

# ¿Cuándo pensar en tratamiento endovascular en TEP?

**Ignacio Cigalini**

Cardiólogo intervencionista

Subjefe | SCITE Hemodinamia, Hospital Privado de Rosario

Coordinador Unidad de Tromboembolismo Pulmonar | Grupo Gamma

Staff | LATE Casilda

## Conflictos de interés

- He recibido honorarios como consultor médico, proctor y speaker de la empresa INARI Medical.

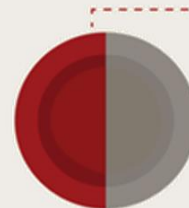
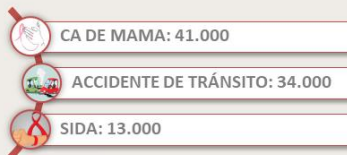
**Blood Clots are Deadly and a Significant,  
Growing Public Health Problem**



Blood clots affect as many as **900,000**  
Americans each year leading to approximately

Affected by Blood Clots  
 Blood Clot Related Deaths  
 = 100,000 people

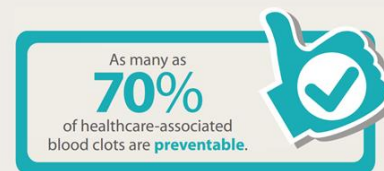
**100,000**  
**PEOPLE DIE EACH YEAR**



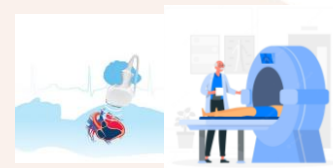
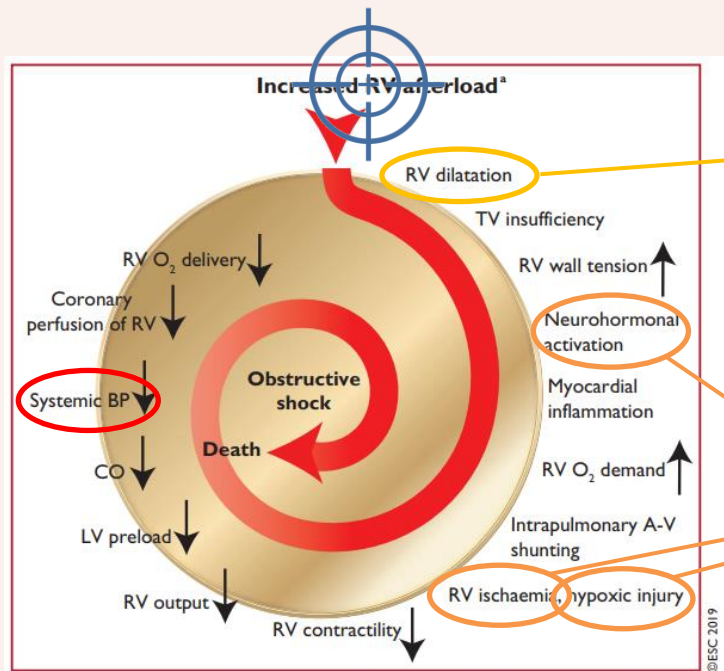
**50%**  
of blood clots are  
healthcare-associated



Although there are many reasons a person might develop a blood clot,  
about half of them are directly related to a recent hospitalization or  
surgery and most of these do not occur until after discharge.



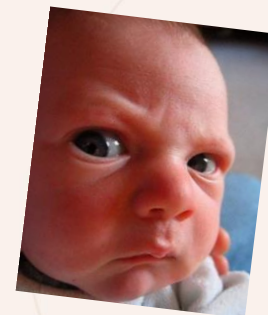
CDC, 2023

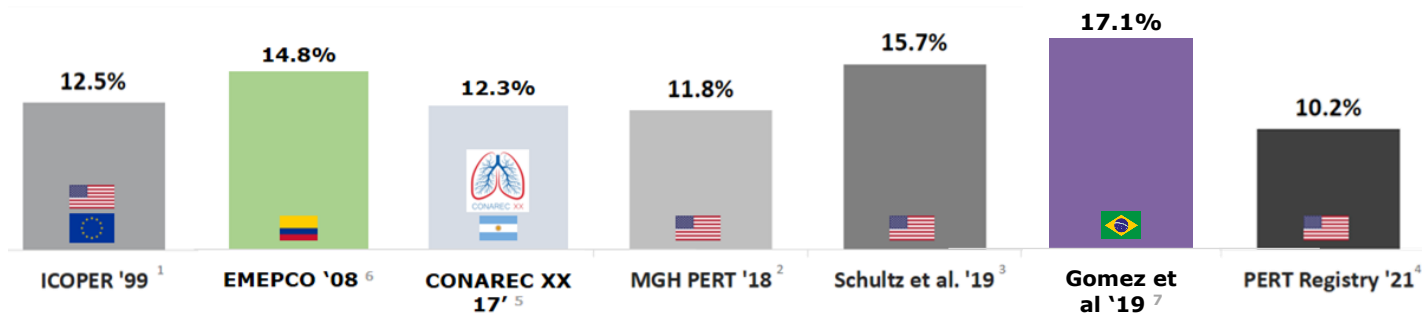


Ecocardiograma  
Tomografía



proBNP  
Troponina  
Ac. Láctico





1. Kucher N, et al. Massive pulmonary embolism. Circulation. 2006 Jan 31;113(4):577-82. doi: 10.1161/CIRCULATIONAHA.105.592592. Epub 2006 Jan 23. PMID: 16432055 2. Secemsky E, et al. Contemporary Management and Outcomes of Patients with Massive and Submassive Pulmonary Embolism. Am J Med. 2018 Dec;131(12):1506-1514.e0 3. Schultz J, et al. A Multidisciplinary Pulmonary Embolism Response Team (PERT) - Experience from a national multicenter consortium. Pulm Circ. 2019 Jan 11;9(3):2045894018824563 4. PERT Consortium® Registry Data. Interim results on 5,048 Patients presented at PERT Symposium October 2021

*30-day all-cause  
mortality by risk level:*

**6-15%**  
for submassive  
PE patients

**25-50%**  
in massive PE  
patients

5- Cigalini I y cols. Rev Argent Cardiol 2019;87:137-145.

6- Dennis RJ y cols. Acta Med Colomb 2008; 33: 111-116

7- Gomez JA y cols. J Bras Pneumol. 2022;48(3):e20210434

**OBSOLETE**

## Estratificación de riesgo subóptima



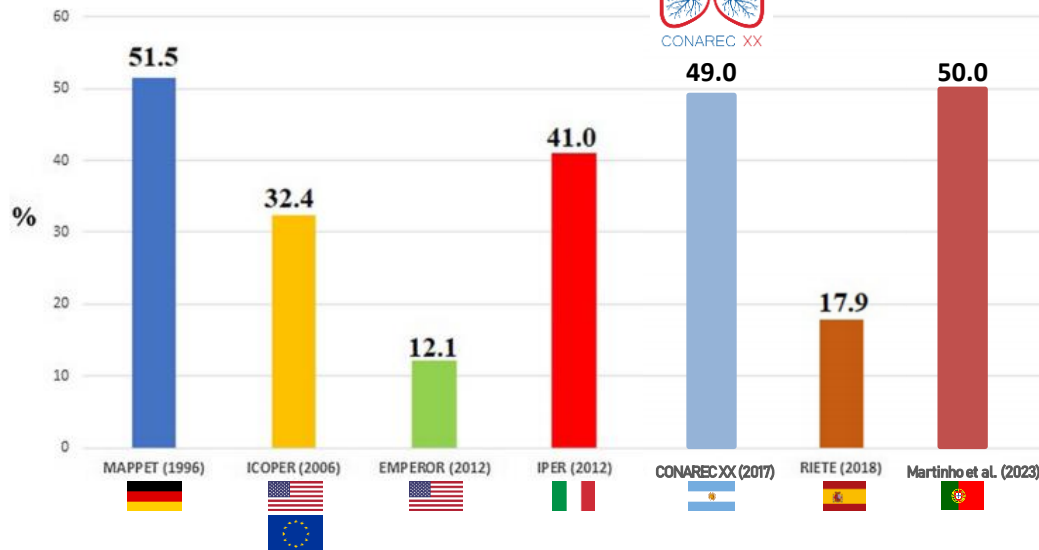
**Table 3** Safety outcomes, subgroup analyses

|                                | All studies         |         |                    | Alteplase           | Tenecteplase         | Other thrombolytics | Group difference |
|--------------------------------|---------------------|---------|--------------------|---------------------|----------------------|---------------------|------------------|
|                                | OR (95% CI)         | P-value | I <sup>2</sup> (%) | OR (95% CI)         | OR (95% CI)          | OR (95% CI)         | P-value          |
| Major bleeding                 | 2.91 (1.95 to 4.36) | <0.001  | 25                 | 1.07 (0.43 to 2.62) | 5.02 (2.72 to 9.26)  | 2.16 (1.03 to 4.54) | 0.02             |
| Fatal/intracranial haemorrhage | 3.18 (1.25 to 8.11) | 0.008   | 0                  | 1.09 (0.27 to 4.40) | 7.32 (1.64 to 32.63) | NA                  | 0.07             |



Marti et al. Eur Heart J (2015) 36, 605–614

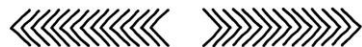
## Vida Real...



**¡Muy bajo uso de Estrategias de Reperusión en pacientes con TEP de Alto Riesgo en diferentes Registros Internacionales!!**

Modificado de *J Thromb Thrombolysis* 48, 323–330 (2019)

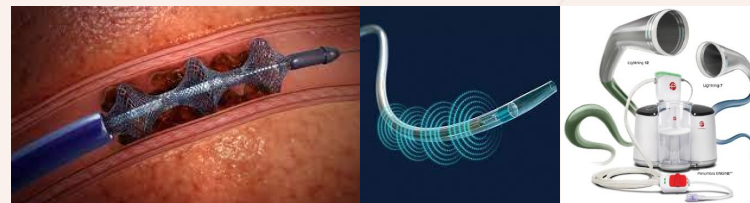
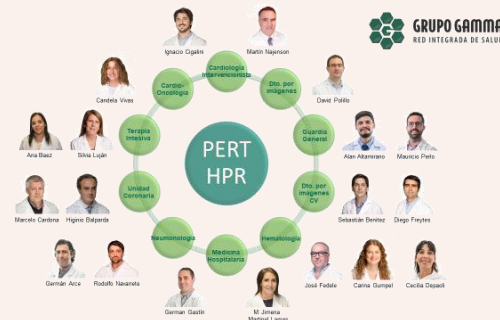
# THINGS TO DO:



Mejorar la Id. de pacientes de mayor riesgo



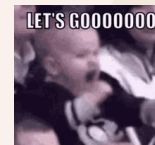
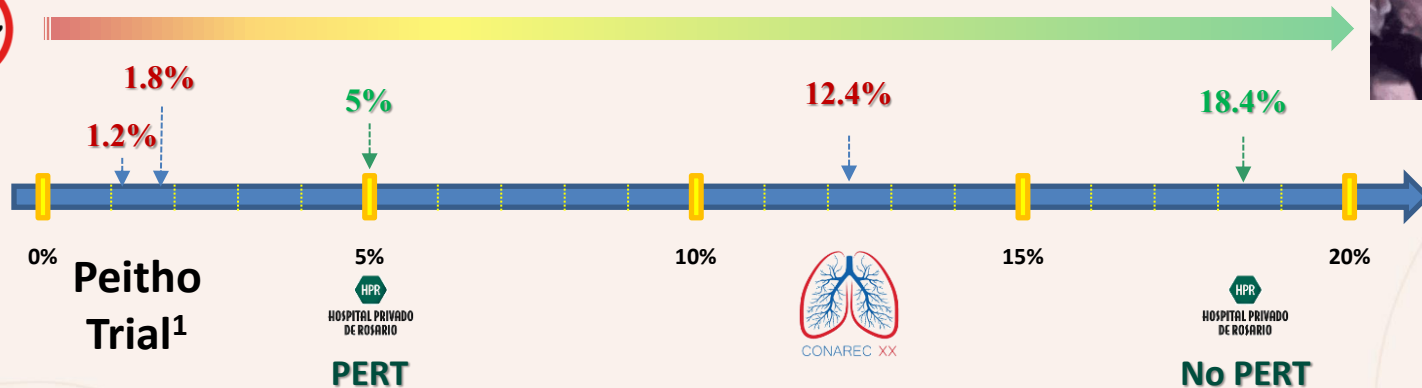
Tto. de reperfusión con mejor perfil de seguridad



## ¿Cuándo pensar en tratamiento endovascular en TEP?

**Intermedio-alto  
Riesgo**

**Alto  
Riesgo**



## Qué la presión arterial no tape el bosque...



“Our current definition and risk stratification tools may not be sufficient to identify these [patients at risk of hemodynamic decompensation] with Submassive PE.”<sup>2</sup>



Porcaro, et al<sup>1</sup>; Khandhar, et al.<sup>2</sup>

~40%

of normotensive PE patients are in **cardiogenic shock** (low CI)\*

FLASH Registry Analysis<sup>3</sup>

~20%

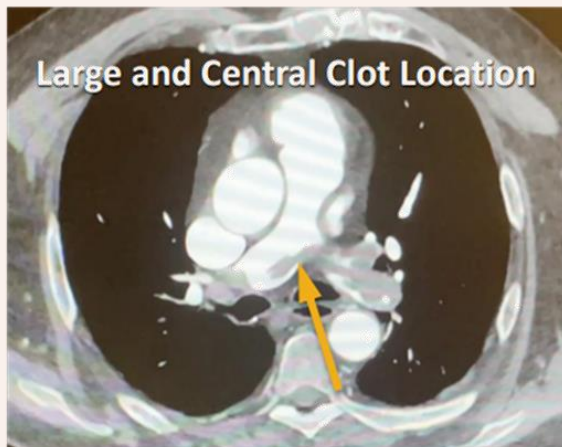
of PE patients with sPESI=0 are in **cardiogenic shock\*\***

\* Low CI defined as  $<1.8 \text{ L/min/m}^2$

\*\* Low CI defined as  $<2.0 \text{ L/min/m}^2$

1. Porcaro et al. Submassive Pulmonary Embolism: Are We Falsely Reassured by Normotension? ACC 2019. Poster Session Abstract. Presentation number:1007-15
2. Khandhar et al. Invasive hemodynamic assessment of patients with submassive pulmonary embolism. Catheter Cardiovasc Interv. 2019;1-6.
3. FLASH Registry results. Presented at SCCM 2022.

## La estratificación de riesgo excluye predictores de eventos adversos y mortalidad



### Large Clot Burden<sup>1</sup>

**>17X**

Risk of 6-month  
all-cause mortality

+ 2.4X risk of AEs\*

*Systemic review & meta-analysis, N=260*

### Central Clot<sup>2</sup>

**>2X**

Risk of PE-related  
mortality

*10-year Registry (2004-2013)  
Average 34-month follow-up, N=530*

1. Meinel et al. Predictive value of computed tomography in acute pulmonary embolism: Systematic review and meta-analysis. Am J Med. 2015;128:747-59.e2.

2. Martinez et al. 2016. Central Venous Peripheral Pulmonary Embolism: Analysis of the Impact on the Physiological Parameters and Long-Term Survival. N AM J Med Sci. 2016

\* Adverse events include death, Pulmonary Hypertension, Intensive Care Treatment.

## La estratificación de riesgo excluye predictores de eventos adversos y mortalidad



**50-65%**

Of patients with  
PE also have  
proximal DVT<sup>1-3</sup>



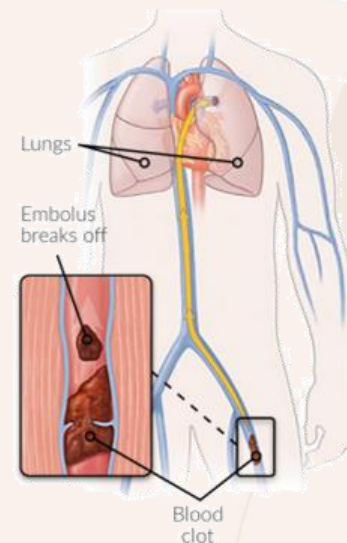
**>4X**

Risk of **90-day  
PE-related mortality**  
in PE patients with  
proximal DVT<sup>4</sup>



**>4X**

Risk of 90-day  
**recurrent VTE**  
in PE patients with  
proximal DVT<sup>4</sup>



1. Hirmerova, et al. The Prevalence of Concomitant Deep Vein Thrombosis, Symptomatic or Asymptomatic, Proximal or Distal, in Patients With Symptomatic Pulmonary Embolism. Clin Appl Thromb Hemost. 2018 Nov.
2. Becattini, et al. Risk Stratification of Patients With Acute Symptomatic Pulmonary Embolism Based on Presence or Absence of Lower Extremity DVT: Systematic Review and Meta-analysis. Chest. 2016 Jan.
3. Nishiwaki, et al. Impact of Concomitant Deep Vein Thrombosis on Clinical Outcomes in Patients With Acute Pulmonary Embolism. American Heart Association. 2019 Nov.
4. Jiménez, et al. Prognostic significance of deep vein thrombosis in patients presenting with acute symptomatic pulmonary embolism. Am J Respir Crit Care Med. 2010 May

## Otros parámetros a tener en cuenta



$FC \geq 100 \text{ lpm}^1$

**x2.7**

Eventos  
adversos  
(muerte por TEP,  
ARM, RCP o  
catecolaminas)



$\text{Índice de Shock} > 1^2$

**x2.3**

Muerte a 30  
días

$$IS = FC / TAS$$



$\text{Lactato} > 3.3 \text{ mMol}^3$

**x3.8**

Muerte  
intrahospitalaria  
(x5.2 en int-alto  
riesgo)



$\text{Echo-PESI} \geq 128^4$

**x2.3**

Muerte a 30 días  
AUC 0.82 vs. 0.75 PESI

$$\text{PESI-Echo} = \text{PESI} + \text{PSAP} - \text{TAPSE}$$

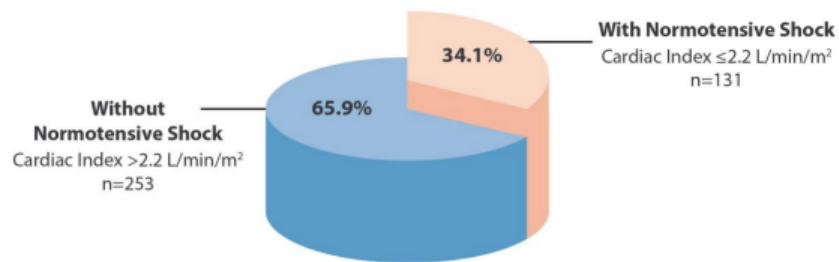
1- Hobohma et al. European Journal of Internal Medicine 82 (2020) 76–82

2- Otero et al. Eur Respir J 2007; 30: 1111–1116

3- Ebner et al. Eur. J. Intern. Med. 2021, 86, 25–31

4- Burgos L; Scatularo E; Cigalini I et al. European Heart Journal: Acute Cardiovascular.2021;10(3):250-257

## Normotensive Shock in Patients With Intermediate-Risk Pulmonary Embolism From the FLASH Registry

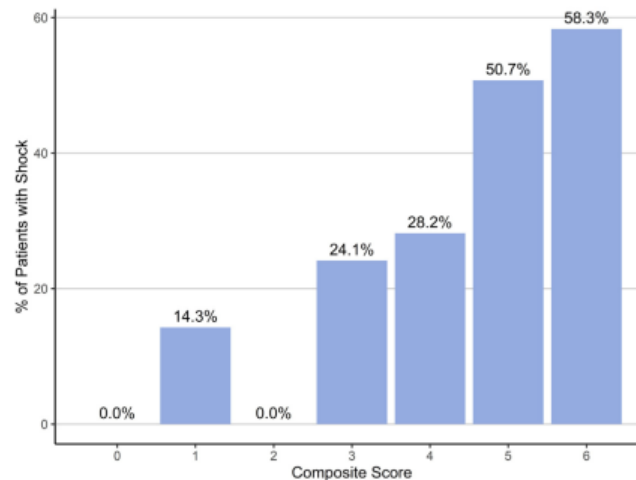


### Composite Shock Score

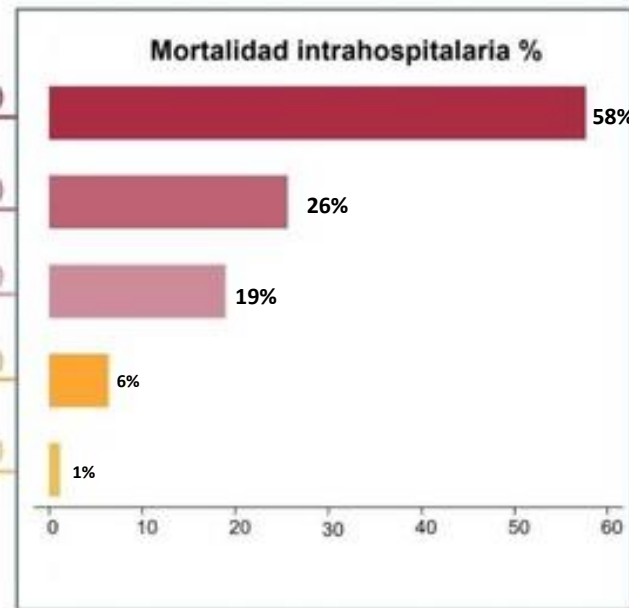
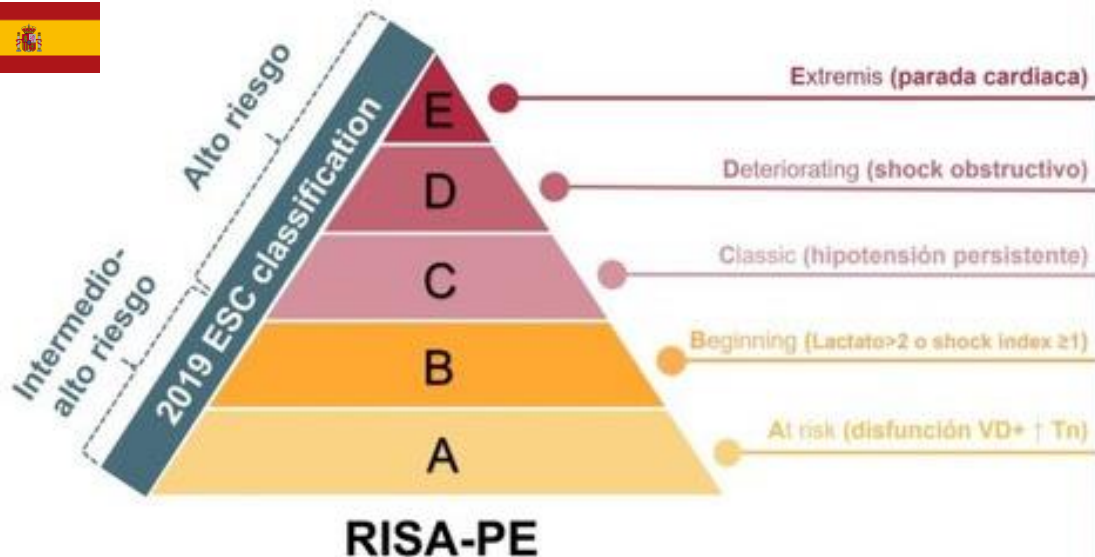
Elevated Troponin + Elevated BNP + Moderate/Severely Reduced RV function + Saddle PE + Concomitant DVT + Tachycardia

### Risk Factor Associated With Normotensive Shock

(OR: 5.84; 95% CI: 2.00-17.04)



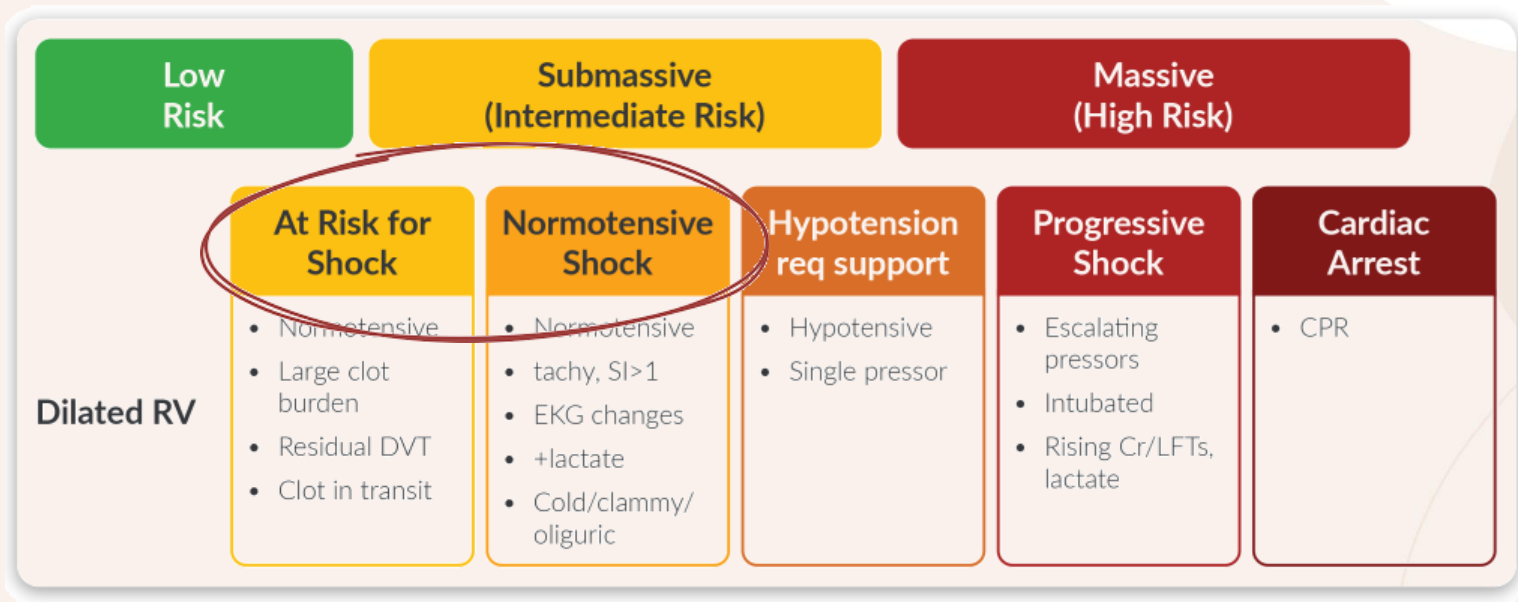
A composite shock score consisting of 1 point each for elevated troponin, elevated B-type natriuretic peptide, concomitant deep vein thrombosis, saddle pulmonary embolism, moderately or severely reduced right ventricular function, and tachycardia was calculated for each patient who had data available for all 6 components. **Bars** represent the proportion of patients with shock out of all patients who had a given score.



Párraga R, Real C, Jiménez-Mazuecos J, Vázquez-Álvarez ME, Valero E, Velázquez M, et al. New risk classification adapting SCAI shock stages to patients with pulmonary embolism (RISA-PE). Minerva Cardiol Angiol 2024 Sep 24. DOI: 10.23736/S2724-5683.24.06609-2

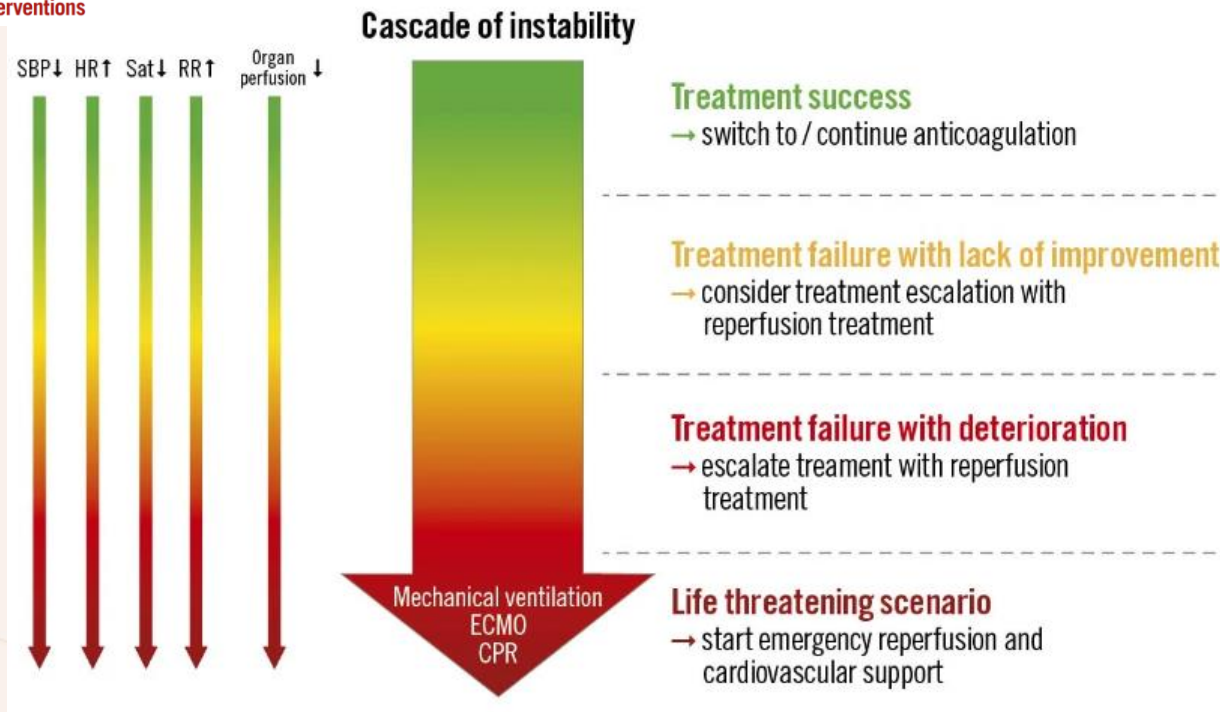


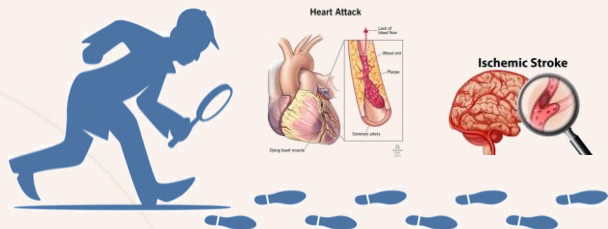
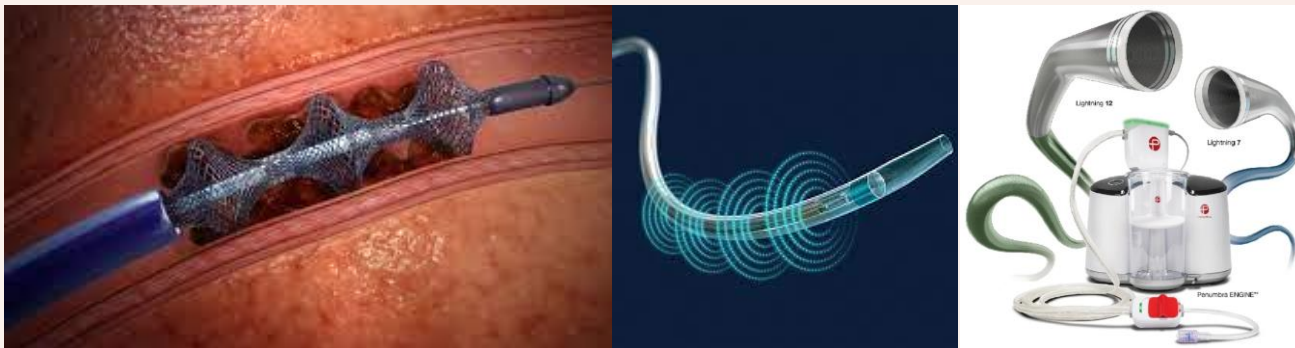
## Stages of Cardiogenic Shock in PE



Slide as presented by Dr Catalin Toma at MADRID ACCIS – 2023 congress (Acute Cardiac Care, Interventions & Support) on June 16th 2023: 'Data and lessons from the FLASH project. Is the paradigm of severe PE management changing?'

**Percutaneous treatment options for acute pulmonary embolism: a clinical consensus statement by the ESC Working Group on Pulmonary Circulation and Right Ventricular Function and the European Association of Percutaneous Cardiovascular Interventions**



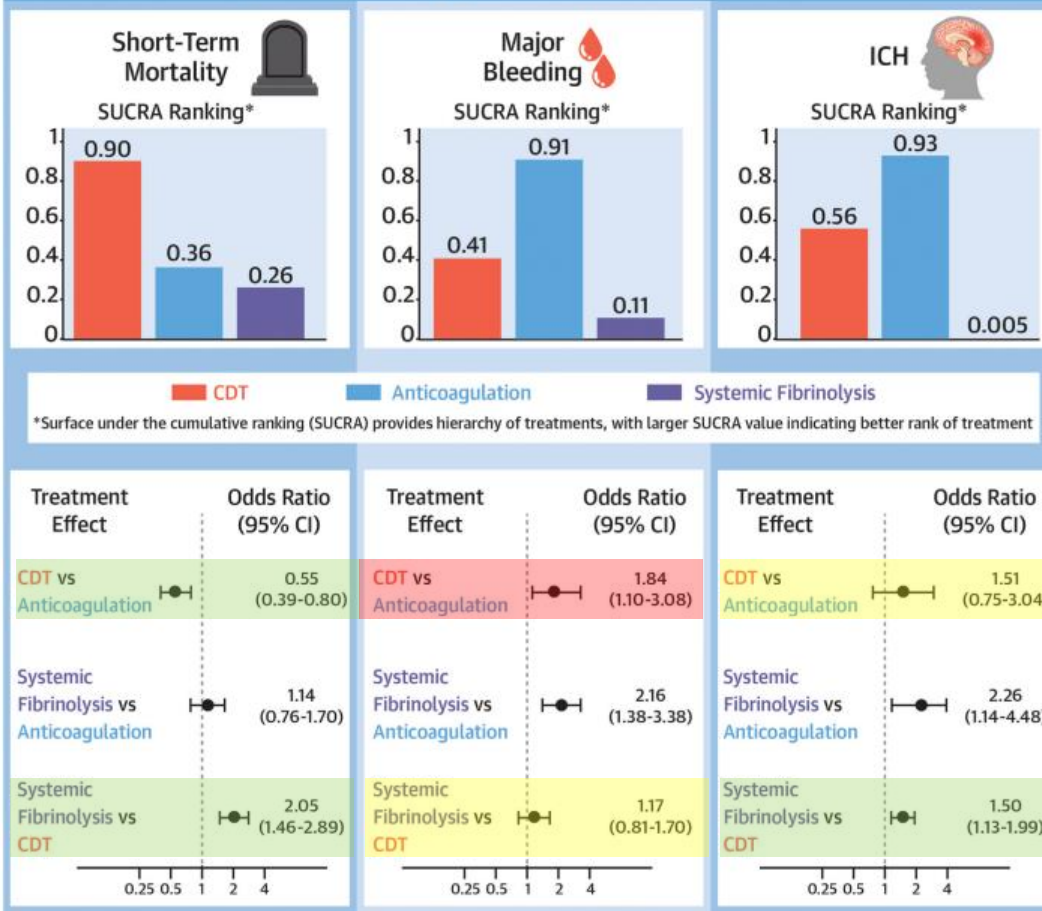


## Efficacy and Safety of Anticoagulation, Catheter-Directed Thrombolysis, or Systemic Thrombolysis in Acute Pulmonary Embolism

Trials included in  
quantitative synthesis  
(meta-analysis)  
(n =45)

- 17 RCTs
- 2 prospective  
non-randomized
- 26 retrospective

n=81705 pts



Zhang RS, et al. J Am Coll Cardiol Interv. 2023;■(■):■-■.



## FLASH REGISTRY: Real World PE Patient Population

**800 Patients**

50 US Sites

**92.1%**

Intermediate-Risk

**7.9%**

High-Risk

**32.1%**

Thrombolytic contraindication

**25.9%**

Depressed cardiac index at baseline\*



Figure 1A

Figure 1A: Pre-procedure angiogram



Figure 1B

Figure 1B: Post-procedure angiogram

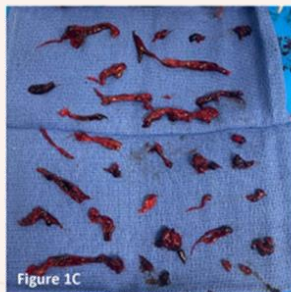
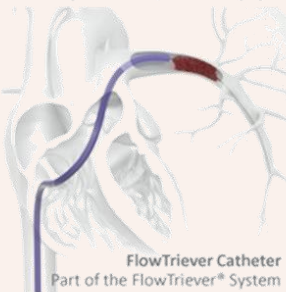


Figure 1C

Figure 1C: Thrombus removed



FlowTrievers Catheter  
Part of the FlowTrievers® System

Figure images provided by Dr. Michael Brown,  
Missouri Cardiovascular Specialists, Columbia, MO

### On-Table Hemodynamic Improvements



**7.6 mmHg**

Mean drop in mean PA pressure



**18.9%**

Mean increase in cardiac index\*\*

### 48-Hour Mortality and Safety Outcomes

**1.8%**

Major adverse events

**0.3%**

All-cause mortality

**0**

Device-related serious adverse events

### 48-Hour Effectiveness Outcomes

**74.5%**

No/mild RV dysfunction

**87.4%**

Decreased supplemental oxygen requirements

**61.2%**

Mean reduction in dyspnea score

### Hospital Stay

**97.7%**

Did not receive thrombolytics

**3.0 nights**

Median post-procedural hospital LOS

**62.6%**

No post-procedural overnight ICU stay

### 30-Day Mortality and Readmissions

**0.8%**

All-cause mortality



**6.2%**

All-cause readmissions

\*Depressed cardiac index is defined as  $< 2 \text{ L/min/m}^2$

\*\*In patients with depressed cardiac index at baseline

## Algoritmo de Estratificación de riesgo y tratamiento

**Bolo Heparina sódica 80UI/kg ev  
o HBPM (a elección del equipo  
tratante) ante la sospecha clínica  
de TEP**

**RIESGO INTERMEDIO-BAJO**  
3% de mortalidad

**CONTINUAR CON  
ANTICOAGULACIÓN  
Y REEVALUAR**

NO

NO

**HNF y reevaluar  
¿persiste  
inestable?  
(\*)**

**SHOCK / TAS < 90 mmHg / Post RCP**

NO

**RIESGO INTERMEDIO-ALTO**  
(PESI ALTO+VD+TROPONINA)  
3 al 15% de mortalidad

SI

**VD severo:**  
2 de 3 condiciones presentes:  
\*Hipoquinesia severa de VD  
\*TAPSE < 14 mm  
\*VD/VI > 1.5 por ECO con VCI > 2 cm

**Ó Scores de riesgo positivo:**  
2 de 3 Scores presentes  
Láctico > 2 mEq/L  
TAPSE/PSAP < 0,4  
BOVA > 4 puntos  
PESI+ECHO > 128  
SHOCK INDEX > 1  
PaPi < 1  
NEWS > 7 puntos

SI

SI

SI

Utilizar HNF si se  
considera  
reperusión o  
riesgo de sangrado  
alto.

**RIESGO ALTO**  
> 15% de mortalidad

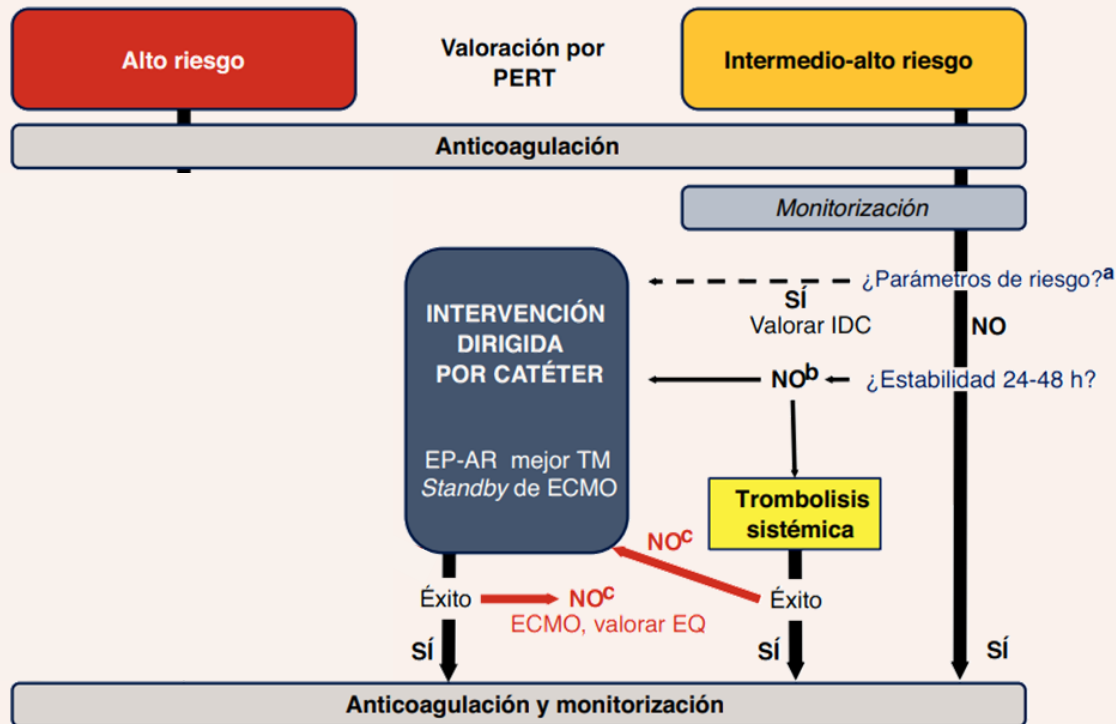
**Trombo  
en**

**Discusión en equipo  
o con el PERT**

**CONSIDERAR  
REPERFUSIÓN**

**Líticos sistémicos:**

- Riesgo Sangrado Bajo
- Paciente no trasladable que requiere reperusión inmediata.
- Terapia Guiada por catéter:**
- Riesgo Sangrado Alto
- Cirugía:**
- TEP crónico reagudizado
- Necesidad de ECMO



- a) Parámetros asociados con shock normotensivo o mortalidad 10%
- b) Valorar, como en EP-AR: CI de TS, ↑ riesgo de sangrado y disponibilidad de IDC.
- c) Evaluar en 2-4 h.



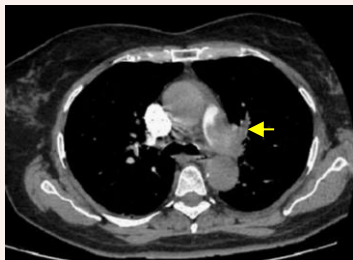
Paciente **femenina de 70 años.**

✓ FRCV: DLP.

✓ AP: Niega

**Disnea súbita CF IV + desaturación** de 4 días de evolución

TA 110/80mmHg, FC 100 lpm, FR 30cpm, Sao2 87% (0.21)



### ETT

- VI 36/24, Fey 62%.
- VD dilatado con función deprimida (TAPSE 16).
- PSAP 55mmHg.

### Laboratorio

- Hto 39,7%, Cr 0.92 mg/dl, Troponina 66.4 ng/l

Disnea  
persistente |  
SaO2 <90%

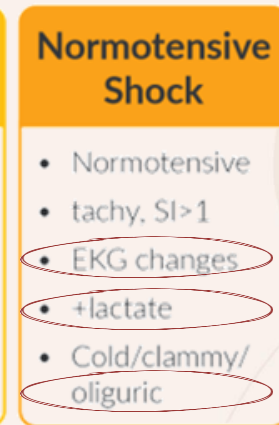
TVP proximal  
extensa

FA ARV

Oligoanuria  
(400ml/12hs)

TVNS





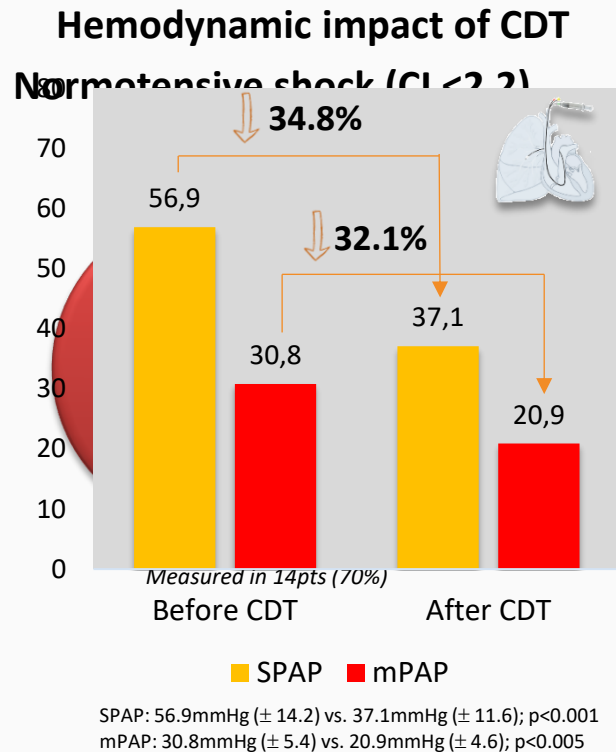
# Elective endovascular reperfusion therapies in intermediate-high risk pulmonary embolism after PERT assesment

I. Cigalini, M. Najenson, C. Petry, M. Cardona, H. Balparda, F. Montiel, M. Montenegro, L. Cabral, J. Fedele, C. Gumpel, C. Depaoli, D. Polillo, L. Zarria, C. Cigalini, C. Dumont

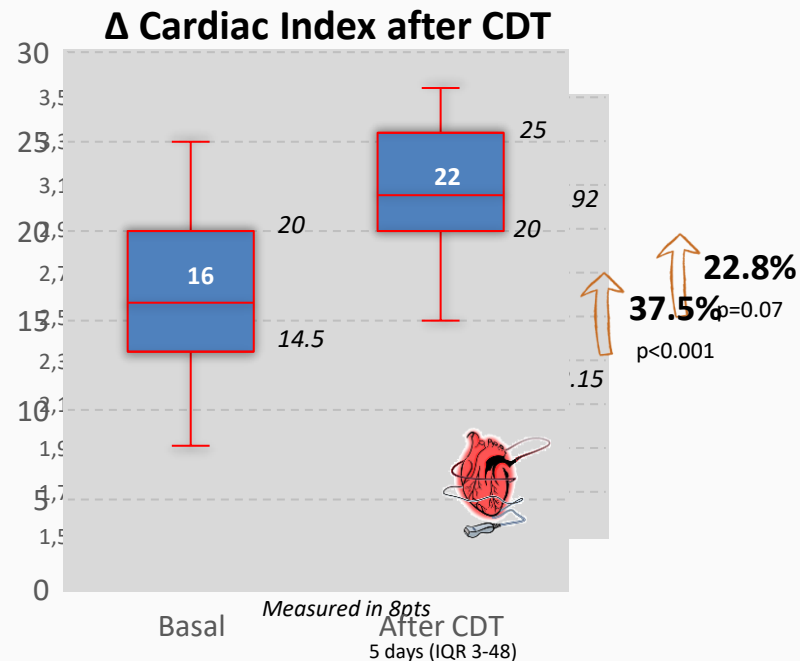
**Hospital Privado de Rosario, Argentina**



# Elective Invasive Approach (n=20)

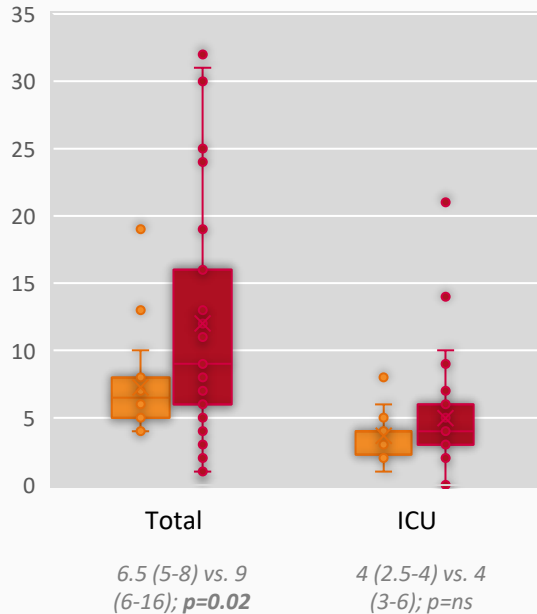


## RV function assessed by TAPSE

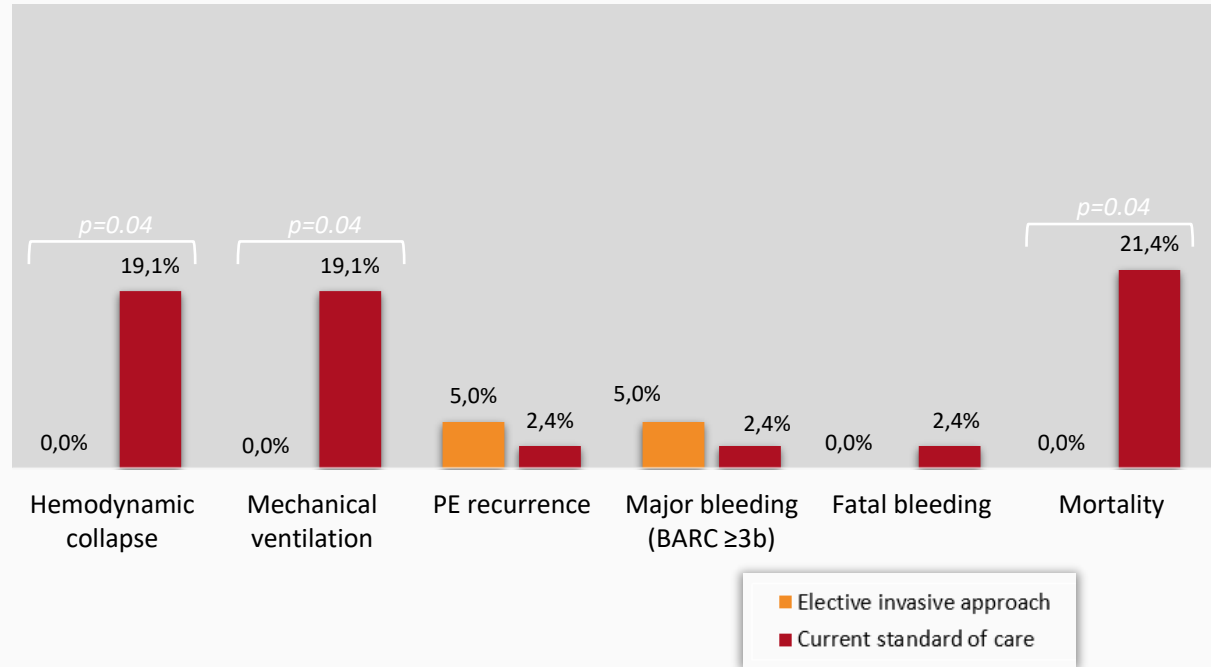


# Results

## Length of stay (days)



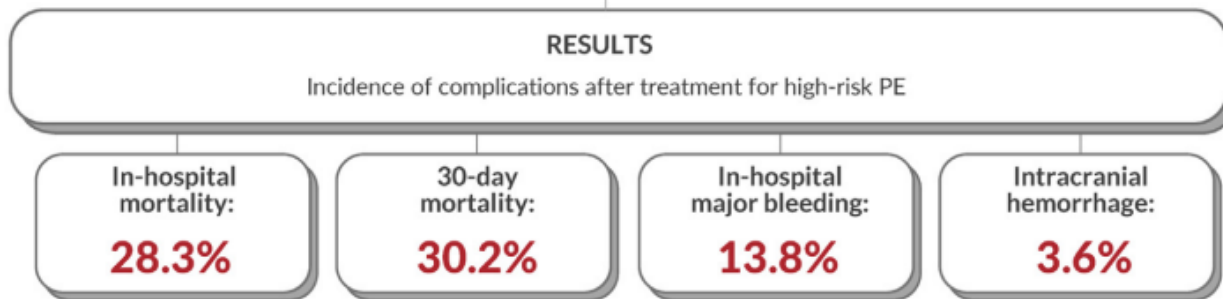
## In-hospital events



## ¿Cuándo pensar en tratamiento endovascular en TEP?

**Intermedio-alto  
Riesgo**

**Alto  
Riesgo**

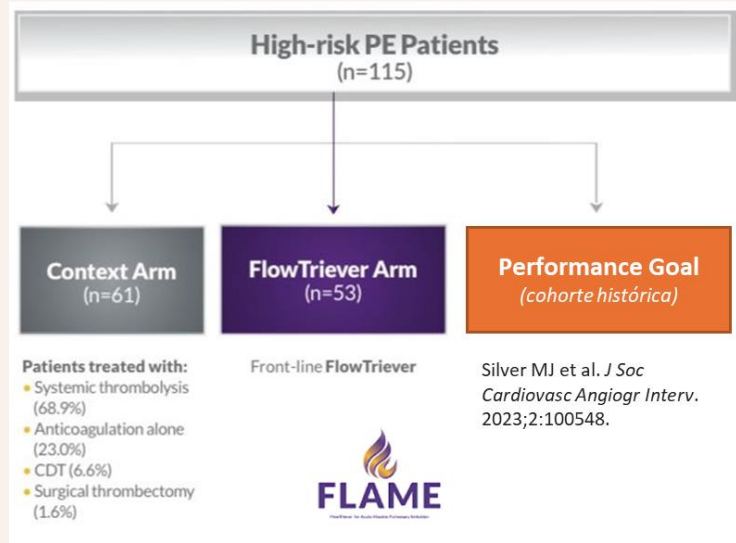


1517 ptes  
2010 - 2020

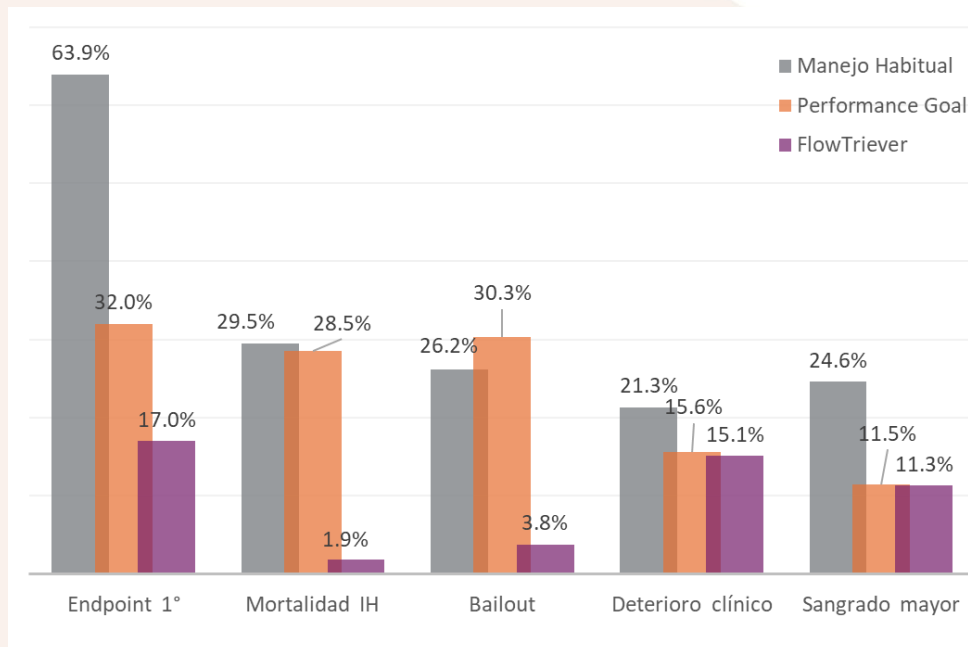


**37.3%**

**11.8%**

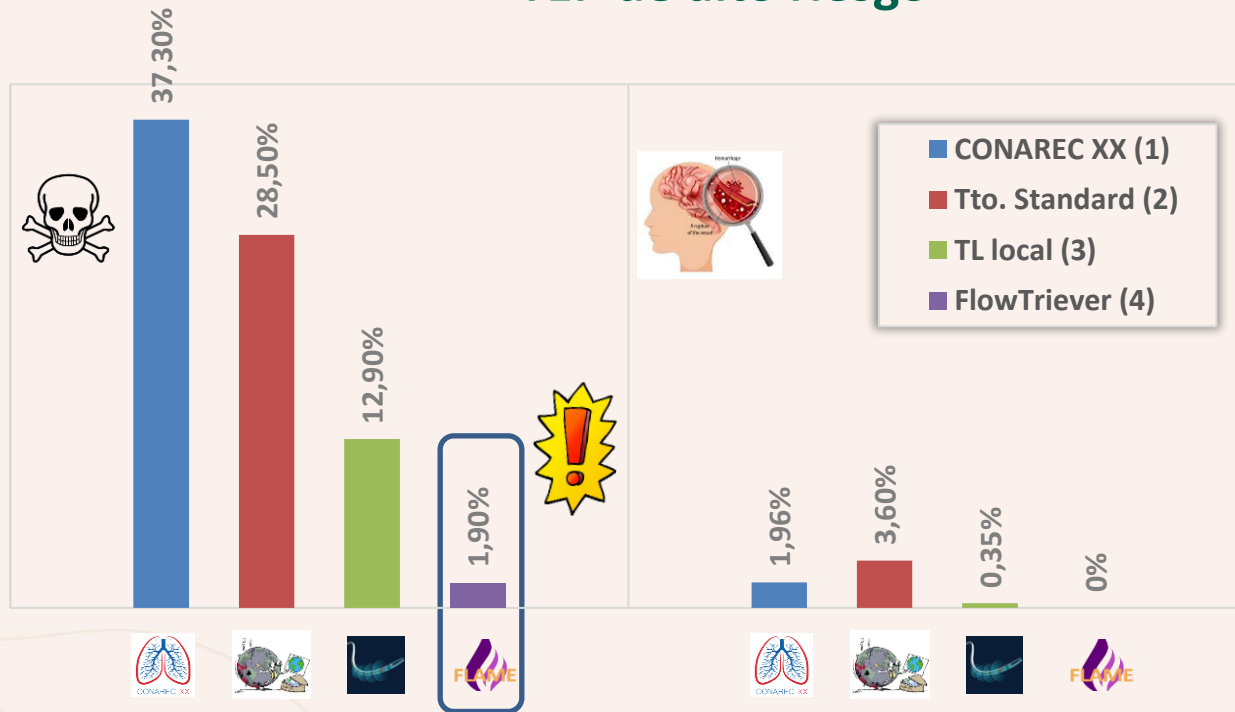


- **No randomizado**, tratamiento a discreción del médico tratante
- Detenido precozmente luego de cumplir el objetivo en análisis interino pre-especificado.



Silver et al. *Circ Cardiovasc Interv.* 2023 Oct;16(10):e013406.

## TEP de alto riesgo



1. Cigalini I y cols. Rev Argent Cardiol 2019;87:137-145.
2. Silver MJ et al. J Soc Cardiovasc Angiogr Interv. 2023;2:100548.
3. Catheterization and Cardiovascular Interventions 89:754–760 (2017)
4. Silver MH et al. Circulation: Cardiovascular Interventions. 2023;16(10):e013406



## SCAI C

- 73yo, melanoma with surgical treatment
- **High Risk PE**
- **High bleeding risk**
- Vitals:
  - BP 70/50
  - HR 120bpm
  - Sat 84%
- Lab:
  - Hb 11.1 | ClCr 45
  - proBNP 17857
  - TnUS 47
- **SBP >90mmHg with Nora 0.15ug/kg/min**



@DR.IGNACIOCIGALINI

Giulio Cercato · Beautiful



61 años

FRC: DLP, OBS.

AP: Traumatismo múltiple 2017, Depresión

**Sincope | Dolor torácico**

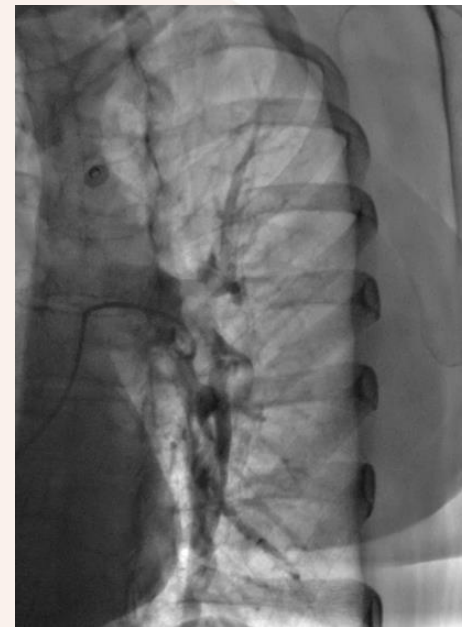
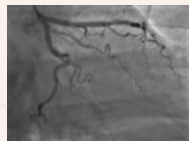
VTE-Bleed score: 3 puntos



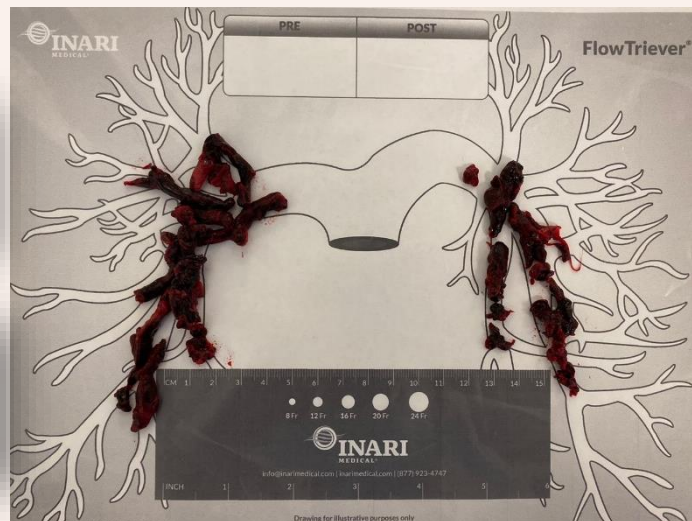
**TA 80/50 mmHg (Nora 0.07 ug/kg/min)**

FC 110lpm

IST anterolateral



AP: 65/20 (35) mmHg  
IC: 1.21L/min/m<sup>2</sup>

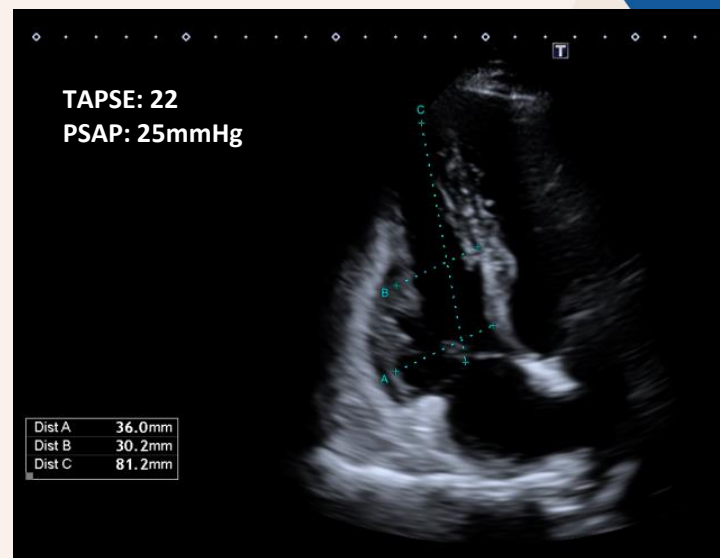


**Trierer24**

|      | Pre                       | Post                      | Δ             |
|------|---------------------------|---------------------------|---------------|
| TA   | 80/50 mmHg                | 140/70 mmHg               | ↑60 mmHg      |
| Nora | 0.07 ug/kg/min            | -                         | Suspensión    |
| FC   | 110 lpm                   | 90 lpm                    | ↓20 lpm       |
| AP   | 65/20 (35) mmHg           | 40/10 (20) mmHg           | ↓ 15mmHg PmAP |
| IC   | 1,21 L/min/m <sup>2</sup> | 2,47 L/min/m <sup>2</sup> | ↑1.26 (+200%) |

**Trierer24**  
**Trierer20 Curve**

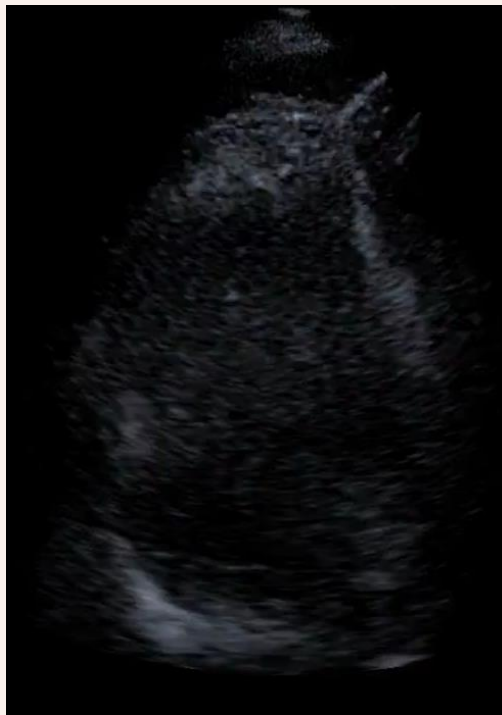
## Seguimiento 3 meses

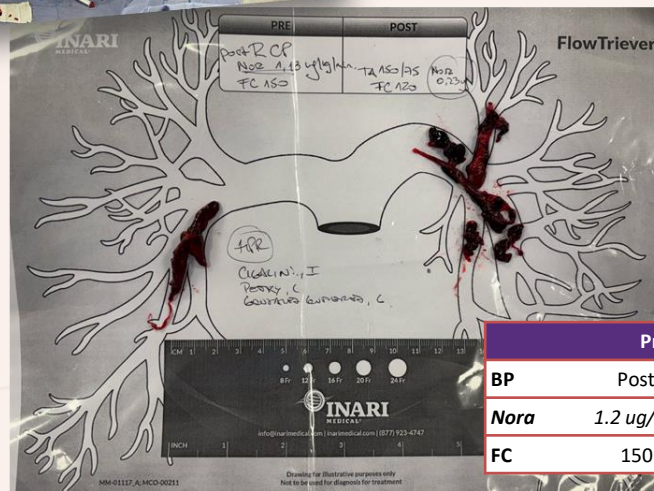




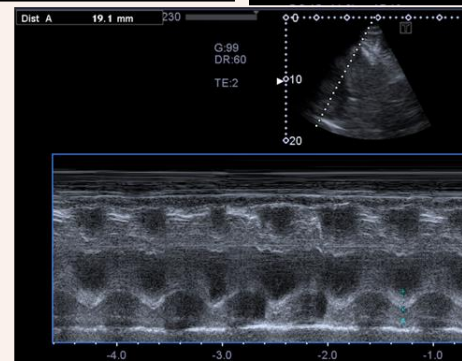
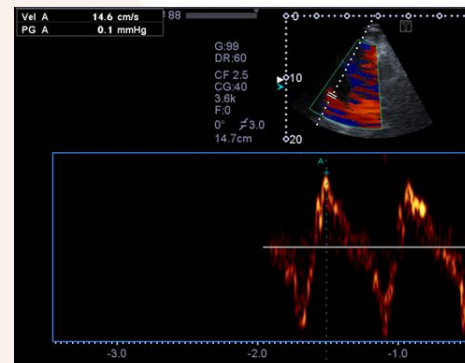
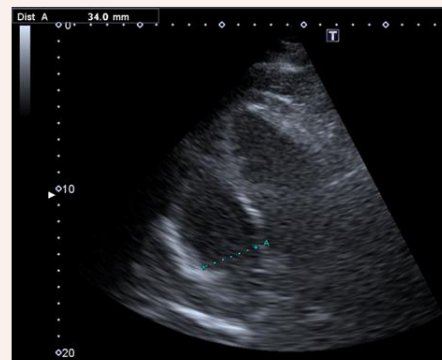
## SCAI E

- 71 yo
- Hospitalized for surgery (thyroid cancer with laryngeal invasion)
- Sudden dyspnea and refractory shock
- Vitals:
  - SBP 50mmHg
  - FC 150lpm
  - MRA!
  - Sat 70% (Fio2 1.0)
- *1ug/kg/min and raising with no response, pre-cardiorespiratory arrest.*

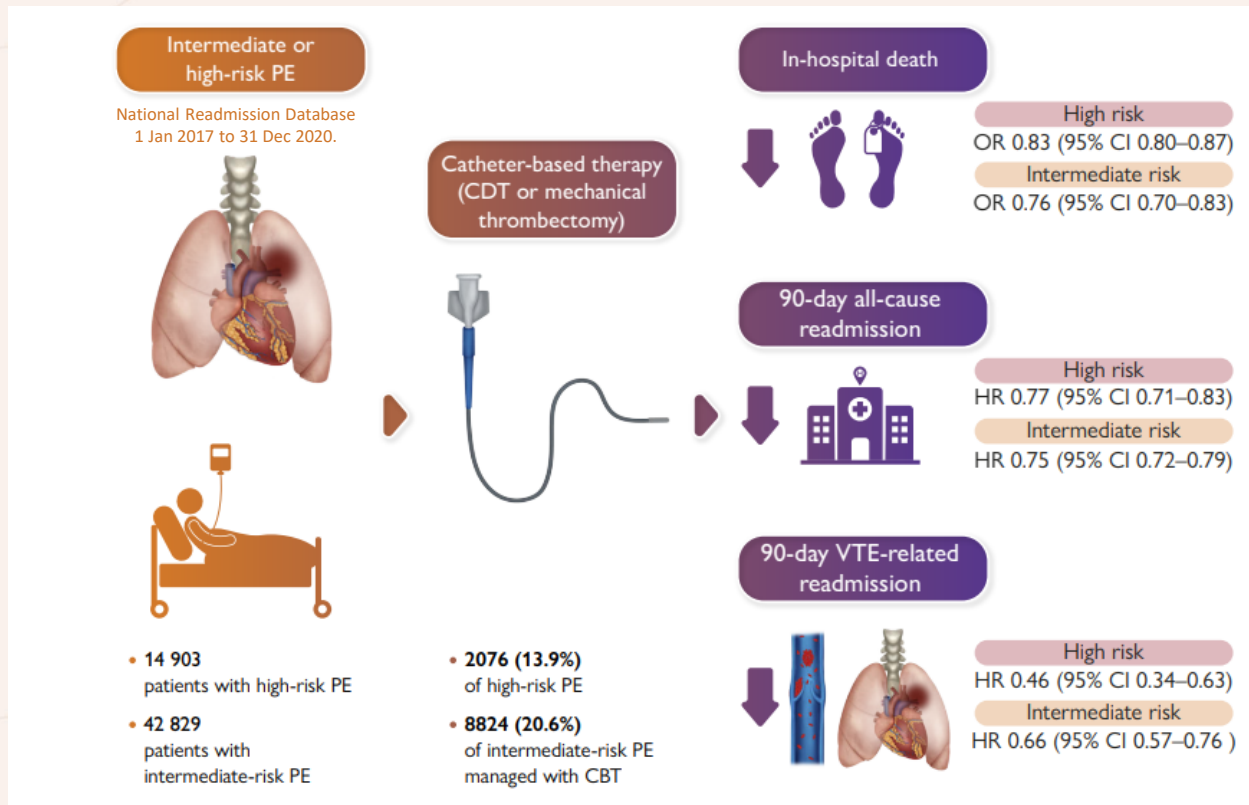


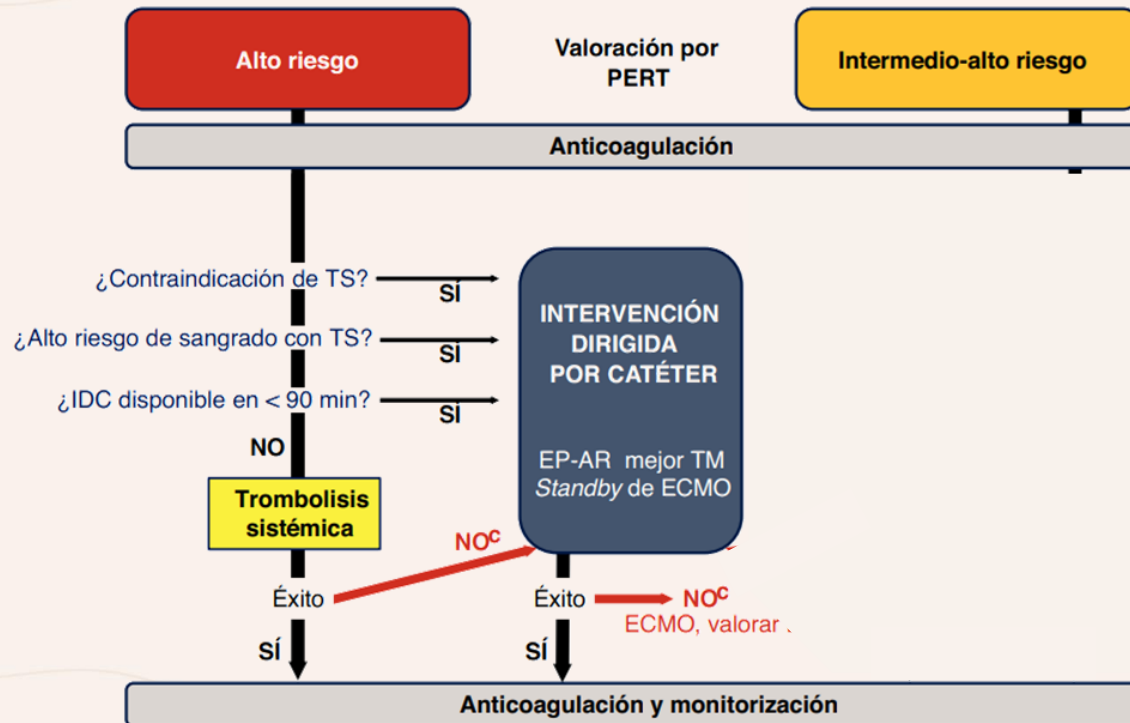


|             | Pre           | Post          |
|-------------|---------------|---------------|
| <b>BP</b>   | Post CPR      | 150/75 mmHg   |
| <b>Nora</b> | 1.2 ug/kg/min | 0.2 ug/kg/min |
| <b>FC</b>   | 150 lpm       | 120 lpm       |



48hs





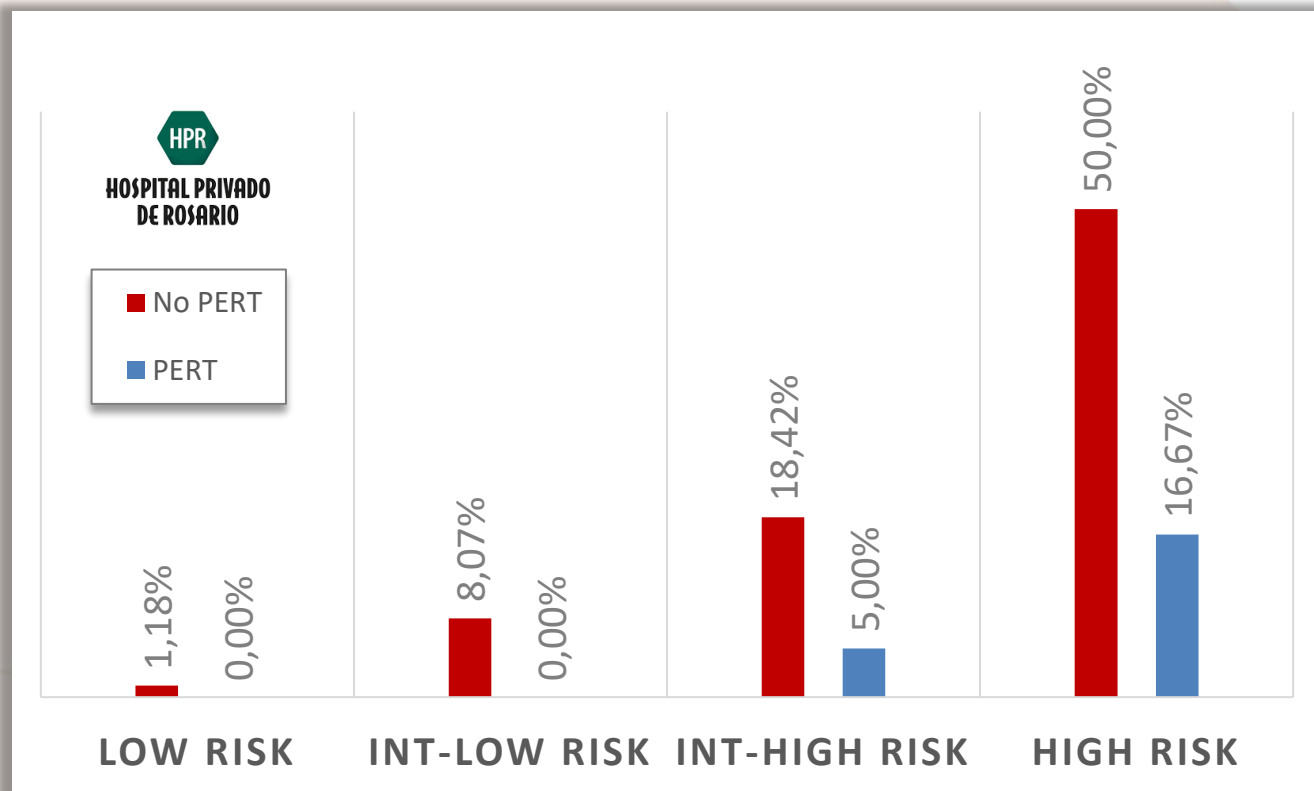
|                                         | No PERT<br>(n=355) | PERT<br>(n=72)   | p      |
|-----------------------------------------|--------------------|------------------|--------|
| <b>Age</b>                              | 64.7 (±14.9)       | 65.5 (±15.5)     | ns     |
| <b>Female gender</b>                    | 163 (45.9%)        | 36 (50%)         | ns     |
| <b>Systolic blood pressure</b>          | 130 (115-140)      | 130 (119-150)    | ns     |
| <b>Heart rythm</b>                      | 85 (75-100)        | 100 (85-115)     | <0.001 |
| <b>Concomitant DVT</b>                  | 198/320 (61.9%)    | 57/71 (80.3%)    | 0.008  |
| <b>PESI</b>                             | 99 (78-116)        | 103.5 (83-125.5) | ns     |
| <b>HS Troponin</b>                      | 20 (5-51)          | 55 (21-136)      | 0.003  |
| <b>Bova Score</b>                       | 2 (0-3)            | 4 (2-5)          | <0.001 |
| <b>VD compromise (ETT/TC)</b>           | 119 (33.5%)        | 59 (81.9%)       | <0.001 |
| <b>TAPSE</b>                            | 22 (20 - 25)       | 18 (15 - 23)     | 0.0001 |
| <b>SPAP by TTE</b>                      | 35 (25-45)         | 50 (40-55)       | <0.001 |
| <b>Central distribution of thrombus</b> | 148 (42.3%)        | 63 (88.7%)       | <0.001 |
| <b>Risk Stratification</b>              |                    |                  |        |
| -Low risk                               | 85 (24%)           | 4 (5.6%)         | <0.001 |
| -Intermediate-low risk                  | 223 (63%)          | 21 (29.6%)       |        |
| -Intermediate-high risk                 | 38 (10.7%)         | 40 (56.3%)       |        |
| -High Risk                              | 8 (2.3%)           | 6 (8.5%)         |        |
| <b>Reperfusion therapies</b>            |                    |                  | <0.001 |
| - "Elective"                            | 5 (1.4%)           | 39 (54.9%)       |        |
| - Rescue                                | 0 (0%)             | 27 (76.9%)       |        |
| - IVC filter                            | 5 (100%)           | 9 (23.1%)        |        |
| <b>IVC filter</b>                       | 35 (9.9%)          | 14 (19.7%)       | 0.02   |
| <b>IH mortality</b>                     | 30 (8.5%)          | 3 (4.1%)         | ns     |
| <b>Major bleeding</b>                   | 14 (4.2%)          | 4 (6.2%)         | ns     |



- ✓ Sicker patients
- ✓ Greater indication for reperfusion and IVF therapies
- ✓ Trend towers lower mortality

Ene/2017 a Jul/2025

\* Excluding patients with therapeutic limitations due to pre-existing conditions with short life expectancy

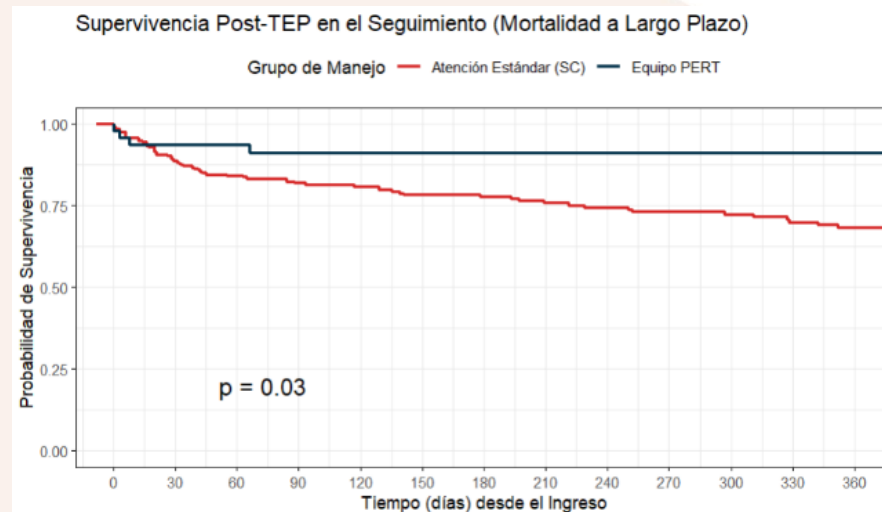


|                    | Univariado |       | Multivariado |       |
|--------------------|------------|-------|--------------|-------|
|                    | Exp(coef)  | P     | Exp(coef)    | p     |
| <b>PERT</b>        | 0.35       | 0.039 | 0.2          | 0.02  |
| <b>Edad</b>        | 1.02       | 0.02  | 1.02         | 0.049 |
| <b>Cáncer</b>      | 4.59       | <0.05 | 4.29         | <0.05 |
| <b>Reperusión</b>  | 0.78       | 0.51  |              |       |
| <b>Alto Riesgo</b> | 3.23       | 0.006 | 3.56         | 0.02  |

Análisis multivariado para la mortalidad en seguimiento (incluyendo mortalidad intrahospitalaria)



  **80%**

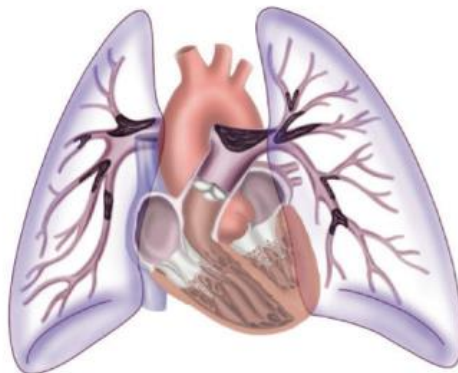


Base de datos HPR, datos no publicados  
Ene/2017 a Jul/2025



### A favor de TL

- Amplia disponibilidad
- Mínima curva aprendizaje
- Bajo coste
- Cierta estabilidad clínica
- Riesgo hemorrágico favorable para rtPA
- Cualquier distribución de trombo
- Cualquier acceso vascular



### Evaluación de:

- Disponibilidad de recursos
- Experiencia del operador
- Estabilidad del paciente
- Riesgo hemorrágico
- Distribución del trombo
- Acceso vascular



### A favor de TM

- Deterioro hemodinámico incluso con necesidad de ECMO
- Cualquier riesgo hemorrágico
- Alta carga trombótica
- Trombo proximal
- Acceso femoral o yugular > 4 mm
- Tolera caída de hemoglobina

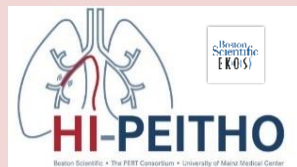


vs. guías actuales



Int-Alto  
Riesgo

CDT



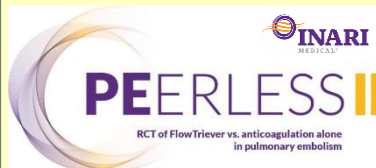
BETULA

PRAGUE-26

STRATIFY



MT



Alto  
Riesgo

MT



Sponsorizados

Iniciados por investigador

