EKOS[™] Endovascular System



ACUTE INTERMEDIATE-RISK PE CASE STUDY:

EKOS THERAPY WITH A LOW-DOSE OPTALYSE PROTOCOL

PHYSICIAN

Anas Safadi, MD, ABVM, FACC, FSCAI Interventional Cardiology & Cardiovascular Diseases Advanced Cardiovascular Care St. Mary Medical Center/Community Healthcare System

Director of Limb Ischemia Program Clinical Assistant Professor of Medicine, Indiana University School of Medicine

PATIENT HISTORY

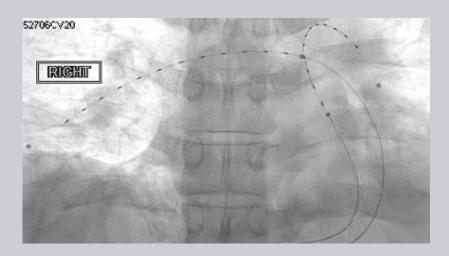
- 42 yo African American male presented with one day history of sudden onset shortness of breath, worse with exertion
- 2 weeks prior he reported left calf pain but thought it was muscle strain
- Left calf pain occurred 1 day after long car ride
- No previous history of DVT, PE, or hypercoagulable state
- Venous US: Thrombus within the mid/distal left posterior tibial vein
- PE: respiratory distress, pulse: 126, RR: 22, O2 saturation: 90%
- Pertinent labs: elevated NT-ProBNP = 1169 and troponin = 91
- EKG: sinus tachycardia, s1q3t3 pattern noted

DIAGNOSTICS

- Extensive bilateral pulmonary emboli including a saddle pulmonary embolism
- RV/LV ratio: 1.5

- · Signs of right heart strain including -
 - Deviation of the interventricular septum
 - Dilatation of the right ventricle
 - Dilatation of the main pulmonary artery

EKOS[™] Endovascular System



TREATMENT TECHNIQUE

- EKOS treatment as per OPTALYSE Protocol
 - Two 6 French sheaths placed in right common femoral vein with US guided access
 - Two 12 cm EKOS catheters placed in the right and left pulmonary arteries
 - Pulmonary artery pressure: 41/10
 - tPA infusion 1mg/hr x 6 hours in each EKOS catheter

- Enoxparin 1mg/kg SQ q12 administered to patient during hospital course
- Patient identified as not requiring ICU due to patient being hemodynamically stable and not having a high O2 requirement - patient underwent EKOS treatment algorithm in hospital's CV outpatient unit with continuous monitoring

TREATMENT NOTES & OUTCOME

- On following day, patient weaned to room air, clinically felt significant improvement in SOB, and was discharged later that day on Apixaban
- Cardiac Echo (one day post EKOS treatment algorithm) → RV/LV ratio: 0.86
- EKOS treatment algorithm was performed as per OPTALYSE Protocol on this patient as shown (in pre cath holding area) leading to
 - Accelerated symptom Improvement
 - Low risk of complications
 - Reduced hospital length of stay
 - Reduction of hospital staff utilization
 - Normalization of RV size

...all of which were done within 48 hours of admission.



For more information, please visit www.bostonscientific.com/ekos

EKOS® ACOUSTIC PULSE THROMBOLYSIS TREATMENT

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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. INDICATIONS FOR USE: The EkoSonic Endovascular System is indicated for the: Ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism. • Infusion of solutions into the pulmonary arteries. • Controlled and selective infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature. All therapeutic agents utilized with the EkoSonic Endovascular System should be fully prepared and used according to the instruction for use of the specific therapeutic agent. CONTRAINDICATIONS: Not designed for peripheral vasculature dilation purposes. • This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition. POTENTIAL COMPLICATIONS: Vessel perforation or rupture • Distal embolization of blood clots • Vessel spasm • Hemorrhage • Hematoma • Pain and tenderness • Sepsis/Infection • Thrombophlebitis • Tricuspid and pulmonic valve damage • Pulmonary infarct due to tip migration and spontaneous wedging, air embolism, and/or thromboembolism • Right bundle branch block and complete heart block • Intimal disruption • Arterial dissection • Vascular thrombosis • Drug reactions • Allergic reaction to contrast medium • Arteriovenous fistula • Thromboembolism • Preumothorax • Perforation of the pulmonary artery. • Cardiac Arrhythmias – most frequently occurring during placement, removal or following displacement into the right ventricle. PI-726201-AA

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