

CAVT™ • The Most Advanced Treatment for PE



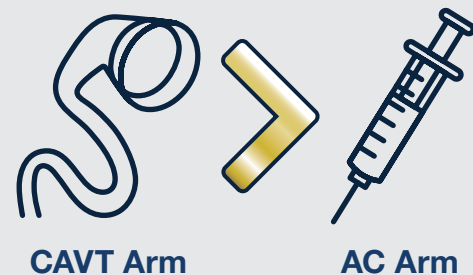
STORM-PE RCT

CAVT • Proven by
Level 1 Evidence

In Collaboration with
The PERT Consortium®



CAVT shows superior efficacy over anticoagulation alone^a



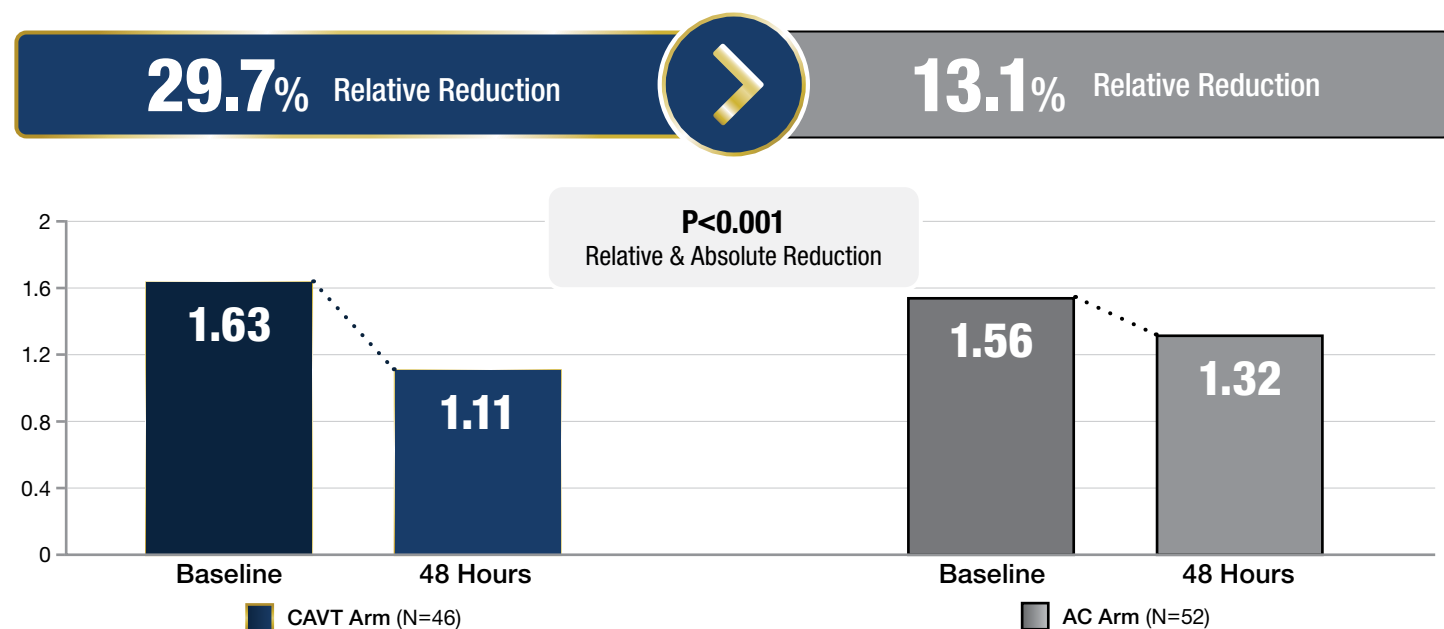
Objective: Evaluate the efficacy and assess the safety of treating acute, intermediate-high risk pulmonary embolism with anticoagulation plus CAVT Computer Assisted Vacuum Thrombectomy with the Indigo™ Aspiration System Lightning Flash™ versus anticoagulation alone

Design: 100 patients randomized 1:1 to CAVT plus anticoagulation (CAVT arm) or anticoagulation alone (AC arm); 22 U.S. and international sites

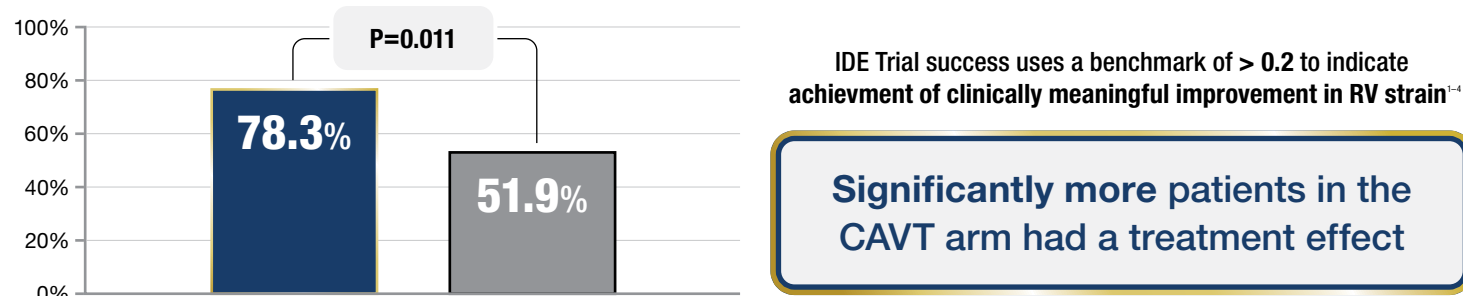
Primary Endpoint (Δ RV/LV)

The CAVT arm demonstrated a significantly greater reduction in right heart strain compared to the AC arm

RV/LV Reduction Baseline to 48 Hours^a



48 Hour RV/LV Reduction > 0.2 (Expanded Analysis)

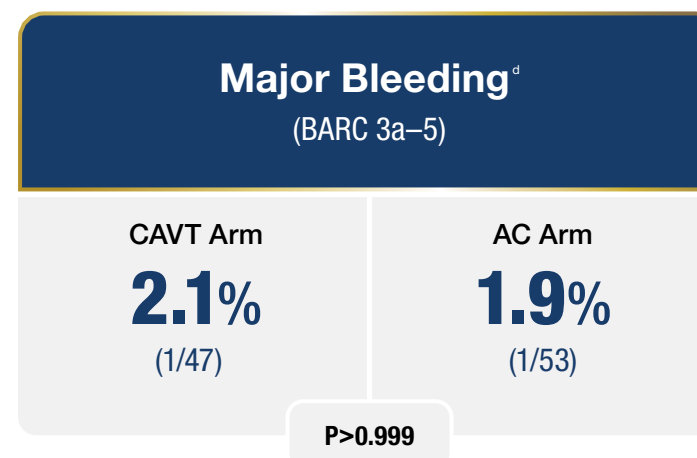
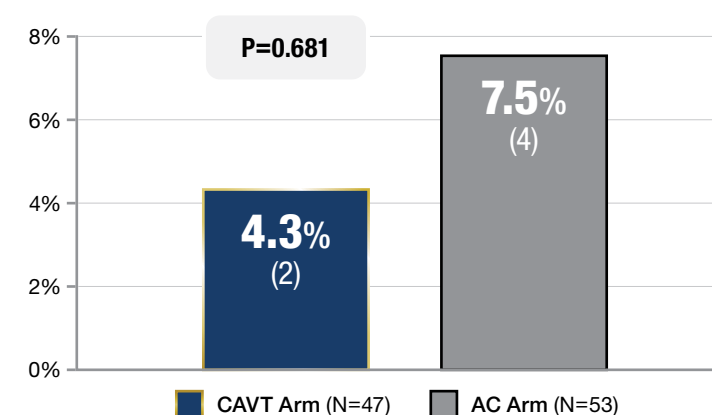


1. Tu T, Toma C, Tapson VF, et al. A prospective, single-arm, multicenter trial of catheter-directed mechanical thrombectomy for intermediate-risk acute pulmonary embolism: the FLARE study. *JACC Cardiovasc Interv.* 2019 May 13;12(9):859–869. doi:10.1016/j.jcin.2018.12.022. 2. Sista AK, Horowitz JM, Tapson VF, et al. Indigo aspiration system for treatment of pulmonary embolism: results of the EXTRACT-PE trial. *JACC Cardiovasc Interv.* 2021 Feb 8;14(3):319–329. doi:10.1016/j.jcin.2020.09.053. 3. Sabri S, Horr S, Stegman B, et al. Novel aspiration thrombectomy and blood reinfusion system for acute intermediate-risk pulmonary embolism: AVENTUS trial results. *J Soc Cardiovasc Angiogr Interv.* 2025 May 2;4(7):103661. doi:10.1016/j.jscv.2025.103661. 4. Ranade M, Foster 3rd MT, Brady PS, et al. Novel mechanical aspiration thrombectomy in patients with acute pulmonary embolism: results from the prospective APEX-AV trial. *J Soc Cardiovasc Angiogr Interv.* 2024 Dec 27;4(1):102463. doi:10.1016/j.jscv.2024.102463. a. STORM-PE demonstrated superiority to anticoagulation utilizing Lightning Flash 1.0 and 2.0. Efficacy was predefined as the difference between treatment arms in change of RV/LV ratio from baseline to 48 hrs.

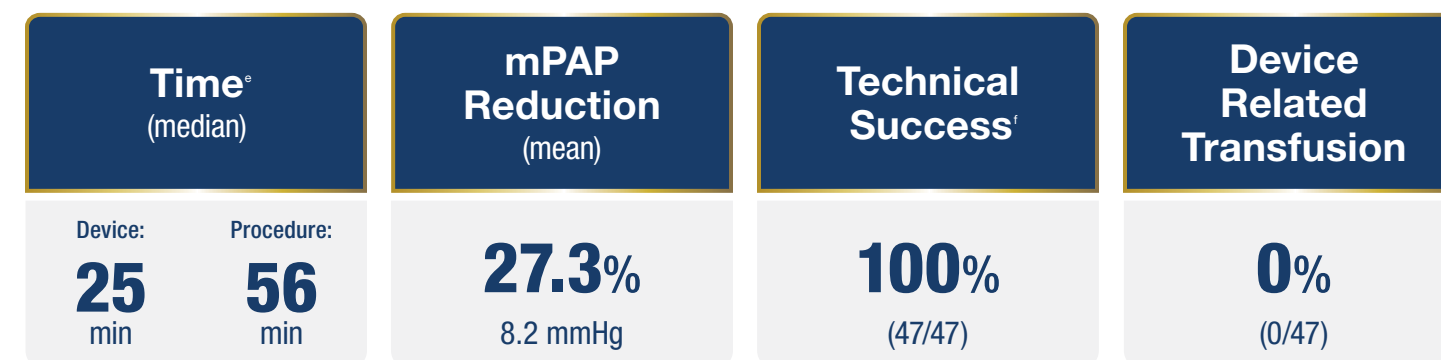
Safety

The CAVT arm safety rate was comparable to the AC arm, with numerically fewer Major Adverse Events (MAE)^b in the CAVT arm^c

Composite MAE ≤ 7 Days (% , n)



Procedural Data · CAVT Arm



b. MAEs within 7 days included: clinical deterioration necessitating rescue therapy, PE-related mortality, symptomatic recurrent PE, and major bleeding. c. STORM-PE was not powered to detect differences in safety. d. 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. e. IQR for Device and Procedure time were [15.0, 41.0] and [42.0, 96.0], respectively. f. Technical Success was defined as ability of catheter to access clot and perform aspiration.

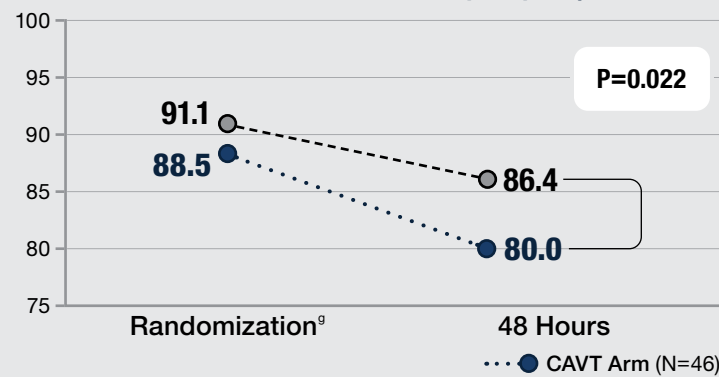


Clinical Outcomes

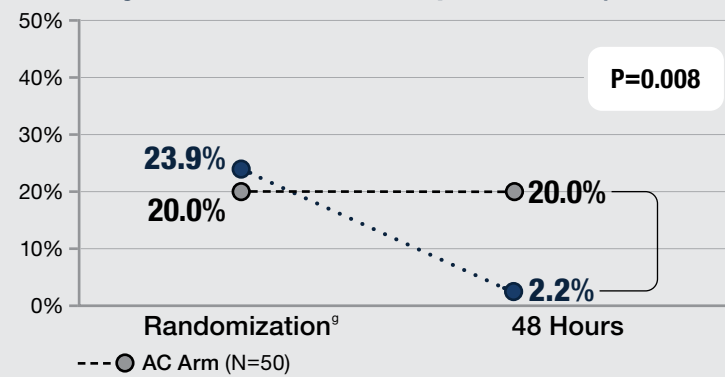
The CAVT arm showed greater & earlier physiological recovery compared to AC alone

The CAVT arm had significantly lower mean heart rate and less tachycardia compared to the AC arm at 48 hours

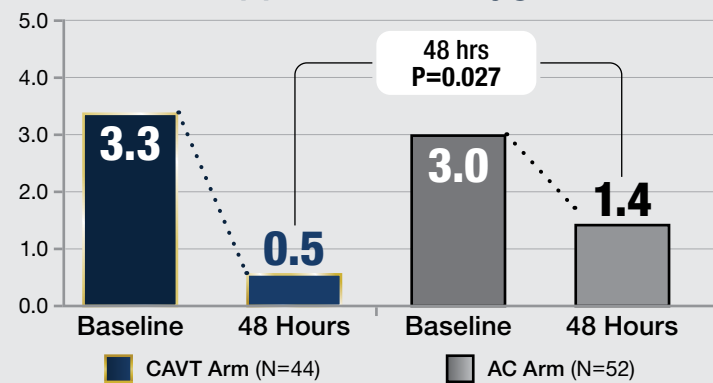
Mean Heart Rate (HR), bpm



Tachycardia HR >100 bpm, % of patients

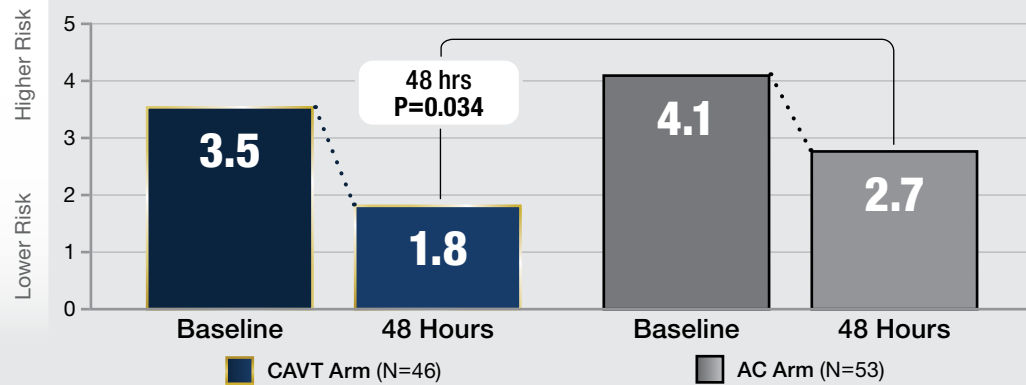


Mean Supplemental Oxygen^h, L/min



Significantly lower supplemental oxygen requirement in the CAVT arm at 48 hours

NEWS2 Score at Baseline & 48 Hoursⁱ



NEWS2 Components

Composite score indicating risk of clinical deterioration

- Respiratory rate
- Supplemental oxygen
- Oxygen requirement
- Systolic blood pressure
- Heart rate
- Consciousness
- Temperature

The CAVT arm had a significantly lower NEWS2 risk score at 48 hours

g. Timepoint closest to randomization, after administration of AC and pre-procedure for the CAVT arm. Paired data represented. h. Patients who did not require supplemental oxygen were assigned a value of 0 L/min. i. NEWS2 = National Early Warning Score 2. Paired data represented. Data reported as mean.



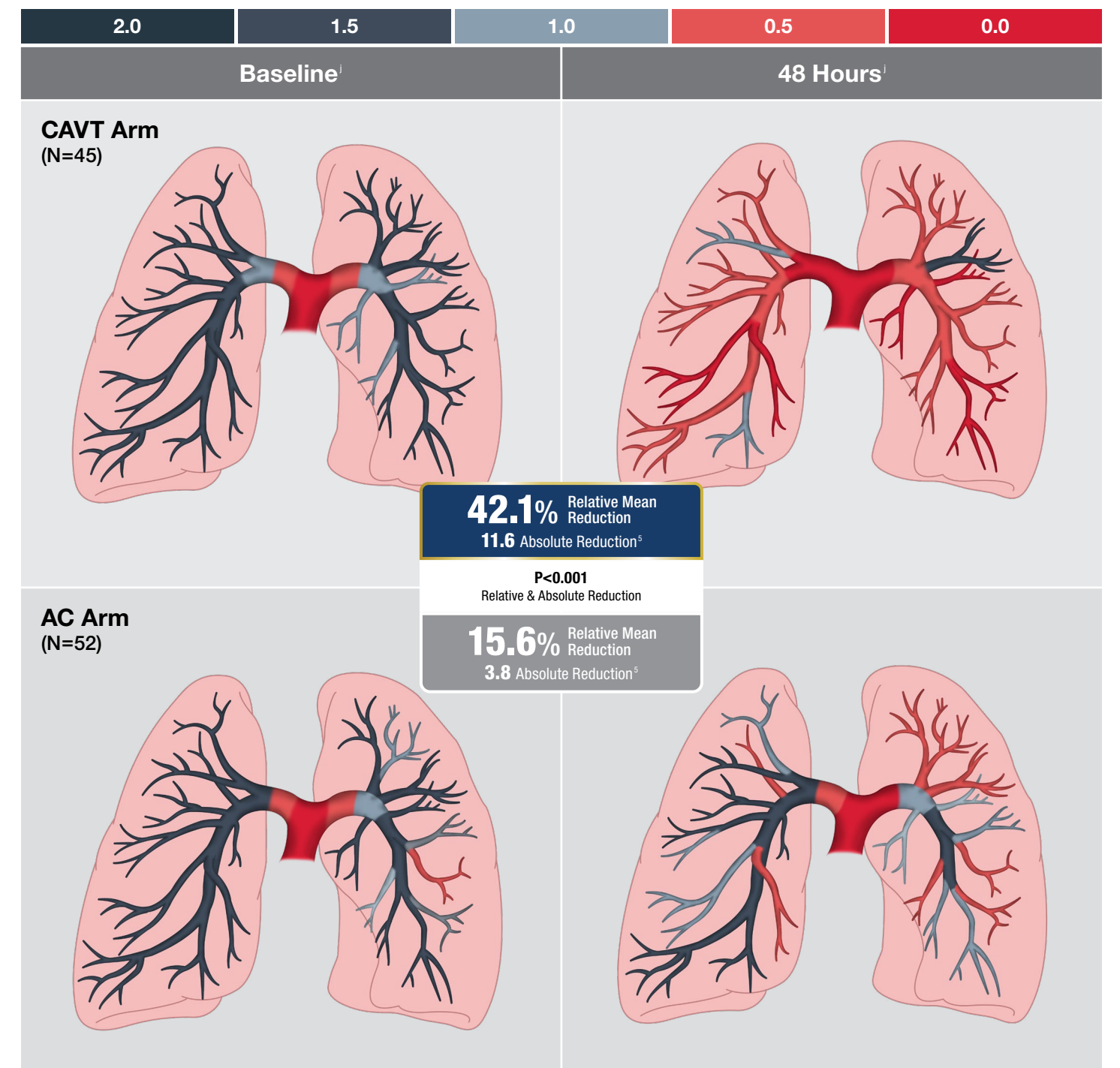
Thrombus Resolution Map

Based on Refined Modified Miller Score (RMMS) analysis of CT imaging read by independent, blinded core laboratory

Change in Thrombus Burden at 48 Hours

Significantly larger reduction in mean RMMS in the CAVT arm (2.7x)

Color Legend | Degree of Thrombus Burden



j. Paired data represented. Illustrative renderings based on median per segment scores; not intended to represent exact relative mean percentages.

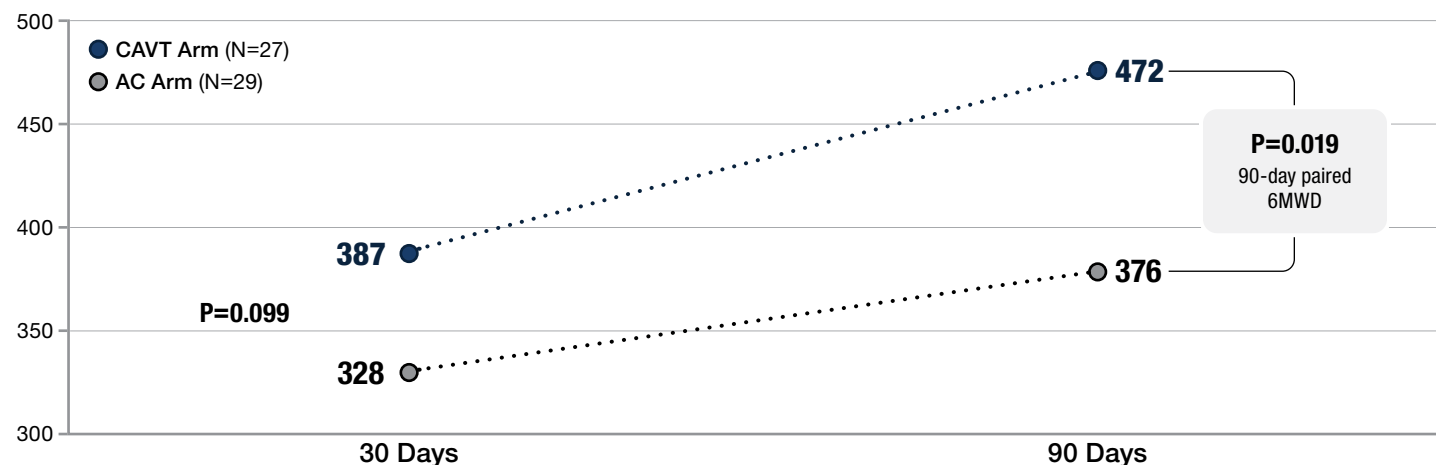


Functional Endpoints

6-Minute Walk Test (6MWT)⁶

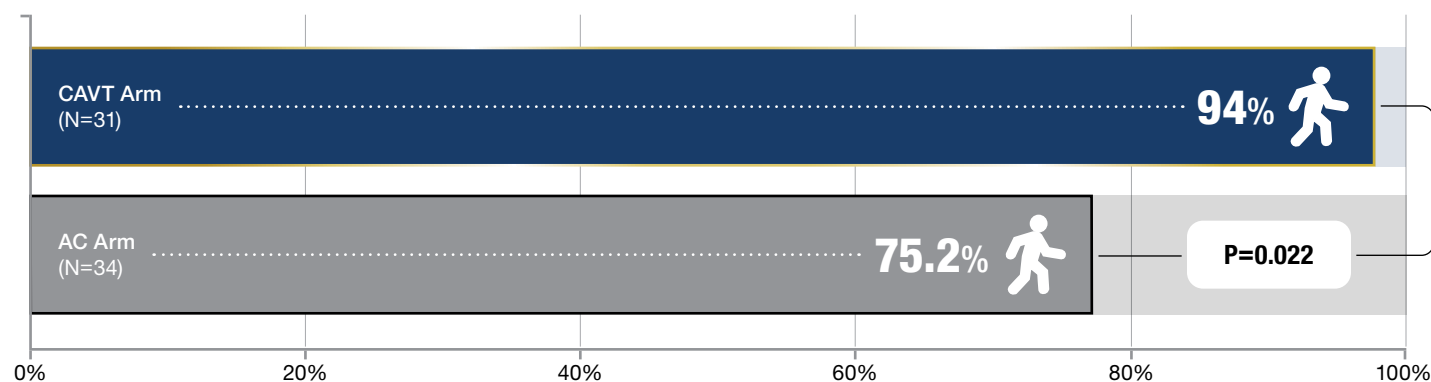
Patients in the CAVT arm walked significantly farther at 90 days and near normalized, walking 94% of their predicted walk distance

Mean 6MWT Distance (6MWD), meters



% of Predicted 6MWD at 90 days

Predicted walk distance⁶ is normalized for sex, age, and body surface area



Read the full STORM-PE Publication in *Circulation*



Lookstein R, Konstantinides SV, Weinberg I, et al. 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. *CIRCULATION*. 2025; [Published online ahead of print]. doi:10.1161/CIRCULATIONAHA.125.077232.

5. Presented by Rosovsky, R. 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. Presented at: VIVA (Vascular InterVentional Advances) 2025; November 3, 2025; Las Vegas, NV, USA.
6. Enright PL, Sherrill DL. Reference equations for the six-minute walk in healthy adults. *Am J Respir Crit Care Med*. 1998;158(5 Pt 1):1384-1387. doi:10.1164/ajrccm.158.5.9710086.



Functional Endpoints

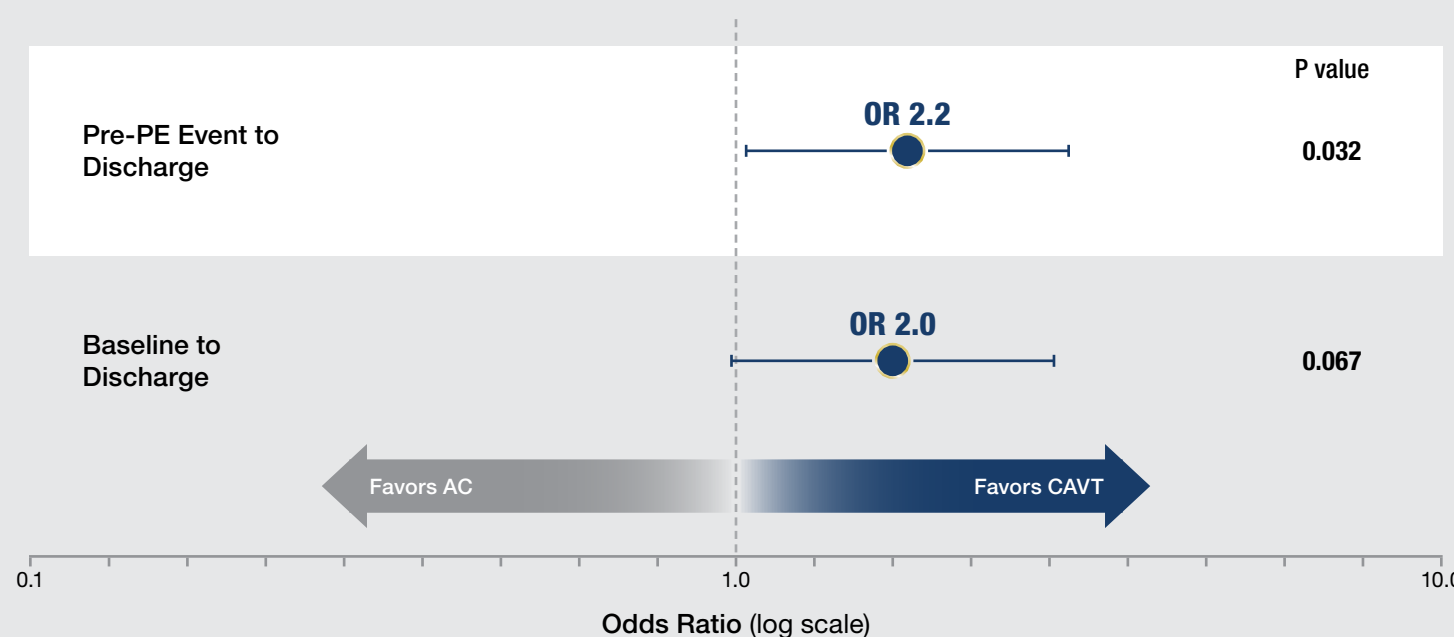


Functional Status – PVFS^k

PVFS is a measure to quantify functional status, covering the full spectrum of functional outcomes, ranging from no symptoms to death, and focusing on both limitations in usual duties/activities and changes in lifestyle.

PVFS Scale Grade	Description
0 – No Functional Limitations	All usual duties/activities at home or at work can be carried out at the same level of intensity. Symptoms, pain, and anxiety are absent.
1 – Negligible Functional Limitations	All usual duties/activities at home or at work can be carried out at the same level of intensity, despite some symptoms, pain, or anxiety.
2 – Slight Functional Limitations	Some usual duties/activities at home or at work are carried out at a lower level of intensity or are occasionally avoided due to symptoms, pain, or anxiety.
3 – Moderate Functional Limitations	Usual duties/activities at home or at work have been structurally modified (reduced) due to symptoms, pain, or anxiety.
4 – Severe Functional Limitations	Assistance needed in activities of daily living due to symptoms, pain, or anxiety; nursing care and attention are required.
D – Death	Death occurred before the scheduled assessment.

Patients in the CAVT arm were 2.2x more likely to progress towards their pre-PE functional status



k. PVFS = Post-VTE (Venous Thromboembolism) Functional Status.
7. Boon GJAM, Barco S, Bertolotti L, et al. Measuring functional limitations after venous thromboembolism: optimization of the Post-VTE Functional Status (PVFS) Scale. *Thromb Res*. 2020 Jun;190:45-51. doi:10.1016/j.thromres.2020.03.020.



STORM-PE RCT

Baseline Clinical Parameters^{5,1}

Both groups were well matched across key baseline measures

	CAVT Arm (N=47)	AC Arm (N=53)
NEWS2 ^m	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 ^m	27.3 ± 3.89	26.1 ± 5.51

Baseline Functional Assessments^{5,1}

Borg Dyspnea Scale	4.7 ± 2.90	4.5 ± 2.85
mMRC ^m ≥ 1	42 (95.5%)	51 (96.2%)
PVFS ^m	3.0 ± 0.97	2.9 ± 1.01

I. Paired data at 48 h, paired data for CAVT ranged from N=45–46 and for AC=52–53. Data presented as mean ± SD.

m.NEWS2 = National Early Warning Score 2; RMMS = Refined Modified Miller Score; mMRC = Modified Medical Research Council Dyspnea Scale; PVFS = Post-VTE (Venous Thromboembolism) Functional Status Scale.

All information within this brochure is referenced as follows:

Primary Endpoints, Safety, Procedure Data, Clinical Outcomes, RMMS, and Baseline Clinical Parameters & Functional Assessments found in:

Lookstein R, Konstantinides SV, Weinberg I, et al. 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. *CIRCULATION*. 2025;[Published online ahead of print]. doi:10.1161/CIRCULATIONAHA.125.077232.

Thrombus Resolution Map, 6-Minute Walk Test, and Functional Status – PVFS are found in:

Presented by Rosovsky, R. 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. Presented at: VIVA (Vascular InterVentional Advances) 2025; November 3, 2025; Las Vegas, NV, USA.

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