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EKOS™ Endovascular System
REAL-PE II

Acute Safety of Contemporary Pulmonary Embolism Treatment With Ultrasound-Assisted Catheter Directed Thrombolysis or Mechanical Thrombectomy in a Matched Sample

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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 contemporary treatment of pulmonary embolism (PE).

Methods

A propensity score matched analysis was conducted to compare risk of major bleeding, inpatient mortality, and 30-day readmission between USCDT and MT groups. Patients were matched on demographics and medical history.

Data Source

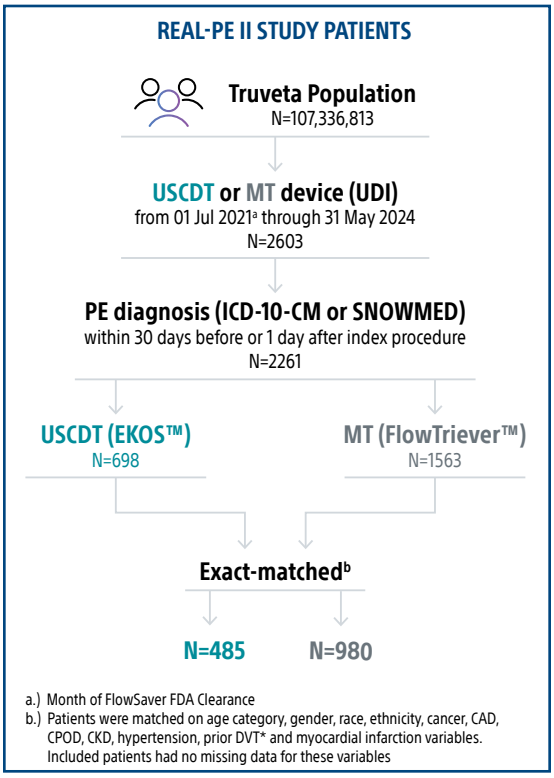
For the REAL-PE II analysis, data from 20 health systems and > 1M patients were provided by Truveta™ (Truveta Inc, Seattle, WA). Truveta aggregates electronic health records including diagnoses, device, use, procedures, encounter information, and lab results from a collective of US health systems for clinical research.

Key Insights

REAL-PE II corroborates and improves upon the results from the REAL-PE analysis; in a propensity-matched population of PE patients treated with EKOS or FlowTriever, EKOS demonstrated:

- Statistically significant lower rates of major bleeding and hospital readmission
- Comparable rates of in-hospital mortality

These results contribute to the understanding of bleeding risks and safety of catheter-based therapies in the hands of real-world operators and may contrast prior assumptions.



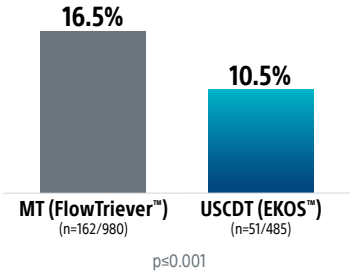
Patients

- 2,261 unique PE Patients before propensity-matching
- 1,465 exact matched[b] patients

Key Results (After Matching)

7-DAY MAJOR BLEEDING EVENT RATE (ISTH)

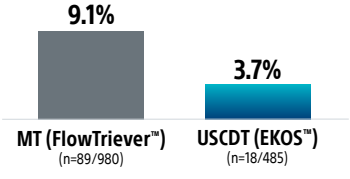
Patients treated with USCDT had significantly lower rates of major bleeding than patients treated with MT



p≤0.001

30-DAY READMISSION RATE

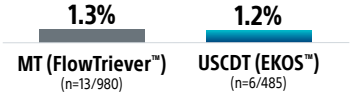
Rates of 30-day readmission were significantly lower for patients treated with USCDT than for those treated with MT



p≤0.001

7-DAY INPATIENT MORTALITY EVENT RATE

In-hospital mortality rates were comparable for patients treated with USCDT (1.2%) or with MT (1.3%)



p=0.730

*CAD = coronary artery disease, CPOD = chronic obstructive pulmonary disease, CKD = chronic kidney disease, DVT = deep vein thrombosis

Boston Scientific provided funding to Truveta for data reporting.

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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PI-2167203-AA