STRIKE-PE STUDY

Computer Assisted Vacuum Thrombectomy (CAVT) for ACUTE PULMONARY EMBOLISM: Generating the Evidence

Robert Lookstein MD MHCDL FSIR FAHA FSVM

Disclosures:
In the past 12 months, my spouse or myself have engaged in financial relationships as follows:

- Advisory Board: Boston Scientific, Medtronic
- Consultant: Penumbra, Imperative Vascular
- Speakers Bureau: Abbott Vascular
- Equity Shareholder: Imperative, Innova Vascular, Thrombolex, Aidoc, Votis, Inspire MD
- Research Support
  - Philips Healthcare, Siemens, Gore, Inquis, Penumbra, Boston Scientific, Reva Medical, Ethicon, Bard Vascular, Instylla, Imperative

STORM-PE TRIAL

Endovascular Therapy Research in PE

Penumbra-sponsored PE studies

STRIKE-PE STUDY

Computer Assisted Vacuum Thrombectomy

Lightning® 12 aspiration catheter with Separator™ wire

Lightning Flash™ (16F catheter)

Penumbra ENGINE® pump with Lightning Aspiration Tubing attached

STRIKE-PE STUDY

Objective: Evaluate real-world long-term functional outcomes, safety, and performance of the Indigo® Aspiration System for the treatment of pulmonary embolism (PE)

ClinicalTrials.gov ID: NCT04798261

- PI: John Moriarty, MD (UCLA, Los Angeles, CA, USA)
- Up to 80 global sites
- Up to 1500 patients with acute intermediate-risk or high-risk PE
- Primary safety endpoint: Composite MAEs at 48 h
  Primary performance endpoint: RV/LV change at 48 h
  Secondary endpoints: QOL & functional outcomes at 90 d
- Long-term follow-up to 1 year
- **Interim analysis of 300 patients through discharge**

STRIKE-PE STUDY

Primary & Secondary Endpoints

Primary performance endpoint*
- Change in RV/LV ratio from baseline to 48 hours postprocedure

Primary safety endpoint†
- Composite of major adverse events (MAEs) within 48 hours:
  - Major bleeding
  - Device-related death
  - Device-related clinical deterioration
  - Device-related pulmonary vascular injury
  - Device-related cardiac injury

Secondary endpoints
- Functional outcomes at 90 days
  - NYHA classification
  - 6-minute walk test (6MWT)
  - Borg dyspnea scale
- Quality of life at 90 days
  - Generic: EQ-5D-5L & EQ VAS
  - Disease-specific: PEmb-QoL
- Incidence of device-related SAEs†
- Any-cause mortality within 30 days†
- Symptomatic PE recurrence within 30 days†

* Per core lab or otherwise per physician.
† Independent medical reviewer–adjudicated.

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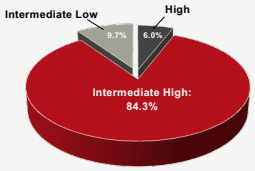
Baseline

PE Early Mortality Risk
(2019 ESC Guidelines)



Interim Analysis (N = 300)	
Demographics	
Age, mean ± SD, y	61.2 ± 14.82
Sex, male, % (n)	53.7% (161)
Medical history, % (n)	
Hypertension	56.7% (170)
Deep vein thrombosis	45.3% (136)
Hyperlipidemia	39.7% (119)
Diabetes	24.7% (74)
COVID-19, active or previous	18.3% (55)
Previous PE	11.7% (35)
Modified Miller score ≥12, % (n)	83.3% (250)

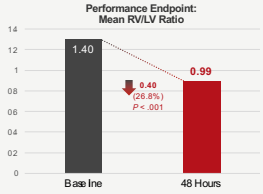
STRIKE-PE STUDY

Periprocedural Characteristics

Periprocedural Characteristics	Interim Analysis (N = 300) median [IQR] or % (n)
Symptom onset to admission time	**41.0 h*** [14.0–104.5]
Symptom onset to puncture time	**2.9 d** [1.5–5.3]
Thrombectomy time	**30.0 min**† [21.0–44.0]‡
Procedure time	**62.0 min**§ [48.0-86.0]‖
ICU length of stay after procedure	**1.0 d**¶ [0.0–2.0]
No ICU stay required	**40.3%** (121)
Hospital length of stay after procedure	**5.0 d** [4.0–7.0]

STRIKE-PE STUDY

Primary Endpoints



Safety Endpoints,* % (n)	Interim Analysis (N = 300)
Major Adverse Events Within 48 h	**2.0%** (6)
Major bleeding†	**2.0%** (6)
Device-related clinical deterioration‡	**0.7%** (2)
Device-related pulmonary vascular injury‡	**0.3%** (1)
Device-related cardiac injury‡	0
Device-related death‡	0

* Independent medical reviewer–adjudicated.
† Major bleeding is defined as meeting BARC Types 3a, 3b, 3c, and 5, in line with AHA guidelines. Type 3a will not be considered as a major bleeding event if it is related to an expected drop in hemoglobin due to fluid administration and if transfusion is less than 2 units.
‡ Adverse events that were judged as probably or definitely related to the Indigo Aspiration System were considered to be device related.

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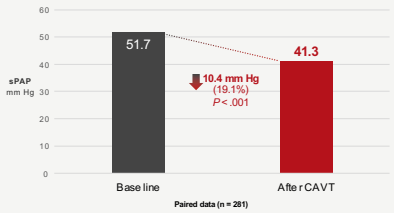
Additional Safety Details

Secondary Safety Endpoints,* % (n)	Interim Analysis (N = 300)
Device-related serious adverse events†	**0.7%** (2)
Any-cause mortality within 30 d	**1.0%** (3)
Recurrent PE within 30 d	**0.7%** (2)
Transfusion Details,* % (n)	**Interim Analysis** (N = 300)
Major bleeding requiring transfusion	1.0% (3)
Device-related transfusion	0.3% (1)

* Independent medical reviewer–adjudicated.
† Adverse events that were judged as probably or definitely related to the Indigo Aspiration System were considered to be device-related.

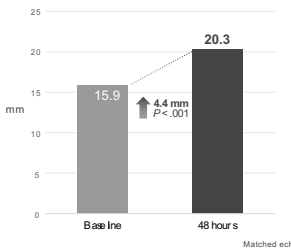
STRIKE-PE STUDY

Mean On-Table Change in Systolic Pulmonary Artery Pressure (sPAP)



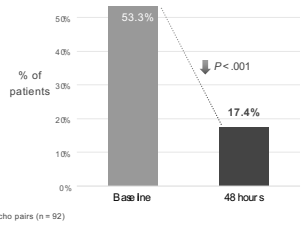
- sPAP is a predictor of right ventricular dysfunction*
- sPAP decreased significantly on the table after CAVT

TAPSE

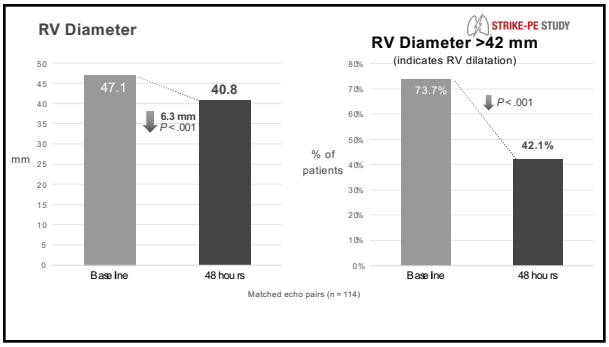


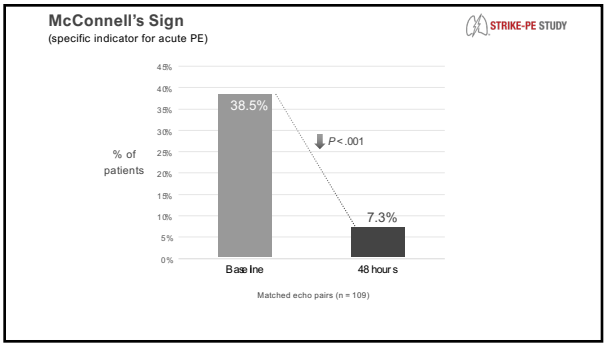
STRIKE-PE STUDY

TAPSE <16 mm
(correlates with an unfavorable prognosis)



Matched echo pairs (n = 92)


RV Diameter
STRIKE-PE STUDY
47.1
40.8
6.3 mm
P < .001
mm
Baseline
48 hours
RV Diameter >42 mm
(indicates RV dilatation)
73.7%
42.1%
P < .001
% of patients
Baseline
48 hours
Matched echo pairs (n = 114)


McConnell's Sign
(specific indicator for acute PE)
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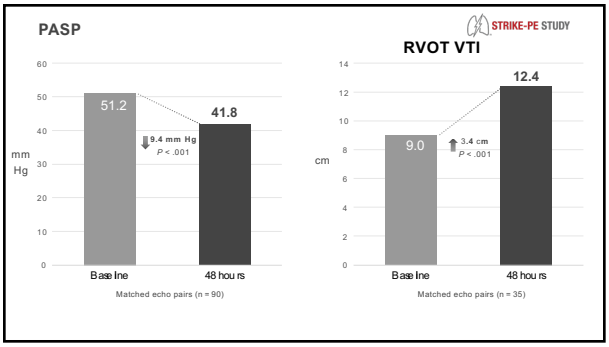
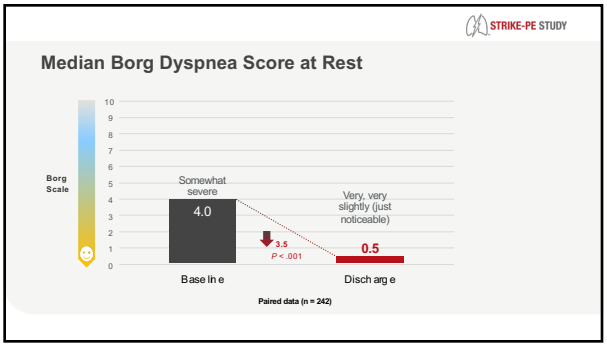
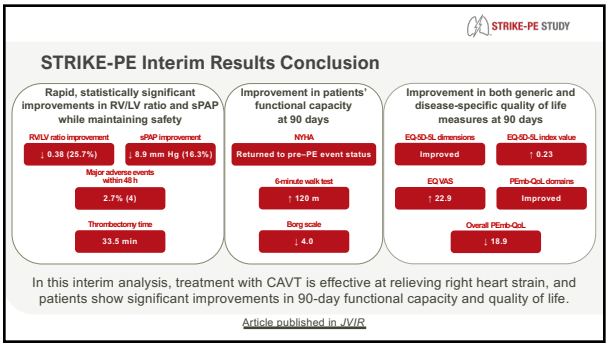
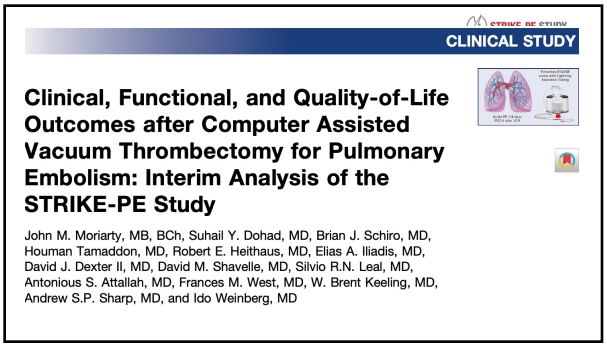
38.5%
7.3%
P < .001
% of patients
Baseline
48 hours
Matched echo pairs (n = 109)


PASP
STRIKE-PE STUDY
51.2
41.8
9.4 mm Hg
P < .001
mm Hg
Baseline
48 hours
Matched echo pairs (n = 90)
RVOT VTI
9.0
12.4
3.4 cm
P < .001
cm
Baseline
48 hours
Matched echo pairs (n = 35)


STRIKE-PE STUDY
Median Borg Dyspnea Score at Rest
Borg Scale
Somewhat severe
4.0
Very, very slightly (just noticeable)
0.5
3.5
P < .001
Baseline
Discharge
Paired data (n = 242)

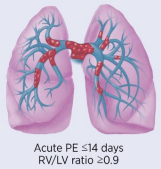

STRIKE-PE STUDY
STRIKE-PE Interim Results Conclusion
Rapid, statistically significant improvements in RV/LV ratio and sPAP while maintaining safety
RV/LV ratio improvement
↓ 0.38 (25.7%)
sPAP improvement
↓ 8.9 mm Hg (16.3%)
Major adverse events within 48 h
2.7% (4)
Thrombectomy time
33.5 min
Improvement in patients' functional capacity at 90 days
NYHA
Returned to pre–PE event status
6-minute walk test
↑ 120 m
Borg scale
↓ 4.0
Improvement in both generic and disease-specific quality of life measures at 90 days
EQ-5D-5L dimensions
Improved
EQ-5D-5L index value
↑ 0.23
EQ VAS
↑ 22.9
PEmb-QoL domains
Improved
Overall PEmb-QoL
↓ 18.9
In this interim analysis, treatment with CAVT is effective at relieving right heart strain, and patients show significant improvements in 90-day functional capacity and quality of life.
Article published in JVIR


CLINICAL STUDY
Clinical, Functional, and Quality-of-Life Outcomes after Computer Assisted Vacuum Thrombectomy for Pulmonary Embolism: Interim Analysis of the STRIKE-PE Study
John M. Moriarty, MB, BCh, Suhail Y. Dohad, MD, Brian J. Schiro, MD, Houman Tamaddon, MD, Robert E. Heithaus, MD, Elias A. Iliadis, MD, David J. Dexter II, MD, David M. Shavelle, MD, Silvio R.N. Leal, MD, Antonious S. Attallah, MD, Frances M. West, MD, W. Brent Keeling, MD, Andrew S.P. Sharp, MD, and Ido Weinberg, MD

Clinical, Functional, and Quality of Life Outcomes After Computer Assisted Vacuum Thrombectomy for Pulmonary Embolism: Interim Analysis of the STRIKE-PE Study

STRIKE-PE: Prospective, international, multicenter study to enroll 600 patients

Interim analysis of **150 patients**
92.7% with high-risk or intermediate-high-risk PE



Primary outcomes

Change in RV/LV ratio at 48 h (effectiveness)	Improvements from baseline to 90 days (all $P < .001$)	
	Borg dyspnea scale	EQ VAS
Δ 0.38 (25.7%) ⇩	Δ 4.0 ⇩	Δ 22.9 ⇧
Composite major adverse event rate (safety)	Overall PEmb-QoL	EQ-5D-5L index value
2.7% (4/150)	Δ 18.9 ⇧	Δ 0.23 ⇧

Moriarty et al. *JVIR*. 2024; 35:1154-1165e6

Journal of Vascular and Interventional Radiology | JVIR

STRIKE-PE STUDY

New Technology: Lightning Flash™

Periprocedural Characteristics; mean (SD), median [IQR], or % (n)	Lightning Flash (N = 86)
Thrombectomy time, min*	**23** [19-35]
Primary endpoint: Percent reduction in RV/LV ratio, baseline to 48 h	**27.8%** (14.1%)†
Percent reduction in sPAP	**24.5%** (18.5%)
Reduction in Borg dyspnea scale score, baseline to discharge	**3** [2-7]

* First Indigo device insertion to last Indigo device removal.
† N = 83.
‡ Access site hematoma.

STRIKE-PE STUDY

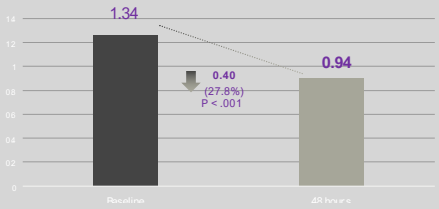
Safety Endpoints and Details

Primary Safety Endpoints,* % (n)	FLASH (n = 86)
Major adverse events within 48 h	**1.2** % (1)
Secondary Safety Endpoints,* % (n)	
Device-related serious adverse events†	**0%**
Any-cause mortality within 30 d	**0%**
Recurrent PE within 30 d	**0%**
Transfusion Details,* % (n)	
Major bleeding requiring transfusion	**0%**
Device-related transfusion	**0%**

* Independent medical reviewer–adjudicated.
† Adverse events that were judged as probably or definitely related to the Indigo Aspiration System were considered to be device-related.

STRIKE-PE STUDY

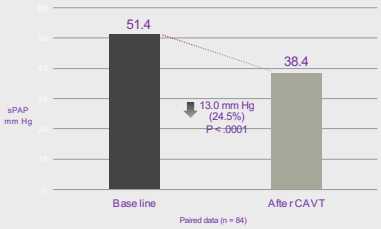
Primary Performance Mean RV/LV Ratio



Matched imaging modality (CTPA or ECHO) pairs (n = 83)

STRIKE-PE STUDY

Mean On-Table Change in Systolic Pulmonary Artery Pressure (sPAP)



Paired data (n = 84)

- sPAP decreased significantly on the table after Indigo aspiration
- sPAP is a predictor of right ventricular dysfunction*

*Cor et Vasa. 2016;58(4):e403-e410.

STRIKE-PE STUDY

HOW CAN WE ADVANCE THE SCIENCE AND CREATE LEVEL ONE EVIDENCE FOR

COMPUTER ASSISTED VACUUM THROMBECTOMY FOR ACUTE PULMONARY EMBOLISM?

STRIKE-PE STUDY

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 TRIAL

IN COLLABORATION WITH PERT CONSORTIUM

Prospective, randomized trial

The *first* RCT comparing:

CAVT Computer Assisted Vacuum Thrombectomy + Anticoagulation

vs

Anticoagulation

Acute, intermediate-high-risk PE

Up to 25 sites

100 participants

Trial endpoints:

Efficacy: RV/LV ratio change within 48 hours

Safety: Major adverse events within 7 days

Patient-Centric: Functional & quality of life outcomes within 90 days

Penumbra

Steering Committee

STORM-PE TRIAL

Dr Rachel Rosovsky
Hematology
Massachusetts General Hospital

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Interventional Cardiology
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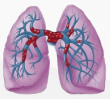
Dr Sahil Parikh
Interventional Cardiology
Columbia University

Richard Davis
Patient representative
South Florida

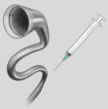
Penumbra

Study Design

STORM-PE TRIAL



Intermediate-high-risk patients
1:1 randomization

Indigo + AC		AC alone
	vs	

Protocol Timeline

STORM-PE TRIAL

- Baseline Visit
- Randomization/Enrollment (day 0)
- Treatment
- 48 hours (±6 hours) — **Primary endpoint:** RV/LV ratio (CTPA)
- Discharge — **Safety endpoint*** at day 7
- 30-day follow-up (±7 days) — **Functional and QOL assessments**
- 90-day follow-up (±14 days)

* Composite of clinical deterioration requiring escalation of care, PE-related mortality, symptomatic recurrent PE, or major bleeding

Wearable Device Substudy

STORM-PE TRIAL

- 24/7 data collection as participants go through their daily routines at work and at home
- Data collected include the following:
  - Heart rate
  - Respiratory rate
  - O_2 saturation via pulse oximetry (SpO_2)
  - Sleep
  - Steps taken and distance travelled
  - Intensity minutes (exercise)
- Data will provide insight into participants' recovery and exercise after PE

Venu® Sq smartwatch by Garmin®
Provided free to participants

STORM-PE TRIAL

Study Devices:
Computer Assisted Vacuum Thrombectomy (CAVT)

Lightning Flash™
(16F catheter)

Penumbra ENGINE® pump with
Lightning Flash™ Aspiration Tubing attached

STORM-PE TRIAL

Significance of STORM-PE Trial

- Generate evidence-based insights into safety and efficacy of two current PE treatment approaches and reinforce findings of previous single-arm studies
- Provide robust level 1 evidence on whether mechanical aspiration thrombectomy with anticoagulation vs anticoagulation alone offers:
  - Superior efficacy in reducing right heart strain
  - Enhanced overall patient recovery
- Potential to influence PE treatment guidelines, optimize therapeutic strategies, and improve patient outcomes

Summary

STORM-PE TRIAL

- First randomized, level 1 data comparing mechanical aspiration thrombectomy to anticoagulation alone
- Advance our understanding of best treatment options for intermediate high-risk PE patients
- Preliminary Flash data for STRIKE-PE is promising regarding efficacy and safety

STORM-PE TRIAL

Thank you!