CAVT™ · The Most Advanced Treatment for PE

STORM-PE RCT

CAVT · Proven by Level 1 Evidence

In Collaboration with
The PERT Consortium™

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CAVT **shows superior efficacy over anticoagulation alone**[a]

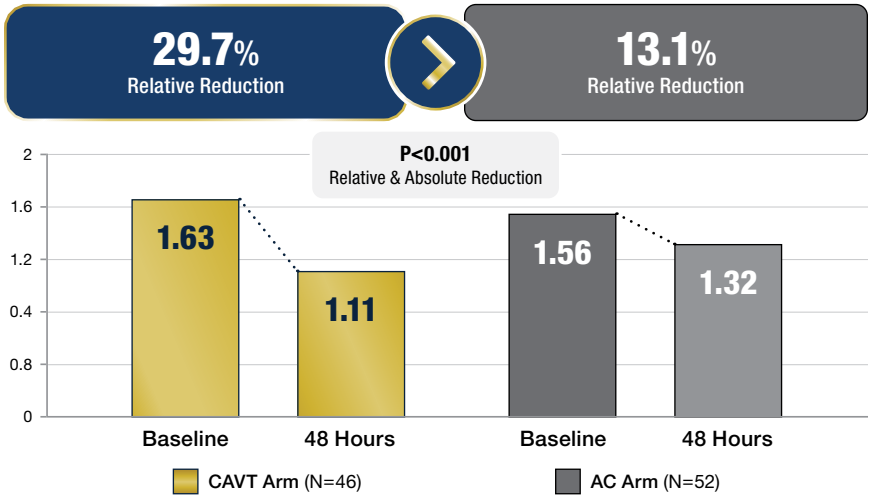
Objective: Evaluate the efficacy and assess the safety of treating acute, intermediate-high risk pulmonary embolism with anticoagulation plus CAVT Computer Assisted Vacuum Thrombectomy with the Indigo™ Aspiration System Lightning Flash™ versus anticoagulation alone

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

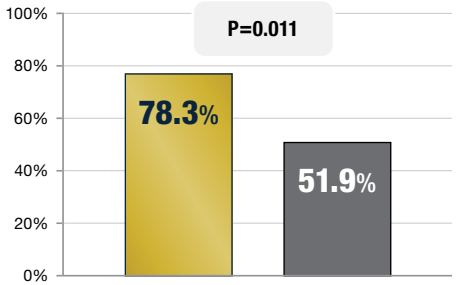
Primary Endpoints (Δ RV/LV)

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

RV/LV Reduction Baseline to 48 Hours



48 Hour RV/LV Reduction > 0.2



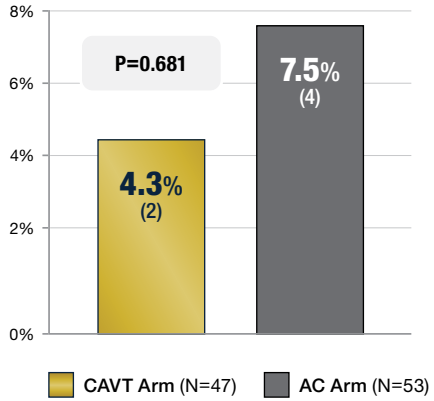
Significantly more patients in the CAVT arm had a treatment effect

a. Efficacy was predefined as the difference between treatment arms in change of RV/LV ratio from baseline to 48 hrs. STORM-PE demonstrated superiority to anticoagulation utilizing Lightning Flash 1.0 and 2.0.

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)



Major Bleeding[d] (BARC 3a–5)	
CAVT Arm	AC Arm
2.1% (1/47)	1.9% (1/53)

P>0.999

Procedural Data · *CAVT* Arm

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

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

DATA NOT YET PUBLISHED. Presented by Lookstein, R. 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 acute pulmonary embolism. Presented at: TCT (Transcatheter Cardiovascular Therapeutics); October 26, 2025; San Francisco, CA, USA.

Baseline Clinical Parameters[g]

Both groups were well matched across key baseline measures

	CAVT Arm (N=47)	AC Arm (N=53)
NEWS2[h]	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[h]	27.3 ± 3.89	26.1 ± 5.51

Baseline Functional Assessments[g]

Borg Dyspnea Scale	4.6 ± 2.90	4.5 ± 2.85
mMRC[h] ≥ 1	43 (93.5%)	51 (96.2%)
PVFS[h]	3.0 ± 0.97	2.9 ± 1.01

g. Paired data at 48 h, paired data for CAVT ranged from N=45–46 and for AC=52–53. Data presented as mean ± SD.
h. NEWS2 = National Early Warning Score 2; RMMS = Refined Modified Miller Score; mMRC = Modified Medical Reaserch Council Dyspnea Scale; PVFS = Post-VTE (Venous Thromboembolism) Functional Status Scale.

More to Come at VIVA 2025

Las Vegas, NV, USA

Learn More About STORM-PE RCT

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

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