CAVT™ · The Most Advanced Treatment for PE

STORM-PE RCT

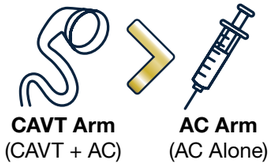
Level 1 Evidence

for Intermediate-High Risk PE

Penumbra

CAVT · Proven by Level 1 Evidence

CAVT shows superior efficacy over anticoagulation alone[a]



STORM-PE RCT

Randomized **1:1**

100 Patients

22 U.S and International Sites

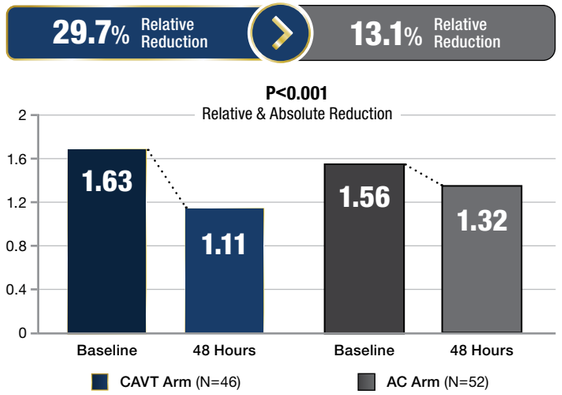
Read the initial STORM-PE Publication in *Circulation*

STORM-PE is the first Level 1 RCT showing that mechanical thrombectomy was superior to anticoagulation alone in reducing right heart strain with no difference in safety profile — At 90 days, CAVT patients walked a football field further and have 12× greater odds of being NYHA Class I (i.e. no functional limitations)

Primary Endpoint (Δ RV/LV)[1]

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

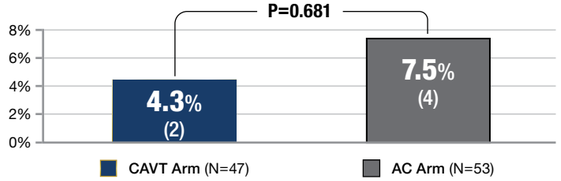
RV/LV Reduction Baseline to 48 Hours[a]



Safety[1,b]

The CAVT arm showed a comparable safety profile to non-intervention with numerically fewer Major Adverse Events (MAE)[c]

Composite MAE ≤ 7 Days, % (n)



Procedural Data

Time[d] (median)	Device: **25** min	Procedure: **56** min	**Technical Success[e]**	**100%** (47/47)
mPAP Reduction (mean)	**27.3%** 8.2 mmHg		**Device Related Transfusion[2]**	**0%** (0/47)

90-Day Outcomes Summary Table

Treatment Type		6MWT with Imputation[f]	NYHA (Class I)[f]	PVFS[f]		Dyspnea/ Breathlessness[f]	QoL
CAVT Arm	Functional Outcomes	**468** meters	**97.4%** (Class I)	**CAVT patients returned to pre-PE status; AC did not**	Patient Reported Outcomes	**Per mMRC, odds favor CAVT at discharge**	**Similar improvement across arms**
AC Arm		**370** meters	**75.6%** (Class I)				

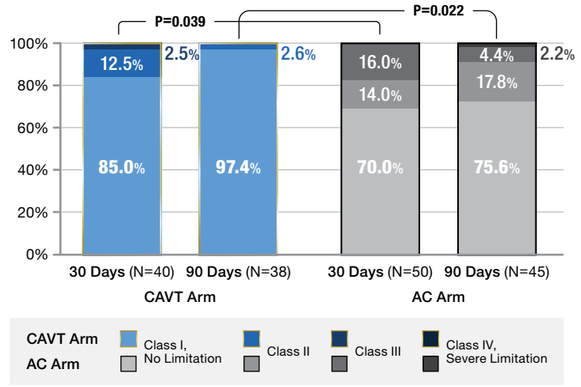
1. Lookstein R, Konstantinides SV, Weinberg I, et al. Randomized controlled trial of mechanical thrombectomy with anticoagulation versus anticoagulation alone for acute intermediate-high risk pulmonary embolism: primary outcomes from the STORM-PE trial. *CIRCULATION*. 2025;[Published online ahead of print]. doi:10.1161/CIRCULATIONAHA.125.077232. **2.** 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. **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. **b.** STORM-PE was powered for the primary endpoint only. **c.** MAEs within 7 days included: clinical deterioration necessitating rescue therapy, PE-related mortality, symptomatic recurrent PE, and major bleeding. **d.** IQR for Device and Procedure time were [15.0, 41.0] and [42.0, 96.0], respectively. **e.** Technical Success was defined as ability of catheter to access clot and perform aspiration. **f.** Statistically significant difference.

90-Day Functional Outcomes[3]

NYHA Classification[b] New York Heart Association

Physical Activity

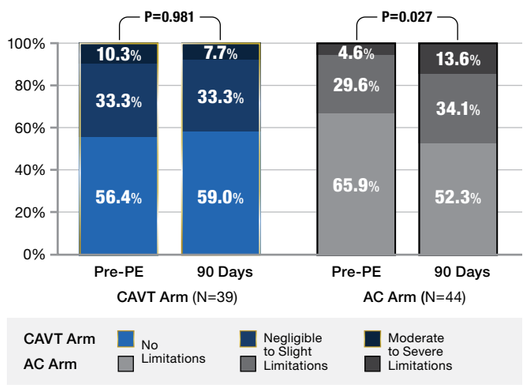
CAVT patients report fewer limitation at 30 and 90 days. And **12× greater** odds of being Class I at 90 days.



PVFS Score[g,h,b] Post-VTE Functional Status

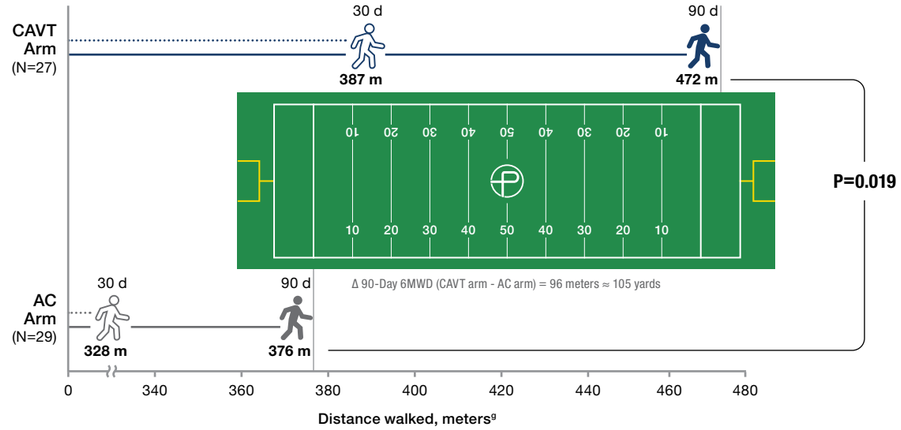
Daily Living

At 90 days, PVFS distribution for the CAVT group more closely resembled pre-PE status, while AC did not



6-Minute Walk Test (6MWT)[2,b]

At 90 days, patients in the CAVT arm who performed the 6MWT walked an average of 96 meters more than the AC arm **– an entire football field further.** These results were consistent with imputation for patients who did not perform the 6MWT.

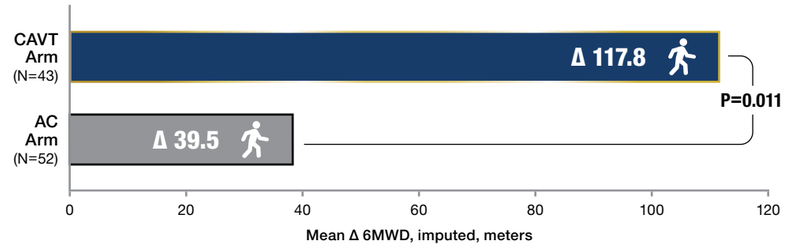


6MWT with Imputation[i,b]

With imputation, change in distance walked was 3-fold greater in CAVT patients

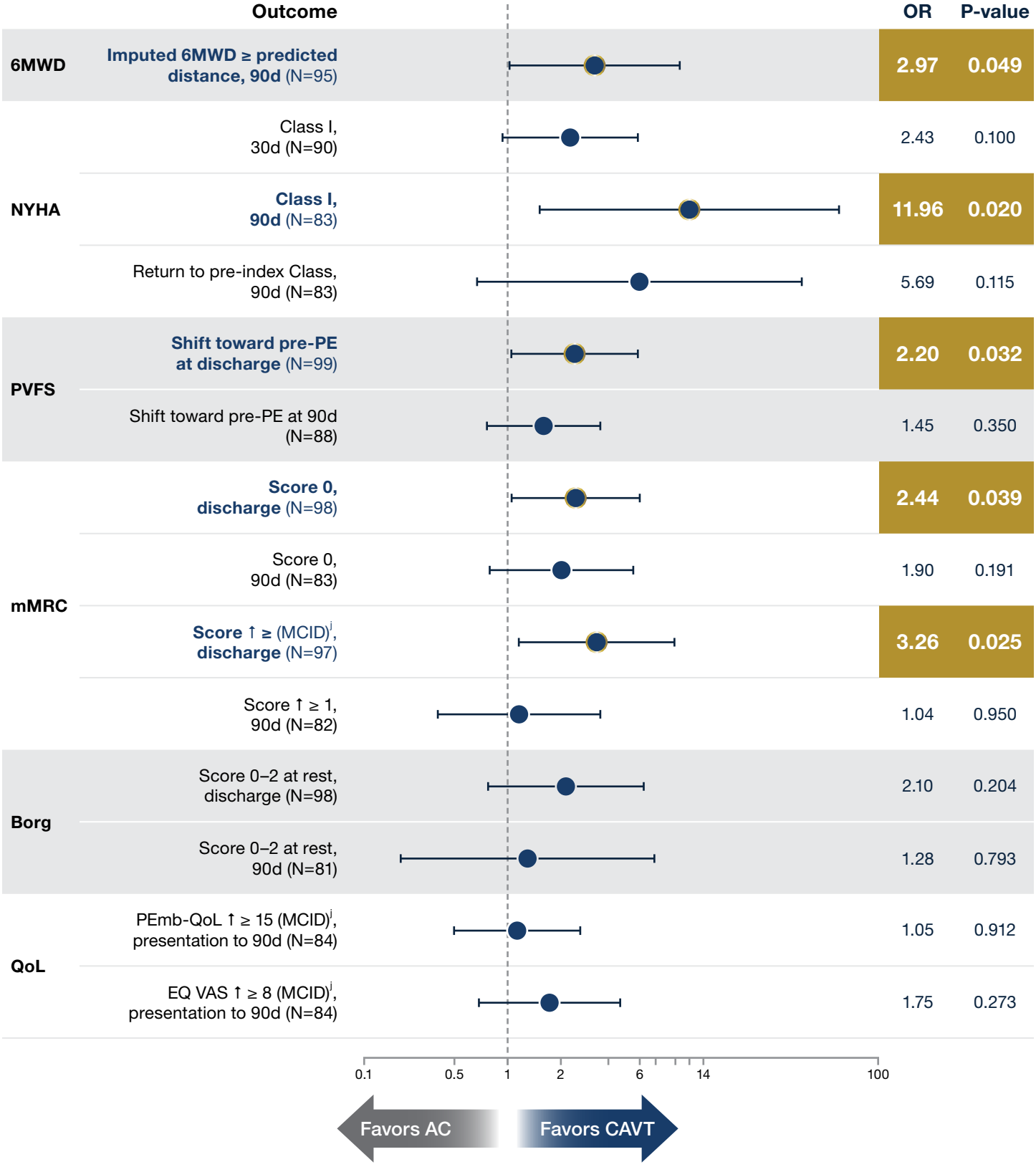
Mean 6MWT with Imputation

	30 Days	90 Days	Mean Δ 6MWD
CAVT Arm (N=43)	**349.9 m**	**467.7 m**	**117.8**
	P=0.487	P<0.001	P=0.011
AC Arm (N=52)	**330.9 m**	**370.4 m**	**39.5**



3. Lookstein R. Clinical, functional, and quality of life outcomes through 90 days in the STORM-PE RCT for mechanical thrombectomy with anticoagulation vs anticoagulation alone in acute intermediate-high risk PE patients. Presented at: Society of Interventional Radiology Annual Scientific Meeting (SIR 2026); 2026; Toronto, ON, Canada. **g.** Matched pair data are represented. **h.** Data was collected and analyzed according to published protocol. Grades 1–2 and 3–4 were clustered post analysis. **i.** Imputation was carried out separately by assigned randomized group and deaths were excluded.

90-Day Functional and QoL Outcomes Favor CAVT[b]



j. MCID: Meaningful Clinically Important Difference

The clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Individual results may vary depending on patient-specific attributes and other factors. Product availability varies by country. Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. Prior to use, please refer to the Instructions for Use (IFU) for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Please contact your local Penumbra representative for more information.

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For the complete Penumbra IFU Summary Statements and more, scan QR code or visit: peninc.info/storm-rct

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