LATE BREAKING Advancements in the Treatment of PE

A CASE-BASED SYMPOSIUM

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Faculty Disclosures

- **Dr. Konstantinides:** Advisory Board—Bayer AG, Boston Scientific, Daiichi-Sankyo, Penumbra; honoraria—Pfizer-BMS
- **Dr. Lookstein:** Advisory Board—Boston Scientific, Medtronic; consultant— Abbott, Cordis, Neptune, Penumbra
- **Dr. Monteleone:** Advisory Board—Abbott, Boston Scientific, Medtronic, RapidAI
- **Dr. Rosovsky:** Institutional research support—BMS, Janssen; advisory/consultant—Abbott, BMS, Dova, Inari, Janssen, Penumbra; national lead investigator—Penumbra; president-elect—Pulmonary Embolism Response Team Consortium
- **Dr. Schiro:** Speaker—Cook, Medtronic, Penumbra

- **Use of Proprietary Names**
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Program Information

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- Supported by an independent educational grant from Penumbra, Inc.

Learning Objectives

- Understand current guidelines and recommendations for management of PE
- Interpret data, immediate, and long-term outcomes for safety and efficacy
- Identify best practices with computer-aided thrombectomy (CAT) and how it compares to current standard of care for PE

PE = pulmonary embolism.

PE Guidelines in 2023: Who Should Be Treated and How? What Does It Take to Expand Guidelines to Have More Patients Treated?

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Risk Classes in PE 2008-2019: Who Are the Candidates for Advanced Therapy (?)

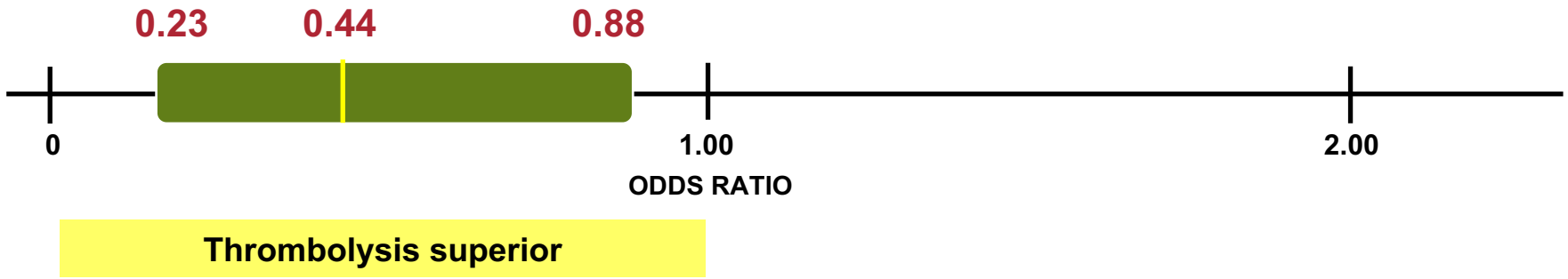
Early mortality risk		Indicators of risk			
		Haemo-dynamic instability	Clinical parameters of PE severity/ comorbidity: PESI III–V or sPESI ≥1	RV dysfunction on TTE or CTPA	Elevated cardiac troponin levels
High		+	(+)	+	(+)
Interme-diate	**Intermediate–high**	-	+	+	+
	Intermediate–low	-	+	One (or none) positive	
Low		-	-	-	Assessment optional; if assessed, negative

Konstantinides SV, et al. *Eur Heart J*. 2020;41(4):543-603.

Systemic Thrombolysis in Intermediate-Risk PE: High Efficacy in the First PEITHO Trial

	Tenecteplase (n=506)		Placebo (n=499)		*P* value
	n	(%)	n	(%)	
All-cause mortality or hemodynamic collapse within 7 days of randomization	13	(2.6)	28	(5.6)	0.015

ITT population



ITT = intention to treat.

Meyer G, et al. *N Engl J Med*. 2014;370(15):1402-1411.

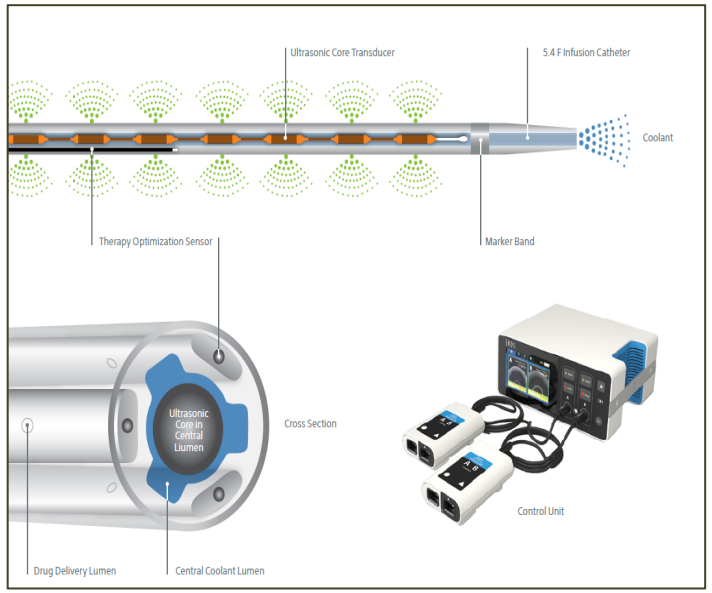
Systemic Thrombolysis in Intermediate-Risk PE: Low Safety in the First PEITHO Trial

	Tenecteplase (n=506)		Placebo (n=499)		*P* value
	n	(%)	n	(%)	
NON-INTRACRANIAL BLEEDING					
Major	32	(6.3)	6	(1.5)	<0.001
Minor	165	(32.6)	43	(8.6)	<0.001
STROKES BY DAY 7					
Total	**12**	**(2.4)**	**1**	**(0.2)**	**0.003**
Hemorrhagic	10		1		
Ischemic	2		0		

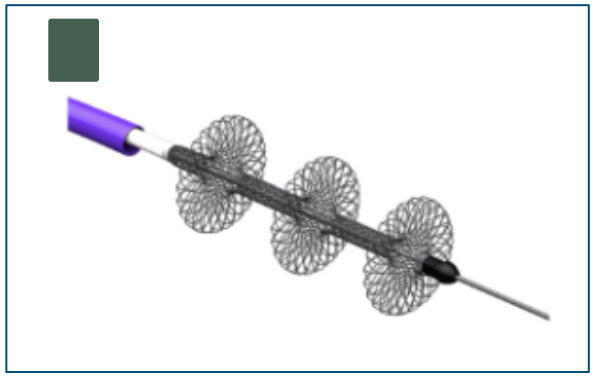
Meyer G, et al. *N Engl J Med*. 2014;370(15):1402-1411.

Progress in Catheter-Directed Treatment (CDT) for PE, 2014-2024

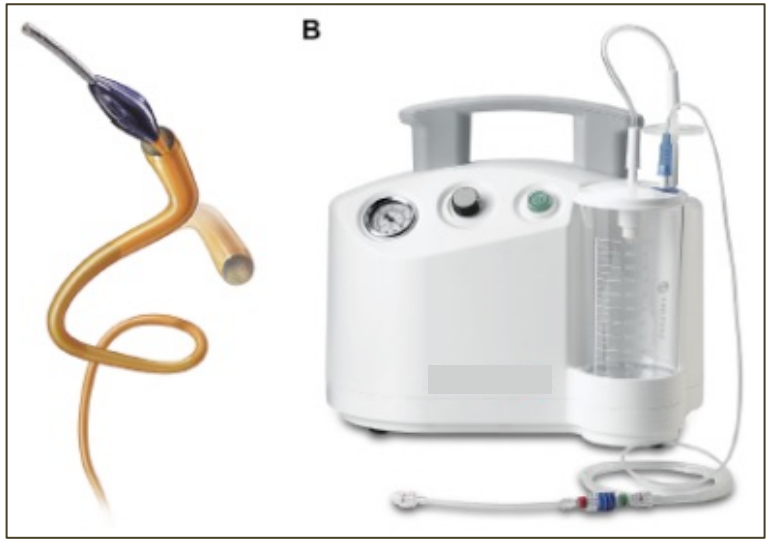
Acoustic pulse (*ultrasound-assisted)* lysis



Mechanical thrombectomy



Mechanical thrombus aspiration



What Did the AHA Scientific Statement 2019 Recommend Regarding Use of CDT?

Device	Mechanism	Technical Considerations	Regulatory Status in United States
EKOSonic	USAT	5F catheter	510(k) Clearance for infusion for treatment of PE
Unifuse	CDL	4F–5F catheter	510(k) Clearance for treatment of peripheral vasculature
Cragg-McNamara	CDL	4F–5F catheter	510(k) Clearance for treatment of peripheral vasculature
Bashir Endovascular Catheter	Pharmacomechanical CDL	7F catheter with a nitinol-supported infusion basket that is expanded within the thrombus	510(k) Clearance for use in peripheral vasculature
AngioVac	Veno-veno bypass; funnel-shaped inflow tip to engage thrombi	26F access for inflow, 16F–20F access for outflow; requires perfusion team	510(k) Clearance for removal of undesirable intravascular material
FlowTreiver	Mechanical clot engagement with aspiration with adjunctive nitinol disks engage and mechanically retrieve clot	20F catheter; must manage blood loss associated with large-bore aspiration	510(k) Clearance for treatment of PE
Indigo System	Mechanical clot engagement with mechanized aspiration	8F catheter; large size of some proximal PE renders en bloc aspiration difficult with 8F device	510(k) Clearance for peripheral artery and venous systems
AngioJet	Rheolytic thrombectomy with option of thrombolytic vs saline spray	6F–8F catheters for venous thrombus; can cause hypotension and bradycardia	510(k) Clearance for peripheral thrombectomy; black-box warning against use in PAs
Aspire Max	Suction thrombectomy with specially designed handheld aspirator	5F–6F catheters	510(k) Clearance for removal of fresh, soft thrombi, and emboli from the peripheral and coronary vasculature

Trials to date evaluating CDT approaches for acute PE have focused on surrogates for improved short-term outcomes.

CDL more rapidly reverses RV dysfunction in acute PE than anticoagulation alone.

Available data on catheter-based embolectomy devices also demonstrate immediate improvements in RV dysfunction.

Currently, no data support a short-term mortality benefit with CDT approaches for the treatment of PE.

AHA = American Heart Association; USAT = ultrasound-accelerated thrombolysis; CDL = catheter-directed thrombolysis; F = French; RV = right ventricular.

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

European Guidelines 2019: Why Such a Low Level of Recommendation for CDT?

RECOMMENDATIONS	CLASS	LEVEL
Reperfusion treatment		
Rescue thrombolytic therapy is recommended for patients with haemodynamic deterioration on anticoagulation treatment.	I	B
As an alternative to rescue thrombolytic therapy, surgical embolectomy or **percutaneous catheter-directed treatment should be considered for patients with hemodynamic deterioration** on anticoagulation treatment.	IIa	C
Routine use of primary systemic thrombolysis is **not** recommended in patients with intermediate- or low-risk PE.	III	B

Konstantinides SV, et al. *Eur Heart J*. 2020;41(4):543-603.

Improving the Evidence for Advanced CDT Options in Acute PE: Ongoing RCTs

ClinicalTrials.gov Identifier	Title	Study design	Study device	PE patient category	Intervention	Control	Primary outcome
NCT03595085	Safety and Efficacy of Catheter-directed Interventions in Acute High Risk Pulmonary Embolism	RCT, 60 patients	Pig-tail	High-risk PE	Catheter-directed fragmentation and thrombolysis	Systemic thrombolysis	30-day mortality
NCT03854266	Low Dose Catheter-directed Thrombolysis for Acute Pulmonary Embolism (BETULA)	RCT, 60 patients	Standard infusion mulit-sidehole cathether	Intermediate-high risk PE	Low-dose alteplase via sidehole catheter	Unfractionated heparin	1-day RV/LV ratio
NCT03218410	Surgical Pulmonary Embolectomy Versus Catheter-directed Thrombolysis in the Treatment of Pulmonary Embolism: A Non-inferiority Study (Lungembolism)	RCT, 60 patients	Standard infusion mulit-sidehole cathether	High or intermediate-high risk PE	Surgical pulmonary embolectomy	Catheter-directed thrombolysis	2 to 3-day RV/LV ratio
NCT04790370	Ultrasound-facilitated, Catheter-directed, Thrombolysis in Intermediate-high Risk Pulmonary Embolism (HI-PEITHO)	RCT, 406 patients	EkoSonic TM Endovascular System	Intermediate-high risk PE with additional criteria of severity	Ultrasound Accelerated catheter-directed thrombolysis	Parenteral anticoagulation	7-day PE mortality, VTE recurrence or cardiorespiratory decompensation
NCT03581877	Peripheral Systemic Thrombolysis Versus Catheter-directed Thrombolysis for Submassive PE	RCT, 158 patients	EkoSonic TM Endovascular System	Intermediate-risk PE	Peripheral low-dose thrombolysis	Ultrasound Accelerated catheter-directed thrombolysis	48-hour change in RV/LV ventricle ratio and pulmonary artery pressures
NCT05111613	The PEERLESS Study (PEERLESS)	RCT 550	FlowTriver System	Intermediate-high-risk PE with absolute contraindication to thrombolytics.	Mechanical thrombectomy for pulmonary embolism using the FlowTriever system	CDT for pulmonary embolism (any commercially available CDT system)	All-cause mortality, or major bleedings at day 7

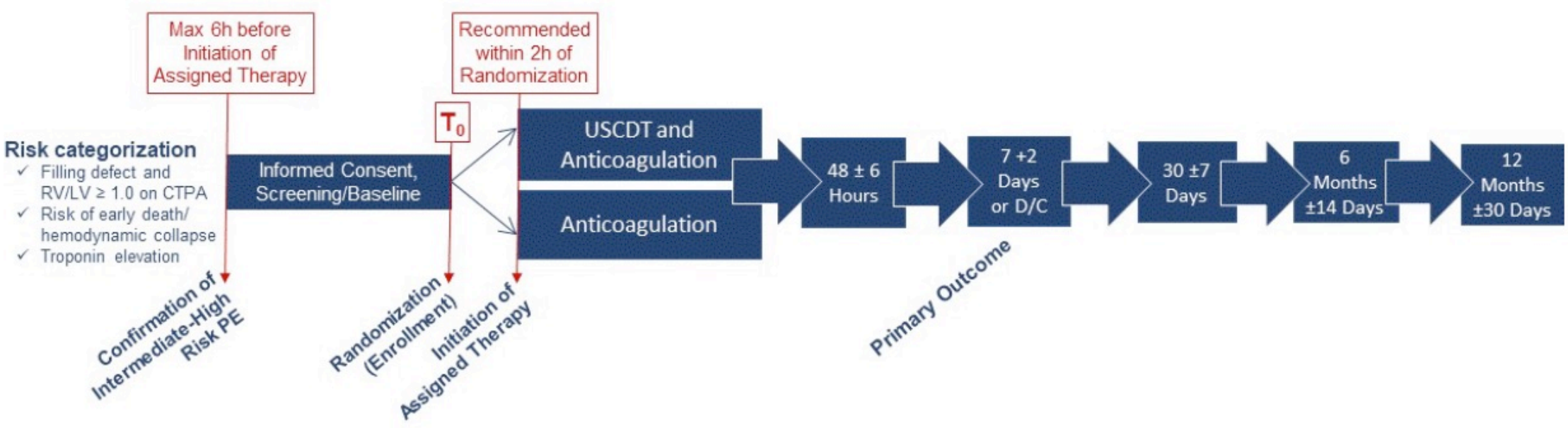
RCT = randomized controlled trial; LV = left ventricular; VTE = venous thromboembolism.

Pruszczyk P, et al. *EuroIntervention*. 2022;18(8):e623-e638.

HI-PEITHO as an Example: Trial Overview

A randomized trial of ultrasound-facilitated, catheter-directed thrombolysis versus anticoagulation for acute intermediate-high-risk pulmonary embolism:

The HIgher-risk Pulmonary Embolism THrOmbolysis study (HI-PEITHO)



Klok FA, et al. *Am Heart J.* 2022;251:43-53.

Time to Rethink Risk Classes in PE?

Early mortality risk		Indicators of risk			
		Haemo-dynamic instability	Clinical parameters of PE severity/ comorbidity: PESI III–V or sPESI ≥1	RV dysfunction on TTE or CTPA	Elevated cardiac troponin levels
High		+	(+)	+	(+)
Interme-diate	Intermediate–high	-	+	+	+
	Intermediate–low	-	+	One (or none) positive	
Low		-	-	-	Assessment optional; if assessed, negative

Konstantinides SV, et al. *Eur Heart J*. 2020;41(4):543-603.

Rethinking PE Risk Classes, Inclusion Criteria

- Age 18-80 years
- Objectively confirmed acute PE, based on computed tomography pulmonary angiography (CTPA) involving at least one main or proximal lobar pulmonary artery
- Elevated risk of early death/hemodynamic collapse, indicated either by **at least two** of the following new-onset criteria
  - ECG-documented tachycardia with heart rate ≥ 100 beats per minute, not due to hypovolemia, arrhythmia, or sepsis
  - SBP ≤ 110 mm Hg over at least 15 minutes
  - Respiratory rate > 20 x min-1 or oxygen saturation on pulse oximetry (SpO2) < 90% (or partial arterial oxygen pressure < 60 mmHg) at rest while breathing room air
- Right-to-left ventricular (RV/LV) diameter ratio ≥ 1.0 on CTPA
- Serum troponin I or T levels above the upper limit of normal (measured by high-sensitivity assay)

ECG = electrocardiogram; SBP = systolic blood pressure.

Klok FA, et al. *Am Heart J.* 2022;251:43-53.

Rethinking Trial Outcomes, Reconciling Patient Safety with Protocol Integrity

Composite of PE-related death, cardiorespiratory decompensation or collapse, or non-fatal symptomatic and objectively confirmed recurrence of PE, **between randomization and day 7**

- Cardiac arrest or need for CPR
- Intubation or non-invasive mechanical ventilation
- Signs of shock: new-onset hypotension plus end-organ hypoperfusion
- Placement on ECMO
- ***National Early Warning Score (NEWS) of 9 or higher*, between 24 hours and 7 days after randomization, confirmed on consecutive measurements taken twice, 15 minutes apart**

ECMO = extracorporeal membrane oxygenation.

Klok FA, et al. *Am Heart J.* 2022;251:43-53.

Extend Focus to Include Long-Term Outcomes, PROMs

- Change in the right ventricular (RV) to left ventricular (LV) end diastolic diameter ratio (RV/LV) as measured by echocardiography between baseline and 48±6 hours
- Individual components of the primary outcome
- GUSTO major (moderate and severe) bleeding within 7 days
- ISTH major bleeding within 7 days, 30 days, and 6 months
- Ischemic or hemorrhagic stroke within 7 days and 30 days
- All-cause mortality within 7 days, 30 days, 6 months, and 1 year
- Functional status over time (WHO scale, exercise testing, post-VTE functional status [PVFS] scale)
- Quality of life over time (PEmbQoL, SF-36, and EQ5D scales) at 6 and 12 months
- Health economic analysis at 30 days and at 12 months (selected sites and countries)

PROM = patient-reported outcome measure; GUSTO = Global Use of Strategies to Open Occluded Coronary Arteries; ISTH = International Society of Thrombosis and Haemostasis; WHO = World Health Organization; PEmbQoL = Pulmonary Embolism Quality of Life; SF-36 = 36-Item Short Form Survey; EQ-5D = EuroQol Five-Dimension questionnaire.

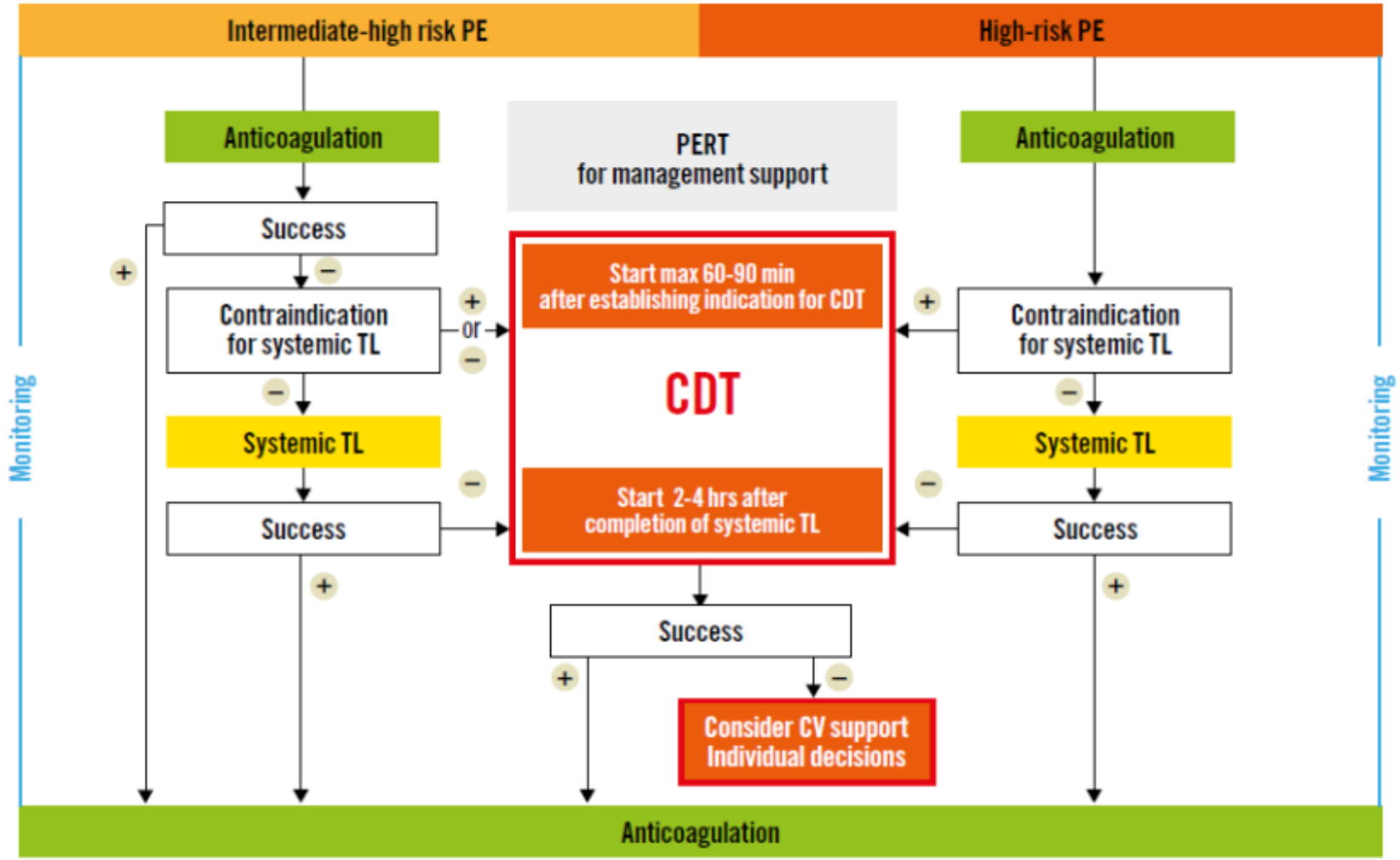
Klok FA, et al. *Am Heart J.* 2022;251:43-53.

Requirements for RCT Evaluating Catheter-Directed Treatment

- Interventional treatment of PE versus current standard of care, with an established clinical primary outcome
- Adequate power to show an impact of USCDT on the prognosis of severe PE as defined by current guidelines
- Trial protocol standardizing
  - Trial flow (time from PE diagnosis and randomization to intervention)
  - CDT procedure itself
  - Anticoagulation regimen
- Clear rules to prevent arbitrary crossover between treatment arms while ensuring timely escalation of therapy in cases of threatening decompensation

USCDT = ultrasound-facilitated catheter-directed thrombolysis.

Last but Not Least: Multidisciplinary Expert Decisions Based on Standardized Local Protocols



CV: cardiovascular; PERT: Pulmonary Embolism Response Team; TL: thrombolysis

Pruszczyk P, et al. *EuroIntervention*. 2022;18(8):e623-e638.

Overview of Current PE Treatment, Data Surrounding Mechanical Thrombectomy, and STORM-PE

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Boston, Massachusetts

Case

- 20-year-old college junior presents to her institution's health services with two days of progressive right calf pain
- Pain so severe, hard to walk
- Told muscle pull
  - Use heat and ibuprofen, made f/u 3 days later
- The following evening became acutely short of breath
- Called back health services who advised she f/u on her planned visit

Case

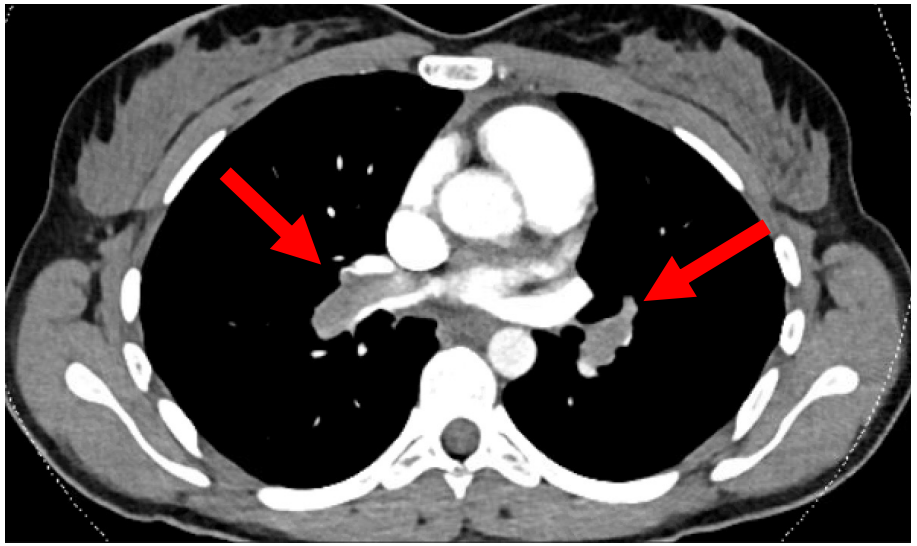
- Called her mother → ER
- She had started oral contraceptive 2 months prior
- She has family history of blood clots
- She is black

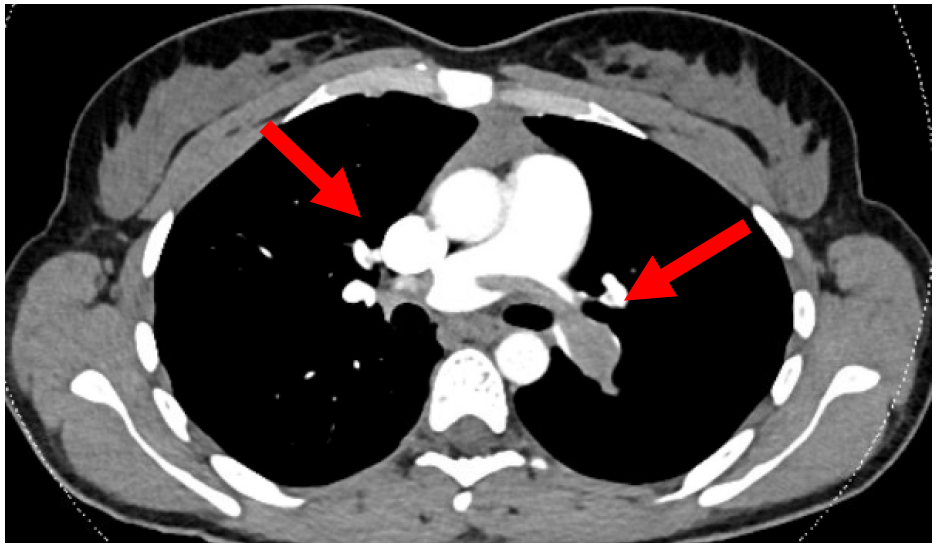
Case

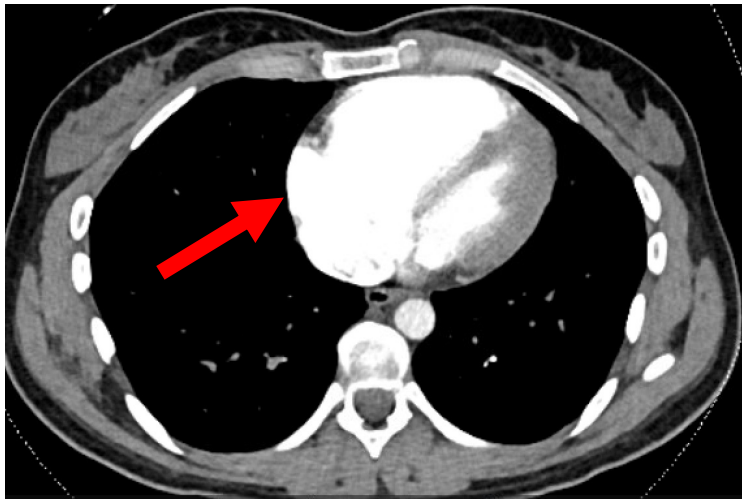
- HR 142, BP 118/62, RR 32, SpO2 89% RA
- EKG: ST
- Elevated troponin (245 → 360)
- Bedside echo

HR = heart rate; BP = blood pressure; RR = respiration rate; SpO2 = oxygen saturation; RA = regional anesthesia; EKG = electrocardiogram.

Saddle PE and Right Heart Strain







Anticoagulation Saves Lives

ANTICOAGULANT DRUGS IN THE TREATMENT OF PULMONARY EMBOLISM
A CONTROLLED TRIAL

TABLE II—RESULTS IN FIRST 35 CASES

Group	Total	Deaths from pulmonary embolism	Non-fatal recurrences	Other deaths
Untreated ..	19	5	5	0
Treated ..	16	0	0	1

TABLE III—RESULTS IN COMPLETE SERIES OF 73 CASES

Group	Total	Deaths from pulmonary embolism	Non-fatal recurrences	Other deaths
Untreated ..	19	5	5	0
Treated ..	54	0	1	2

Barritt DW, et al. Lancet. 1960;1(7138):1309-1312.

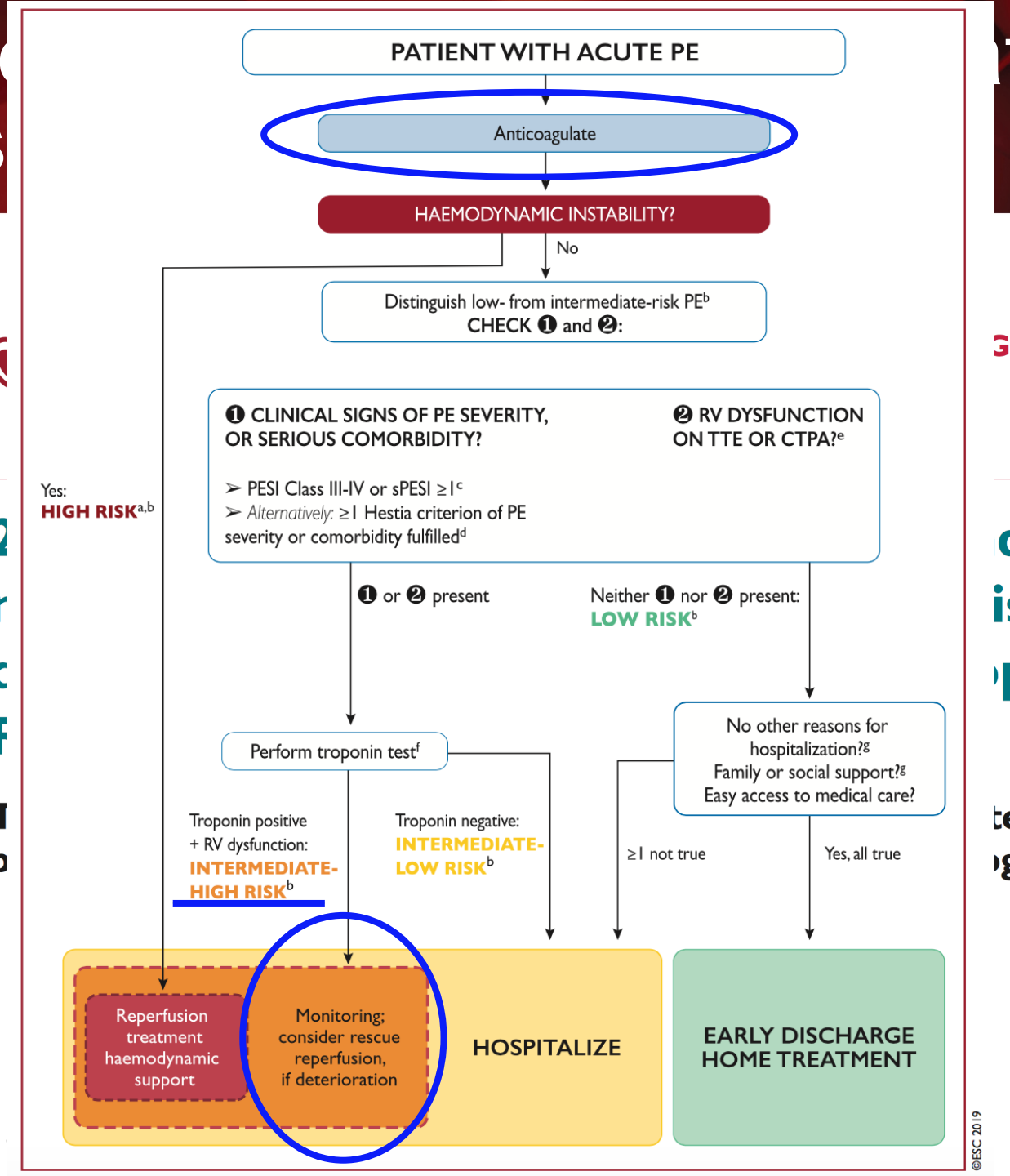
Risk Stratification

Early mortality risk		Indicators of risk				
		Haemodynamic instability[a]	Clinical parameters of PE severity and/or comorbidity: PESI class III–V or sPESI ≥I	RV dysfunction on TTE or CTPA[b]	Elevated cardiac troponin levels[c]	
High		+	(+)[d]	+	(+)	→ *Primary reperfusion + anticoagulation*
Intermediate	Intermediate-high	–	+[e]	+	+	→ *Anticoagulation ± rescue reperfusion*
	Intermediate-low	–	+[e]	One (or none) positive		→ *Anticoagulation ± rescue reperfusion*
Low		–	–	–	Assessment optional; if assessed, negative	→ *Anticoagulation ± early discharge*

Where does our patient fit in?

Konstantinides SV, et al. *Eur Heart J*. 2020;41(4):543-603.

Guidanc… Mass… …tment of …Little



GUIDELINES

ESC Guidelines 25 YEARS

Konstantinides SV, et al. *Eur Heart* …

Ultima

- Randomized, parallel-assignment, multicenter study of UACDT using the EkoSonic System™
- 59 participants (n=30 UACDT + heparin; n=29 heparin only) intermediate-risk PE
- Results (positive for UACDT)

Outcome Measure	UACDT + Heparin	Heparin Only	p-value
RV/LV ratio 24 hrs	-0.30	-0.03	p <0.0001
PA mean pressure 24 hrs	-5.7 mmHg	NA	NA
Minor bleeding	10% (n=3)	3% (n=1)	NA
Major bleeding	0	0	NA

Key takeaway: UACDT was superior to anticoagulation with heparin alone, relieved right heart strain associated with PE, no major bleeding

UACDT = ultrasound-assisted catheter-directed thrombolysis; PA = pulmonary artery.
Kucher N, et al. *Circulation*. 2014;129(4):479-486.

Single-Arm Catheter-Directed Therapy Studies

- Comparable change in RV/LV ratio for different treatment modalities
- UACDT requires longer treatment time, increased hospital length of stay and is associated with higher percentage of major bleeding compared to mechanical thrombectomy

SEATTLE II[5] (N=150) EkoSonic Endovascular System	FLARE[6] (N=106)[a] Inari Medical FlowTriever	EXTRACT-PE[7] (N=119) Penumbra Indigo System	RESCUE[8] (N=109) Bashir Endovascular Catheter
Primary Efficacy (Change in RV/LV ratio)			
24%[b]	25.1%	27.3%	33.3%[b]
Primary Safety			
Major Bleeding within 72 hrs: 10%	Major Adverse Events within 48 hrs: 3.8%	Major Adverse Events within 48 hrs: 1.7%[c]	Major bleeding within 72 hrs: 0.92%
Major Bleeding[d]			
Within 72 hrs: 10%	Within 48 hrs: 1.0%	Within 48 hrs: 1.7%	Within 72 hrs: 0.92%
All-Cause Mortality (30 days)			
2.7%	1.0%	2.5%	0.92%
Device Time			
12-24 hrs	**57 min** (mean)	**37 min** (median)	5 hrs
Hospital Length of Stay (Days (± SDI))			
8.8 ± 5	4.1 ± 3.5	3.7 ± 2.5	2.88 ± 1.6
Pulmonary Embolism (PE) **Recurrence** Rate (30 days)			
n/a	1.9%	0%	0%

a. 2 Patients were removed from the intention-to-treat population because of treatment with adjunctive thrombolytic therapy at index procedure. Denominators for all analyses exclude these 2 patients, who were analyzed separately.
b. Percent reduction calculated for subjects that had CT scan completed within 48 +/- 6 hrs
c. 2 patients experienced 3 events (groin access site bleeding, hemoptysis, death due to sustained ventricular tachycardia post-procedure).
d. Definitions of major bleeding differed for each trial. Please refer to the specific publications for further information

CT = computed tomography.

[5]Piazza G, et al. *JACC Cardiovasc Interv*. 2015;8(10):1382-1392. [6]Tu T, et al. *JACC Cardiovasc Interv*. 2019;12(9):859-869. [7]Sista AK, et al. *JACC Cardiovasc Interv*. 2021;14(3):319-329. [8]Bashir R, et al. *JACC Cardiovasc Interv*. 2022;15(23):2427-2436.

Strike PE

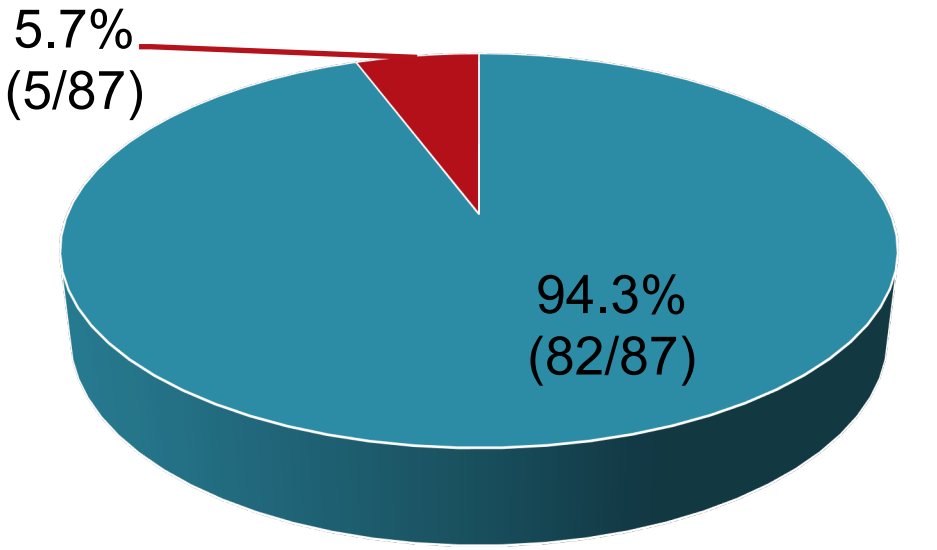
- Objective: Evaluate real-world long-term functional outcomes, safety, and performance of the Indigo® aspiration system for the treatment of PE
- Up to 55 global sites
- 600 patients
- Patient-centric endpoints | QOL and functional
- Long-term follow-up to 1 year
- Interim analysis of 87 patients through 90-day follow-up

Pump with aspiration tubing attached

12 F aspiration catheter with separator wire

Strike PE: Interim Analysis

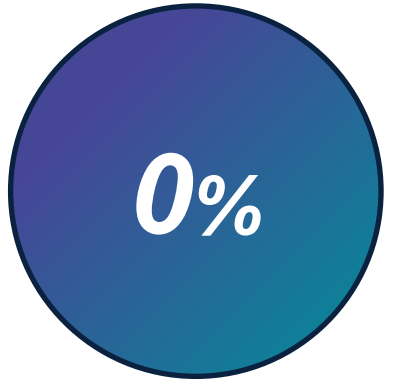
PE Risk Classification



Median device time

Median ICU stay

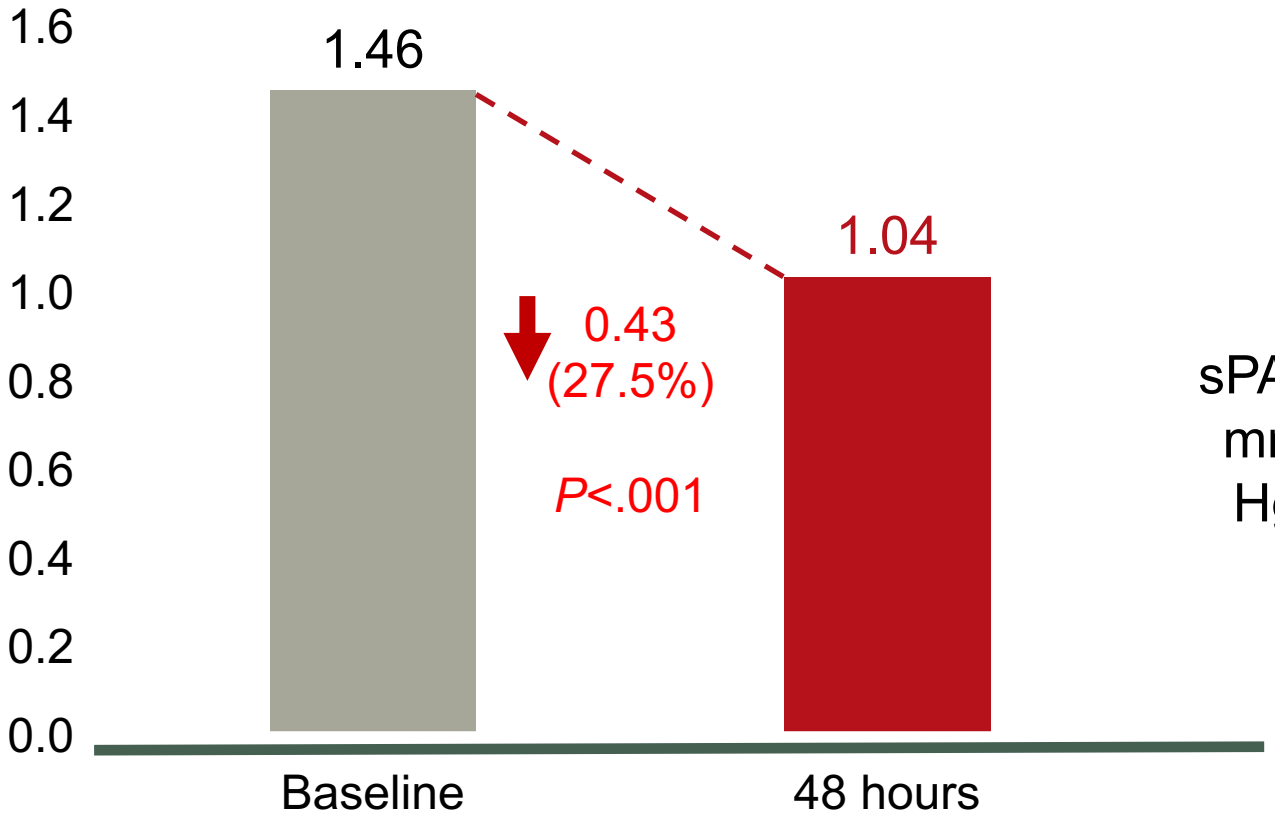
Major adverse events within 48 hours



Mortality

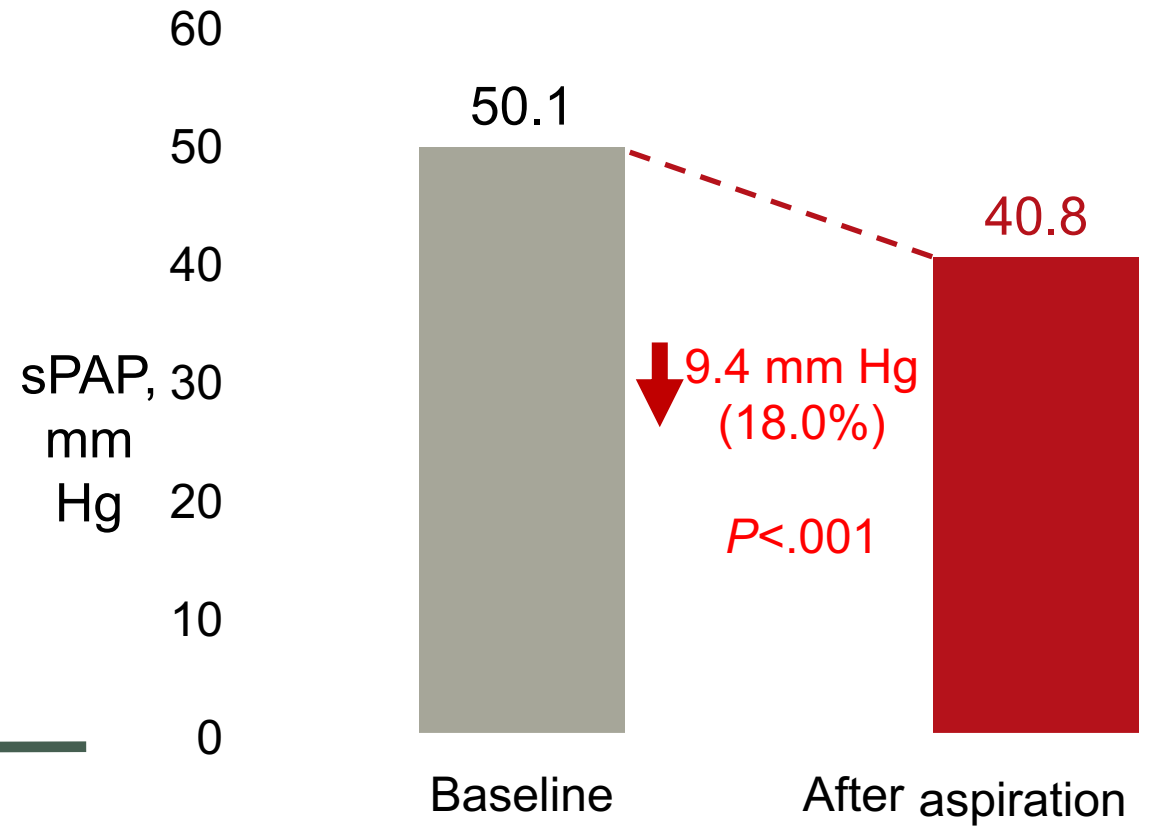
Strike PE: Interim Analysis

Mean Change in RV/LV Ratio
(CTA else ECHO)



Change calculated by using matched imaging modality pairs (n=77)

Mean Change in Systolic
Pulmonary Artery Pressure (sPAP)

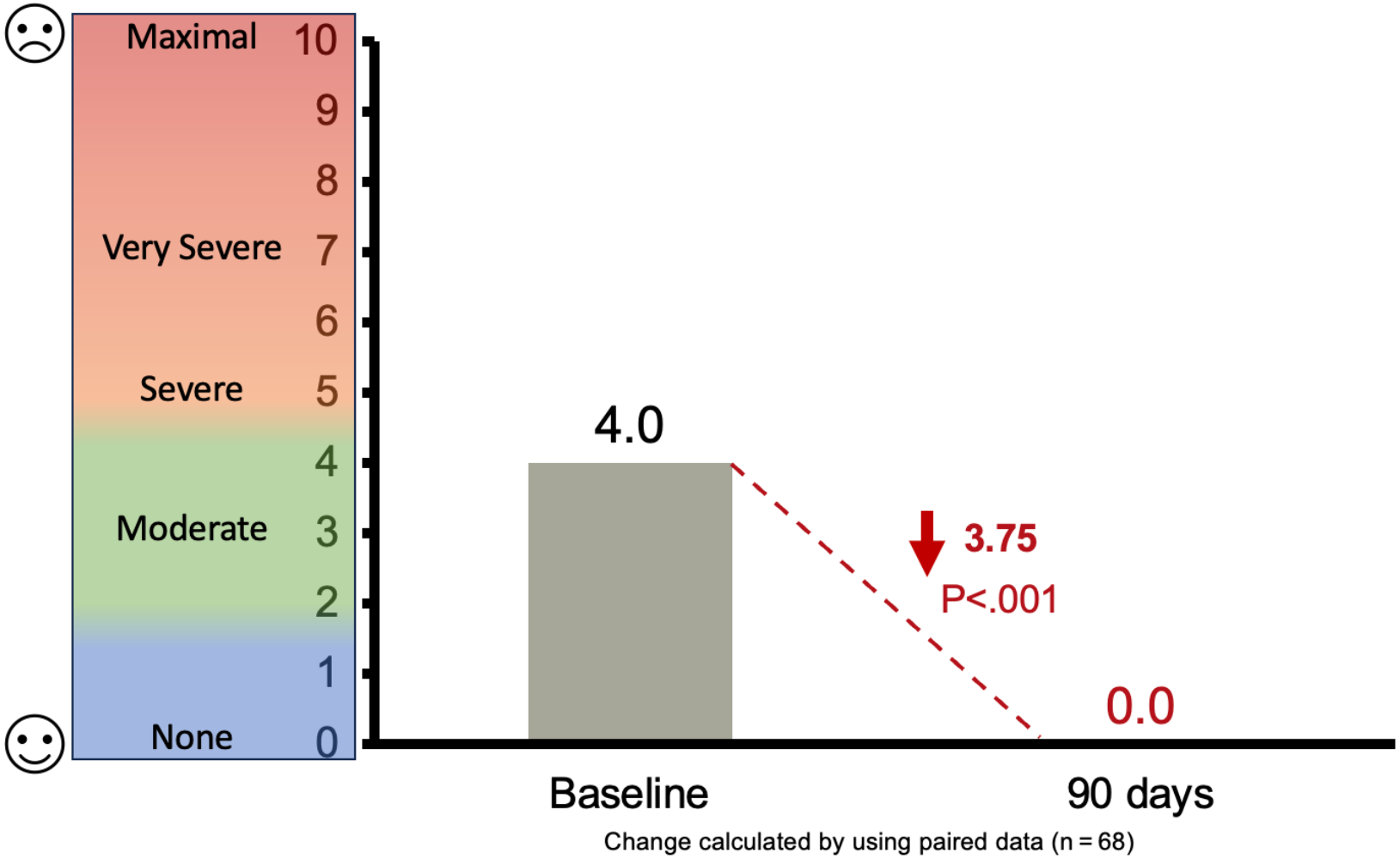


Change calculated by using paired data (n=80)

CTA = computed tomography angiography.

Strike PE: Interim Analysis

Median Change in Borg Scale of Perceived Dyspnea at Rest



Change calculated by using paired data (n = 68)

Strike PE: Interim Analysis

- In a **real-world population** of PE patients, data from STRIKE-PE align with data from single-arm IDE studies
  - An acceptable safety profile and **low rate of major adverse events**
  - **Significant RV/LV ratio reduction**
  - **Significant reduction in sPAP**
- STRIKE-PE also provides valuable **insight into patient functional outcomes and quality of life**, demonstrating at 90 days
  - Improvements that were statistically significant
  - Improvements that exceeded each measure's minimal clinically important difference for PE or lung disease

IDE = investigational device exemption.

Clinical Trials

- PEERLESS trial
- HI-PEITHO trial
- STORM-PE trial
- APEX-AV trial
- PE-TRACT trial

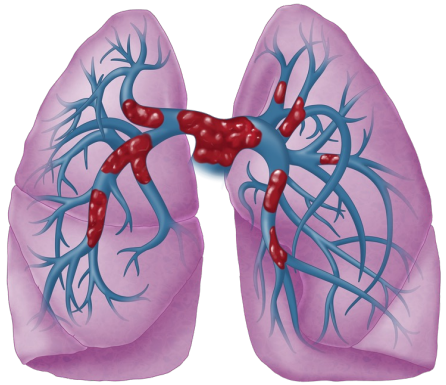
STORM-PE

A Prospective, Multicenter, Randomized Controlled Trial Evaluating Anticoagulation Alone vs Anticoagulation plus Mechanical Aspiration with the Indigo® Aspiration System for the Treatment of Intermediate High Risk Pulmonary Embolism

STORM-PE

In collaboration with PERT Consortium

Study Design



Intermediate-high risk patients

1:1 randomization

Computer-aided peripheral thrombectomy + AC

vs

AC alone

AC = anticoagulant.

Key Eligibility

Inclusion

- Clinical signs and symptoms consistent with acute PE with duration of 14 days or less
- Classification of intermediate-high-risk PE as demonstrated by right ventricular dysfunction with RV/LV ratio ≥ 1.0 on CTPA and elevated cardiac biomarkers, including cardiac troponin, BNP, and/or NT-proBNP above the upper limit of normal

Exclusion

- Administration of thrombolytic agents or glycoprotein IIb/IIIa receptor antagonist within 30 days prior to baseline imaging
- Hemodynamic instability
- Patients on ECMO
- National Early Warning Score 2 (NEWS2) ≥ 9
- Active cancer or cancer/tumor requiring active therapy (surgery, chemotherapy, targeted therapy, or radiation) in previous 6 months or during course of trial (except non-melanoma skin cancer) or tumor with caval invasion

NT-proBNP = N-terminal pro-brain natriuretic peptide.

Study Endpoints

Primary

- Change in RV/LV ratio at 48 hours as assessed by CTPA

Secondary

- Major adverse events (MAEs) within 7 days: a composite of clinical deterioration requiring escalation of care, PE-related mortality, symptomatic recurrent PE, or major bleeding
- Functional outcome through 90 days
- Quality of life (QoL) through 90 days
- All-cause mortality within 90 days
- PE-related mortality within 90 days
- Symptomatic PE recurrence within 90 days

QoL and Functional Outcome Measures

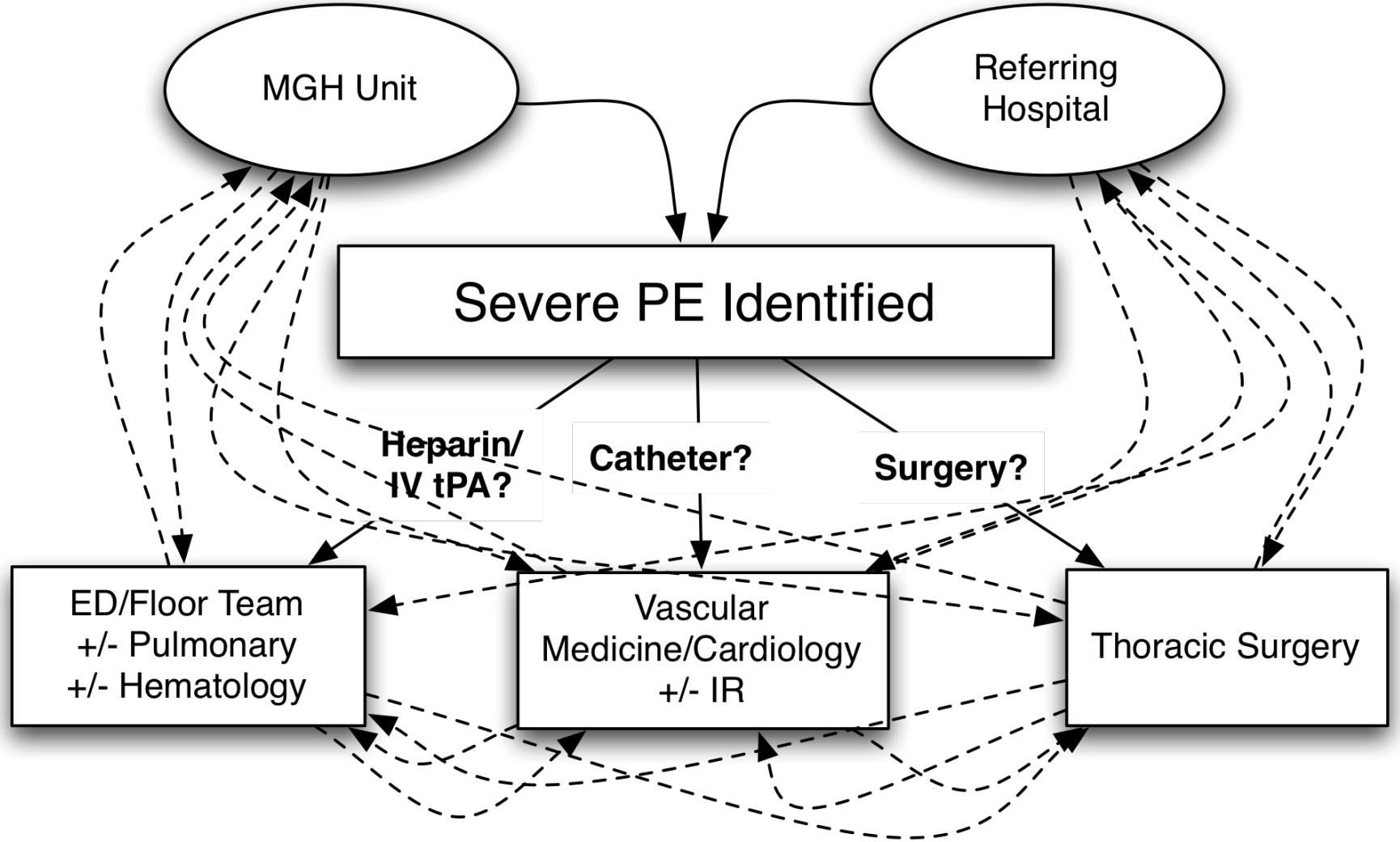
- PEmb-QoL Questionnaire
- EQ-5D-5L Questionnaire and EQ-VAS
- 6MWT
- Borg Scale and mMRC for dyspnea
- NYHA Classification
- Post-VTE functional status scale (PVFS)
- Wearable device sub-study

5L = five levels; VAS = visual analogue scale; 6MWT = six-minute walk test; mMRC = Modified Medical Research Council; NYHA = New York Heart Association.

Case Decision-Making

- Intermediate-high-risk PE

Case Decision-Making



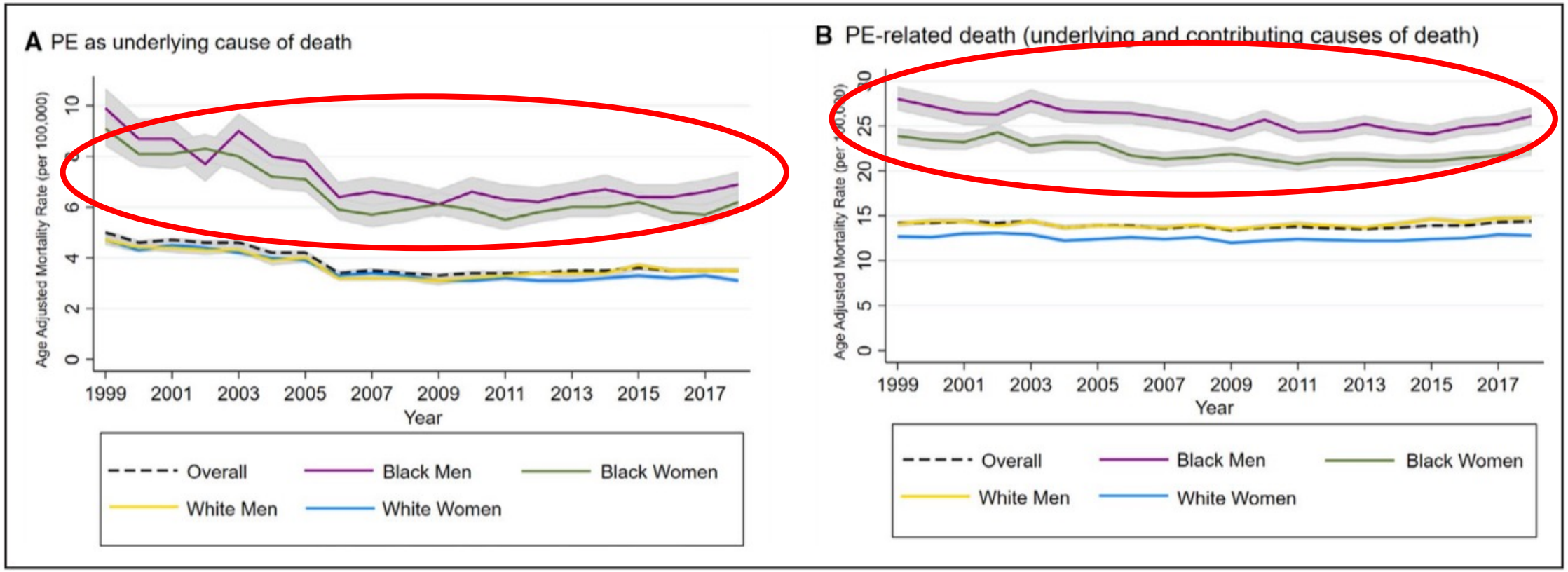
MGH = ; IV = intravenous; tPA = tissue-type plasminogen activator; ED = emergency department; IR = interventional radiology; ICU = intensive care unit.
Courtesy Kabrhel C.

Case Decision-Making

- Intermediate-high-risk PE
- Expeditiously started on LMWH
- PERT called

LMWH = low molecular weight heparin; PERT = pulmonary embolism response team.

Racial Disparities



Martin KA, et al. *J Am Heart Assoc*. 2020;9(17):e016784.

Closing Reflections

- PE is a major cause of morbidity and mortality
- Anticoagulation is mainstay of therapy…but how do we decide which patient needs advanced therapy and, if so, what kind?
  - Risk stratification
  - PERT
  - Single-arm studies
- We need RCT!
- STORM-PE is first randomized data comparing mechanical aspiration thrombectomy to anticoagulation alone
- STORM-PE with many others will advance our understanding of best treatment options for intermediate-high-risk PE patients
- Racial and gender disparities in VTE exist; we need to address/combat inequities

Thank You

PE Case Presentation

Peter Monteleone, MD, FACC, FSCAI
Director, Ascension Cardiovascular Research
Assistant Professor
UT Austin Dell School of Medicine
Austin, Texas

64-Year-Old Male

- Remote history of RLE DVT
- Presents to ED with complaints per daughter of recurrent pre-syncope
- *Finally* presented to ED because of “sudden blindness in both eyes right before passing out”
- In setting of 7 days or progressive dyspnea

64-Year-Old Male

- HR 122 BP 96/48 94% @ 4L NC
- GEN: dyspneic, tachypneic
- NEURO: non-focal
- CV: tachycardic, no murmurs

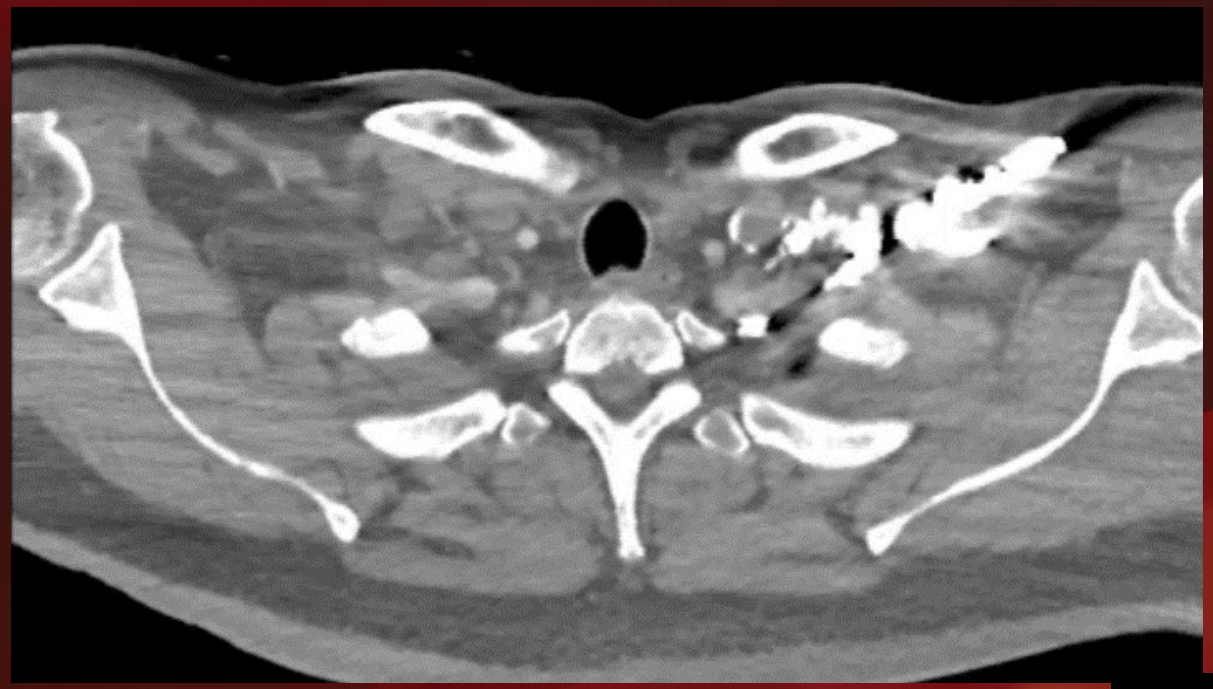
- EKG sinus tachycardia
- tropT 0.14

NC = nasal cannula; CV = cardiovascular; tropT = troponin T rapid test.

64-Year-Old Male

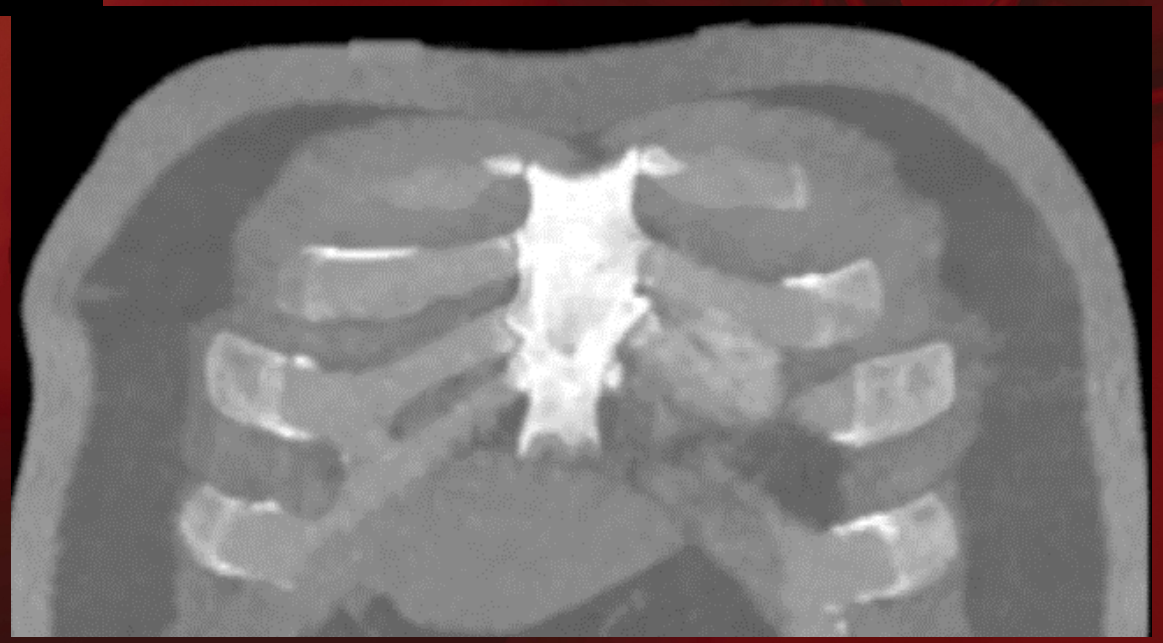
- Stroke code called
- CTA head/neck benign
- CTA chest

CTA = computed tomography angiography.



Large-burden bilateral pulmonary embolism

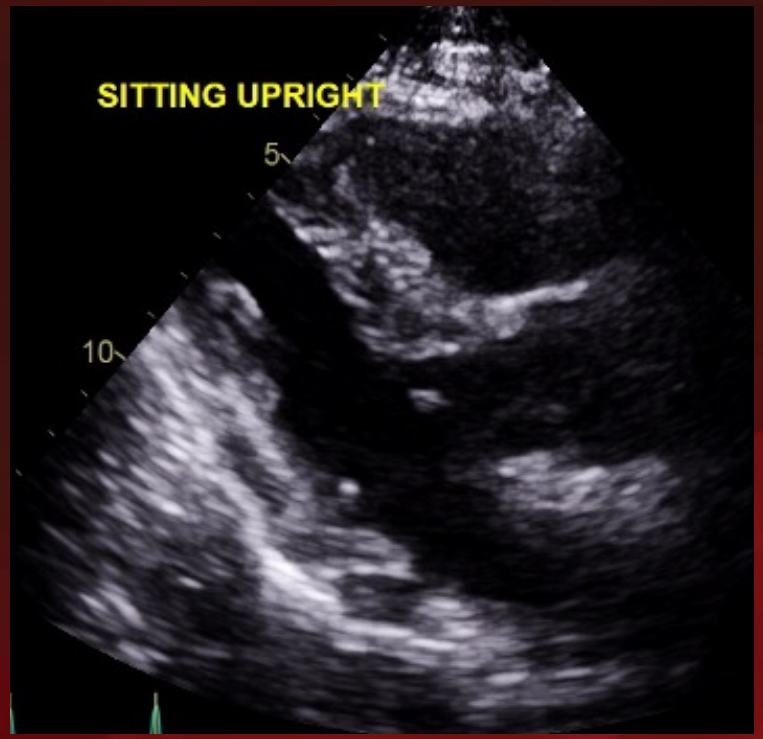
RV enlargement RV/LV ratio 1.3

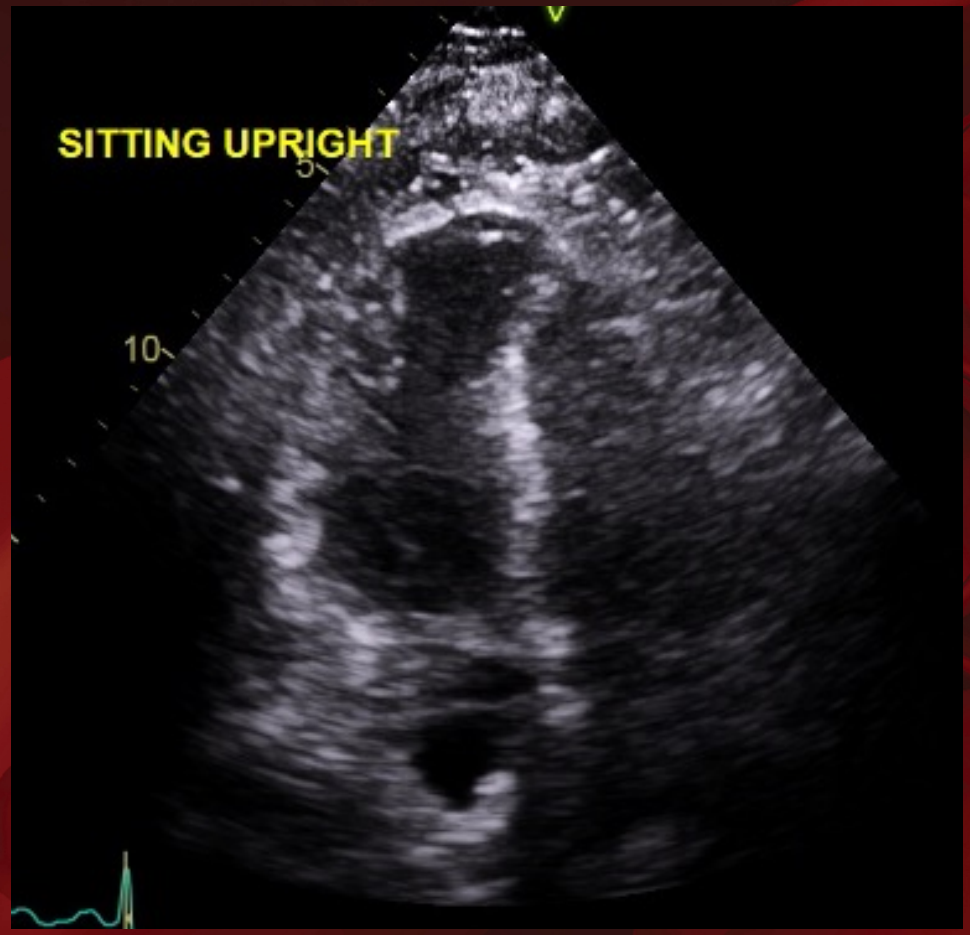


64-Year-Old Male

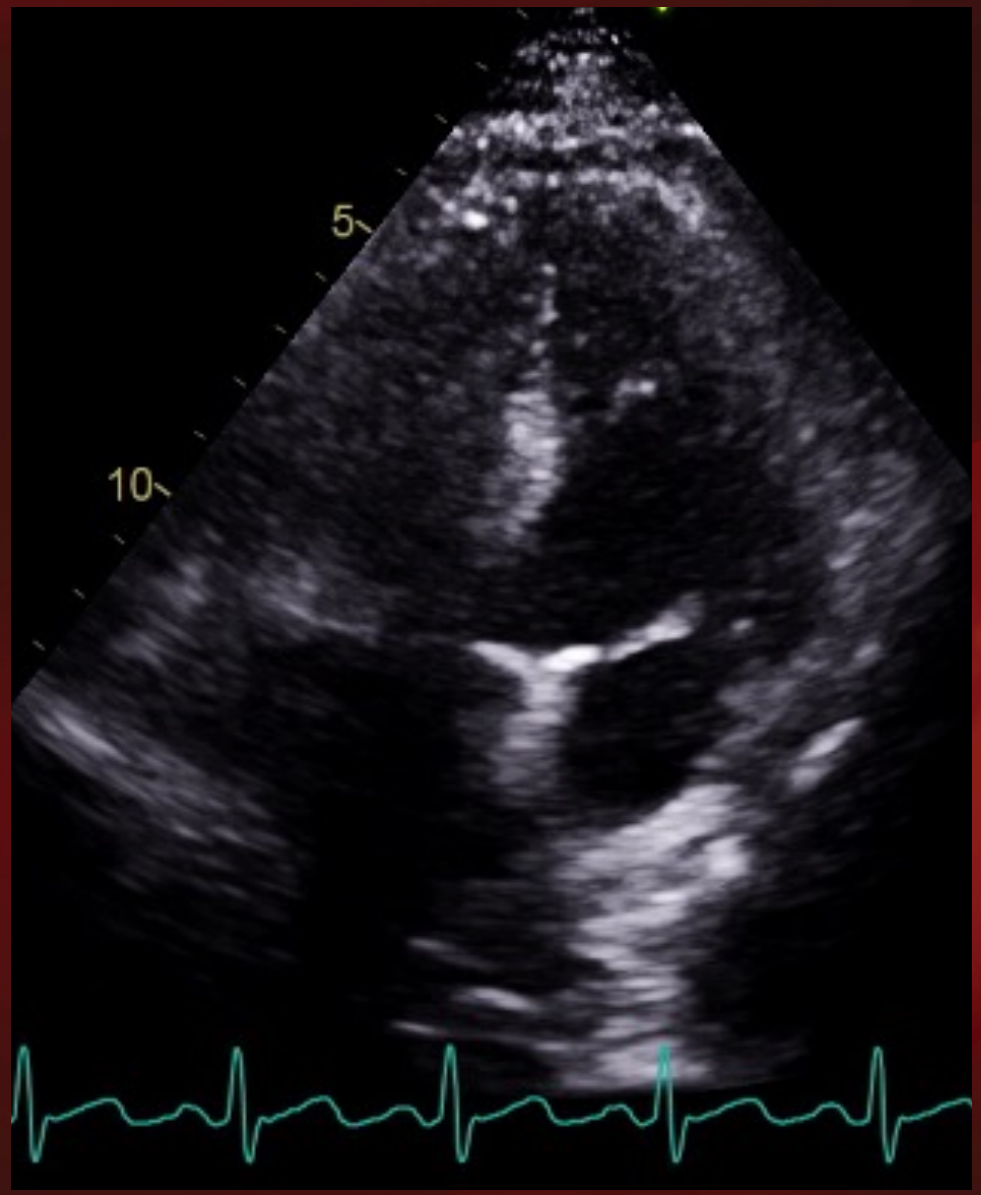
- Stroke team assessment
  - “Rare neurologic causes of BInocular blindness”
  - In setting of tenuous hemodynamic stability “likely possibility of hypotension in setting of PE” as primary etiology
  - MRI brain performed and unremarkable
- TTE performed (including in setting of evaluation for consideration of venous/arterial embolism)

MRI = magnetic resonance imaging; TTE = transthoracic echocardiogram.

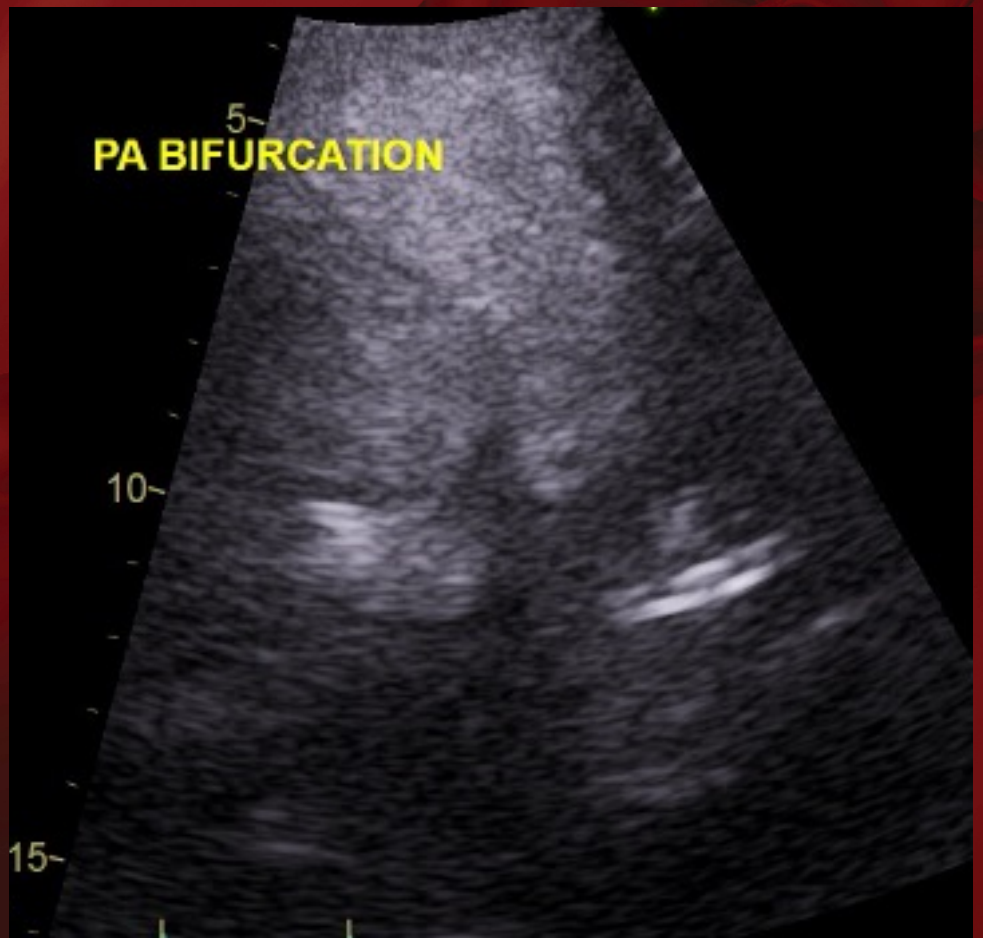




- RV dilated RV/LV 1.3
- RV dysfunctional
- RV apical hyperkinesis



- Agitated saline “bubble” study negative
- Visualized thrombus at pulmonary arterial bifurcation



64-Year-Old Male

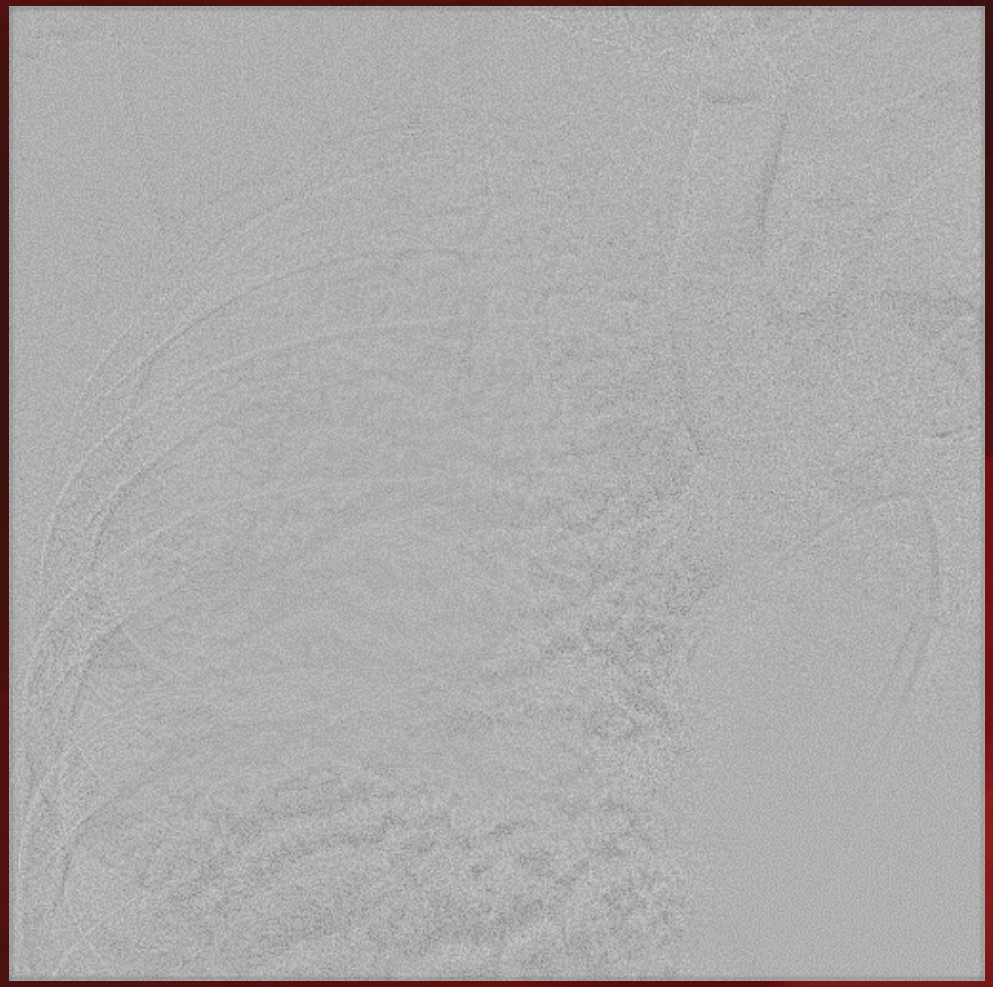
HR *122* BP *96/48* *94% @ 4L NC*

tropT *0.14*

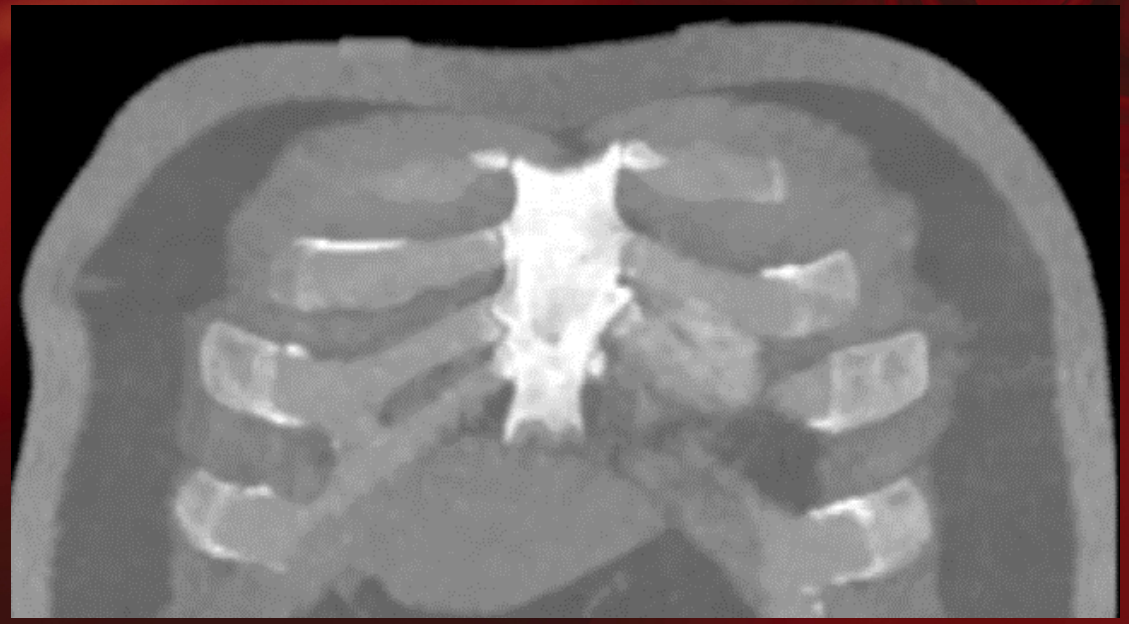
Early mortality risk		Indicators of risk			
		Haemodynamic instability	Clinical parameters of PE severity and/or comorbidity: PESI class III-V or sPESI ≥I	RV dysfunction on TTE or CTPA	Elevated cardiac troponin levels
High		+	(+)[d]	+	(+)
Intermediate	Intermediate-high	-	+[e]	+	+
	Intermediate-low	-	+[e]	One (or none) positive	
Low		-	-	-	Assessment optional; if assessed, negative

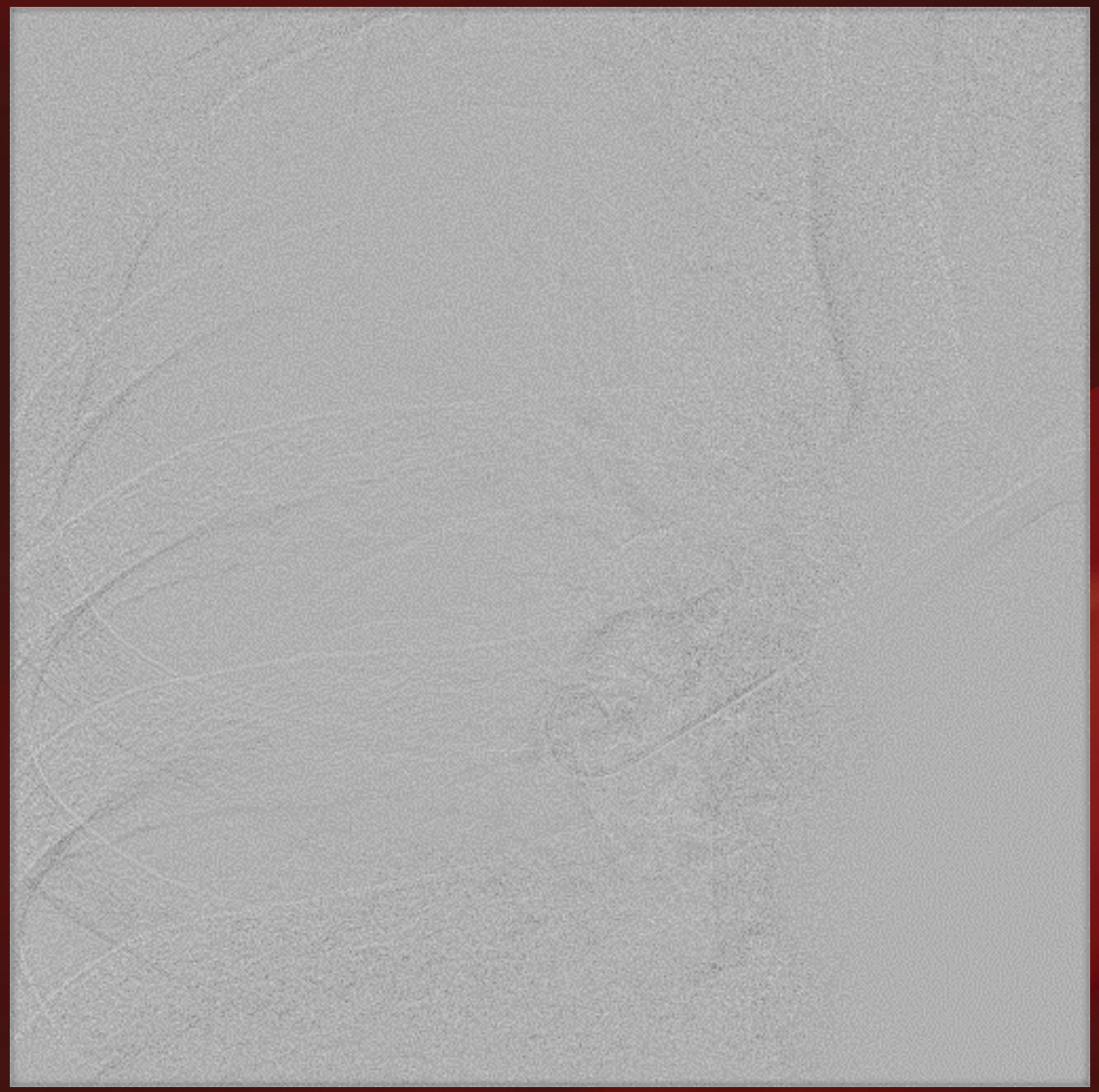
“Anatomic” Considerations

- “Saddle” pulmonary embolism
- Large thrombus burden
- 7 days old in the PA (at least)



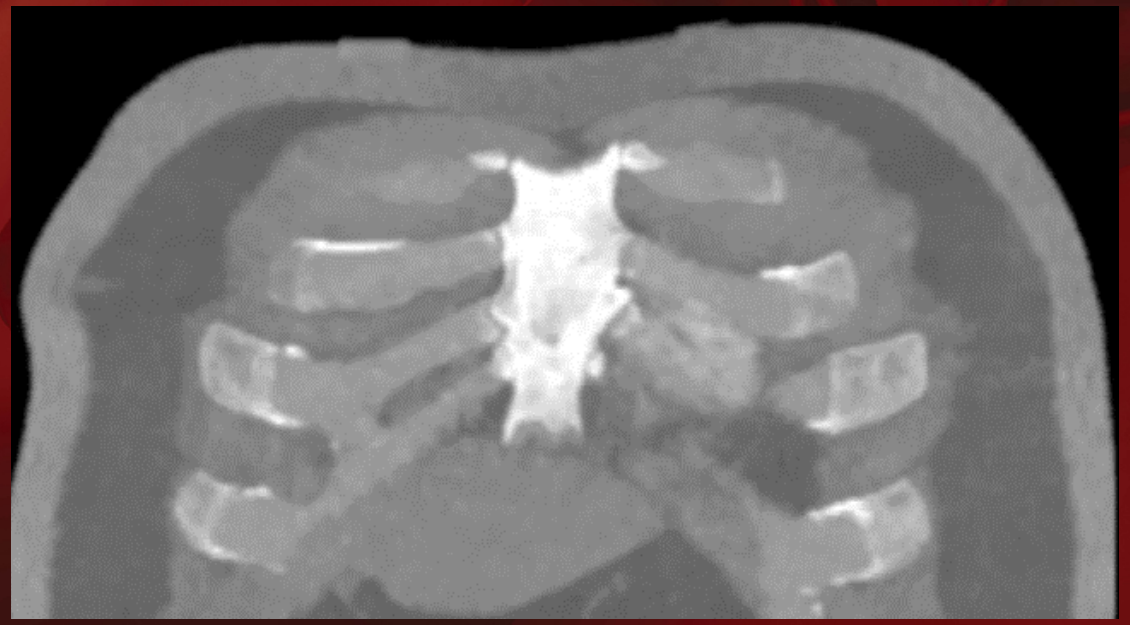
- Stiff guidewire into R PA
- Sheath delivered
- Tachypneic and cannot breath hold
- Limited pigtail angiogram
- “Lots” of clot

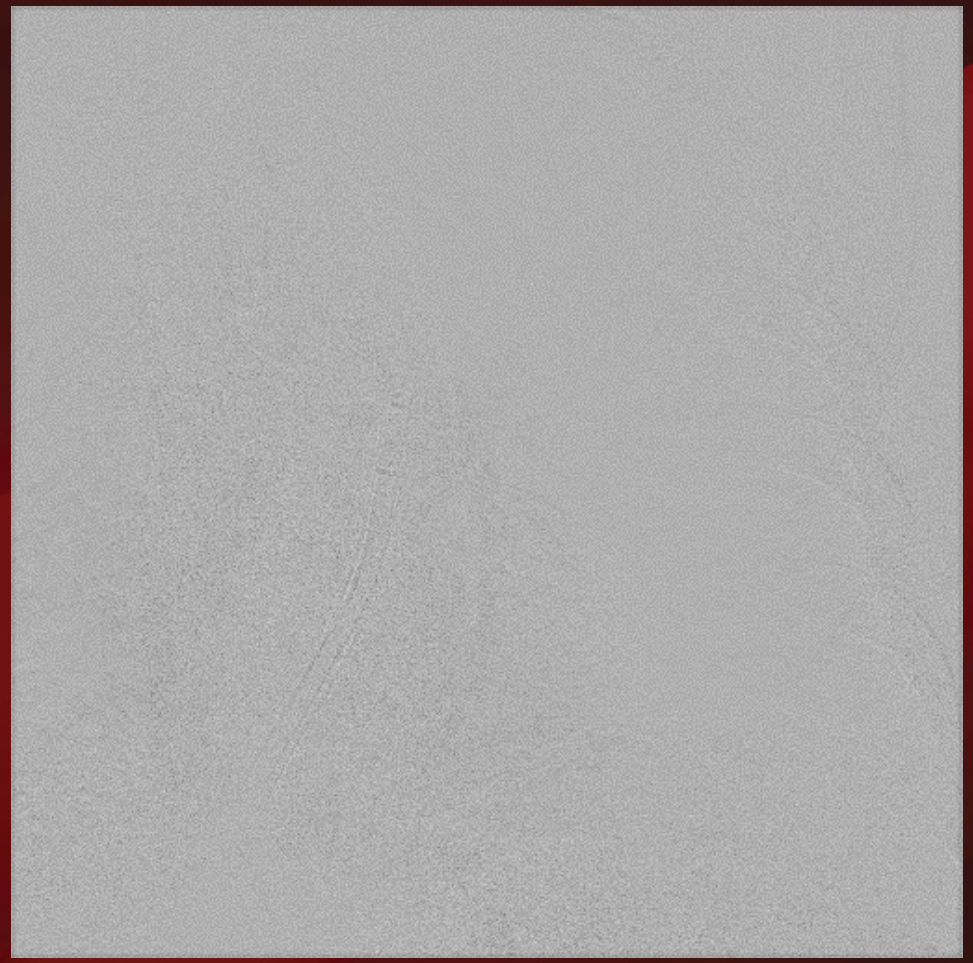




- Organized thrombus… rotational advance of the device with multiple passes
- Improved filling of lower lobes
- Rewire into superior lobes with multiple passes
- Persistent tachypnea limits imaging
- Large burden of thrombus evacuated

- Transitioned to left lung
- Large burden organized but non-occlusive thrombus
- Multiple passes with device rotation



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64-Year-Old Male

- PA pressures improved immediately (70 → 40)
- Clinical improvement and effective debulking more important than a “perfect picture”

Over the Next 24 Hours…

- HR improved 120 → 86
- SBP improved 96 → 124
- Discharged on RA
- Follow-up TTE pending

Conclusions

- Mechanical thrombectomy plays a valuable role in advanced PE therapies…especially in highest risk scenarios
- Not all thrombus is “fresh”…and not all of it is easily evacuated from the PA
- Powered continuous aspiration improves versatility for dealing with organized or complex thrombus (“park and pull” versus “powered advance/rotate”)
- Computer-assisted thrombectomy makes powered thrombectomy possible and safe
- Not always about perfect pictures…about debulking and achieving flow/distal tissue perfusion

Case Study

Brian J. Schiro, MD, RPVI, FSIR
Medical Director
Baptist and Doctors Hospital Noninvasive Vascular Lab
Program Director
Independent Interventional Radiology Residency
Miami, Florida

Case

61-year-old male with schizophrenia admitted with bowel obstruction and colonic mass. Underwent resection 6 days prior and had acute episode of SOB with SaO_2 83%.

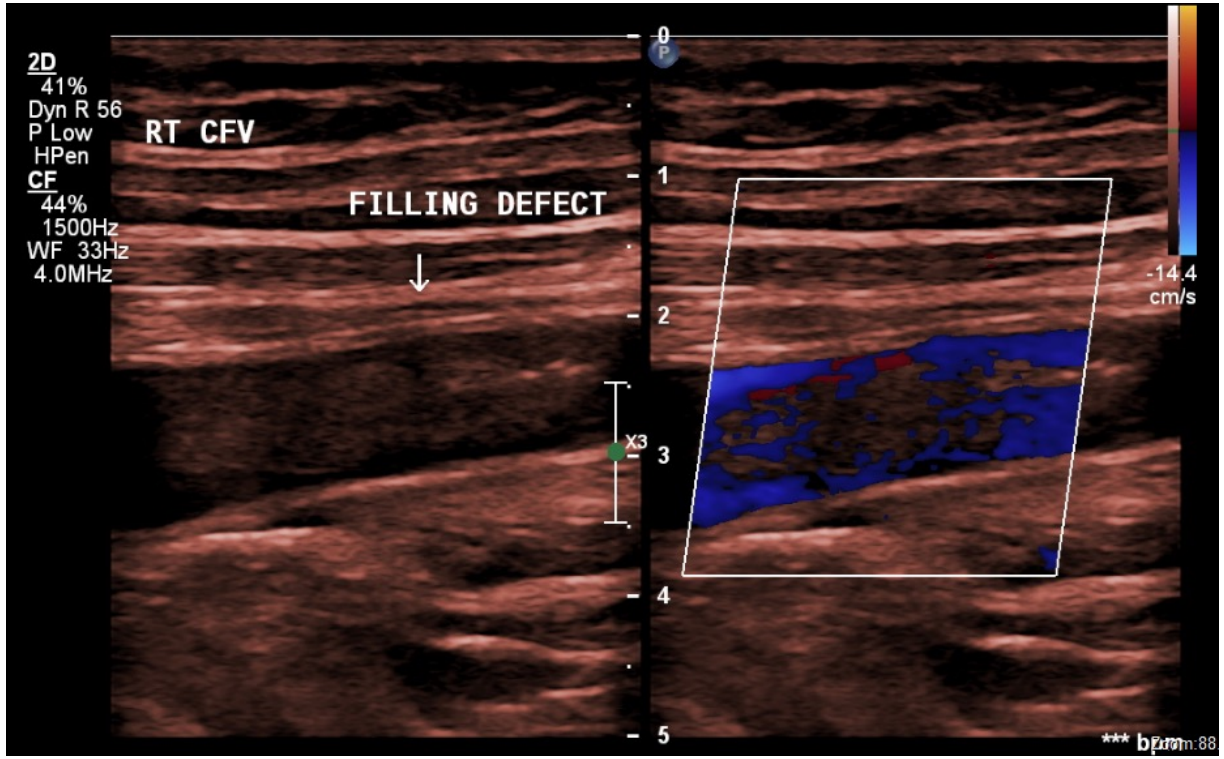
VS

HR: 111 RR: 17 BP: 115/59 SpO2: 83% on RA

Labs

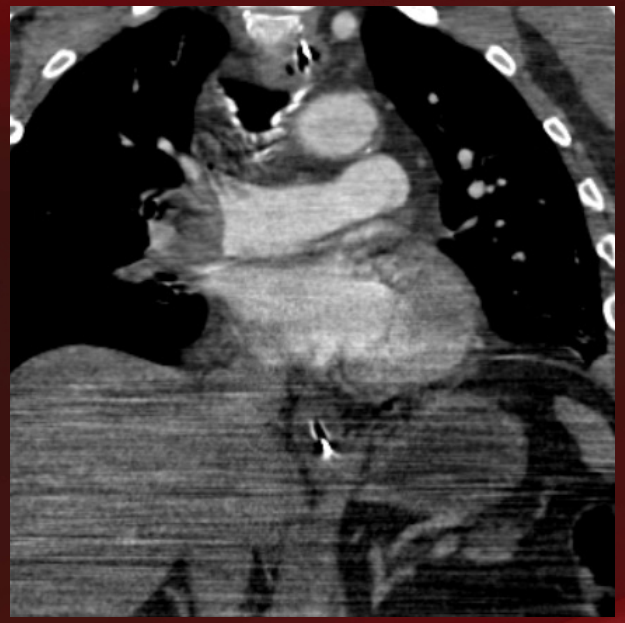
Troponin I: 0.81 ng/mL

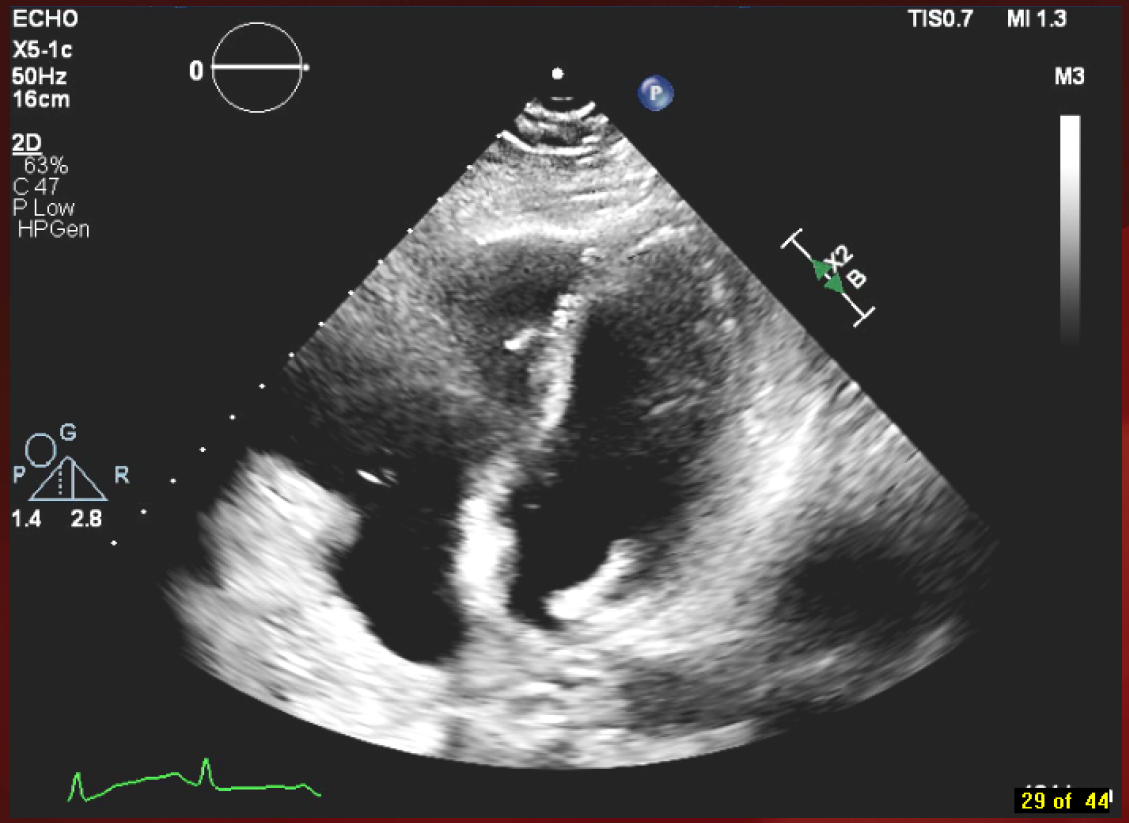
ProBNP: 2,080 pg/mL



SOB = shortness of breath; VS = vital signs.


46.8 mm
34.1 mm

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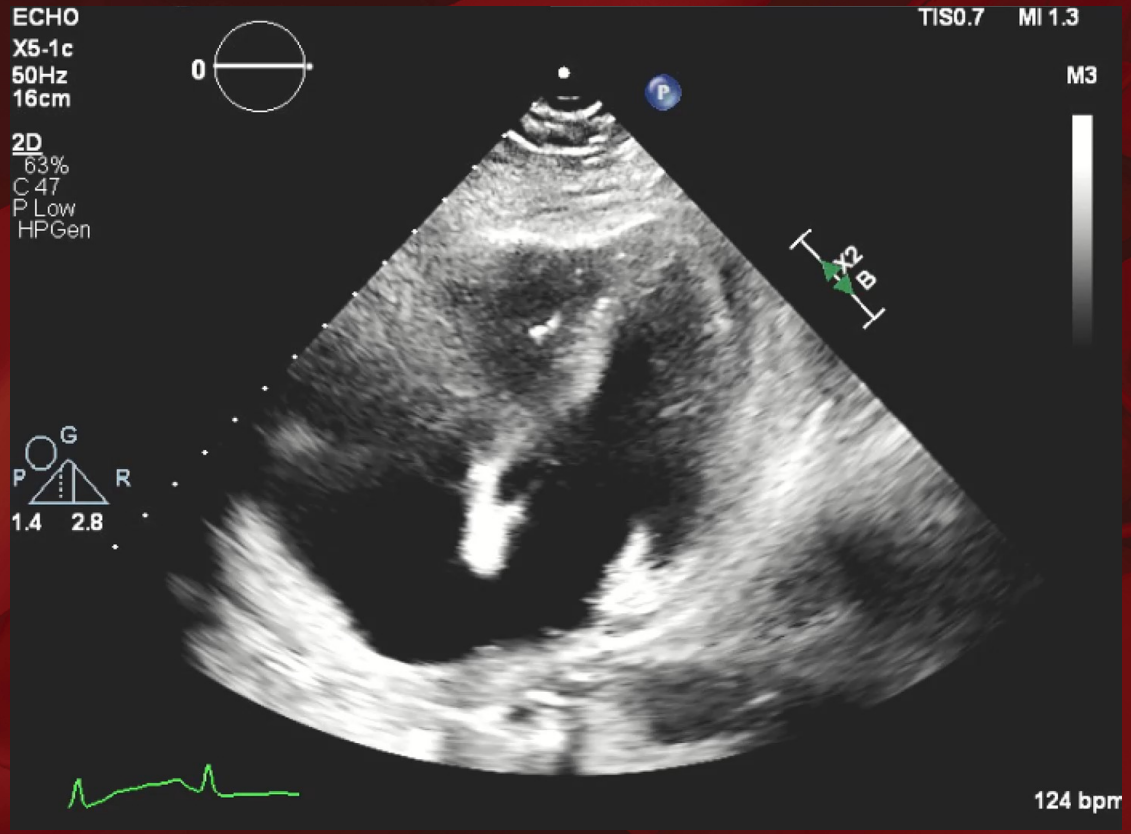
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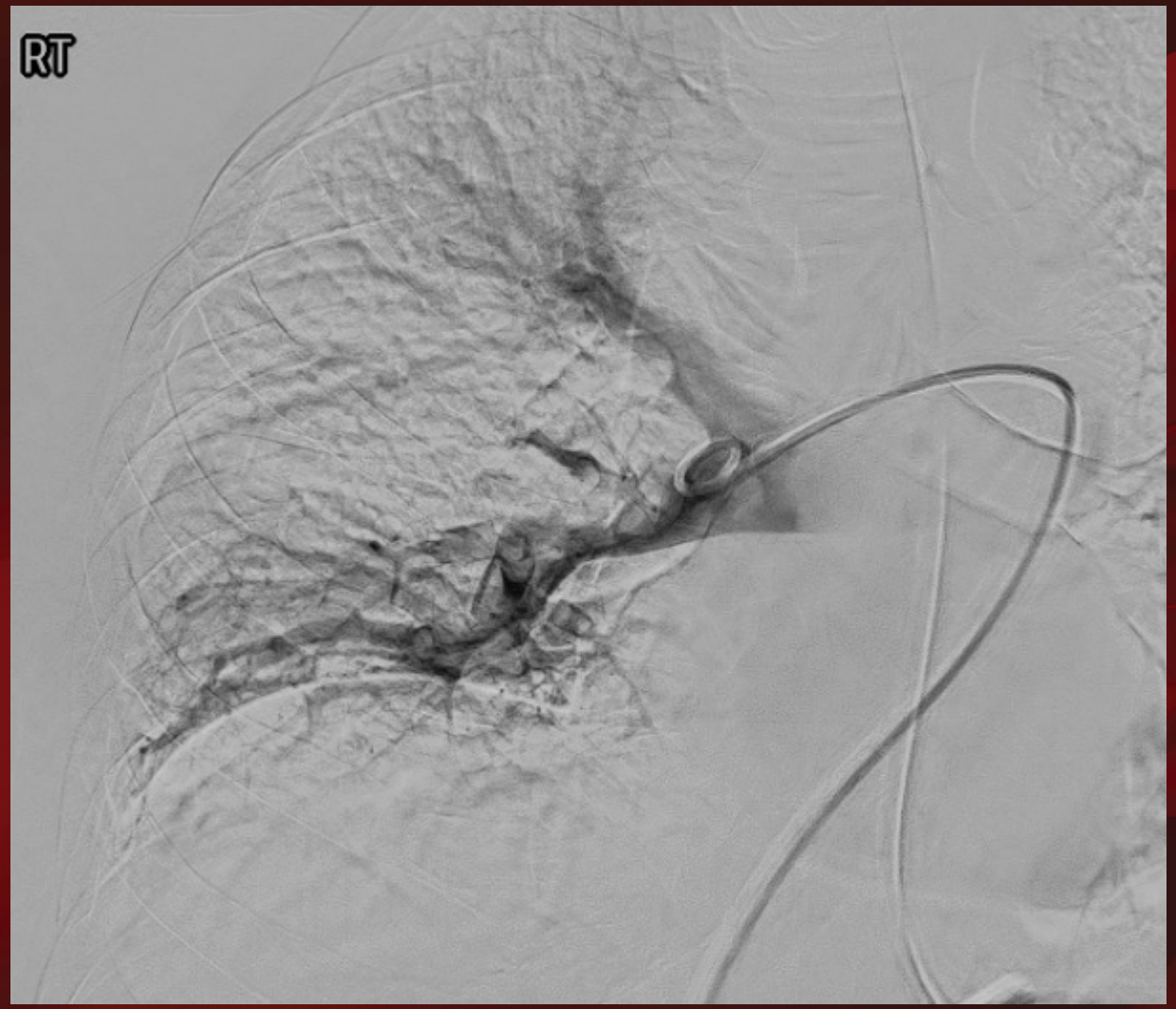
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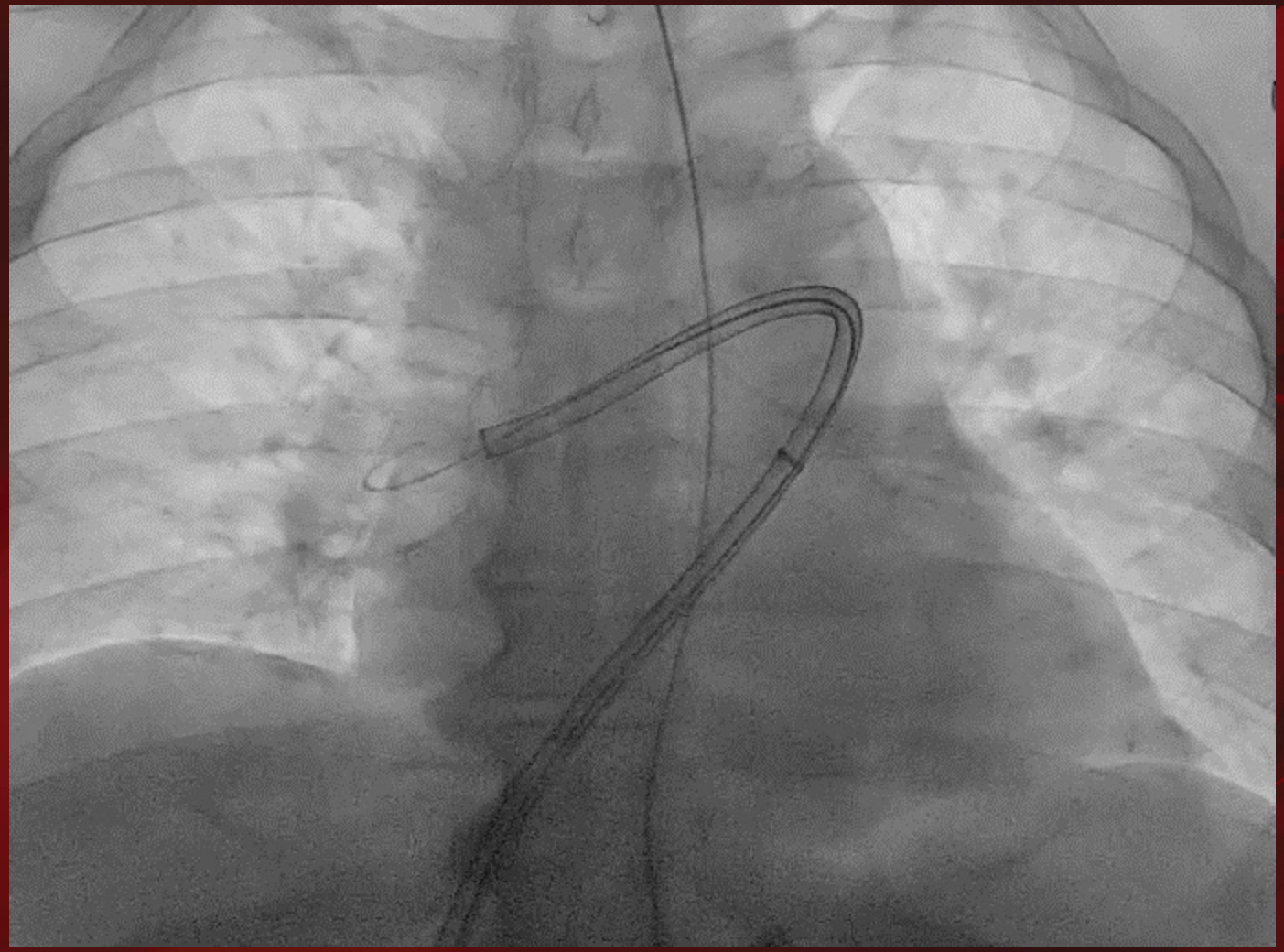

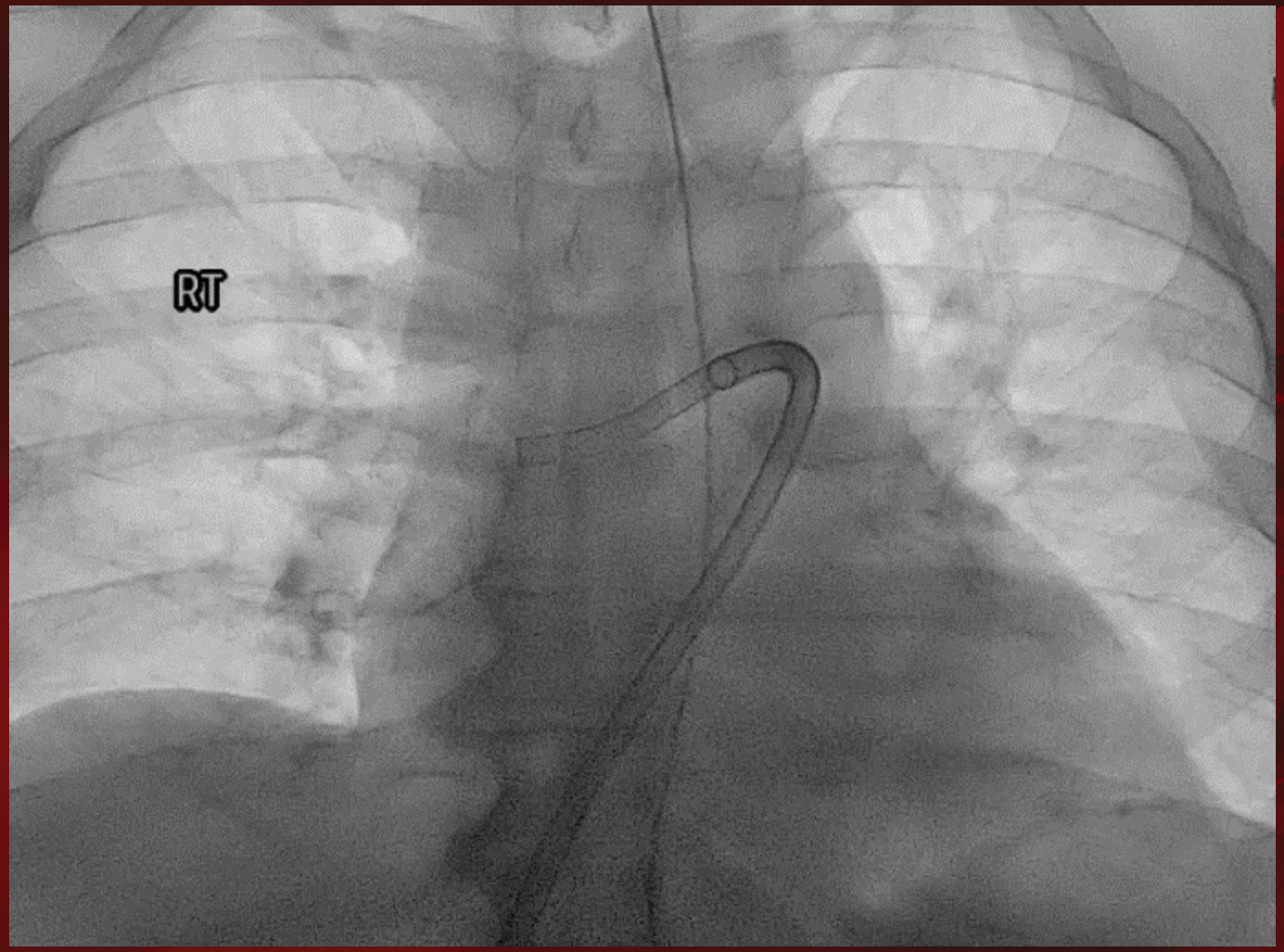
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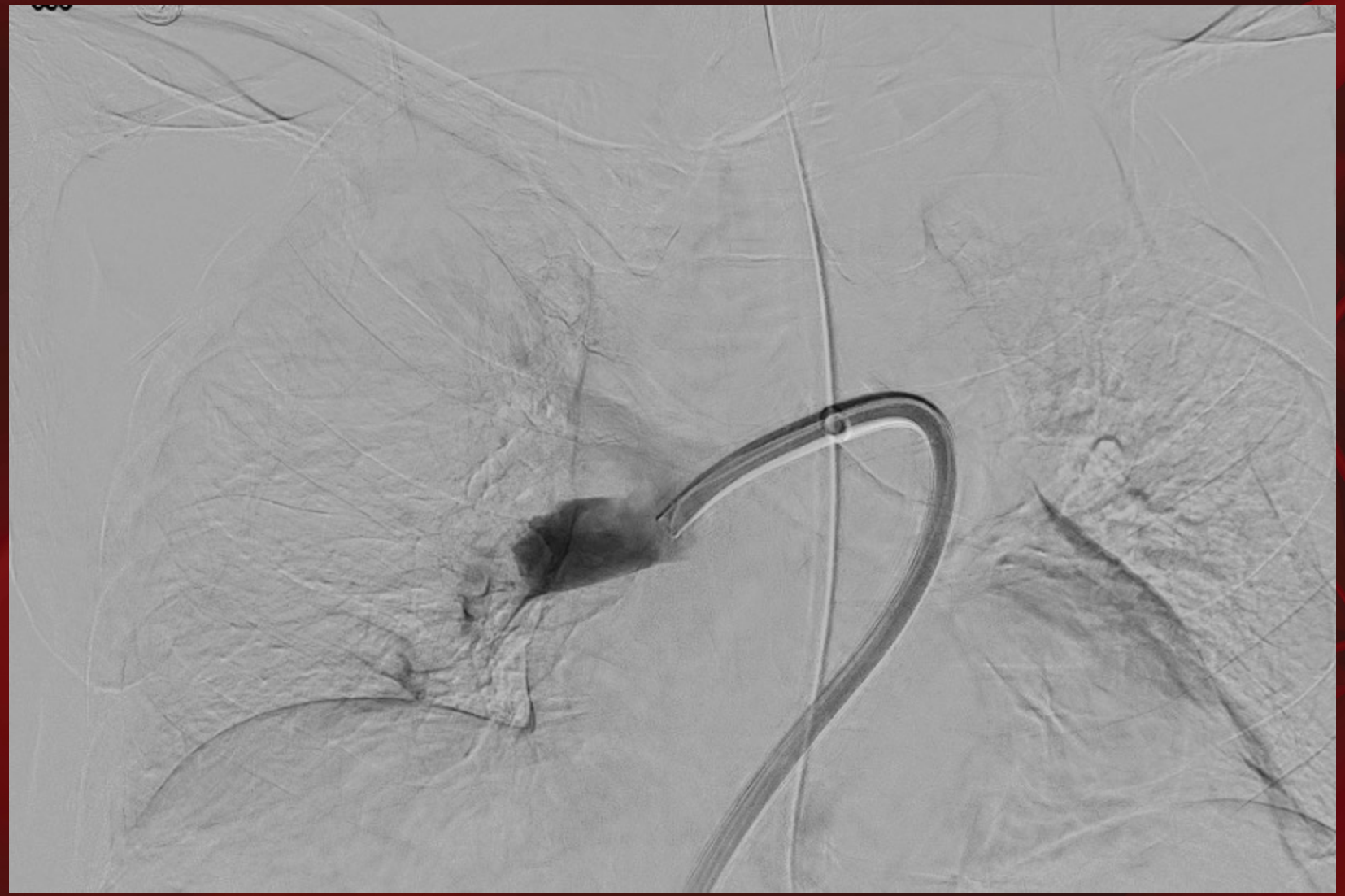

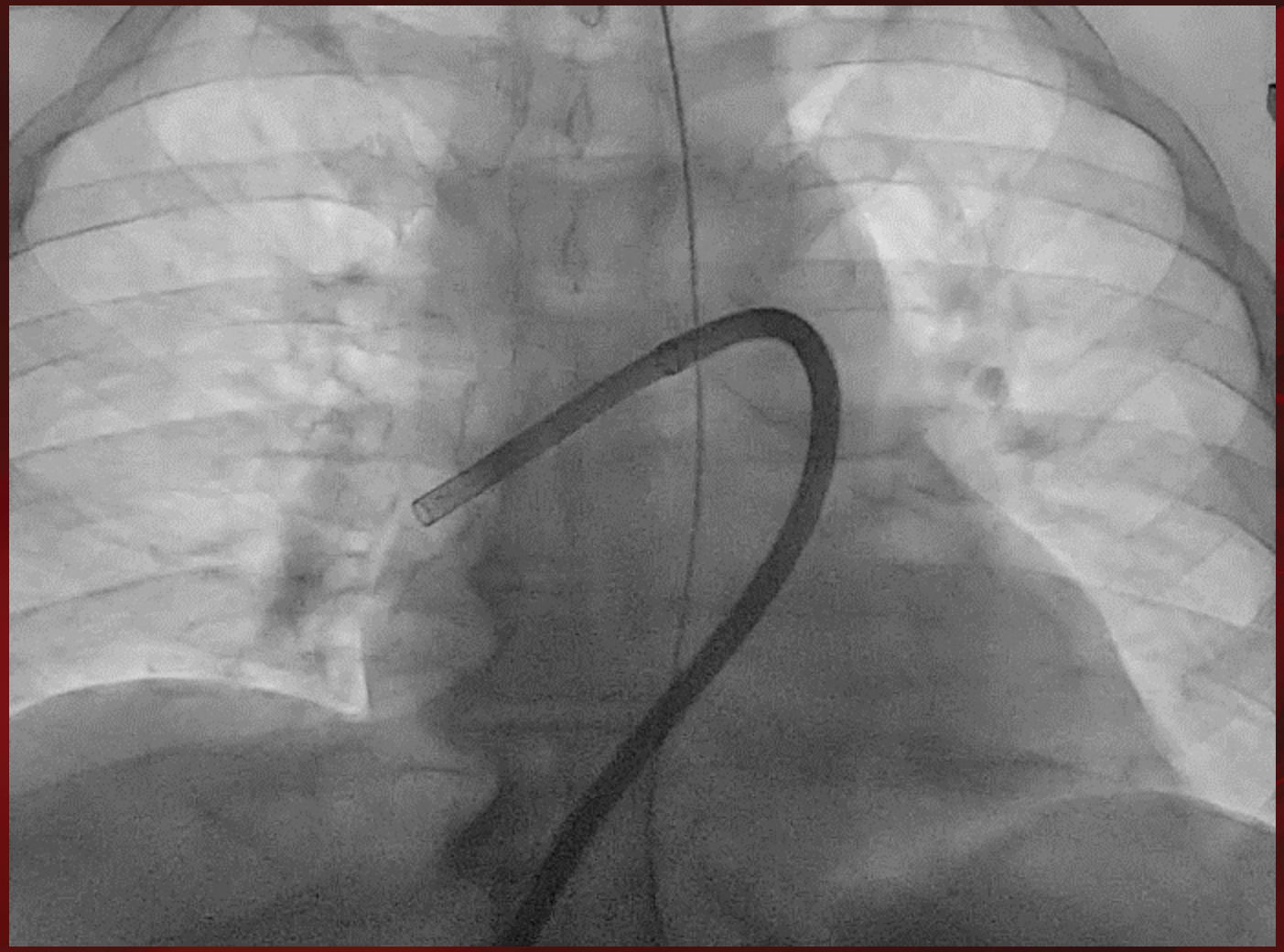

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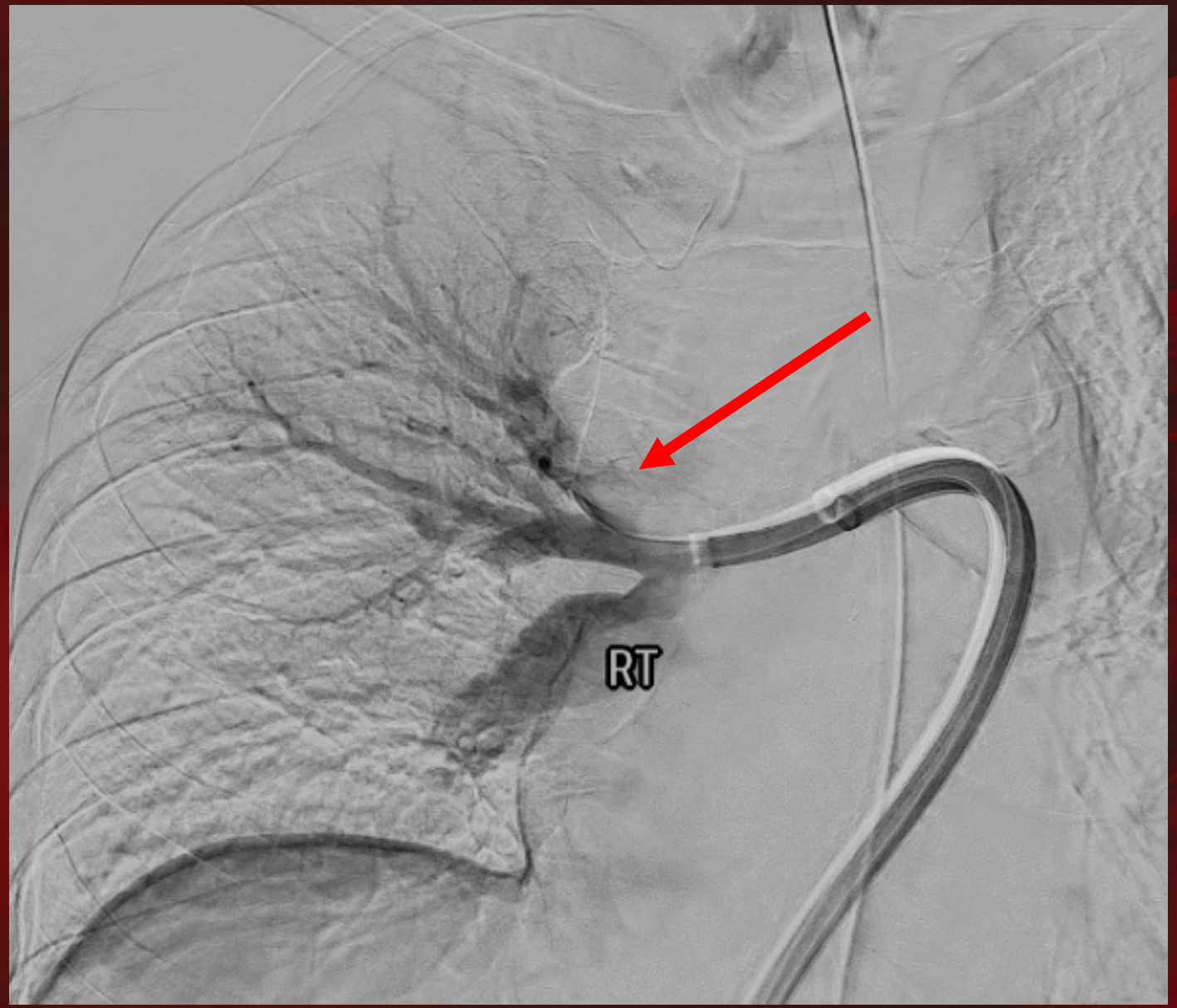
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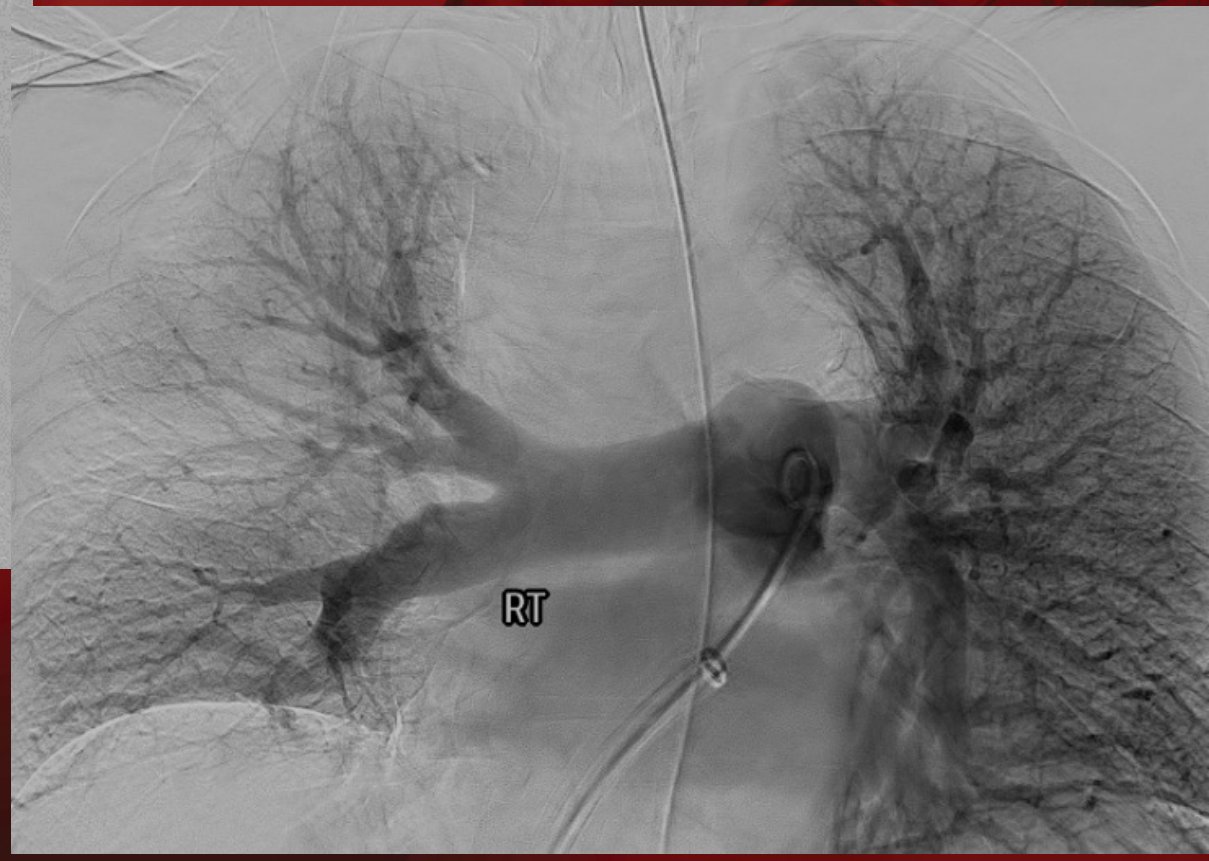
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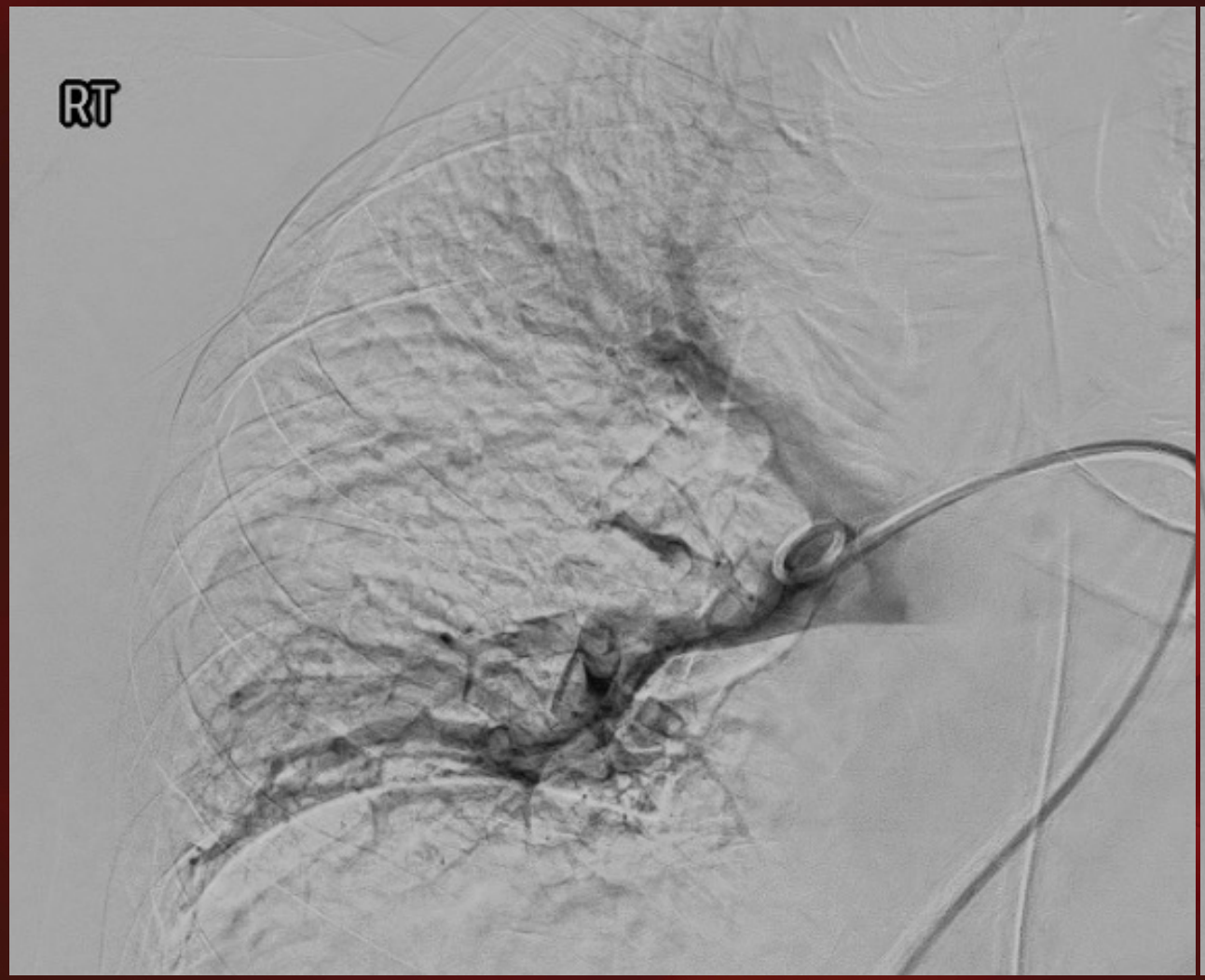
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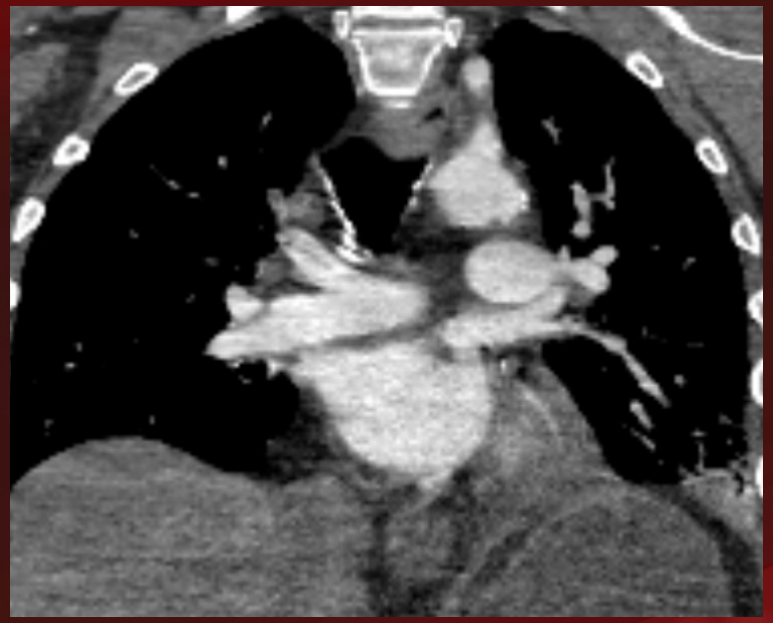

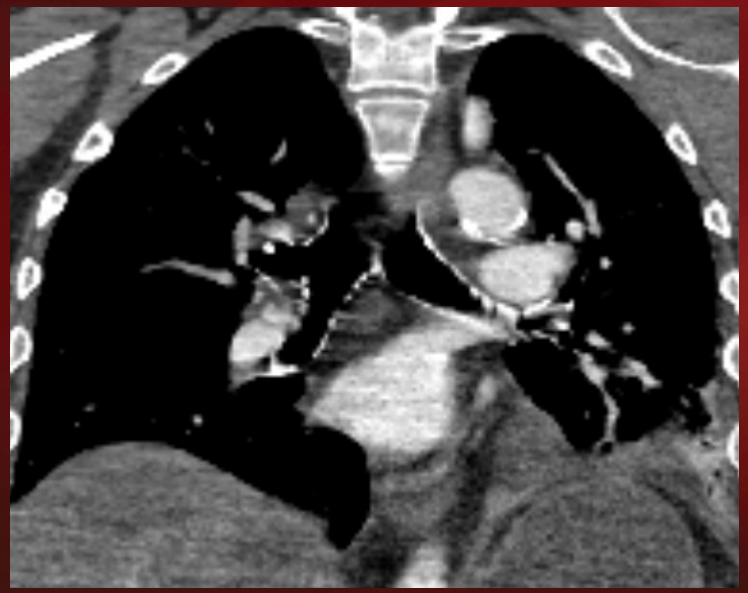

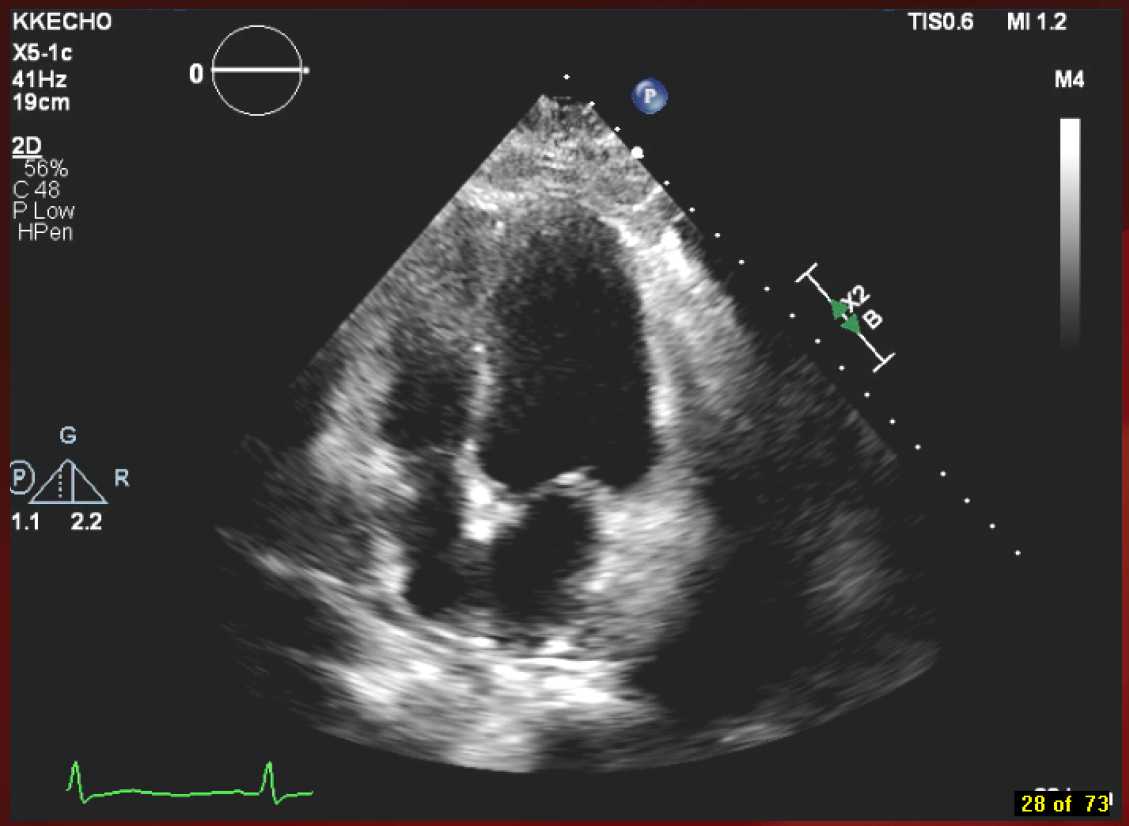
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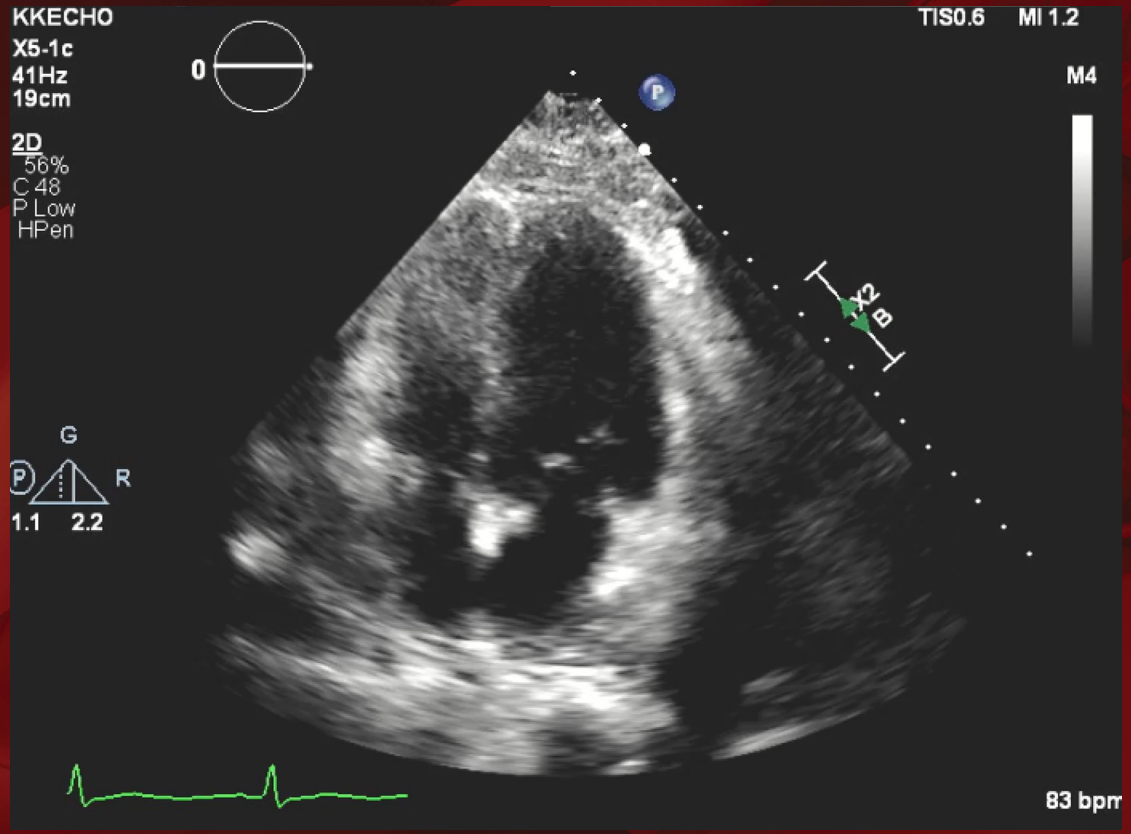
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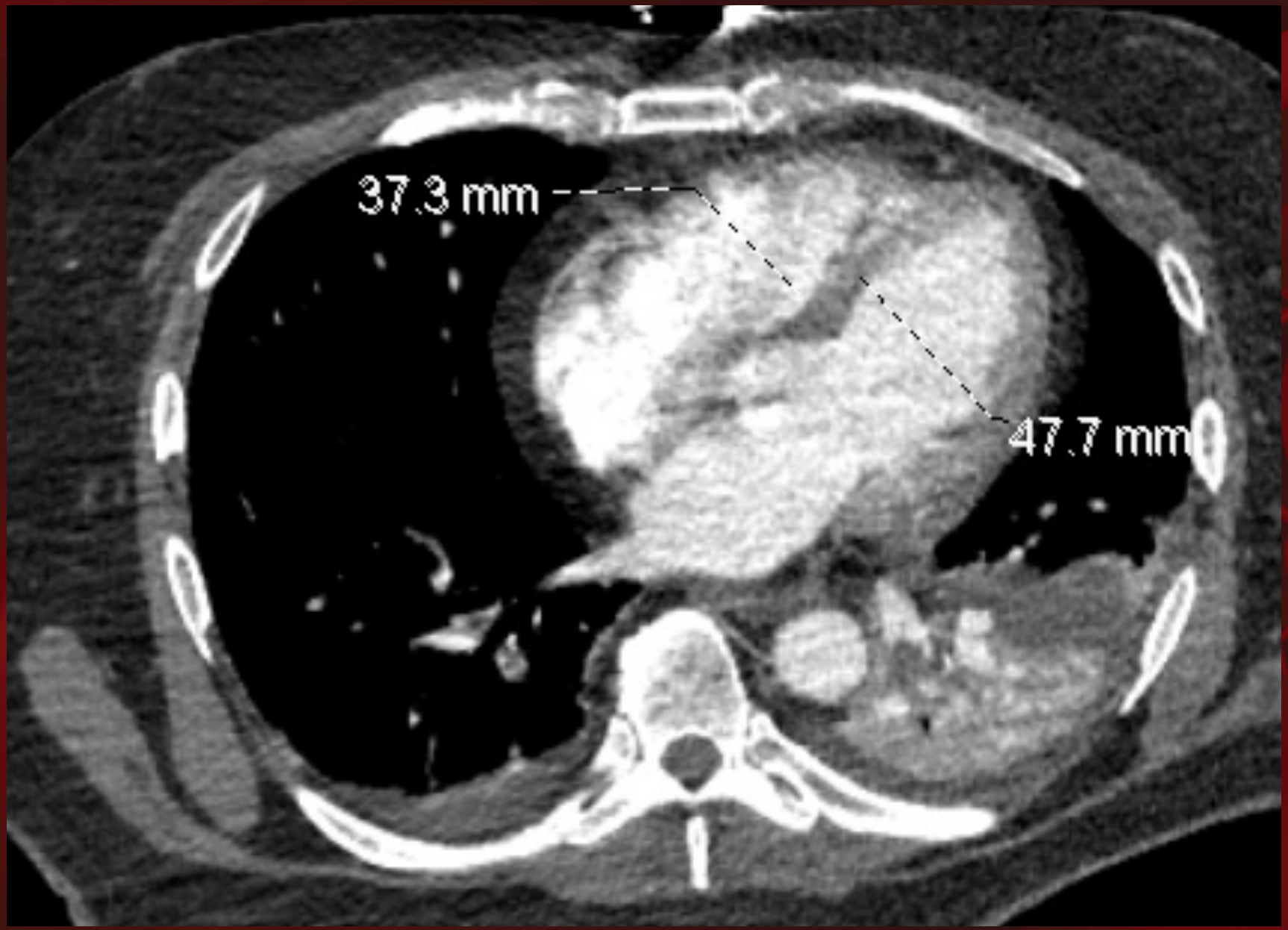
37.3 mm
47.7 mm

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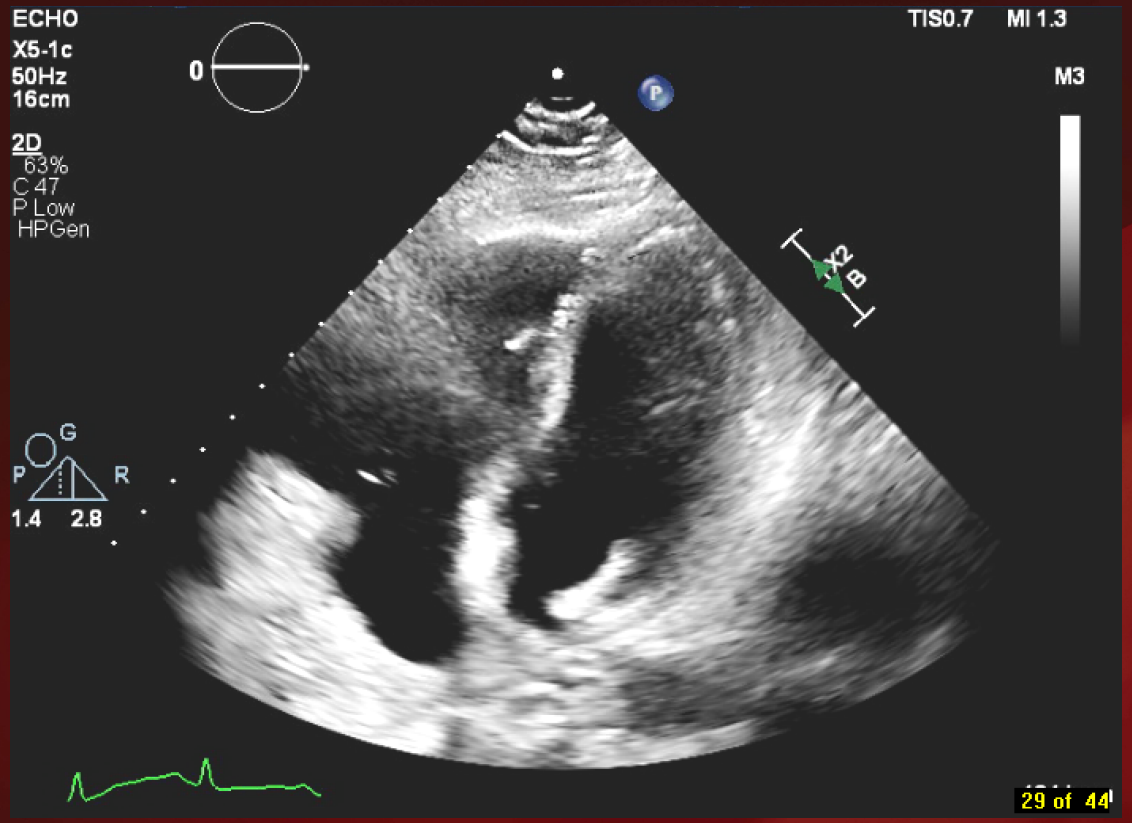
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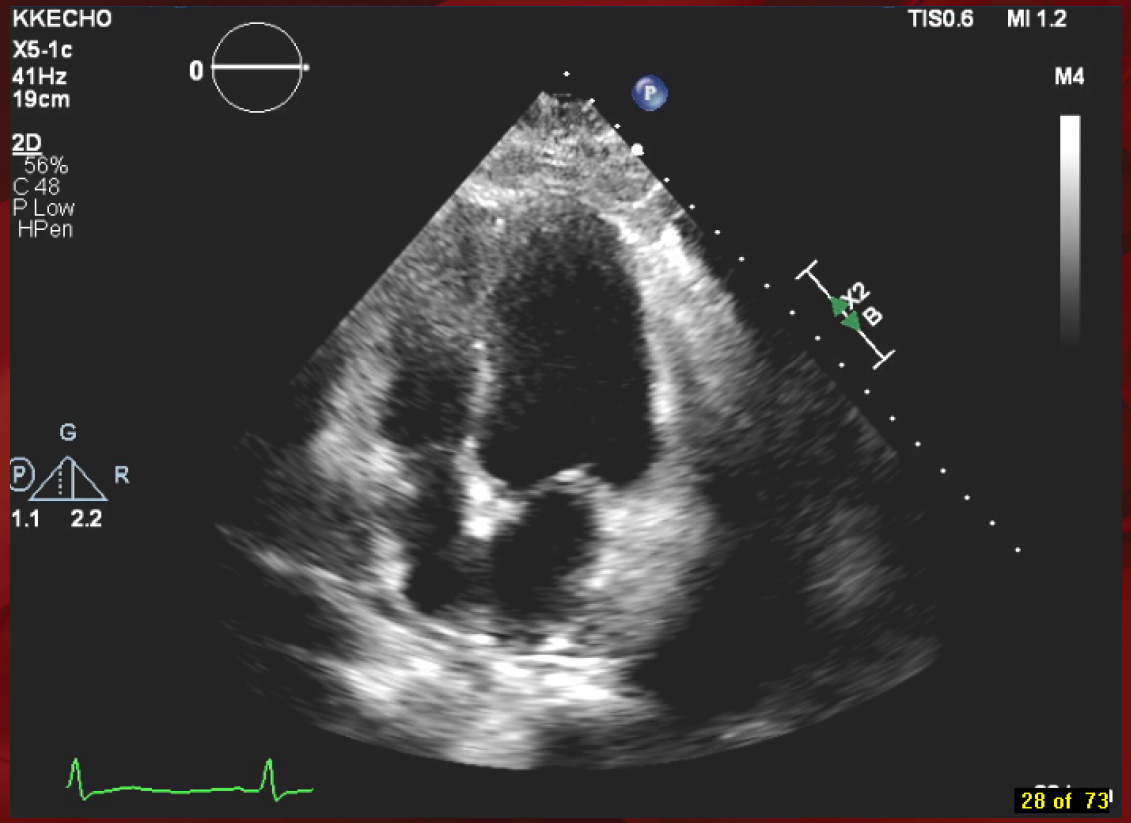
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