Literature Update

Critical Care BC

Sept 2023

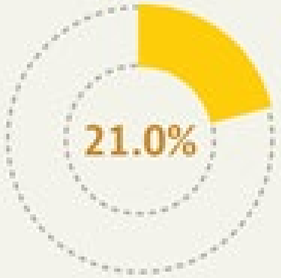
Review

PREPARE II

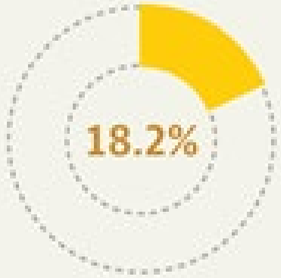
FINDINGS

Cardiovascular collapse

Fluid bolus
113 of 538 patients



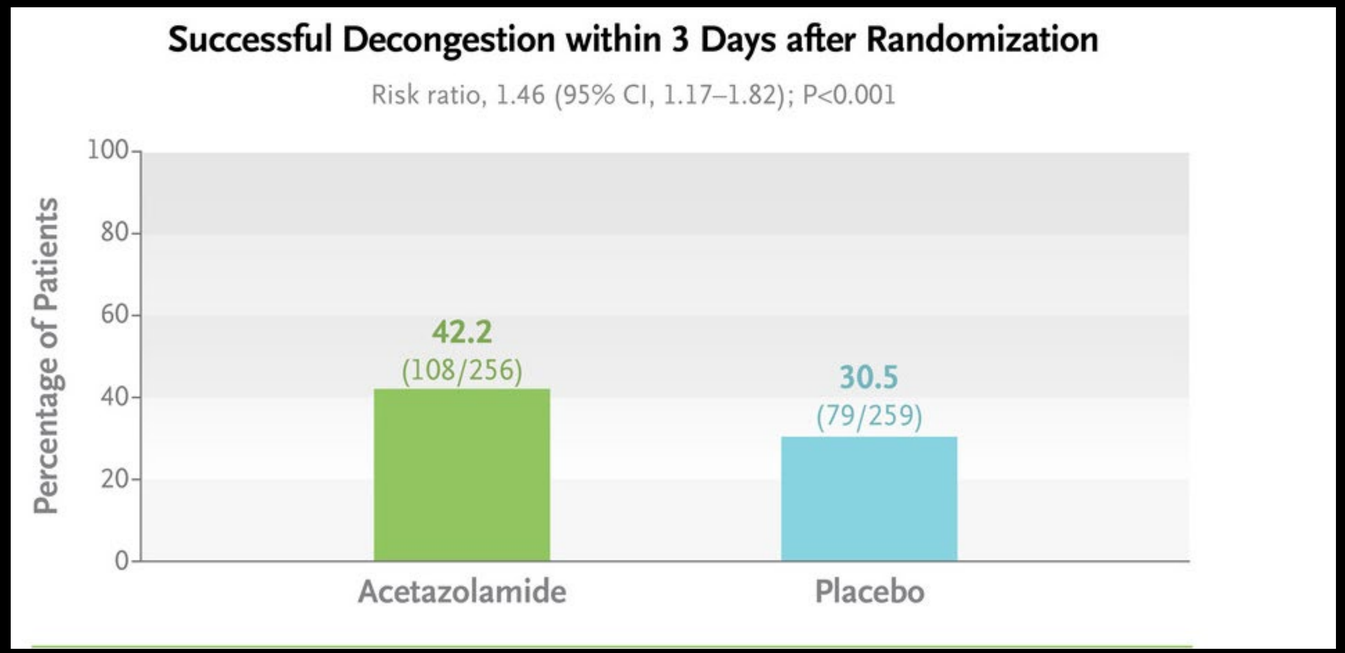
No fluid bolus
96 of 527 patients



The between-group difference was not significant:

Absolute difference, **2.8%**
(95% CI, −2.2% to 7.7%); *P* = .25

ADVOR



This Month

Critical Care Medicine
Society of Critical Care Medicine
The Intensive Care Professionals

SPECIAL ARTICLES

Executive Summary: Guidelines for Evaluating New Fever in Adult Patients in the ICU

O'Grady, Naomi P. MD, FCCM, FIDSA[1]; Alexander, Earnest PharmD, FCCM[2]; Alhazzani, Waleed MBBS, MSc, FRCPC[3]; Alshamsi, Fayez MBBS[4]; Cuellar-Rodriguez, Jennifer MD[5]; Jefferson, Brian K. DNP, ACNP-BC, FCCM[6]; Kalil, Andre C. MD, MPH, FCCM, FIDSA[7]; Pastores, Stephen M. MD, MACP, FCCP, FCCM[8]; Patel, Robin MD, FIDSA, FRCPC[9]; van Duin, David MD, PhD, FIDSA[10]; Weber, David J. MD, FIDSA, FSHEA, FRSM, FAST[10]; Deresinski, Stanley MD, FIDSA[11]

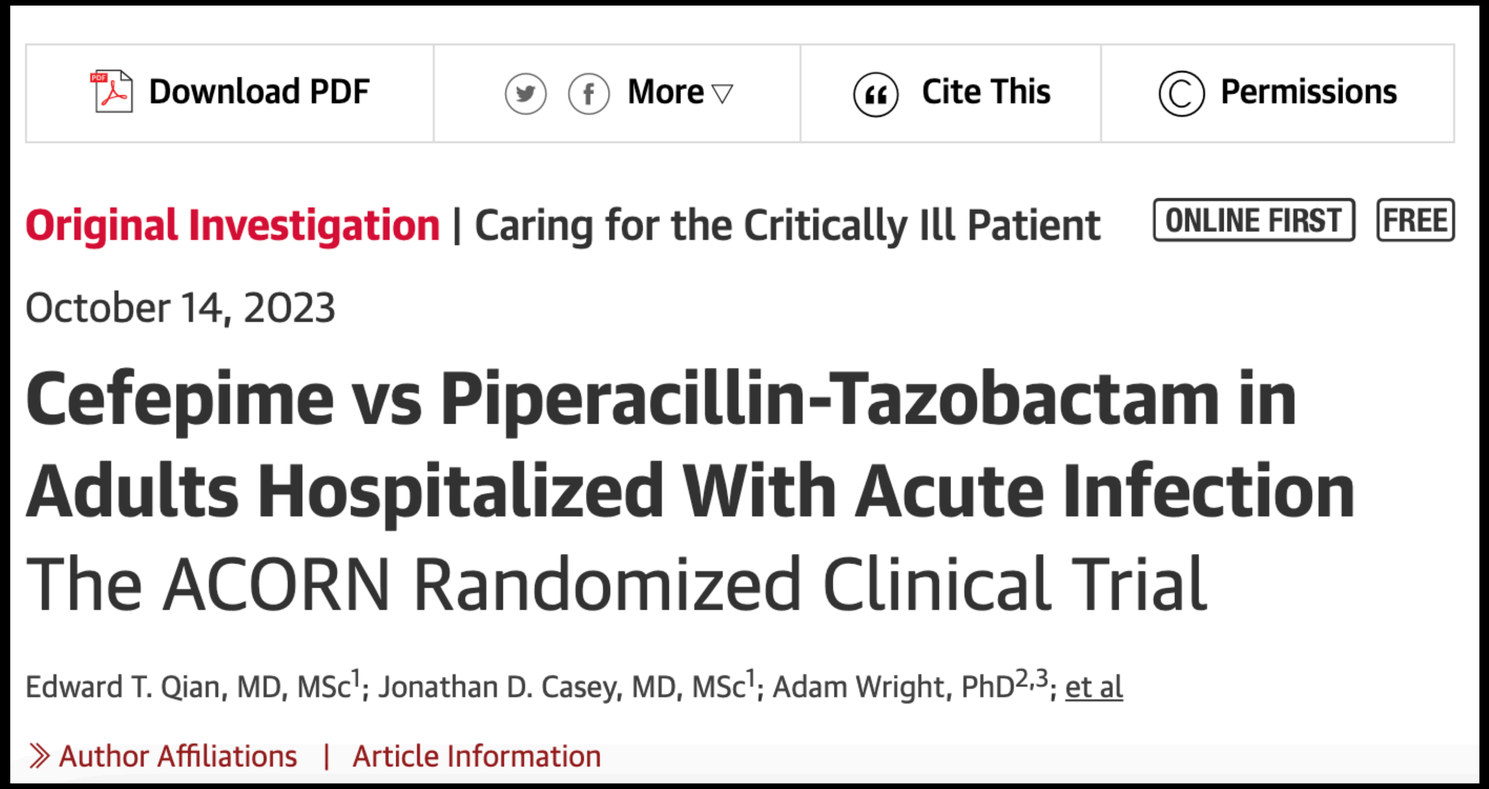
Author Information

Critical Care Medicine 51(11):p 1566-1569, November 2023. | ***DOI:*** 10.1097/CCM.0000000000006021

Society of Critical Care Medicine and the Infectious Diseases Society of America Guidelines for Evaluating New Fever in Adult Patients in the ICU

ACORN

Piptazo isn’t nephrotoxic…
and don’t use cefepime



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Original Investigation | Caring for the Critically Ill Patient ONLINE FIRST FREE

October 14, 2023

Cefepime vs Piperacillin-Tazobactam in Adults Hospitalized With Acute Infection

The ACORN Randomized Clinical Trial

Edward T. Qian, MD, MSc[1]; Jonathan D. Casey, MD, MSc[1]; Adam Wright, PhD[2,3]; et al

» Author Affiliations | Article Information

JAMA®

QUESTION Does the choice between cefepime and piperacillin-tazobactam affect the risks of acute kidney injury or neurological dysfunction in adults hospitalized with acute infection?

CONCLUSION Among hospitalized adults, the risk of acute kidney injury did not differ between cefepime and piperacillin-tazobactam, but neurological dysfunction was more common with cefepime.

POPULATION

1439 Men **1071** Women

Adults hospitalized with acute infection

Median age: **58** years

LOCATION

1
Medical center in Nashville, Tennessee

INTERVENTION

2634 Patients randomized
2511 Patients analyzed

1214
Cefepime
Administered as an intravenous push over 5 minutes

1297
Piperacillin-tazobactam
Administered as a bolus for the initial administration and then extended infusion over 4 hours for subsequent doses

PRIMARY OUTCOME

Highest stage of acute kidney injury or death by day 14 (measured on a 5-level ordinal scale; range: no acute kidney injury to death)

FINDINGS

Highest stage of acute kidney injury or death by day 14

Cefepime

Survived with stage 3 acute kidney injury	**7.0%** (85 of 1214 patients)
Died	**7.6%** (92 of 1214 patients)

Piperacillin-tazobactam

Survived with stage 3 acute kidney injury	**7.5%** (97 of 1297 patients)
Died	**6.0%** (78 of 1297 patients)

There was no significant between-group difference:
Odds ratio, 0.95 (95% CI, 0.80 to 1.13); *P* = .56

Qian ET, Casey JD, Wright A, et al; Vanderbilt Center for Learning Healthcare and the Pragmatic Critical Care Research Group. Cefepime vs piperacillin-tazobactam in adults hospitalized with acute infection: the ACORN randomized clinical trial. *JAMA*. Published online October 14, 2023. doi:10.1001/jama.2023.20583

STRATUS Trial
Small Volume Blood Collection

Original Investigation | Caring for the Critically Ill Patient ONLINE FIRST FREE

October 12, 2023

Small-Volume Blood Collection Tubes to Reduce Transfusions in Intensive Care

The STRATUS Randomized Clinical Trial

Deborah M. Siegal, MD[1,2,3,4]; Emilie P. Belley-Côté, MD, PhD[1,2,8]; Shun Fu Lee, PhD[1,8]; et al

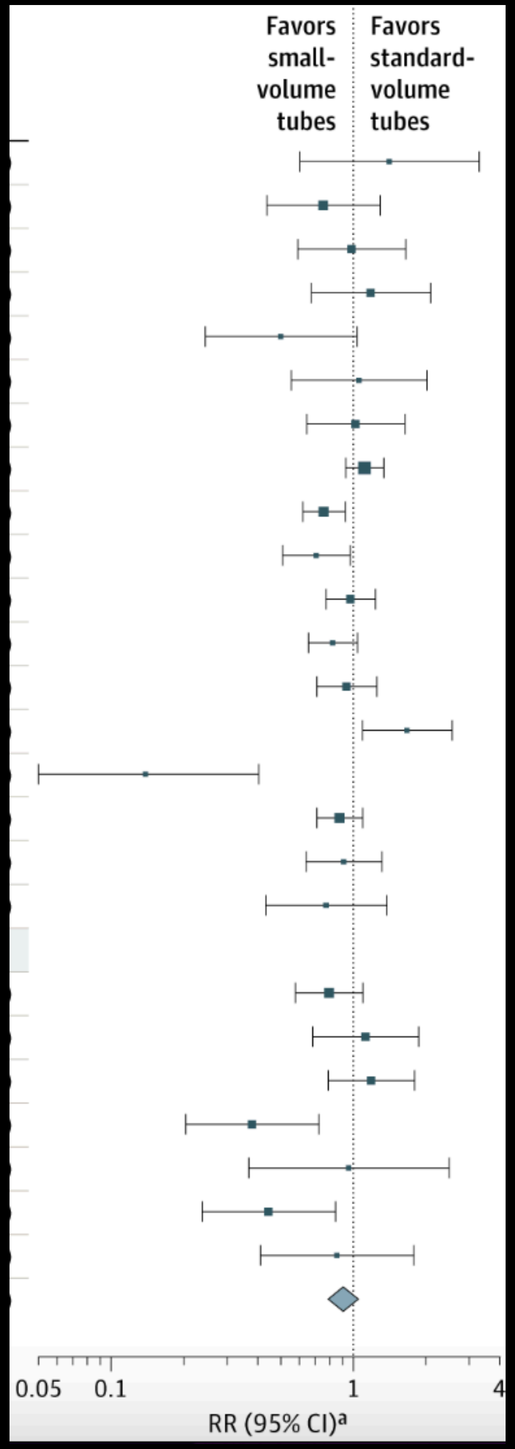
Table 1. Cluster Characteristics

Characteristics	No.
Overall	25
Province in Canada	
Quebec	14
Ontario	9
Manitoba	1
New Brunswick	1
Total cluster size, median (IQR), patients	854 (594-1037)
Cluster-period size, median (IQR), patients	63 (43-85)

Table 3. Outcomes for the Study of Small-Volume vs Standard-Volume Tubes for Blood Collection

	Primary population (n = 21 201)[a]			
	Small-volume tubes (n = 10 261)	Standard-volume tubes (n = 10 940)	Relative risk (95% CI)[b]	Mean difference (95% CI)[b]
Primary outcome				
RBC units transfused in ICU per patient per median ICU stay				
Least-squares mean (95% CI)	0.72 (0.52 to 0.98)	0.79 (0.58 to 1.07)	0.91 (0.79 to 1.05)[c]	−0.07 (−0.19 to 0.03)
Crude mean (SD)	0.78 (2.23)	0.88 (2.79)		

- Supplier = Same
- Price = Same?
- Volume 4-6ml vs 1.8-3.5ml



Product catalogue search

Your Selections

Clear All

- BD Vacutainer® ×
- Specimen collection ×
- BD Vacutainer® blood collection tubes ×

Keywords

Capability

- [x] Specimen collection (46)

Product Line

- [ ] Blood specimen collection (46)

Product Category

368493

BD Vacutainer® blood collection tubes - chemistry

BD Vacutainer® Serum tube, clot activator, silicone-coated interior

Compare

366430

BD Vacutainer® blood collection tubes - chemistry

BD Vacutainer® Serum tube, no additive, silicone-coated interior

Compare

367871

BD Vacutainer® blood collection tubes - chemistry

BD Vacutainer® Plasma tube, 75 USP units of sodium heparin (spray coated)

Compare

9 less PRBCs / 100 patients / ICU

CRYOSTAT-2

Original Investigation | Caring for the Critically Ill Patient ONLINE FIRST FREE

October 12, 2023

Early and Empirical High-Dose Cryoprecipitate for Hemorrhage After Traumatic Injury

The CRYOSTAT-2 Randomized Clinical Trial

Ross Davenport, PhD[1]; Nicola Curry, MD[2]; Erin E. Fox, PhD[3]; et al

» Author Affiliations | Article Information

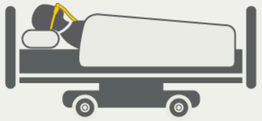
JAMA. Published online October 12, 2023. doi:10.1001/jama.2023.21019

JAMA®

QUESTION Does early transfusion of high-dose cryoprecipitate in addition to standard care improve survival in patients with trauma and bleeding who require activation of a major hemorrhage protocol (MHP)?

CONCLUSION The addition of early and empirical high-dose cryoprecipitate to usual care did not improve clinical outcomes in patients with trauma and bleeding.

POPULATION



1251 Men **330** Women

Patients 16 years or older with major trauma hemorrhage in the emergency department

Median age: **39** years

LOCATIONS

26
Major trauma centers in the UK and the US

INTERVENTION

1604 Participants randomized
1531 Participants analyzed

799
Cryoprecipitate
Standard treatment with an additional 3 pools of cryoprecipitate (6-g fibrinogen) as early as possible

805
Standard care
Standard treatment according to the local MHP with a balanced ratio of red blood cells and fresh frozen plasma

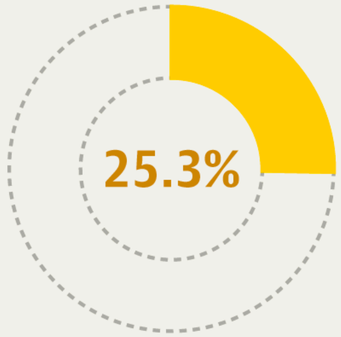
PRIMARY OUTCOME

All-cause mortality at 28 days

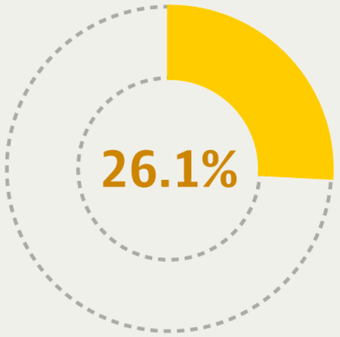
FINDINGS

All-cause mortality at 28 days

Cryoprecipitate
192 of 760 participants



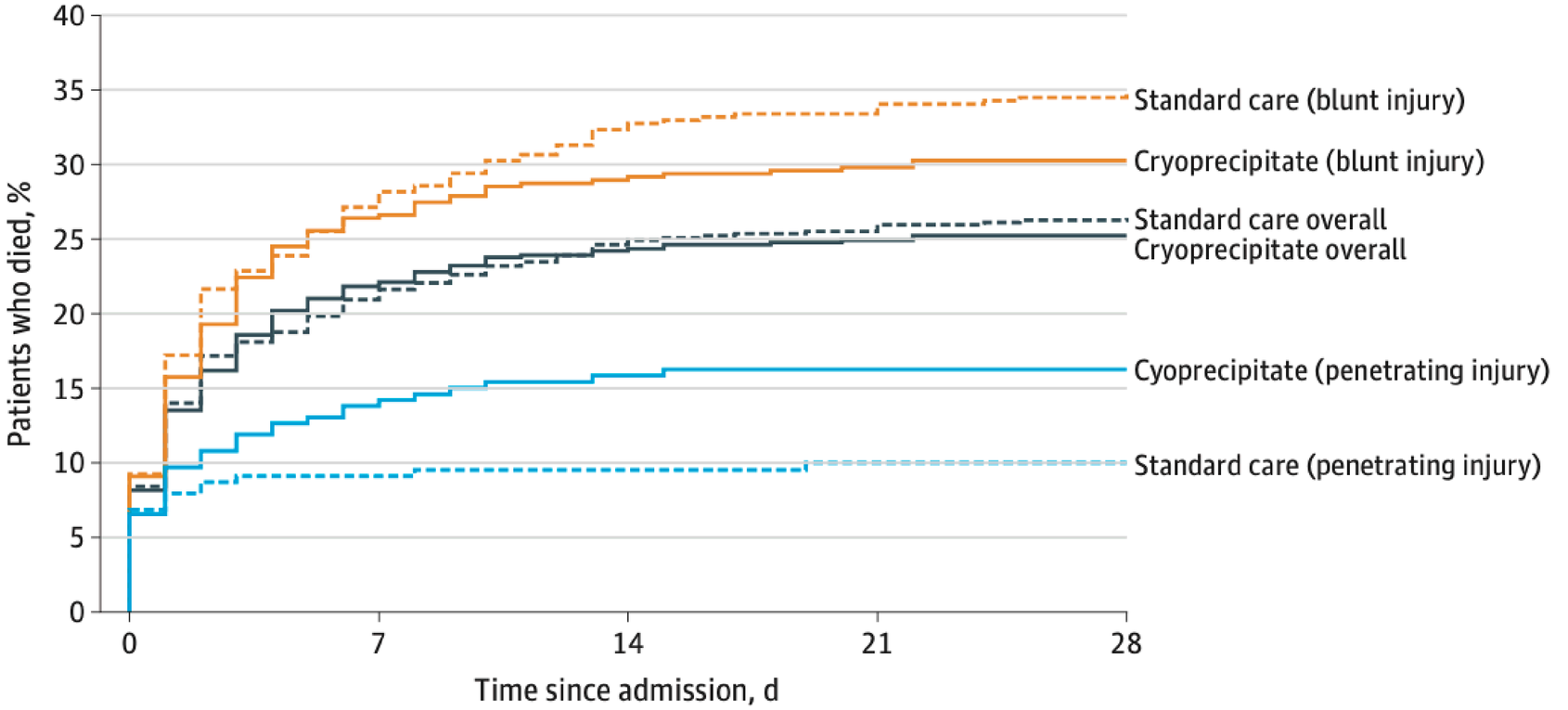
Standard care
201 of 771 participants



There was no improvement in mortality:
Odds ratio, 0.96 (95% CI, 0.75-1.23); *P* = .74

Davenport R, Curry N, Fox EE, et al; for the CRYOSTAT-2 Principal Investigators. Early and empirical high-dose cryoprecipitate for hemorrhage after traumatic injury: the CRYOSTAT-2 randomized clinical trial. *JAMA*. Published online October 12, 2023. doi:10.1001/jama.2023.21019

Figure 2. Mortality Overall and by Injury Type



No. of patients at risk

Cryoprecipitate overall	784	567	532	514	498
Standard care overall	795	569	518	501	479
Cryoprecipitate (blunt injury)	495	348	332	323	310
Standard care (blunt injury)	518	353	320	307	289
Cryoprecipitate (penetrating injury)	289	219	200	191	188
Standard care (penetrating injury)	277	216	198	194	190

The median number of days observed was 28 days for all groups. Mortality at day 28 was analyzed as a binary outcome with odds ratios, 95% CIs, and *P* values reported in the results and in Figure 3.

UK-REBOA

Original Investigation | Caring for the Critically Ill Patient ONLINE FIRST FREE

October 12, 2023

Emergency Department Resuscitative Endovascular Balloon Occlusion of the Aorta in Trauma Patients With Exsanguinating Hemorrhage

The UK-REBOA Randomized Clinical Trial

Jan O. Jansen, PhD[1,2]; Jemma Hudson, PhD[1]; Claire Cochran, MSc[1]; et al

» Author Affiliations | Article Information

JAMA®

QUESTION Does the addition of resuscitative endovascular balloon occlusion of the aorta (REBOA) to standard care reduce mortality in trauma patients with exsanguinating hemorrhage?

CONCLUSION In trauma patients with exsanguinating hemorrhage, a strategy that includes REBOA, when used in the emergency department, does not reduce, and may increase, mortality compared with standard care.

POPULATION

62 Men **28** Women

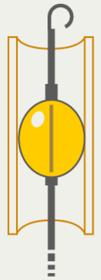
Trauma patients aged ≥16 years with exsanguinating hemorrhage

Median age: **41** years

LOCATIONS

16
Major trauma centers in the UK

INTERVENTION



90 Patients randomized
89 Patients analyzed

46

REBOA intervention + standard care

Technique of endovascular aortic occlusion for the purpose of resuscitation as part of overall resuscitation strategy

44

Standard care

Intubation, balanced blood product transfusion, tourniquet application, and interventions for hemorrhage control

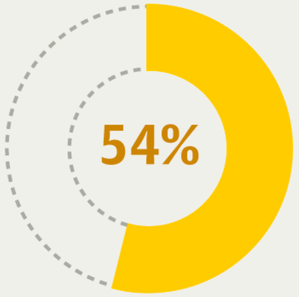
PRIMARY OUTCOME

All-cause mortality at 90 days

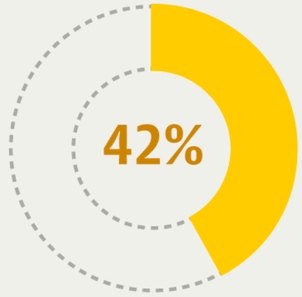
FINDINGS

All-cause mortality at 90 days

REBOA intervention + standard care
25 of 46 patients



Standard care
18 of 43 patients

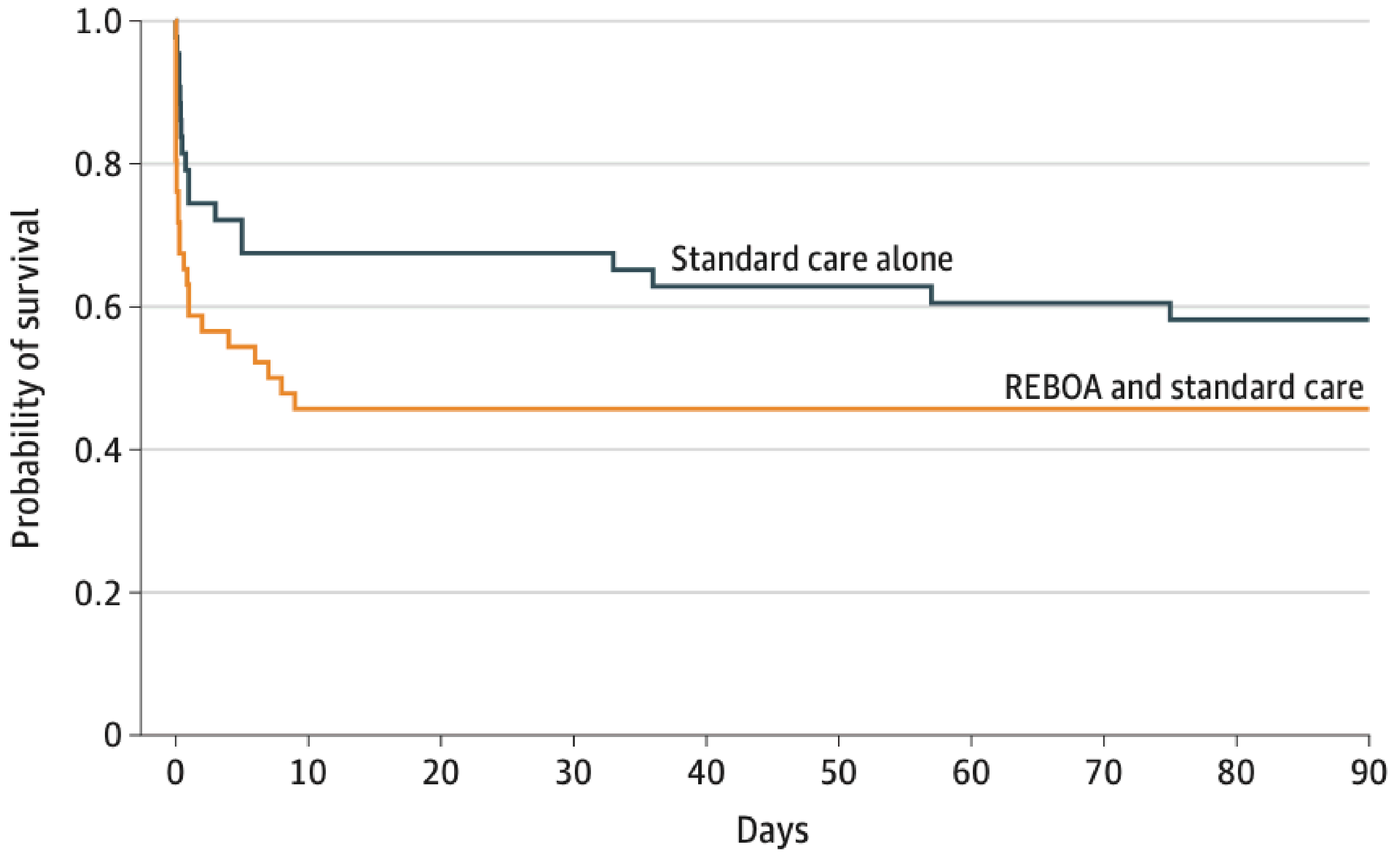


Prespecified stopping rule for harm was met and study was terminated:

Odds ratio, 1.58 (95% credible interval, 0.72 to 3.52);
Posterior probability of odds ratio >1 (harm) = 86.9%

Jansen JO, Hudson J, Cochran C, et al. Emergency department resuscitative endovascular balloon occlusion of the aorta in trauma patients with exsanguinating hemorrhage: the UK-REBOA randomized clinical trial. *JAMA*. Published online October 12, 2023. doi:10.1001/jama.2023.20850

B Kaplan-Meier survival estimates



No. at risk										
Standard care alone	43	29	29	29	27	27	26	26	25	25
REBOA and standard care	46	21	21	21	21	21	21	21	21	21

REBOA indicates resuscitative endovascular balloon occlusion of the aorta.

FLAME Trial

Mechanical Thrombectomy in high risk PE

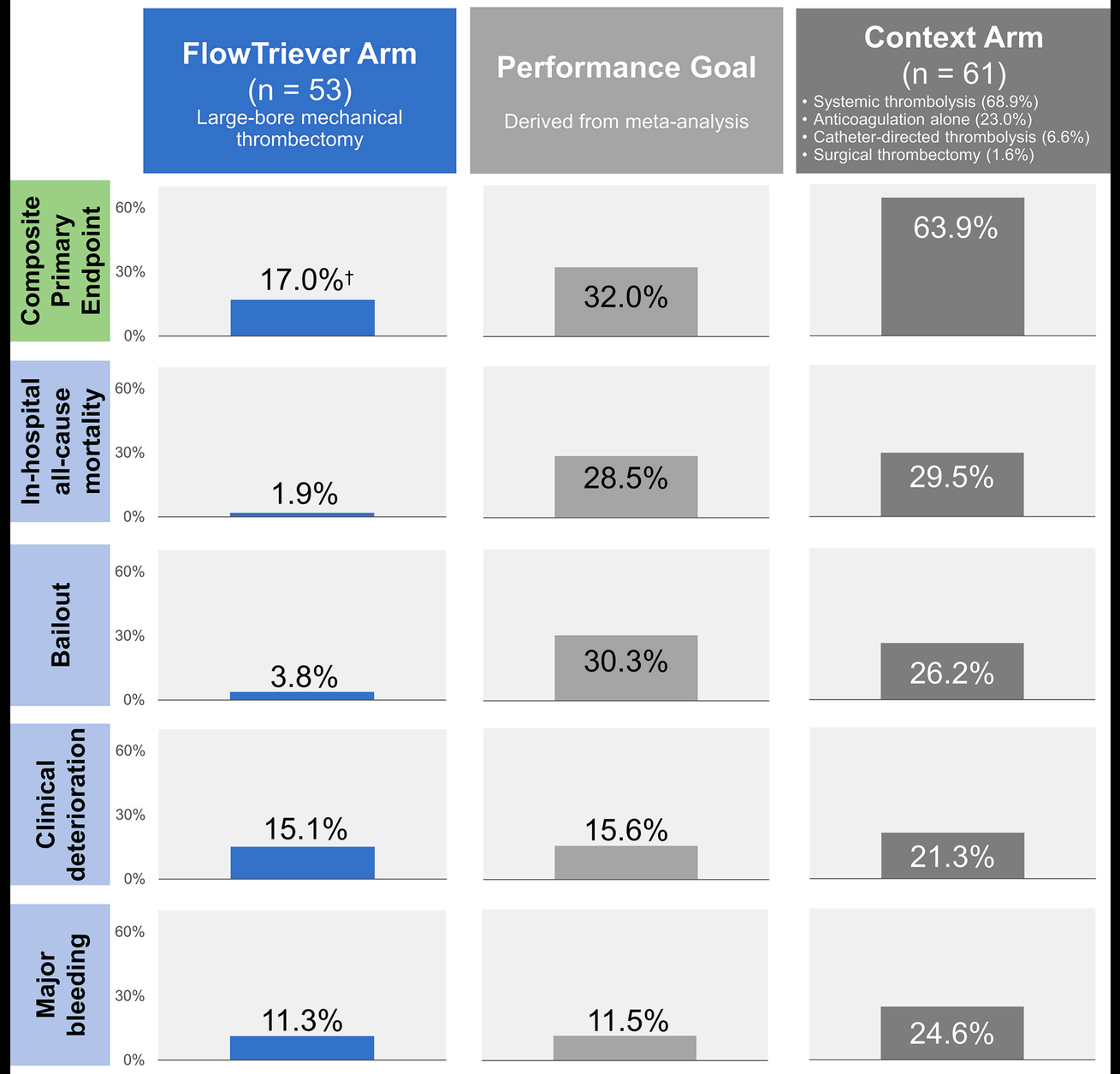
Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Outcomes in High-Risk Pulmonary Embolism Patients Undergoing FlowTriever Mechanical Thrombectomy or Other Contemporary Therapies: Results From the FLAME Study

Mitchell J. Silver, DO; C. Michael Gibson, MD; Jay Giri, MD, MPH; Sameer Khandhar, MD; Wissam Jaber, MD; Catalin Toma, MD; Bushra Mina, MD; Terry Bowers, MD; Lee Greenspon, MD; Herman Kado, MD; David M. Zlotnick, MD; Mithun Chakravarthy, MD; Aaron R. DuCoffe, MD; Paul Butros, MD; James M. Horowitz, MD

Outcomes in High-risk Pulmonary Embolism: Results from the FLAME Study



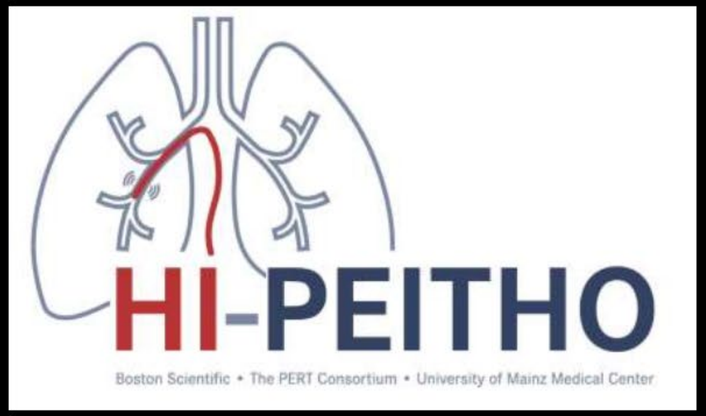
The FlowTriever Arm and Context Arm were parallel registries designed to capture relevant information on the treatment and management of high-risk PE by care pathway. The Context Arm was not intended as a comparator to the FlowTriever Arm.

†Significantly lower than Performance Goal ($P<0.01$).

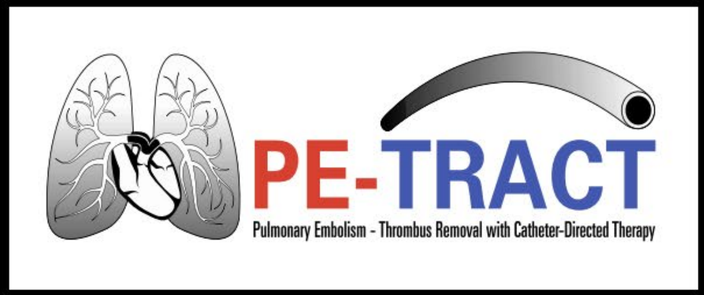
Ronco’s Corner

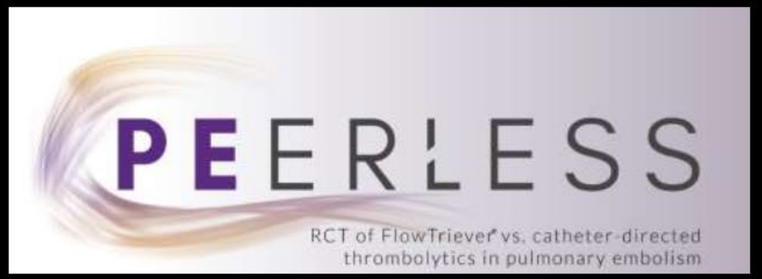
In 2023…..

- We have Four on-label endovascular devices for acute pulmonary embolism
  - EKOS Ultrasound accelerated thrombolysis (USAT)
  - FLOWTRIEVER retrieval/aspiration system (LBAT)
  - INDIGO aspiration system (CAVT)
  - Bashir pharmacomechanical thrombolysis (PMT)


HI-PEITHO
Boston Scientific • The PERT Consortium • University of Mainz Medical Center


STORM-PE
TRIAL


PE-TRACT
Pulmonary Embolism - Thrombus Removal with Catheter-Directed Therapy


PEERLESS
RCT of FlowTriever vs. catheter-directed
thrombolytics in pulmonary embolism


STRIKE-PE STUDY

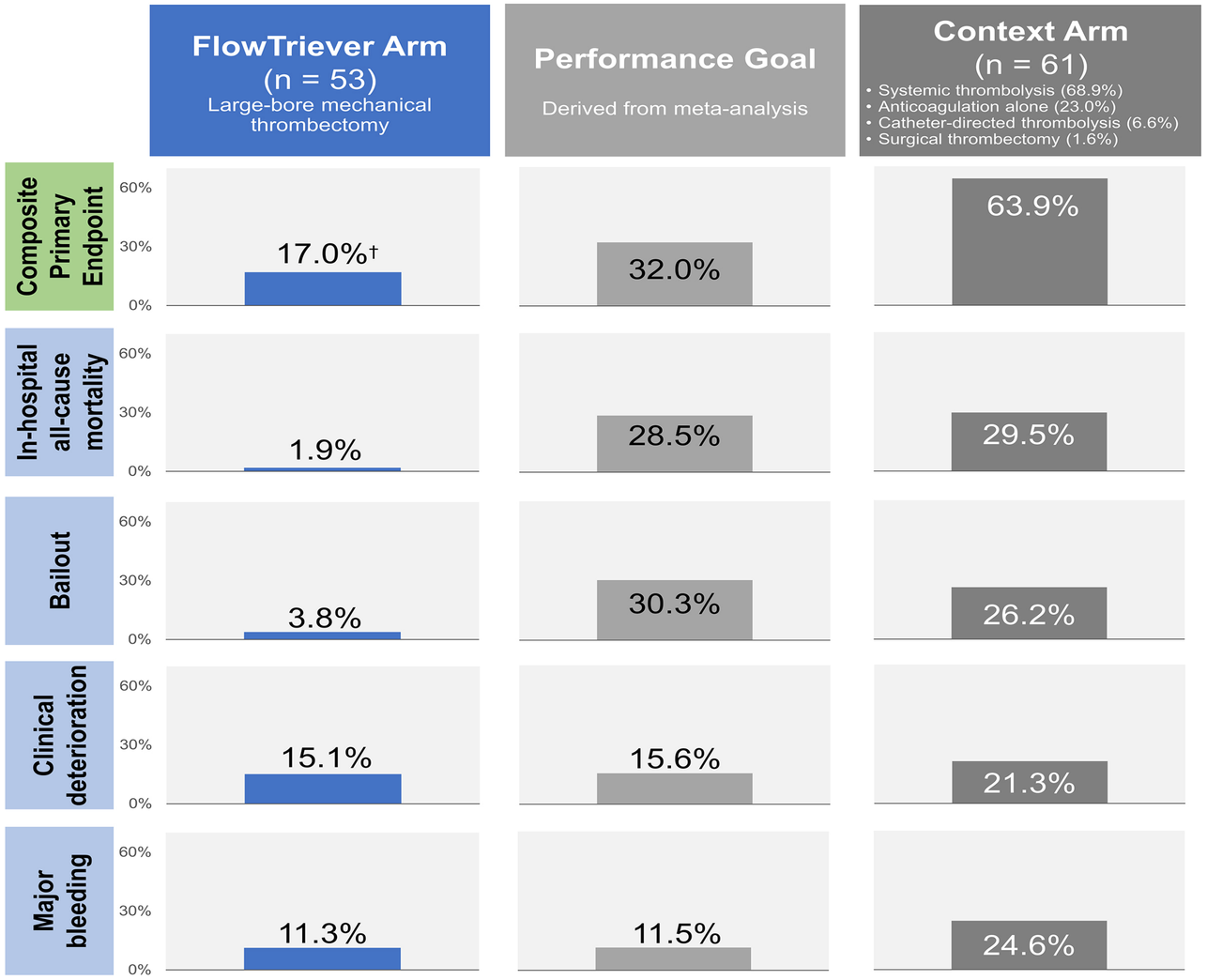

APEX-AV

HI-PEITHO	PEERLESS	PE-TRACT	STORM-PE TRIAL	PEERLESS II
RCT-1:1 EKOS VS. ANTICOAG **INTERMEDIATE HIGH**	RCT 1:1 FLOWTRIEVER VS CDT **INTERMEDIATE HIGH**	RCT 1:1 ENDOVASC VS ANTICOAG **INTERMEDIATE**	RCT 1:1 INDIGO VS ANTICOAG **INTERMEDIATE HIGH**	RCT 1:1 FLOWTRIEVER VS ANTICOAG **INTERMEDIATE**
406 SUBJECTS 65 GLOBAL SITES	550 SUBJECTS 30 SITES	500 SUBJECTS 30 NORTH AMERICAN SITES	100 SUBJECTS 20 GLOBAL SITES	1200 PATIENTS
(PE)-RELATED MORTALITY, CARDIORESPIRATORY DECOMPENSATION OR COLLAPSE, NONFATAL SYMPTOMATIC AND OBJECTIVELY CONFIRMED RECURRENCE OF PE	MORTALITY ICH ISTH MAJOR BLEEDING CLINICAL DETERIORATION ICU LOS. (DISCHARGE)	PV02 AT 90 DAYS NYHA CLASSIFICATION AT ONE YEAR ISTH MAJOR BLEED AT 7 DAYS	RV/LV RATIO AT 48 HOURS (PE)-RELATED MORTALITY, CARDIORESPIRATORY DECOMPENSATION OR COLLAPSE, NONFATAL SYMPTOMATIC AND OBJECTIVELY CONFIRMED RECURRENCE OF PE	ALL-CAUSE MORTALITY BY 30 DAYS CLINICAL DETERIORATION AND/OR BAILOUT BY 30 DAYS ALL-CAUSE HOSPITAL READMISSION BY 30 DAYS DYSPNEA SCORE AT 48-HOUR VISIT
12 MONTHS	30 DAY FOLLOW UP	12 MONTHS	90 DAY FOLLOW UP	90 DAY FOLLOW UP

Large-Bore Thrombectomy

- Large-bore thrombectomy can rapidly extract thrombus and relieve RV strain without thrombolytics
- No level 1 evidence to support either Mechanical Thrombectomy or Catheter Directed Thrombolysis for PE management
- Neither are standard of care
- Guidelines suggest considering these alternative advanced therapies when thrombolytics fail or are contraindicated, or hemodynamic deterioration occurs
- Paucity of data comparing the two modalities
  - PEERLESS is ongoing prospective trial (expect completion 2024)
  - PE-TRACT will start enrolling soon

Outcomes in High-risk Pulmonary Embolism: Results from the FLAME Study



The FlowTriever Arm and Context Arm were parallel registries designed to capture relevant information on the treatment and management of high-risk PE by care pathway. The Context Arm was not intended as a comparator to the FlowTriever Arm.

†Significantly lower than Performance Goal ($P<0.01$).

Mitchell J. Silver. Circulation: Cardiovascular Interventions. Outcomes in High-Risk Pulmonary Embolism Patients Undergoing FlowTriever Mechanical Thrombectomy or Other Contemporary Therapies: Results From the FLAME Study, Volume: 16, Issue: 10, Pages: e013406, DOI: (10.1161/CIRCINTERVENTIONS.123.013406)

FlowTriever Acute Safety Results: Reports across 5 peer-reviewed studies

In over 1,000 patients studied, the pooled rate of patients with procedural complications was <3%.

	Tu et al. [1] FLARE IDE Trial	**Toma et al.** [2] Retrospective multicenter study	**Buckley et al.** [3] Retrospective single-center study	**Toma et al.** [4] FLASH prospective registry	**Silver et al.** [5] FLAME prospective registry	**Total**
N treated with FlowTriever	104	34	28	799	53	1,007
Risk stratification	100% intermediate-risk	47% intermediate-risk, 53% high-risk	64% intermediate-risk, 36% high-risk	92% intermediate-risk, 8% high-risk	100% high-risk	N/A
Intraprocedural deaths	0%	0%	0%	0%	0%	0%
All-cause mortality (in-hospital or 48 hours)	0%	2.9% (1)	3.6% (1)	0.3% (2)	1.9% (1)	0.5% (5)
Procedural complications:	**% (n)**	**% (n)**	**% (n)**	**% (n)**	**% (n)**	**% (n)**
Intraprocedural clinical deterioration†	3.8% (4)	5.9% (2)	NR	0.3% (2)	15.1% (8)	1.6% (16)
Pulmonary vascular injury†	1.0% (1)	NR	3.6% (1)	0%	0%	0.2% (2)
Cardiac injury†	0%	NR	NR	0.1% (1)*	0%	0.1% (1)
Major vascular access site injury/complication‡	0%	NR	NR	0%	7.5% (4)	0.4% (4)
						Total: 2.3% (23)

† Related to procedure, unrelated to device (unless otherwise noted) ‡ Requiring intervention to treat NR=not reported * Adjudicated to have unknown relationship to device

FLASH Registry Data Summary

800 patients | 32% contraindicated to lytics | 85% intermediate-high or high risk | 65% Concomitant DVT

Excellent Safety Outcomes[1]

1.8%
Major adverse events at 48-hours

0
Device-related deaths

<1.0%
All-cause mortality at 30-day follow-up

Immediate Clinical Improvement[1]

-7.6 mmHg
Mean PAP decrease

-12 bpm
Heart rate decrease

+19%
Cardiac index increase*

*in patients with baseline CI<2.0 L/min/m²

Minimum Hospital Resource Utilization[1]

62.6%
No overnight ICU stay post-procedure

2.4%
Required adjunctive PE therapy

3
Hospital overnights post-procedure†

† median

Long-term 6-month Outcomes[2]

95.1%
Normal RV function

90.1%
Mild or absent dyspnea

398 m
6MWT distance†

1.0%
CTEPH

† median

1. Toma C, *et al.* Acute Outcomes for the Full US Cohort of the FLASH Mechanical Thrombectomy Registry in Pulmonary Embolism. EuroIntervention 2023;18:1201-1212.
2. Khandhar S, *et al.* Long-term Outcomes Following Mechanical Thrombectomy for Intermediate- and High-risk Pulmonary Embolism: Six-month FLASH Registry Results. JSCAI 2023; In press.

Computer Assisted Vacuum Thrombectomy

Lightning® 12 aspiration catheter with Separator™ wire

Lightning® Flash (16F)

Penumbra ENGINE® pump with Lightning aspiration tubing attached

STRIKE-PE Study Objective & Design

- Objective: Evaluate real-world long-term functional outcomes, safety, and performance of the Indigo® Aspiration System for the treatment of PE
- Up to 55 global sites
- 600 patients
- Patient-centric endpoints – functional & quality of life (QoL)
- Long-term follow-up to 1 year
- **Interim analysis of 150 patients through 90-day follow-up**

Primary & Secondary Endpoints

Primary performance endpoint*

- Change in RV/LV ratio from baseline to 48 hours post-procedure

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

- **Quality of life at 90 days**
  - Disease specific: PEmb-QoL
  - Generic: EQ-5D-5L & EQ-VAS
- Functional outcomes at 90 days
  - NYHA classification
  - 6 Minute Walk Test (6MWT)
  - Borg Scale
- 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.

Key Eligibility Criteria

- **Key inclusion criteria**
  - Clinical signs and symptoms consistent with acute PE (≤14 days)
  - Right ventricle/left ventricle (RV/LV) ratio of ≥0.9*
  - Endovascular treatment with the Indigo Aspiration System
  - Patient is ≥18 years old

- **Key exclusion criteria**
  - Contraindication to systemic or therapeutic doses of anticoagulants
  - Stage III/IV cancer or cancer requiring active chemotherapy during the study
  - Known serious, uncontrolled sensitivity to radiographic agents
  - Life expectancy of <180 days
  - Patients on ECMO

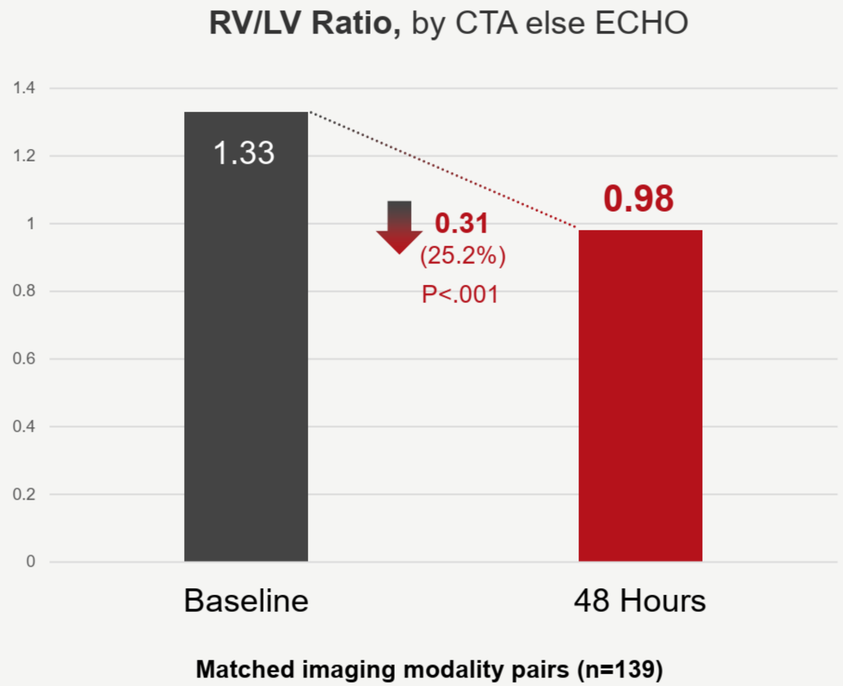
* Collected via CTPA or ECHO

Periprocedural Characteristics

Periprocedural Characteristics, median [IQR] or % (n)	**Interim analysis** (N=150)
Symptom onset to admission time, h*	**32.5** [12.0–108.0]
Symptom onset to puncture time, d	**1.1** [0.6–2.2]
Thrombectomy time, min†	**33.5** [21.0–46.0]‡
ICU length of stay after procedure, nights§	**1.0** [0.0–2.0]‖
No ICU stay required	**38.0%** (57)
Hospital length of stay after procedure, d	5.0 [4.0–7.0]

* Patients admitted before symptom onset were imputed to an admission time of 0.
† First Indigo device insertion to last Indigo device removal.
‡ N = 146.
§ Patients indicated as not admitted to the ICU have ICU length of stay imputed to 0.
‖ N = 145.

Primary Endpoints



Matched imaging modality pairs (n=139)

Primary Safety Endpoints,* % (n)	**Interim analysis** (N=150)
Major Adverse Events within 48 h (composite)	**2.7%** (4)
Major bleeding‡	**2.7%** (4)
Device-related clinical deterioration†	**1.3%** (2)
Device-related pulmonary vascular injury†	**0.7%** (1)
Device-related cardiac injury†	**0%** (0)
Device-related death†	**0%** (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.
‡ 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.

Secondary Endpoints

Secondary Endpoints,* % (n)	**Interim analysis** (N=150)
Device-related serious adverse events†	**1.3%** (2)
Any-cause mortality within 30 d	**2.0%** (3)
Recurrent PE within 30 d	**1.3%** (2)

* 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 Interim Results Conclusion

- Rapid, statistically significant improvements in RV/LV ratio and sPAP while maintaining safety

RV/LV Ratio Improvement
↓ **0.31** (25.2%)

sPAP Improvement
↓ **8.0 mm Hg** (16.7%)

Low Composite MAE Rate
2.7% (4/150)

- Treatment with CAVT improved both generic and disease-specific QOL measures

EQ-5D-5L
✓ Improvement

EQ-5D-5L Index Value
✓ Improvement

EQ VAS
✓ Improvement

PEmb-QoL
✓ Improvement

PEmb-QoL Overall
✓ Improvement

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SiVENT

Can adding sigh breaths to usual care increase vent free days?

Original Investigation | Caring for the Critically Ill Patient

ONLINE FIRST

October 25, 2023

Sigh Ventilation in Patients With Trauma

The SiVent Randomized Clinical Trial

Richard K. Albert, MD[1]; Gregory J. Jurkovich, MD[2]; John Connett, PhD[3]; et al

» Author Affiliations | Article Information

JAMA. Published online October 25, 2023. doi:10.1001/jama.2023.21739

Visual Abstract

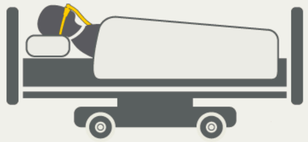
Editorial Comment

JAMA®

QUESTION Does adding sigh breaths to the usual care of trauma patients receiving mechanical ventilation increase ventilator-free days?

CONCLUSION This randomized clinical trial found that compared with usual care, sigh breaths added to usual care did not significantly increase ventilator-free days among trauma patients receiving mechanical ventilation but may improve clinical outcomes.

POPULATION



394 Men **130** Women

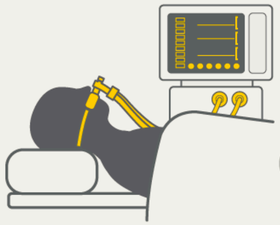
Adults receiving mechanical ventilation because of trauma

Mean age: **43.9** years

LOCATION

15
Academic trauma centers in the US

INTERVENTION



524 Patients randomized

261

Sighs + usual care
Sigh volumes producing plateau pressures of 35 cm H_2O every 6 minutes + usual care

263

Usual care
Care provided at the discretion of the treating physician

PRIMARY OUTCOME

Median ventilator-free days by day 28

FINDINGS

Median ventilator-free days by day 28

Sighs + usual care

Day 0 — **18.4 days** (IQR, 7.0-25.2) — Day 28

Ventilator-free

Usual care

Day 0 — **16.1 days** (IQR, 1.1-24.4) — Day 28

Ventilator-free

The results were not significant:

Unadjusted between-group difference, 1.9
(95% CI, 0.1 to 3.6)

Prespecified adjusted mean difference, 1.4
(95% CI, −0.2 to 3.0)

Albert RK, Jurkovich GJ, Connett J, et al. Sigh ventilation in patients with trauma: the SiVent randomized clinical trial. *JAMA*.
Published October 25, 2023. doi:10.1001/jama.2023.21739

WEAN-SAFE Observation Trial