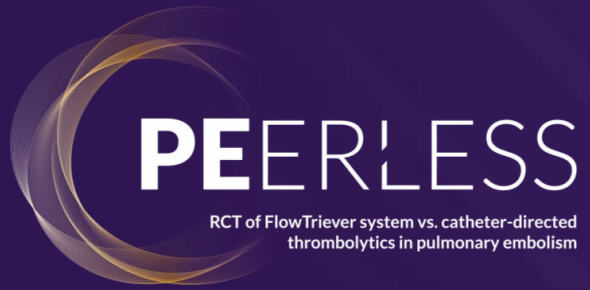


Results from the first RCT evaluating

The FlowTriever[®] System in Intermediate-risk PE

Inari Investor Event



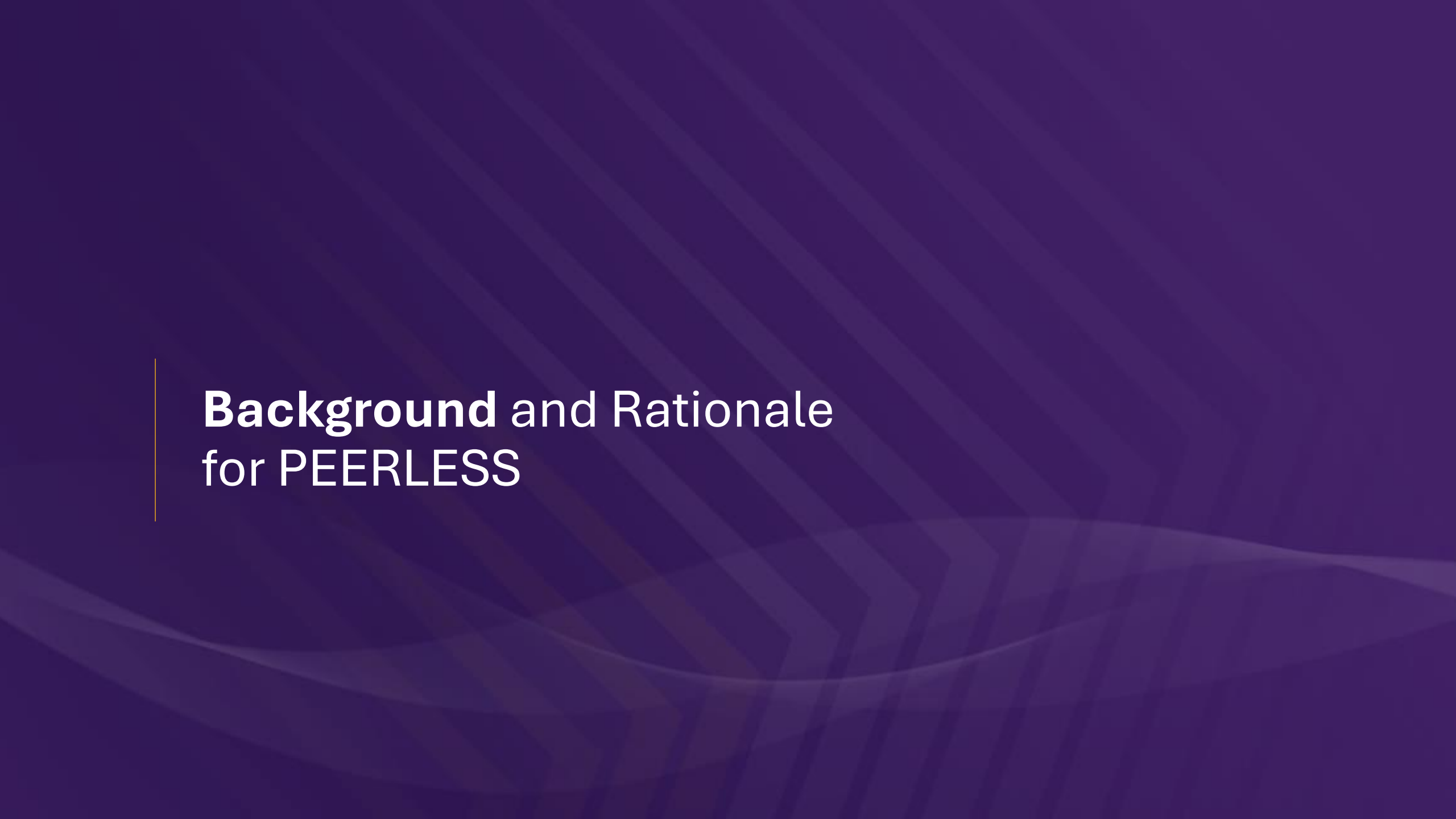
Wissam A Jaber, MD
(Global Co-Principal Investigator)

*Emory University School of
Medicine*



James Horowitz, MD
(Steering Committee)

NYU Langone Health



**Background and Rationale
for PEERLESS**

Intermediate-risk PE Patients are at Risk of Deterioration, Mortality

Treatment with anticoagulation only

1 in 3 normotensive patients in cardiogenic shock

34%

present with low cardiac index¹



Risk of decompensation and/or mortality in-hospital

5.0%

Decompensation ≤ 7 days²

1.8%

Mortality ≤ 7 days²



Persisting mortality risk post-discharge

10.7%

30-day mortality³

~50% of which occurred after discharge.

1. Bangalore, S., et al. Prevalence and Predictors of Cardiogenic Shock in Intermediate-Risk Pulmonary Embolism: Insights from the FLASH Registry. JACC: Cardiovascular Interventions. 2023;16:958-972.
2. Meyer et al., Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism, New England Journal of Medicine (2014), doi: 10.1056/NEJMoa1302097
3. Secemsky et al., Contemporary Management and Outcomes of Patients with Massive and Submassive Pulmonary Embolism, The American Journal of Medicine (2018), doi: <https://doi.org/10.1016/j.amjmed.2018.07.035>

Time to Effect for Thrombolytics vs. FlowTrier

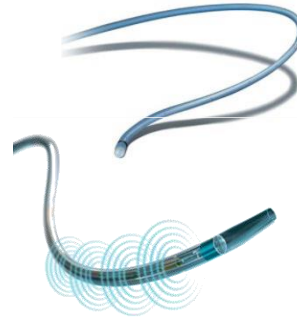
Quantitative angiography of systemic thrombolysis in PE shows that:

80%

Of clot remains after 2 hours of thrombolysis^{1,2}

50%

Of clot remains after 6 hours of thrombolysis¹



Catheter-directed thrombolitics (CDT) requires a drip of lytics over time. **Infusion times typically range from 12-24 hours.**³



Thrombectomy with FlowTrier acts on clot quickly, aiming to **offload the right heart and allow for fast recovery.**

1. Goldhaber et al., Acute pulmonary embolism treated with tissue plasminogen activator. The Lancet (1986), doi: 10.1016/s0140-6736(86)90411-3

2. Goldhaber et al., Recombinant tissue-type plasminogen activator versus a novel dosing regimen of urokinase in acute pulmonary embolism: a randomized controlled multicenter trial. JACC (1992), doi: 10.1016/0735-1097(92)90132-7

3. Chiarello, Sista. Catheter-Directed Thrombolysis for Submassive Pulmonary Embolism. Semin Intervent Radiol 2018; 35(02): 122-128

What's Unique About FlowTriever Thrombectomy?



Large Bore, Rapid Aspiration

Significantly faster flow rates vs. small/medium-bore catheters.¹



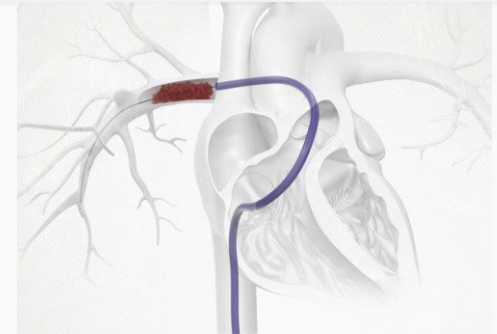
FlowSaver® Blood Return System

Minimized blood loss to maximize clot removal.



Advanced Trackability

4th gen flexibility, trackable, always over-the-wire.



Effectiveness – unloading right ventricle (RV) quickly, completely, in single session.

Safety – preventing adverse events and the known negative impact of blood loss.

1. Experimental data on file. The aspiration flow rate of Triever catheters is more powerful than a continuous aspiration catheter with 8' tubing under continuous pump-based aspiration. Triever 24 = 178 cc/s; Triever 20 = 112 cc/s; Triever 16 = 68 cc/s;

PEERLESS is the First RCT Evaluating FlowTrier, and the First Major PE RCT in ~10 years



2014

PEITHO Trial¹

Tenecteplase plus heparin for intermediate-risk PE reduced risk of death or decompensation but at the expense of increased major bleeding.

2024

PEERLESS Trial

FlowTrier superior to CDT in intermediate-risk PE (primary endpoint win ratio).

FUTURE

PEERLESS II Trial

FlowTrier vs. anticoagulation in intermediate-risk PE.

PERSEVERE Trial

FlowTrier vs. standard of care in high-risk PE.

1. G Meyer et al. N Engl J Med. 2014.

PEERLESS Trial Results

Presented at TCT 2024 by Dr. Wissam Jaber (Co-PI)

PEERLESS Trial Design

RCT: FlowTrier vs. catheter-directed thrombolytics (CDT) in pulmonary embolism (PE)



550 PATIENTS RANDOMIZED 1:1

Intermediate-risk acute PE, low contraindication to lytics (low risk of bleeding).

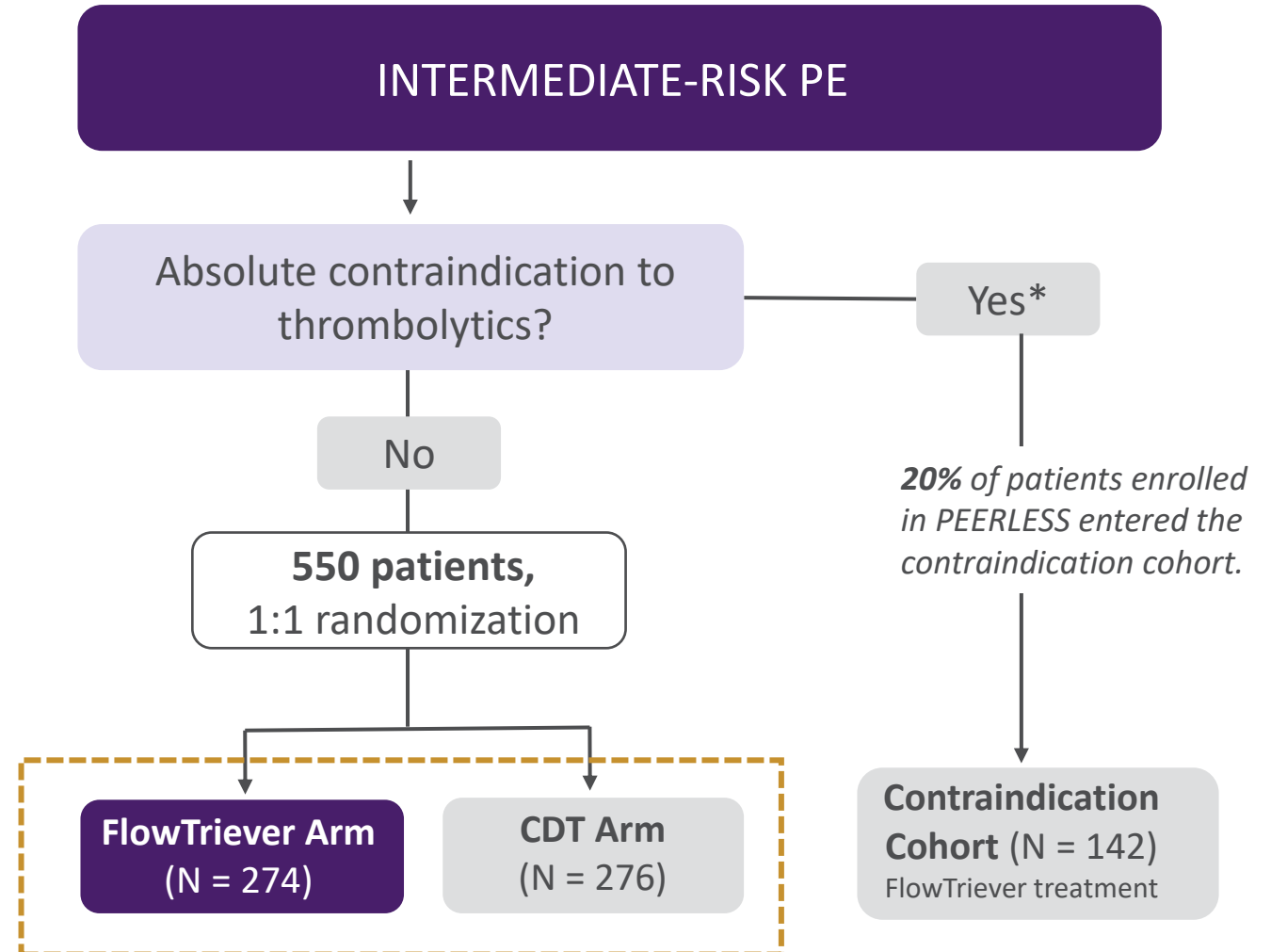
PRIMARY ENDPOINT

Win Ratio composite at discharge (7d max):

1. All-cause mortality
2. Intracranial hemorrhage
3. Major bleeding (ISTH)
4. Clinical deterioration and/or bailout
5. ICU admission and ICU length of stay (LOS)

FOLLOW UP

Through 30 days



*Patients deemed contraindicated by intervening physician based on appropriate local/hospital guidelines

Well-matched population at lower bleeding risk

International population with only 4% relative contraindications to lytics (vs. 32% in FLASH)



Enrollment:

57 sites in the USA,
Germany, and
Switzerland
February 2022 to
February 2024



% of patients with contraindications to lytics	
PEERLESS Trial	~4%
<i>FLASH Registry</i> ¹	32%

In PEERLESS, all absolute contraindications (and most relative contraindications) were enrolled in separate contraindication cohort with FlowTrievers.

Baseline Characteristics	CDT N = 276	FlowTrievers N = 274
Age, years	61.2 ± 14.8	63.7 ± 13.0
Female sex	134 (48.6)	125 (45.6)
Race and ethnicity		
White	193 (74.5)	184 (72.4)
Black or African American	56 (21.6)	67 (26.4)
Other	10 (3.9)	3 (1.2)
Hispanic or Latino	27 (10.8)	13 (5.2)
Relative contraindication to lytics	11 (4.0)	12 (4.4)
VTE-BLEED score ≥ 2	77 (27.9)	68 (24.8)
BMI, kg/m ²	36.6 ± 9.4	34.5 ± 8.6
Active cancer	17 (6.2)	13 (4.7)
Concomitant DVT	168 (60.9)	178 (65.0)
Saddle PE	109 (39.5)	104 (38.0)
Elevated cardiac troponin	265 (96.0)	256 (93.4)
RV/LV ratio (CTPA or echo)	1.31 ± 0.27	1.27 ± 0.26
Mean PA pressure, mmHg	31.1 ± 7.2	30.0 ± 7.6

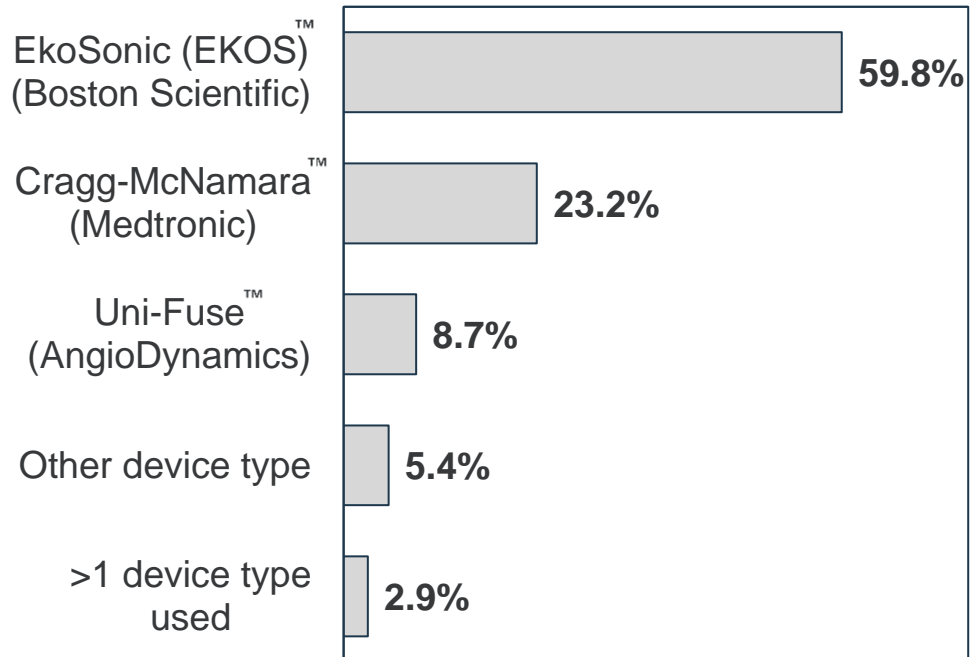
1. Toma, C., et al. EuroIntervention.2023; 18:1201-1212

Device and Procedure Information

CDT dosing consistent with clinical practice



CDT treatment



	CDT N = 276	FlowTrier N = 274
Device time, minutes	915.7 ± 464.7	47.9 ± 27.2
Estimated blood loss, mL	14.4 ± 22.2	87.7 ± 87.6
Estimated residual thrombus, %	29.6 ± 29.3	16.2 ± 15.7

Values reported as mean ± SD.
 Device time (Treatment catheter time): N=269 CDT, N=272 FlowTrier.
 Estimated blood loss: N=228 CDT, N=245 FlowTrier.
 Estimated residual thrombus: N=95 CDT, N=242 FlowTrier.

tPA infusion rate per lung, mg/hour	1.0 [0.5, 1.0]
tPA infusion duration per lung, hours	12.0 [6.0, 15.6]
Total tPA dose per patient, mg	16.0 [12.0, 24.0]

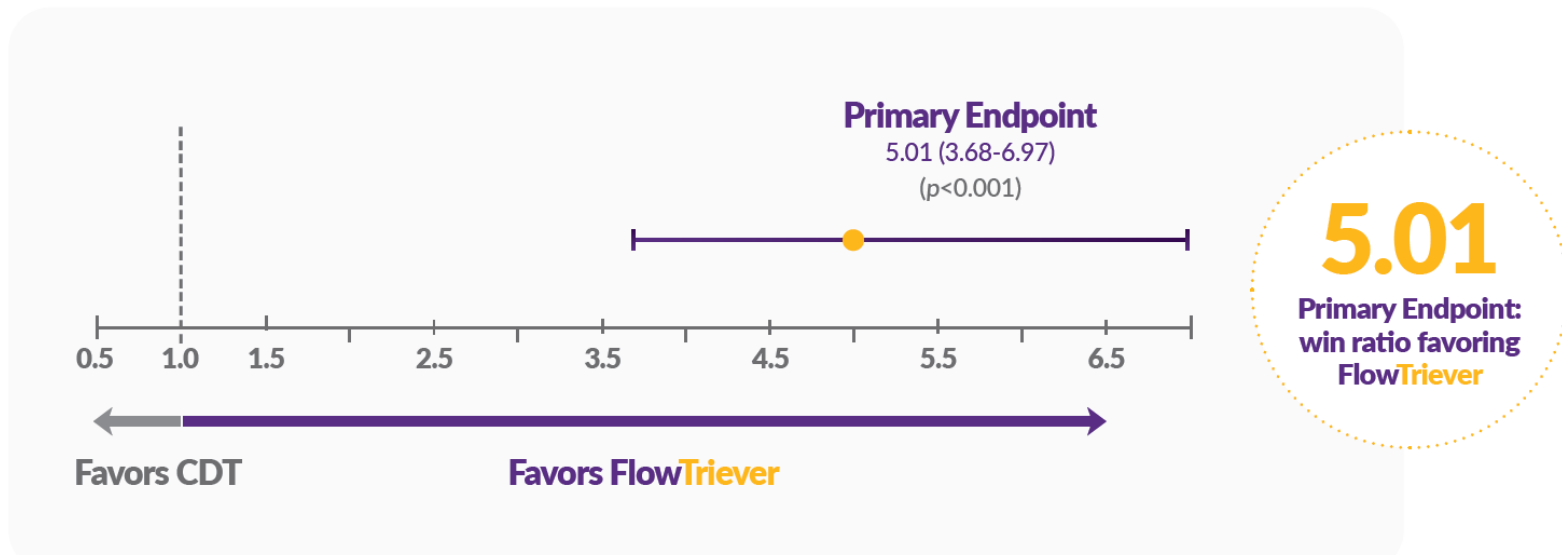
Values reported as median [IQR].
 tPA infusion rate and duration per lung: N=242.
 Total tPA dose: N=261.

Results: Clear Superiority Win for FlowTrievers

5X more wins with FlowTrievers vs. CDT on primary endpoint of 5 clinically relevant components



The primary advantage of a win ratio approach is the ability to rank the outcomes included in the composite by clinical importance and assess them in a hierarchical manner.



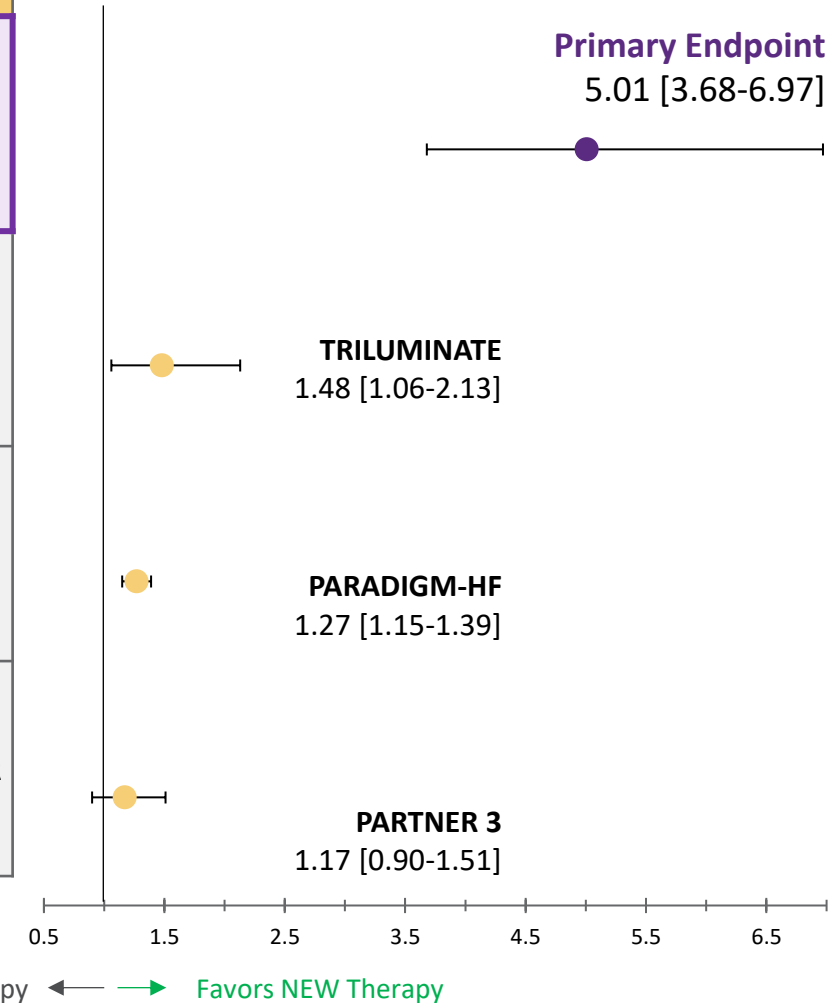
	Win ratio [95% CI]	P value
Primary Endpoint: 5-component win ratio*	5.01 [3.68 – 6.97]	<0.001
*Primary endpoint components: 1) all-cause mortality, 2) intracranial hemorrhage, 3) major bleeding, 4) clinical deterioration and/or escalation to a bailout therapy, and 5) ICU admission and length of stay.		

Two-sided P value calculated using a modified generalized Wilcoxon test (F-S test) proposed by Finkelstein & Schoenfeld.

A win ratio of 5.01 represents 5.01 times more wins for FlowTrievers than CDT when every patient in each study arm is compared across the study's 5 components in hierarchical order: 1. all-cause mortality; 2. intracranial hemorrhage (ICH); 3. major bleeding; 4. clinical deterioration and/or escalation to bailout; and 5. ICU admission and ICU length-of-stay (LOS). The win ratio primary endpoint was assessed through discharge or 7 days post-procedure, whichever occurred first.

Win Ratio is Well-established in Major Cardiovascular Trials

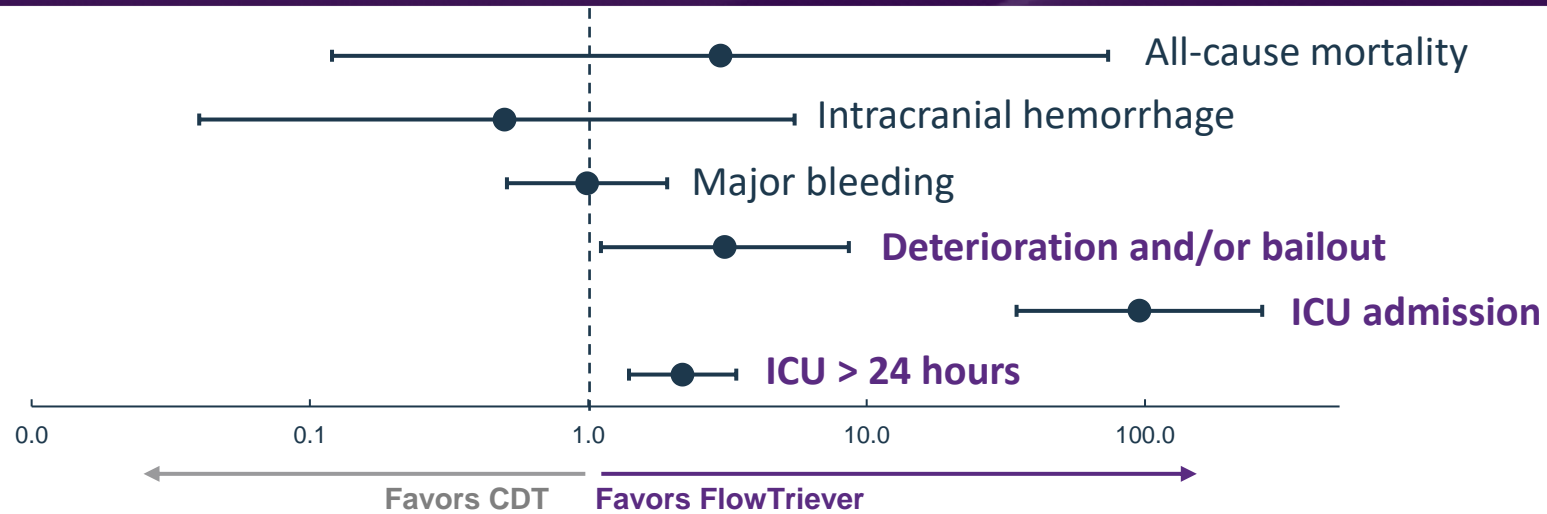
Trial	Population	Intervention	Win Ratio Components	Results/Impact
PEERLESS (2024)	Intermediate-risk PE	LBMT vs CDT	<ul style="list-style-type: none"> • Death • ICH • Major bleeding • Clinical Deterioration/Bailout • ICU admission and LOS 	Informs endovascular treatment selection for PE patients.
TRILUMINATE¹ (2023)	Symptomatic severe TV regurgitation	TEER vs Medical therapy	<ul style="list-style-type: none"> • Death or TV surgery • HF hospitalization • KCCQ 	TEER was safe, effective in reducing TR severity, and was associated with an improvement in QoL.
PARADIGM-HF^{2,3} (2014/2020)	HFrEF	Sacubitril/valsartan vs Enalapril	<ul style="list-style-type: none"> • CV death • First HF hospitalization 	Established superiority of sacubitril/valsartan to ACE inhibitors, leading to its FDA approval.
PARTNER 3^{4,5} (2019/2023)	Low-risk severe aortic stenosis	TAVR vs SAVR	<ul style="list-style-type: none"> • Death • Disabling stroke • Nondisabling stroke • Rehospitalization days 	At 1 year, TAVR was superior in reducing death, stroke, or rehospitalization. At 5 years, TAVR demonstrated similar outcomes to surgery.



1. P Sorajja et al. N Engl J Med. 2023
2. JJV McMurray et al. N Engl J Med. 2014
3. JP Ferreira et al. J Am Coll Cardiol HF. 2020
4. MJ Mack et al. N Engl J Med. 2019
5. MJ Mack et al. N Engl J Med. 2023

FlowTrieve Superiority Driven by Hard Clinical Outcomes and ICU Utilization

Components of primary endpoint win ratio:



Components of Primary Endpoint:	CDT	FlowTrieve	Odds ratio [95% CI]	P value
All-cause mortality	1 (0.4)	0 (0.0)	2.99 [0.12–73.70]	1.00
Intracranial hemorrhage	1 (0.4)	2 (0.7)	0.50 [0.04–5.51]	0.62
Major bleeding	19 (6.9)	19 (6.9)	0.99 [0.51–1.92]	1.00
Clinical deterioration and/or escalation to bailout therapy	15 (5.4)	5 (1.8)	3.09 [1.11–8.63]	0.038
Postprocedural ICU admission	272 (98.6)	114 (41.6)	95.4 [34.6–263.6]	< 0.001
ICU stay > 24 hours*	178 (65.4)	53 (46.5)	2.18 [1.40–3.40]	< 0.001

Values reported as n (%) or OR [95% CI]. P values calculated using two-sided Fisher's exact test. *Percentages reported out of patients with post-procedure ICU admission.

FlowTriever Had 3X Fewer Deteriorations/Bailouts

Deteriorations were also more severe in the CDT arm



	CDT N = 276	FlowTriever N = 274	P value
Clinical deterioration and/or escalation to bailout	15 (5.4)	5 (1.8)	0.038
Patients with clinical deterioration	10 (3.6)	4 (1.5)	
Cardiac arrest	2 (0.7)	0 (0.0)	
High-grade atrioventricular block	1 (0.4)	0 (0.0)	
Respiratory failure	3 (1.1)	0 (0.0)	
Increased oxygen requirement	0 (0.0)	1 (0.4)	
Hypotension	4 (1.4)	3 (1.1)	
Patients with escalation to bailout*	6 (2.2)	1 (0.4)	
Successful bailout [†]	5 (1.8)	0 (0.0)	
Unsuccessful bailout [‡]	1 (0.4)	1 (0.4)	

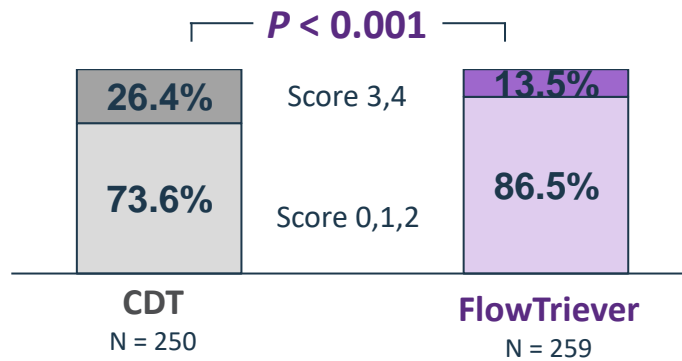
Values reported as n (%). P value calculated using two-sided Fisher's exact test. *Bailout: N=275 CDT. †5 CDT patients underwent FlowTriever bailout procedure without adverse event, experienced postprocedural improvement, and were discharged without further intervention. ‡1 patient in each arm had a PE that could not be treated after multiple bailout attempts (systemic tPA, FlowTriever, CDT) and ultimately died after >7 days.

FlowTriever Patients Recovered Faster

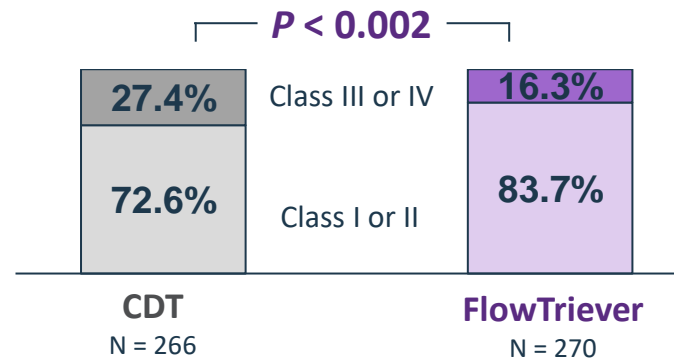
Greater improvement of clinical symptoms and hemodynamics at 24 hours



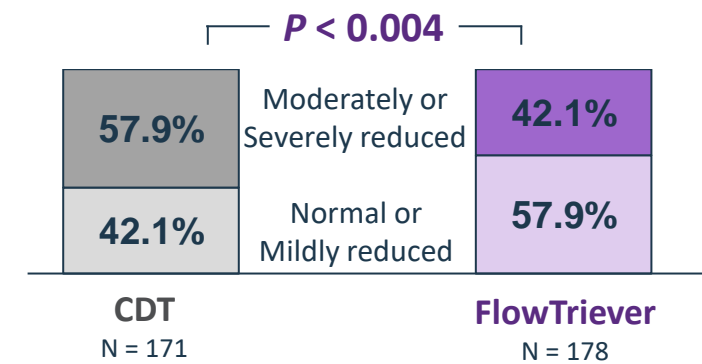
mMRC dyspnea score



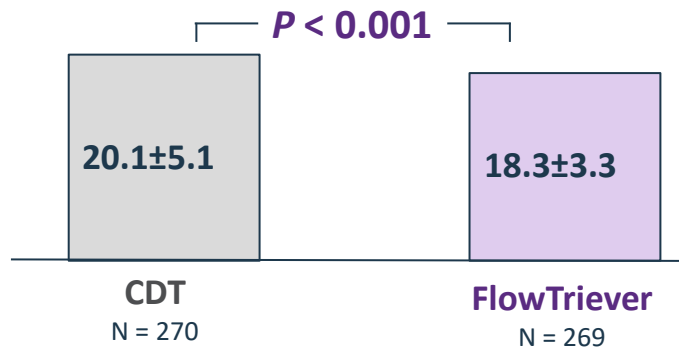
NYHA classification



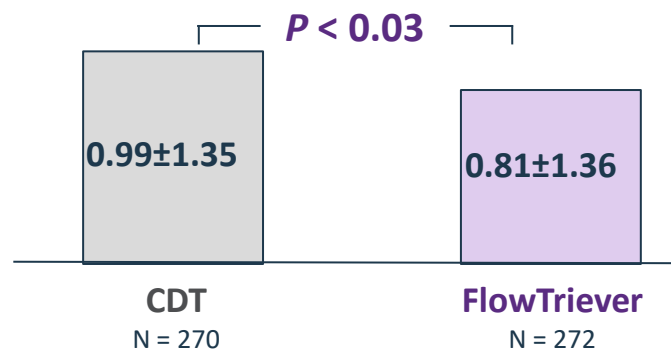
RV function (echo)



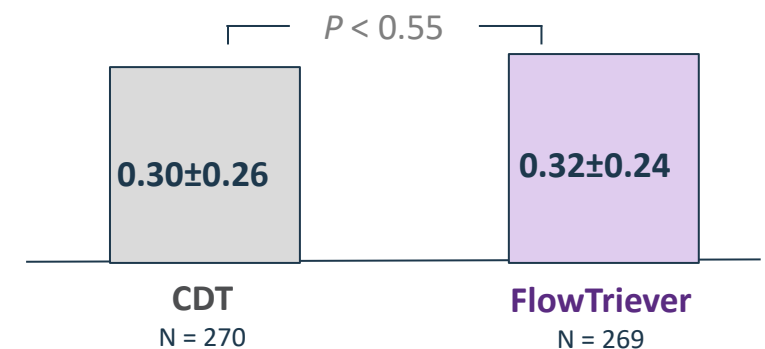
Respiratory rate



Modified Borg dyspnea score at rest



Reduction in RV/LV ratio from baseline



Bleeding Events Similar in This Lower Bleed Risk Population

FlowTrier major bleeding triggered mostly by Hgb drop, & FT required fewer transfusions ≥ 2 units



	CDT N = 276	FlowTrier N = 274	P value
Major bleeding (ISTH)	19 (6.9)	19 (6.9)	1.00
Adjudicated reasons for major bleeding			
• Fatal bleeding*	1 (0.4)	0 (0)	
• Symptomatic bleeding in a critical area or organ	2 (0.7)	2 (0.7)	
Intracranial hemorrhage [†]	1	2	
Hemarthrosis	1	0	
• Hgb drop ≥ 2 g/dL (1.24 mmol/L) and/or transfusion ≥ 2 units	16 (5.8)	17 (6.2)	
Access site source	10	8	
Transfusions administered with ≥ 2 units	8	1	
# units transfused	3.3 \pm 1.8	2.0	
CRNM bleeding events[‡]	9 (3.3)	7 (2.6)	0.80
Minor bleeding events[‡]	1 (0.4)	6 (2.2)	0.07

Values reported as n (%) or mean \pm SD. P values calculated using two-sided Fisher's exact test. *CDT fatal bleeding involved thrombolytic- and anticoagulation-related intra-abdominal hematomas leading to hemorrhagic shock and death on postprocedural Day 5. [†]CDT ICH involved thrombolytic- and anticoagulation-related cerebral hemorrhage on Day 1 (n=1); FlowTrier ICH involved anticoagulation-related cerebral hemorrhage on Day 1 in a patient who had a fall with minor head trauma prior to treatment (n=1) and anticoagulation-related ischemic stroke with hemorrhagic conversion on Day 2 (n=1). [‡]N=275 CDT.

FT Patients Went Home Faster w/ Fewer Readmissions

Shorter ICU stay, hospital stay, and fewer 30-day readmissions



FlowTriever Results (vs. CDT)	~ 60% Fewer ICU admissions	~ 1 DAY Shorter total hospital stay	~ 60% Fewer all-cause readmissions
--------------------------------------	-----------------------------------	--	---

	CDT N = 276	FlowTriever N = 274	P value
Total hospital LOS, days	5.3 ± 3.9	4.5 ± 2.8	0.002
Post procedure LOS, days	4.0 ± 3.7	3.2 ± 2.7	< 0.001
Post procedure ICU admission	272 (98.6)	114 (41.6)	< 0.001
stay ≤ 24 hours	94 (34.1)	61 (22.3)	< 0.001
stay > 24 hours	178 (64.5)	53 (19.3)	
Post procedure ICU LOS, hours	39.3 ± 28.0	14.2 ± 25.4	< 0.001
30-day all-cause readmission[†]	19 (7.9)	8 (3.2)	0.03
30-day PE-related readmission[†]	2 (0.8)	0 (0.0)	0.237

Values reported as n (%) or mean ± SD. [†]30-day readmission: N=239 CDT, N=251 LBMT. Total and postprocedure hospital stay reported through 30 days. Postprocedure ICU stay reported through discharge / 7 days. P values calculated using two-sided Fisher's exact test or two-sided Wilcoxon rank sum test with continuity correction.

Excellent Acute Safety and 30-Day Mortality

PEERLESS RCT reaffirms safety results seen in previous prospective FlowTrievers studies^{1,2}



FlowTrievers Outcomes*:

0

Deteriorations related to cardiac arrest, arrhythmia, or respiratory failure

6 with CDT

0

Deaths at discharge or 7 days

1 with CDT

0.4%

All-cause mortality within 30-days

0.8% with CDT (p=0.62)

<90 mL estimated blood loss (EBL)

*30-day outcomes were similar between the two groups, except for all-cause readmissions which favored FlowTrievers

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. Silver et al. Outcomes in High-Risk Pulmonary Embolism Patients Undergoing FlowTrievers Mechanical Thrombectomy or Other Contemporary Therapies: Results From the FLAME Study. *Circulation: Cardiovascular Interventions*. 2023 Oct.

In an acute, intermediate-risk PE population where 96% had no contraindications to lytics, **PEERLESS met its primary endpoint***, demonstrating superiority of FlowTrievers vs. CDT.

FlowTrievers patients also experienced:

- ✓ **Less clinical deterioration or escalation of therapy**
- ✓ **Faster clinical and hemodynamic improvement at 24 hours**
- ✓ **Less ICU admission/stay and shorter hospital length of stay**
- ✓ **Fewer readmissions through 30 days**
- ✓ **Excellent safety and low 30-day mortality, validating previous studies^{1,2}**

*Primary endpoint win ratio of 5 components: 1) all-cause mortality, 2) intracranial hemorrhage, 3) major bleeding, 4) clinical deterioration and/or escalation to a bailout therapy, and 5) ICU admission and length of stay.

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. Silver et al. Outcomes in High-Risk Pulmonary Embolism Patients Undergoing FlowTrievers Mechanical Thrombectomy or Other Contemporary Therapies: Results From the FLAME Study. *Circulation: Cardiovascular Interventions*. 2023 Oct.

Circulation

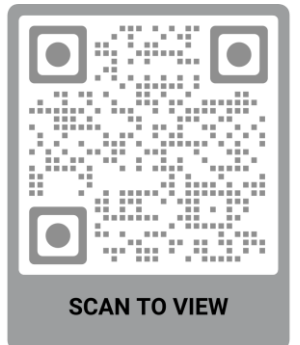
CIRCULATION. 2024; [published online ahead of print] DOI: 10.1161/CIRCULATIONAHA.124.072364

Large-bore Mechanical Thrombectomy versus Catheter-directed Thrombolysis in the Management of Intermediate-risk Pulmonary Embolism: Primary Results of the PEERLESS Randomized Controlled Trial

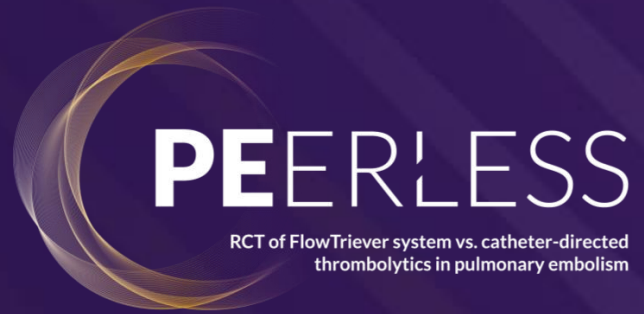
Wissam A. Jaber, MD; Carin F. Gonsalves, MD; Stefan Stortecky, MD; MPH; Samuel Horr, MD; Orestis Pappas, MD; Ripal T. Gandhi, MD; Keith Pereira, MD; Jay Giri, MD, MPH; Sameer J. Khandhar, MD; Khawaja Afzal Ammar, MD, MS; David M. Lasorda, DO; Brian Stegman, MD; Lucas Busch, MD; David J. Dexter II, MD; Ezana M. Azene, MD, PhD; Nikhil Daga, MD; Fakhir Elmasri, MD; Chandra R. Kunavarapu, MD; Mark E. Rea, MD; Joseph S. Rossi, MD, MSCI; Joseph Campbell, MD; Jonathan Lindquist, MD; Adam Raskin, MD; Jason C. Smith, MD; Thomas M. Tamlyn, MD; Gabriel A. Hernandez, MD; Parth Rali, MD; Torrey R. Schmidt, DO; Jeffrey T. Bruckel, MD, MPH; Juan C. Camacho, MD; Jun Li, MD; Samy Selim, MD; Catalin Toma, MD; Sukhdeep Singh Basra, MD, MPH; Brian A. Bergmark, MD; Bhavraj Khalsa, MD, MBA; David M. Zlotnick, MD; Jordan Castle, MD; David J. O'Connor, MD and C. Michael Gibson, MS, MD for the PEERLESS Committees and Investigators

Circulation

<https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.124.072364>



SCAN TO VIEW



Thank you
Open for Q&A

Study Administration



Role	Individual	Affiliation
Global Principal Investigators	Carin F. Gonsalves, MD Wissam A. Jaber, MD	Thomas Jefferson University Hospital Emory University Hospital
European Principal Investigator	Stefan Stortecky, MD, MPH	Bern University Hospital
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Independent Image Review	Peter M. Farrugia, MD	Monmouth Medical Center
Independent Data Validation	Xiaohua Chen	BAIM Institute for Clinical Research

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L. Busch, Universitätsklinikum Düsseldorf	J. Kerrigan, Ascension St. Thomas West	N. Daga, Huntington Memorial Hospital
K. Fengler, Herzzentrum Leipzig GmbH	G. Hoots, Tampa General / USF	K. Natarajan, Ascension St. Vincent Hospital
S. Stortecky, Inselspital – Bern	D. Dexter, Sentara Norfolk	E. Redstone, St. Luke's University Medical Center
J. Camacho [J. Lee], Sarasota Memorial Hospital	R. Gandhi, Baptist Health South Florida	J. Bruckel, University of Rochester
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W. Jaber, Emory University	T. Todoran, MUSC	B. Bergmark, Mass General Brigham
R. Leonardi, Lexington Medical Center	J. Castle, Providence Sacred Heart	O. Pappas, Saint Vincent Hospital AHN
M. Rea, Summa Health	M. Bunte, Saint Luke's Health System Kansas City	C. Bavare, Houston Methodist
A. Raskin, Mercy Health – West	S. Horr, HCA TriStar	P. Rali, Temple Health
D. Zlotnick, Gates Vascular Institute	B. Stegman, CentraCare St. Cloud	C. Toma, UPMC Presbyterian
A. Kaki, Ascension St. John Hospital	P. Gandotra [S. Selim], Northwell Health	J. Campbell, OhioHealth Riverside Methodist
C. Gonsalves, Jefferson Health	J. Li, University Hospitals	K. Ammar [R. Tumuluri], Aurora St. Luke's Medical Center
S. Khandhar and J. Giri, University of Pennsylvania	S. Sethi, Columbia University / NYP	T. Schmidt [A. Vora], UPMC Harrisburg
E. Azene, Gundersen Health	W. Dixon, Tallahassee Memorial Hospital	D. Lasorda, Allegheny General Hospital
K. Pereira, St. Louis University SSM	B. Khalsa, Providence St. Joseph Hospital	S. Yallapragada, HCA Medical City Heart and Spine
B. Carroll, Beth Israel Deaconess	J. Smith, Loma Linda University	L. Tabaza, Virtua Health
S. Basra, Memorial Hermann	D. Rothschild, Norton Healthcare	L. Lewis, Novant New Hanover Medical Center
F. Elmasri, Radiology Imaging Specialists	D. O'Connor, Hackensack University Medical Center	P. Fong, Vanderbilt University Medical Center
J. Rossi, University of North Carolina	A. Pop, Ascension Alexian Brothers	C. Kunavarapu, HCA Methodist Main

Inclusion

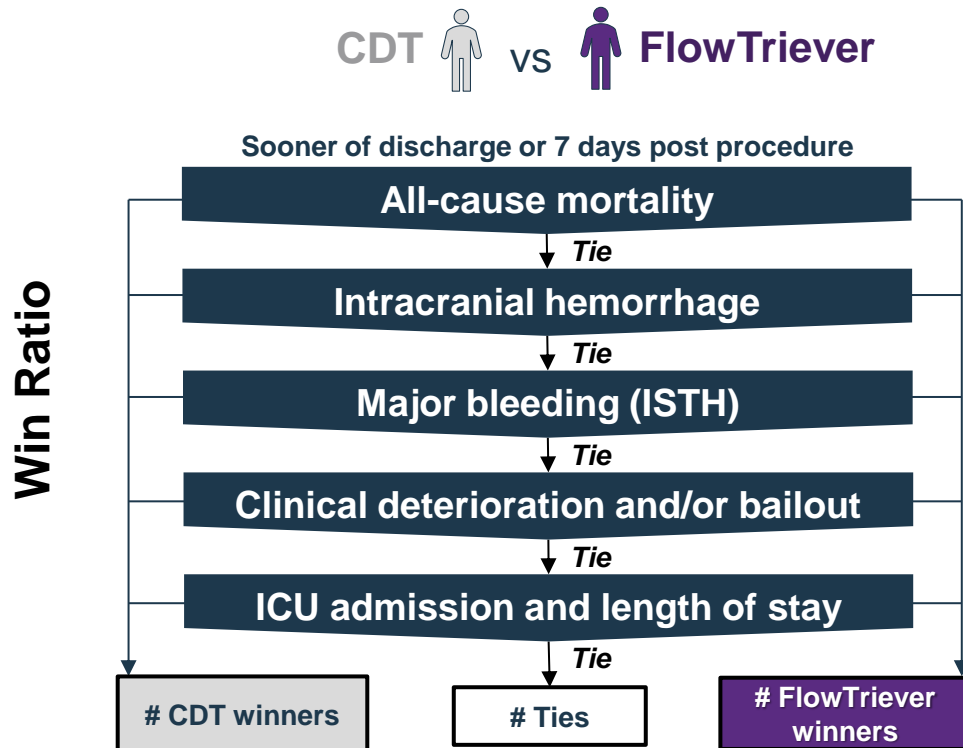
- SBP > 90 mmHg + central clot + RV dysfunction
- Symptom onset within 14 days
- Intervention planned within 72 hours
- + ≥ 1 additional clinical risk factor
 - Elevated cardiac troponin
 - History of heart failure
 - History of chronic lung disease
 - Heart rate ≥ 110 bpm
 - SBP < 100 mmHg
 - RR ≥ 30 breaths per min
 - Oxygen saturation < 90%
 - Syncope related to PE
 - Elevated lactate

Exclusion

- Unable to receive AC
- Right heart clot in transit
- Life expectancy < 30 days
- CTEPH/CTED
- sPAP ≥ 70 mmHg on invasive hemodynamics

Primary

Secondary



Win ratio components assessed individually Win ratio of first 4 components of primary endpoint Clinically relevant non-major and minor bleeding	Discharge (or 7 days)
Change in RV/LV ratio from baseline Dyspnea score (mMRC and Borg*) RV function* (echo) Respiratory rate* NYHA classification*	24h visit
All-cause mortality All-cause and PE-related readmissions Hospital length of stay Dyspnea score (mMRC and Borg*) PEmb-QOL and EQ-5D-5L NYHA classification* Device- or drug-related SAEs	30 days or 30d visit

All safety endpoints were adjudicated by an independent CEC

* exploratory

Outcomes at 30 Days

Both arms had low mortality and similar outcomes at 30 days



	CDT N = 276	FlowTrier N = 274	P value
All-cause mortality within 30 days	2/240 (0.8)	1/251 (0.4)	0.62
Patients with SAE through 30d visit			
Device- and/or drug-related SAE	28/244 (11.5)	34/256 (13.3)	0.59
Drug-related SAE	28/244 (11.5)	31/254 (12.2)	0.89



FlowTrier:
0.4%
All-cause
mortality
30-days

mMRC dyspnea score 3 / 4
10.2% CDT | 7.4% FlowTrier
P = 0.47*

NYHA class III / IV
9.2% CDT | 6.6% FlowTrier
P = 0.45*

PEmb-QOL Score
20.4±20.0 CDT | 19.3±18.9 FlowTrier
P = 0.64

**P* value testing full distribution.

Bleeding in Patients with Contraindication to Thrombolytics

PE patients with at least 1 contraindication to thrombolytics are **5X more likely** to experience a major bleed¹

Bleeding rates are often lower in studies with exclusions for contraindications:



1.5% ICH²

9.2% major bleed²

N=1,061

Meta-analysis of studies with
contraindication exclusions



1.9% ICH³

8.7-15.9% major bleed³

In-hospital, N=1,915

Real-world studies without
contraindication exclusions

3.0% ICH⁴

21.7% major bleed⁴

In-hospital, N=304

¹Curtis et al., Risk factors associated with bleeding after alteplase administration for pulmonary embolism: a case control study, *Pharmacotherapy* (2014), doi: 10.1002/phar.1440

²Chatterjee et al., Thrombolysis for pulmonary embolism and risk of all-cause mortality, major bleeding, and intracranial hemorrhage, *JAMA* (2014), doi: 10.1001/jama.2014.5990

³Geller et al., Outcomes of catheter-directed versus systemic thrombolysis for the treatment of pulmonary embolism: A real-world analysis of national administrative claims, *Vascular Medicine* (2020), doi: 10.1177/1358863X20903371

⁴Goldhaber et al., Acute pulmonary embolism: clinical outcomes in the international cooperative pulmonary embolism registry (ICOPER), *The Lancet* (1999), doi: 10.1016/S0140-6736(98)07534-5

Evidence Supporting the FlowTrier System

Largest PE Thrombectomy Registries



FLASH Registry^{1,2}
N=800 Real-world Registry
Intermediate-Risk and High-risk PE

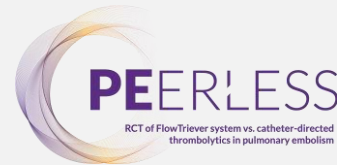
- 1.8% major adverse events (MAEs) at 48 hours
- 0.8% all-cause mortality at 30-day visit
- 95% normal RV function at 6-month visit
- 1% intraprocedural MAEs in patients with severe pulmonary hypertension (N=99)



FLAME Study³
N=115 High-risk PE

- 1.9% all-cause mortality in 53 high-risk patients treated with FlowTrier

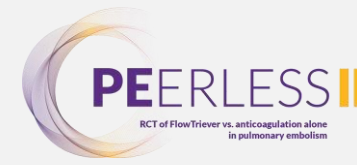
3 Industry-leading Randomized Controlled Trials



PEERLESS RCT⁴
N=550 Intermediate-risk PE

FlowTrier vs. Catheter-directed thrombolysis (CDT)

- FlowTrier superior to CDT on primary 5-component win ratio
- FlowTrier had less clinical deterioration or escalation
- FlowTrier had faster recovery, less ICU use, shorter hospital length of stay, and fewer readmissions through 30 days



PEERLESS II RCT⁵
N=1,200 Intermediate-risk PE

FlowTrier vs. anticoagulation



PERSEVERE RCT
N=200 High-risk PE

FlowTrier vs. standard-of-care

1. Khandhar et al. JSCAI. 2023 May.

2. Toma, C., et al. EuroIntervention.2023; 18:1201-1212

3. Silver et al. Cardiovascular Interventions. 2023 Oct.

4. PEERLESS results presented at TCT 2024 by Dr. Wissam Jaber

5. Giri et al. Journal of the Society for Cardiovascular Angiography & Interventions (2024): 101982.

Limitations of Fibrinolytic Therapy



Pulmonary Emboli

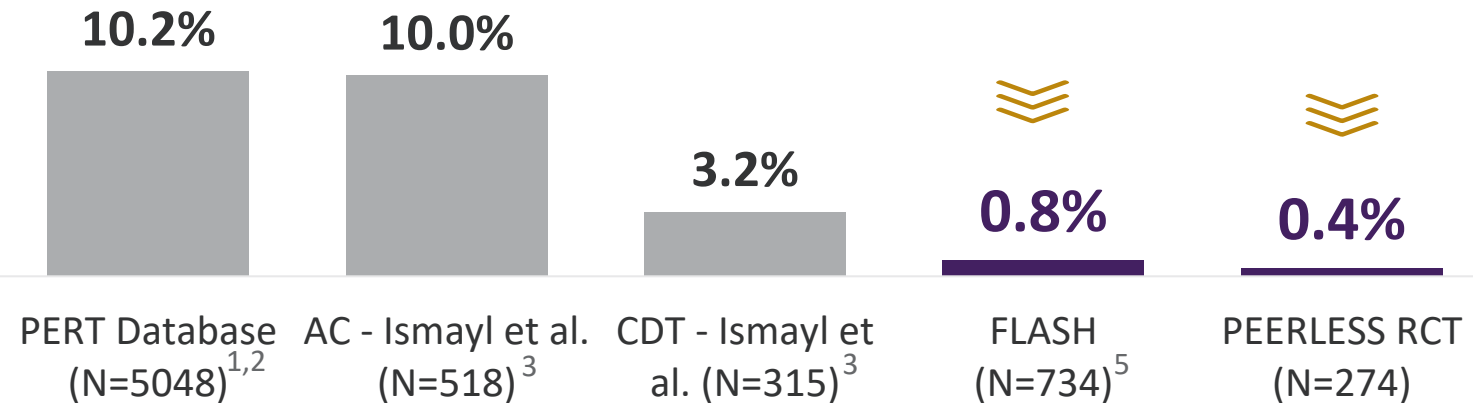
STEMI Emboli

- Thrombus aspirated from a patient with PE and another patient with STEMI on the same day
Images courtesy of Dr. Sripal Bangalore

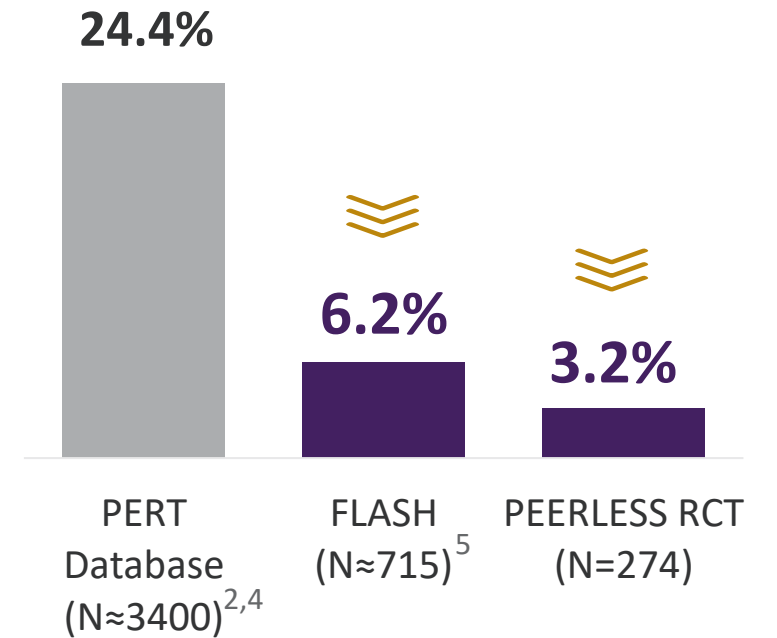
PEERLESS in Context of Historical Studies

**Historical data is provided for reference only as these studies are not directly comparable.*

30-day All Cause Mortality



30-day Readmission (All Cause)



1. PERT Consortium Quality Database. October 2021 (Presented by Secemsky E)
2. Darki A & Jaber WA. Endovascular Today. July 2022 Supplement (PERT Updates)

3. Ismayl M, et al. Am J Cardiol. 2022 (Catheter-directed thrombolysis meta-analysis)
4. PERT Consortium Quality Database. October 2020 (Presented by Lookstein R)
5. Toma C, et al. EuroIntervention 2023;18:1201-1212.

Indications for use (IFU)

The FlowTrieve Retrieval/Aspiration System is indicated for: (1) The non-surgical removal of emboli and thrombi from blood vessels, and (2) The injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The FlowTrieve Retrieval/Aspiration System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. Trieve Catheters are intended for use in treating clot in transit in the right atrium, but not in conjunction with FlowTrieve Catheters. The FlowSaver blood return system is used with Inari Medical catheters and sheaths for autologous blood transfusion.

Caution: Federal (USA) law restricts these devices to sale distribution and use by or on order of a physician.

See Instructions for Use for complete indications for use, contraindications, warnings, and precautions.

For all non-Inari products, please refer to manufacturer Instructions for Use/Intended Purpose for complete indications for use, contraindications, warnings and precautions.

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