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EKOS™ Endovascular System

OPTALYSE-3D

Increased Vascular Volumes in Response to Treatment with Ultrasound-Facilitated, Catheter-Directed Thrombolysis in the OPTALYSE-PE Trial

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Background

Previous research has shown loss of distal vascular volume is associated with right ventricular (RV) dysfunction, increased oxygen requirements post discharge, and mortality.[1,2] OPTALYSE-3D examined changes in the small vessel volumes in response to ultrasound-assisted, catheter-directed thrombolysis (USCDT), large-bore mechanical thrombectomy (LBMT), or anticoagulation only (AC).

Patients

Primary Analysis: 53 patients (USCDT)

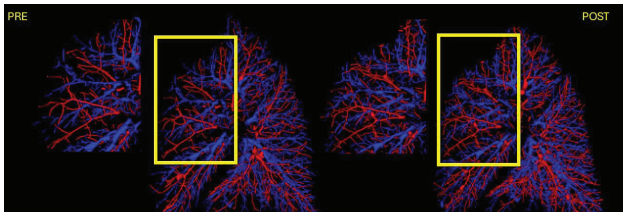
Exploratory Analysis: 10 patients (LBMT) 10 patients (AC)

Methods

3D reconstruction using clinical CT data and automated lung segmentation were performed to compute total vascular volume (TBV), small vessel volume (<5mm^2, BVsmall) and medium vessel volume (>5mm^2 and <20mm^2, BVmed). All vascular measures were normalized by total lung volume.

Arteries and veins were separated using a convolutional neural network.

CT-BASED 3D RECONSTRUCTION OF PATIENT UNDERGOING USCDT



More complete visualization of the distal vessels in the yellow box demonstrates reperfusion following USCDT treatment.

Conclusions

OPTALYSE-3D demonstrates a significant increase in small and medium venous volumes following treatment with USCDT. The vascular response observed with USCDT was not dependent on the dose of thrombolytic administered. This effect was not observed in the LBMT or AC exploratory arms.

Results

USCDT

Vascular Measures	Baseline	Post	p-value
Small Size Arterial Volume	7.3 [3.6–15.3]	7.6 [3.4–16.1]	0.86
Small Size Venous Volume	**4.3 [2.9–10.1]**	**7.4 [3.1–11.3]**	**0.0009**
Medium Size Arterial Volume	14.6 [10.8–20.0]	15.7 [11.2–19.2]	0.54
Medium Size Venous Volume	**8.9 [6.7–12.3]**	**10.6 [8.5–13.7]**	**<0.0001**

*all vascular measures represent ml of vascular volume per liters of lung

Takeaway: There is an observed increase in both small and medium sized venous vessels volumes following USCDT.

EXPLORATORY COHORTS - LBMT

Vascular Measures	Baseline	Post	p-value
Δ Small Size Arterial Volume	20.4 [15.1–23.3]	13.97 [11.6–17.7]	0.28
Δ Small Size Venous Volume	9.6 [7.3–13.0]	8.7 [7.1–10.0]	0.63
Δ Medium Size Arterial Volume	13.4 [11.2–15.1]	16.6 [10.7–18.2]	0.32
Δ Medium Size Venous Volume	6.0 [5.5–9.2]	9.7 [7.8–11.4]	0.049

EXPLORATORY COHORTS - AC

Vascular Measures	Baseline	Post	p-value
Δ Small Size Arterial Volume	18.5 [9.2–19.6]	16.4 [13.9–16.9]	0.63
Δ Small Size Venous Volume	10.7 [4.8–12.9]	9.6 [8.5–12.2]	0.85
Δ Medium Size Arterial Volume	16.3 [12.7–18.8]	13.0 [10.1–15.6]	0.004
Δ Medium Size Venous Volume	9.0 [7.4–9.6]	9.0 [7.6–10.7]	0.43

Takeaway: No statistically significant differences in venous volumes were detected following treatment with LBMT or AC.

EKOS™ 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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