • This device is not designed for use as a peripheral vascular dilator. • During normal use, ultrasound energy may cause a temperature rise in the treatment zone. The catheter surface temperature is limited to a maximum of 43 °C. • Therapeutic agents, such as thrombolytics, should be administered through the drug port whereas theprocedural fluids (such as saline and contrast agent) should be administered through the coolant port or central lumen. **ADVERSE EVENTS** Potential adverse events which may be associated with use of the EkoSonic Endovascular System when used as indicated include, but are not limited to: • Allergic Reaction (contrast, device, or other) • Arrhythmia • Burn • Cardiac Tamponade • Cardiac Trauma • Death • Embolism (air, device, plaque, thrombus, tissue, or other) • Hematoma • Hemorrhage • Hypotension • Infection/Sepsis • Ischemia/Necrosis • Need for additional intervention or surgery • Pain • Pneumothorax • Renal Insufficiency/Failure • Respiratory Failure • Thrombosis/Thrombus • Vasospasm • Vessel Occlusion • Vessel Trauma (AV fistula, dissection, perforation, pseudoaneurysm, rupture or injury) **92844459 A.1**

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