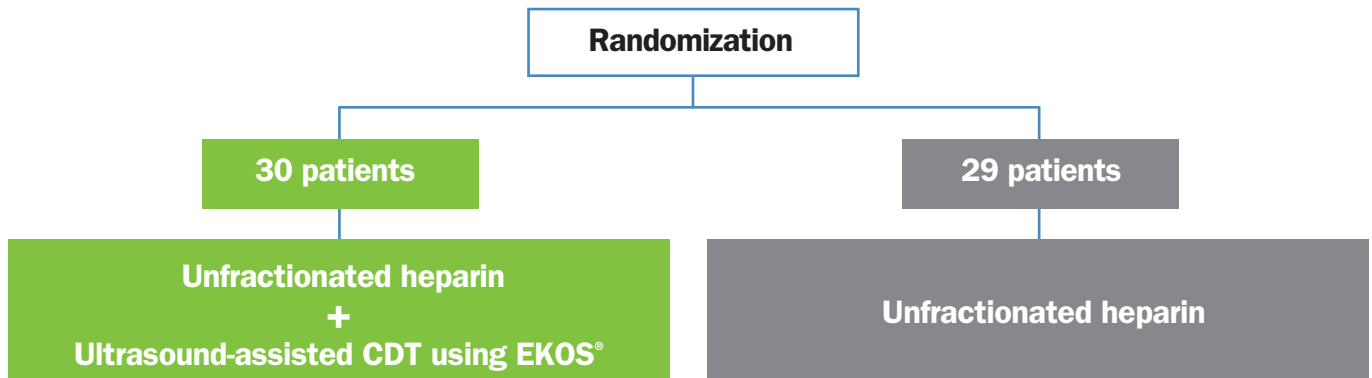


Randomized, Controlled Trial of Ultrasound-Assisted Catheter-Directed Thrombolysis for Acute Intermediate-Risk Pulmonary Embolism

Nils Kucher, MD et al. *Circulation* 2014; 129: 479-486

Patients: Acute PE with RV/LV ratio ≥ 1.0



Methods



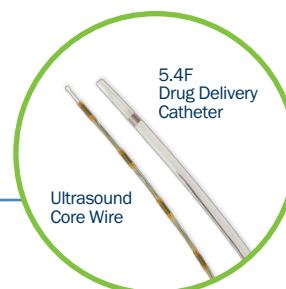
Ultrasound-Assisted Catheter-Directed Thrombolysis Using EKOS®

Insertion of the Catheter System

- In cardiac catheterization lab
- Venous access – common femoral vein;
 - 6F sheath for unilateral PE
 - 10F double-lumen sheath for bilateral PE
- 0.035" guidewire and angiographic catheter to cross occlusion
- With guidewire tip within large lower-lobe segmental branch, angiographic catheter exchanged for EKOS® Drug Delivery Catheter
- Guidewire removed and EKOS® Ultrasound Core Wire inserted
- Infusions started then ultrasound turned on

Infusion Protocol

- rtPA 1mg/h; saline coolant 35ml/h
- Patients monitored in the intermediate or ICU
- After five hours, rtPA reduced to 0.5mg/h
- At 15 (+/- 1) hours, rtPA infusion, saline coolant and ultrasound discontinued
- EkoSonic® devices removed in the intermediate or ICU

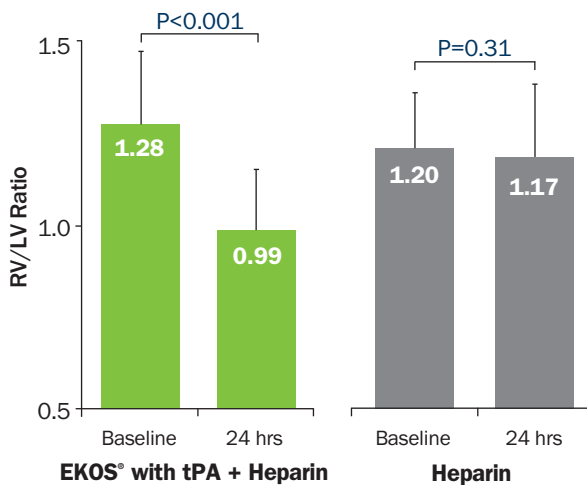


[†] Unfractionated heparin administered immediately after randomization

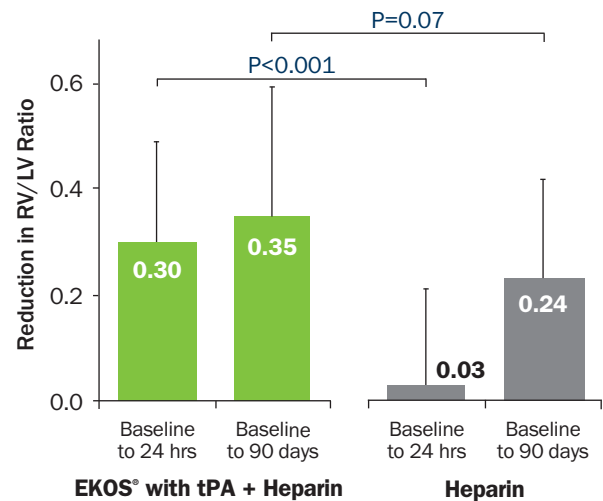
Key Results

Acute PE patients treated with EKOS® showed:

RV/LV ratio significantly improved at 24 hours



Reduction in RV/LV ratio significantly greater at 24 hours and improved at 90 days

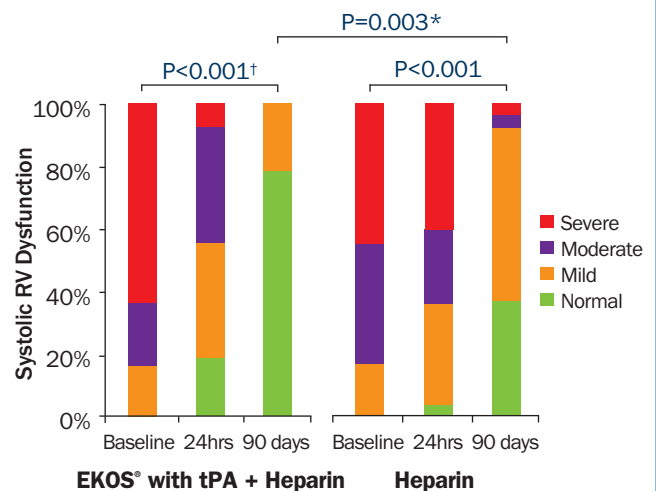


No deaths or significant bleeding complications

Clinical outcomes at 90 days	EKOS® with tPA + Heparin N = 30		Heparin N = 29		p-value
Death	0	0%	1*	0%	0.49
Recurrent venous thromboembolism	0	0%	0	0%	1.00
Major bleeding	0	0%	0	0%	1.00
Minor bleeding	3**	10%	1	†3%	0.61

* Rehospitalization and death from advanced pancreatic cancer
 ** Two patients with transient mild hemoptysis without medical intervention, one patient with groin hematoma requiring manual compression
 † One patient with transient anal bleeding following endoscopic removal of colon polyp

Systolic RV dysfunction significantly improved



* Two-sided exact Mantel-Haenzel test
 † Wilcoxon rank sum test

CONCLUSION

ULTIMA confirmed that a fixed-dose, ultrasound-assisted catheter-directed thrombolysis using EKOS® regimen was superior to anticoagulation alone in improving RV dysfunction at 24 hours without an increase in bleeding complications.