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# Embolie pulmonaire aiguë grave

Nicolas Meneveau CHU Besançon

# Déclarations de liens d'intérêts

**Speaker:** Nicolas Meneveau

I have the following potential conflicts of interest to declare:

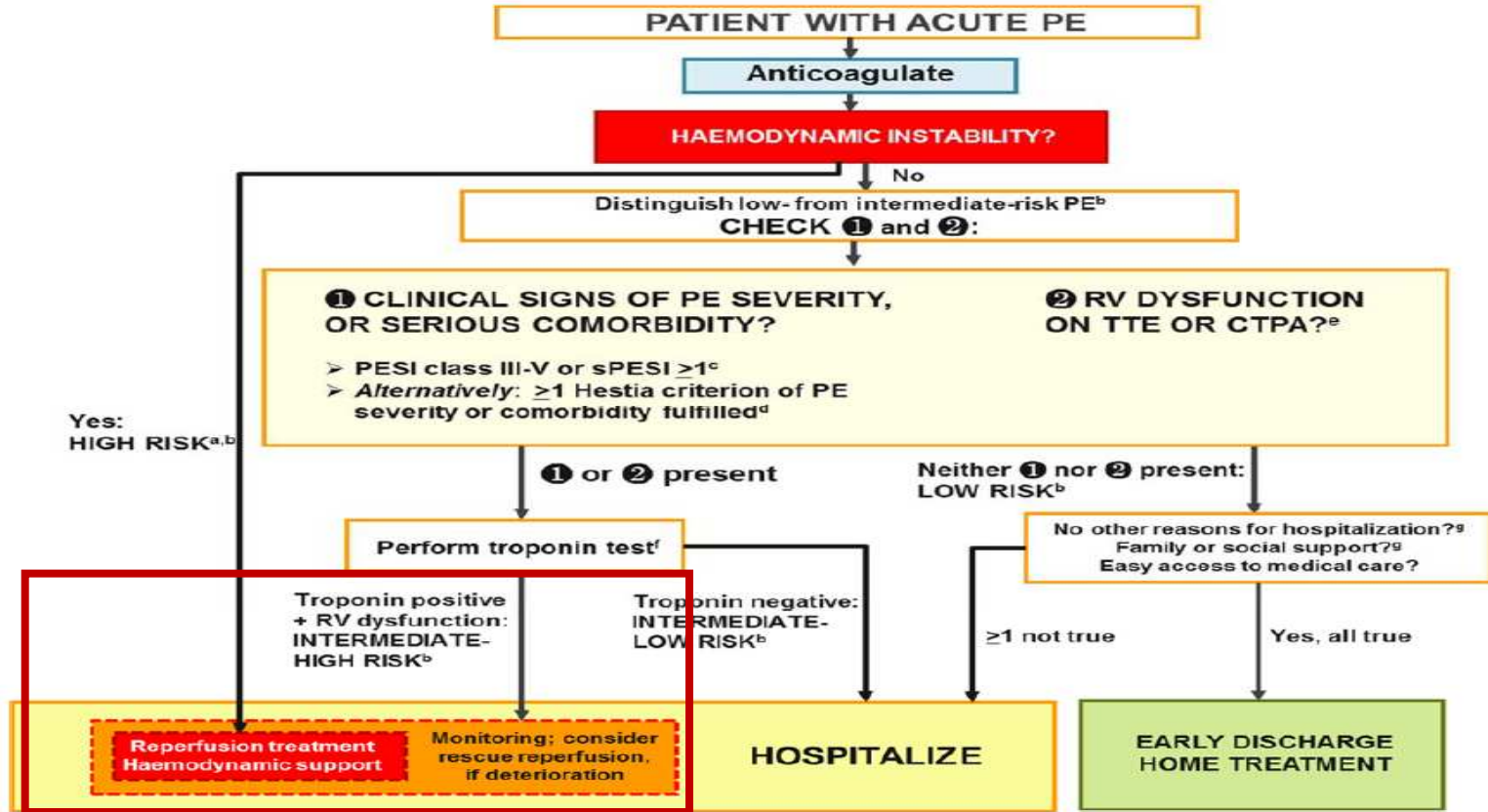
**Consultant:**

Abbott, Alliance BMS/Pfizer, Edwards Lifesciences,  
Sanofi Regeneron, Terumo

**Honoraria:**

AstraZeneca, Servier

# Risk-adjusted management strategy for acute PE

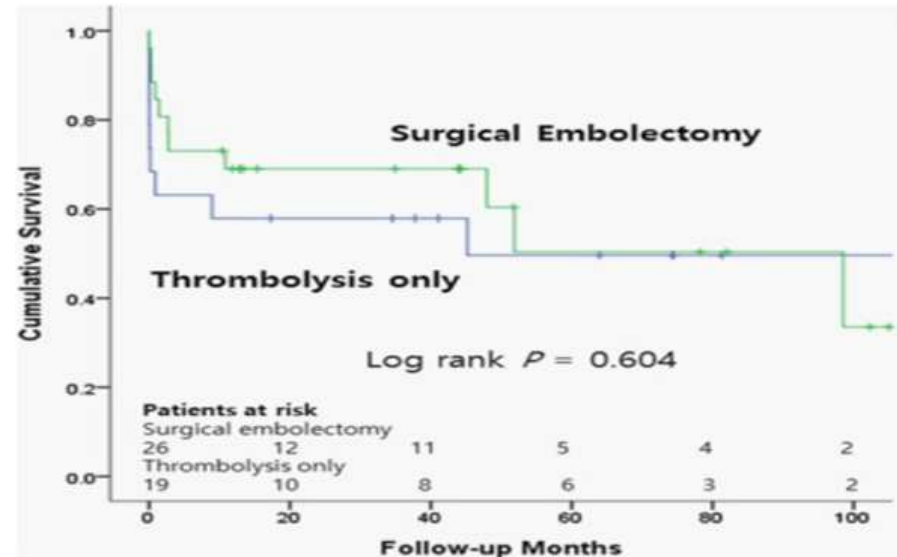
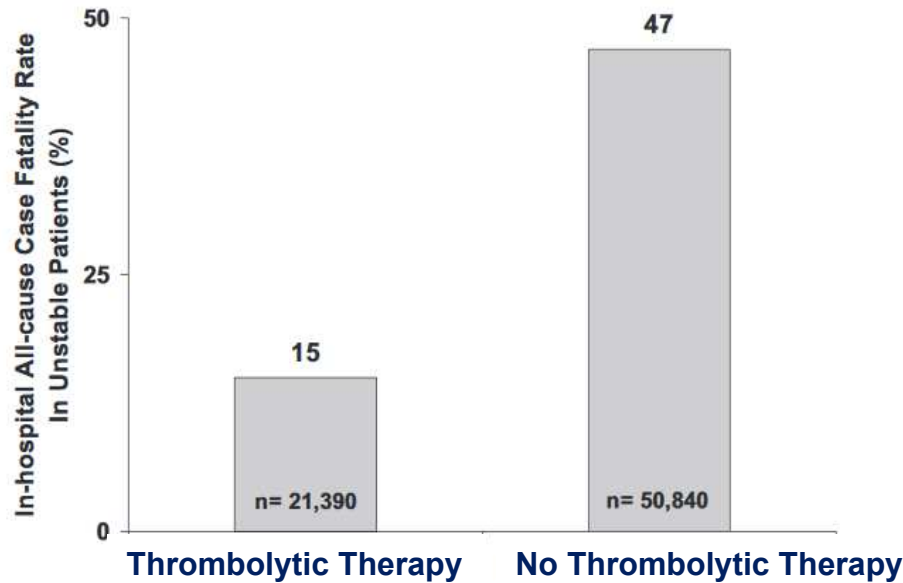


# IV thrombolytic therapy in high-risk PE : Saves lives but underused

All cause mortality rate in unstable pts in USA  
from 1999 to 2008 :

- 2/3 of pts eligible for lysis do not receive the TTT

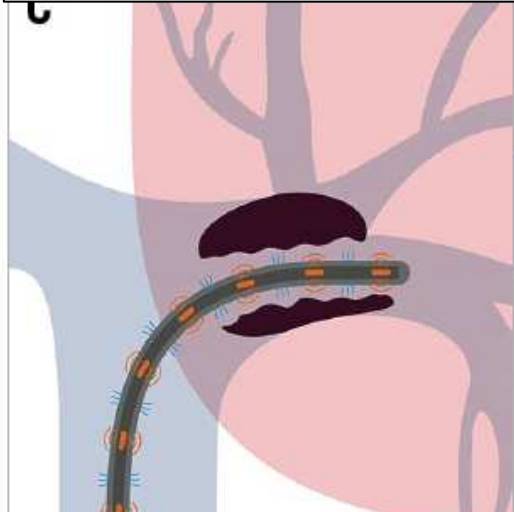
Poor preoperative state & comorbidities make  
most pts poor candidates for surgery



Substantial proportion of high-risk PE pts undertreated

# Catheter-directed thrombolysis

Local delivery of low doses of thrombolytics



**Potential drawbacks :**  
bleedings,  
delayed effectiveness

Uni\*Fuse<sup>®</sup>  
Pulse\*Spray<sup>®</sup>



Side holes for intra-thrombus drug delivery

EkoSonic<sup>®</sup>



Infusion Catheter :  
Multi-sidehole drug  
delivery catheter

Ultrasonic Core :  
MicroSonic Device  
containing high-frequency  
& low-energy US  
transducers\*

# USAT for high & intermediate-high risk PE : the SEATTLE II prospective study



- 150 pts with acute high-risk (n=31) or intermediate-risk (n=119) PE

## CT-confirmed PE

- Symptoms  $\leq 14$  days AND
- High/intermediate-risk PE
- RV/LV diameter  $\geq 0.9$

## USAT low-dose fibrinolysis

- tPA 1 mg/h for 24 h (1 device)
- OR
- tPA 1 mg/h for 12h (2 devices)
- TOTAL tPA dose = 24 mg

## Outcomes

- 29 % decrease in CT-measured RV/LV diameter over 48h
- 30% decrease in sPA pressure by the end of the procedure
- 30% decrease in PA obstruction over 48h
- Major bleeding rate = 10%
- No intracranial hemorrhage

- **OPTALYSE PE trial** : shorter delivery duration (2 – 6h) and lower-dose tPA (1–2 mg/lung/h) was also associated with improved RV function & reduced clot burden

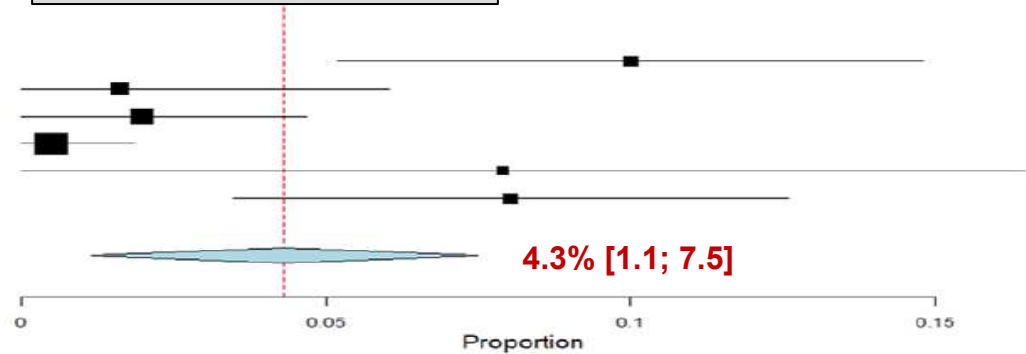
# Safety of USAT

## Studies

- Piazza G. SEATTLE [35] 2015
- Kucher N. ULTIMA [4] 2013
- Tapson VF. OPTALYSE-PE [36] 2018
- Kuo WT. PERFECT Registry [69] 2015
- Ozcinar et al. [76] 2017
- Bloomer TL et al. [77] 2017

Overall ( $I^2=79.03\%$ ,  $P<0.001$ )

### USAT & major bleeding

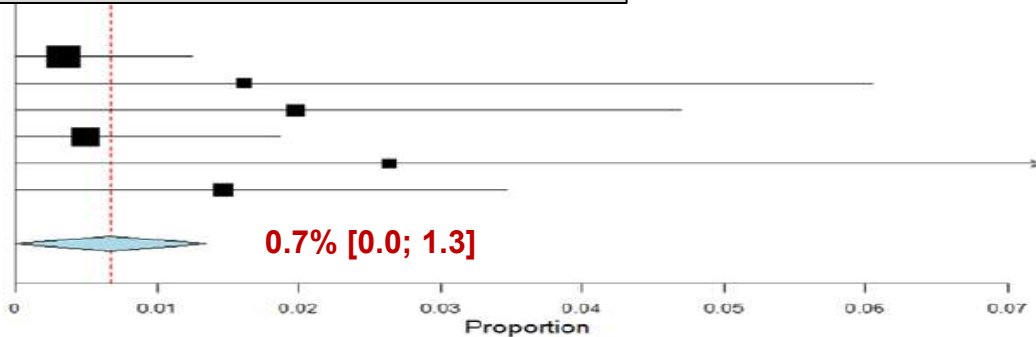


## Studies

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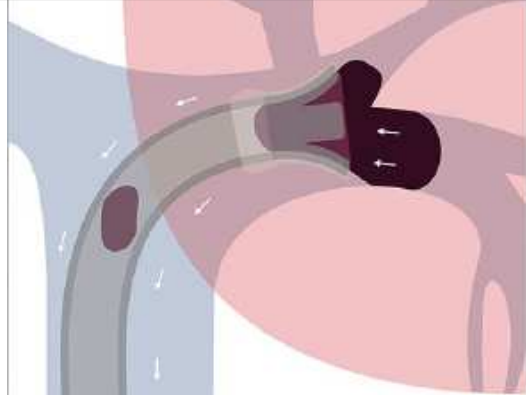
Overall ( $I^2=0\%$ ,  $P=0.728$ )

### USAT & intracranial haemorrhage



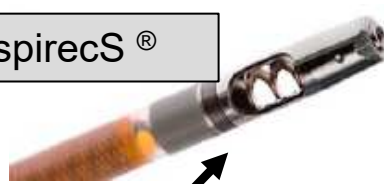
# Aspiration thrombectomy

Decrease thrombus burden without distal embolization



- Large-volume blood loss ?  
- Early stages of development

AspirecS<sup>®</sup>



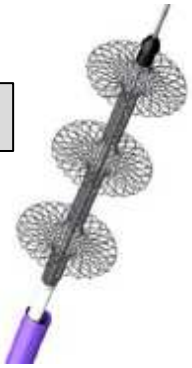
AngioVac<sup>®</sup>



Indigo<sup>®</sup>



FlowTrievers<sup>®</sup>



Greenfield<sup>®</sup>



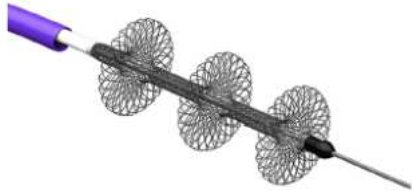
# Catheter-directed mechanical thrombectomy for intermediate-risk PE

## The FLARE Study

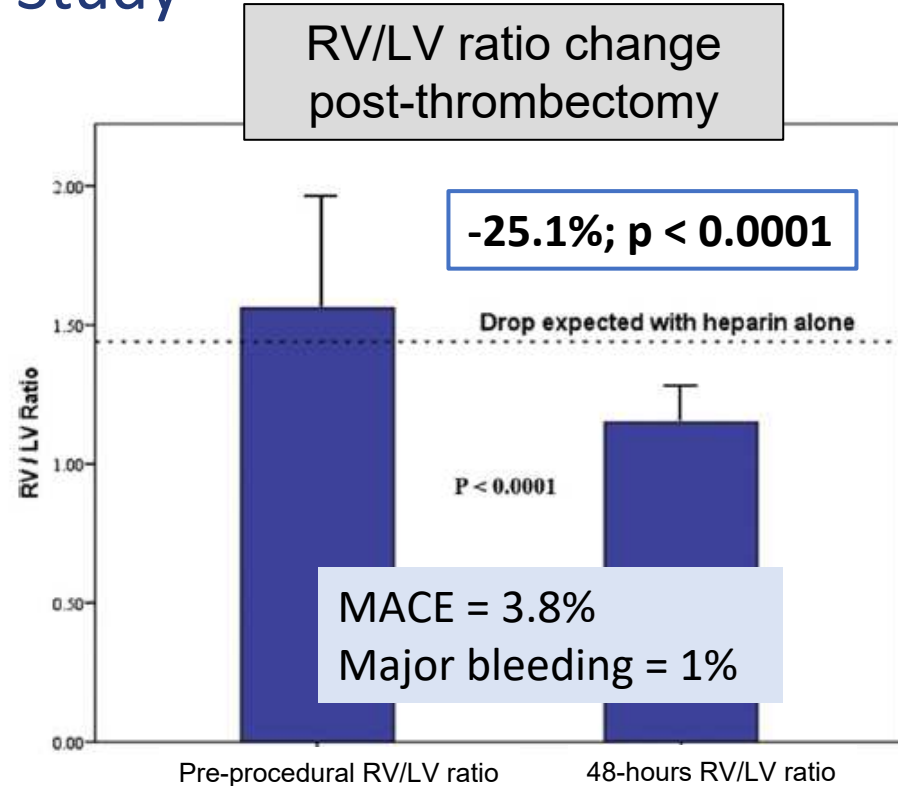
FlowTrievers<sup>®</sup>

Inari Medical, Irvine CA.

A FlowTrievers Catheter (4 sizes : 6-10 to 19-25 mm)



B Triever Aspiration Catheter (16 – 24 Fr)



# Longer-Term Outcomes Following Mechanical Thrombectomy for Intermediate- and High-Risk Pulmonary Embolism: 6-Month FLASH Registry Results

FLASH

Khandhar S, et al. *JSCAI*. 2023 May. Doi: [10.1016/j.jscai.2023.101000](https://doi.org/10.1016/j.jscai.2023.101000)

**Purpose:** Report patient outcomes 6 months after treatment with the FlowTrier® System for pulmonary embolism

## Study Overview

Type	Prospective, all-comer, multi-center registry
Population	Intermediate- and high-risk pulmonary embolism (PE)
Intervention	The FlowTrier System
Sample size	N=799 (full US cohort), 75% completed study

## Methods

- Functional outcomes measured using the 6-minute walk test, Pulmonary Embolism Quality of Life (PEmb-QoL) questionnaire, & modified Medical Research Council dyspnea score
- Echocardiographic measurements of RV size and function at baseline, 48 hours, 30 days, and 6 months
- CTED and CTEPH assessments at 6 months

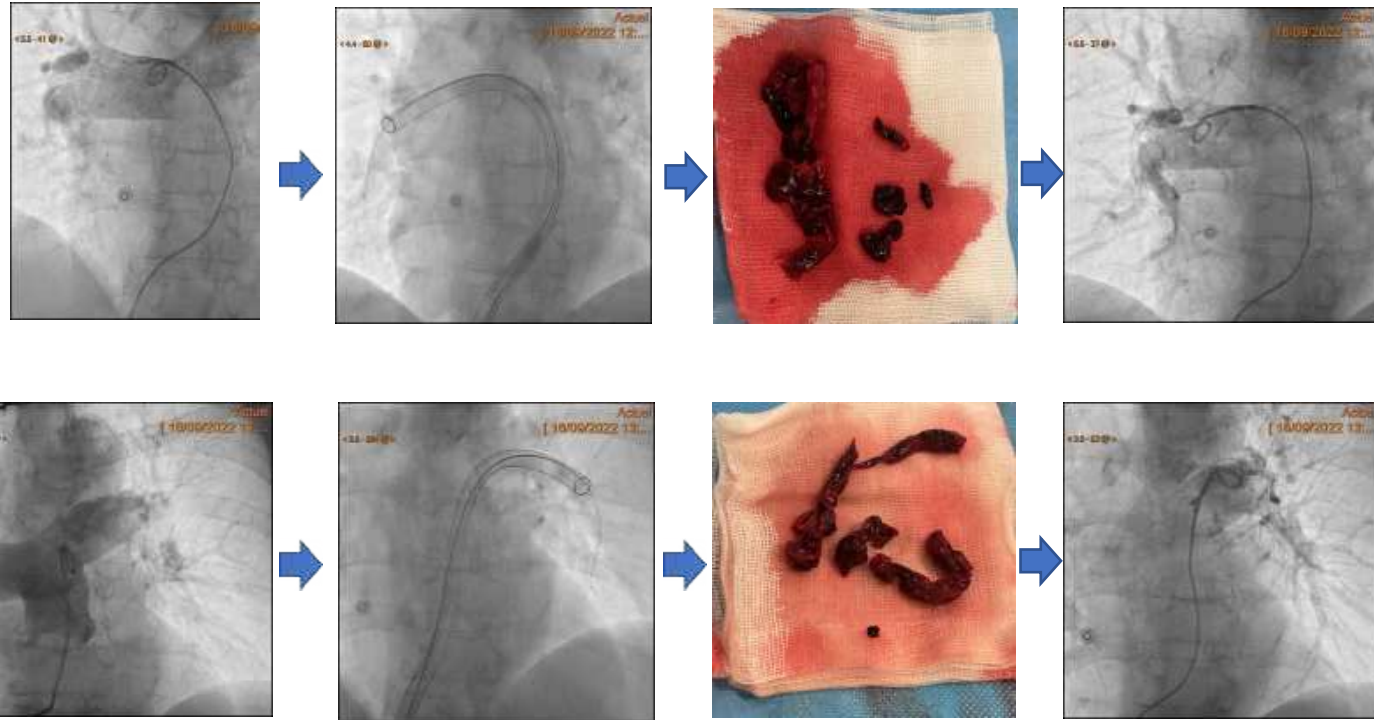
## Results

Patients with normal RV function	6-minute walk test distance	
<b>15.1%</b> → <b>95.1%</b>	<b>180 m</b> → <b>398 m</b>	
at baseline      at 6 months	at 48hrs      at 6 months	
Median PEmb-QoL scores	Median dyspnea scores	
<b>9.38</b> → <b>4.85</b>	<b>3.0</b> → <b>0.0</b>	
at baseline      at 6 months	at baseline      at 6 months	
<b>4.6%</b>	<b>1.9%</b>	<b>1.0%</b>
All-cause mortality	CTED	CTEPH
at 6 months	at 6 months	at 6 months

CTED: chronic thromboembolic disease; CTEPH: chronic thromboembolic pulmonary hypertension

**Conclusion:** Six months after treatment with the FlowTrier System for pulmonary embolism, there were low rates of all-cause mortality, CTED, and CTEPH, and significant improvements were seen in patients' quality of life and functional outcomes

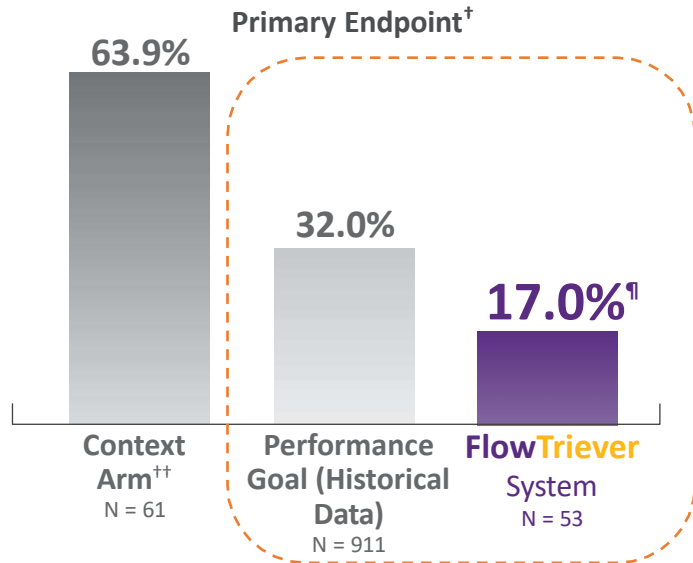
# Clinical Case



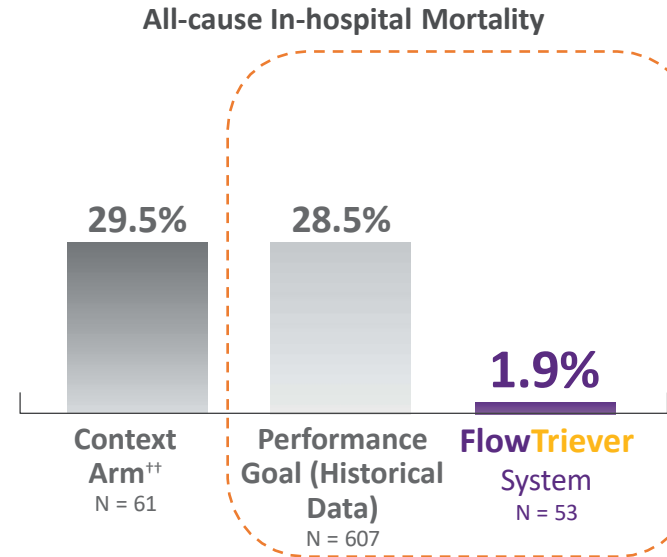
# Catheter-directed mechanical thrombectomy for high-risk PE

Results from FLAME: The largest prospective study of interventional treatment in high-risk PE

## SIGNIFICANTLY LOWER IN-HOSPITAL ADVERSE OUTCOMES



## LOW MORTALITY IN HIGH-RISK PE



# Catheter-directed mechanical thrombectomy for intermediate-risk PE

## The EXTRACT-PE Study

Indigo aspiration system  
(Penumbra, Inc, Alameda, CA)

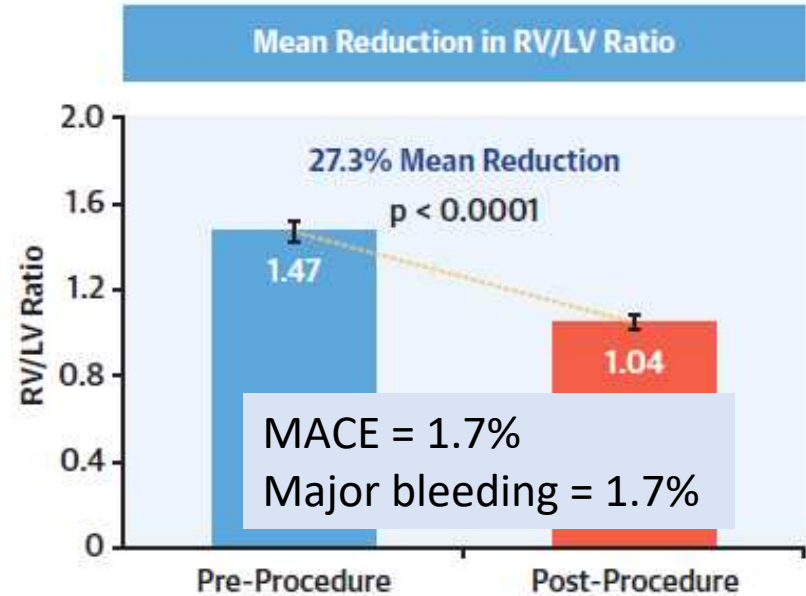


Indigo aspiration catheter  
(8 Fr)



Indigo aspiration pump  
(- 28.5 mmHg)

RV/LV ratio change post-thrombectomy



# Advantages & potential limitations of catheter-based PE interventions

## Advantages

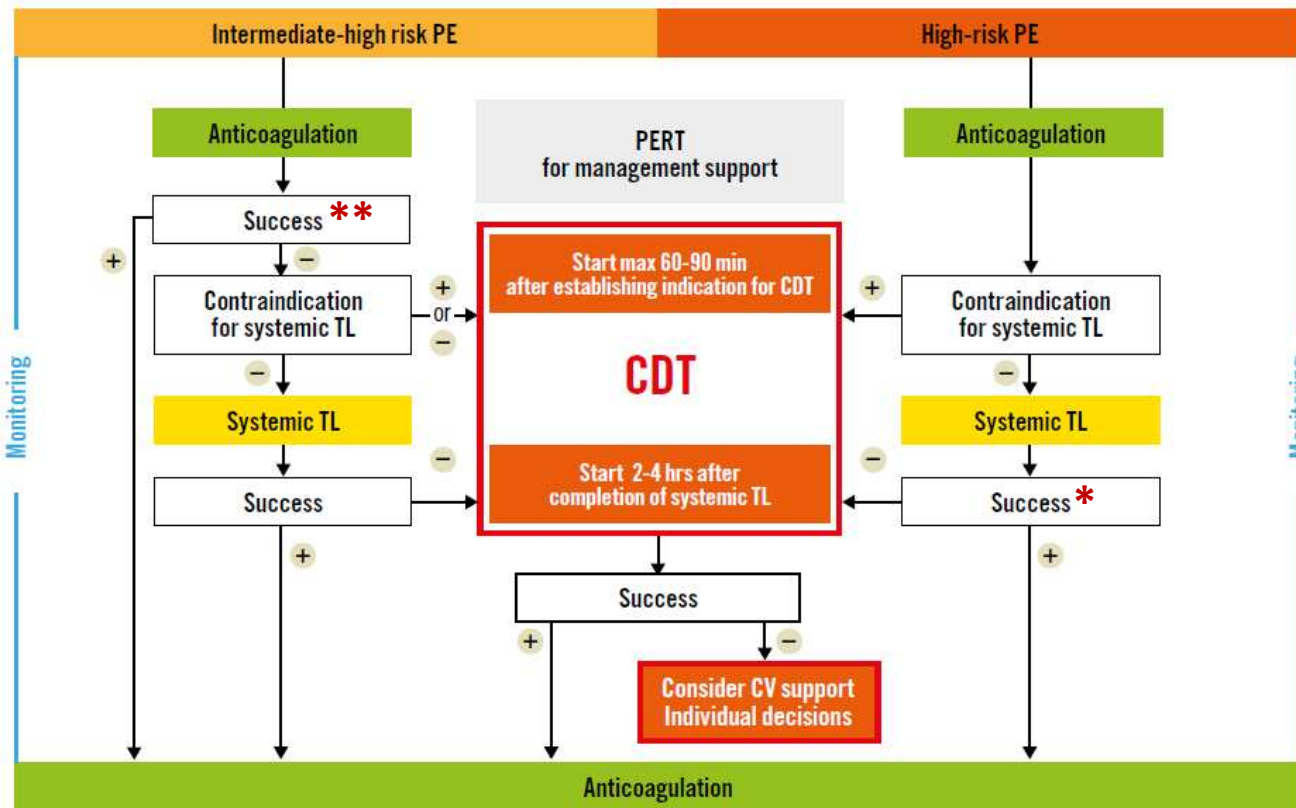
- Rapid initiation of therapy
- Efficacy on surrogate hemodynamic outcomes
- Shorter length of hospital stay
- Safety profile :
  - Low complications rates
  - Major bleeding rates # 1 - 5% (very few fatal & intracranial bleeding)

## Potential Limitations

- Appropriate expertise & resources
- Expensive procedures
- Learning curve
- Limited data in high-risk PE pts
- Few long-term data with regard to recurrent PE, mortality, & CTEPH

# Take-home message

ESC Guidelines 2019. Percutaneous catheter-directed treatment should be considered for pts with high-risk PE, in whom thrombolysis is contraindicated or has failed (IIaC)



- \* Treatment Failure with lack of improvement (pt unstable, HRPE)
  - Systemic lysis => wait 2hrs
- \*\* Treatment failure with lack of improvement (IHRPE) :
  - Anticoagulant => wait 24-48hrs
  - HR > 100/min
  - BP 90-100 mmHg
  - RR > 20/min
  - SaO<sup>2</sup> < 90%
  - Active cancer, chronic HF