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EKOS™ Endovascular System

The REAL-PE Analysis

Modern Treatment of Pulmonary Embolism (USCDT versus MT): Results from Real-World, Big Data Analysis (REAL-PE)

Authors
Peter Monteleone, MD; Ryan Ahern, MD; Subhash Banerjee, MD; Kush Desai, MD; Daniella Kadian-Dodov, MD; Emily Webber PhD; Sally Omidvar MS MSPH; Patrick Troy, MD; Sahil Parikh, MD

Objective
Investigate the safety of ultrasound-assisted catheter-directed thrombolysis (USCDT; i.e. the EKOS System, Boston Scientific, Marlborough, MA) and mechanical thrombectomy (MT; i.e. the Flowtriever™ System, Inari Medical™, Irvine, CA) in real-world treatment of pulmonary embolism (PE).

Data Source
Truveta™, Inc. (Bellevue, WA) is a growing collective of more than 30 health systems in the U.S., providing 17% of the daily clinical care across all 50 states from 800 hospitals and 20,000 clinics. Comprised of nearly 100 million de-identified patient records, linked across health systems, and augmented with social determinants of health (SDOH) and claims data, the Truveta Studio platform enables real-world analysis and powerful insights to inform healthcare decision making.

Patients
Patients treated with ultrasound-assisted catheter-directed thrombolysis (USCDT; i.e. the EKOS System) or mechanical thrombectomy (MT; i.e. the FlowTriever System) for pulmonary embolism (PE) were identified through ICD10, SNOMED, UDI, and Truveta codes. Only patients diagnosed in the electronic health records with a PE within 30 days before the date of the USCDT or MT procedure or up to 1 day after the procedure were included in the analysis. The primary analysis was based on all data available in the Truveta Studio (index procedures Jan 2009 through early May 2023). A contemporary analysis was also performed (index procedures Jan 2018 through early May 2023).

Methods
Adverse events within 1 week of the procedure were investigated including: major bleeding (modeled after ISTH and BARC3b definitions), intracerebral hemorrhage (ICH), and in-hospital death. Events were identified utilizing LOINC, CPT, SNOMED, ICD-9 and ICD-10 codes and laboratory results.

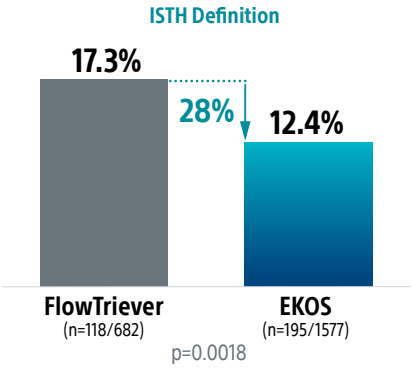
Key Results Summary

In comparison to patients treated with the Inari Medical FlowTriever System (N = 682), **patients treated with the EKOS System (N = 1577) had**:

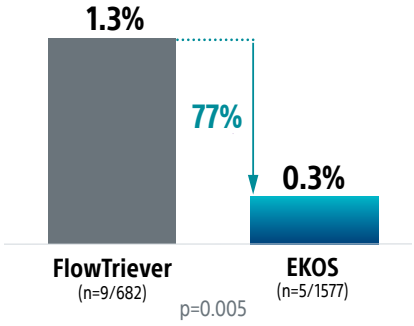
- A statistically significant **28% lower rate** of major bleeding events
- A statistically significant **77% lower rate** of intracerebral hemorrhage (0.3% incidence of ICH in patients treated with EKOS).
- **Comparable** in-hospital mortality rates, 30-day all-cause readmission rates, and median lengths of hospital stay

Key Results*

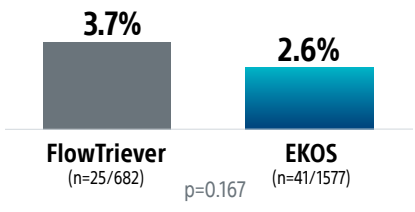
Rates of Major Bleeding
28% lower rate of major bleeding events
In the REAL-PE analysis, patients treated with the EKOS System had significantly lower rates of major bleeding than patients treated with the Inari Medical FlowTriever System.



Rates of Intracerebral Hemorrhage (ICH)
77% lower rate of ICH
Rates of ICH were significantly lower for patients treated with the EKOS System than for those treated with the FlowTriever System.



In-Hospital Mortality Rates
For the more than 2200 patients studied in the REAL-PE analysis, in-hospital mortality rates were comparable for patients treated with the EKOS System (2.6%) or with the FlowTriever System (3.7%).



*Primary analysis, patients with index procedures Jan 2009 through early May 2023.

Median Length of Hospital Stay

Patients who received intervention with the EKOS System had a median length of hospital stay equal to those treated with the FlowTriever™ System (3.6 days).

30-Day All-Cause Readmission Rates

There was no meaningful difference in 30-day all-cause readmission rates between patients treated with the EKOS System than those treated with the FlowTriever System (EKOS 5.1%, FlowTriever 5.4%, p=0.777).

Conclusions

In the REAL-PE analysis—a real-world, 2200-patient dataset evaluating advanced therapies for PE—**patients treated with the EKOS System (N=1577) had:**

- 28% lower rates of major bleeding
- 77% lower rates of ICH
- comparable in-hospital mortality rates, 30-day all-cause readmission rates, and median lengths of hospital stay when compared to patients treated with the FlowTriever System (N=682).

These findings from the primary analysis (2009–2023) were consistent in the contemporary analysis (2018–2023), which reflects more recent practice.

Reference

Monteleone P, et al. Modern Treatment of Pulmonary Embolism (USCDT versus MT): Results from Real-World, Big Data Analysis (REAL-PE). Journal of the Society for Cardiovascular Angiography & Interventions; Oct 2023.

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EKOS™ Endovascular System

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 the procedural 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)

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