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Faculty Disclosures

- **Suhail Dohad, MD, FACC, RVT:** Advisory Board—Abbott Vascular, Boston Scientific, Johnson & Johnson/Biomed/Shockwave, Medtronic, Penumbra, ReCor/Otsuka Pharmaceuticals; research funding—Abbott Vascular, Boston Scientific, Johnson & Johnson/Biomed/Shockwave, Medtronic, Penumbra, ReCor/Otsuka Pharmaceuticals; speaker's fees—Abbott Vascular, Boston Scientific, Johnson & Johnson/Biomed/Shockwave, Medtronic, Penumbra, ReCor/Otsuka Pharmaceuticals

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Program Information

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- Supported by an educational grant from Penumbra, Inc.

Learning Objectives

- Analyze the evolving clinical landscape of pulmonary embolism (PE), including historical evidence gaps and recent advances in clinical trial data, to better understand current standards of care and unmet clinical needs.

- Evaluate the application of new evidence and interventional techniques for PE management through real-world case presentations, enhancing decision-making skills for diverse patient scenarios.

- Discuss emerging directions in PE clinical research and anticipate how ongoing and future studies may shape best practices, improve patient outcomes, and inform guideline development.

Current PE Landscape: Historical Data and Evidence Gaps

Eric A. Secemsky, MD, MSc, RPVI, FACC, FAHA, FSCAI, FSVM

Director | Vascular Intervention | Beth Israel Deaconess Medical Center Section Head | Interventional Cardiology and Vascular Research | Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology
Associate Professor of Medicine | Harvard Medical School
Boston, Massachusetts

Pulmonary Embolism Portends a High Risk of Mortality
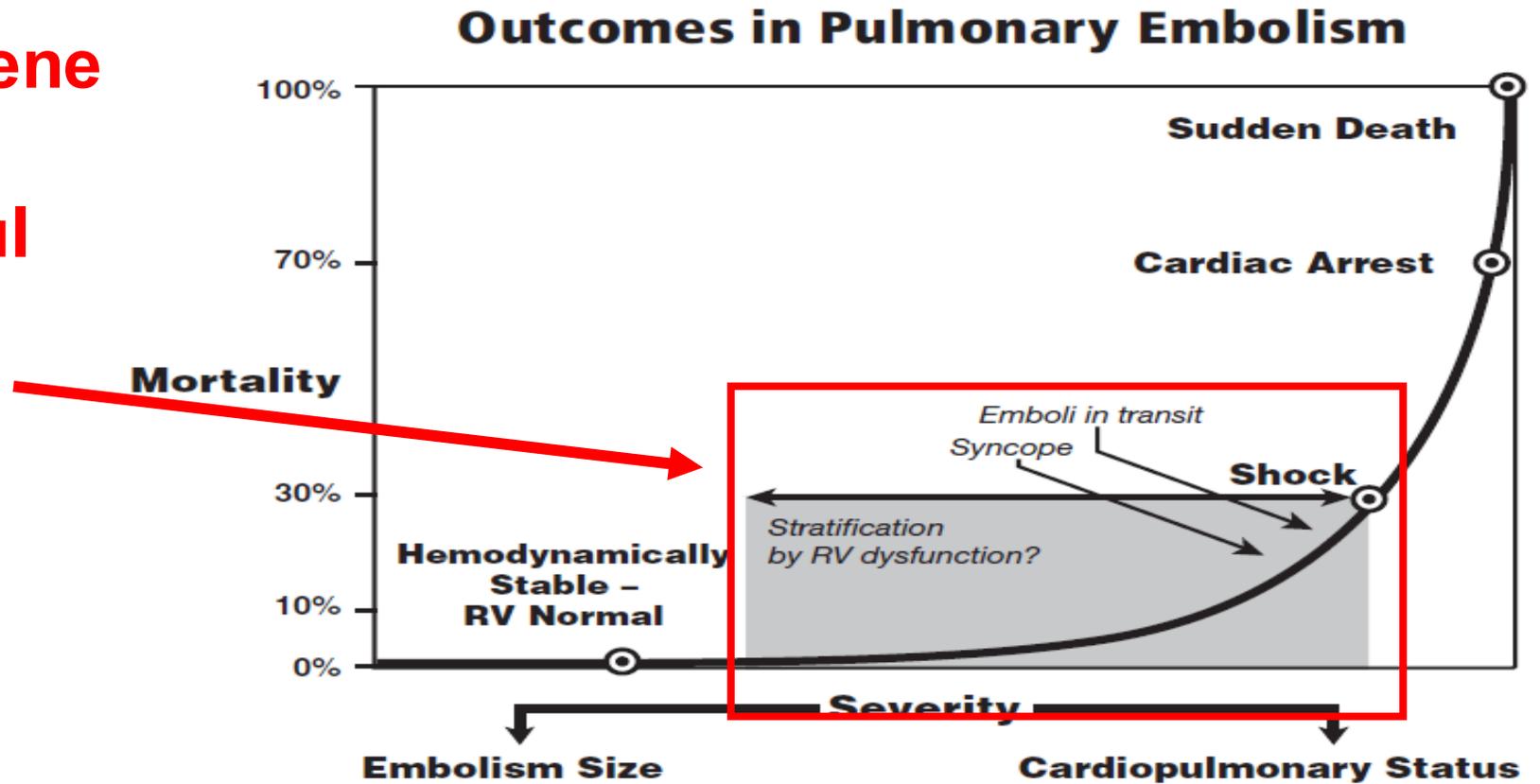
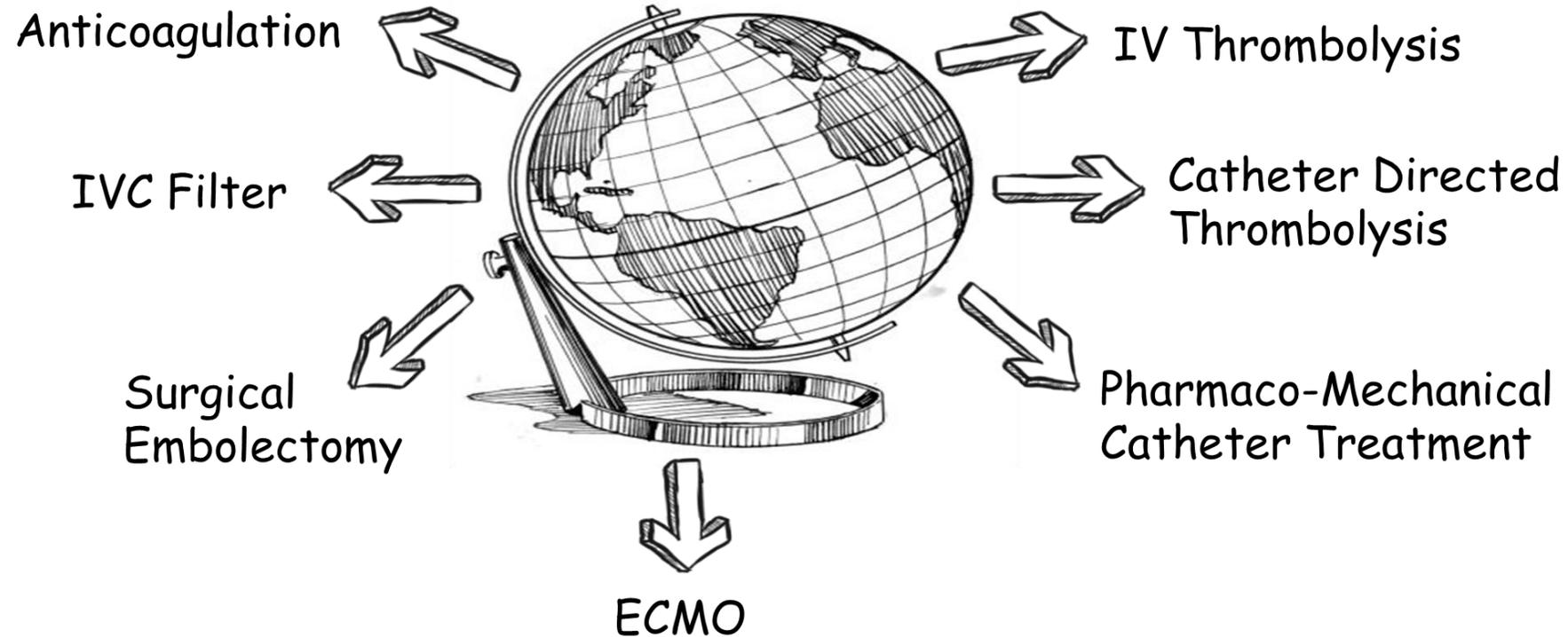**We can't always predict who will progress to high-risk PE.**
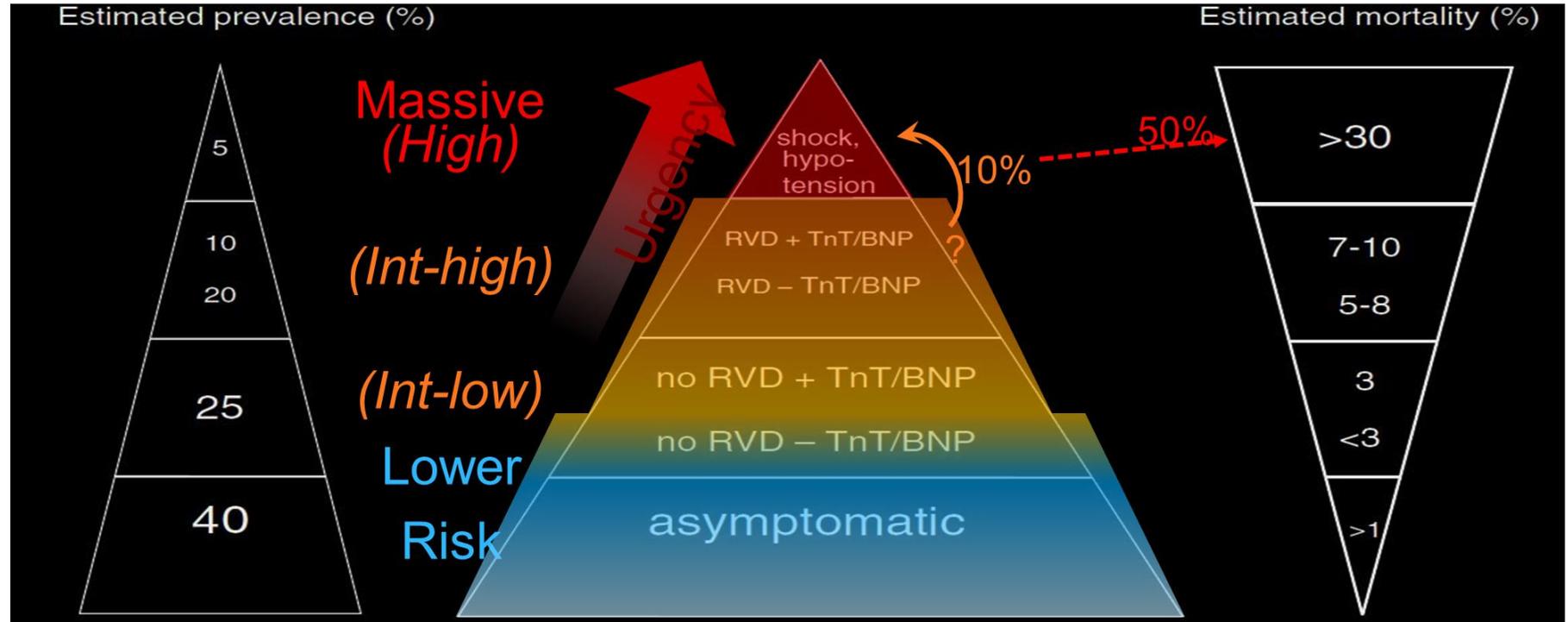
PE = pulmonary embolism; RVD = right ventricle dysfunction; TnT = troponin T; BNP = brain natriuretic peptide.
Abrahams-van Doorn PJ, Hartmann IJC. *Insights Imaging*. 2011;2:(6):705-715. Konstantinides SV, et al. *Eur Heart J.* 2014;35(43):3033-3069, 3069a-3069k. Becattini C, Agnelli G. *Thromb Haemost*. 2008;100(5):747-751. Grifoni S, et al. *Circulation*. 2000;101(24):2817-2822. Jaff MR, et al. *Circulation*. 2011;123(16):1788-1830.

Rationale for Advanced Therapy

We need to intervene early enough to make a meaningful clinical impact.

Outcomes in Pulmonary Embolism

Wood KE. *Crit Care Clin*. 2011;27(4):885-906.

PE Therapeutic Options Are Now Plentiful

Anticoagulation

IVC Filter

Surgical Embolectomy

ECMO

IV Thrombolysis

Catheter Directed Thrombolysis

Pharmaco-Mechanical Catheter Treatment

IVC = inferior vena cava; ECMO = extracorporeal membrane oxygenation.

Seven Catheter-Based Devices Have an Indication for the Treatment of PE in the United States

Device	Mechanism of Action
Catheter-Directed Thrombolytics	
EKOSonic *	USAT
Unifuse	Non-USAT
Cragg-McNamara	Non-USAT
Bashir Endovascular	Pharmacomechanical CDL
Thrombectomy Devices	
Flowtreiver *	Mechanical clot engagement with aspiration with adjunctive nitinol disks engage and mechanically retrieve clot
Indigo System	Mechanical clot engagement with mechanized aspiration
AlphaVac	Mechanical clot engagement with mechanized aspiration and veno-veno bypass; funnel shaped inflow tip to engage thrombi

USAT = ultrasound-assisted catheter-directed thrombolysis; CDL = catheter-directed lysis.
Kobayashi T, Giri JS [www.acc.org]. Last updated January 24, 2020. https://www.acc.org/Latest-in-Cardiology/Articles/2020/01/01/24/42/Peripheral-Matters-Current-Status-of-Interventional-Therapies-in-Acute-Pulmonary-Embolism.

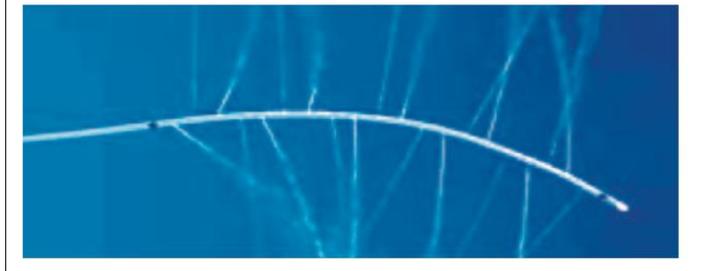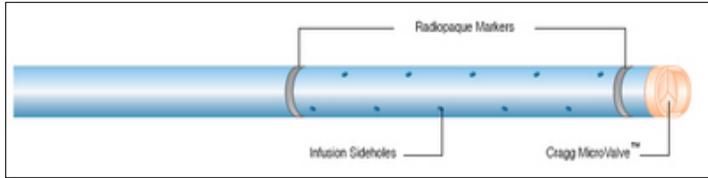# Weighing the Risks and Benefits of Advanced PE Therapies

- Prevent early mortality/clinical decompensation

- Improve symptoms

- ?Prevent CTEPH/post-PE syndrome
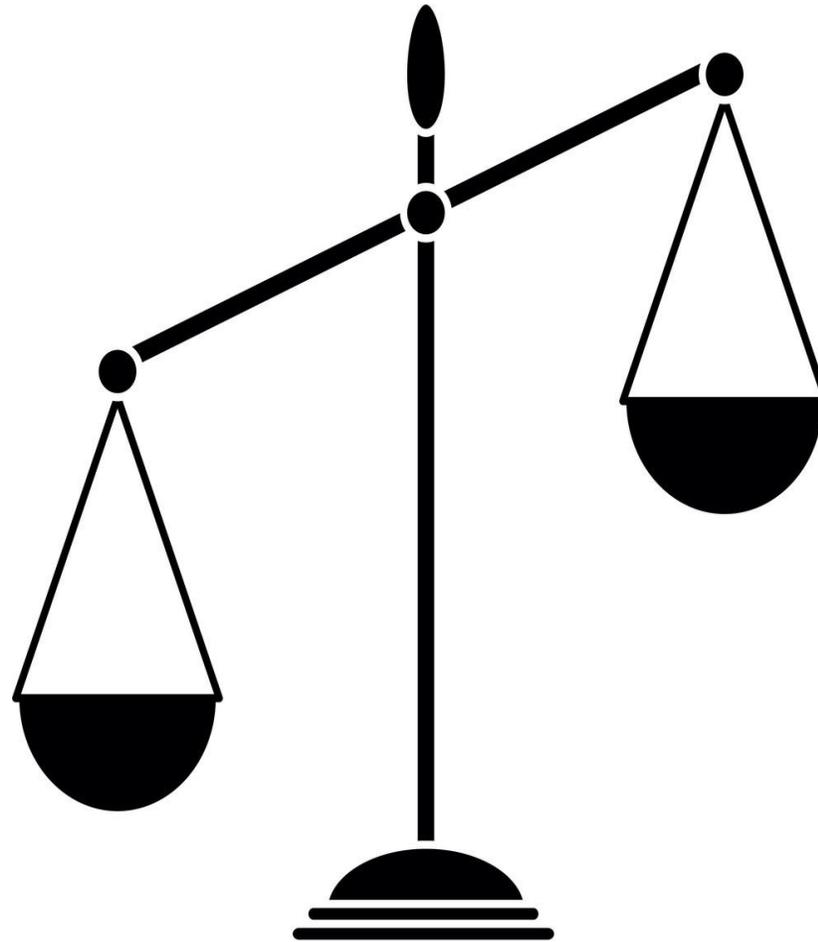
- Major bleeding

- Intracerebral bleeding

- Vascular injury

- ?Precipitate decompensation

CTEPH = chronic thromboembolic pulmonary hypertension.

Catheter-Directed Thrombolysis Devices

Cragg-McNamara
- 4-5 F
- 100 cm catheter length
- 5-10 cm infusion length

Unifuse
- 4-5 F
- 100 cm catheter length
- 5-10 cm infusion length

EKOS
- 5F
- 100 cm catheter length
- 5-10 cm infusion length

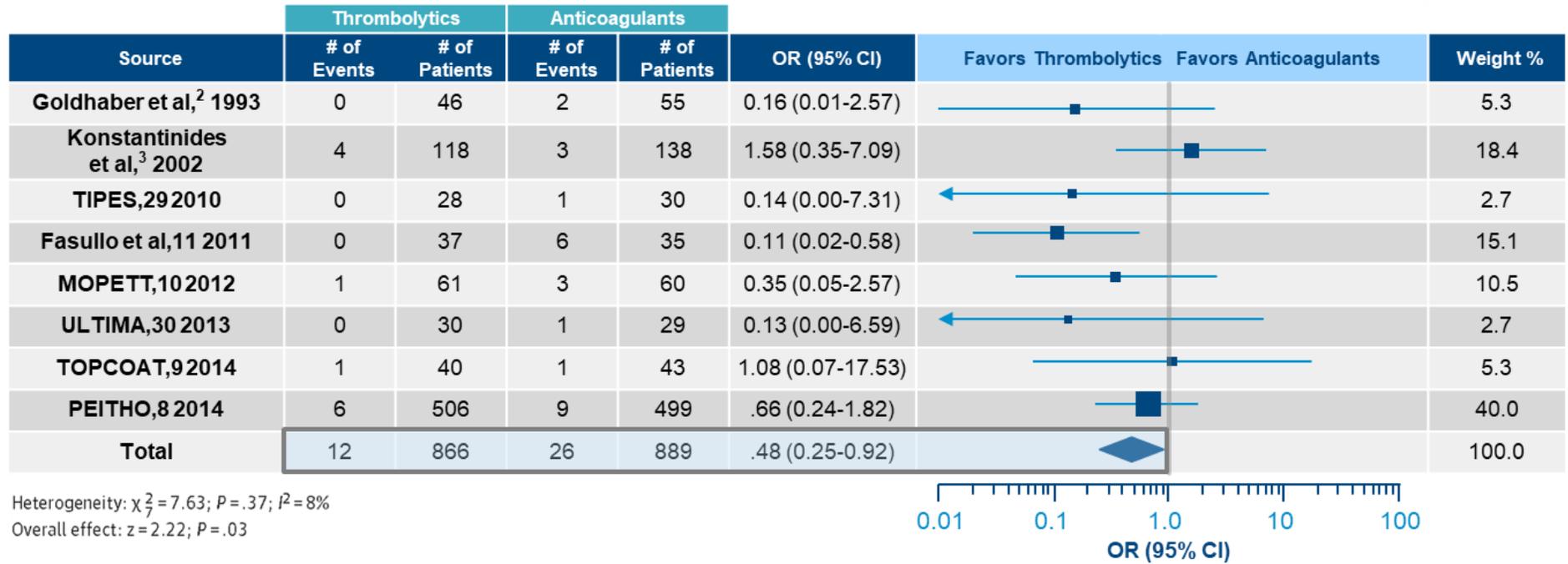**Thrombolex**
- 7F
- Nitinol Expandable Basket

STANDARD

SPECIALIZED

Thrombolysis for Intermediate-Risk PE

All-cause mortality

Source	Thrombolytics		Anticoagulants		OR (95% CI)	Favors Thrombolytics Favors Anticoagulants	Weight %
	# of Events	# of Patients	# of Events	# of Patients			
Goldhaber et al,[2] 1993	0	46	2	55	0.16 (0.01-2.57)		5.3
Konstantinides et al,[3] 2002	4	118	3	138	1.58 (0.35-7.09)		18.4
TIPES,[29] 2010	0	28	1	30	0.14 (0.00-7.31)		2.7
Fasullo et al,[11] 2011	0	37	6	35	0.11 (0.02-0.58)		15.1
MOPETT,[10] 2012	1	61	3	60	0.35 (0.05-2.57)		10.5
ULTIMA,[30] 2013	0	30	1	29	0.13 (0.00-6.59)		2.7
TOPCOAT,[9] 2014	1	40	1	43	1.08 (0.07-17.53)		5.3
PEITHO,[8] 2014	6	506	9	499	.66 (0.24-1.82)		40.0
Total	12	866	26	889	.48 (0.25-0.92)		100.0

Heterogeneity: $\chi^2_7 = 7.63$; $P = .37$; $I^2 = 8\%$
Overall effect: $z = 2.22$; $P = .03$

OR (95% CI) scale: 0.01 0.1 1.0 10 100

Intermediate-risk PE				
All-cause mortality (8)	12/866 (1.39)	26/889 (2.92)	NNT=65	.03
Major bleeding (8)	67/866 (7.74)	20/889 (2.25)	NNH=18	<.001

Chatterjee S, et al. *JAMA*. 2014;311(23):2414-21.

ULTIMA: EKOS CDT

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

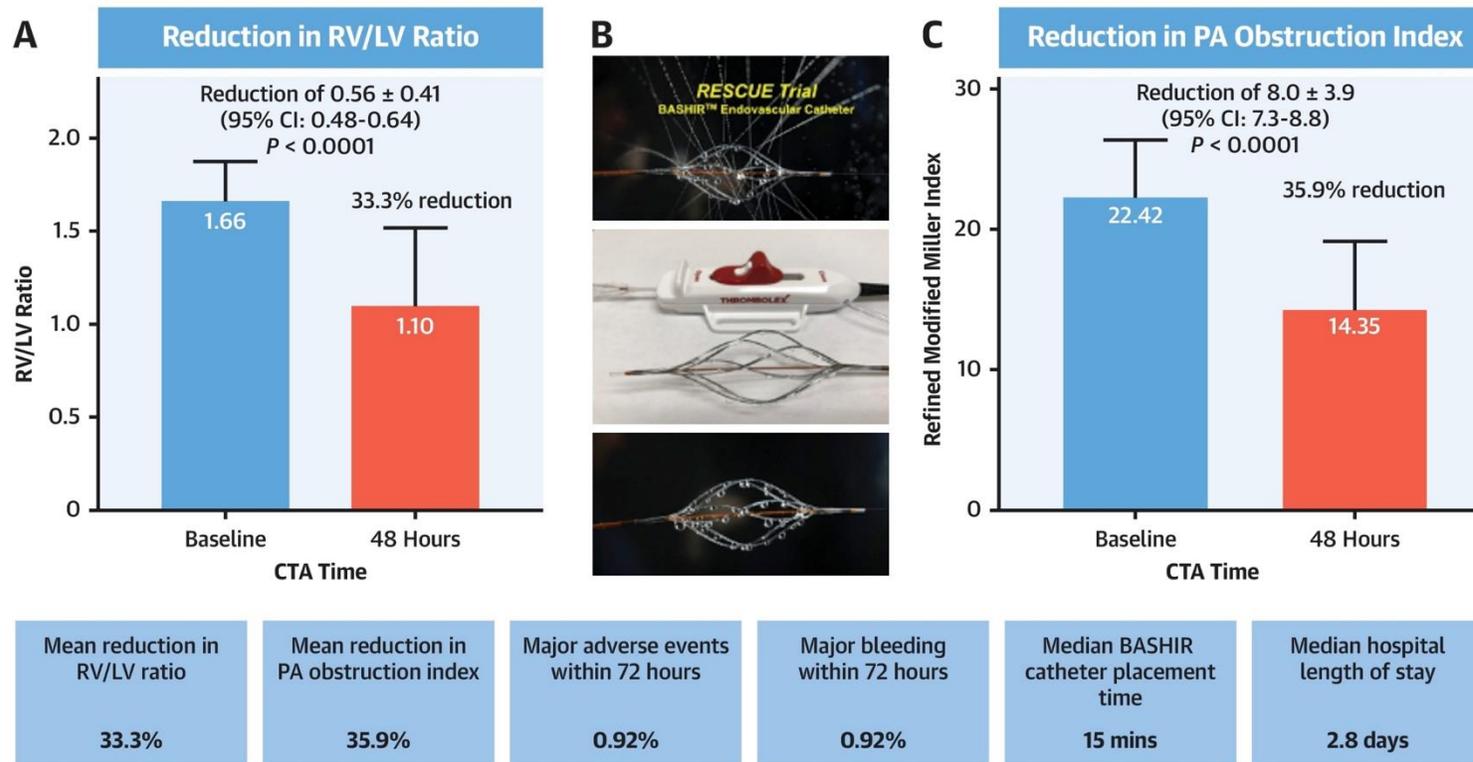**No statistical difference in safety outcomes 0% ICH / Major Bleeding in either group**
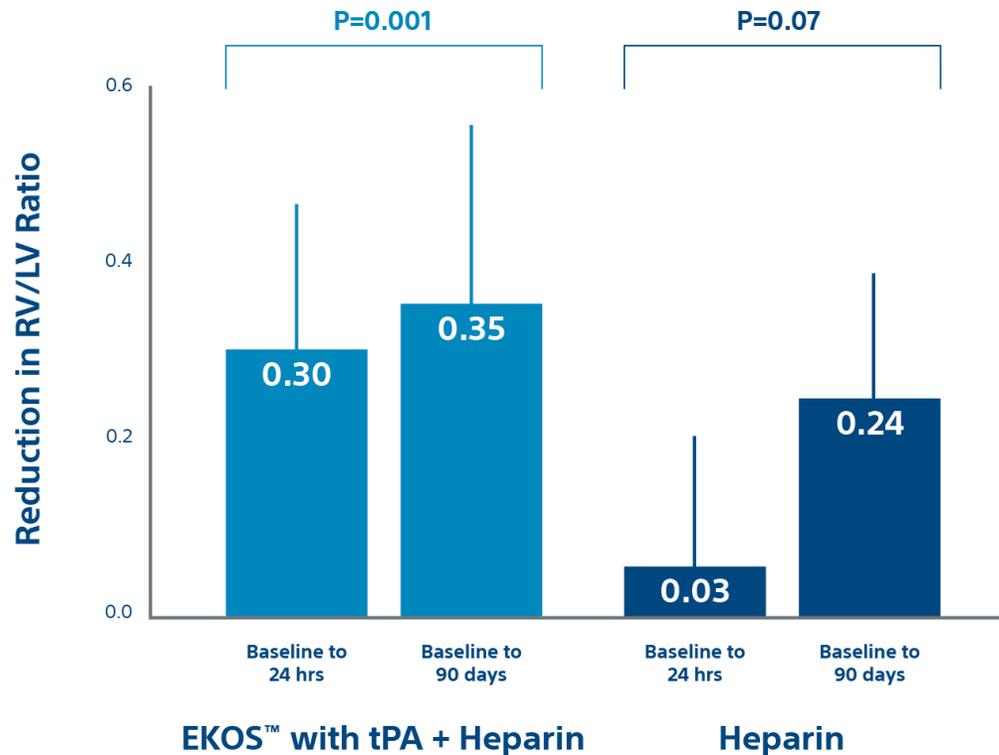
Clinical outcomes at 90 days	EKOS™ with tPA + Heparin N=30		Heparin N=29		P-Value
Death	0	0%	1*	0%	0.49
VTE	0	0%	0	0%	1.00
Major bleeding	0	0%	0	0%	1.00
Minor bleeding	3**	10%	1	3%***	0.61

RV = right ventricular; LV = left ventricular; VTE = venous thromboembolism.
Kucher N, et al. *Circulation*. 2014;129(4):479-486.

The RESCUE Study: Thrombolex

CENTRAL ILLUSTRATION: Primary Efficacy and Safety Endpoint Results of the RESCUE Trial

A — Reduction in RV/LV Ratio

Reduction of 0.56 ± 0.41
(95% CI: 0.48-0.64)
P < 0.0001

33.3% reduction

Baseline: 1.66
48 Hours: 1.10

RV/LV Ratio — CTA Time

B — RESCUE Trial BASHIR™ Endovascular Catheter

C — Reduction in PA Obstruction Index

Reduction of 8.0 ± 3.9
(95% CI: 7.3-8.8)
P < 0.0001

35.9% reduction

Baseline: 22.42
48 Hours: 14.35

Refined Modified Miller Index — CTA Time

Mean reduction in RV/LV ratio	Mean reduction in PA obstruction index	Major adverse events within 72 hours	Major bleeding within 72 hours	Median BASHIR catheter placement time	Median hospital length of stay
33.3%	35.9%	0.92%	0.92%	15 mins	2.8 days

Bashir R, et al. J Am Coll Cardiol Intv. 2022;15(23):2427–2436.

Major Bleeding and ICH with CDT

Studies	Estimate (95% C.I.)	Ev/Trt
Piazza G.SEATTLE 2015	0.100 (0.052, 0.148)	15/150
Kucher N. ULTIMA 2013	0.016 (0.000, 0.060)	0/30
Tapson VF.OPTALYSE-PE 2018	0.020 (0.000, 0.047)	2/101
Kuo WT. PERFECT Registry 2015	0.005 (0.000, 0.019)	0/100
Ozcinar et al. 2017	0.079 (0.000, 0.165)	3/38
Bloomer TL et al. 2017	0.080 (0.035, 0.126)	11/137
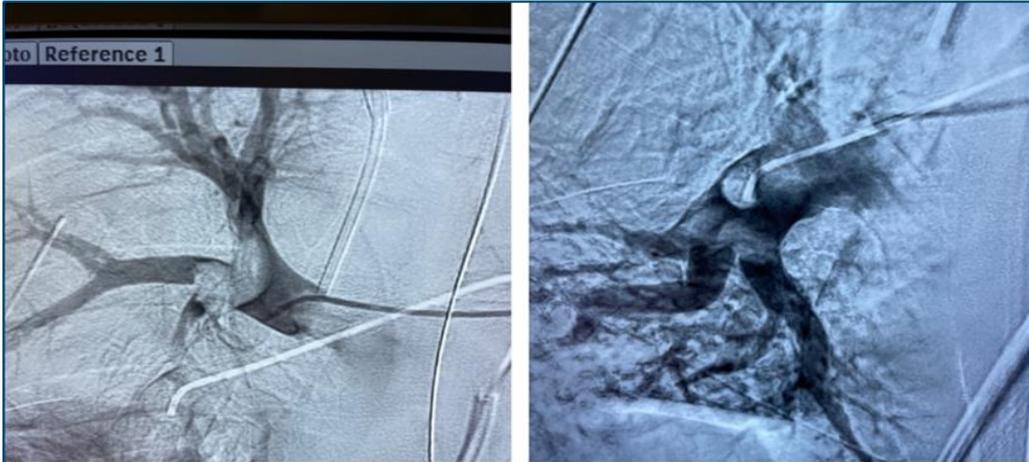Overall (I^2=79.03 % , P< 0.001)	0.043 (0.011, 0.075)	31/556

Major Bleeding: 4.3%
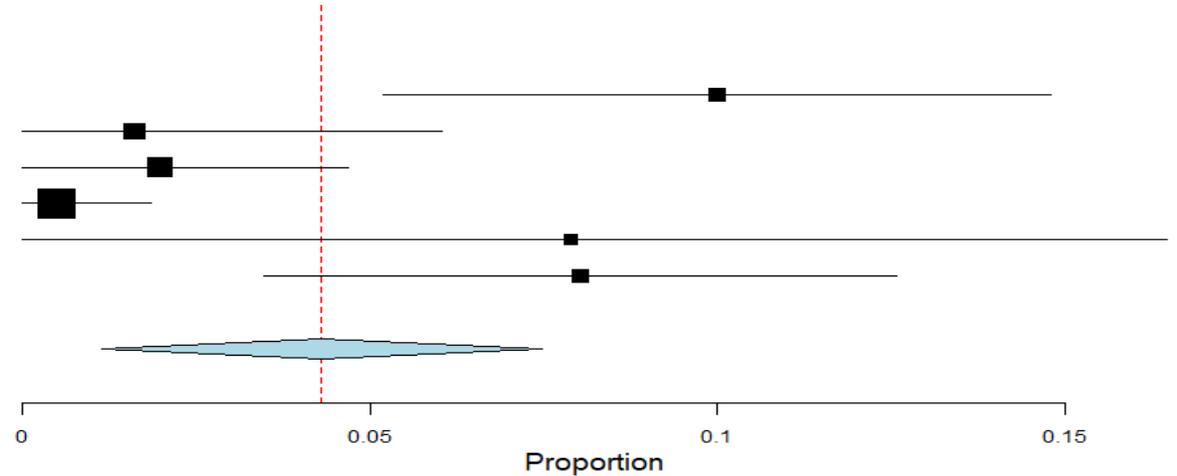
Studies	Estimate (95% C.I.)	Ev/Trt
Piazza G.SEATTLE 2015	0.003 (0.000, 0.012)	0/150
Kucher N. ULTIMA 2013	0.016 (0.000, 0.060)	0/30
Tapson VF.OPTALYSE-PE 2018	0.020 (0.000, 0.047)	2/101
Kuo WT. PERFECT Registry 2015	0.005 (0.000, 0.019)	0/100
Ozcinar et al. 2017	0.026 (0.000, 0.077)	1/38
Bloomer TL et al. 2017	0.015 (0.000, 0.035)	2/137
Overall (I^2=0 % , P=0.728)	0.007 (-0.000, 0.013)	5/556

ICH: 0.7%

Giri J, et al. *Circulation*. 2019;140(20):e774-e801.
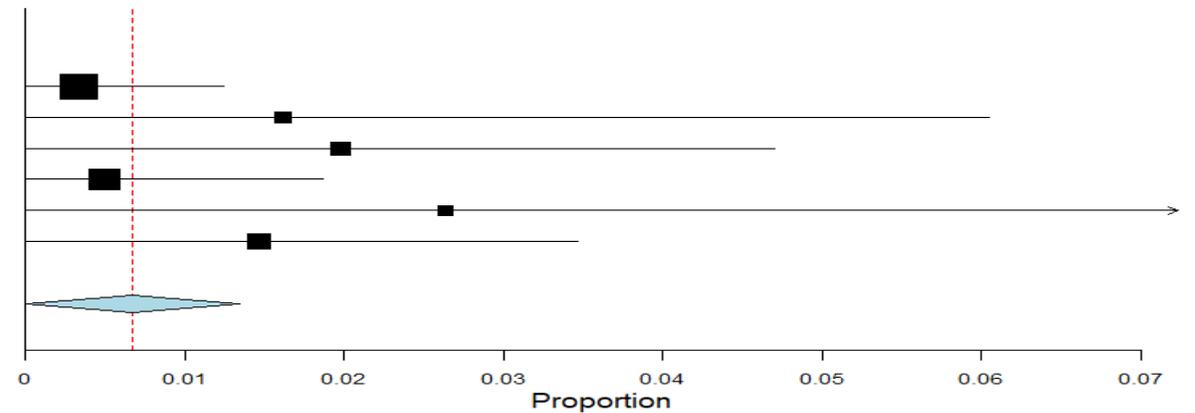
Penumbra Aspiration Thrombectomy

Extract PE Trial

Primary Efficacy Endpoint (mITT)

Mean Change in RV/LV Ratio
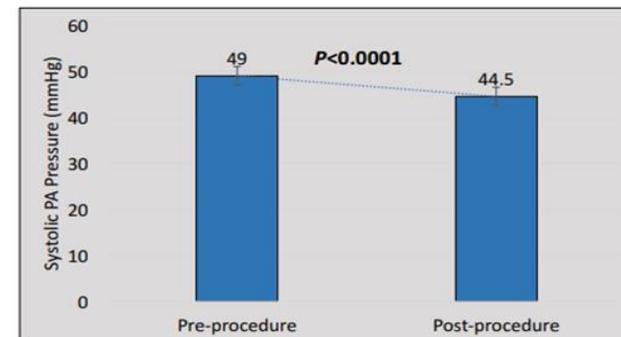
- Baseline: 1.46
- 48 Hours: 1.04
- P<0.0001
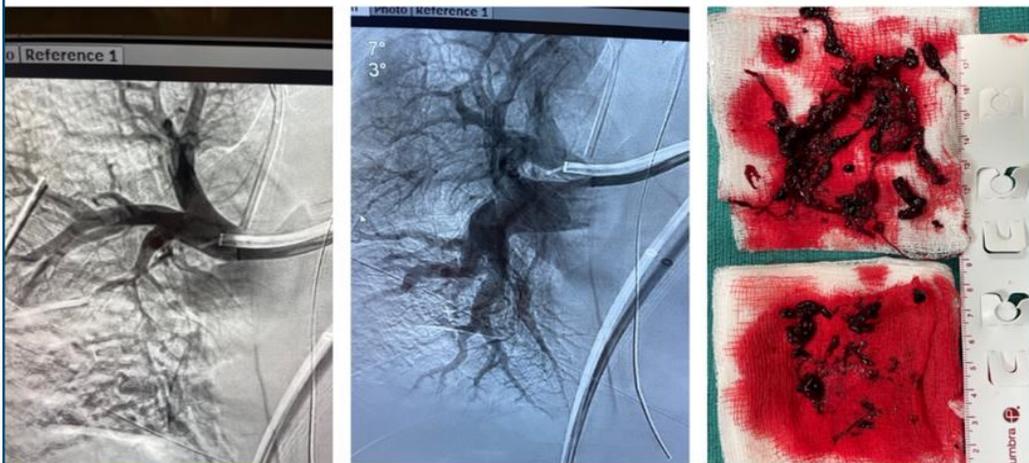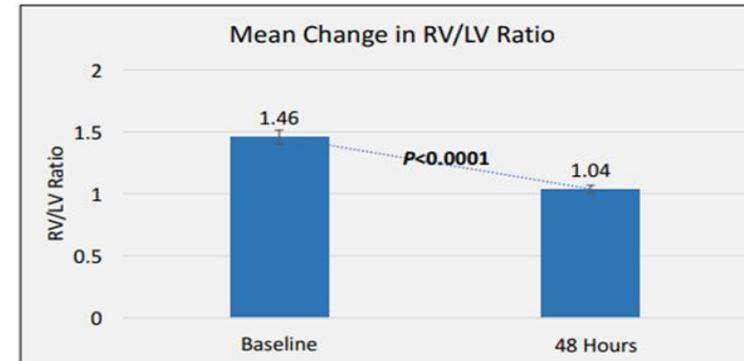
RV/LV ratio based on mITT patients (no intraprocedural - 48-hour tPA or adjunctive intervention to reduce clot burden) with evaluable CTA at 48 hours
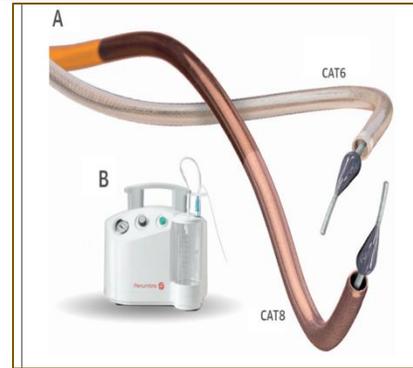
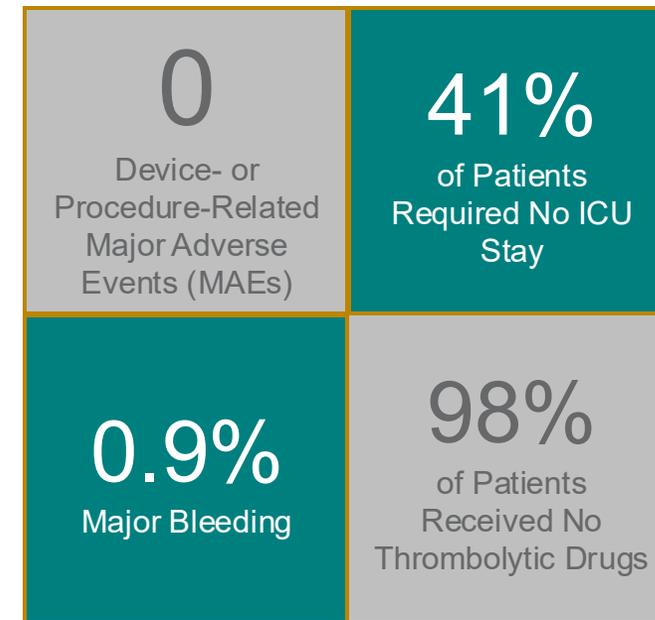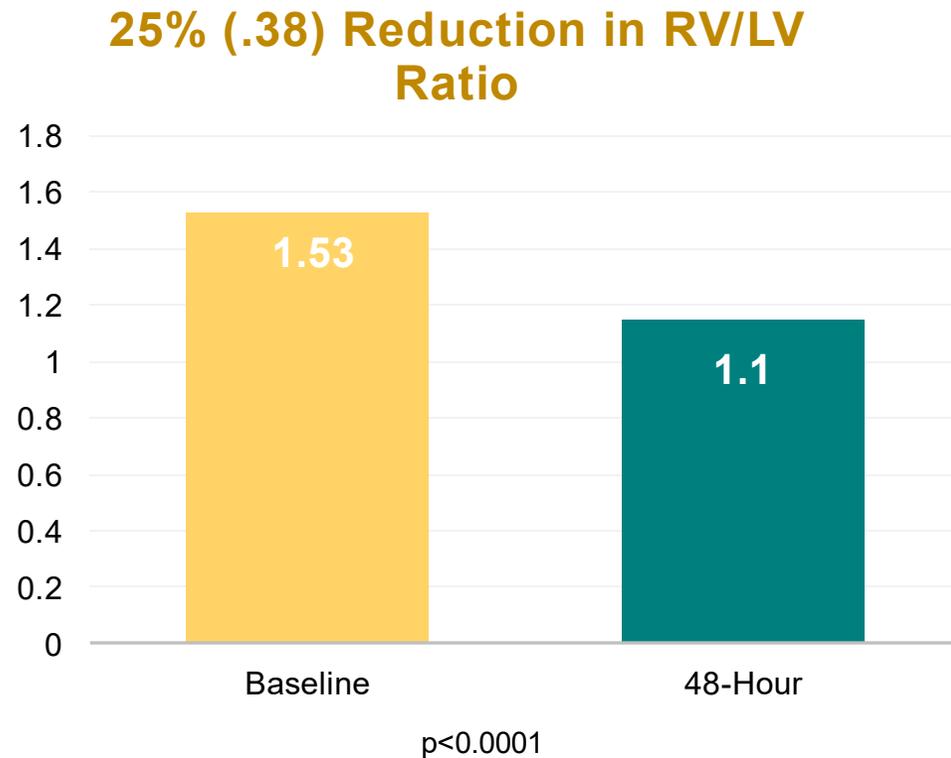Reduction of 0.42
(95% CI 0.37-0.46)
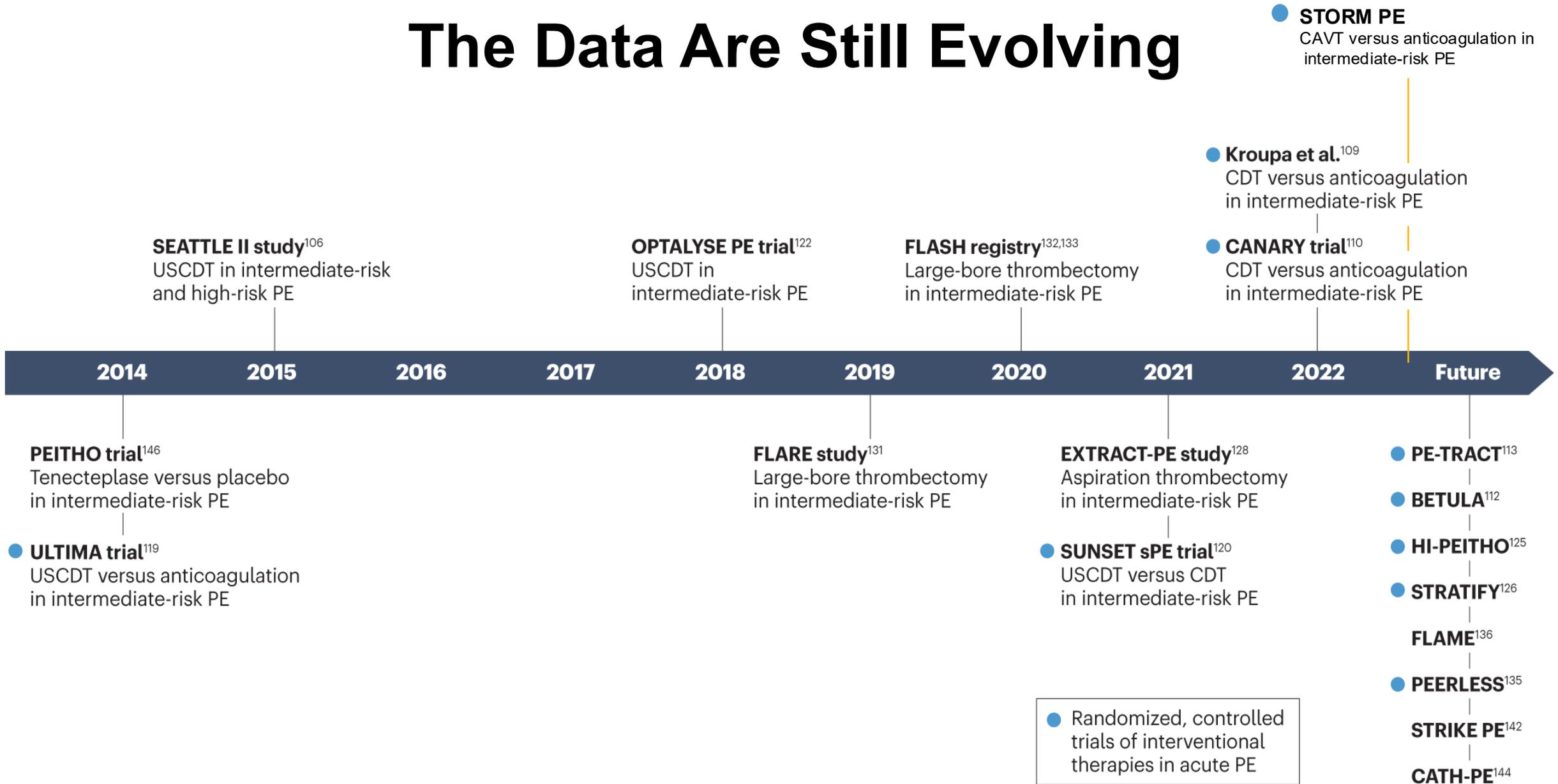
26.9% Reduction

Systolic Pulmonary Artery Pressure

- Pre-procedure: 49
- Post-procedure: 44.5
- P<0.0001

Reduction of 4.7 mmHg
(95% CI 3.0-6.4)

Sista AK, et al. *JACC Cardiovasc Interv*. 2021;14(3):319-329.

Mechanical Thrombectomy: Flare Trial

Prospective, multicenter, single-arm study evaluating the FlowTriever®
System in 106 patients with acute intermediate-risk PE at 18 US

25% (.38) Reduction in RV/LV Ratio

Baseline	1.53
48-Hour	1.1

p<0.0001

0 Device- or Procedure-Related Major Adverse Events (MAEs)	**41%** of Patients Required No ICU Stay
0.9% Major Bleeding	**98%** of Patients Received No Thrombolytic Drugs

Tu T, et al. *JACC Cardiovasc Interv.* **2019;12(9):859-869.**

The Data Are Still Evolving

STORM PE
CAVT versus anticoagulation in intermediate-risk PE

Kroupa et al.[109]
CDT versus anticoagulation in intermediate-risk PE

SEATTLE II study[106]
USCDT in intermediate-risk and high-risk PE

OPTALYSE PE trial[122]
USCDT in intermediate-risk PE

FLASH registry[132,133]
Large-bore thrombectomy in intermediate-risk PE

CANARY trial[110]
CDT versus anticoagulation in intermediate-risk PE

2014	2015	2016	2017	2018	2019	2020	2021	2022	Future

PEITHO trial[146]
Tenecteplase versus placebo in intermediate-risk PE

FLARE study[131]
Large-bore thrombectomy in intermediate-risk PE

EXTRACT-PE study[128]
Aspiration thrombectomy in intermediate-risk PE

ULTIMA trial[119]
USCDT versus anticoagulation in intermediate-risk PE

SUNSET sPE trial[120]
USCDT versus CDT in intermediate-risk PE

PE-TRACT[113]

BETULA[112]

HI-PEITHO[125]

STRATIFY[126]

FLAME[136]

PEERLESS[135]

STRIKE PE[142]

CATH-PE[144]

- Randomized, controlled trials of interventional therapies in acute PE

Götzinger F, et al. *Nat Rev Cardiol*. 2023;20(10):670-684.

Where Is the US Field Now?

Among Medicare Beneficiaries with hospitalized PE through 12/2023

- Increase in all catheter-based interventions

- Increase in mechanical thrombectomy

- Decline in catheter-directed thrombolysis

- Decline in systemic thrombolysis

Watson NW, et al. *J Soc Cardiovasc Angiogr Interv*. 2025;4(8):103736.
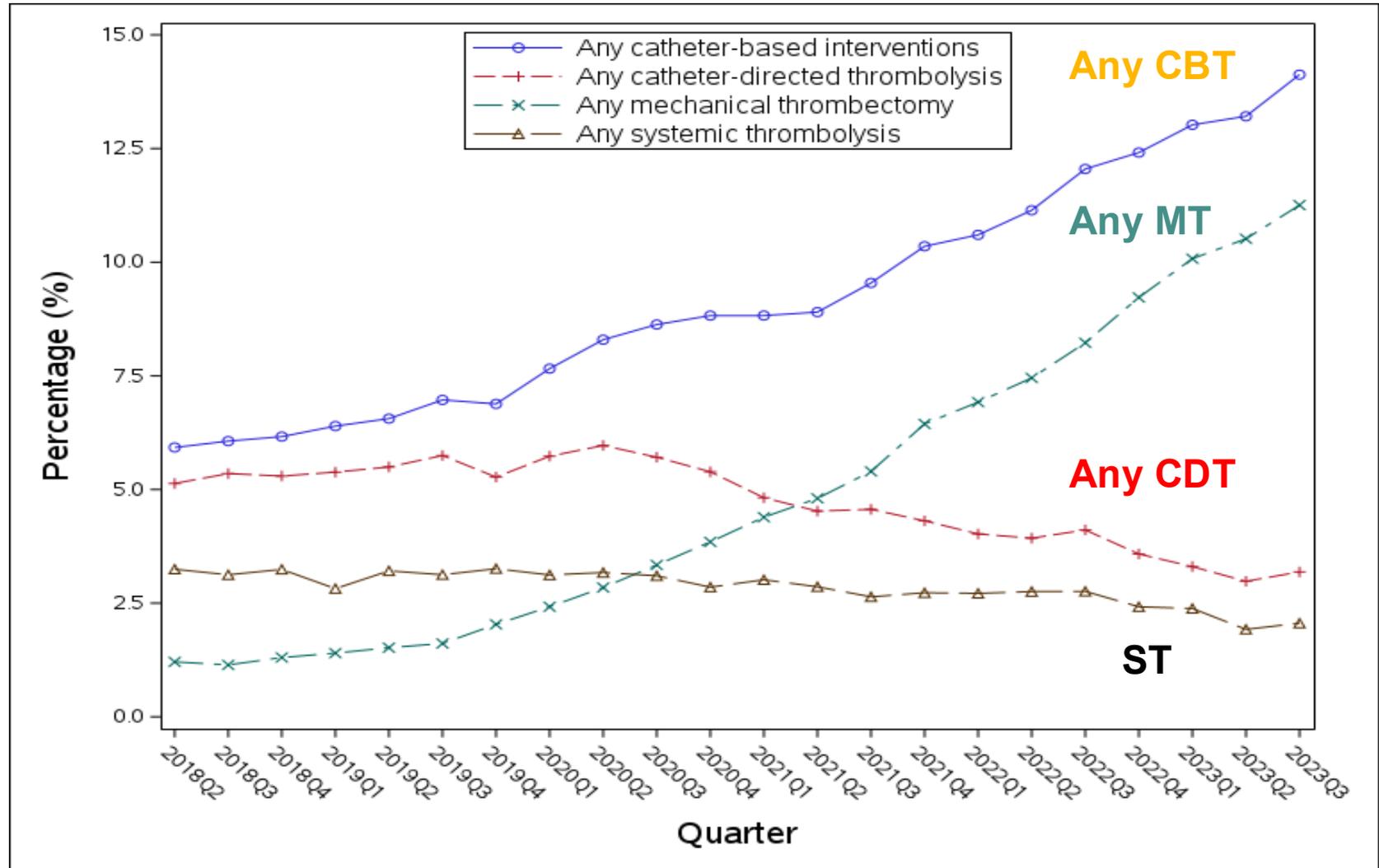
How I Choose My PE Device

When I Use CDT

- Peripheral thrombi
- Low bleeding risk (eg, younger patients)
- Technically challenging anatomy
- Failed thrombectomy
- Operator without thrombectomy expertise (ie, I'm out of town)
- Access site availability/challenges

When I Use Thrombectomy

- Proximal and central thrombus, clot in transit
- Large thrombus burden
- Hemodynamically unstable/borderline stable
- Absolute/relative contraindications to lytics and/or anticoagulation
- No ICU beds available

ICU = intensive care unit.

PE Response Teams (PERT)

Outcomes	References
Increased use of advanced therapies	2, 6
Decreased use of IVC filters	1, 4
Reduced time to therapeutic anticoagulation	4, 7
Decreased mortality	4,6,7,8
Decreased cost	8
Decreased LOS	7,8
Decreased bleeding	4

Published experiences
1. BIDMC (Carrol AJM 2020)
2. MGH (Rosovsky JTT 2019, Kabrhel Chest 2016)
3. Cornel/NYU (Sista Vasc Med 2018)
4. Cleveland Clinic (Chaudhury AJC 2019)
5. PERT consortium (Schultz Pulm Circ 2019)
6. UVA (Myc Resp Research 2020)
7. University of Rochester (Wright AJC 2021)
8. University of Kentucky (Annabathula JTT 2021)

2019 ESC Guidelines: Should consider using a PERT (2a C)

Knuuti J, et al. *Eur Heart J.* 2020;41(3):407-477.

Thank You

- esecemsk@bidmc.harvard.edu
- @EricSecemskyMD

*Smith Center for Outcomes Research
in Cardiology
375 Longwood Avenue, 4th Floor
Boston, Massachusetts 02215*

STRIKE-PE Study
Lightning Flash (16 Fr) Subset
N=244

As presented at TCT 2025

STRIKE-PE Visit Schedule and Endpoints
Long-Term Patient-Centric Follow-Up

Primary endpoints
- RV/LV ratio
- Composite MAEs

Secondary endpoints (30 d)
- All-cause mortality
- Symptomatic recurrent PE

Secondary endpoint
- Device-related SAEs

Baseline / preprocedure → Procedure (day 0) → 48 hours → Discharge → 90-day follow-up visit → 1-year follow-up visit
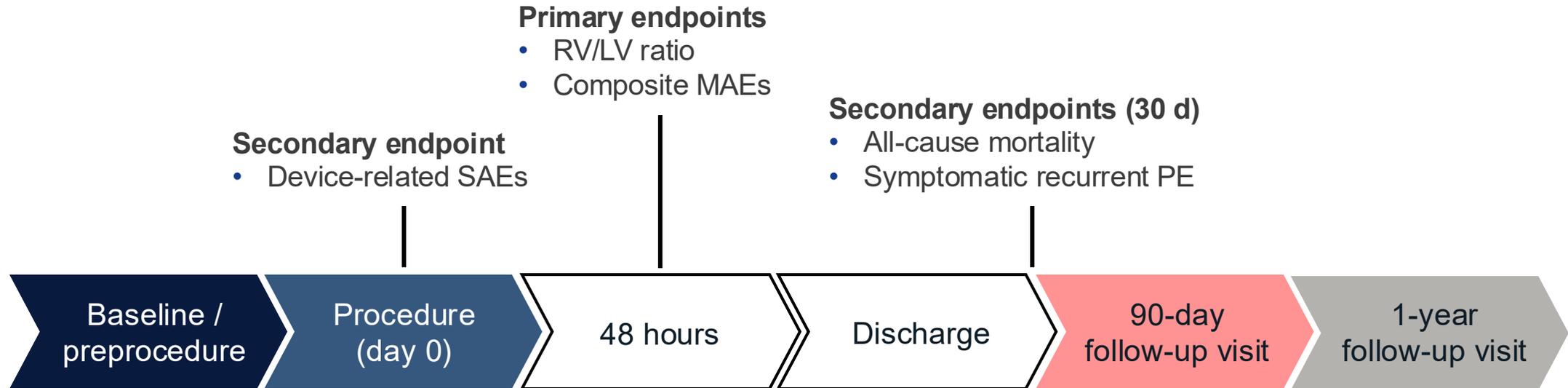
Secondary endpoints: functional outcomes and quality of life

- ✓ Borg dyspnea scale
- ✓ 6-minute walk test (6MWT)
- ✓ NYHA class
- ✓ EQ visual analog scale (VAS)
- ✓ EQ-5D-5L index value
- ✓ PEmb-QoL

MAEs = major adverse events; NYHA class = New York Heart Association classification of heart failure; PEmb-QoL = Pulmonary Embolism Quality of Life questionnaire; SAEs = serious adverse events.

Baseline and Periprocedural Data

Demographics*

Mean age
62.7 y

54.5% Male
45.5% Female

PE Classification*

High: 4.5%
Intermediate-low: 8.6%
Intermediate-high: 86.9%
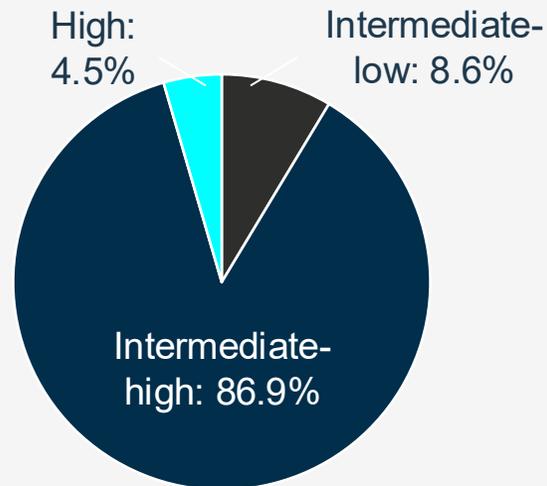
Periprocedural data N=244	Median [Q_1–Q_3] or % (n)
Thrombectomy time	25 min [17-35]
Procedure time	56.5 min [45-71]
Estimated blood loss	300 mL [200-400]
No ICU stay required	41.4% (101)
ICU length of stay after procedure	3 days [2-3]
Hospital length of stay	5 days [4-7]

Sharp A, et al. Presented at: Transcatheter Cardiovascular Therapeutics (TCT) 37th Annual Symposium; 2025.

Improved Hemodynamic Status
Reduction in On-Table Systolic Pulmonary Artery Pressure (sPAP)

sPAP, mm Hg, mean

52.9 — Pre-CAVT

40.0 — Post-CAVT

12.9 mm Hg (23.6%) *P*<.001

Rapid on-table hemodynamic improvement
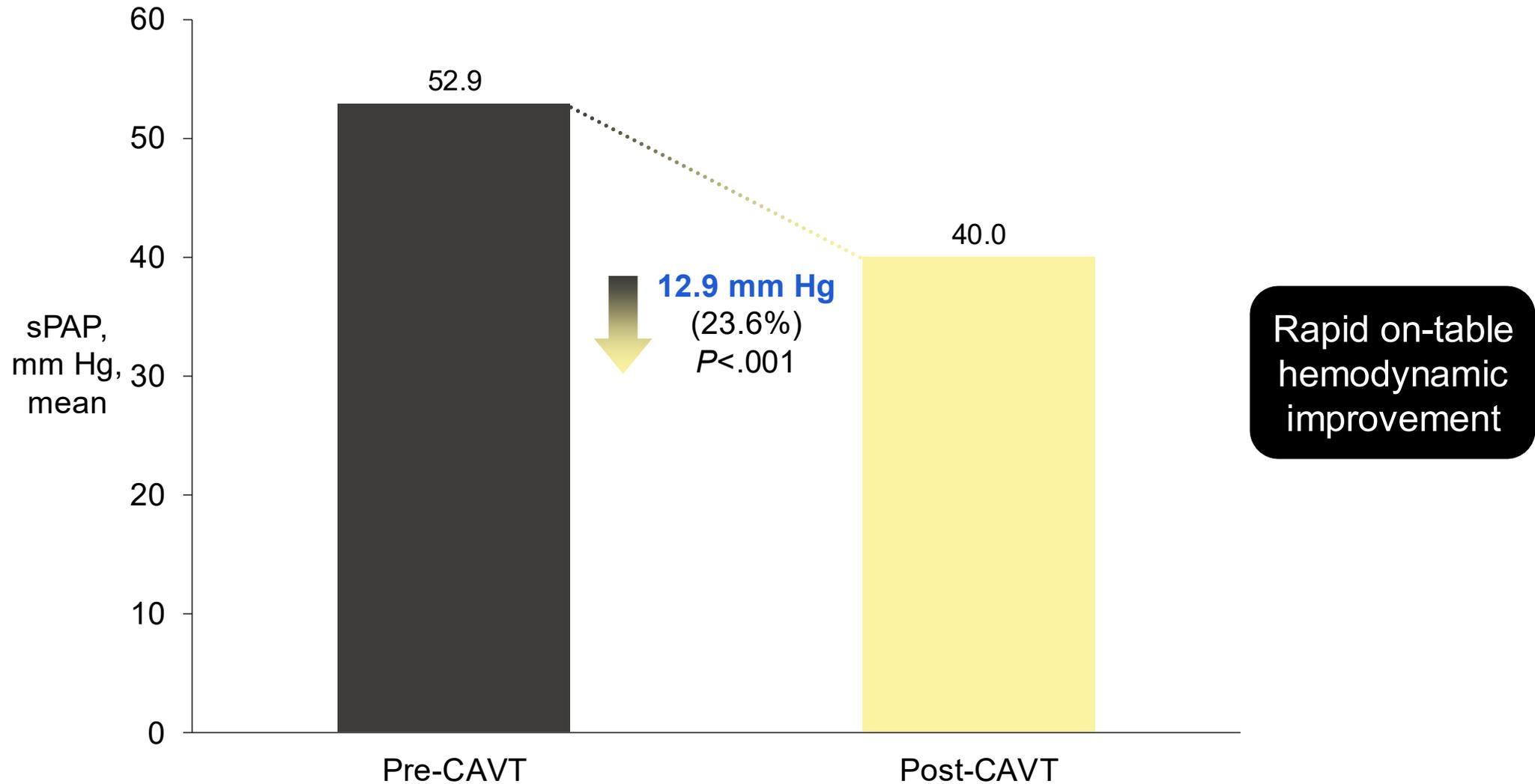
Paired data (n=234).
Sharp A, et al. Presented at: Transcatheter Cardiovascular Therapeutics (TCT) 37th Annual Symposium; 2025.

Decreased Thrombus Burden
Modified Miller Score (MMS)
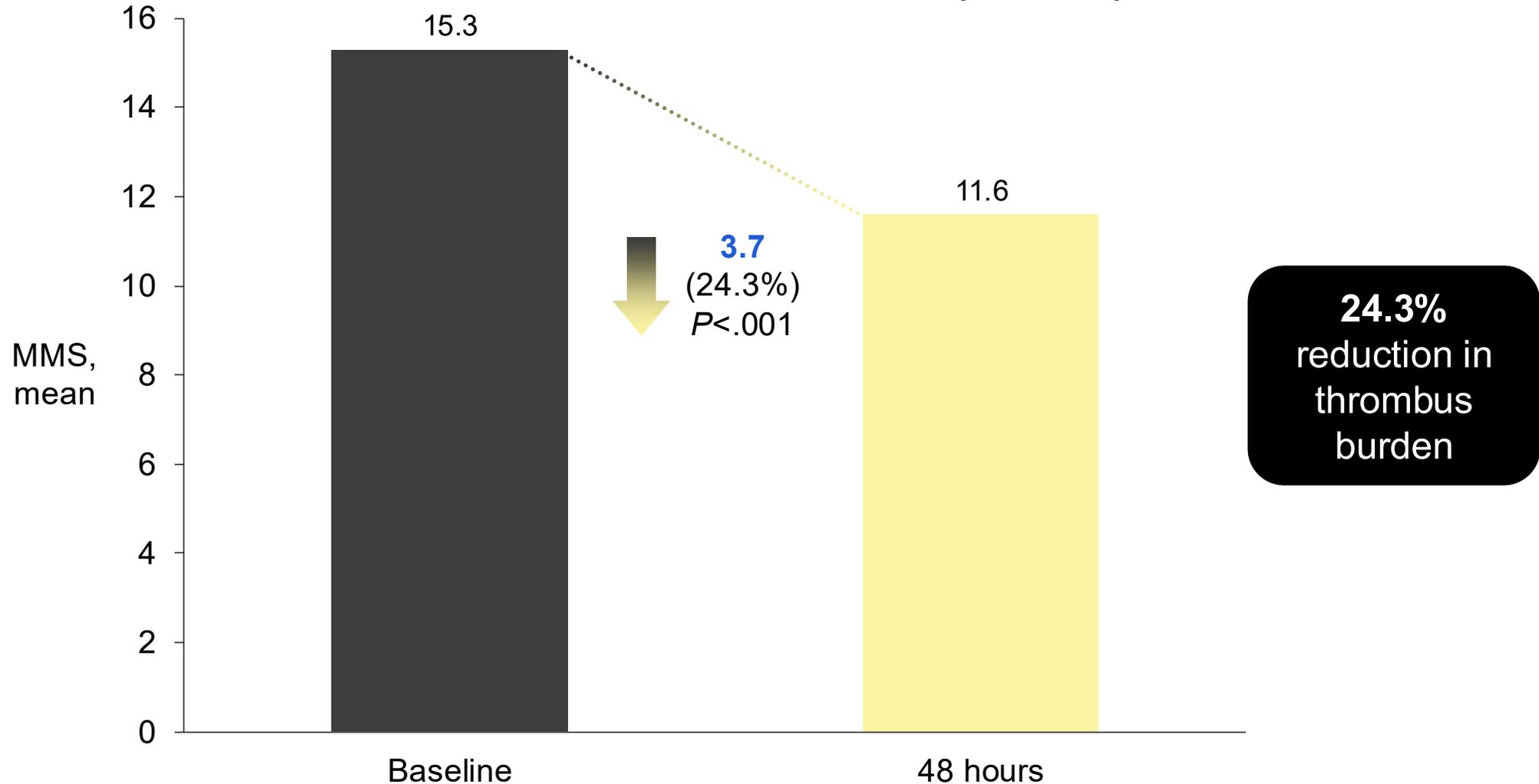
24.3% reduction in thrombus burden

MMS, mean

15.3 — Baseline

11.6 — 48 hours

3.7 (24.3%) *P*<.001
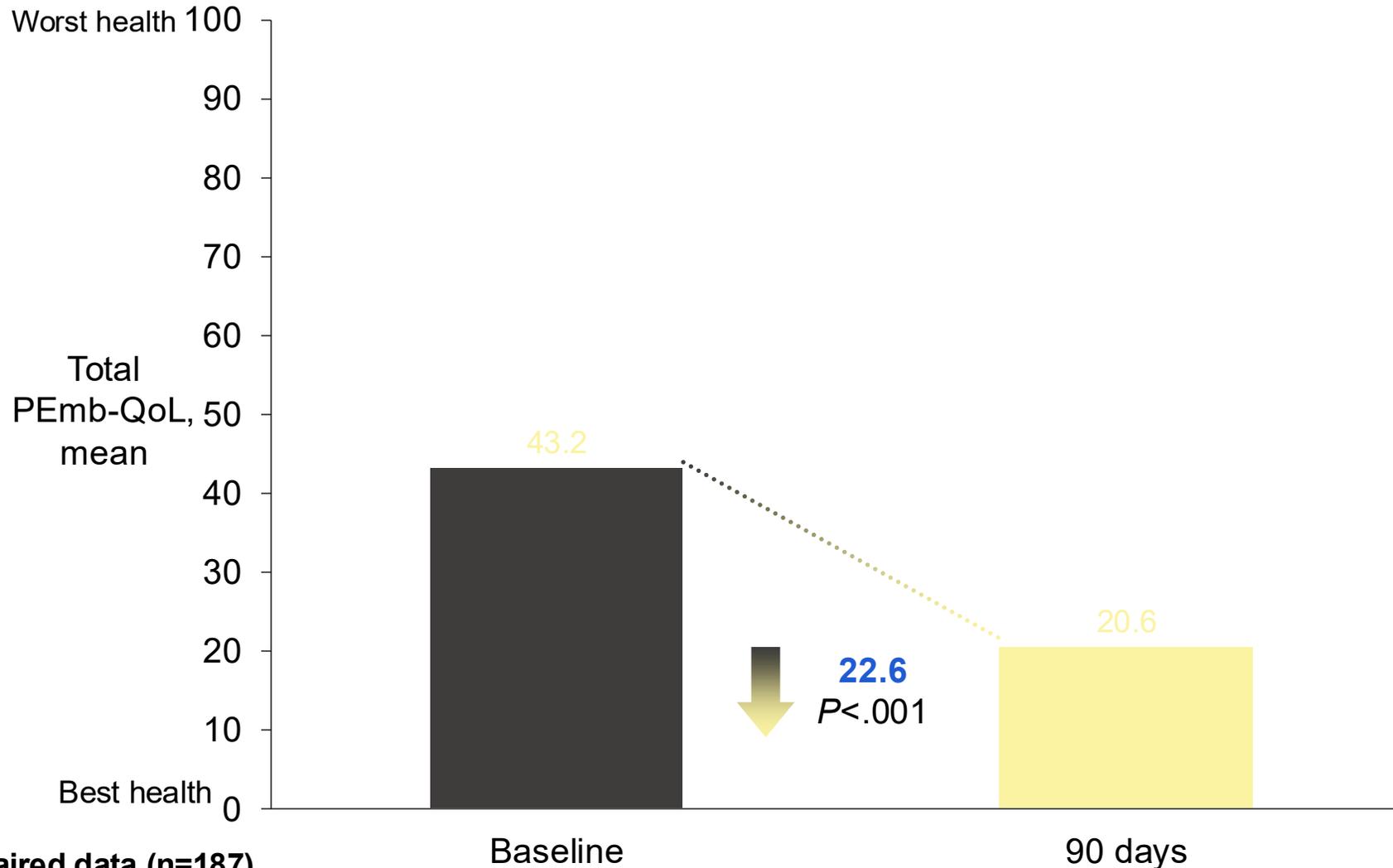
Primary Performance Endpoint: RV/LV Ratio*
Significant Improvement in RV Strain

0.39
(27.3%)
P<.001
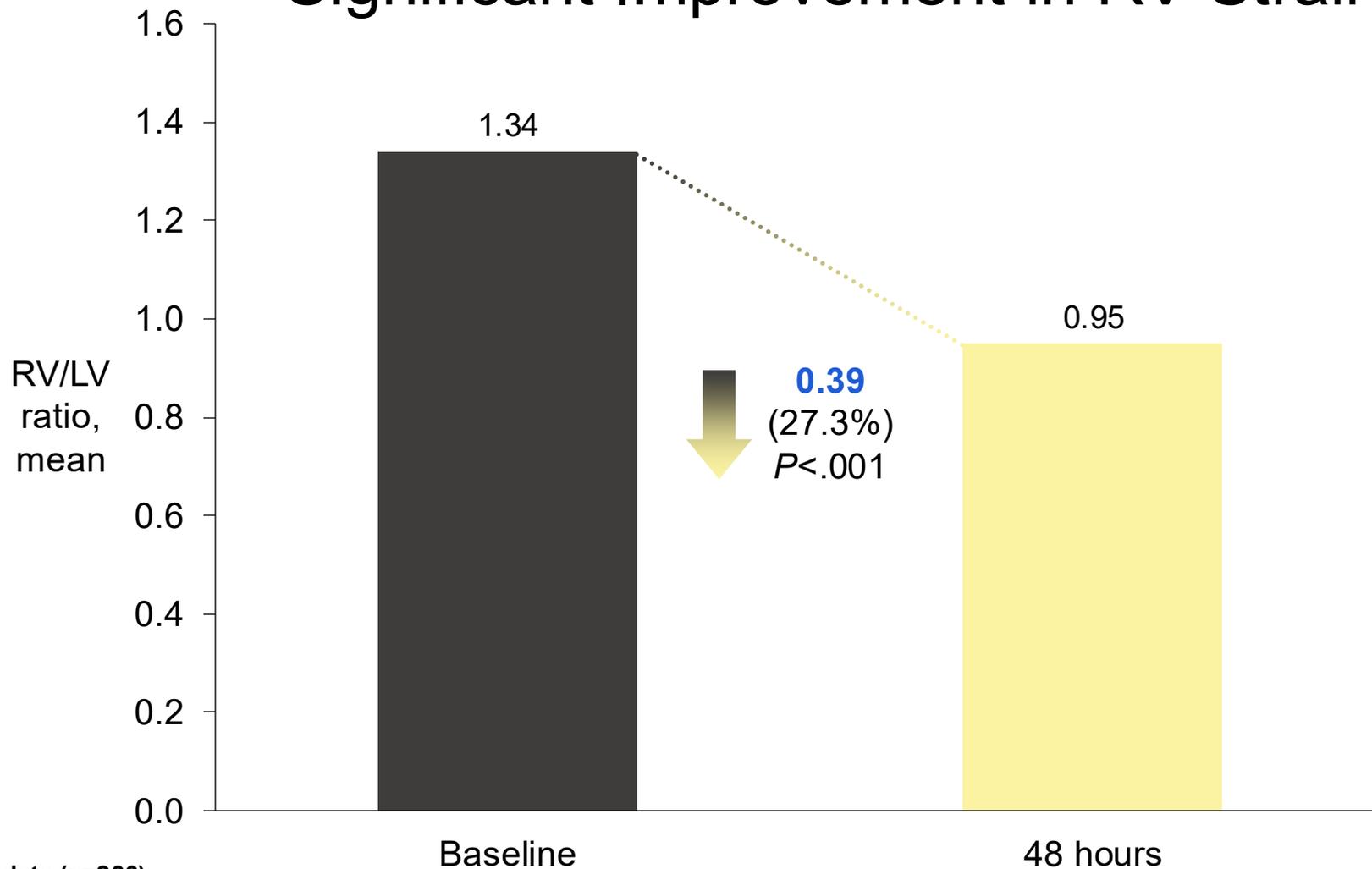
Near normalization of RV/LV ratio by 48 h supports RV offloading and stabilization

Paired data (n=236).
*Measured by paired images acquired by using the same imaging modality (CT pulmonary angiography or echocardiography) and evaluated by core lab else physician.
CT = computed tomography.
Sharp A, et al. Presented at: Transcatheter Cardiovascular Therapeutics (TCT) 37th Annual Symposium; 2025.

Safety Endpoints

Primary Safety Endpoint (N = 244)	
Composite major adverse events (MAEs) within 48 h*	**0.8% (2)**
Major bleeding[†]	0.8% (2)
Device-related clinical deterioration[‡]	0
Device-related cardiac injury[‡]	0
Device-related pulmonary vascular injury[‡]	0
Device-related death[‡]	0

Safety Details (N = 244)	
Secondary safety endpoints*	
Device-related serious adverse events[‡]	0
All-cause mortality within 30 d	1.2% (3)
Symptomatic PE recurrence within 30 d	0
Transfusion details*	
Major bleeding requiring transfusion[§]	0.4% (1)
Device-related transfusion[ǁ]	0

Data presented as % (n).
*Independent medical reviewer-adjudicated. †Major bleeding is defined as meeting BARC Types 3a, 3b, 3c, and 5, in line with AHA guidelines. Type 3a will not be considered as a major bleeding event if it is related to an expected drop in hemoglobin due to fluid administration and if transfusion is less than 2 units. ‡Adverse events that were judged as probably or definitely related to the CAVT devices were considered to be device-related. §Defined as events that were independent medical reviewer-adjudicated as major bleeding within 48 hours and had action taken of transfusion. ǁDefined as events that were independent medical reviewer-adjudicated as probably or definitely device-related and had action taken of transfusion.
BARC = Bleeding Academic Research Consortium; CAVT = computer-assisted vacuum thrombectomy.
Sharp A, et al. Presented at: Transcatheter Cardiovascular Therapeutics (TCT) 37th Annual Symposium; 2025.

Improved Quality of Life at 90 Days
Increase in EQ Visual Analog Scale (VAS)

Best health 100

90

80 — US population norm,
age 55-64 years: **78.8**[*]

78.0

70

EQ VAS,
mean

60

53.3

50

24.7
P<.001

40

30
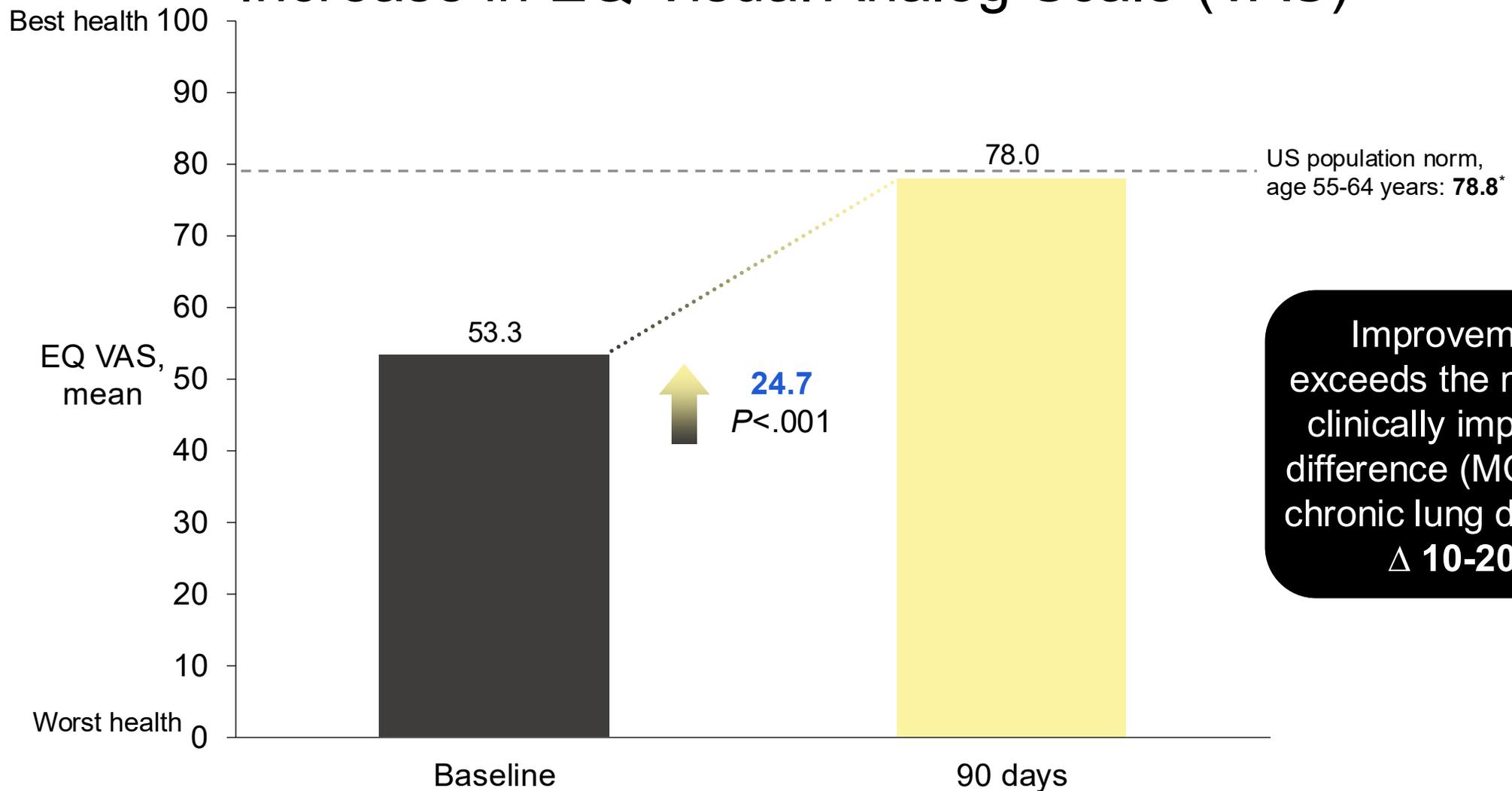
Improvement
exceeds the minimal
clinically important
difference (MCID) for
chronic lung disease:
△ **10-20**[†]

20

10

Worst health 0

Baseline

90 days

Paired data (n=190).
[*]Jiang et al. *Qual Life Res*. 2021;30(3):803-816.
[†]Ries AL. *COPD*. 2005;2(1):105-110.
Sharp A, et al. Presented at: Transcatheter Cardiovascular Therapeutics (TCT) 37th Annual Symposium; 2025.

Improved Quality of Life at 90 Days
Increase in EQ-5D-5L Index Value (US Patients)

Best health 1.0

US population norm,
age 55-64 years: **0.815**[*]

0.800

0.472

EQ-5D-5L
index value,
mean

0.328
P<.001

Improvement
exceeds the
minimal clinically
important difference
(MCID) for general
use: Δ **0.033-0.074**[†]

Worst health

Baseline
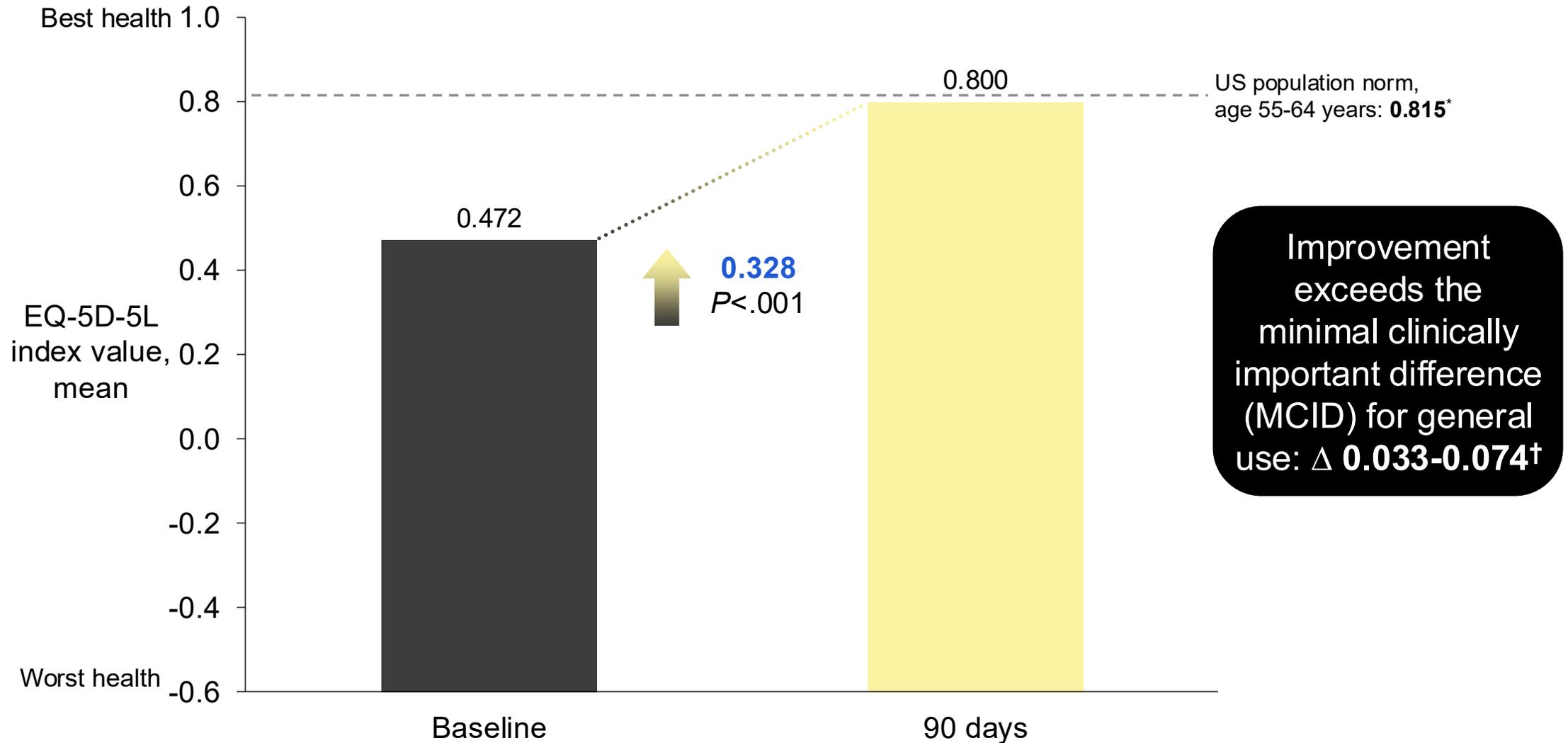
90 days

Paired data (n=185).
Sharp A, et al. Presented at: Transcatheter Cardiovascular Therapeutics (TCT) 37th Annual Symposium; 2025.

Improved PE-Specific Quality of Life at 90 Days
Pulmonary Embolism Quality of Life Questionnaire (PEmb-QoL)

Worst health 100

90

80

70

60

Total PEmb-QoL, mean 50

40

43.2

30

20

20.6

10

Best health 0

Baseline

90 days

22.6
P<.001

Improvement exceeds the minimal clinically important difference (MCID) for PE: Δ **15***

Paired data (n=187).
*Akaberi et al. *J Thromb Haemost*. 2018;16(12):2454-2461.
Sharp A, et al. Presented at: Transcatheter Cardiovascular Therapeutics (TCT) 37th Annual Symposium; 2025.

Conclusion

STRIKE-PE patients treated with CAVT using
the novel 16F catheter system experienced

**Improved on-table
hemodynamics**
Δ sPAP, -12.9 mm Hg

**Improved RV strain
at 48 h**
Δ RV/LV ratio, -27.3%

Low MAE rate
0.8% (2/244)

Short device time
25 min

Improved quality of life
Δ EQ VAS, +24.7
Δ EQ-5D-5L index value, +0.328
Δ Total PEmb-QoL, -22.6

Randomized Controlled Trial of Mechanical Thrombectomy with Anticoagulation versus Anticoagulation Alone for Acute Intermediate-High Risk PE: Primary Outcome, Functional Endpoints, and Core Lab Findings from STORM-PE

Robert Lookstein, MD, MHCDL, FSIR, FAHA, FSVM

Icahn School of Medicine at Mount Sinai; New York, NY

On behalf of the STORM-PE Investigators

Co-authors: Stavros V. Konstantinides, MD, Ido Weinberg, MD, Suhail Y. Dohad, MD, Zachary Rosol, MD, Grzegorz Kopeć, MD, PhD, John M. Moriarty, MD, Sahil A. Parikh, MD, Andrew Holden, ONZM, Richard Channick, MD, Braedon McDonald, MD, PhD, Khanjan H. Nagarsheth, MD, Kei Yamada, MD, Rachel P. Rosovsky, MD, MPH, Robert A. Lookstein, MD

Background

- Endovascular therapy for the treatment of acute PE emerged >12 years ago

  - Currently, 7 FDA cleared devices

- However, there are **no reported RCTs** comparing outcomes of mechanical thrombectomy (MT) + anticoagulation (AC) vs AC alone

- **STORM-PE** is the **first** completed RCT in over 10 years

  - And first ever RCT of MT vs AC
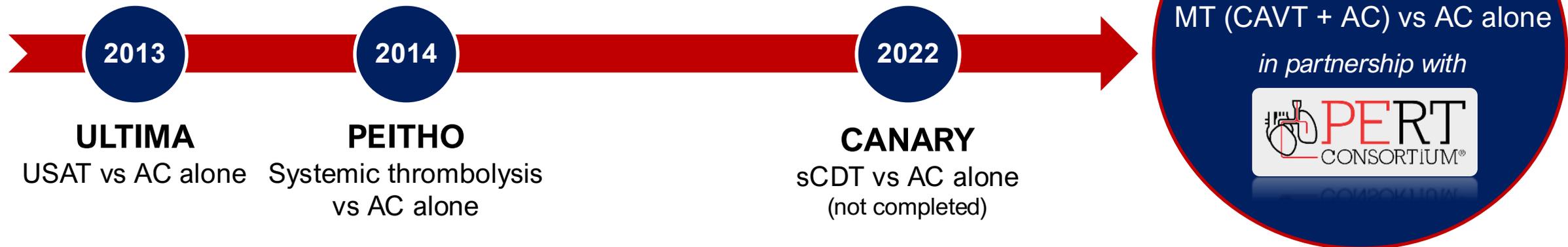
2025
STORM-PE RCT
MT (CAVT + AC) vs AC alone
in partnership with

| 2013 | 2014 | 2022 |

ULTIMA
USAT vs AC alone

PEITHO
Systemic thrombolysis
vs AC alone

CANARY
sCDT vs AC alone
(not completed)

Endpoints: Primary Efficacy

	PRIMARY EFFICACY ENDPOINT
Endpoint	**Change in RV/LV ratio at 48 hours**
Definition*	**Change in RV/LV ratio on original therapy assessed by CTPA between baseline (defined as initial CTPA for PE diagnosis) and 48 ± 6 hours** **Adjudicated by an independent blinded core laboratory**
Power	**Highly powered (90%) with assumed RV/LV ratio difference of 0.25 between arms**
Test	**Superiority of CAVT against AC for a significant difference in RV/LV ratio Δ with t-test at one-sided alpha of 0.025**

*Patients receiving rescue therapy without 48-hour endpoint imaging had a 0 change in RV/LV ratio assigned (N=2). Rescue therapy was defined as clinical deterioration (treatment failure) that required treatment outside of treatment arm. Patients stayed within assigned arm. Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.

Trial Device and Procedure

- Lightning Flash timeline
  - FDA cleared in Dec 2022
  - Commercially available in Jan 2023
  - First STORM-PE patient enrolled Jul 2023

- Investigators had limited experience with the new technology
  - Prior to enrolling, trial operators completed two PE procedures or had previous Penumbra CAVT experience

- Trial sites agreed the technology had a strong safety profile with clinical equipoise for randomization

Computer assisted vacuum thrombectomy (CAVT) using the 16F catheter system

Microprocessor with thrombus removal algorithm

USB port on back of Penumbra ENGINE®

Flow Switch

Lightning Flash™ (16F catheter)

Penumbra ENGINE® Canister

Penumbra ENGINE® pump with Lightning Flash™ Aspiration Tubing attached

Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.
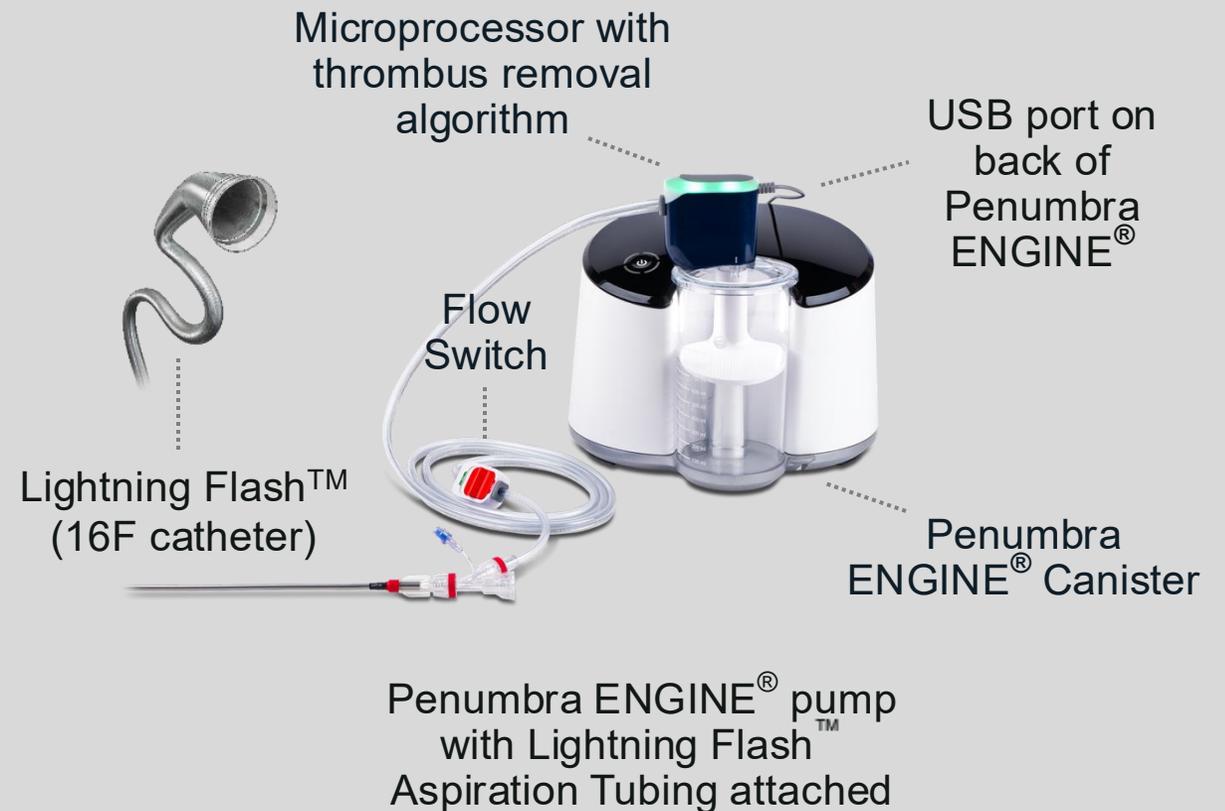
Key Eligibility Criteria, Sites, and Enrollment

Inclusion

- ✓ Clinical signs and symptoms of acute PE (≤ 14 days)
- ✓ CTPA showing filling defect in ≥1 main or proximal lobar pulmonary artery
- ✓ RV/LV ratio ≥ 1.0 on CTPA
- ✓ Elevated cardiac biomarkers

Exclusion

- ✗ Hemodynamic instability or on ECMO
- ✗ CTEPH or CTED findings
- ✗ Primary brain or metastatic brain cancer
- ✗ Life expectancy <90 days
- ✗ NEWS2 score ≥9

Patients enrolled July 2023-June 2025

1 site
6 enrolled

1 site
6 enrolled

19 sites
82 enrolled

1 site
6 enrolled
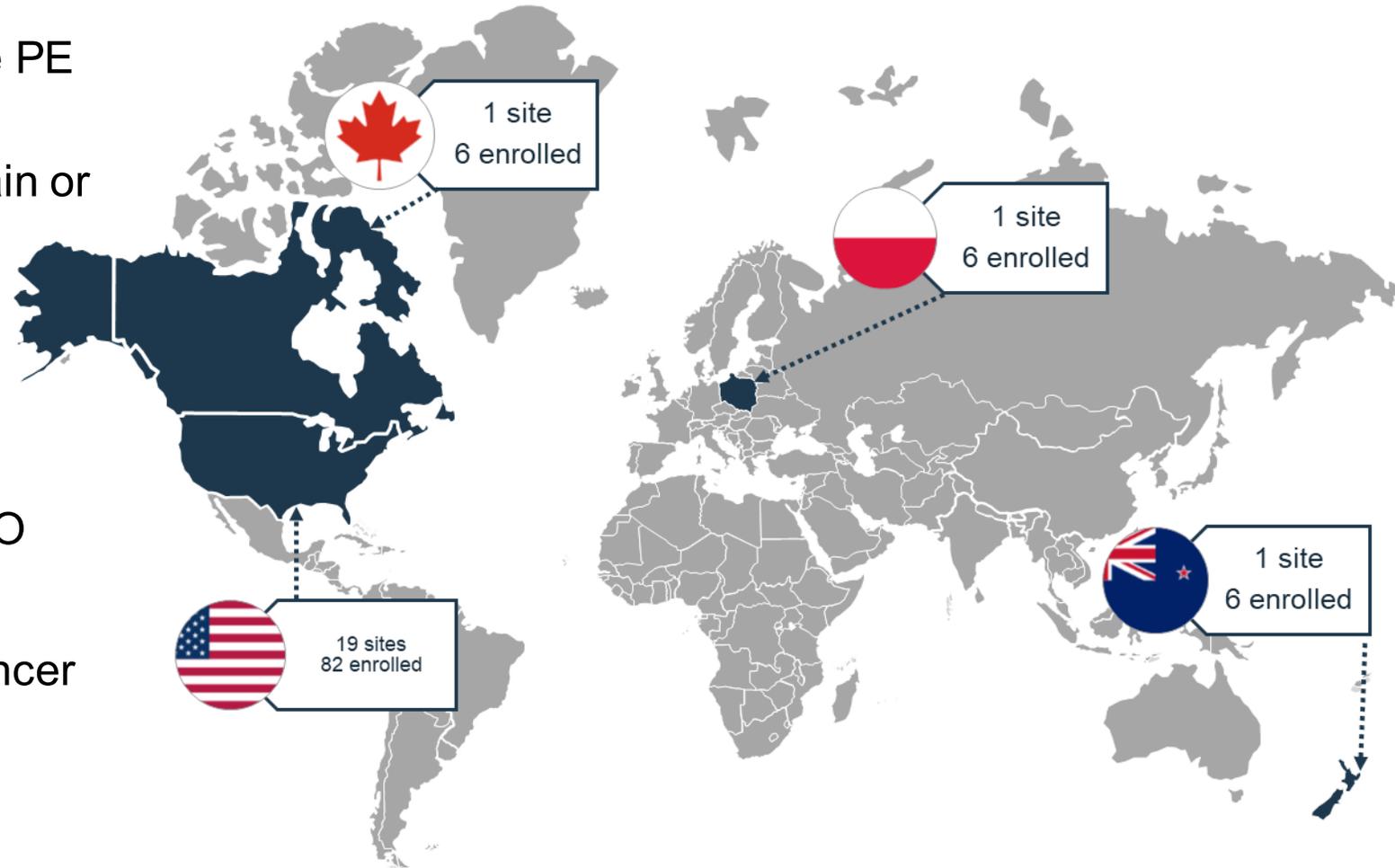
CTED = chronic thromboembolic disease; ECMO = extracorporeal membrane oxygenation; CTPA = computed tomography pulmonary angiography.
Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.

Patient Flow for STORM-PE RCT

767 Assessed for eligibility

667 excluded
- **546** did not meet eligibility criteria
- **86** declined to participate
- **30** inability to treat in randomization window
- **5** trial operator not available

100
Randomized
(ITT population)

47 CAVT arm

1 missing CTPA

46 analyzed for primary outcome

48 $\pm$ 6 hrs

53 AC arm

1 Missing CTPA

52 analyzed for primary outcome
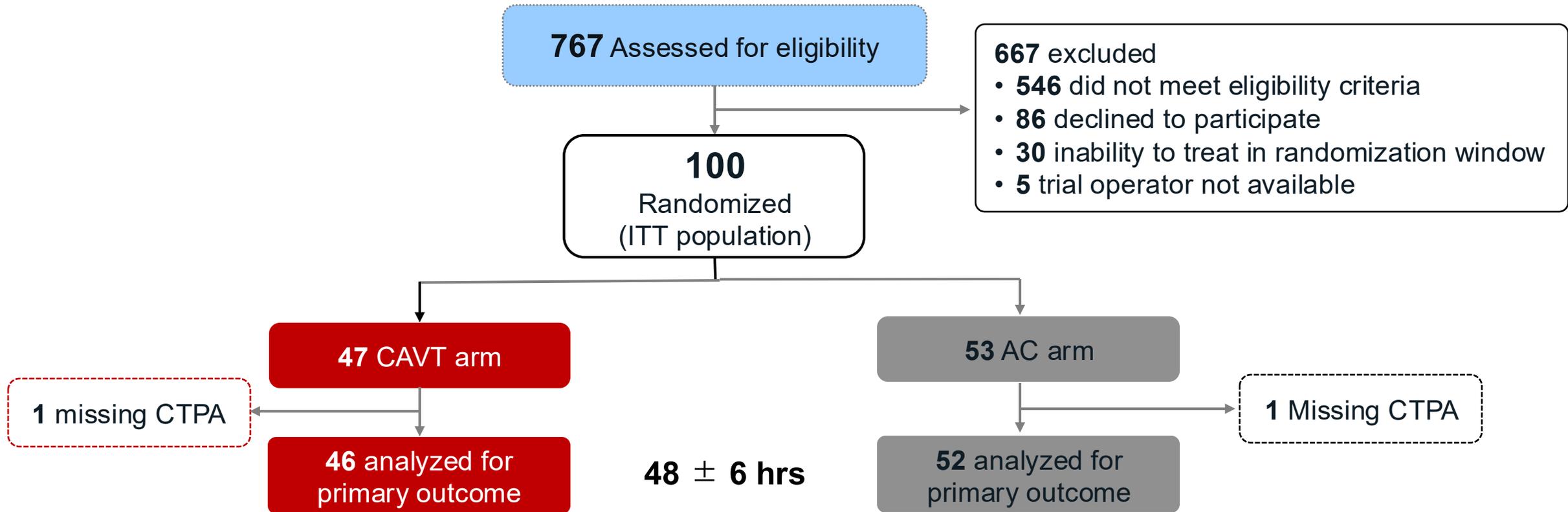
7-day MAE rate assessed in ITT population

Visit Schedule and Data Collection

✓ **Standardized treatment:** initiated within **24** hours from baseline CTPA and **≤ 12** hours from randomization

Baseline → **Day 0** Randomization → **48 Hours** Primary Endpoint → **Discharge** Safety Endpoint → **30 Days** → **90 Days** Final Visit

Baseline	Day 0 Randomization	48 Hours Primary Endpoint	Discharge Safety Endpoint	30 Days	90 Days Final Visit
✓ NEWS2		✓ NEWS2	✓ NEWS2	✓ QoL	✓ QoL
✓ CTPA		✓ CTPA	✓ MAE ≤7 days	✓ Functional	✓ Functional
✓ Vitals		✓ Vitals	✓ Wearable device	✓ Wearable device	✓ Wearable device
✓ QoL					
✓ Functional					

QoL and **Functional** Assessments:

✓ EQ-5D-5L   ✓ PEmb-QoL   ✓ 6MWT*   ✓ mMRC   ✓ PVFS   ✓ Borg scale   ✓ NYHA

*Assessed at 30-day and 90-day follow-up visits

mMRC = modified Medical Research Council Dyspnea Scale; NEWS2 = National Early Warning Score 2; PVFS = Post-VTE (venous thromboembolism) Functional Status Scale.

Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.

Baseline and Medical History Information

Both groups were well matched across key baseline measures

Demographic characteristics	CAVT N=47	AC N=53
Demographic characteristics		
Age (years)	59.5 ± 13.2	61.2 ± 14.2
Female Sex	18 (38.3%)	28 (52.8%)
Race		
White	22 (50.0%)	35 (70.0%)
Black	18 (40.9%)	13 (26.0%)
Other	0 (0%)	1 (2.0%)
Unknown/Not reported	4 (9.1%)	1 (2.0%)
Medical History		
Arterial Hypertension†	21 (44.7%)	35 (66.0%)
Diabetes	9 (19.1%)	9 (17.0%)
DVT	30 (63.8%)	32 (60.4%)
Previous PE	12 (25.5%)	10 (18.9%)

Index PE presentation data	CAVT N=47	AC N=53
Index PE presentation data		
Syncope	9 (19.1%)	8 (15.1%)
Elevated cardiac biomarkers	47 (100%)	53 (100%)
Baseline Clinical Parameters*		
NEWS2	3.5 ± 1.95	4.1 ± 2.07
Heart Rate, bpm	93.2 ± 17.36	98.2 ± 15.87
Oxygen Saturation, %	96.0 ± 2.59	95.4 ± 2.44
RV/LV Ratio	1.63 ± 0.36	1.56 ± 0.35
RMMS	27.3 ± 3.89	26.1 ± 5.51
Baseline Functional Assessments*		
Borg Dyspnea Scale	4.7 ± 2.90	4.5 ± 2.85
mMRC ≥ 1	42 (95.5%)	51 (96.2%)
PVFS	3.0 ± 0.97	2.9 ± 1.01

*Paired data at 48 hours/discharge for CAVT ranged from N=45-46 and for AC N=52-53. Data reported as mean $\pm$ SD or number (%). †P<0.05.
DVT = deep vein thrombosis; RMMS = refined modified Miller score
Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.

Anticoagulation Strategy
No difference between CAVT and AC arm

	CAVT (N=47)	AC (N=53)
AC Strategy		
LMWH Alone	7 (14.9%)	10 (18.9%)
UFH Alone	28 (59.6%)	31 (58.5%)
LMWH and UFH	12 (25.5%)	12 (22.6%)
Time to Therapeutic, hours*		
Any UFH patient	6.8 [4.8, 12.2]	6.4 [4.9, 8.6]

*CAVT N=34 and AC N=38

% of Patients Reaching Therapeutic Level of Anticoagulation Within 48-hour Visit

CAVT (N=46): 87.0%
AC (N=52): 90.4%

Data reported as median [IQR] or number (%).
LMWH = low molecular weight heparin; UFH = unfractionated heparin
Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.
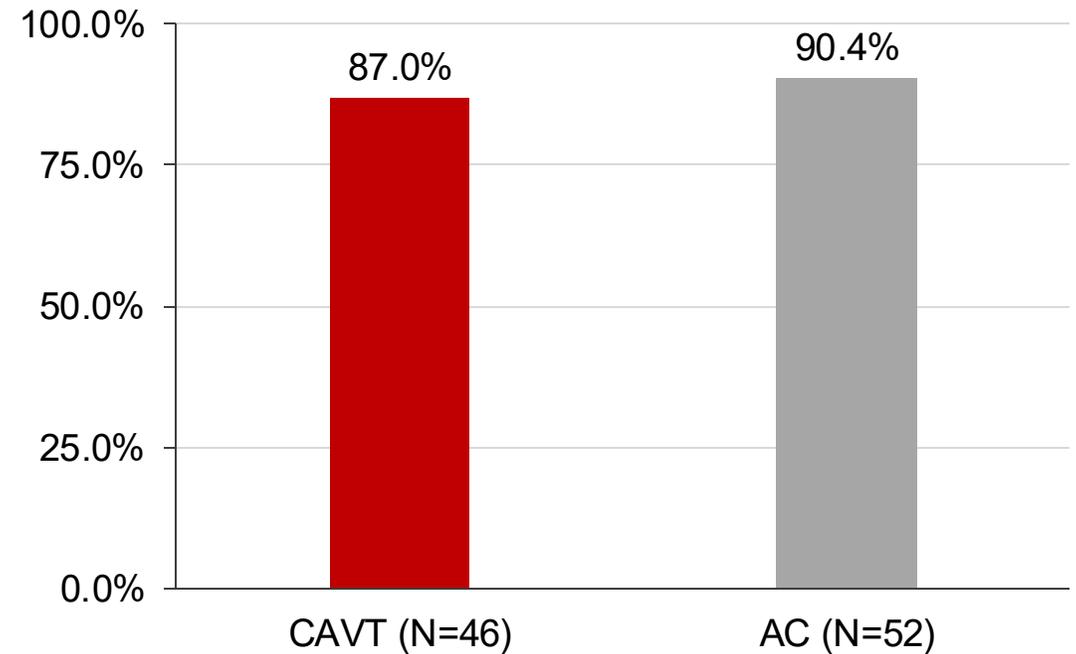
CAVT Arm Procedural Information and Details

	Thrombectomy Time, min (median)	25.0 [15.0, 41.0]
	Procedure Time, min (median)	56.0 [42.0, 69.0]
	Estimated Blood Loss, mL	296.5 ± 179.4
	Technical Success Ability of catheter to access clot and perform aspiration	47/47 (100%)
	Systolic PA Pressure Reduction, mm Hg	-10.8 ± 8.46 (21.7%)
	Mean PA Pressure Reduction, mm Hg	-8.2 ± 5.71 (27.3%)
	Device- or Procedure-related Transfusion	0/47 (0%)
	Access Site Complications	0/47 (0%)

Primary Efficacy Endpoint: RV/LV Ratio
Superior reduction in the CAVT arm

P < 0.001

29.7% relative reduction	vs	13.1% relative reduction

RV/LV Ratio	CAVT	AC	P value
Baseline	1.63 ± 0.36	1.56 ± 0.35	0.397
48 hours	1.11 ± 0.28	1.32 ± 0.31	< 0.001
Absolute Reduction*	**0.52 ± 0.37**	**0.24 ± 0.40**	**< 0.001**

*Paired data CAVT N=46 and AC=52

Bar chart:
- CAVT (N=46): Baseline 1.63, 48 hours 1.11
- AC (N=52): Baseline 1.56, 48 hours 1.32
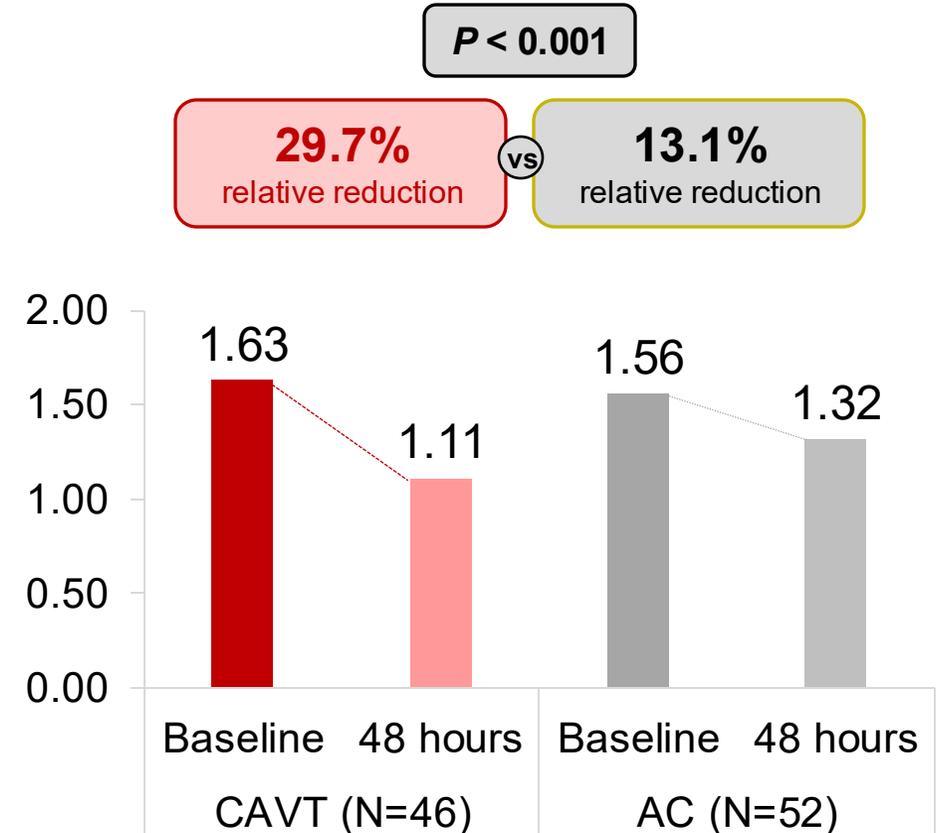
Between-group difference (95% CI) in absolute reduction: Δ 0.27 (0.12, 0.43)

Data reported as mean ± SD
Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.

Secondary Safety Endpoints Through 90 Days
Safety comparable in CAVT and AC arm

	CAVT (N=47)	AC (N=53)	P value
Composite MAE ≤ 7 Days	**2 (4.3%)**	**4 (7.5%)**	**0.681**
Clinical Deterioration Requiring Rescue Therapy	1 (2.1%)	3 (5.7%)	0.620
PE-related Mortality	2 (4.3%)	0 (0.0%)	0.218
Symptomatic Recurrent PE	0 (0.0%)	0 (0.0%)	> 0.999
Major Bleeding*	1 (2.1%)	1 (1.9%)	> 0.999
Additional Details ≤ 7 Days			
Major Bleeding Requiring Transfusion	1 (2.1%)	1 (1.9%)	NA
AC-related MAEs	0 (0.0%)	2 (3.8%)	NA
Device- or Procedure-related MAEs	0 (0.0%)	NA	NA
Secondary Endpoint ≤ 90 Days			
Symptomatic Recurrent PE (90 Days)	1 (2.1%)	1 (1.9%)	> 0.999

All-cause mortality *P*=0.133
PE-related mortality *P*=0.131

CAVT All-cause mortality
CAVT PE-related mortality
AC All-cause mortality
AC PE-related mortality

Freedom from Mortality — Days to Mortality
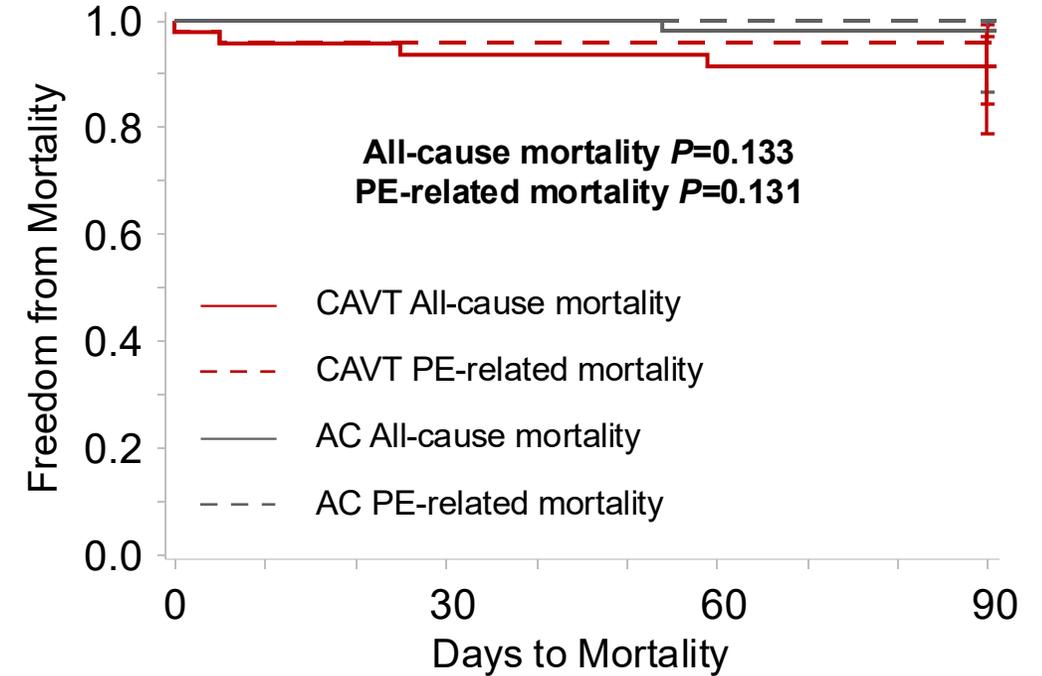
Comparable 90-day safety rates
No device-related mortality
No PE-related mortality >7 days

Vertical bars represent 95% confidence intervals using the log-log transformation

Data reported as number (%). Safety endpoints are not powered for statistical comparisons.
*Death, clinical deterioration, and major bleeding all occurred in the same CAVT patient.
Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.

Change in Thrombus Burden at 48 Hours
Significantly larger reduction in mean RMMS* in the CAVT arm (2.7x)

Degree of thrombus burden

| 2.0 | 1.5 | 1.0 | 0.5 | 0.0 |

← MORE — LESS →

Baseline **48 Hours**

CAVT

42.1%
relative mean reduction

P<0.001

AC

15.6%
relative mean reduction
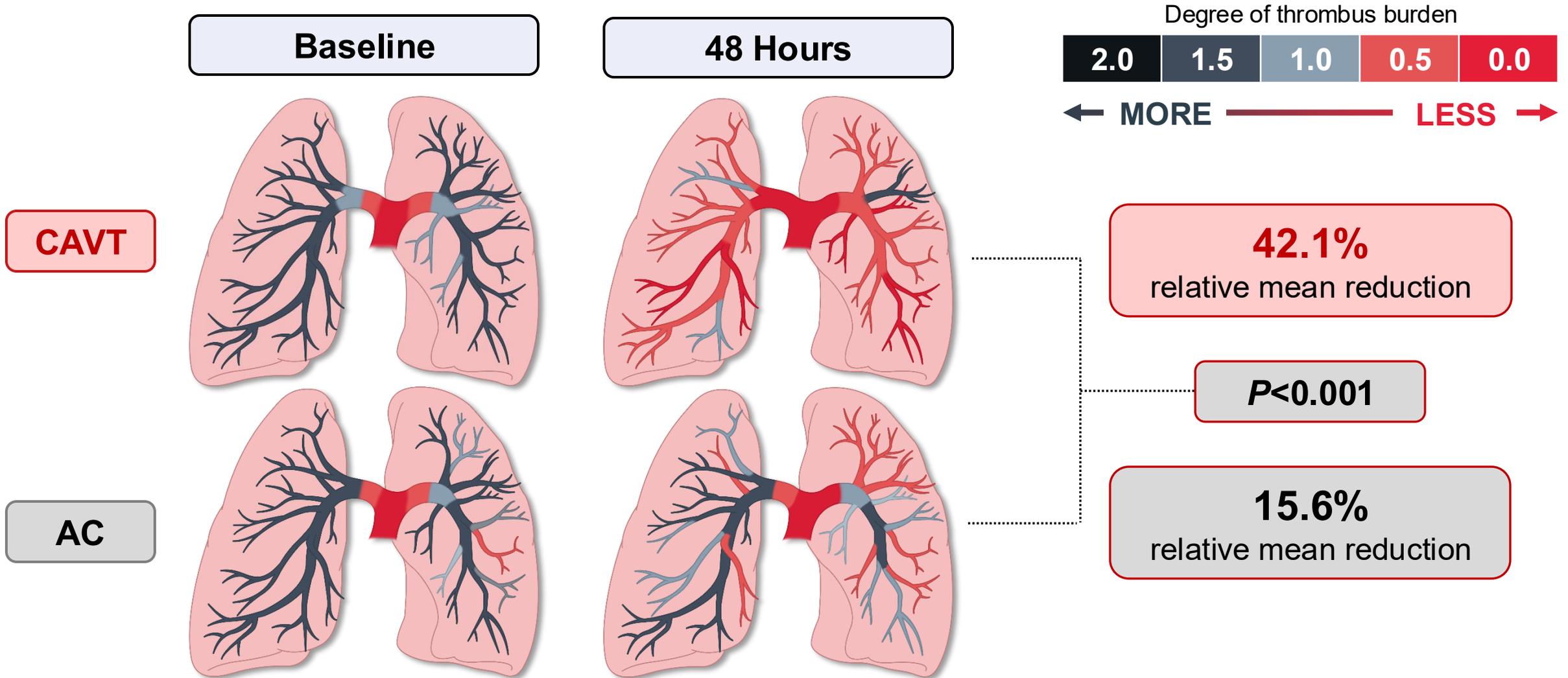
Paired data represented CAVT N=45 and AC N=52. Image based on median per segment scores.
*Adjudicated by a blinded imaging core laboratory
Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.

NEWS2 at Baseline and 48 Hours
Composite score indicating risk of clinical deterioration

48 h *P* = 0.034

CAVT (N=46) — Baseline: 3.5, 48 hours: 1.8

AC (N=53) — Baseline: 4.1, 48 hours: 2.7

Higher Risk / Lower Risk
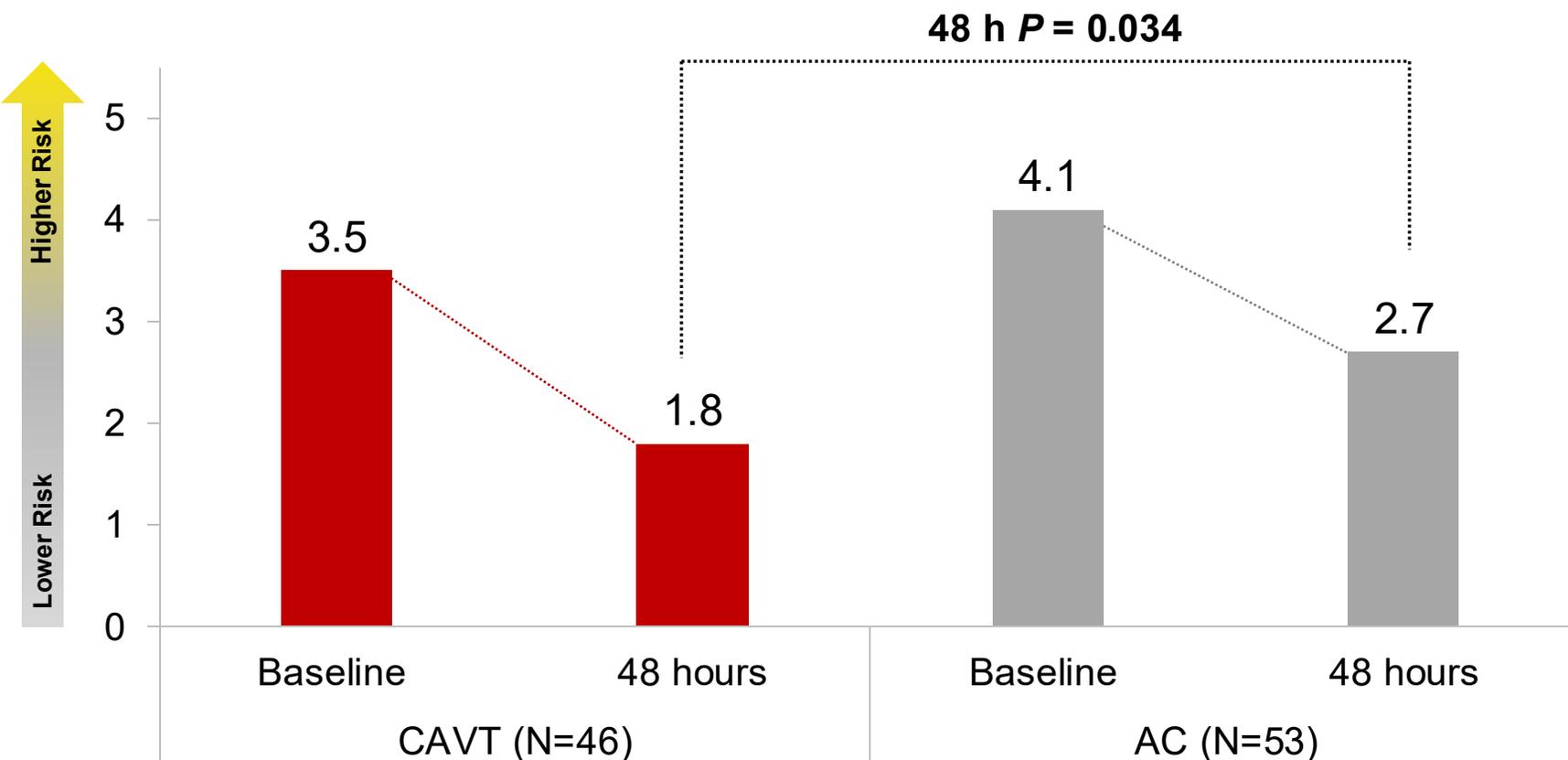
NEWS2 Components
- ✓ Respiratory rate
- ✓ Supplemental oxygen
- ✓ Oxygen requirement
- ✓ Systolic blood pressure
- ✓ Heart rate
- ✓ Consciousness
- ✓ Temperature

CAVT arm had a significantly lower NEWS2 risk at 48 hours

NEWS2 = National Early Warning Score 2
Paired data represented. Data reported as mean.
Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.

Functional Endpoint: PVFS Scale
Functional Limitation Ordinal Scale Focusing on Aspects of Daily Life

P value

Pre-PE Event to Discharge — OR 2.2 — 0.032

Baseline to Discharge — OR 2.0 — 0.067

Favors AC ← → Favors CAVT

0.1   1.0   10.0

Odds Ratio (log scale)
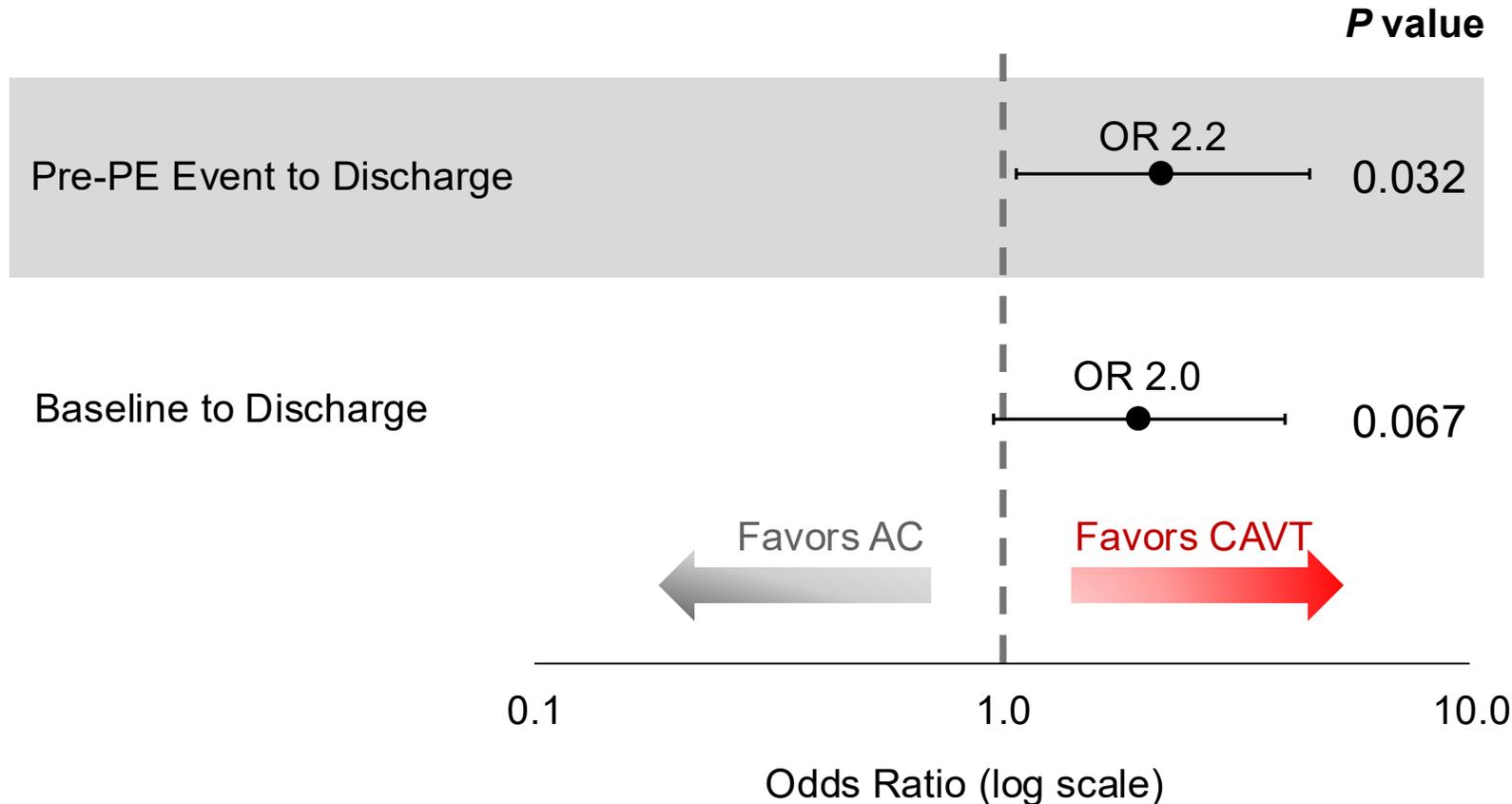
CAVT patients were 2.2x more likely to move toward their pre-PE functional status
(significantly less change in PVFS score from pre-PE event to discharge)

Complete case data used.
Lookstein RA, et al. Presented at: TCT 37th Annual Symposium; 2025.

Functional Endpoint: 6 Minute Walk Test (6MWT)

Mean 6MWT Distance (6MWD), meters

Mean Δ 6MWD Between 30 & 90 Days

500

472

450

P = 0.019

400

387

376

P = 0.099

350

328

300

30 days   90 days

--▲-- CAVT (N=27)   ···●··· AC (N=29)

CAVT   Δ 85

AC   Δ 48

0   20   40   60   80   100
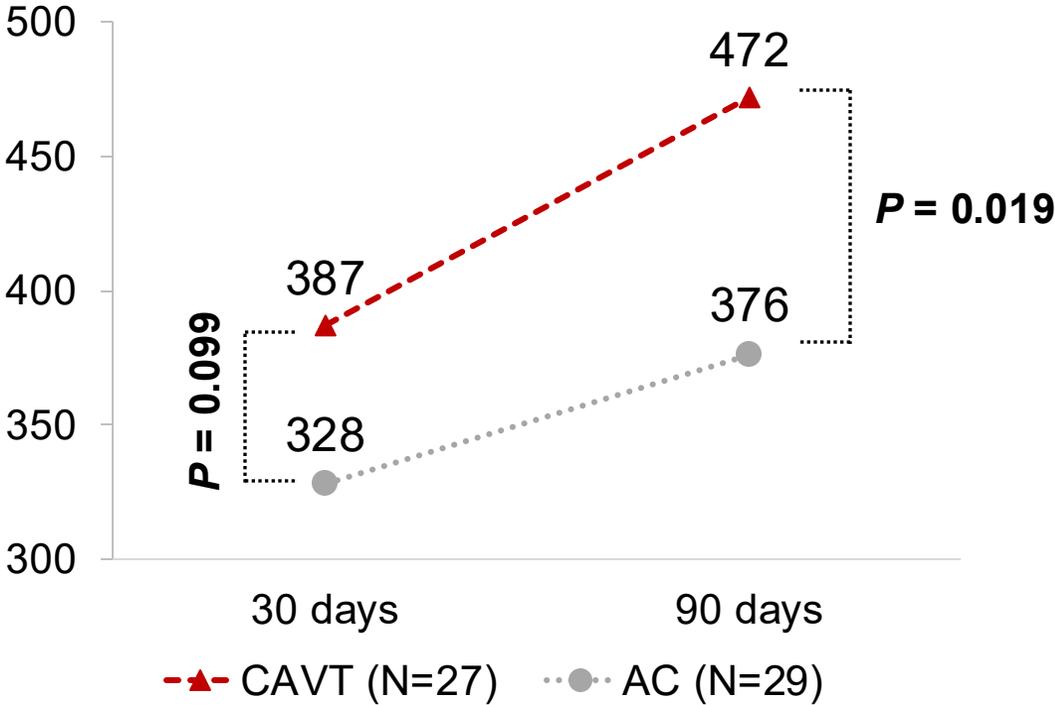
Distance, meters
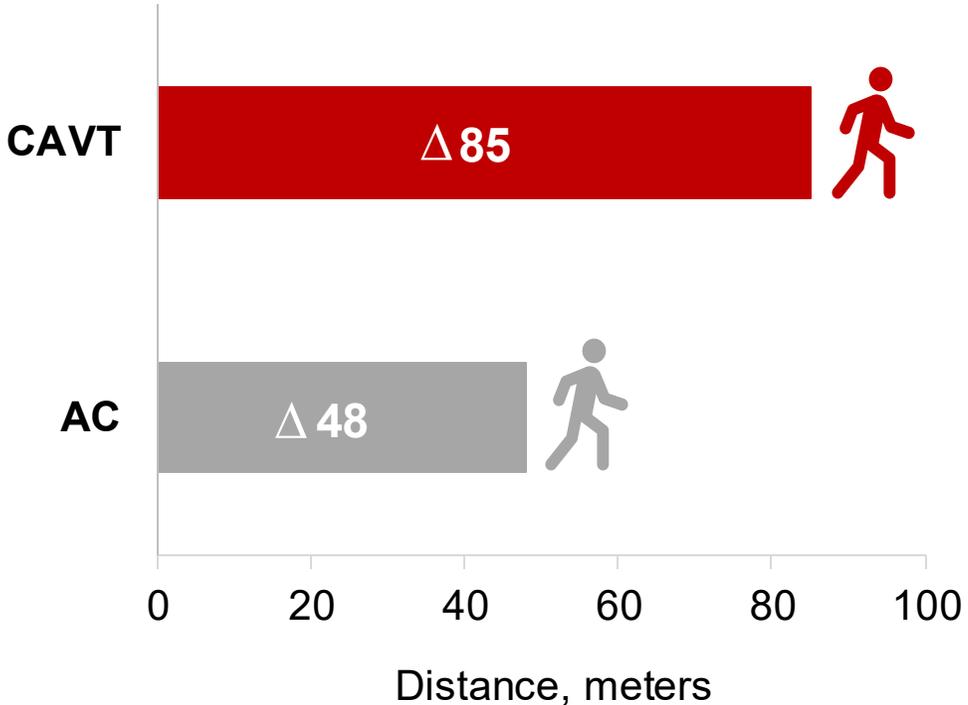
CAVT patients walked significantly farther at 90 days & had a 1.8x improvement in walking distance from 30 to 90 days compared to AC alone

Conclusion

STORM-PE is the first RCT to report the results of mechanical thrombectomy with AC versus AC alone.

The CAVT arm demonstrated **superior reduction in RV dilatation** and a similar safety profile to the AC arm.

Treatment with CAVT resulted in reduced PA pressures, **early physiological recovery** and greater reduction in pulmonary obstruction compared to AC alone.
- RMMS, heart rate, oxygen, and NEWS2
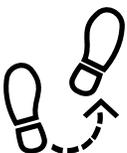
Patients treated with CAVT demonstrated **greater improvement in functional outcomes**.
- PVFS, 6MWT

These promising results reinforce the role of mechanical thrombectomy, specifically **CAVT**, as an **effective treatment strategy** in patients with acute intermediate-high-risk PE.

Thank You

In partnership with The PERT Consortium®

Sites

Ascension Seton Austin, TX, USA	**Kingwood Hospital** Kingwood, TX, USA	**Rush University Medical Center** Chicago, IL, USA
Auckland City Hospital Grafton, Auckland, New Zealand	**Krakowski Szpital Specjalistyczny św. Jana Pawła II** Krakow, Poland	**Sentara Norfolk General Hospital** Norfolk, VA, USA
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Corewell Health Dearborn Hospital Dearborn, MI, USA	**Northwestern Memorial Hospital** Chicago, IL, USA	**University of Maryland Medical Center** Baltimore, MD, USA
Foothills Medical Centre Calgary, Alberta, Canada	**Radiology and Imaging Specialists** Lakeland, FL, USA	**Wellstar Health System** Marietta, GA, USA
Joseph Maxwell Cleland Atlanta VA Medical Center Decatur, GA, USA		

Blinded, Independent, Imaging Core Laboratory VasCore, Boston, MA, USA	Clinical Events Committee (CEC) NAMSA Northwood, OH	Data Safety Monitoring Board (DSMB) NAMSA, Northwood, OH

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UCLA

Richard Davis
Patient Steering Committee
Representative

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Vascular Medicine
Massachusetts General
Brigham

A Prospective, Multicenter, Randomized Controlled Trial Evaluating Anticoagulation Alone vs Anticoagulation plus Computer Assisted Vacuum Thrombectomy for the Treatment of Intermediate-High-Risk Acute Pulmonary Embolism: Rationale and Design of the STORM-PE Study

Rachel P. Rosovsky, MD, MPH; Stavros V. Konstantinides, MD, FESC; John M. Moriarty, MD; Suhail Y. Dohad, MD; Ido Weinberg, MD; Sahil A. Parikh, MD; Richard N. Channick, MD; Robert A. Lookstein, MD, MS, FSIR, FAHA, FSVM;

Randomized Controlled Trial of Mechanical Thrombectomy with Anticoagulation Versus Anticoagulation Alone for Acute Intermediate-High Risk Pulmonary Embolism: Primary Outcomes From the STORM-PE Trial

Robert A. Lookstein, MD, MS, FSIR, FAHA, FSVM; Stavros V. Konstantinides, MD, FESC; Ido Weinberg, MD; Suhail Y. Dohad, MD; Zachary Rosol, MD, FACC, FSCAI; Grzegorz Kopeć, MD, PhD; John M. Moriarty, MD; Sahil A. Parikh, MD; Andrew Holden, ONZM, MBChB, FRANZCR, EBIR; Richard N. Channick, MD; Braedon McDonald, MD, PhD, FRCPC; Khanjan H. Nagarsheth, MD; Kei Yamada, MD; Rachel P. Rosovsky, MD, MPH, for the STORM-PE Trial Investigators

CardioVascular Learning Network | CME

PE Cases

Suhail Dohad, MD, FACC, RVT
Director of Complex Coronary Intervention
and Endovascular Fellowship
Medical Director of Aortic and Ischemic Limb
Disease
Los Angeles, California

Case 1

Case 1

HPI: 60-year-old African American female with no PMH presented with **1 day of acute exertional left-sided chest pain/SOB**, **syncopal episode** at 0630 prior to presenting to the ED.

ROS: No fever, chills, cough, dizziness, LE swelling. No head trauma. Not on anticoagulation. No recent travel, emotional stress/events, or weight gain.

PMH: None, but no routine care

SH/FH: NC

All: NKDA

Meds: None

VS: 164/99, HR 80, RR 19, 98% RA.

Initial labs: trop 0.23→0.27, Hb 12.4, WBC 9, Na 141, glucose 128, K 4.2.

CXR cardiomegaly, slightly increased pulmonary vasculature.

PMH = past medical history; SOB = shortness of breath; ED = emergency department; ROS = review of symptoms; LE = lower extremity; SH/FH = social history/family history; NKDA = no known drug allergy.

25 mm/s   10 mm/mV   150 Hz   4x2.5s + 3 channels...   Pace: ● On   ○ Off
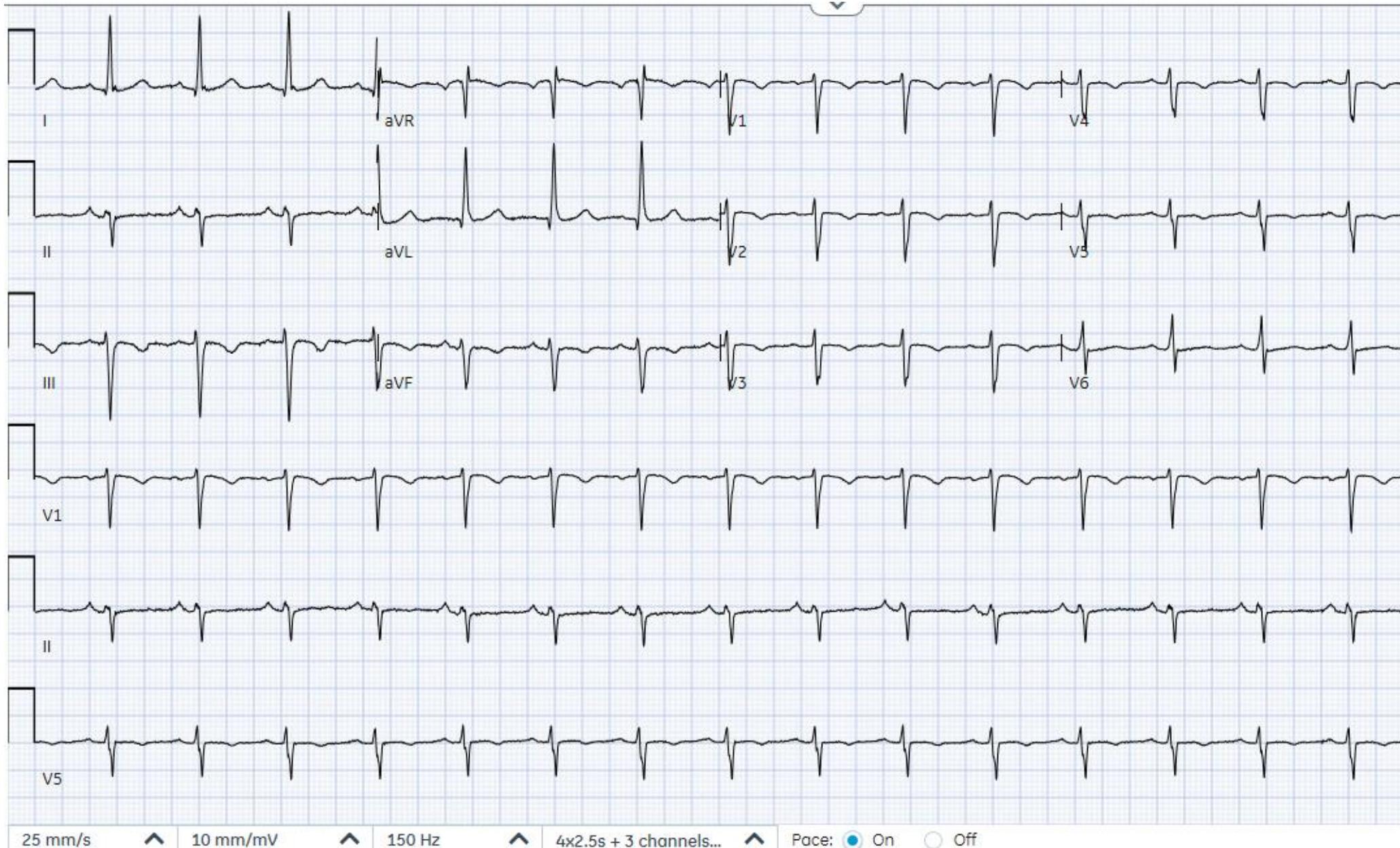
Case 1

A&P: Inpatient admission for ACS rule out and syncope work up

ED course

- Syncope in the ED bathroom
- Persistent PEA arrest, CPR x 45 mins
- Emergently cannulated for VA ECMO at bedside (noted minimal pulsatility)
- ECG with concerns for ?borderline STE inferior leads
- Tele: Vfib where she received shocks x 2
- Labs: COVID +
- Brought to cath lab for emergent coronary angiogram, Impella CP®, +/- pulmonary angiogram

A&P = assessment and plan; ACS = acute coronary syndrome; PEA = pulseless electrical activity; CPR = cardiopulmonary resuscitation;
VA ECMO = venoarterial extracorporeal membrane oxygenation; ECG = electrocardiogram; STE = ST elevation.

Repeat ECG

25 mm/s   10 mm/mV   150 Hz   4x2.5s + 3 channels...   Pace: ● On   ○ Off
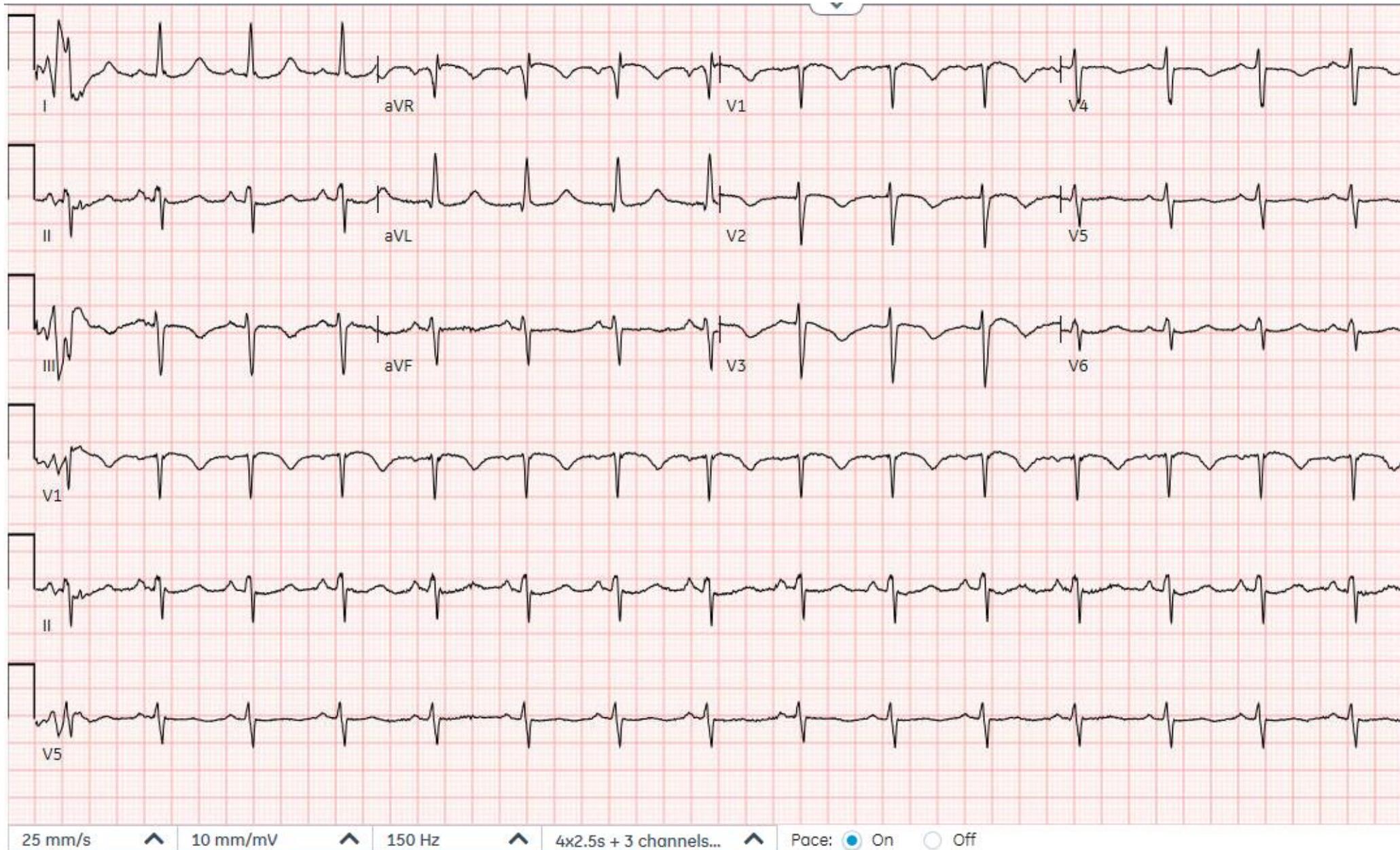
Coronary Angiogram
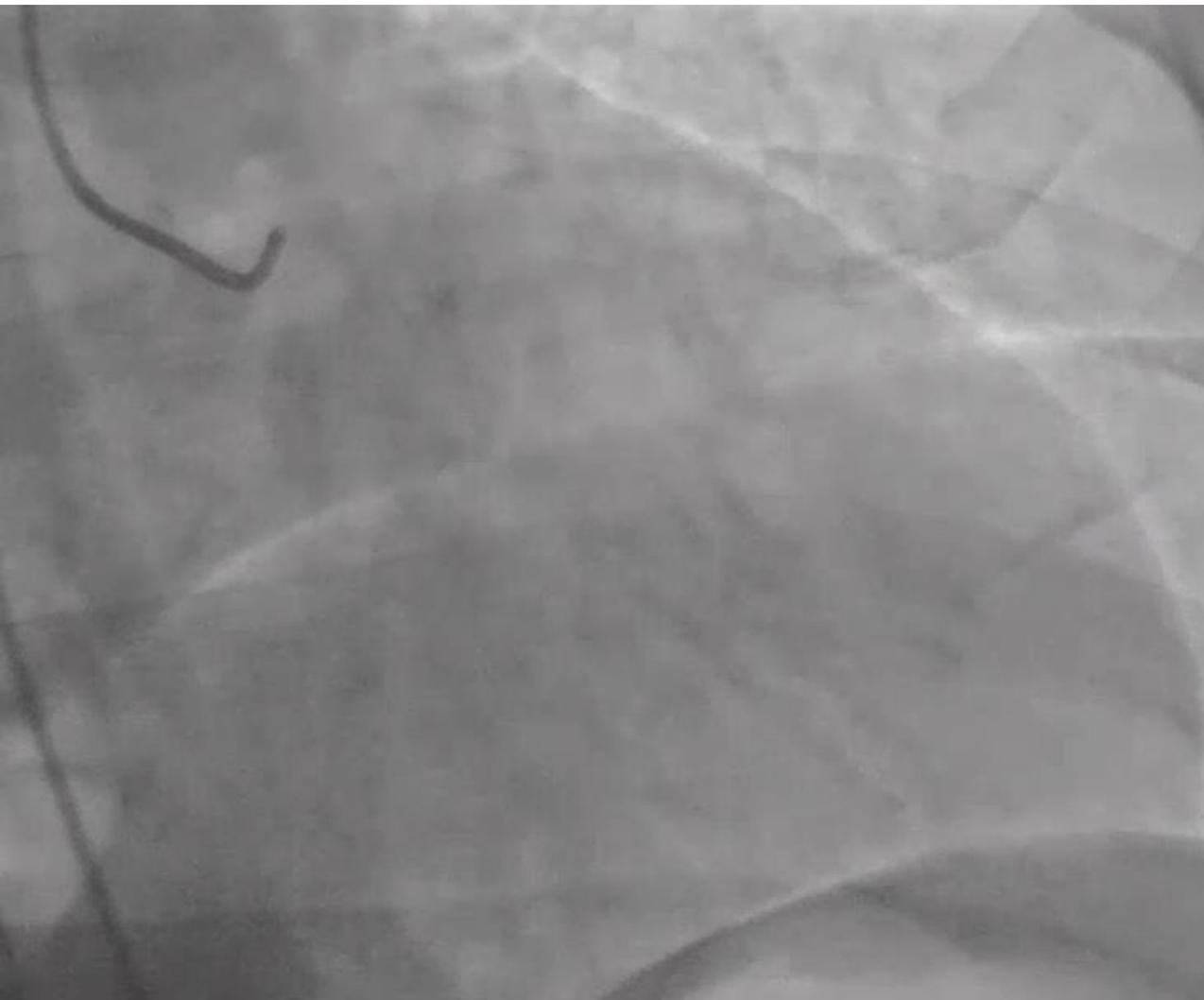
Coronary Angiogram

Right dominant circulation. No significant CAD.
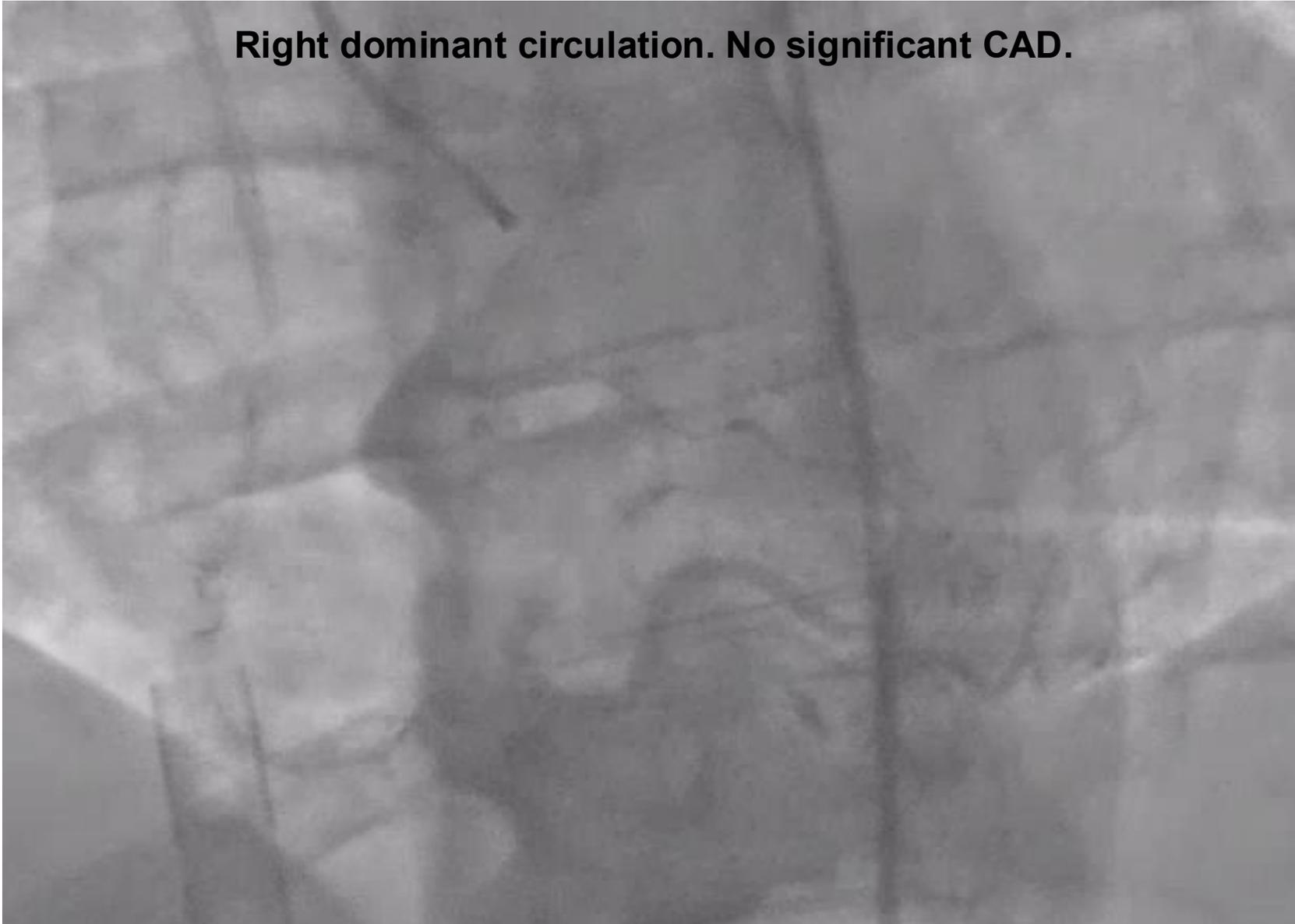
CAD = coronary artery disease.

Central venous catheter

Impella CP placement via RFA
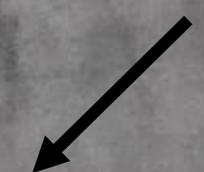
6 Fr pigtail with a 0.035"
angled glidewire via
LFV into PA

Venous cannulation

RFA = retrograde
femoral artery; LFV =
left femoral vein; PA =
pulmonary artery.

Baseline Bilateral Pulmonary Angiogram

Extensive bilateral PEs

PE = pulmonary embolism.
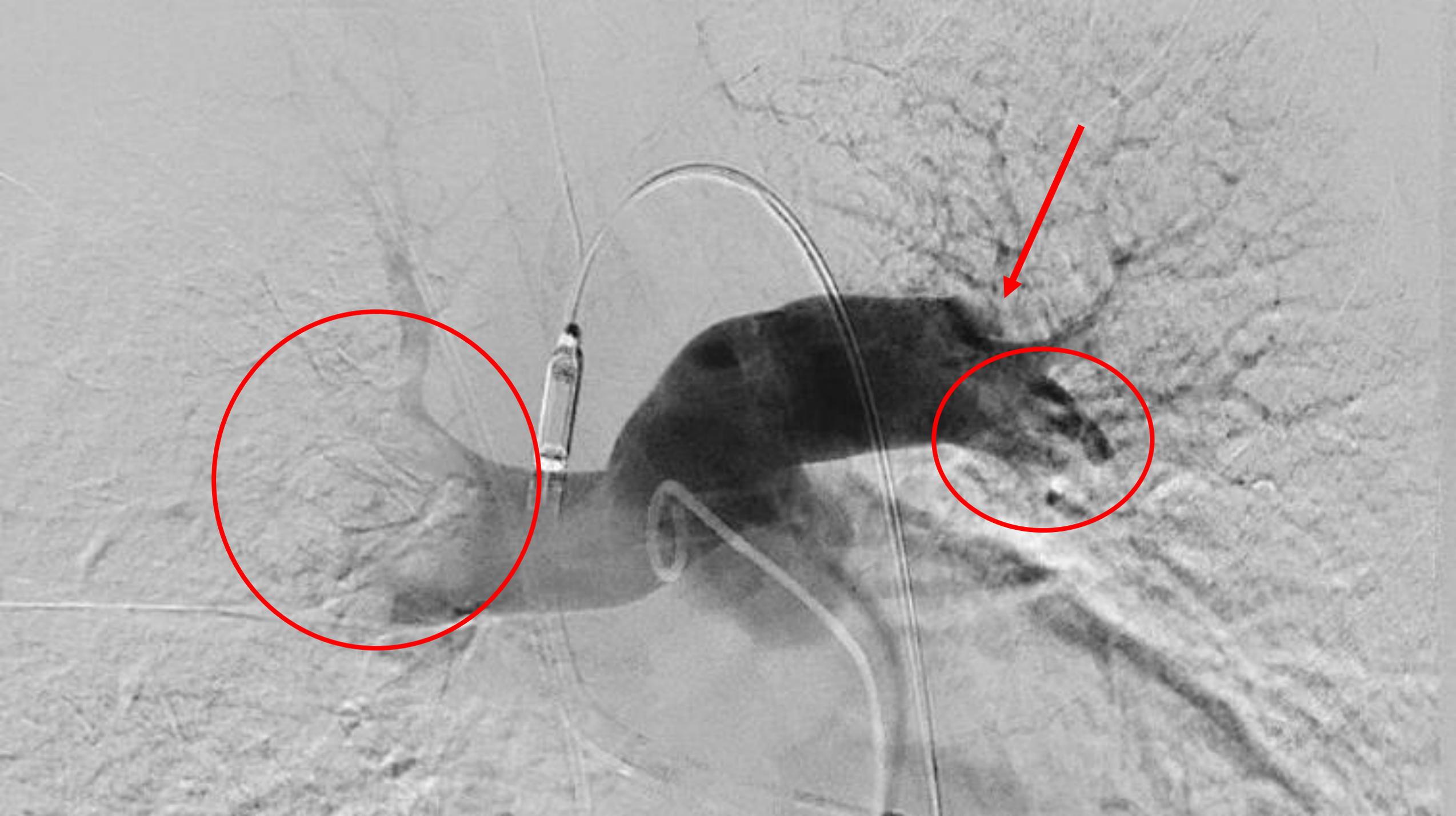
190 cm Amplatzer Super Stiff
16 Fr Dryseal Gore Sheath

16 Fr Penumbra Flash (R side)
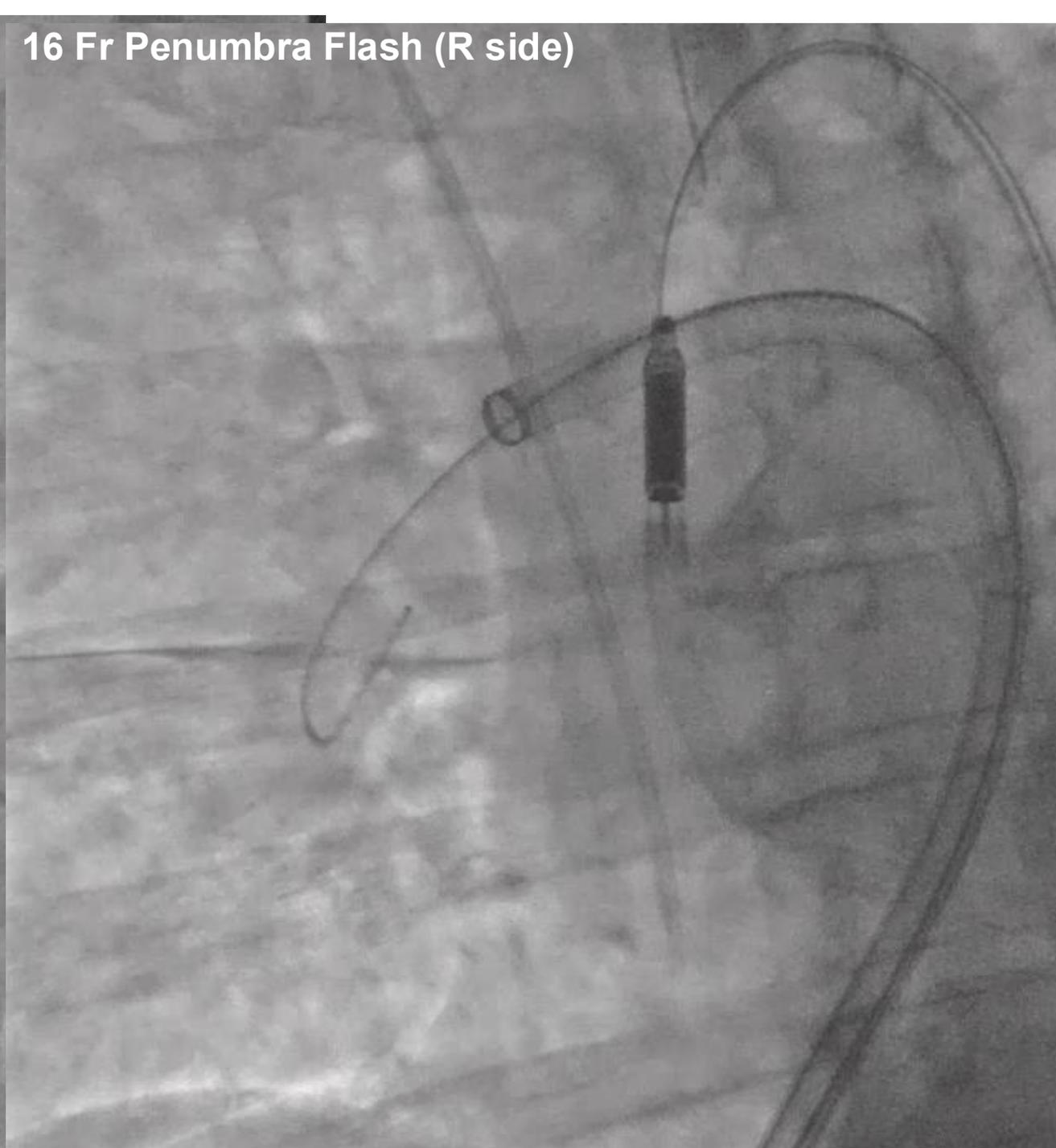
Using a 5 Fr Bertstein catheter and an angled glidewire, redirect Penumbra Flash to the contralateral side
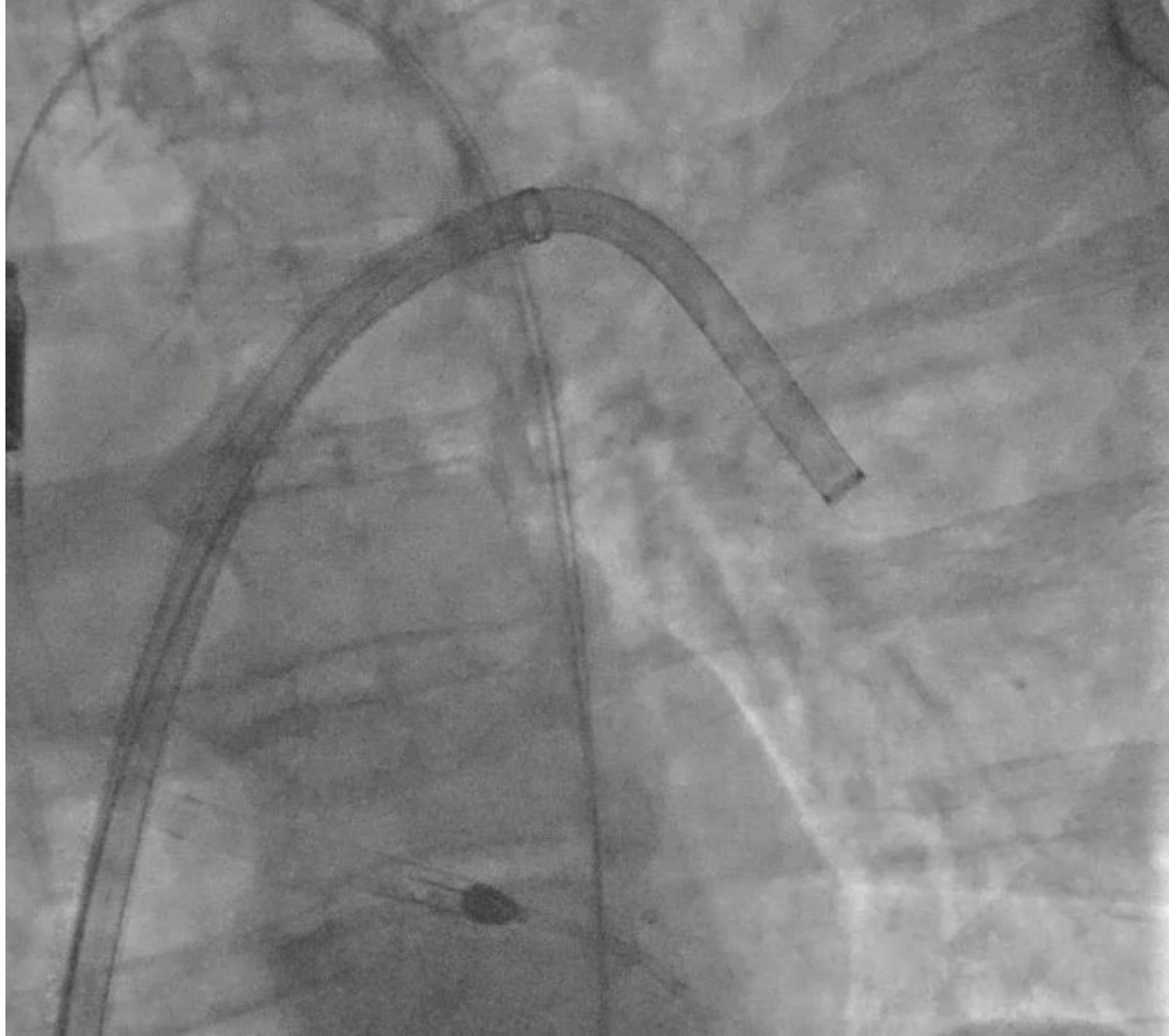
*Decreased VA ECMO flow down to 1.5 L while performing aspiration thrombectomy

Final Bilateral Pulmonary Angiogram
Improved pulmonary flow bilaterally
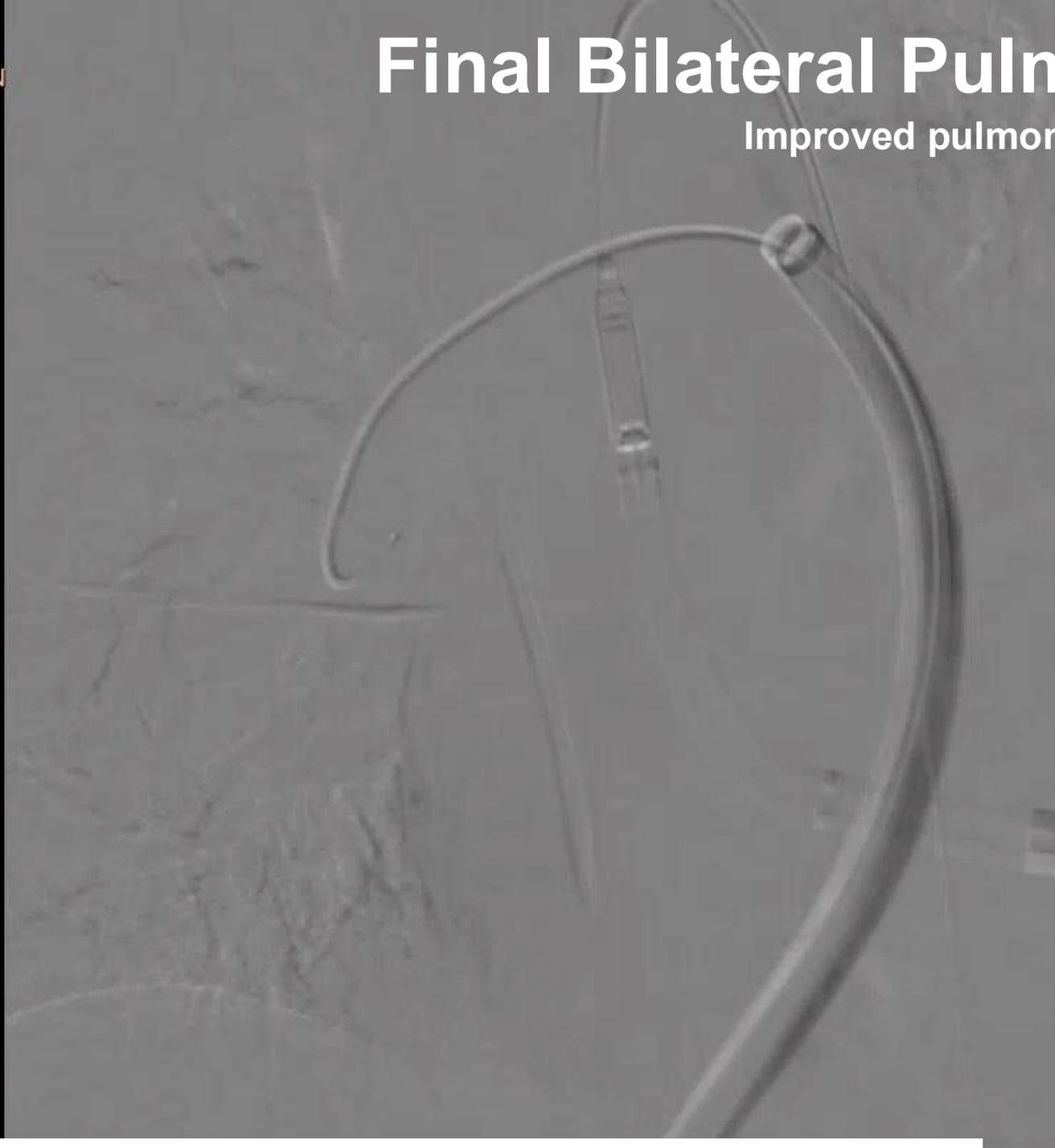
Before
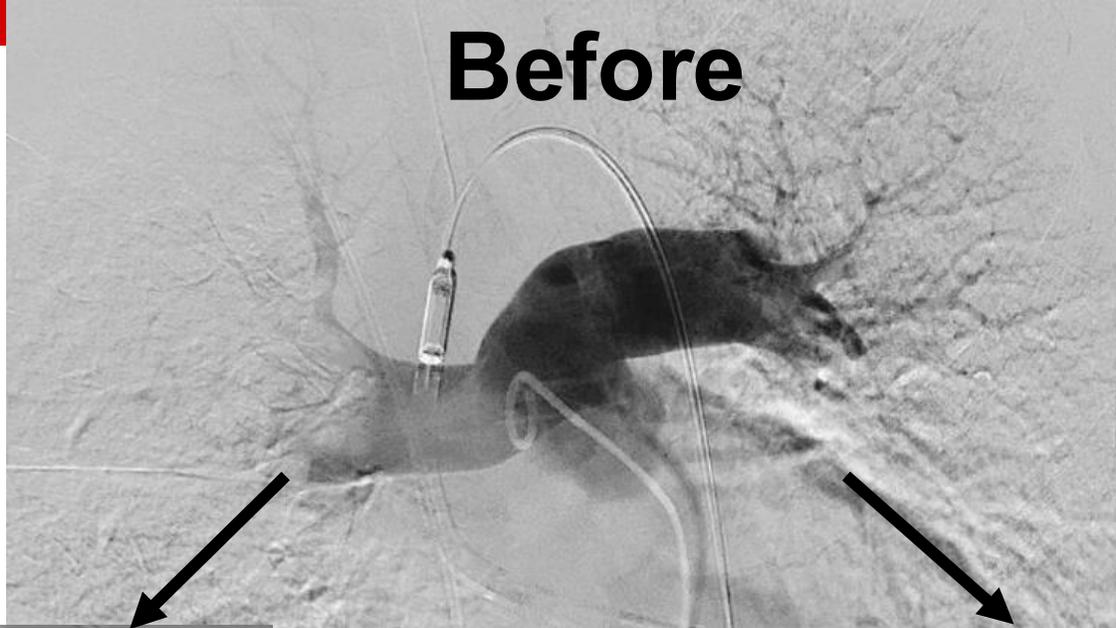
After
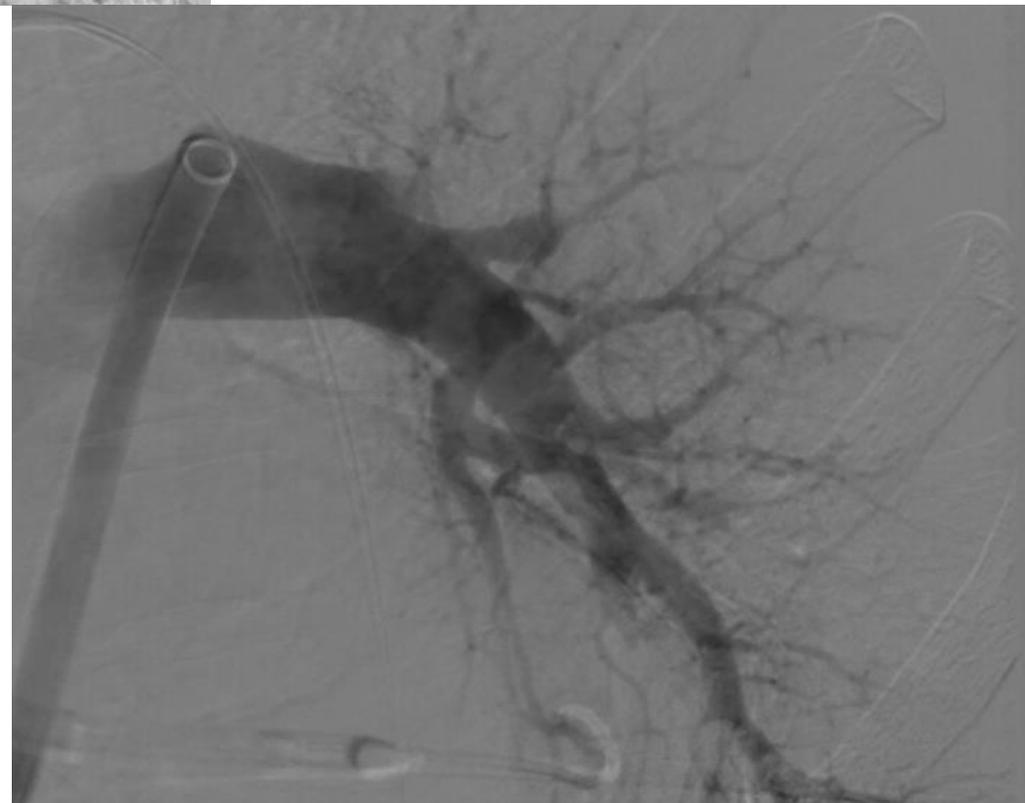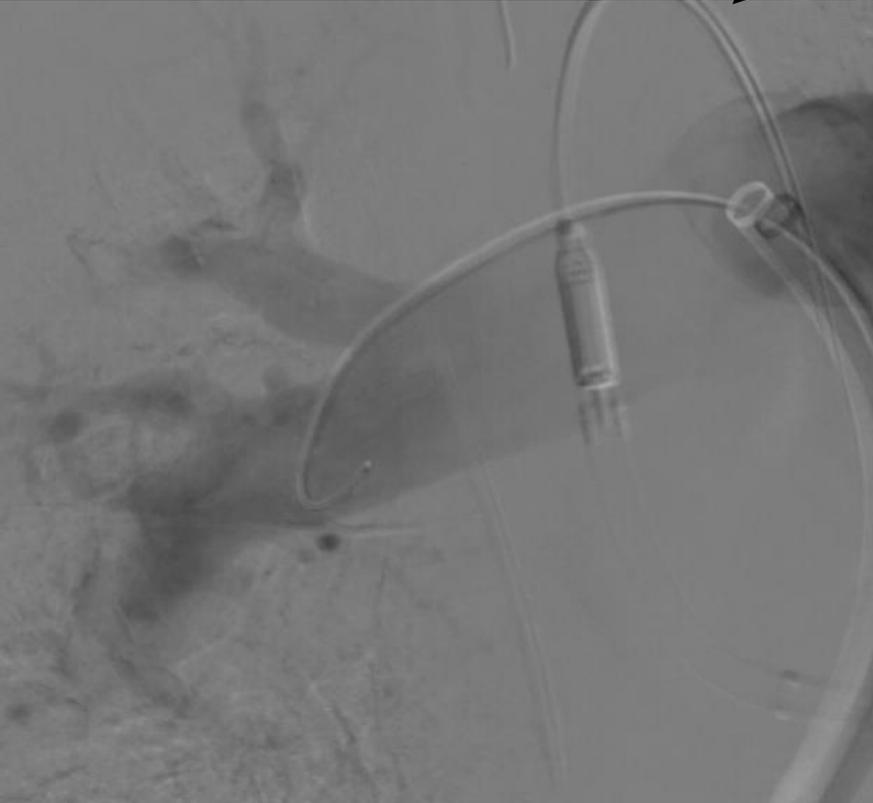
Case: STORM—Therapy Escalation?

Case 2

- Patient is a 68 y/o AA female with a BMI of 45 with long-standing h/o HTN, hyperlipidemia, mild renal dysfunction, and mild diabetes

- Admitted with SOB—had been unwell for a week and unable to walk to the bathroom for last 2 days

- Progressively weak and SOB and brought by her daughter to the ER—CT angio shows large b/l pulmonary emboli

- Tries to be active—recently limited by Achilles injury and wearing a boot on her right ankle/foot.

	08/13/24 1729
HGB	13.9
CREAT	**1.54***
K	4.0
BNP	**1,032***

	08/13/24 1729
GLUC	**117***
NA	139
K	4.0
CL	104
CO2	25
ANIONGAP	14
BUN	**28.4***
CREAT	**1.54***
CA	9.9

BMI = body mass index; h/o = history of; HTN = hypertension; ER = emergency room; CT = computed tomography; b/l = bilateral; HGB = hemoglobin; K = potassium; BNP = B-type natriuretic peptide; NA = sodium; CL = chloride; CO2 = carbon dioxide; BUN = blood urea nitrogen; CA = calcium.

Physiological parameter	Score						
	3	2	1	0	1	2	3
Respiration rate (per minute)	≤8		9–11	12–20		21–24	≥25
SpO$_2$ Scale 1 (%)	≤91	92–93	94–95	≥96			
SpO$_2$ Scale 2 (%)	≤83	84–85	86–87	88–92 / ≥93 on air	93–94 on oxygen	95–96 on oxygen	≥97 on oxygen
Air or oxygen?		Oxygen		Air			
Systolic blood pressure (mmHg)	≤90	91–100	101–110	111–219			≥220
Pulse (per minute)	≤40		41–50	51–90	91–110	111–130	≥131
Consciousness				Alert			CVPU
Temperature (°C)	≤35.0		35.1–36.0	36.1–38.0	38.1–39.0	≥39.1	

National Early Warning score

From Royal College of Physicians 2012

Originally consisting of pulse rate, respiratory rate, blood pressure, temperature, and oxygen saturation, it was updated in 2017 to NEWS2, which incorporated new onset of confusion and a separate scoring system for oxygen saturation in patients with type 2 respiratory failure.

Royal College of Physicians (RCP). *National Early Warning Score (NEWS) 2: Standardising the assessment of acute-illness severity in the NHS*. Updated report of a working party. RCP; 2017.

Post-admission EKG and echo with McConnel sign
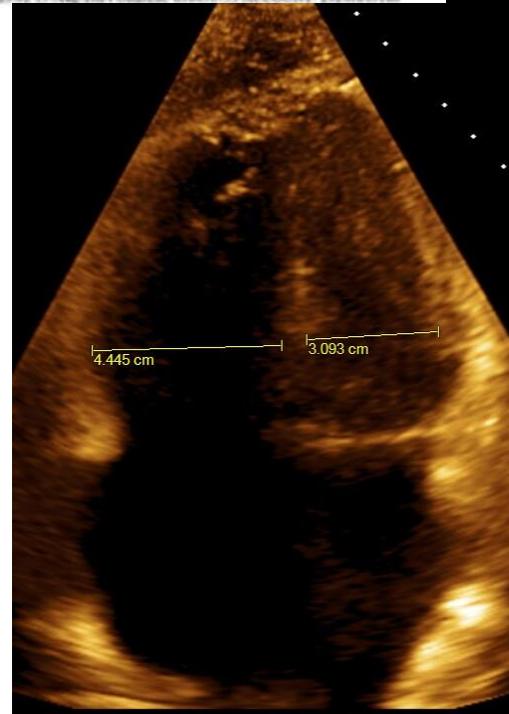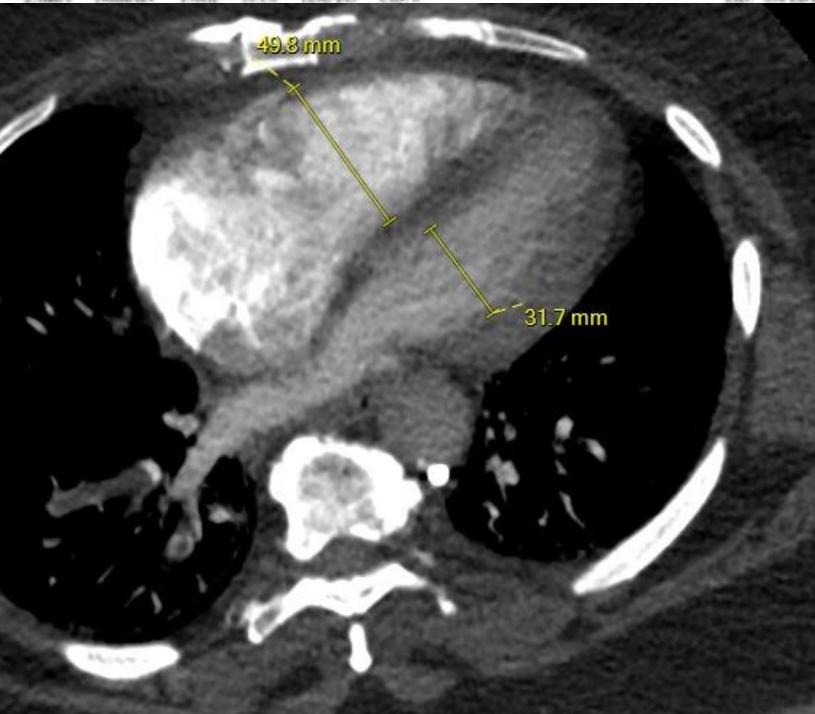
RV/LV ratio 1.44 by echo

RV/LV ratio 1.57 by CT angio

EKG = electrocardiogram; RV = right ventricular; LV = left ventricular.
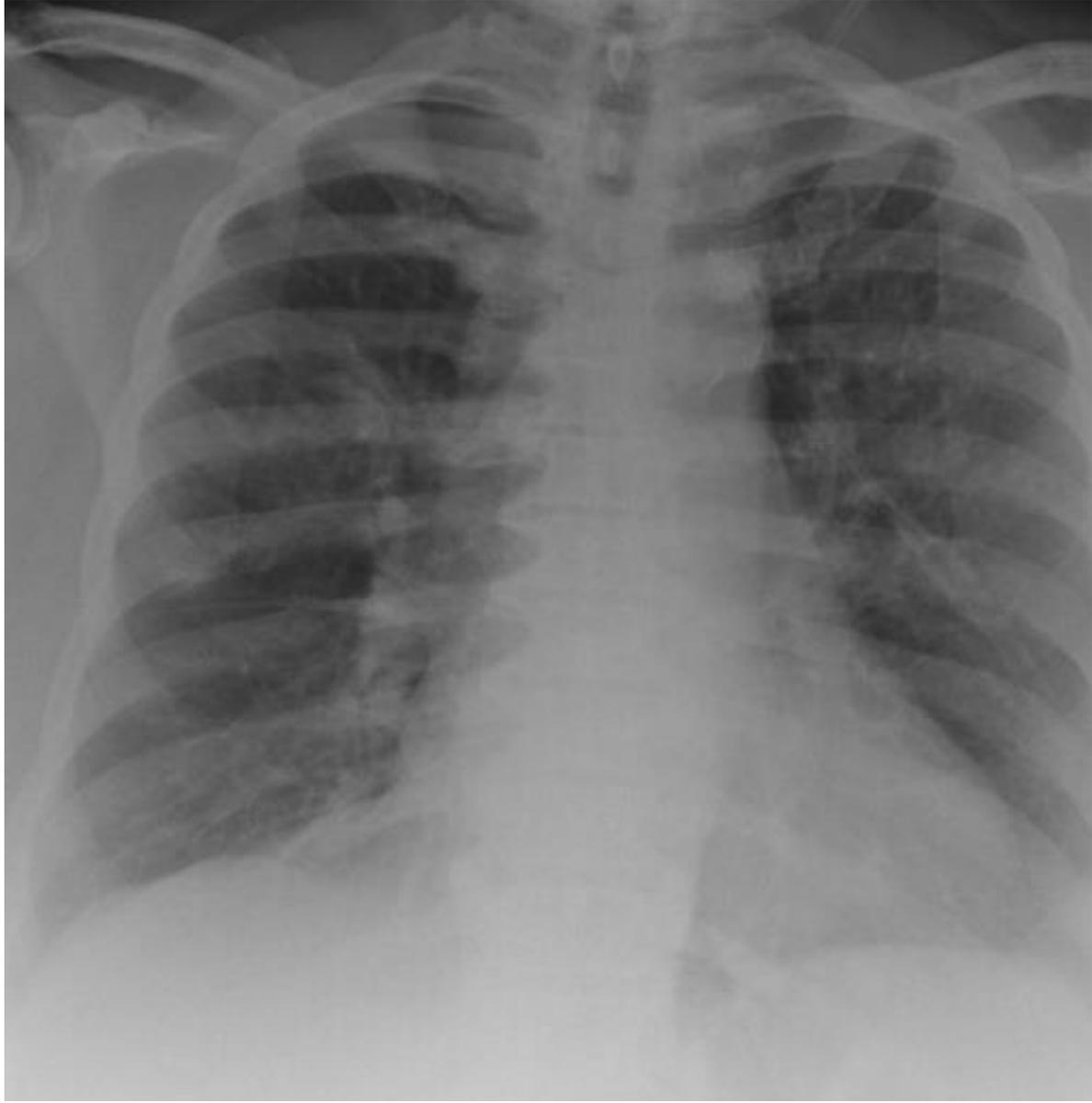
Repeat CT angio at 48hrs—large clot burden on left—mild improvement on right
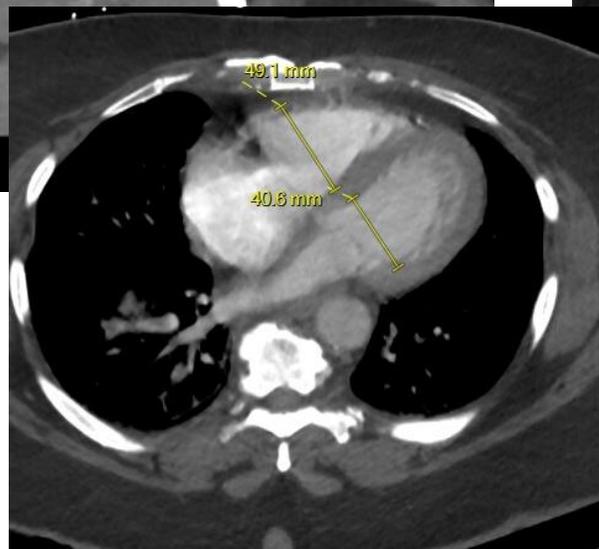
RV/LV ratio by CT at 48 hrs—1.22

8/15/2024 11:04:18 Saved strip re-labeled to SR (YAZ) PR 0.19 QRS 0.09 RR 0.74 QT 0.35 QTc 0.41
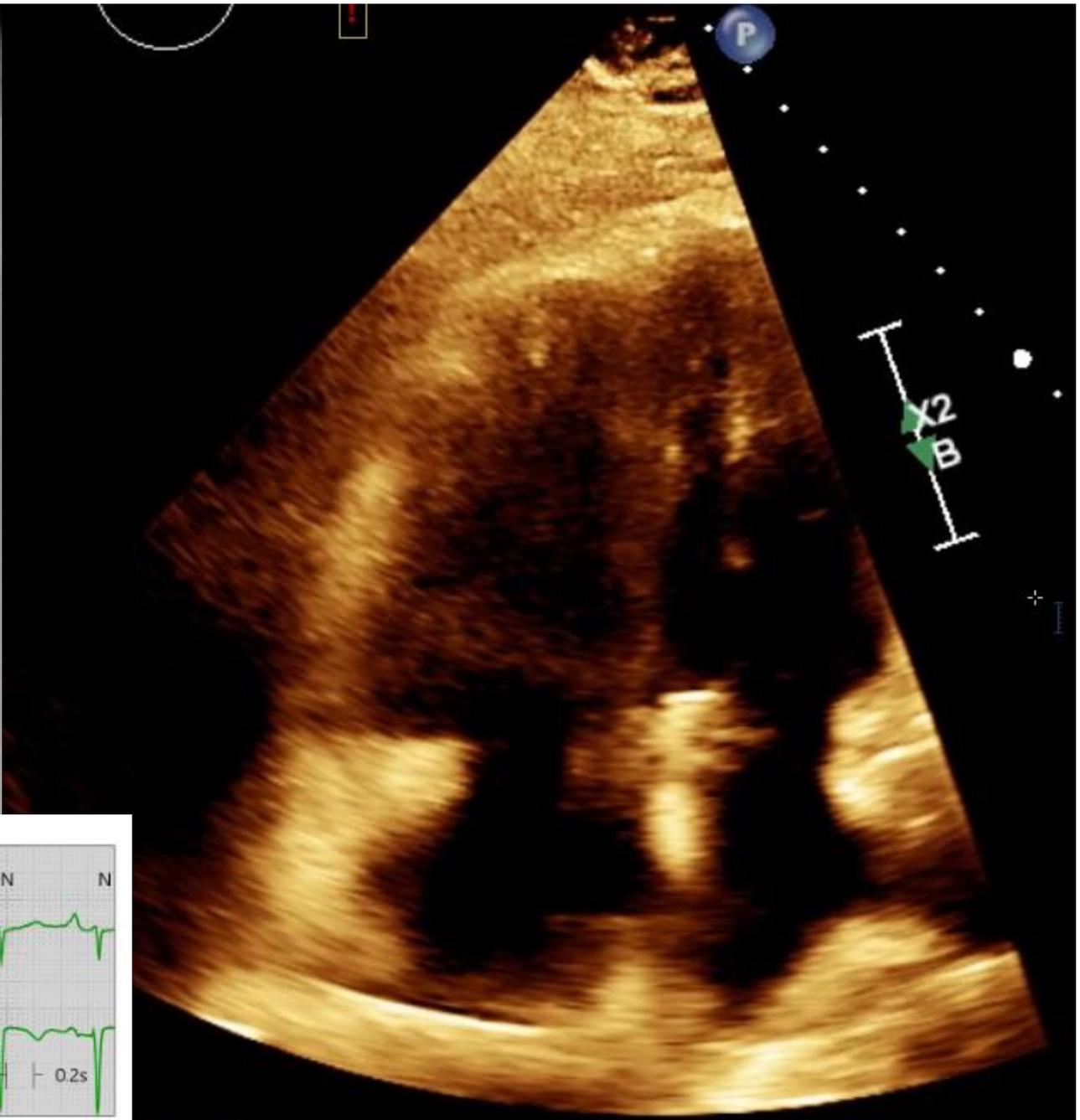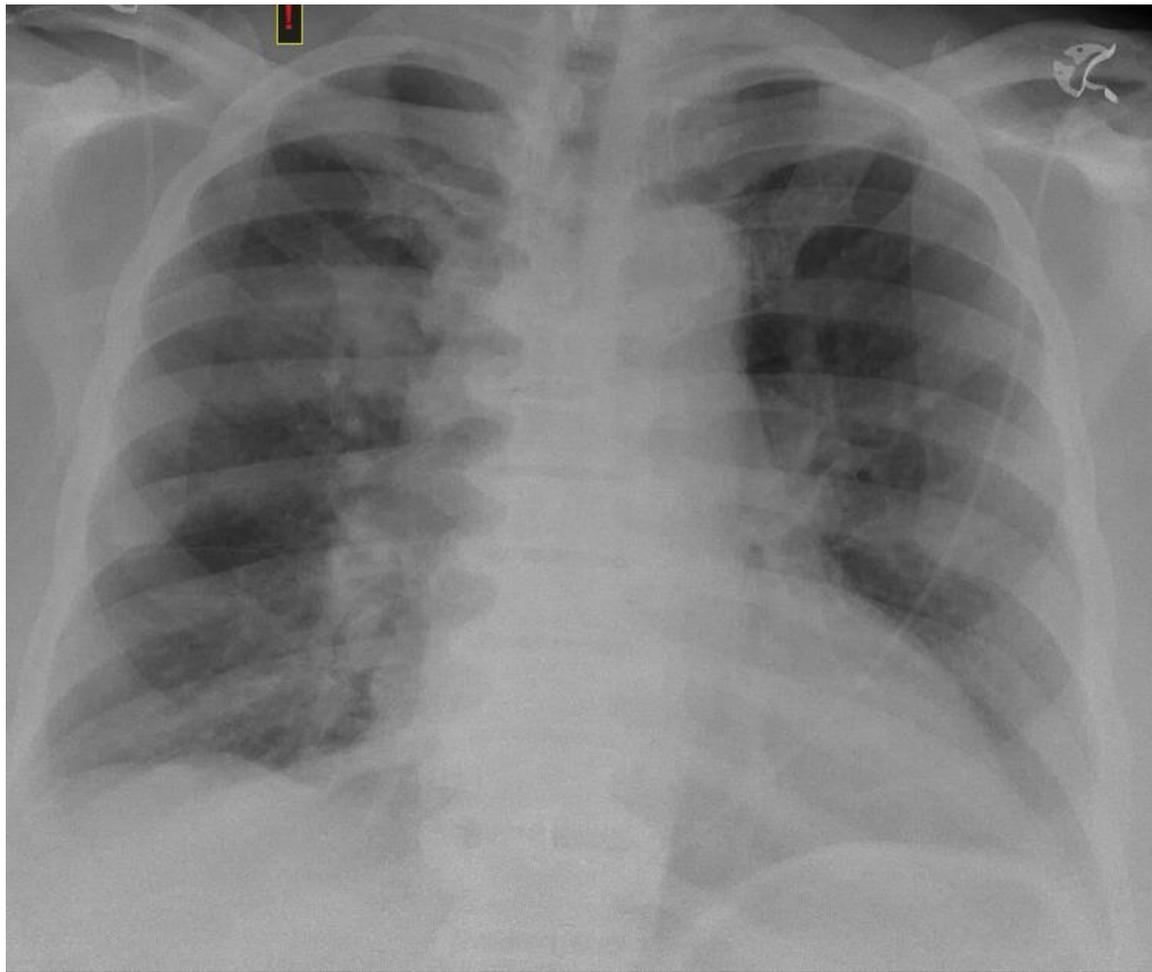
8/18/2024—Discharged 8/21/24

- Progressive dry cough—no hemoptysis—repeat CT and CXR done show—? Pulmonary infarction vs pneumonitis.

- Extensive thrombus, but NEWS2 score remains low: -6

- Still on nasal oxygen with easy desaturation with any activity and heart rate to 120s

- Poor exercise/effort tolerance

- No other complaints and no bleeding issues

- DVT with small amount of remaining thrombus by duplex in calf veins

8/16/2024 15:00:09 Saved strip re-labeled to SR CESAR PR 0.16 QRS 0.11 RR 0.67 QT 0.36 QTc 0.44

3/20/2024 01:45:36 Saved strip re-labeled to SR MLC) PR 0.19 QRS 0.07 RR 0.74 QT 0.39 QTc 0.45
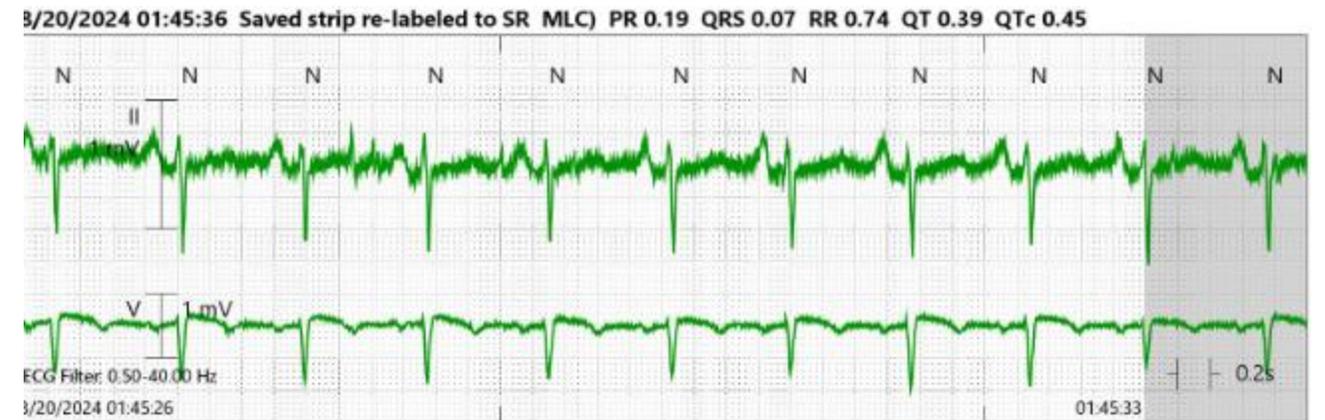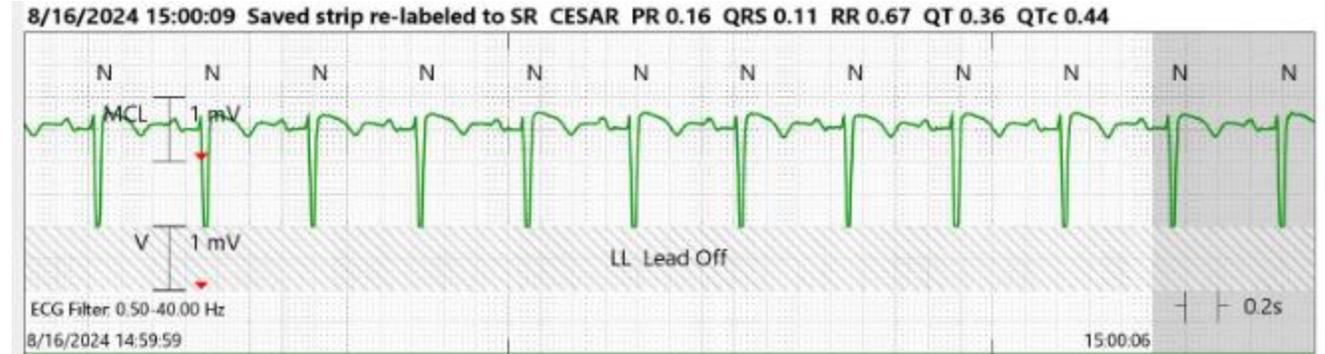
Current Scheduled Medications:
valsartan, 160 mg, daily
apixaban, 10 mg, BID
Followed by [START ON 8/23/2024] apixaban, 5 mg, BID
atorvastatin, 40 mg, daily
gabapentin, 100 mg, TID
lamoTRIgine, 50 mg, daily
nebivolol, 10 mg, daily
oxyBUTYnin, 10 mg, daily
sertraline, 150 mg, daily
fluticasone propion-salmeterol, 1 puff, 2 times per day

CXR and CT Angio at Repeat ED Eval 9/3/2024
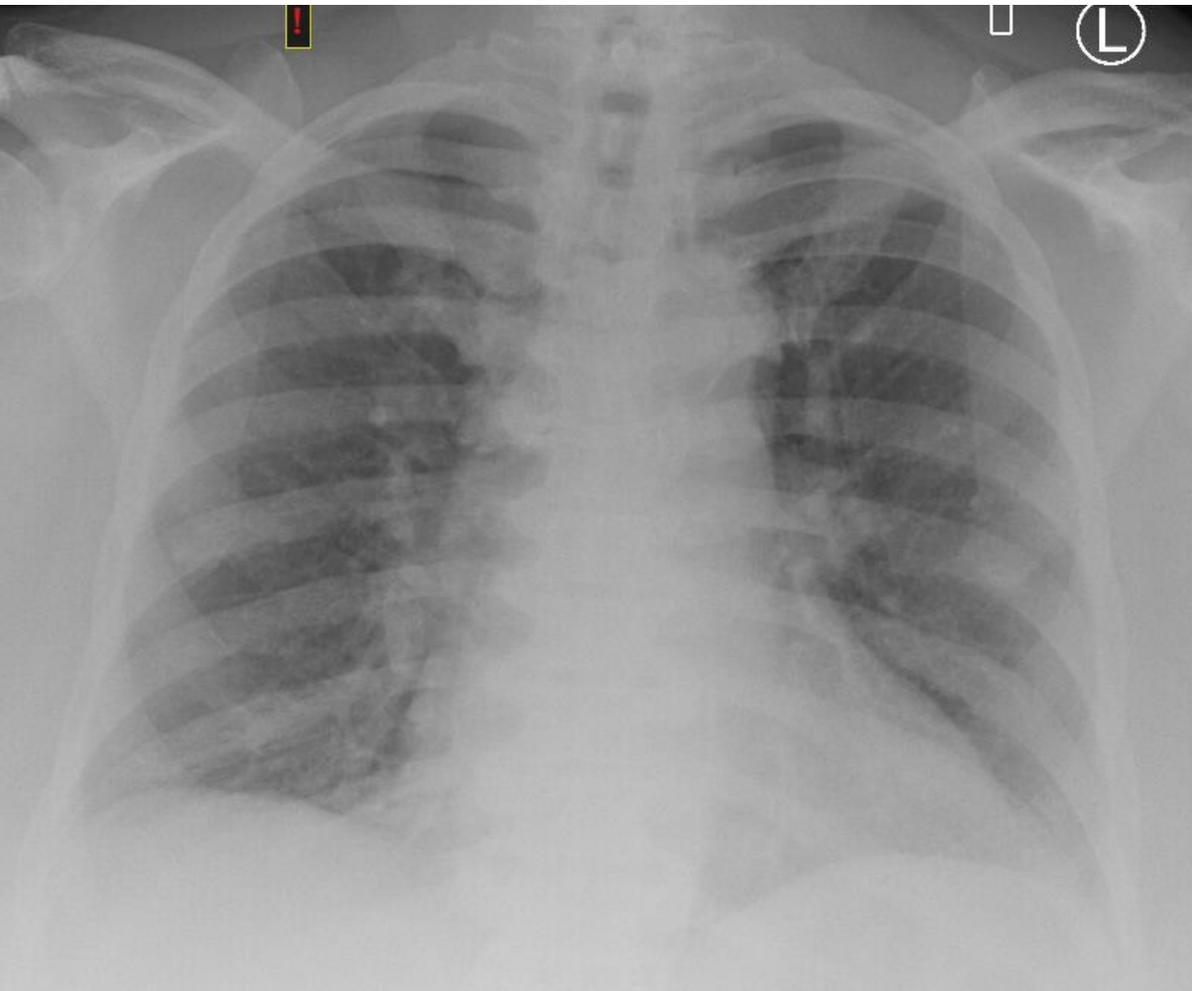
ED Discharge Note

Patient with some shortness of breath; we did a repeat CTA given this is her second presentation and showed decreased clot burden. She is not hypoxic or tachycardic.

Compliant with all her therapies, and she has likely some chronic dyspnea—concern for pulmonary hypertension.

Also has incidental findings of coronary artery disease but negative troponin and fatty liver and right adrenal adenoma which can be followed up as outpatient. Negative troponin and well-appearing patient who has no symptoms right now at the bedside seems reasonable to follow-up outpatient.

CTA = computed tomography angiography.

Admission 8/14

48 hr f/u CT

30-day CT
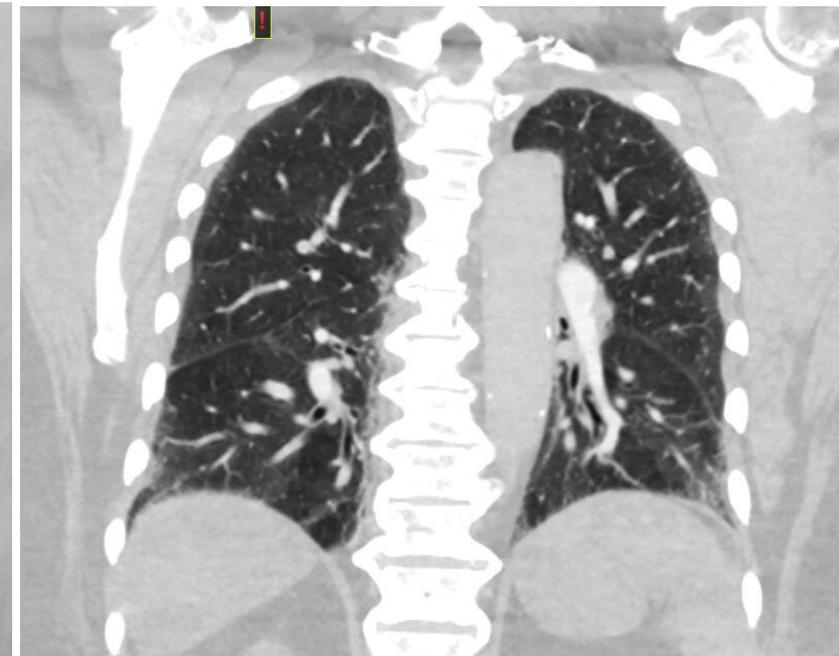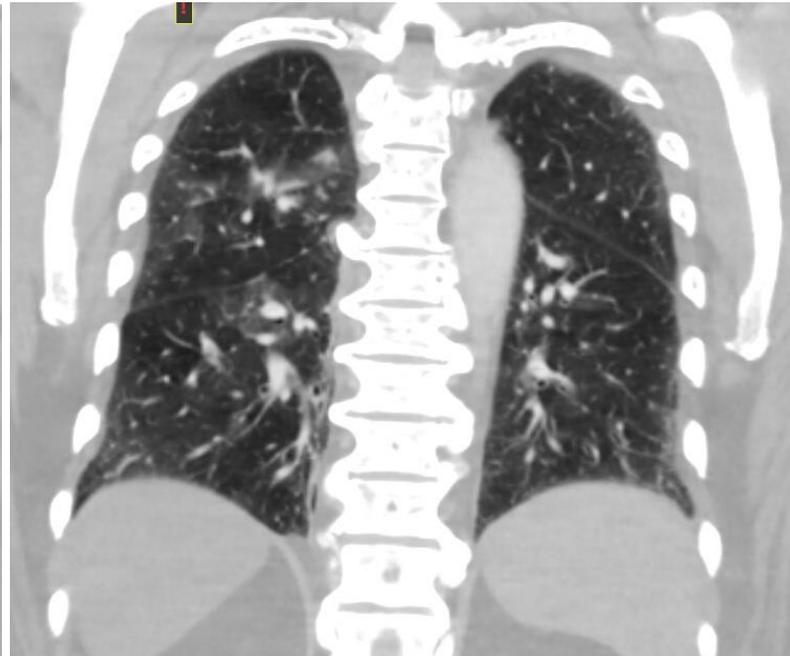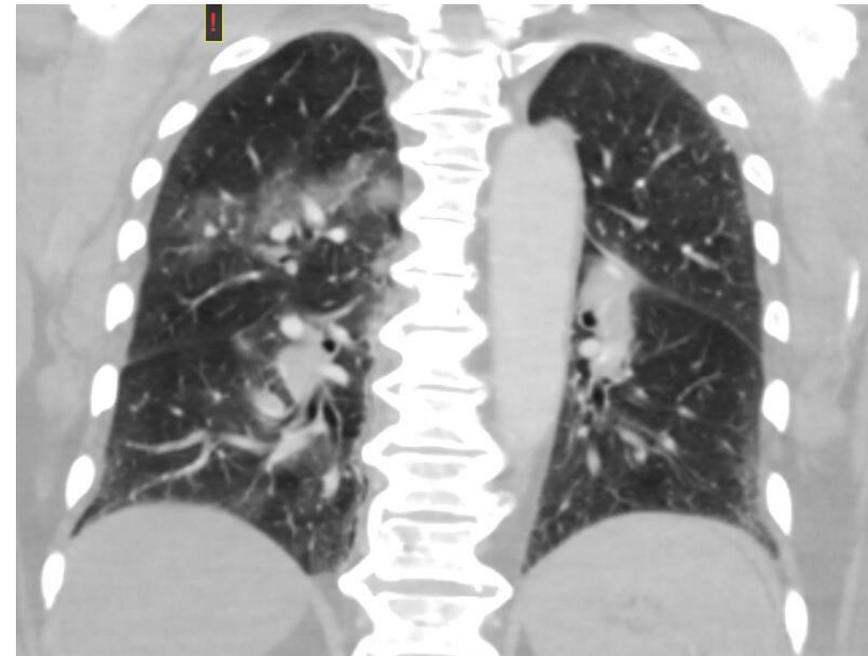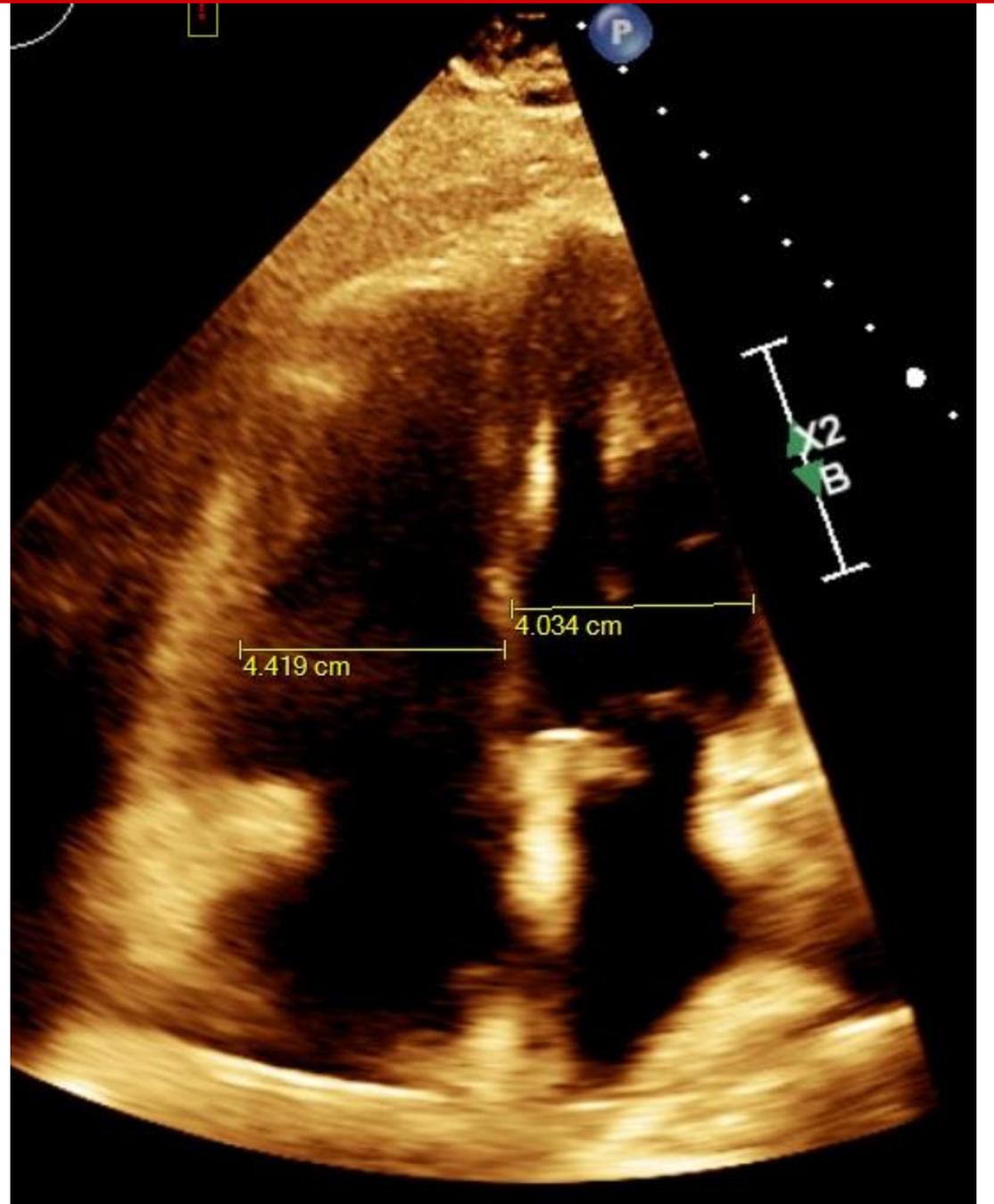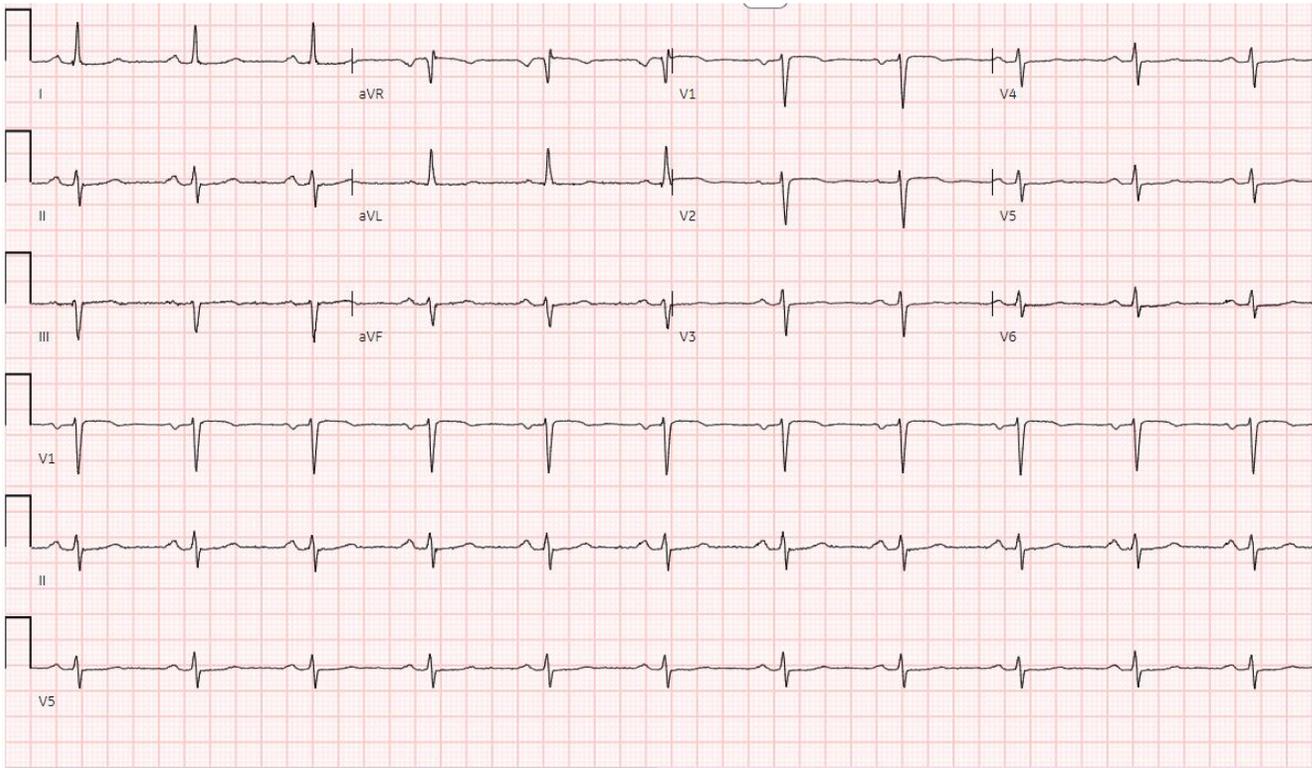
RV/LV ratio—1.09

UCLA PE Response Team—Case 1

- 69-yo male, acute SOB x 48hrs
  - Day 3 post-dural AVF embolization
  - Central chest pain
  - Tachy to 130s on minimal exercise (fitness monitoring wristwatch)
  - No leg swelling
- Amlodipine, ASA, atorvastatin, metoprolol 25 BID
- HR 105, BP 96/70, O2S: 74%
- HFNC 50/50% to maintain >92%
- HsTrop 25, BNP 860

SOB = shortness of breath; AVF = arteriovenous fistula; ASA = acetylsalicylic acid; HR = heart rate; BP = blood pressure; O2S = oxygen saturation; HFNC = high-flow nasal cannula; HsTrop = high-sensitive troponin; BNP = B-type natriuretic peptide.
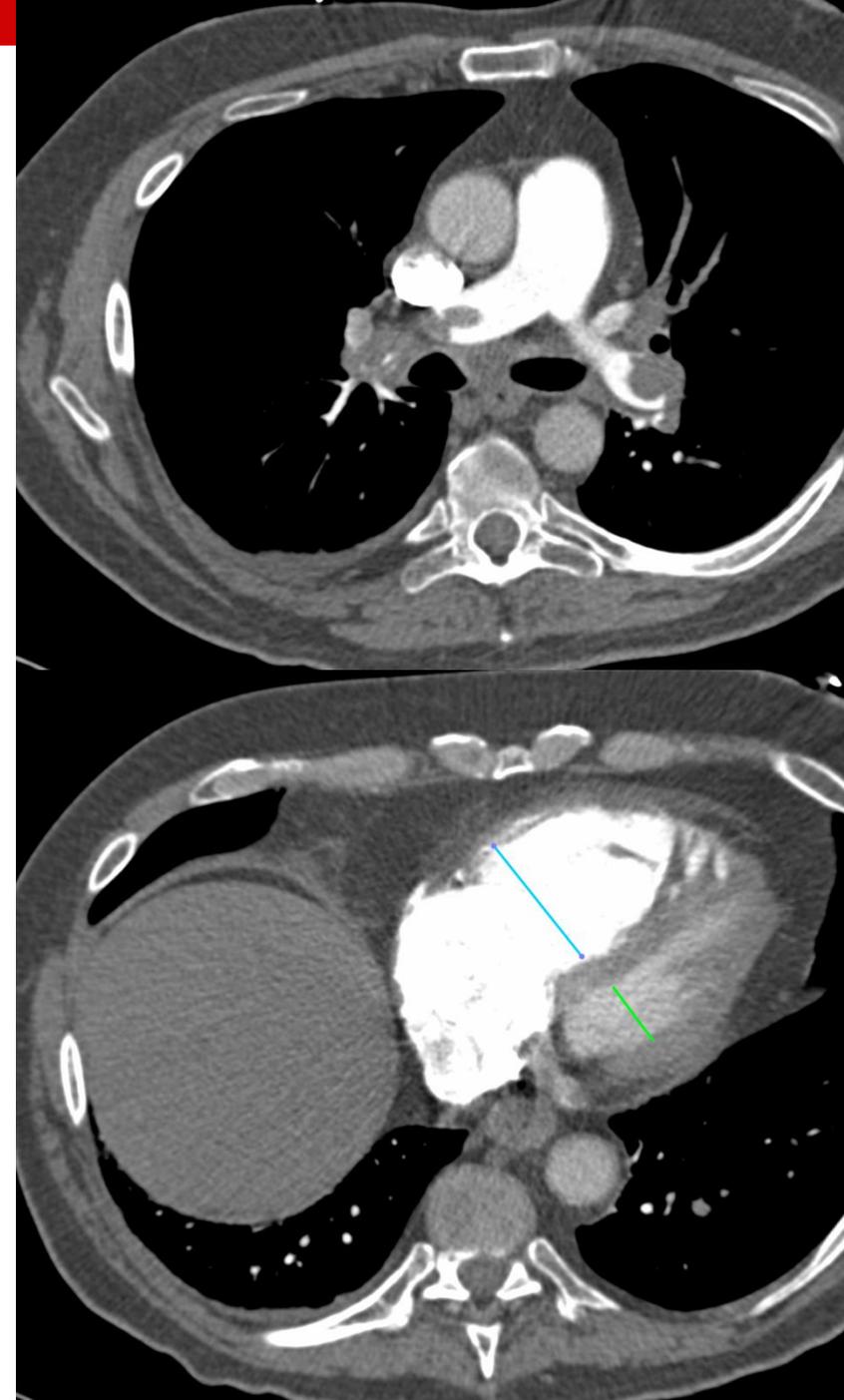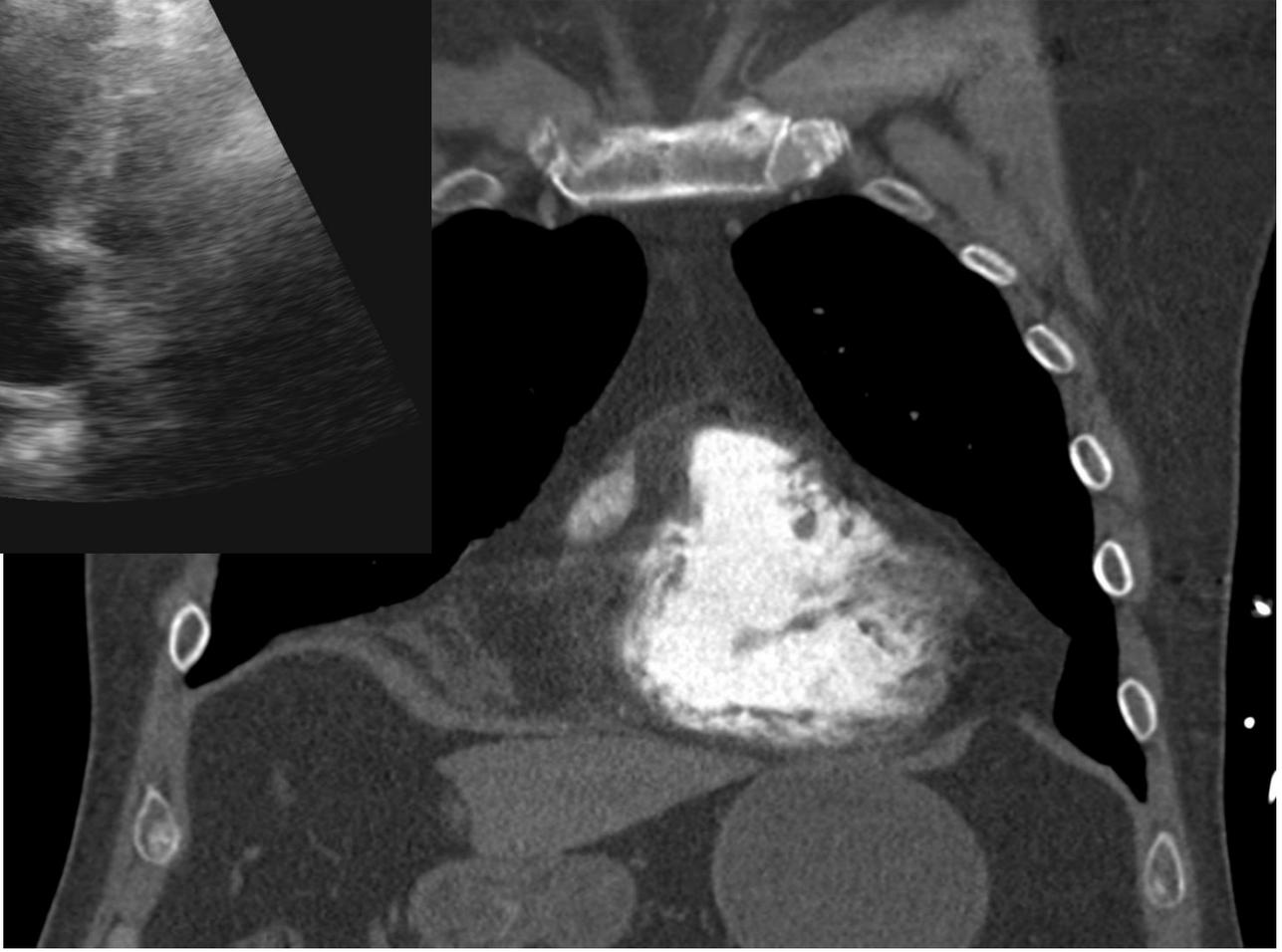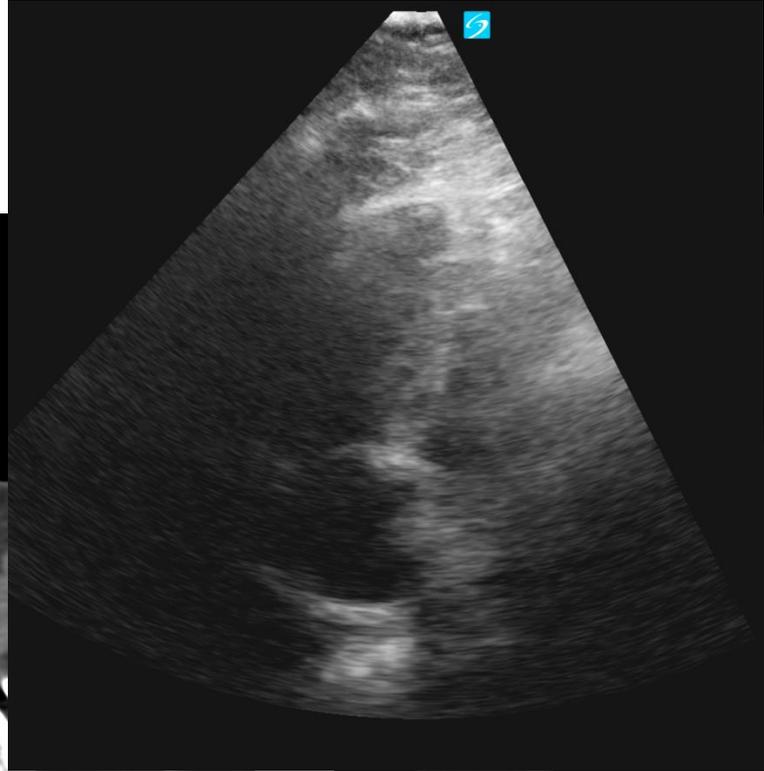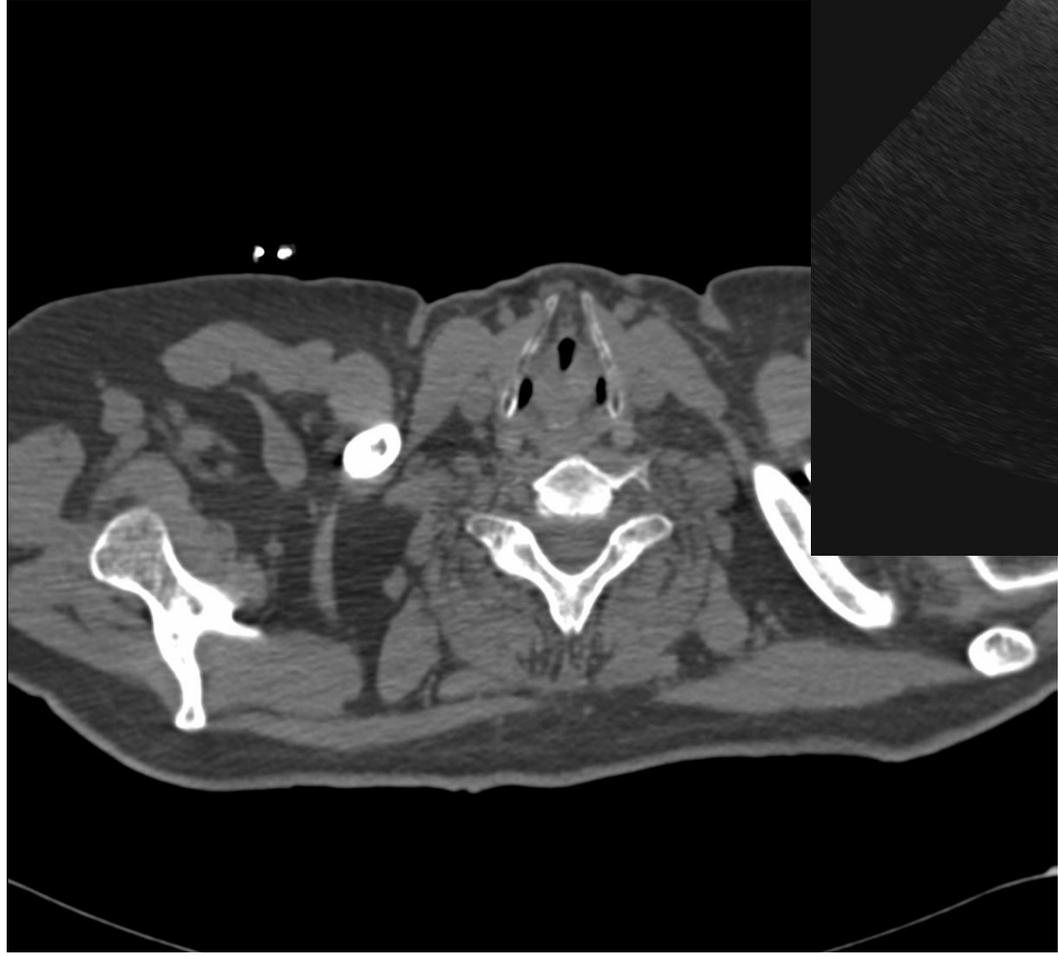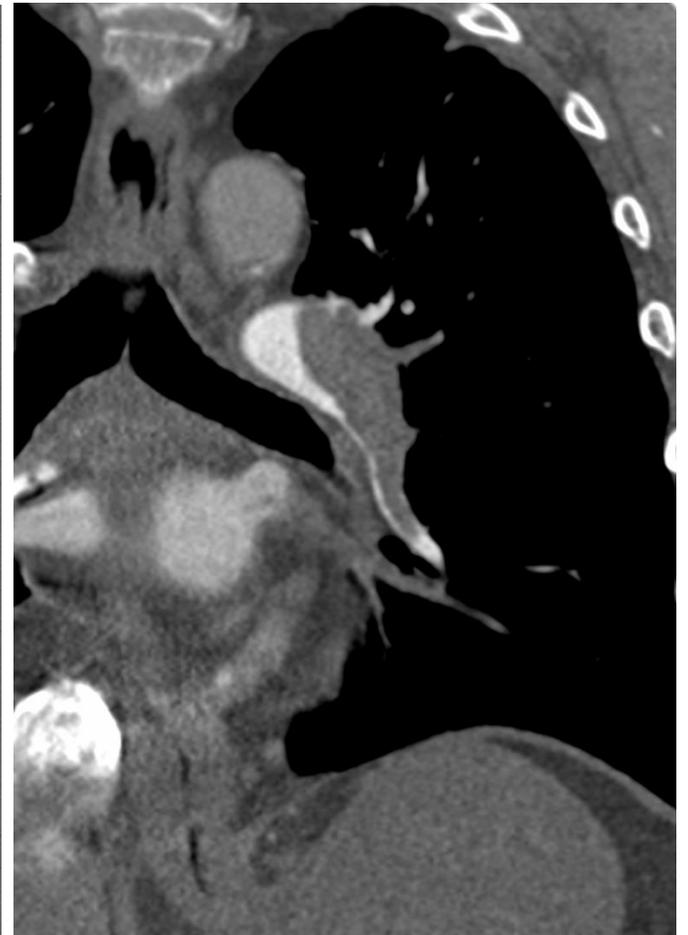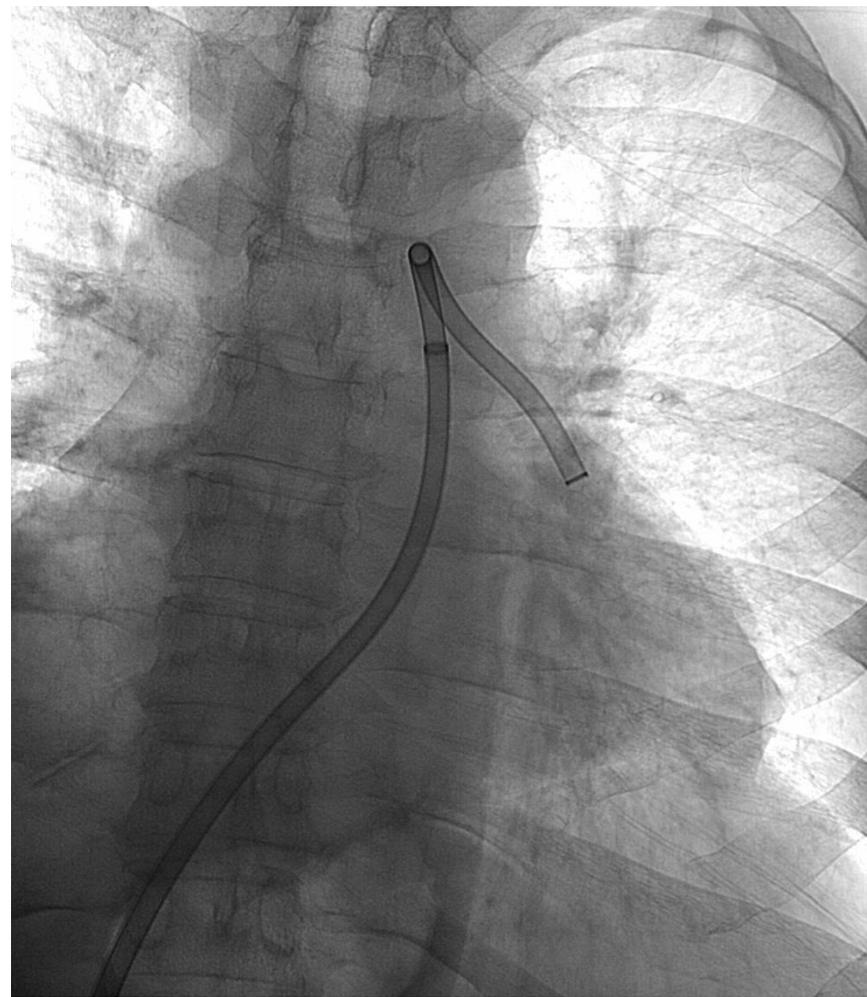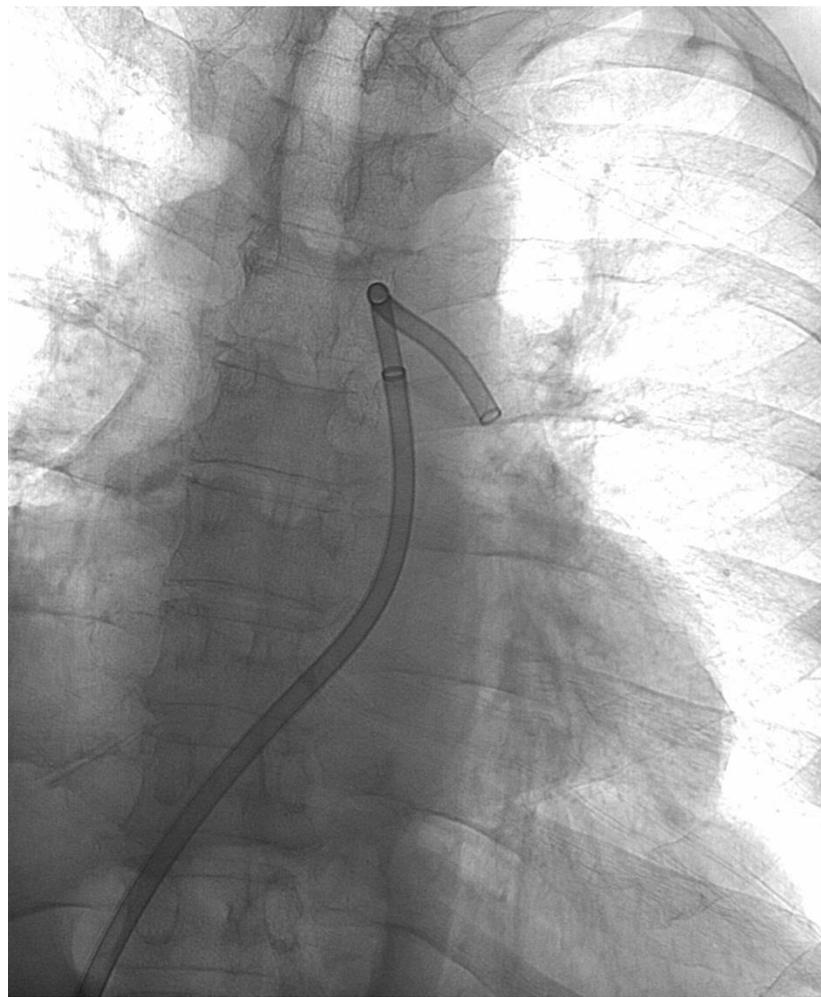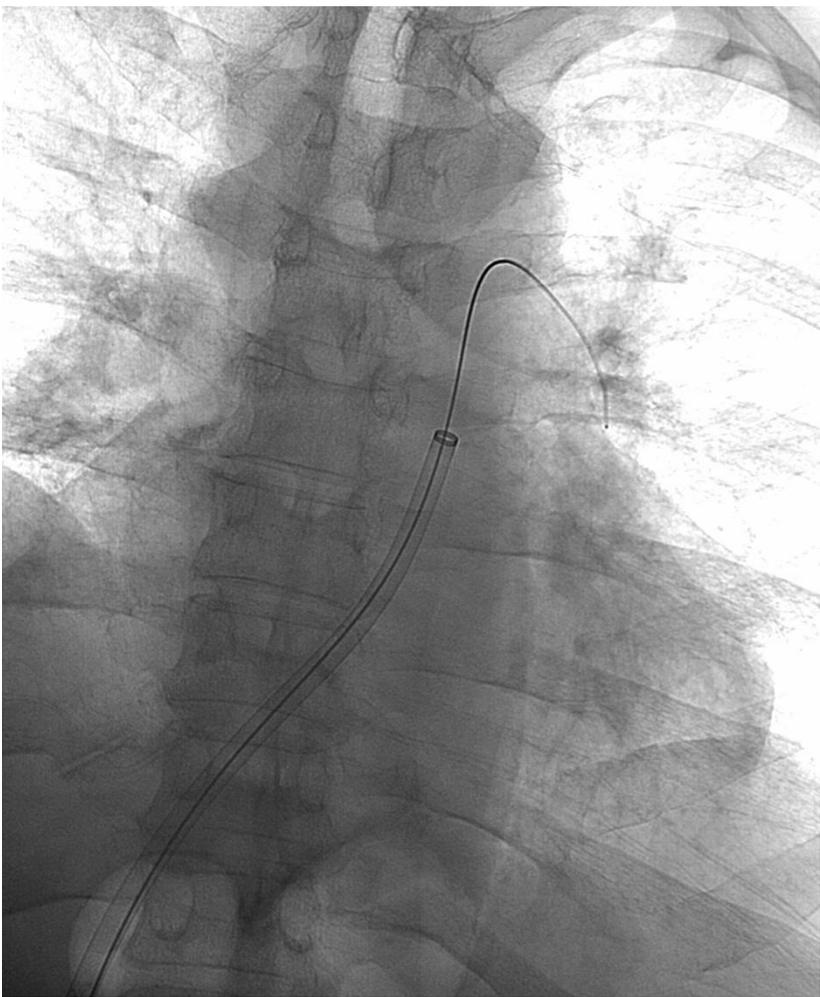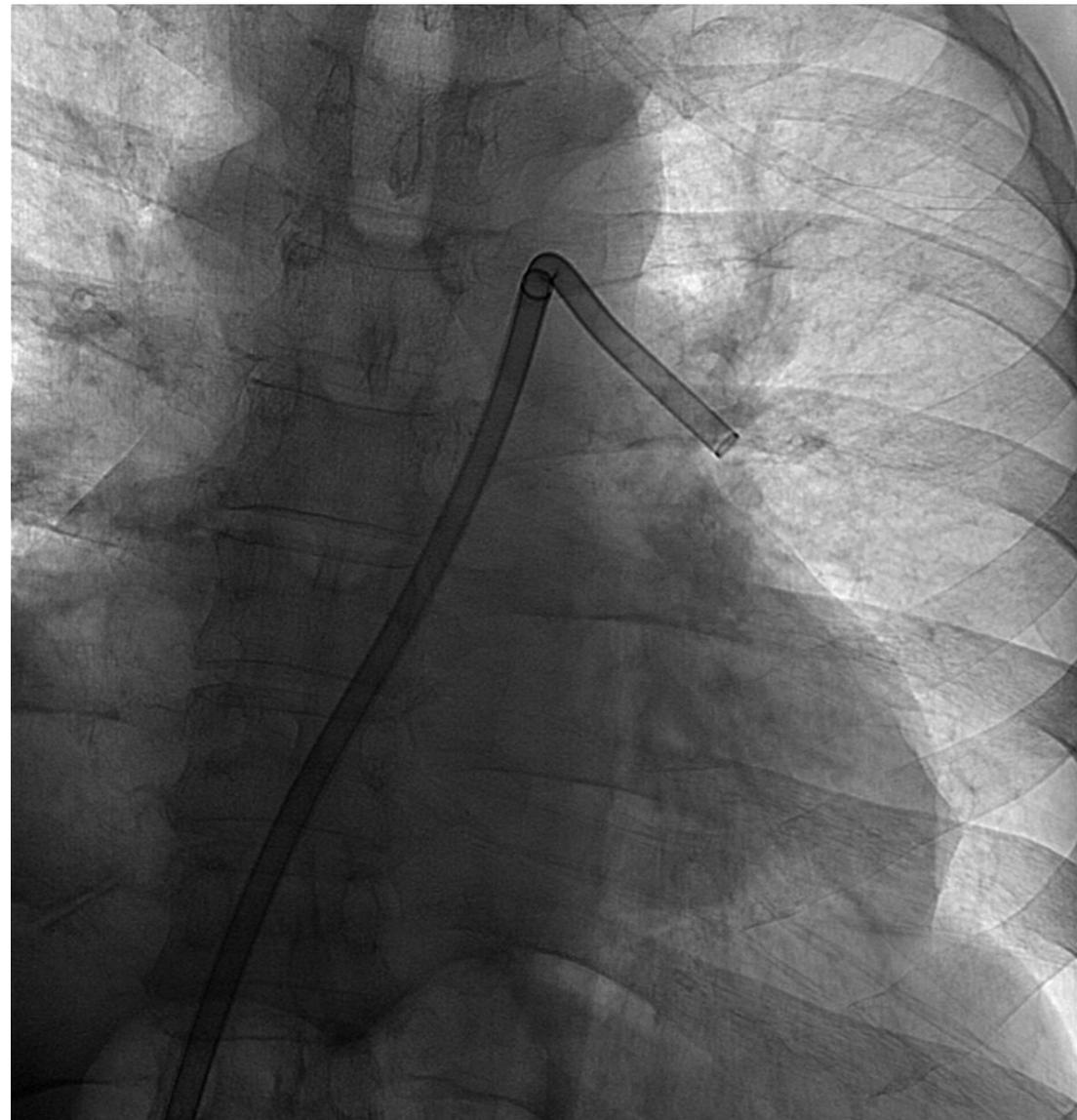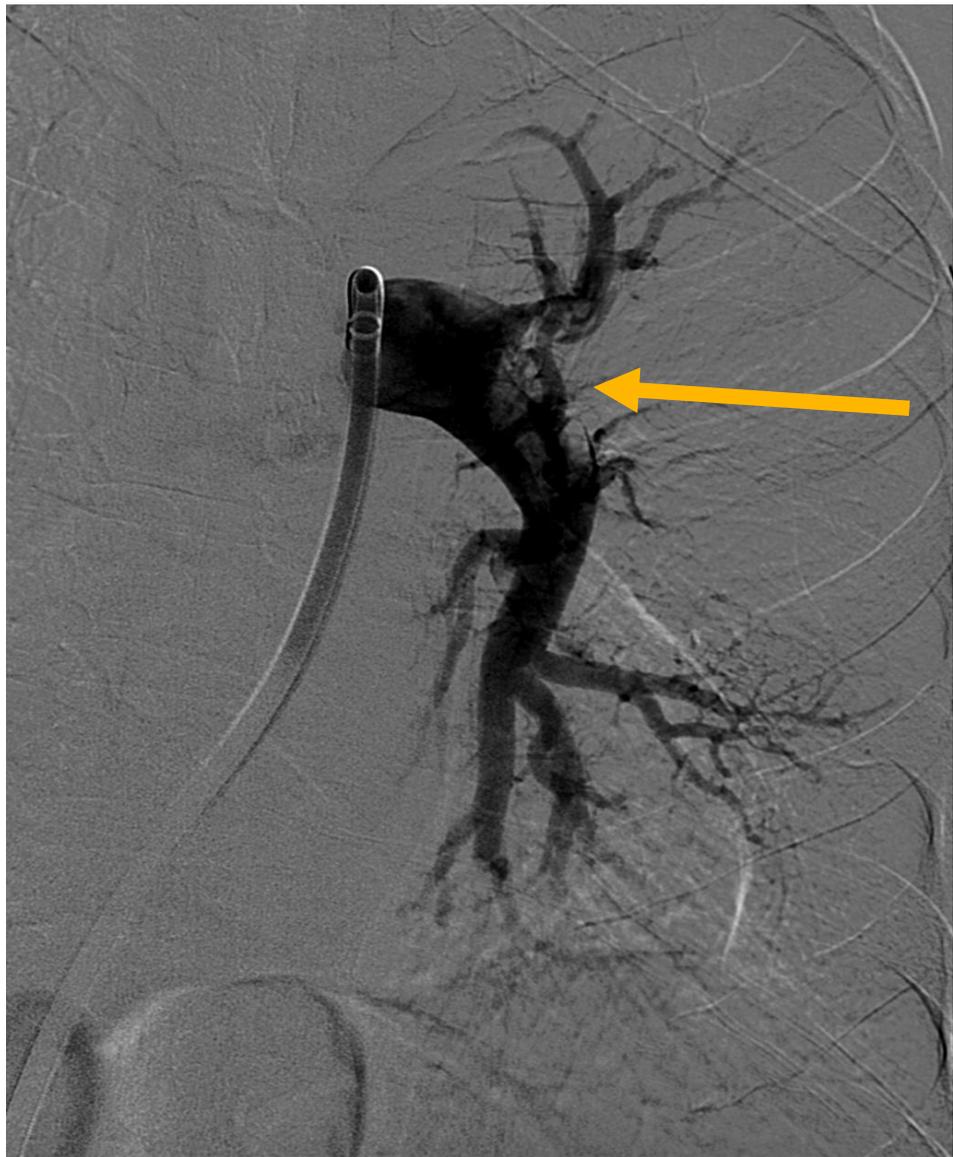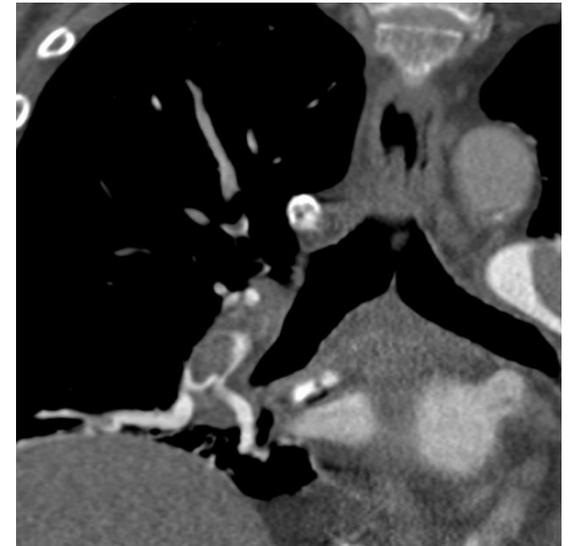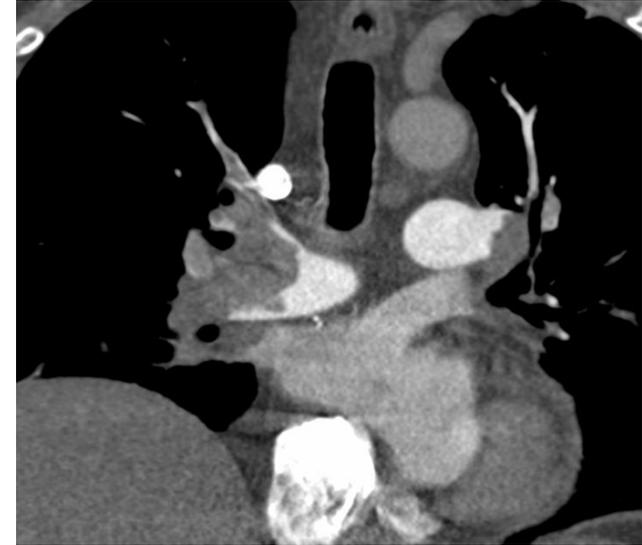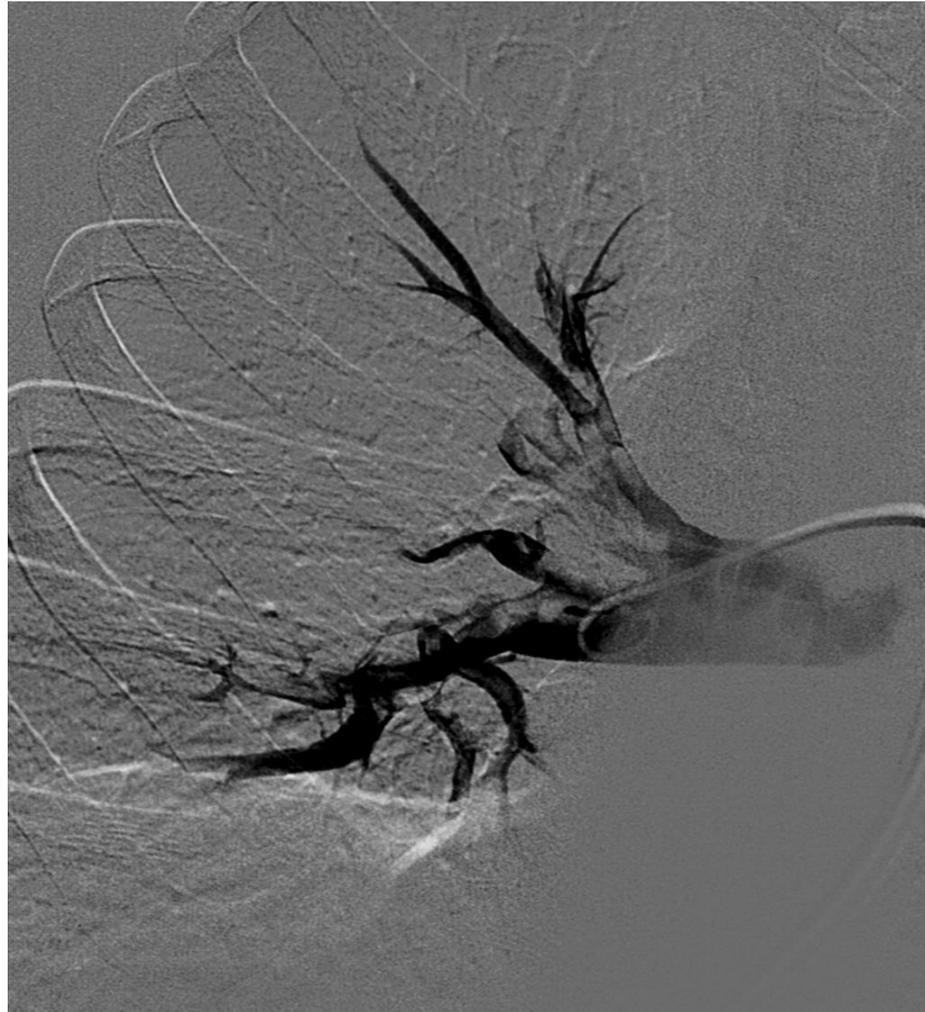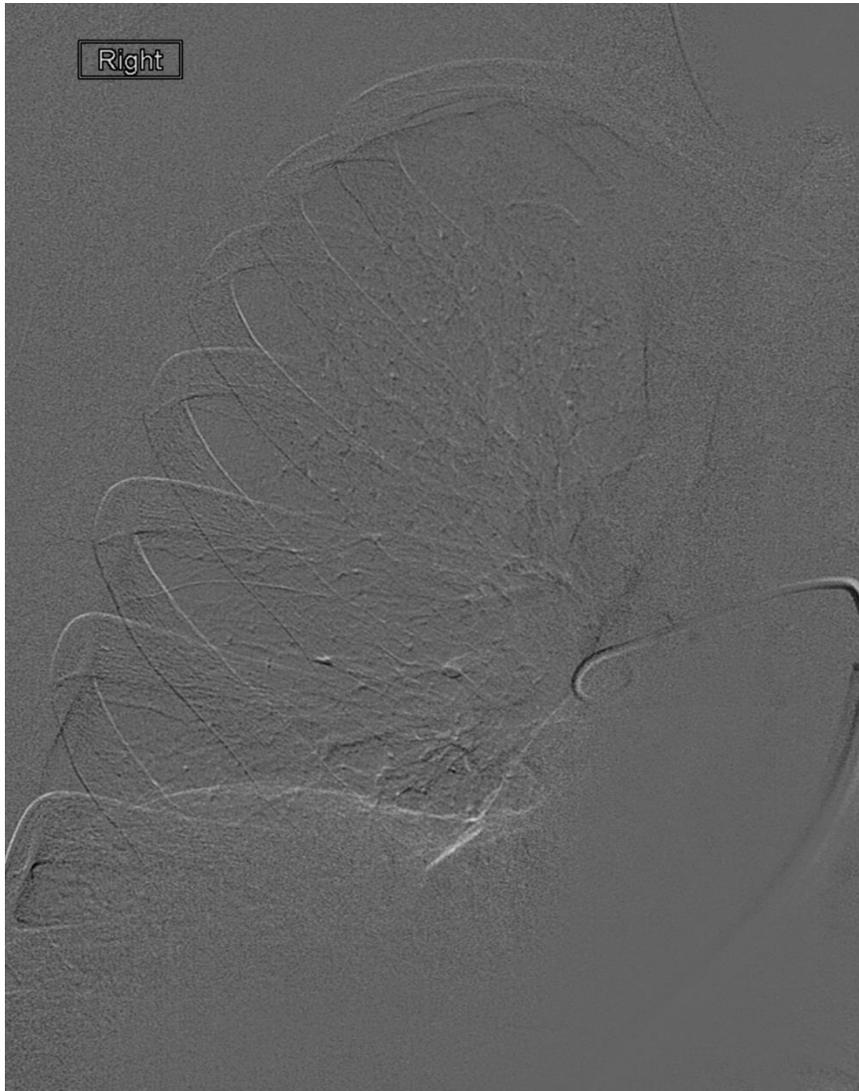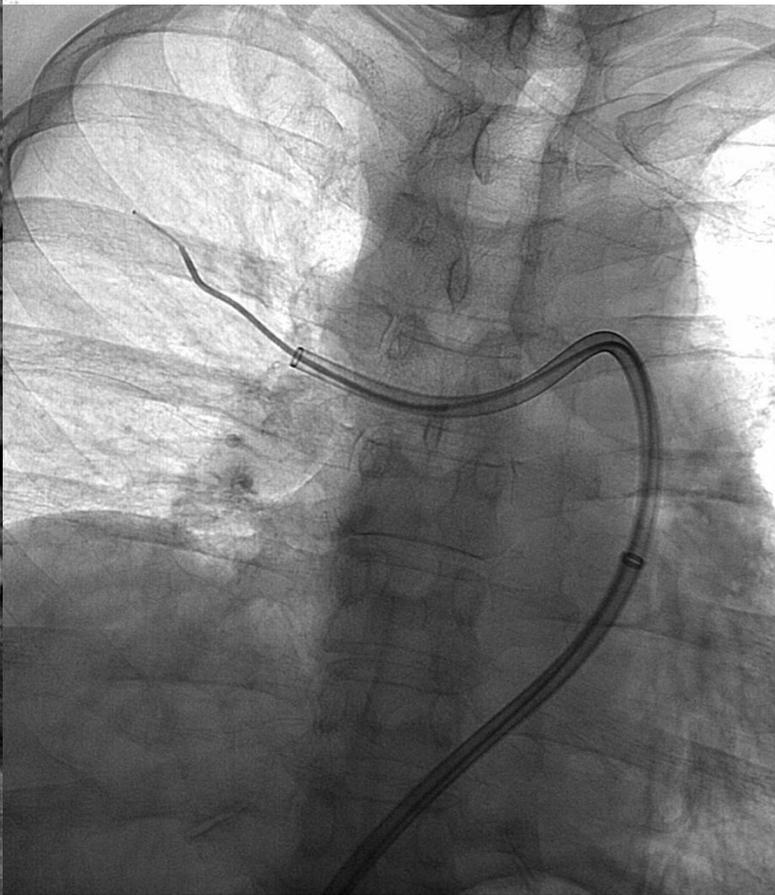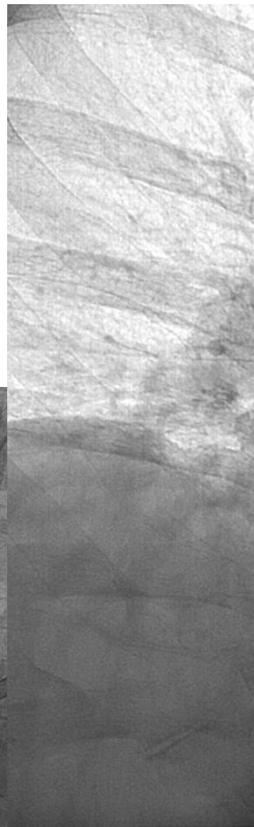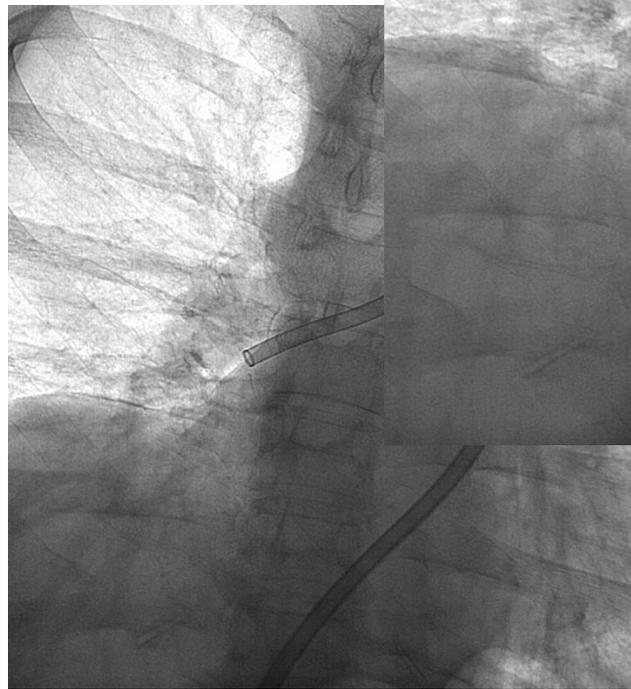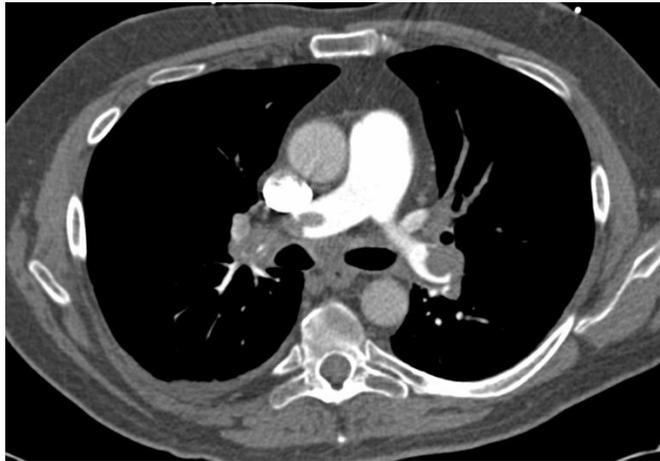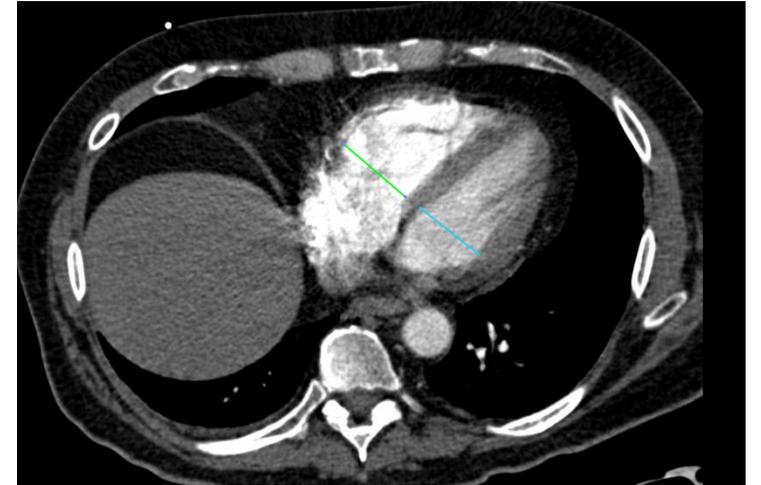
STRIKE-PE Study

- Pre: 51/22 (31)
- Post: 35/10 (17)
- O2S: 98% on 2l 1 hr post
- Procedure time: 48 mins
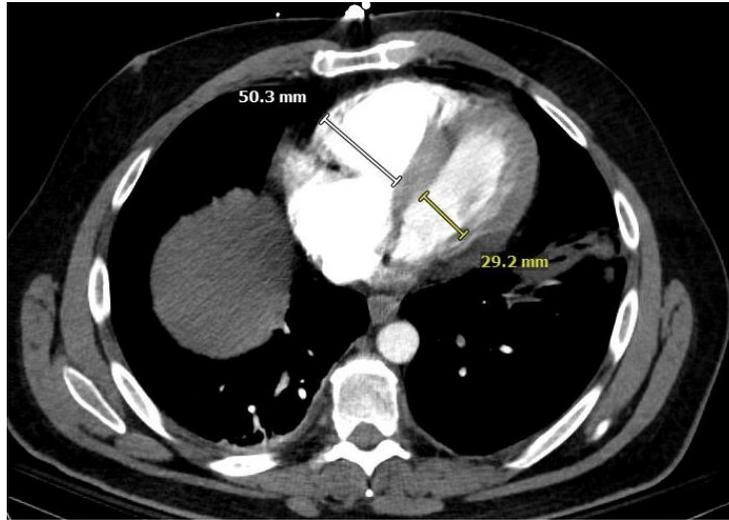- EBL: 250 cc

EBL = estimated blood loss.

48-Hr F/u
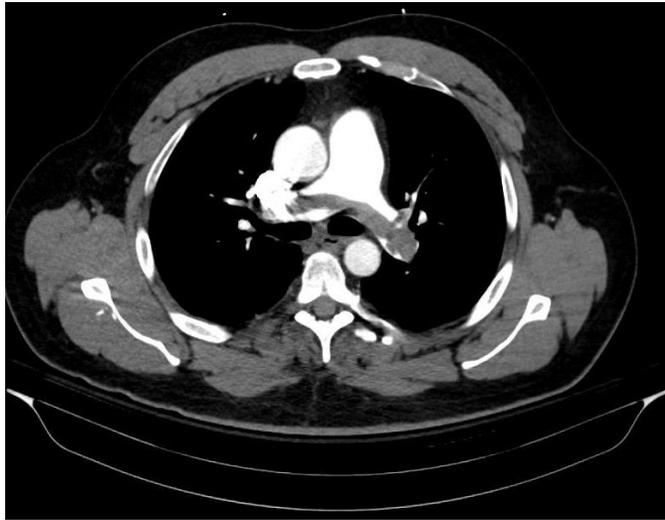
- CTA—RV:LV 2.3 > 1.1
- Ambulating with stable O2S
- Apixaban DOAC
- D/c day 3
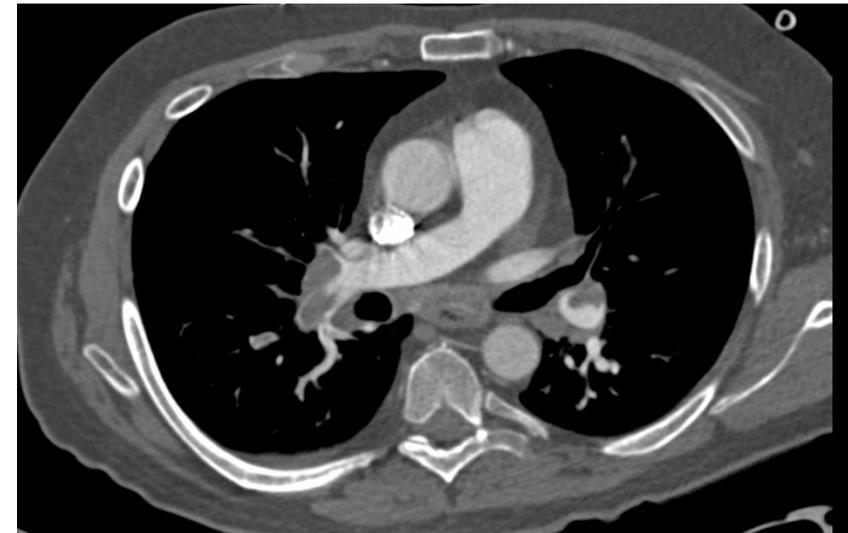
F/u = follow-up; CTA = computed tomography angiographyDOAC = direct oral anticoagulant; D/c = discharged.

Case 2

- 41-yo male, post-hernia repair, orchiopexy
- SOB, tachyC 130s, BNP 342, trop 0.82

EBL 450, 8-Min Asp, 42-Min Procedure Time