Randomized Controlled Trial of Mechanical Thrombectomy with Anticoagulation Versus Anticoagulation Alone for Acute Intermediate-High Risk Pulmonary Embolism: **Primary Results from STORM-PE**

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On behalf of the STORM-PE Investigators

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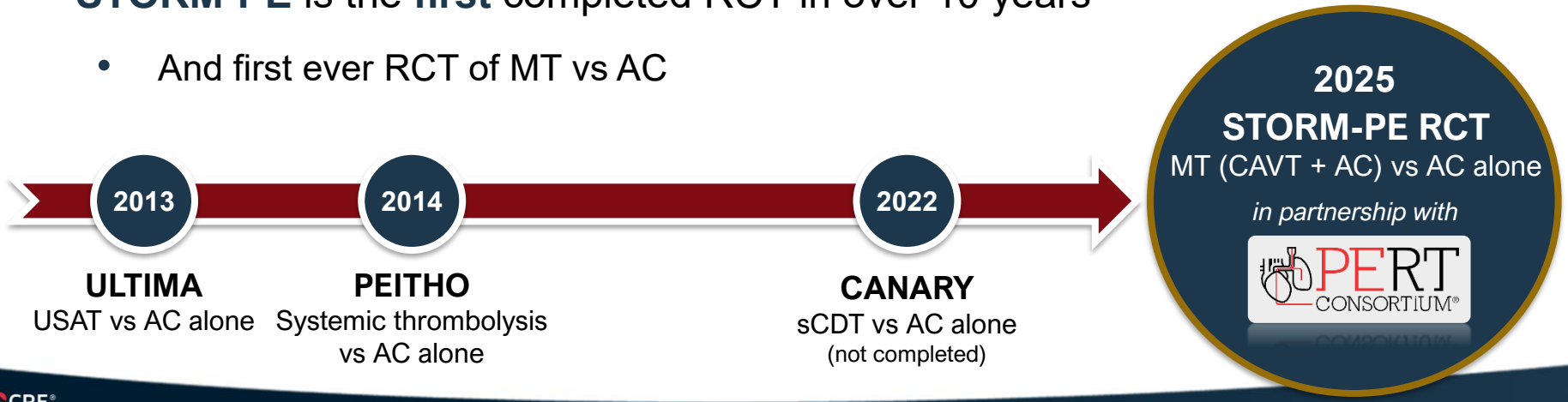
Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Boston Scientific, INARI, Penumbra, Ethicon, Black Swan, Instylla, Gore, Reva Medical, Imperative Vascular, Inquis Medical, Becton Dickinson
Consultant Fees/Honoraria	Boston Scientific, Penumbra, Medtronic, Imperative Vascular, Abbott Vascular, AIDOC, Siemens Healthineers
Individual Stock(s)/Stock Options	Imperative Vascular, Innova Vascular, Thrombolex, Summa Vascular, AIDOC, Votis
Royalties/Patent Beneficiary	**N/A**
Executive Role/Ownership Interest	**N/A**
Other Financial Benefit	**N/A**

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



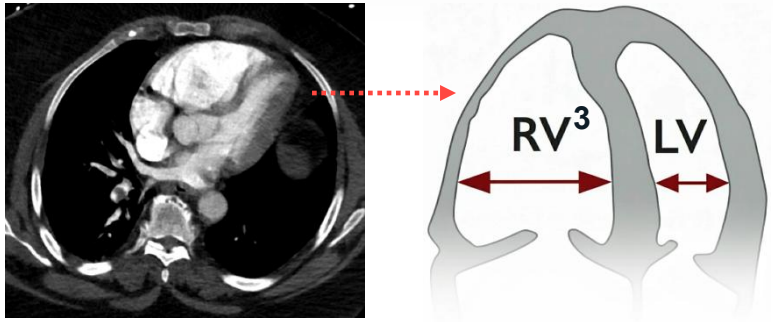
AC, anticoagulation; CAVT, computer assisted vacuum thrombectomy; sCDT, standard catheter-directed thrombolysis; MT, mechanical thrombectomy; PE, pulmonary embolism; RCT, randomized controlled trial; USAT, ultrasound-assisted catheter-directed thrombolysis

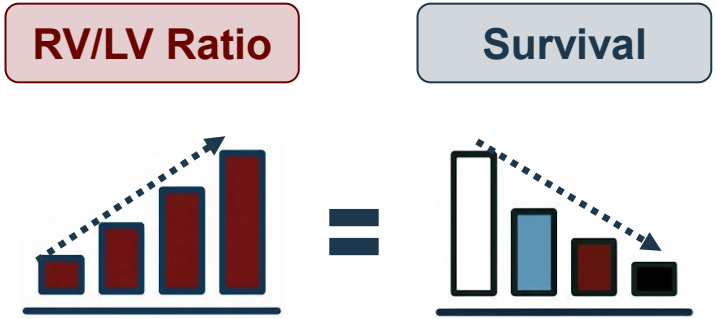
RV/LV Ratio

An elevated RV/LV ratio (≥ 1.0) is associated with a greater than

- **two-fold** increase in the risk of **early death**[1] and
- **three-fold** increase in the risk of **PE death**[1]

Small changes in RV strain are associated with incrementally **better** or **worse** prognosis[2]





RV/LV, right ventricular/left ventricular

1. Becattini, C. et al. Computed tomography to assess risk of death in acute pulmonary embolism: a meta-analysis. Eur Respir J. 2014;43(6);1678-1690 2. Ghaye, B. et al. Severe pulmonary embolism: pulmonary artery clot load scores and cardiovascular parameters as predictors of mortality. Radiology. 2006;239(3):884-891. 3. Konstantinides, S. et al. 2019 ESC Guidelines. Eur Heart J. 2020;54(3):543–603.

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.

Endpoints: Secondary Safety

Major Adverse Events ≤ 7 days

MAE Components	Definition	Test
Clinical Deterioration Requiring Rescue Therapy	NEWS2 ≥ 9 and rescue therapy (eg, mechanical thrombectomy, thrombolytics, CPR, ECMO, surgical embolectomy, etc)	The proportion analyzed with a 95% binomial confidence interval and Fisher's exact test for the difference between the CAVT and AC arms**
PE-related Mortality	Mortality deemed PE-related by the CEC, procedural and/or CAVT device and AC relationship also adjudicated by CEC	
Symptomatic Recurrent PE	Symptomatic new PE objectively confirmed on CTPA, echocardiography, or invasive contrast pulmonary angiography	
Major Bleeding*	BARC 3a-5 bleeding events	

*Major bleeding was defined as meeting BARC types 3a, 3b, 3c, or 5. Type 3a was not considered major bleeding if it was related to an expected decrease in hemoglobin level due to fluid administration and if transfusion was less than 2 units. **Test is not powered for statistical comparisons.

BARC, Bleeding Academic Research Consortium; CEC, clinical events committee; CPR, cardiopulmonary resuscitation; ECMO, extracorporeal membrane oxygenation; NEWS2, National Early Warning Score 2

Visit Schedule & Data Collection

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

✓ **Objective criteria** required for **crossover: NEWS2 ≥ 9**

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 & **Functional** Assessments:

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

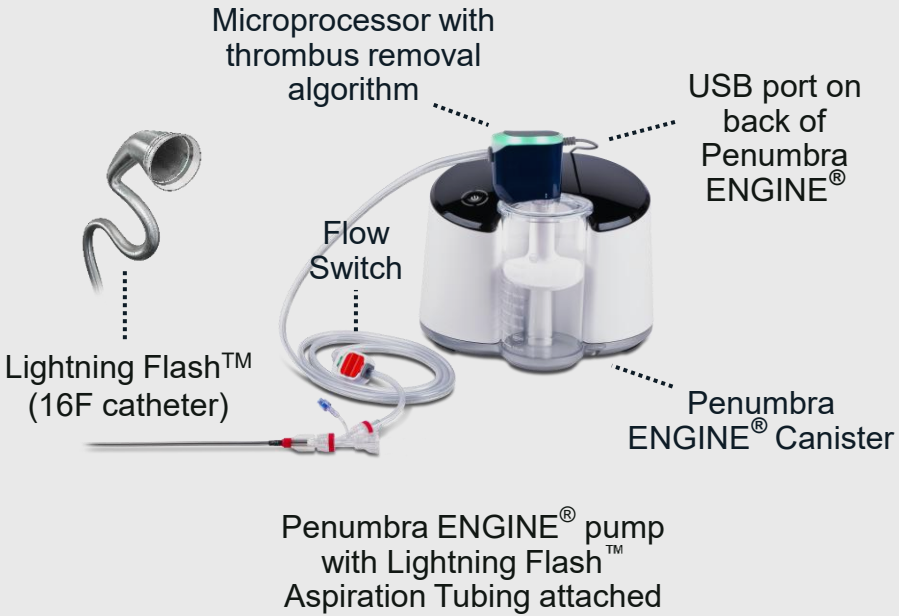
*Assessed at 30-day & 90-day follow-up visits

6MWT, six-minute walk test; CTPA, computed tomography pulmonary angiography; MAE, major adverse event; mMRC, modified Medical Research Council Dyspnea Scale; NEWS2, National Early Warning Score 2; NYHA, New York Heart Association Functional Classification; PEmb-QoL, Pulmonary Embolism Quality of life Questionnaire; PVFS, Post-VTE (venous thromboembolism) Functional Status Scale

Trial Device & 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



Key Eligibility Criteria, Sites & Enrollment

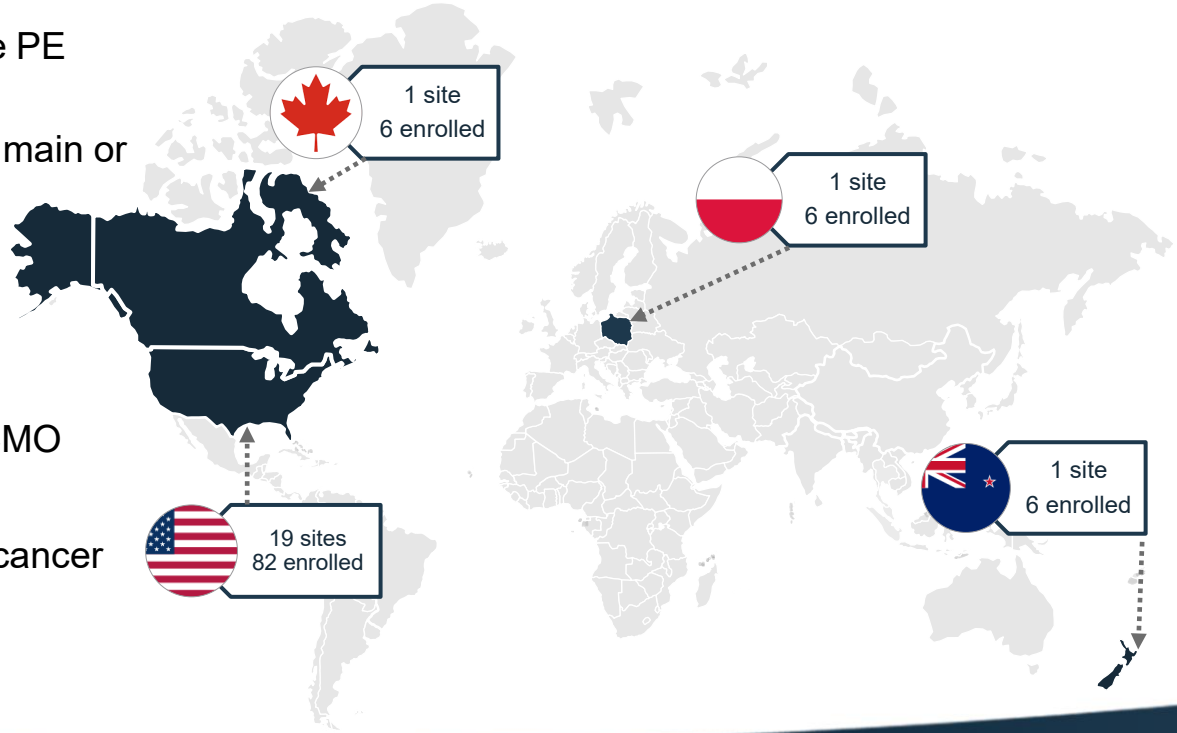
Inclusion

- ✓ Clinical signs & 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

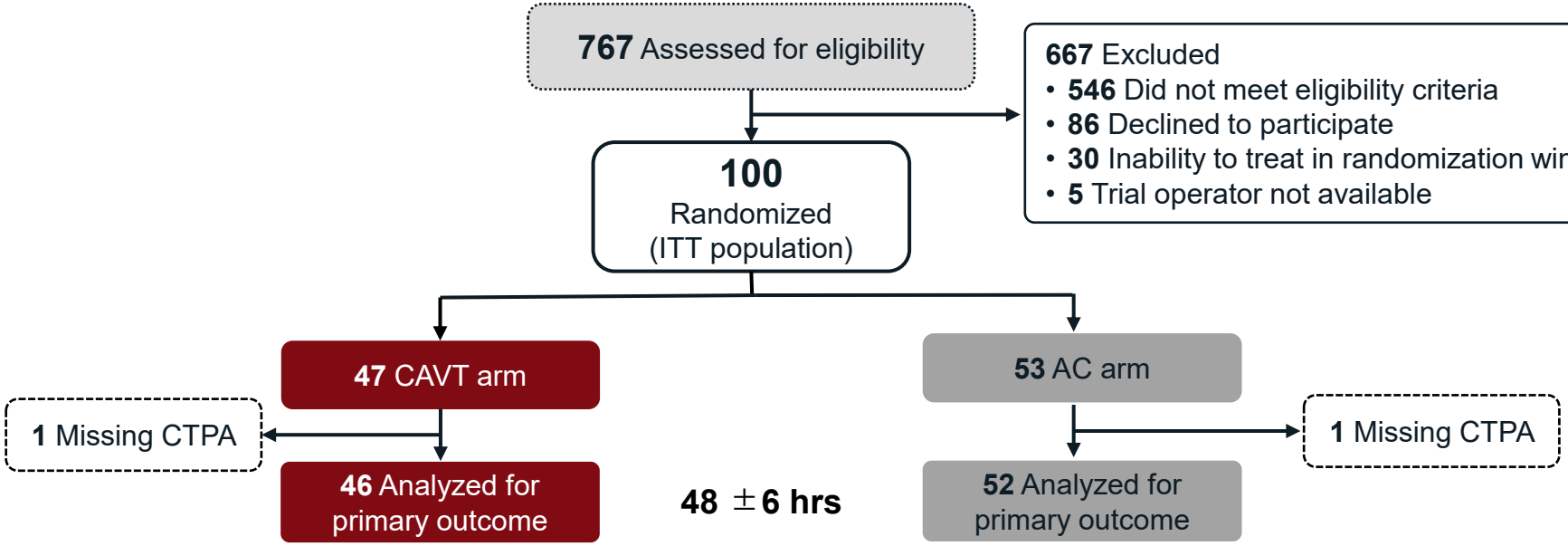
- × Hemodynamic instability or on ECMO
- × CTEPH or CTED findings
- × Primary brain or metastatic brain cancer
- × Life expectancy < 90 days

Patients enrolled July 2023 – June 2025



CTED, chronic thromboembolic disease; CTEPH, chronic thromboembolic pulmonary hypertension; ECMO, extracorporeal membrane oxygenation

Patient Flow for STORM-PE RCT



7-day MAE rate assessed in ITT population

ITT, intent-to-treat

Baseline & Medical History Information

	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 or 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%)

	CAVT N = 47	AC N = 53
Index PE Presentation Data		
Syncope	9 (19.1%)	8 (15.1%)
Hemoglobin, g/dL	14.1 ± 1.88	13.9 ± 1.74
Abnormal††	4 (8.5%)	4 (7.5%)
Hematocrit, %	42.7 ± 5.13	41.9 ± 4.64
Abnormal††	4 (8.5%)	6 (11.3%)
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

DVT, deep vein thrombosis; RMMS, refined modified Miller score

*Paired data at 48 h CAVT N=46 and AC=53
**Paired data at 48 h CAVT N=46 and AC=52
***Paired data at 48 h CAVT N=45 and AC=52

Data reported as mean ± SD or number (%)
† $P < 0.05$
†† Abnormal was defined as levels below the normal range

Baseline Functional Assessments & Quality of Life

	CAVT N=47	AC N=53
Functional Assessments		
Borg Dyspnea Scale*	4.6 ± 2.90	4.5 ± 2.85
mMRC ≥ 1*	43 (93.5%)	51 (96.2%)
PVFS*	3.0 ± 0.97	2.9 ± 1.01
Quality of Life		
EQ-5D-5L Index Score†	0.56 ± 0.42	0.57 ± 0.36
EQ VAS	52.6 ± 24.4	55.3 ± 23.2
PEmb-QoL Overall Score	38.7 ± 22.9	44.8 ± 25.2

*CAVT N=46
†US patients only CAVT N=38 and AC N=44

Baseline characteristics, Functional assessments, and QOL were comparable between groups.

Both groups were **well matched and aligned across key baseline measures.**

VAS, Visual Analog Scale
Data reported as mean ± SD or number (% of patients)

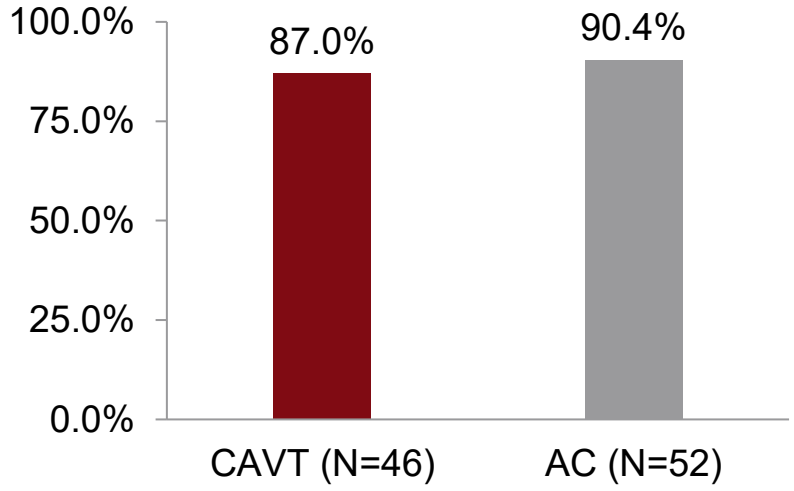
Anticoagulation Strategy

No difference between CAVT & 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 & 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



LMWH, low molecular weight heparin; UFH, unfractionated heparin

Data reported as median [IQR] or number (%)

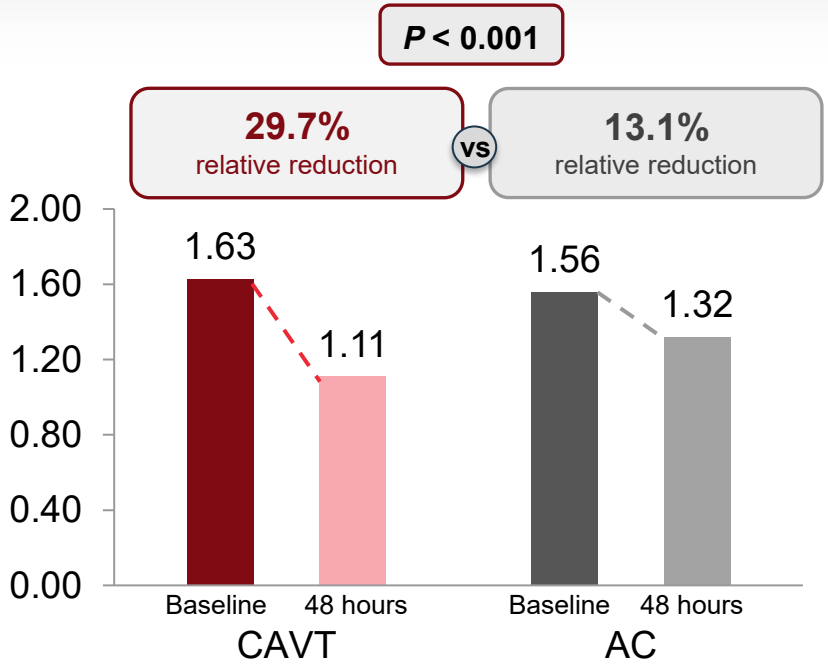
CAVT Arm Procedural Information & Details

Thrombectomy Time, min (median) Procedure Time, min (median)	25.0 [15.0, 41.0] 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 Mean PA Pressure Reduction, mm Hg	-10.8 ± 8.46 (21.7%) -8.2 ± 5.71 (27.3%)
Device- or Procedure-related Transfusion Access Site Complications	0/47 (0%) 0/47 (0%)

Primary Efficacy Endpoint: RV/LV Ratio Change at 48 h

Superior reduction in the CAVT arm

RV/LV Ratio	CAVT (N=46)	AC (N=52)	*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**
Between-group difference (95% CI) in reduction: Δ 0.27 (0.12, 0.43)			

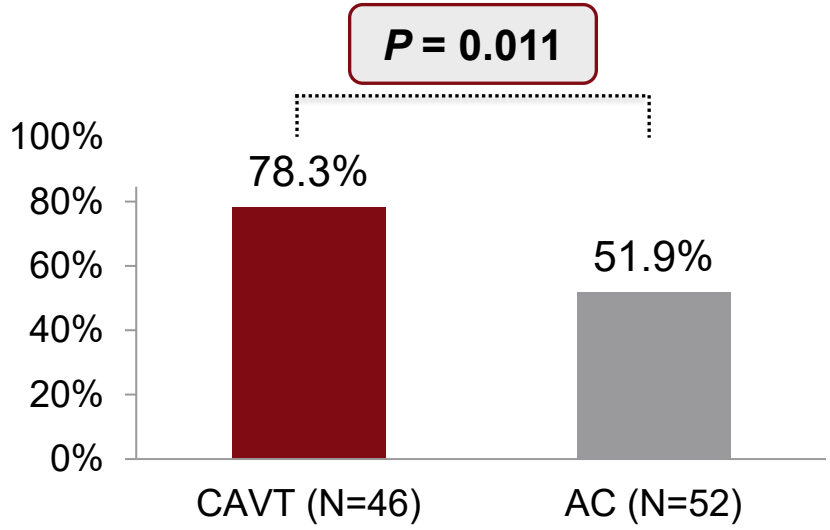


CAVT 2.3x greater reduction than AC

*Paired data
One patient in each arm had a 0 change in RV/LV ratio assigned

48 h RV/LV Reduction > 0.2

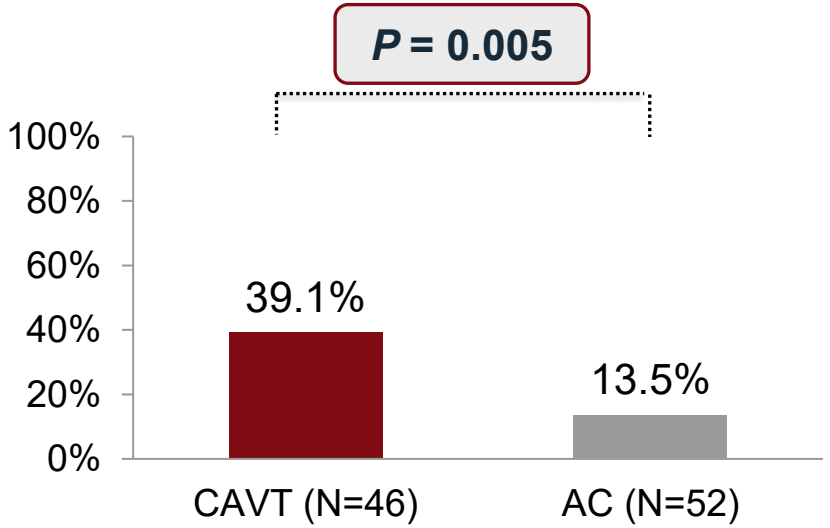
Significantly more patients in the CAVT arm had a treatment effect



IDE trial success uses a benchmark of **> 0.2** to indicate **achievement of clinically meaningful improvement in RV strain**[1-4]

48 h RV/LV ≤ 1.0

Significantly more patients in the CAVT arm had a normalized RV/LV ratio



2.9x more patients treated with **CAVT** returned to a normal RV/LV ratio at 48 hours

1. Tu T, et al. A Prospective, Single-Arm, Multicenter Trial of Catheter-Directed Mechanical Thrombectomy for Intermediate-Risk Acute Pulmonary Embolism: The FLARE Study. JACC Cardiovasc Interv. 2019;12;859-869. 2. Sista AK, et al. Indigo Aspiration System for Treatment of Pulmonary Embolism: Results of the EXTRACT-PE Trial. JACC Cardiovasc Interv. 2021;14;319-3292. 3. Sabri S, et al. Novel Aspiration Thrombectomy and Blood Reinfusion System for Acute Intermediate-Risk Pulmonary Embolism: AVENTUS Trial Results. J Soc Cardiovasc Angiogr Interv. 2025;4. 4. Ranade M, et al. Novel Mechanical Aspiration Thrombectomy in Patients With Acute Pulmonary Embolism: Results From the Prospective APEX-AV Trial. J Soc Cardiovasc Angiogr Interv. 2025;4:102463.

Secondary Safety Endpoint: Major Adverse Events ≤ 7 d

Safety comparable between CAVT & AC arm

MAE Composite, Components, & Additional Details	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
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

*Death, clinical deterioration, and major bleeding all occurred in the same CAVT patient.

Safety Event Details

PE-related Mortality

CAVT (N=2*) vs AC (N=0)

***P* = 0.218**

	Description
Day 0*	Cardiac arrest from hemoptysis during index procedure. No pathological evidence of vascular injury.
Day 5	Cardiac arrest during DVT thrombectomy using non-CAVT device.

CEC adjudicated the mortality events as not device- and not procedure-related

Clinical Deterioration Requiring Rescue Therapy

CAVT (N=1*) vs AC (N=3)

***P* = 0.620**

	NEWS2	Rescue Therapy
Day 1	9	CAVT (16 F)
Day 2	10	IV thrombolytics + CAVT (16 F)
Day 3	10	Catheter-directed thrombolysis

3 AC patients successfully rescued from clinical deterioration

*Day 0 death, clinical deterioration (CPR due to the SAE), and major bleeding all occurred in the same CAVT patient.

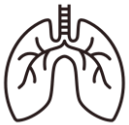
Conclusion

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

CAVT successfully decreased PA pressure with a statistically **superior reduction** in RV/LV ratio compared to AC alone.

There was a **comparable safety profile** between the CAVT and AC arm with no device- or procedure-related adverse events.

These promising results reinforce the role of MT, specifically **CAVT**, as a **safe and effective treatment strategy** in patients with acute intermediate-high-risk PE.



STORM-PE trial leadership is excited to present our additional secondary outcomes including functional endpoints in the near future.

Thank You

In partnership with The PERT Consortium®

Sites

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