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Virginia Heart Attack Coalition

PE Response Team

MICHAEL KELLEY, MD

INTERVENTIONAL CARDIOLOGY
CARILION CLINIC NRV
CHRISTIANSBURG, VA

Proud partner of VCSQI

Introduction

OBJECTIVE: Align all hospitals in Virginia with a standardized approach to PE management to ensure consistency in care delivery.

GOALS:

- **Adoption of Best Practices:** Encouraging the use of evidence-based protocols across all institutions.
- **Interdisciplinary Collaboration**: Emphasizing the importance of communication between different specialties to provide holistic care.
- **Data Collection and Sharing:** Developing a statewide registry to track outcomes, complications, and the effectiveness of different treatment approaches.

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Integration with National Guidelines

Alignment with National Guidelines: Ensure that the state's guidelines for PE management are in line with recommendations from major health organizations such as:

- American College of Chest Physicians (CHEST)
- American Heart Association (AHA)
- Society of Interventional Radiology (SIR)
- American College of Emergency Physicians (ACEP)

Updates and Continuous Improvement: Regularly reviewing and updating state guidelines to incorporate the latest evidence and innovations in PE management.

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PE patient population profile

MASSIVE PE
[High risk]
5% PE population
30% in-hospital mortality
40%[1] mortality @ 3 months

SUBMASSIVE PE
[Moderate/Intermediate risk]
40% PE population
4%[2,3] in-hospital mortality
12%[1] mortality @ 3 months

MINOR PE
[Low risk]
55% PE population
Good prognosis
Low mortality rate

1. Goldhaber SZ et al. Acute pulmonary embolism: clinical outcomes in the International Cooperative Pulmonary Embolism Registry (ICOPER). Lancet 1999;353:1386-1389
2. Meyer G et al. Fibrinolysis for Patients with Intermediate Risk Pulmonary Embolism. New Engl J Med 2014; 370: 1402-11
3. Casazza F et al. Clinical features and short term outcomes of patients with acute pulmonary embolism. The Italian Pulmonary Embolism Registry (IPER). Thrombosis Research 2012; 130:847-852

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PE Risk Stratification

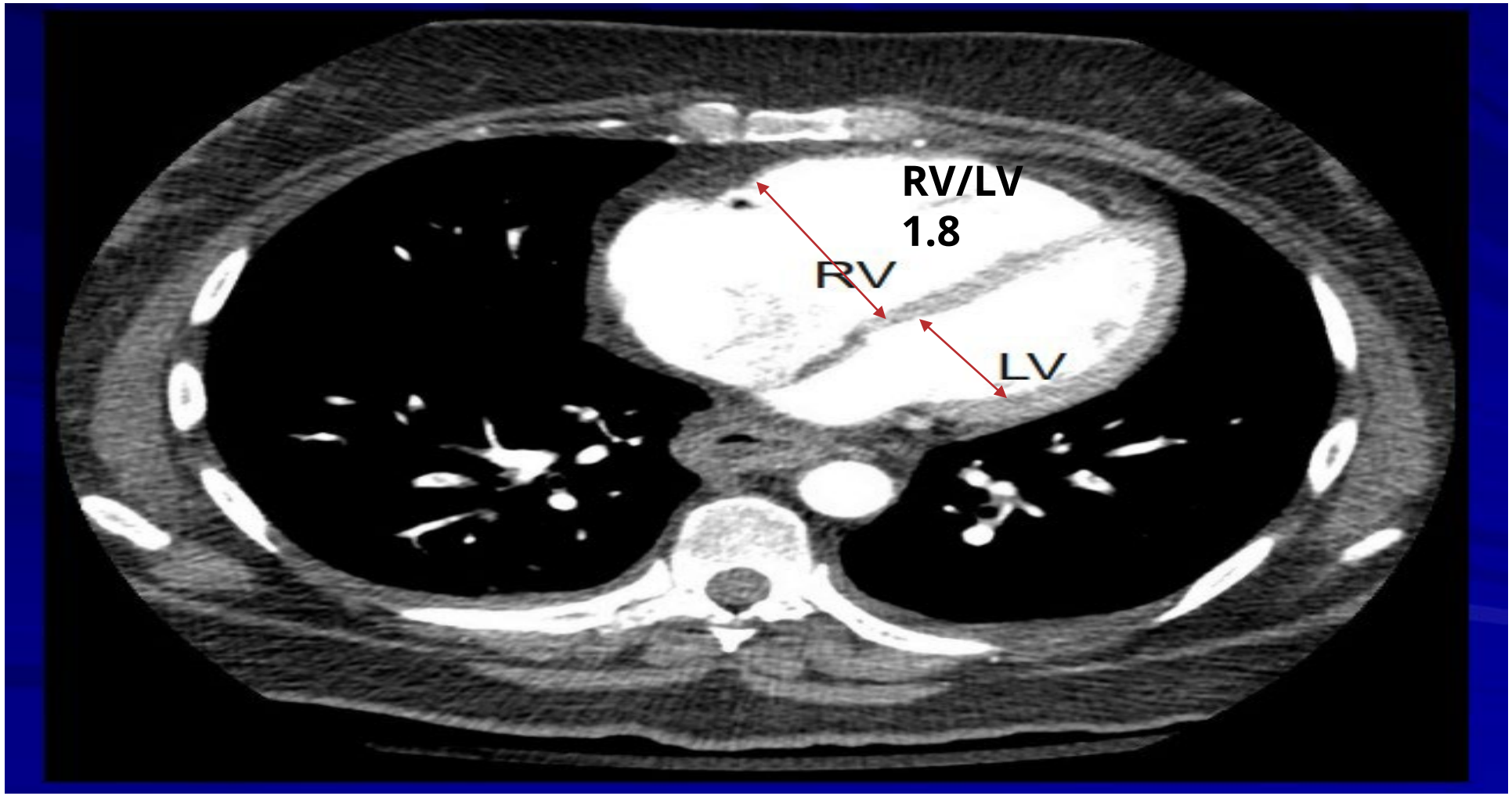
Patient risk stratification (per AHA 2011 guidelines)		
Massive PE	**Submassive PE**	**Low Risk**
High risk	**Intermediate risk**	**Low risk**
•Sustained hypotension (systolic BP <90 mmHg for ≥15 min) •Inotropic support •Signs or symptoms of shock •Cardiac arrest	•Systemically normotensive (systolic BP ≥90 mmHg) •RV strain •Abnormal troponin (HS trop > 50)	•Systemically normotensive (systolic BP ≥90 mmHg) •No RV dysfunction •No myocardial necrosis

RV Strain

- RV/LV ratio > 0.9 or RV systolic dysfunction on echo
- RV/LV ratio > 0.9 on CT
- Elevation of BNP (>90 pg/mL)
- Elevation of NTpro-BNP (>500 pg/mL)
- Troponin elevation

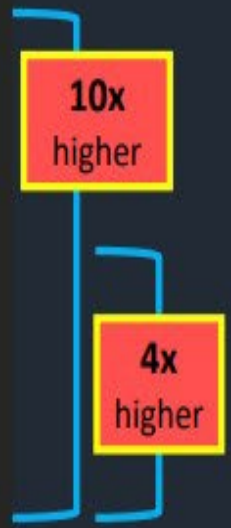
Jaff et al. Management of massive and submassive pulmonary embolism, iliofemoral deep vein thrombosis, and chronic thromboembolic pulmonary hypertension: A scientific statement from the American Heart Association. Circulation 2011;123(16):1788-1830.

Acute PE: RV strain



Study outcome events in 906 patients using 2014 ESC model

Risk Category	sPESI	RVD or Elevated Troponin	Death at 30 days
High	>0	Both	23/105: **22%** (CI; 14.0-29.8)
Intermediate-high	>0	Both	21/272: **7.7%** (CI; 4.5-10.9
Intermediate-low	>0	Either one or neither one	20/333: **6.0%** (CI; 3.4-8.6)
Low	0	Neither one	1/196: **0.5%** (CI; 0-1.5)



Becattini C, et al. Eur Respir J 2016; 48: 780–786

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Interventional Options

- Catheter-directed thrombolysis
  - EKOS
- Catheter-directed thrombectomy
  - Inari
  - Penumbra

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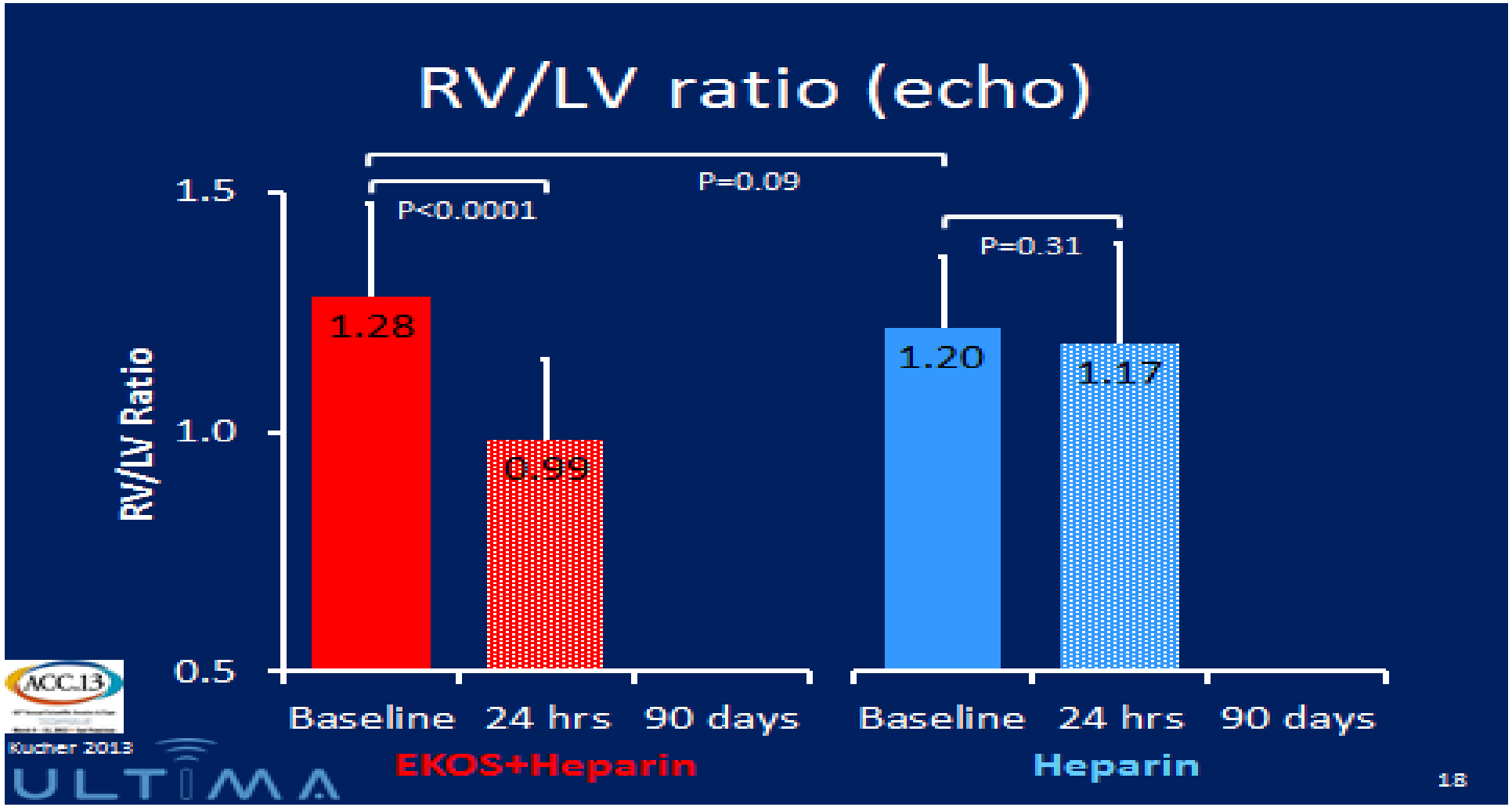
ULTIMA Trial



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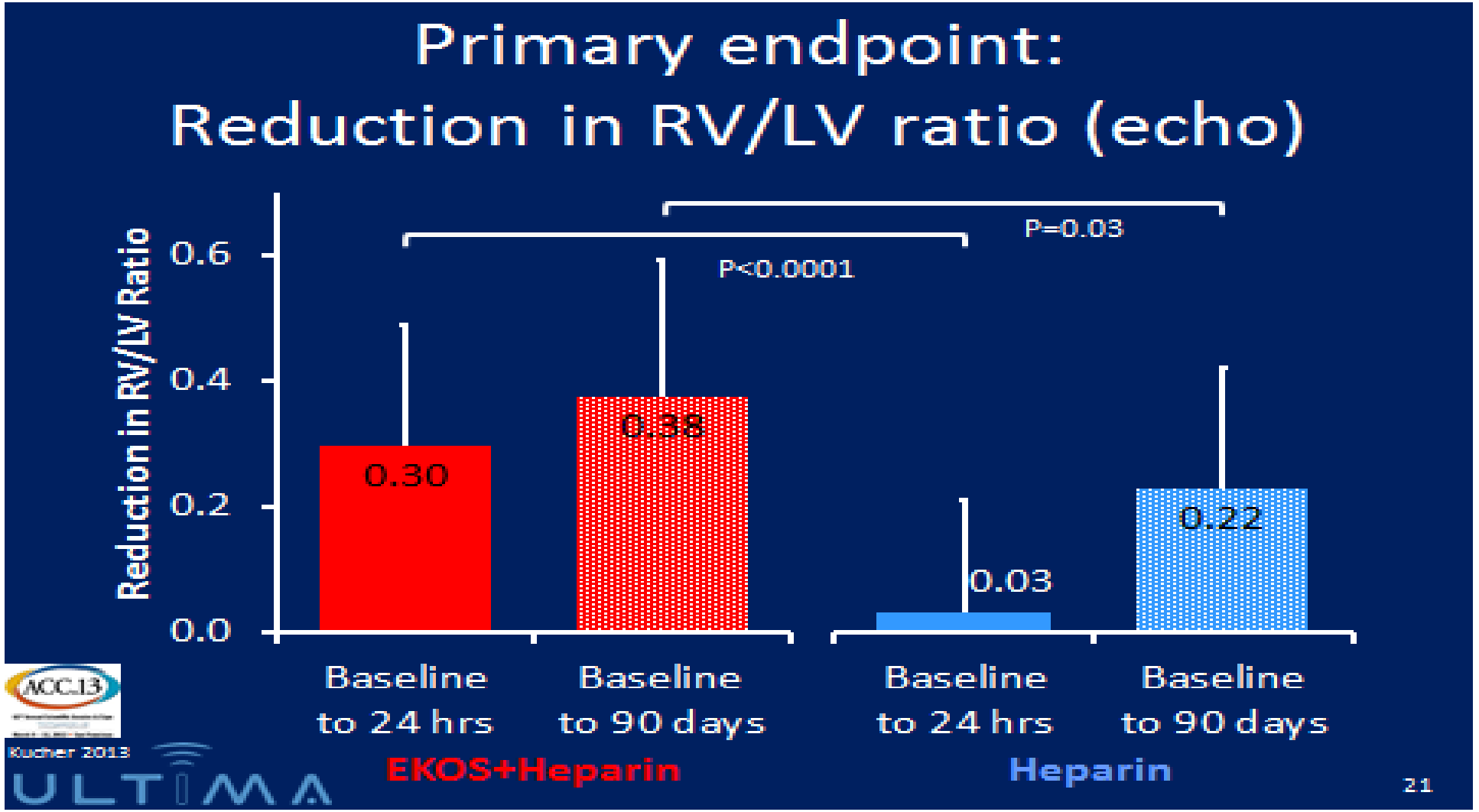
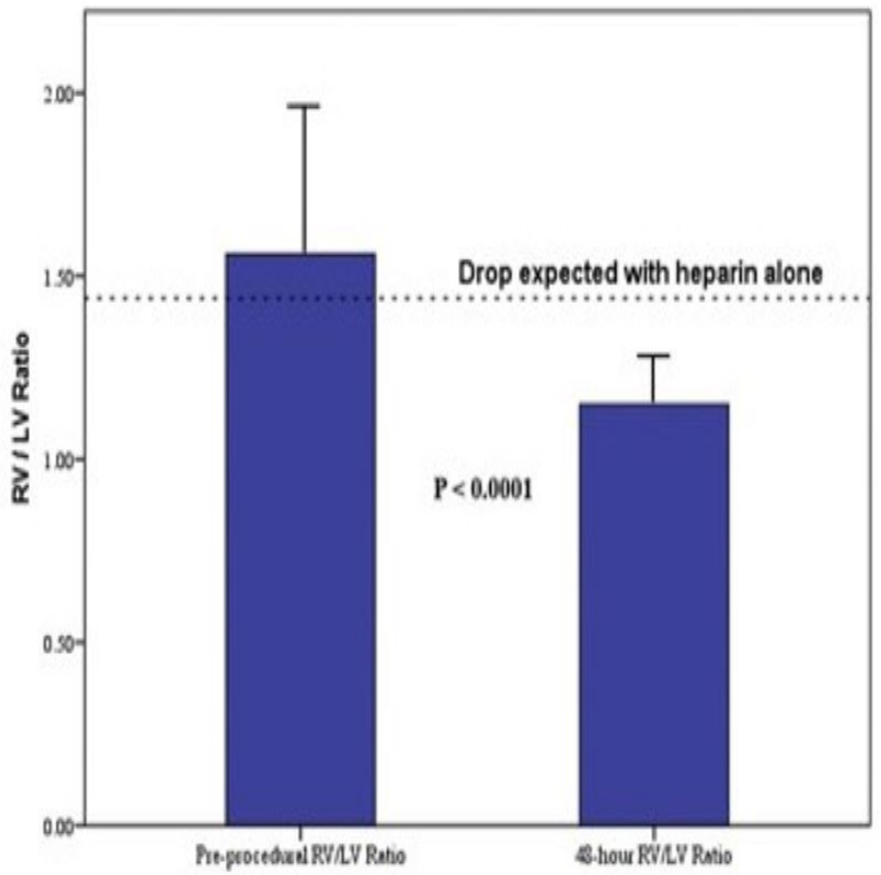
ULTIMA Trial

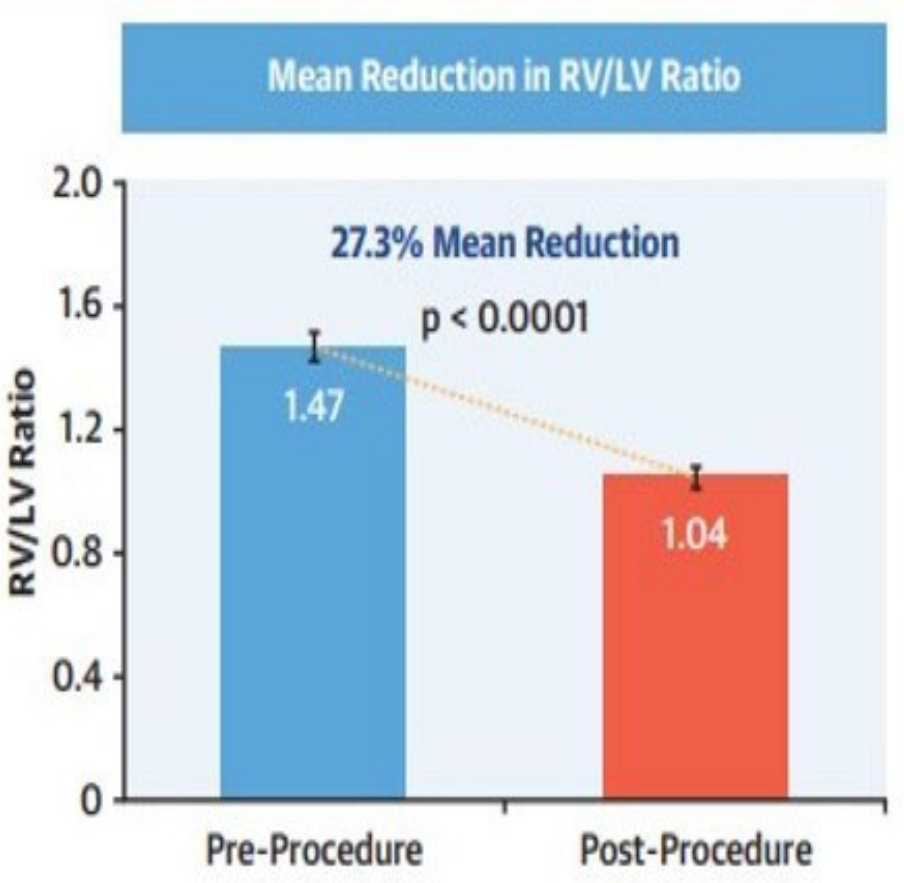


Intermediate Risk PE Studies

Inari: Flare



Penumbra: Extract



Flash Registry: Inari

800 all-comer patient population across 50 US clinical sites

Characteristic	n (%) or mean ± SD
Age, years	61.2 ± 14.6
History of DVT	143 (17.9%)
History of PE	85 (10.7%)
History of PHTN	77 (9.7%)
Concomitant DVT	512 (65.0%)
Systolic PA pressure ≥70 mmHg	99 (12.7%)
Lytics contraindication	256 (32.1%)

Characteristic	n (%) or mean ± SD
High-risk PE	63 (7.9%)
Intermediate-high-risk PE	611 (76.7%)
Intermediate-low-risk PE	59 (7.4%)
Intermediate-risk PE (unknown)	64 (8.0%)
sPESI	1.6 ± 1.1
Positive biomarker(s)*	720 (94.6%)
RV/LV Ratio (CT or echo)	1.50 ± 0.5
Saddle PE	319 (40.0%)
Unilateral PE	68 (8.5%)
Bilateral PE	411 (51.5%)

*troponin and/or BNP

Flash Registry: Inari

Excellent safety results and 30-day mortality outcomes

INARI MEDICAL

Primary Endpoint
MAE at 48-hours

1.8% **(14/788)**

0 device-related deaths
11 major bleeds (0 ICH)
3 intraprocedural AEs*

<1%

All-cause mortality at
30-day follow-up
N=734

FLASH

*1. cardiac injury due to ECMO (not device related) 2. hypotension in a patient with an extraperitoneal hematoma (not device related) 3. Tricuspid regurgitation incidentally noted two months post-procedure (unknown relationship to device)

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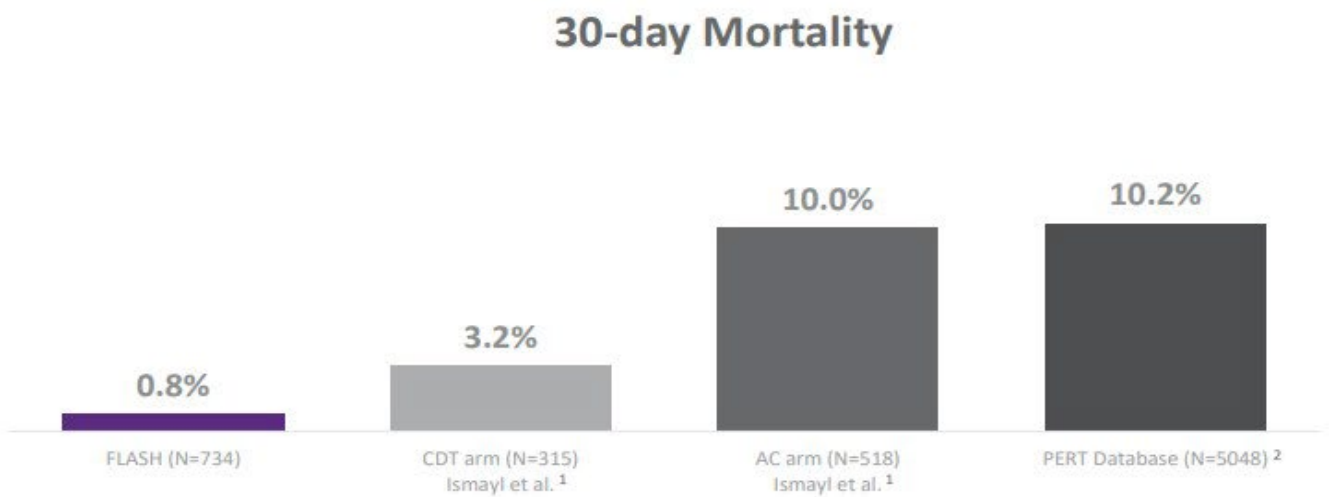
Flash Registry: Inari

FLASH 30-day mortality in perspective



1. Ismayl M, et al. Am J Cardiol. 2022 (Catheter-directed thrombolysis meta-analysis) 2.PERT Consortium Quality Database. Presented by R. Lookstein. (December 2021)

90% Survival Improvement in High-risk PE

FLAME

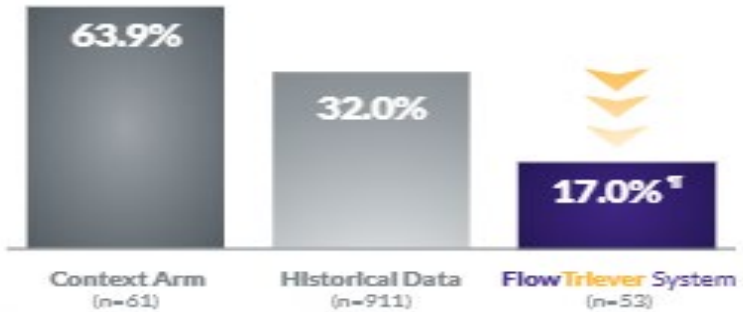
FLAME is the largest prospective study of interventional treatment in high-risk PE, a patient population with a historical in-hospital mortality rate >25%.[1-4] The results show a dramatic improvement in survival in patients treated with the FlowTriever® system.

High-risk PE Patients
(n=115)

Context Arm (n=61)	FlowTriever Arm (n=53)	Prior Therapy Arm (n=1)
Patients treated with: • Systemic thrombolysis (68.9%) • Anticoagulation alone (23.0%) • CDT (6.6%) • Surgical thrombectomy (1.6%)	Front-line FlowTriever	**Non-high-risk PE patients** who received advanced therapy but progressed to high-risk PE in the same setting

Significantly Lower In-hospital Adverse Outcomes

Primary Endpoint†



>90% Reduction in High-risk PE Mortality*

In-hospital Mortality

Future Trials

PEERLESS

- **FLOWTRIEVER VS CDT FOR INTERMEDIATE-HIGH RISK PE**
- Estimated enrollment: 550 patients
- Randomized / parallel assignment
- Also, nonrandomized cohort of 150 patients with contraindications to thrombolysis
- Estimated study start date: March 31, 2022
- Estimated study completion date: Nov 15, 2023

PRIMARY ENDPOINT

Win ratio composite at discharge (7 days max):

1. All-cause mortality
2. ICH
3. ISTH major bleeding
4. Clinical deterioration and / or bailout
5. ICU admission and ICU LOS

ClinicalTrials.gov Identifier: NCT05111613

Case 1

- 68 y/o male who presents with syncope
- Intermediate-high risk PE:
  - RV strain: RV/LV 1.5
  - Elevated HS troponin, 920
  - Large central clot: Saddle PE
- Venous Duplex: R femoral vein DVT

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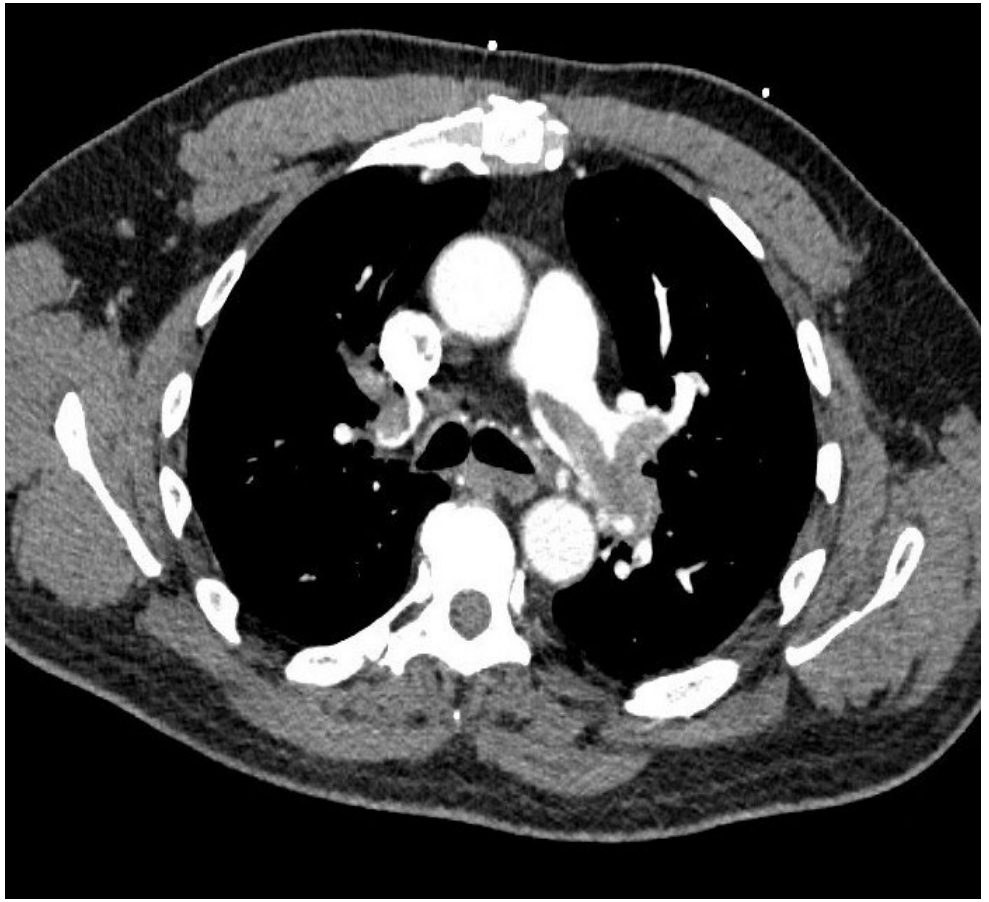
Chest CTA: Saddle PE



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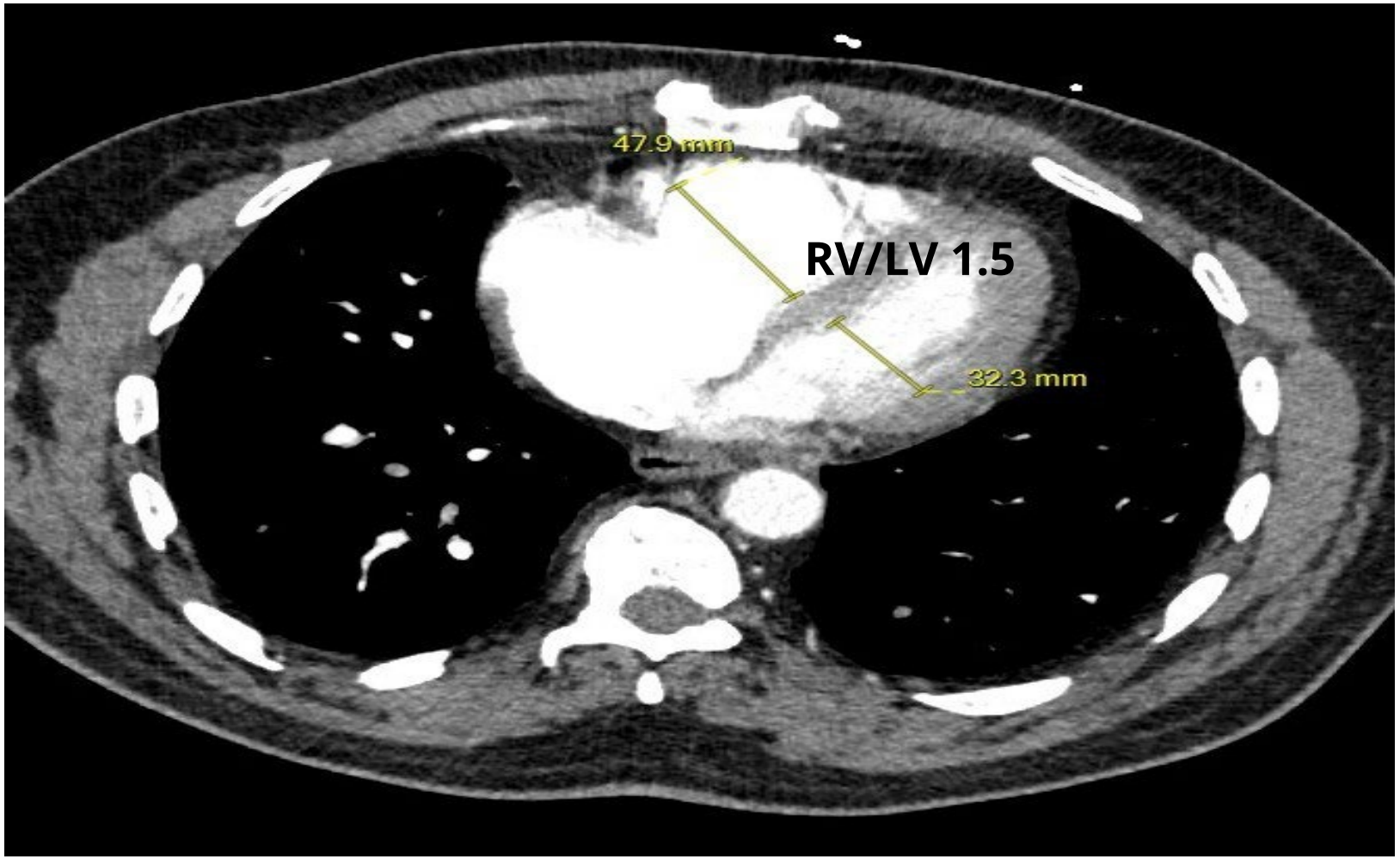
Chest CTA: RV Strain



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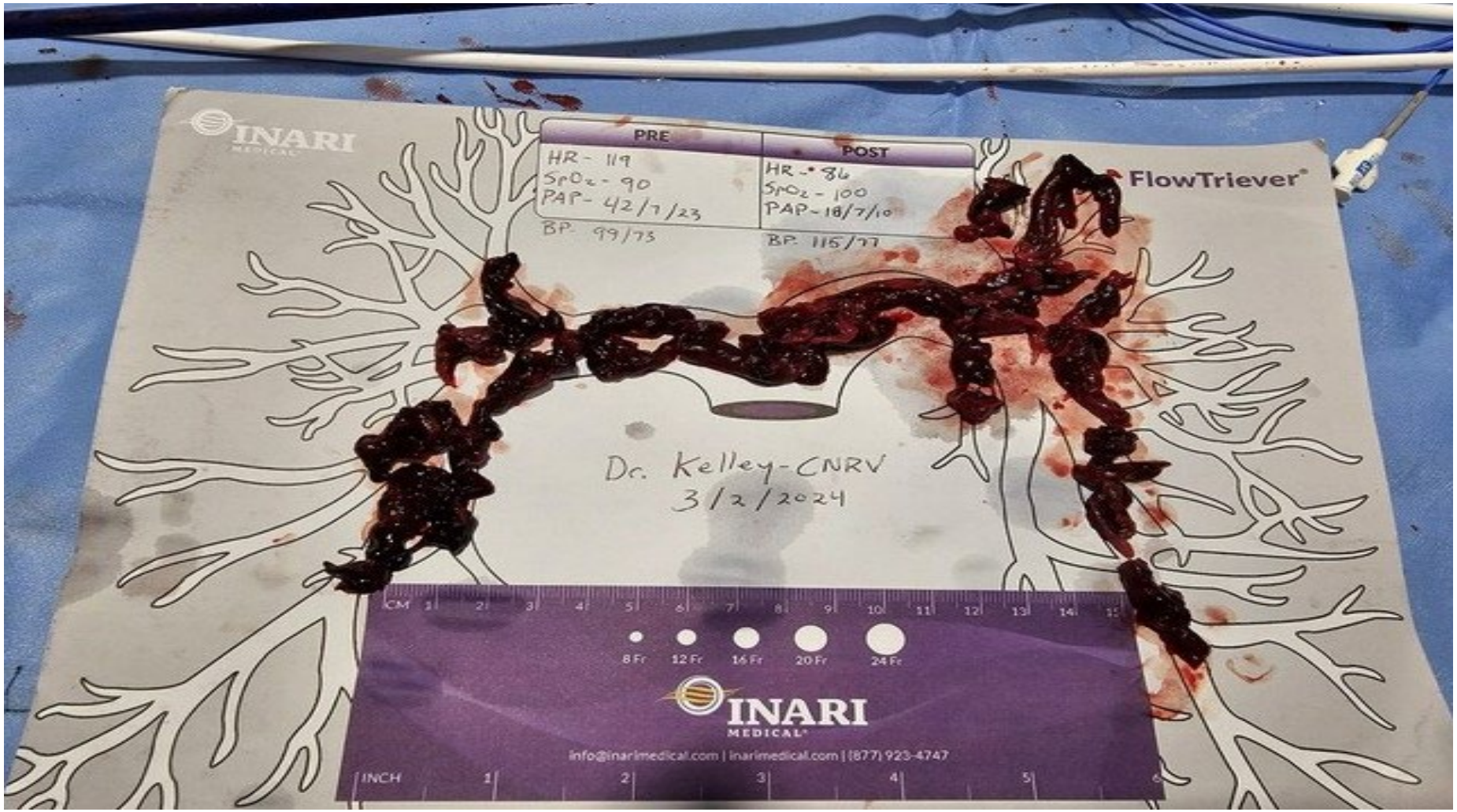
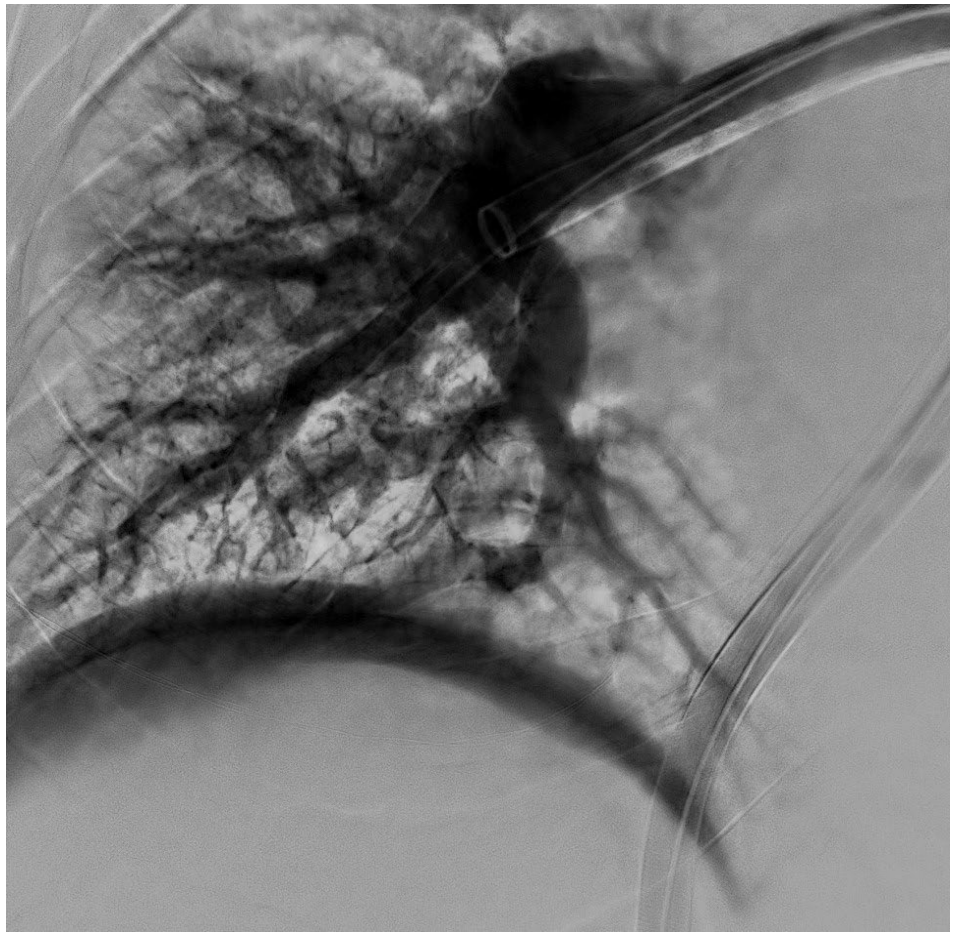
PE Thrombectomy



PA Angiogram



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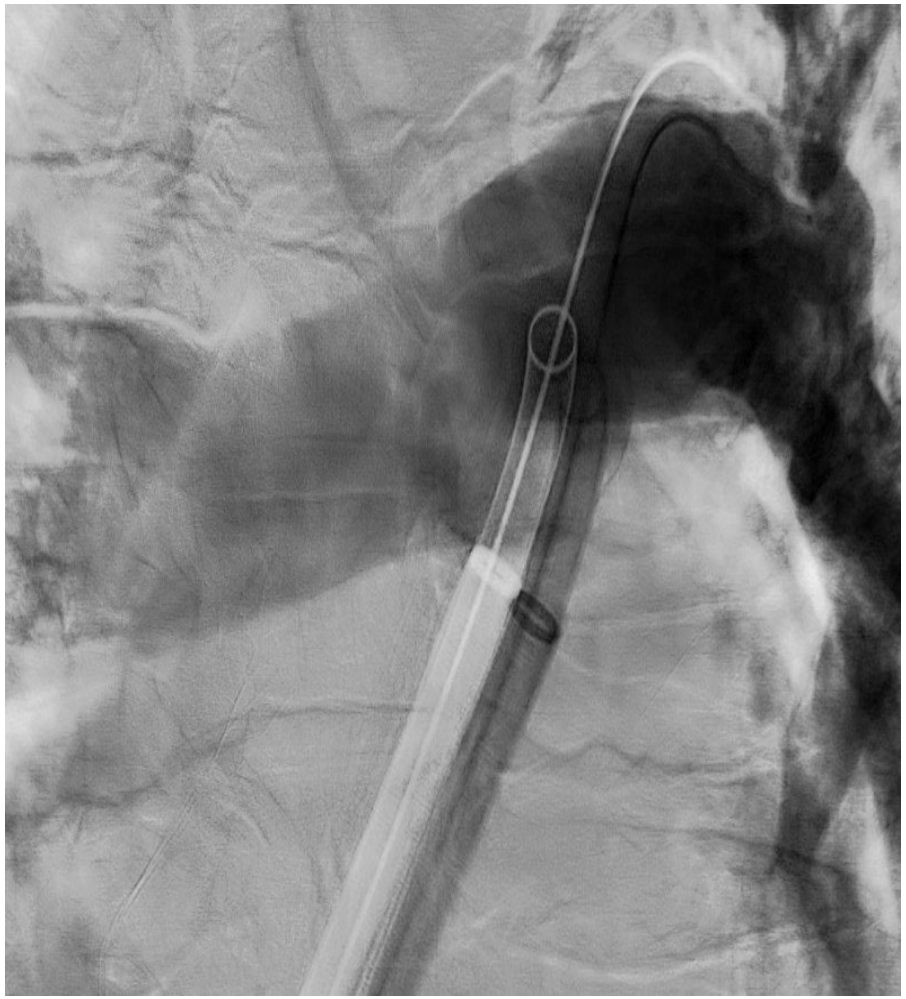
PA Angiogram



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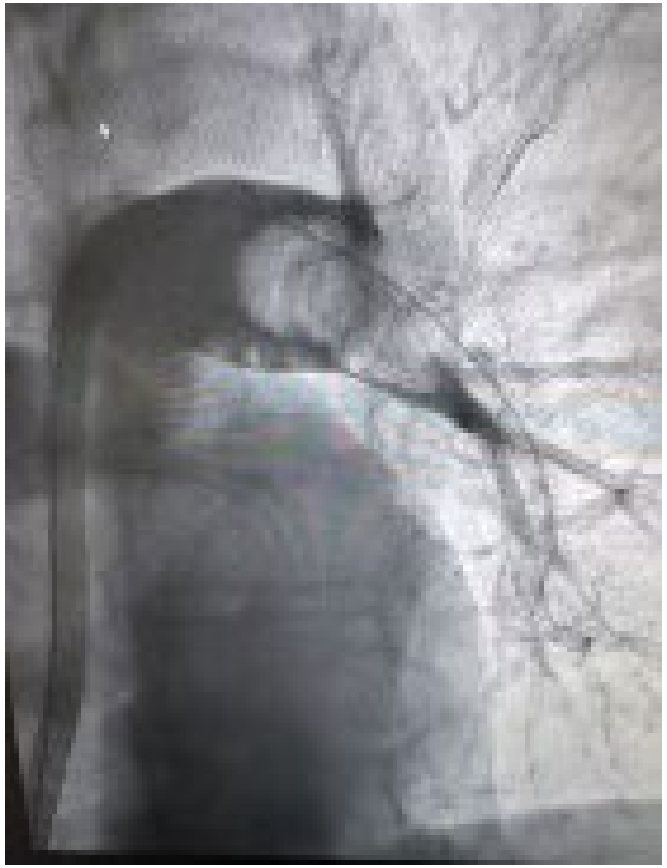
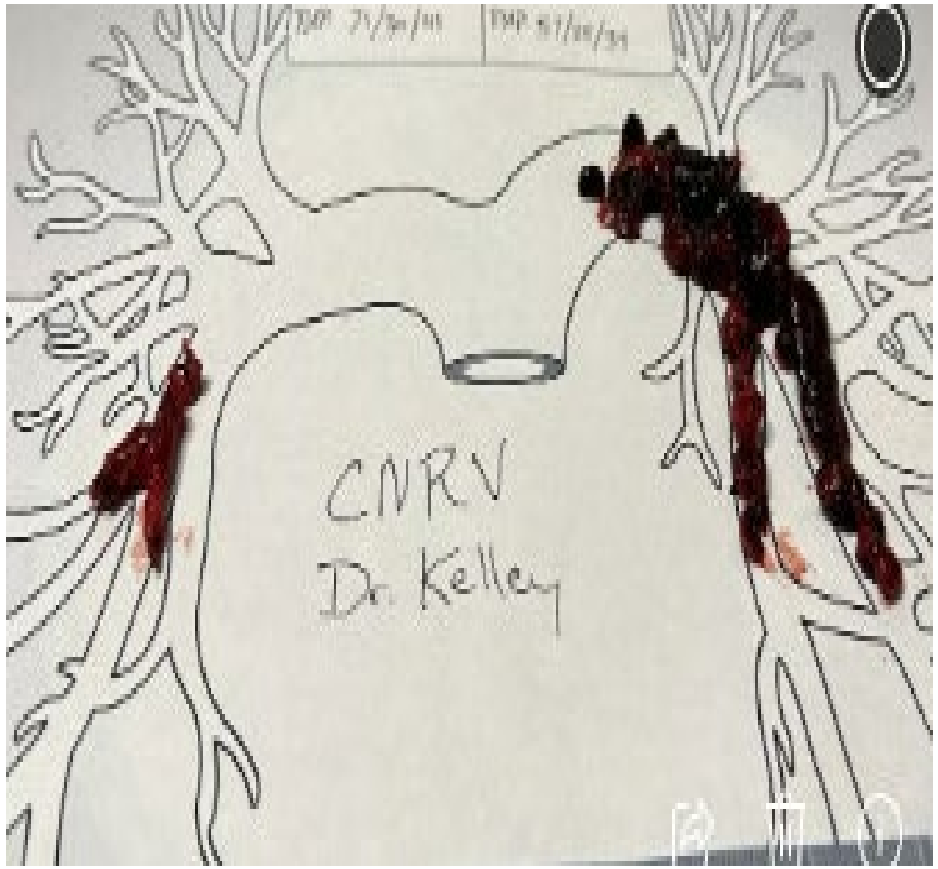
Post Echo

Case 2
Acute Intermediate-High Risk PE, RV/LV 1.6
PE Thrombectomy with Inari





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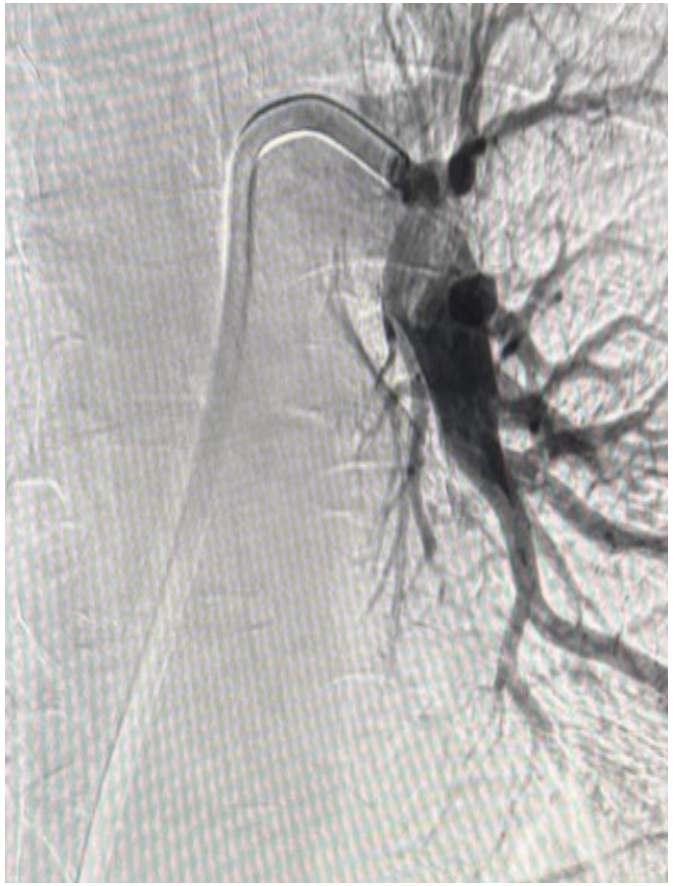
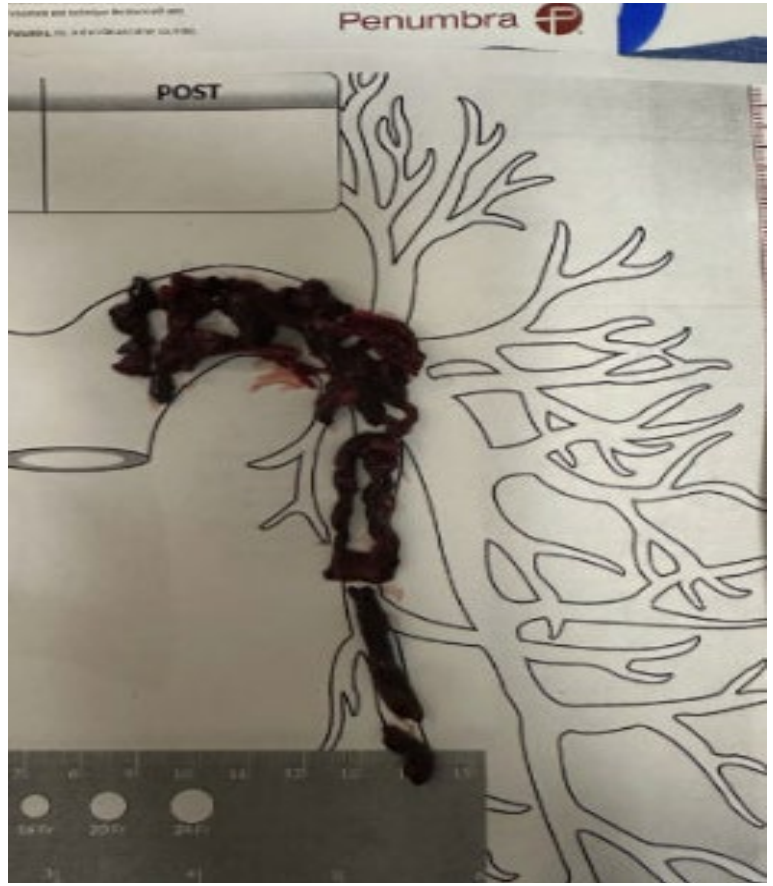
Case 3
Acute Intermediate-High Risk PE, RV/LV 1.2
PE Thrombectomy with Penumbra





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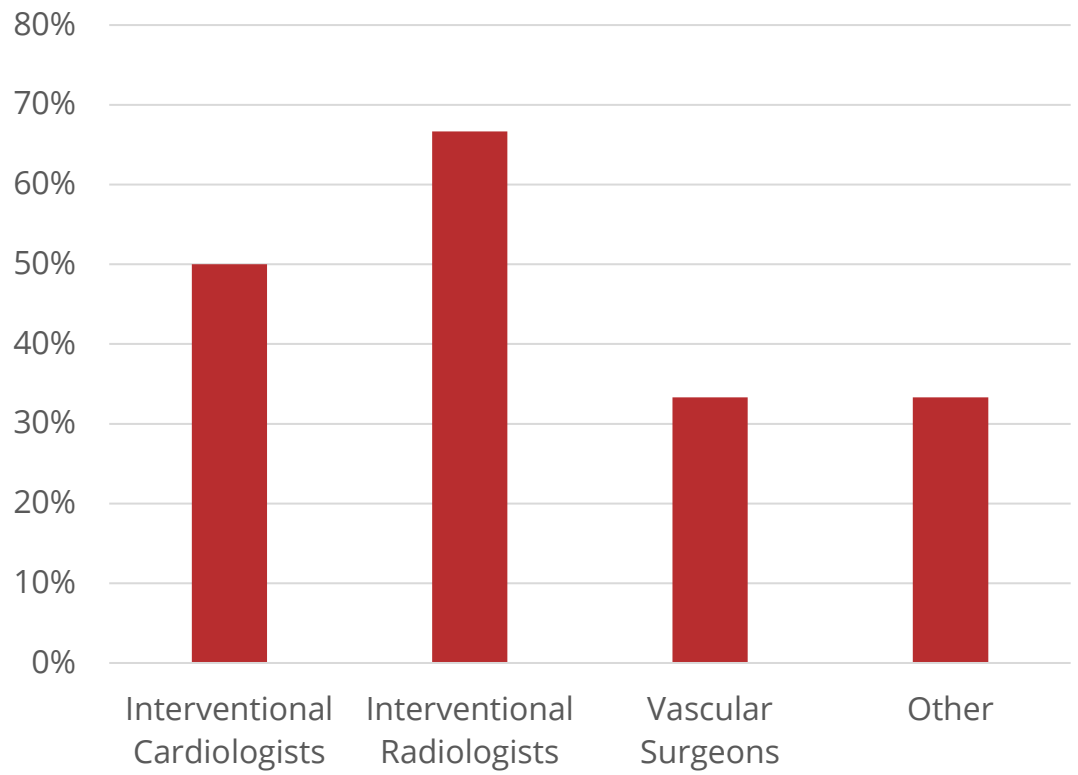
Survey Results

N=8

What is the annual volume of pe interventions at your institution?

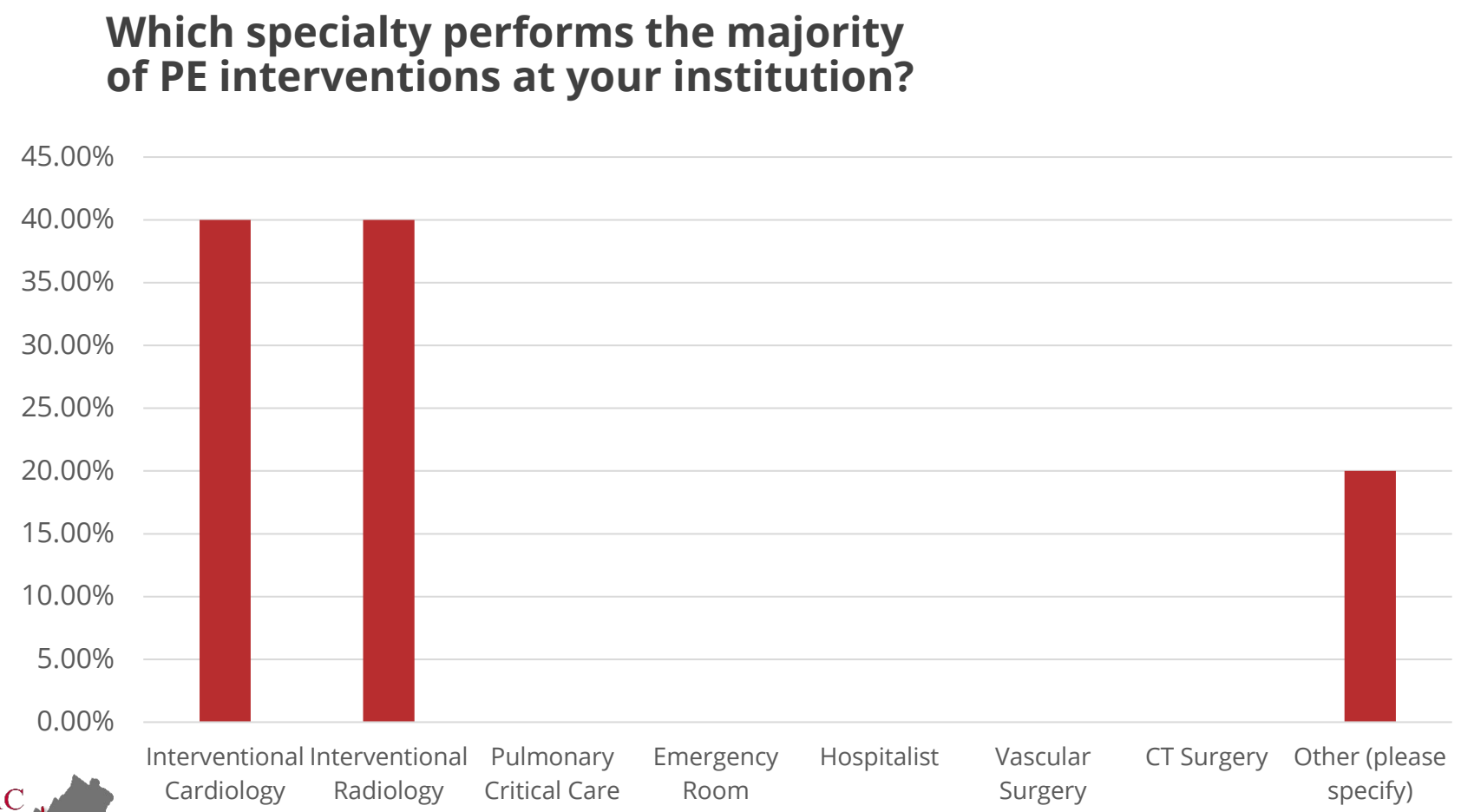
- 25 (based on projected volumes)
- 40
- 40-70
- Unsure (2)

Who performs the pe interventions at your institution? Check all that apply.



Survey Results

N=8



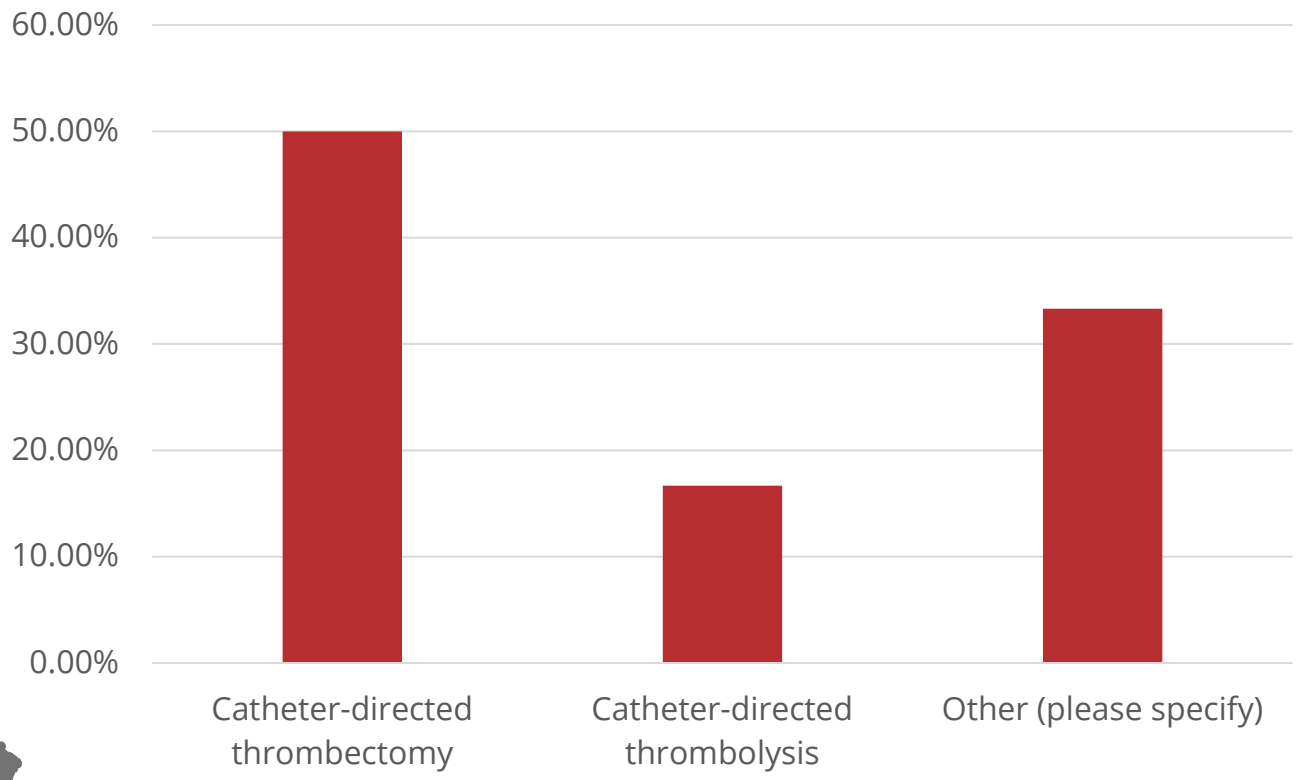
Other:

- Unsure

Survey Results

N=8

Which procedure is predominantly used in your PE response program?



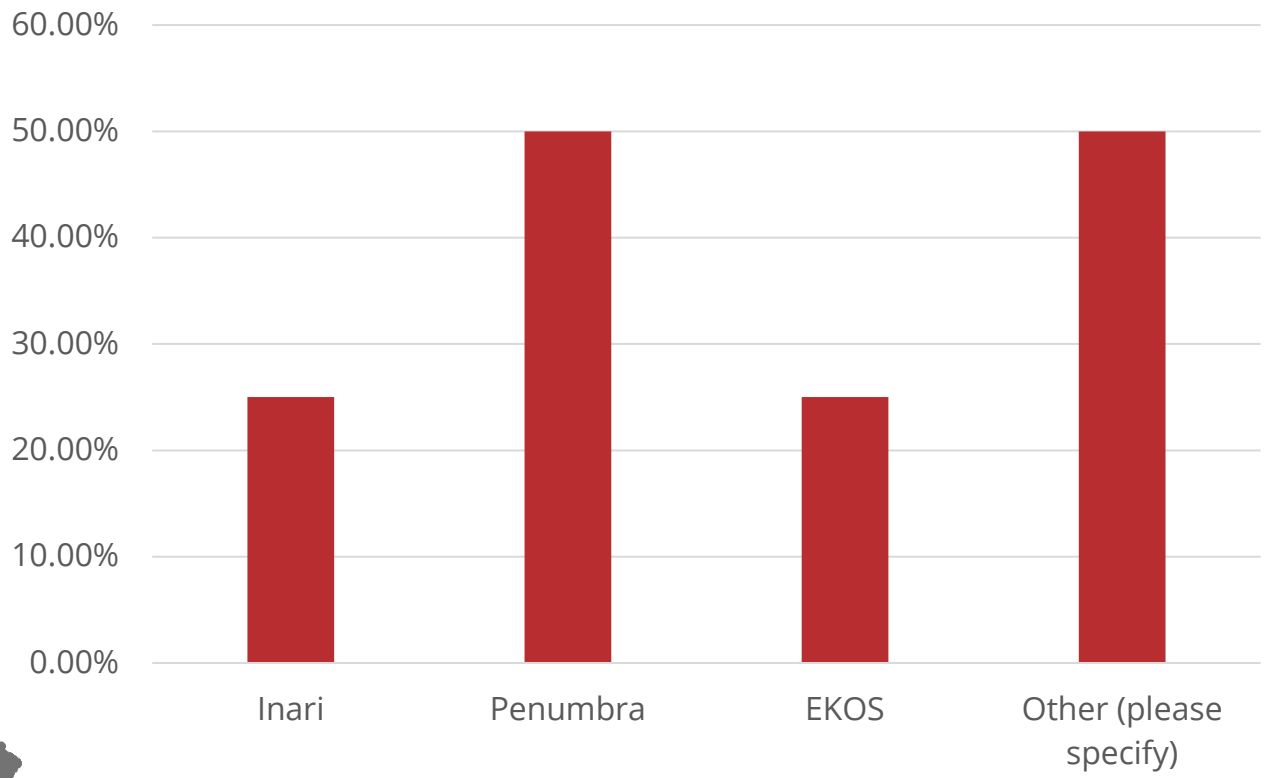
Other:

- Do not have data available at this time
- Mix of all

Survey Results

N=8

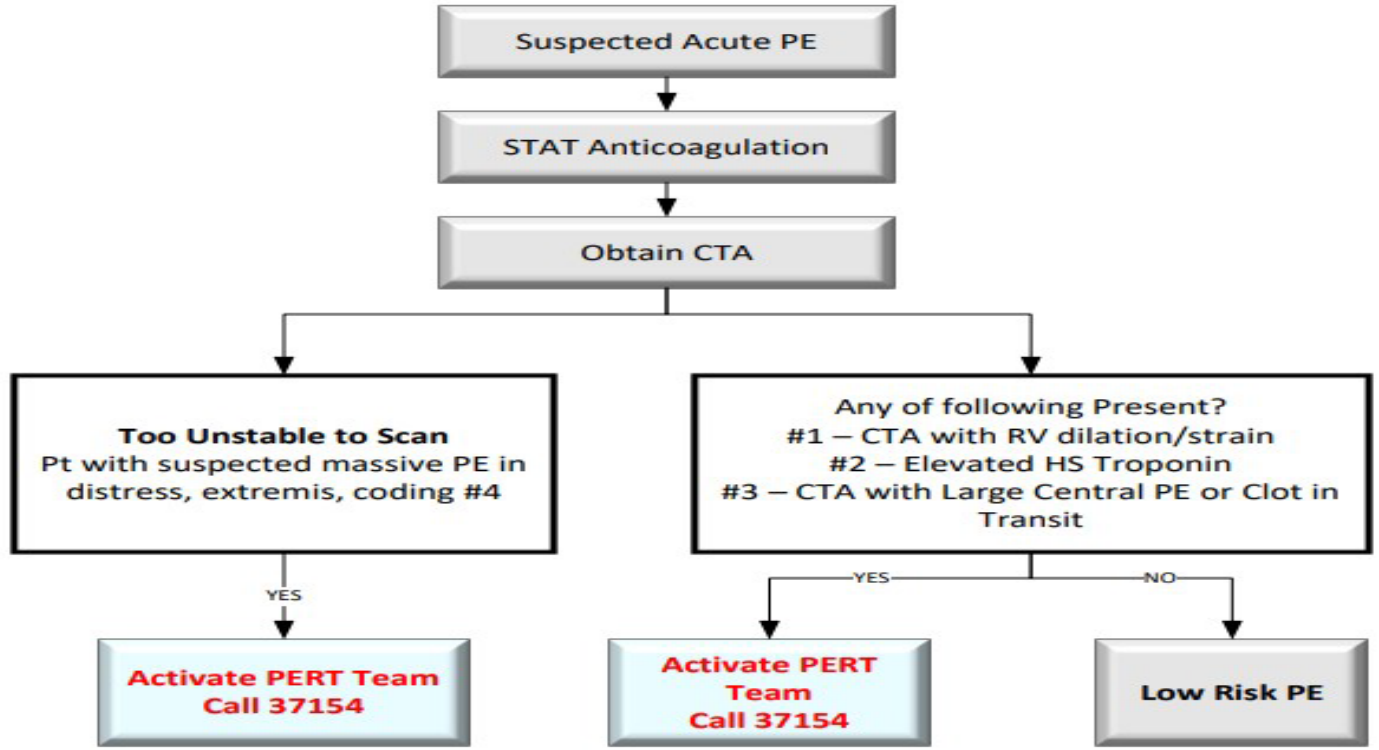
Which devices are used for your PE interventions? Check all that apply.



Other:

- Uncertain
- Mix of all

Appendix A: PERT-CNRV Consult Activation – for Intermediate and High-Risk PE



PERT Activation by Calling the Transfer Center at 37154

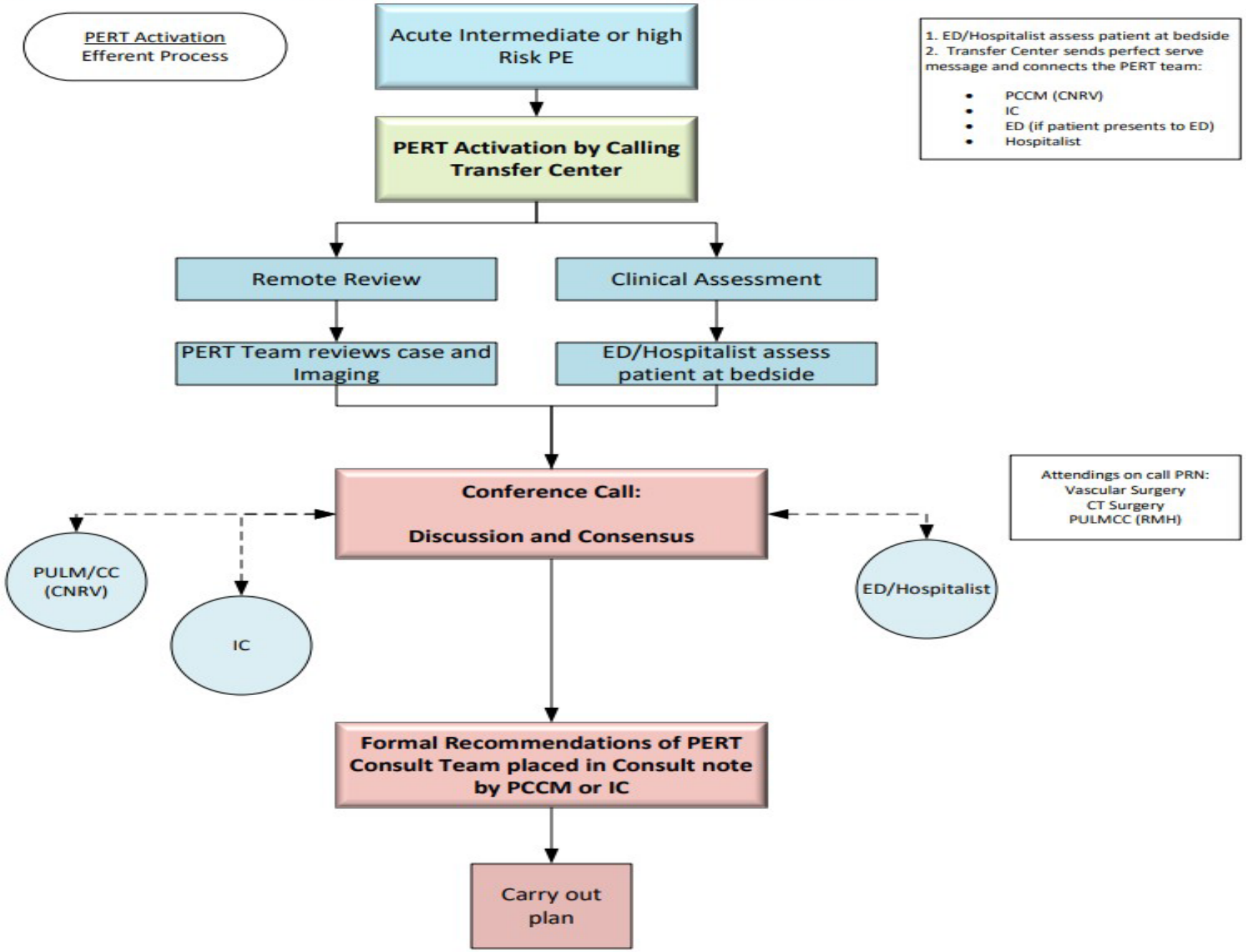
Additional Remarks:

Work up of Suspected PE:
-CBC, BMP, Trop, Pro-BNP, Lactic, EKG,CXR, CTA, PT, PTT, Type & Screen
-CrCl/GFR > 15: Enoxaparin 1mg/kg (Pharmacy will adjust based on CrCl). Max dose 150mg
-CrCl/GFR < 15: or AXI: Heparin bolus + Infusion

#1 CTA findings of RV Strain or Dilation:
-RV:LV chamber ration >1
-Contrast Reflux into IVC
-Septal Flattening or bowing
#2 HS Trop – 1 Elevation >= 50mg/L
#3 Large Central PE = Saddle PE, L or R main PA PE; or a Clot in Transit (RA, RV, IVC)
#4 Suspected massive/unstable PE: Should have high degree of clinical suspicion based on presentation , risk factors, prior or known VTE, POCUS, + LE Deuplex, etc

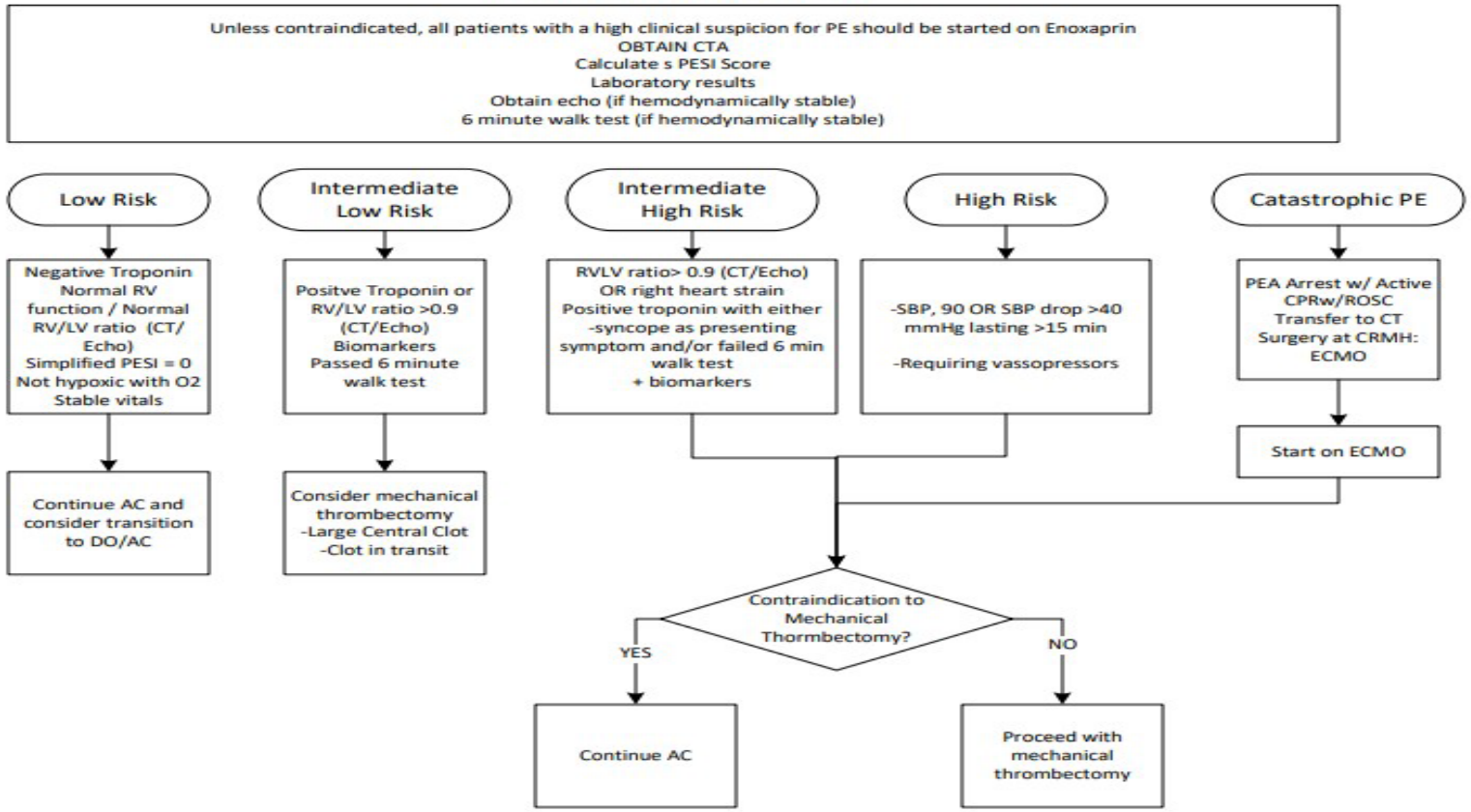
STAT ECHO: No longer necessary for activation don't delay POCUS may be helpful to r/o alternative etiologies ECHO and Duplex can be completed next day (POCUS: Point of Care Ultrasound)

Appendix B: PERT-CNRV Decision Process



Appendix C: PERT-CNRV Treatment Algorithm

Acute Pulmonary Embolism Clinical Treatment
DETAILS and DECISION TREE



Simplified PESI Scoring:

Predictor variable	Points
Age, year >80	1
History of Cancer	1
History of chronic cardiopulmonary disease	1
Hear rate, bpm >= 100	1
Systolic BP, mmHg ,100	1
O2 Saturation <90%	1

Next Steps

- Enhanced participation among different centers
  - Physician and non-physician leaders
- Standardized PERT protocol for the state
- Data Collection:
  - Case Volumes
  - Devices Used
  - Clinical Outcomes:
    - Mortality, bleeding rates, hospital stay
    - PA pressures
    - RV/LV ratio
    - Outcomes for PE and shock

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Thank You

For additional questions or inquiries, please contact:

Sherri@VCSQI.org

Mpkelley@carilionclinic.org