

Embolia Polmonare. Stato dell'arte del trattamento interventistico

PDTA

**Domenico Tavella
Università di Verona**



Table 8 Classification of pulmonary embolism severity and the risk of early (in-hospital or 30 day) death

Early mortality risk		Indicators of risk			
		Haemodynamic instability ^a	Clinical parameters of PE severity and/or comorbidity: PESI class III–V or sPESI ≥1	RV dysfunction on TTE or CTPA ^b	Elevated cardiac troponin levels ^c
High		+	(+) ^d	+	(+)
Intermediate	Intermediate–high	-	+ ^e	+	+
	Intermediate–low	-	+ ^e	One (or none) positive	
Low		-	-	-	Assesment optional; if assessed, negative

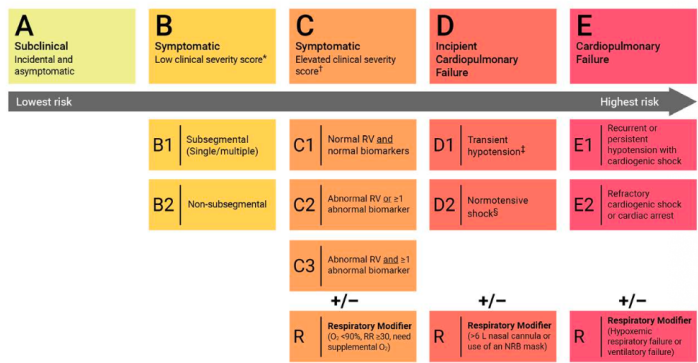
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Table 5. Progression of Acute PE Risk Categorization Schemas

Year	Organization	Risk Category	Clinical Criteria
2011	AHA Scientific Statement ¹	Low risk	Normotensive; no right ventricular dysfunction or myocardial necrosis (elevated troponin)
		Submassive	Systolic BP ≥90 mm Hg and either right ventricular dysfunction or myocardial necrosis
		Massive	Systolic blood pressure <90 mm Hg for >15 minutes or requiring inotropic support
2019	ESC Acute Pulmonary Embolism Risk Scheme ²	Low risk	Nonelevated risk score (eg, PESI class I-II or sPESI=0) Normal right ventricle on imaging
		Intermediate-low risk	Elevated risk score (eg, PESI class III-IV or sPESI ≥1) None or 1 positive of either troponin or right ventricular dysfunction on imaging
		Intermediate-high risk	Elevated risk score (eg, PESI class III-IV or sPESI ≥1) Both positive troponin and right ventricular dysfunction on imaging
		High risk	Hemodynamic instability
		Very high risk	Hemodynamic collapse
2026	AHA/ACC Acute PE Clinical Categories	A	Subclinical – incidental and asymptomatic PE
		B	Symptomatic PE with low clinical severity score (eg, PESI class I-II, sPESI=0, Hestia=0)
		C	Symptomatic PE with elevated clinical severity score (eg, PESI class III-V, sPESI ≥1, Hestia ≥1)
		D	Incipient cardiopulmonary failure (eg, normotensive shock)
		E	Cardiopulmonary failure



AHA/ACC Acute PE Clinical Categories



- 2. In hemodynamically stable patients diagnosed with acute PE in AHA/ACC PE Categories C and D, using a validated PE-specific risk score is reasonable to identify patients with a higher risk for short-term adverse outcomes.⁵⁻⁸
- 3. In hemodynamically stable patients diagnosed with acute PE in AHA/ACC PE Categories C and D, the National Early Warning Score (NEWS) and its updated version, NEWS2, may be reasonable alternatives to a PE-specific risk score to identify patients with a higher risk for short-term adverse outcomes who may require monitoring for clinical deterioration.⁹⁻¹²

TN I
D-Dimero
Disfunzione V-DX
PESI
sPESI
Geneve
Bova Score
Hestia Criteria
CPES Score
Shock Index
NEWS – NEWS2

Sesso Femminile
Età < 40
Gravidanza/Puerperio
Eta > 80
Neoplasie
MVC-TV
M. Reumatologiche
Trombofilia nota; Deficit Prot C,S
Anti-Trombina III;
Iperviscosità ematica
Chirurgia Maggiore o Ortopedica
Immobilità
Obesità
Ictus



Possible Members of the PERT

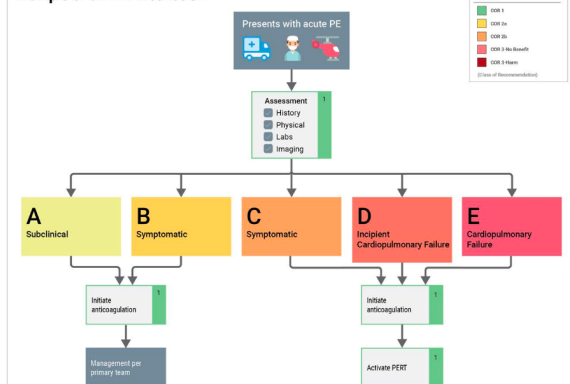


6.8 Recommendations for multidisciplinary pulmonary embolism teams

Recommendation	Class ^a	Level ^b
Set-up of a multidisciplinary team and a programme for the management of high- and (in selected cases) intermediate-risk PE should be considered, depending on the resources and expertise available in each hospital.	IIa	C

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Example of a PERT Activation



4.1.4. Pulmonary Embolism Response Team

Recommendation for PERT

Referenced studies that support the recommendation are summarized in the Evidence Table.

COR	LOE	Recommendations
1	B-NR	1. In patients with acute PE who are at increased risk of adverse outcomes (ie, AHA/ACC PE Categories C-E)*, a multidisciplinary PERT assessment is recommended to improve in-hospital clinical care delivery. ¹⁻¹⁸



Terapia medica > anticoagulazione

Terapia Interventistica

Terapia «ibrida»



4.4.3. Mechanical Thrombectomy

Recommendations for Mechanical Thrombectomy

Referenced studies that support recommendations are summarized in the Evidence Table.

COR	LOE	Recommendations
2a	B-NR	1. In patients with acute PE in AHA/ACC PE Category E1, it is reasonable to choose MT plus anticoagulation over anticoagulation alone to prevent further clinical decompensation and acute mortality. ¹⁻³
2b	B-NR	2. In patients with acute PE in AHA/ACC PE Categories D1-2 in whom advanced therapy is being considered, MT plus anticoagulation may be considered over anticoagulation alone to prevent further clinical deterioration. ⁴⁻⁶
2b	C-LD	3. In patients with acute PE in AHA/ACC PE Categories C2-3, the benefit of MT plus anticoagulation compared with anticoagulation alone is unclear in preventing short-term fatal/nonfatal clinical deterioration and improving long-term survival and functional capacity. ⁷
2b	B-NR	4. In patients with acute PE in AHA/ACC PE Categories D1-E1 in whom advanced therapy is being considered, the efficacy of MT to reduce short-term fatal/nonfatal clinical deterioration and improve long-term survival, functional capacity, and quality of life over systemic thrombolysis is unclear, but MT may be considered over systemic thrombolysis to reduce major bleeding risks. ^{3,8}
3: No Benefit	C-EO	5. In patients with acute PE in AHA/ACC PE Categories A-C1, MT is not recommended over anticoagulation alone for improving clinical outcomes or symptoms.

4.2.4. Mechanical Circulatory Support

Recommendations for Mechanical Circulatory Support

Referenced studies that support recommendations are summarized in the Evidence Table.

COR	LOE	Recommendations
1	B-NR	1. In patients with known or suspected acute PE on VA-ECMO, continuation of parenteral systemic anticoagulation is recommended in the absence of bleeding to prevent further thrombotic or embolic complications. ^{1,2}
2a	B-NR	2. In patients with acute, refractory cardiogenic shock as a result of known or suspected acute PE (AHA/ACC PE Category E2), it is reasonable to institute VA-ECMO, provided appropriate resources are available, to stabilize hemodynamics and improve oxygenation. ³⁻⁶
2b	C-LD	3. In patients with acute PE in AHA/ACC PE Category E2 who are placed on VA-ECMO support, the usefulness of additional advanced therapies is not well established. ⁷⁻⁹

AHA GL 2026

Treatment in the acute phase

When oral anticoagulation is initiated in a patient with PE who is eligible for a NOAC (apixaban, dabigatran, edoxaban, or rivaroxaban), a NOAC is the recommended form of anticoagulant treatment.

Set-up of multidisciplinary teams for management of high-risk and selected cases of intermediate-risk PE should be considered, depending on the resources and expertise available in each hospital.

ECMO may be considered, in combination with surgical embolectomy or catheter-directed treatment, in refractory circulatory collapse or cardiac arrest.

ESC GL 2019



INTERVENTISTICA PERCUTANEA

- FLOWTRIEVER
- PENUMBRA
- EKOS (EKOSONIC ENDOVASCULAR SYSTEM)



PERIPHERAL INTERVENTIONS
CLINICAL RESEARCH

EuroIntervention 2023;18:1201-1212 published online ahead of print Sep

Acute outcomes for the full US cohort of the FLASH mechanical thrombectomy registry in pulmonary embolism

Catalin Toma^{1*}, MD; Wissam A. Jaber², MD; Mitchell D. Weinberg³, MD, MBA; Matthew C. Bunte⁴, MD, MS; Sameer Khandhar⁵, MD; Brian Stegman⁶, MD; Sreedevi Gondi⁷, MD; Jeffrey Chambers⁸, MD; Rohit Amin⁹, MD; Daniel A. Leung¹⁰, MD; Herman Kado¹¹, MD; Michael A. Brown¹², MD; Michael G. Sarosi¹³, MD; Ambarish P. Bhat¹⁴, MD; Jordan Castle¹⁵, MD; Michael Savin¹⁶, MD; Gary Siskin¹⁷, MD; Michael Rosenberg¹⁸, MD; Christina Fanola¹⁹, MD, MSc; James M. Horowitz²⁰, MD; Jeffrey S. Pollak²¹, MD; for the FLASH investigators

Abstract

Background: Evidence supporting interventional pulmonary embolism (PE) treatment is needed.

Aims: We aimed to evaluate the acute safety and effectiveness of mechanical thrombectomy for intermediate- and high-risk PE in a large real-world population.

Methods: FLASH is a multicentre, prospective registry enrolling up to 1,000 US and European PE patients treated with mechanical thrombectomy using the FlowTriever System. The primary safety endpoint is a major adverse event composite including device-related death and major bleeding at 48 hours, and intra-procedural adverse events. Acute mortality and 48-hour outcomes are reported. Multivariate regression analysed characteristics associated with pulmonary artery pressure and dyspnoea improvement.

Results: Among 800 patients in the full US cohort, 76.7% had intermediate-high risk PE, 7.9% had high-risk PE, and 32.1% had thrombolytic contraindications. Major adverse events occurred in 1.8% of patients. All-cause mortality was 0.3% at 48-hour follow-up and 0.8% at 30-day follow-up, with no device-related deaths. Immediate haemodynamic improvements included a 7.6 mmHg mean drop in mean pulmonary artery pressure (-23.0% ; $p<0.0001$) and a 0.3 L/min/m² mean increase in cardiac index (18.9%; $p<0.0001$) in patients with depressed baseline values. Most patients (62.6%) had no overnight intensive care unit stay post-procedure. At 48 hours, the echocardiographic right ventricle/left ventricle ratio decreased from 1.23 ± 0.36 to 0.98 ± 0.31 ($p<0.0001$ for paired values) and patients with severe dyspnoea decreased from 66.5% to 15.6% ($p<0.0001$).

Conclusions: Mechanical thrombectomy with the FlowTriever System demonstrates a favourable safety profile, improvements in haemodynamics and functional outcomes, and low 30-day mortality for intermediate- and high-risk PE.



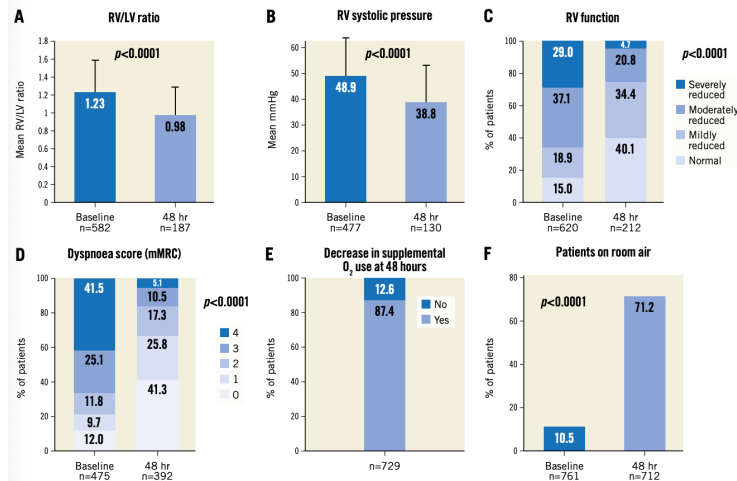
PE risk stratification	High-risk PE	63 (7.9)	797
	Intermediate-risk PE	734 (92.1)	797
	Intermediate-high	611 (83.2)	734
	Intermediate-low	59 (8.0)	734
	Intermediate (not further classified)	64 (8.7)	734
sPESI score		1.6±1.1	751
sPESI = 0		123 (16.4)	751
sPESI ≥1		628 (83.6)	751
PE location at screening	Saddle PE	319 (40.0)	798
	Unilateral PE	68 (8.5)	798
	Bilateral PE	411 (51.5)	798
Concomitant DVT		512 (65.0)	788
Proximal only		152 (29.9)	508
Distal only		266 (52.4)	508
Both		90 (17.7)	508
Positive biomarker(s) [‡]		720 (94.6)	761
RV/LV ratio (CTPA)		1.56±0.47	624
RV/LV ratio (echo)		1.23±0.36	582
RV/LV ratio (CTPA or echo composite [§])		1.50±0.46	756
Elevated RV/LV ratio >0.9		734 (97.1)	756
Depressed cardiac index (<2.0 L/min/m ²)		176 (25.9)	680
Severe PHTN (sPAP ≥70 mmHg)		99 (12.7)	781



Table 3. Safety and mortality outcomes.

Safety outcomes at 48 hours		% (n/N)
Major adverse event composite		1.8 (14/788)
Device-related death		0.0 (0/788)
Major bleeding		2.7 (21/788)
Intraprocedural device- or procedure-related AE		0.4 (3/788)
Clinical deterioration		0.3 (2/788)
Pulmonary vascular injuries		0.0 (0/788)
Cardiac injuries		0.1 (1/788)
Serious adverse event		4.3 (34/791)
All-cause mortality		% (n/N)
At 48-hour follow-up		0.3 (2/794)
At 30-day follow-up		0.8 (6/734)

AE: adverse event



Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE



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

Mitchell J. Silver¹, DO; C. Michael Gibson, MD; Jay Giri², MD, MPH; Sameer Khandhar, MD; Wissam Jaber³, MD; Catalin Toma, MD; Bushra Mina, MD; Terry Bowers⁴, MD; Lee Greenspon⁵, MD; Herman Kado, MD; David M. Zlotnick, MD; Mithun Chakravarthy, MD; Aaron R. DuCoffe, MD; Paul Butros, MD; James M. Horowitz⁶, MD

Major bleeding†	15 (24.6%; 14.5%–37.3%)
BARC 3b	16
BARC 3c	2
BARC 5a	0
BARC 5b	1

Table 2. Primary End Point in the FlowTrieve Arm

	FlowTrieve arm (n=53)	Performance goal
Primary end point*	9 (17.0%†; 8.1%–9.8%)	32.0%
Primary end point components*		
All-cause mortality	1 (1.9%; 0.0%–	28.5%

Table 3. Primary End Point in the Context Arm

	Context arm (n=61)
Primary end point*	39 (63.9%; 50.6%–75.8%)
Primary end point components*	
All-cause mortality	18 (29.5%; 18.5%–42.6%)
Cardiovascular death	16



The NEW ENGLAND

JC

ESTABL

Ultras

4.4.2. Catheter-Directed Thrombolysis

Recommendations for Catheter-Directed Thrombolysis
Referenced studies that support recommendations are summarized in the Evidence Table.

COR	LOE	Recommendations
2a	C-LD	1. In patients with acute PE in AHA/ACC PE Category E1, CDL plus anticoagulation is reasonable to prevent further clinical deterioration and early mortality. ^{1,8}
2b	B-NR	2. In patients with acute PE in AHA/ACC PE Categories D1-2 in whom advanced therapy is being considered, CDL plus anticoagulation may be considered to prevent further clinical deterioration. ²

Table 4. Mortality
Population).*

Event

Death from any

Outcomes through

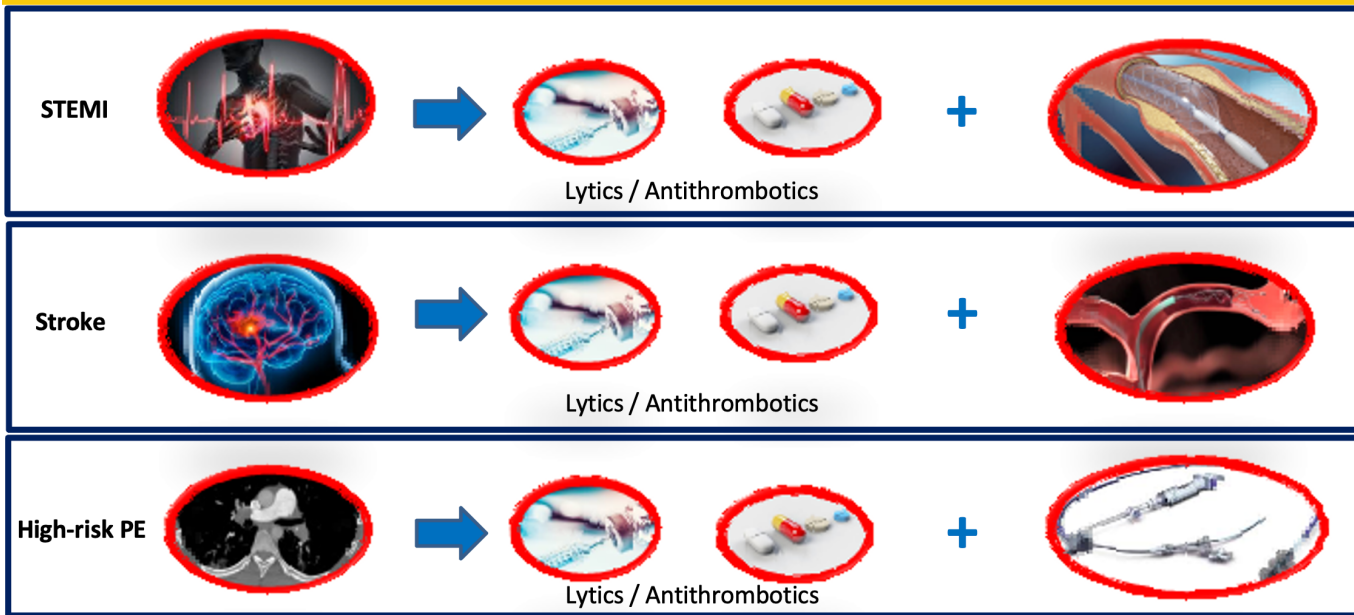
Death from any cause	5 (1.8)	3 (1.1)	1.7 (0.4–6.9)
Symptomatic recurrence of pulmonary embolism	1 (0.4)	2 (0.7)	0.5 (0.0–5.5)
Any serious adverse event†	40 (14.8)	44 (16.2)	0.9 (0.6–1.3)§

The mean total dose of alteplase was 8.85 ± 0.67 mg for the 20 patients who had catheter placement on one side only and 16.92 ± 3.47 mg for the 251 patients who had catheter placement into both the right and left pulmonary arteries; the mean total infusion rate was 7.16 ± 0.52 hours. Activated heparin was the most commonly used anticoagulant agent in both the intervention group (in 71.6% of the patients) and the control group (in 55.7%), followed by low-molecular-weight heparin (used in 50.6% and 53.9%, respectively).

Relative Major Bleeding Events through 30 Days (Treated Population).*

	Intervention (N = 271) no. of patients (%)	Control (N = 271) no. of patients (%)	Relative Risk (95% CI)†	P Value‡
according to ISTH criteria				
Major bleeding	10 (3.7)	4 (1.5)	2.5 (0.8–7.9)	0.17
Minor bleeding	11 (4.1)	6 (2.2)	1.8 (0.7–4.9)	0.32
Severe bleeding	11 (4.1)	8 (3.0)	1.4 (0.6–3.4)	0.64
Severe bleeding within 7 days according to GUSTO criteria	9 (3.3)	4 (1.5)	2.3 (0.7–7.2)	0.26
Death				
Within 7 days	1 (0.4)	0	NE	1.00
Within 30 days	1 (0.4)	0	NE	1.00
Intracranial hemorrhage				
Within 7 days	0	0	NE	1.00
Within 30 days	0	0	NE	1.00

Life threatening events: from drug only to pharmaco-invasive approach



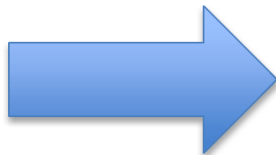
(Courtesy of Thomas Cuisset) Timone Hospital - Marseille



« NSTEMI-like » approach

Very- high risk NSTEMI
Invasive strategy < 2h

High risk PE with Lytics CI
Thrombectomy < 2h

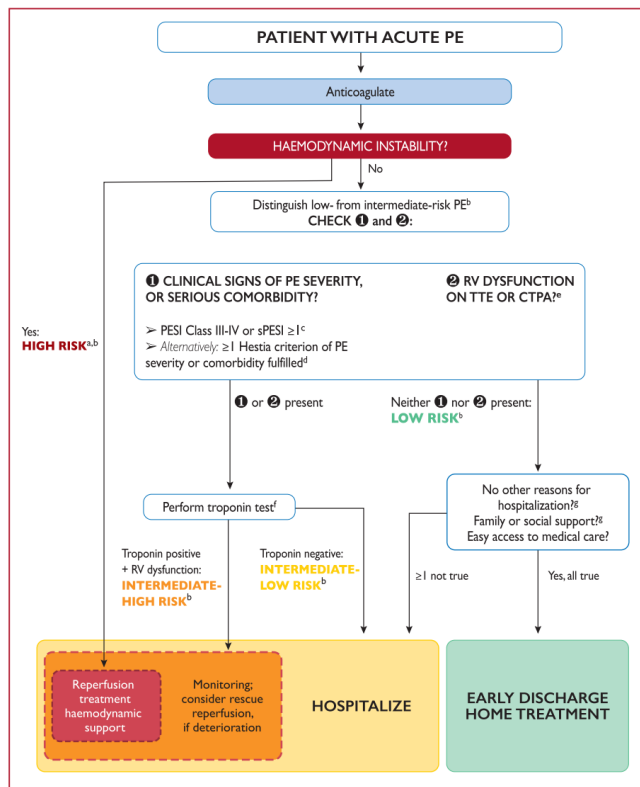


High risk NSTEMI
Invasive strategy < 24h

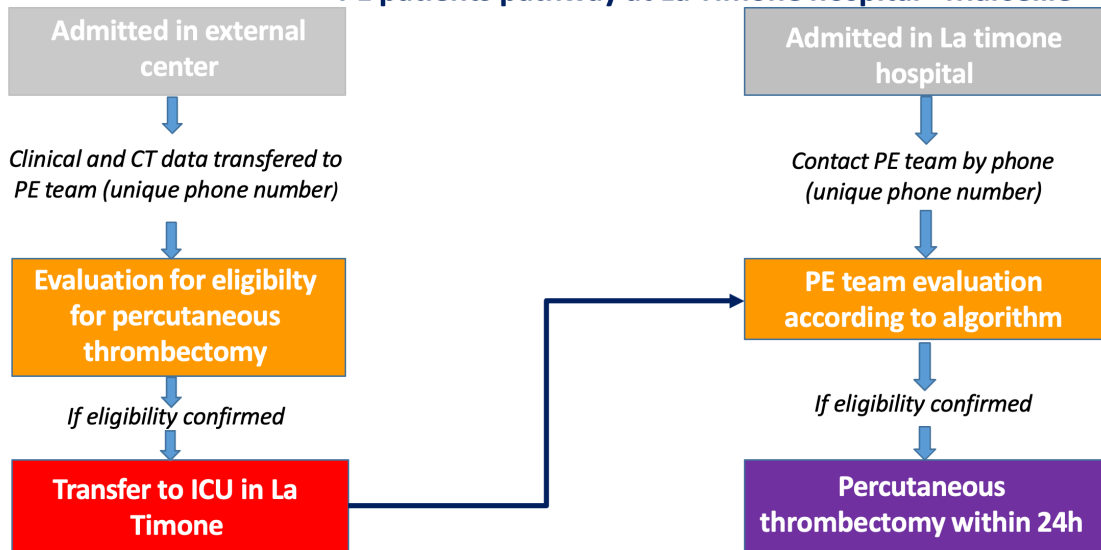
Int High risk NSTEMI
Thrombectomy < 24h

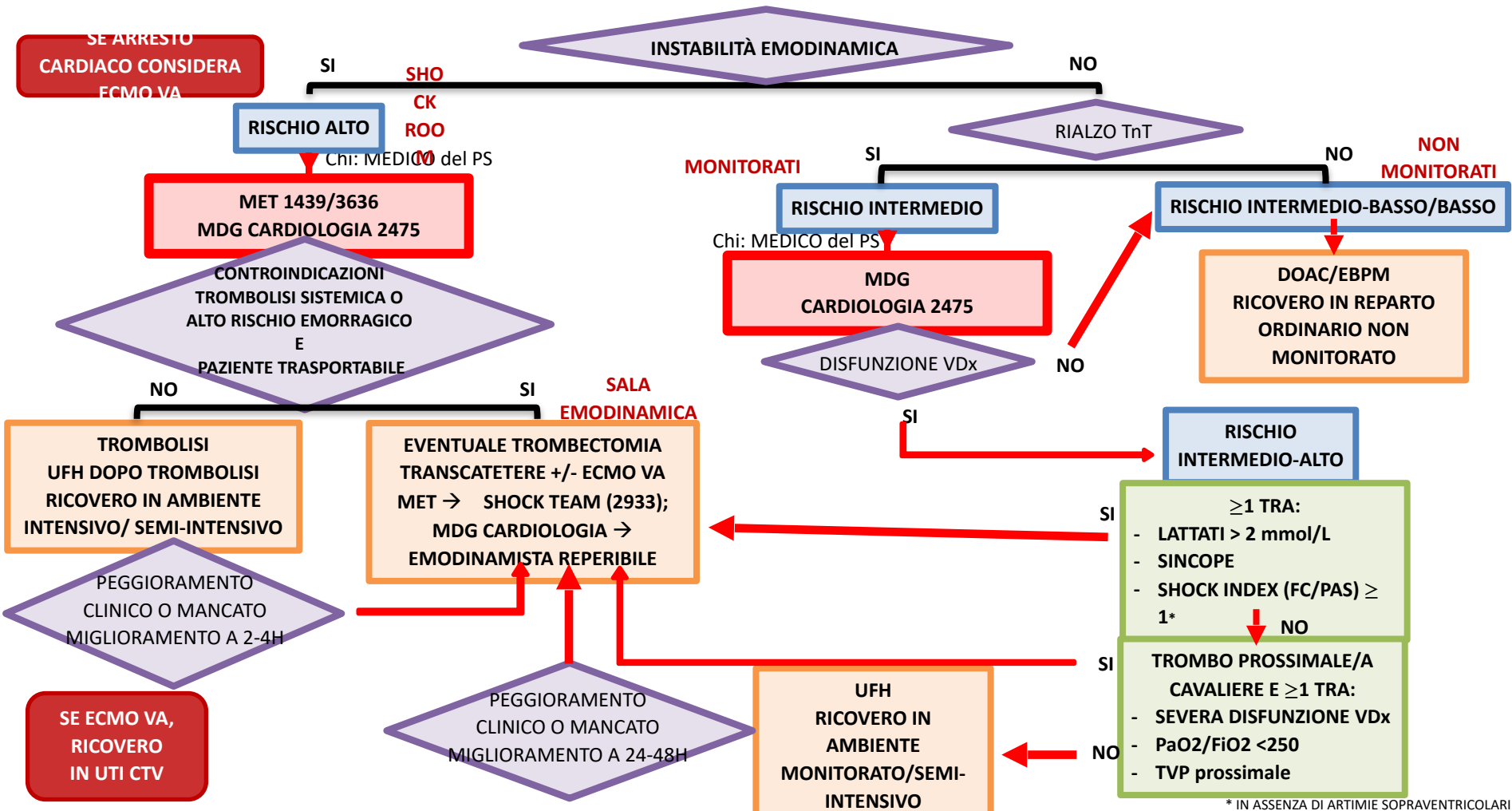
(Courtesy of Thomas Cuisset) Timone Hospital - Marseille





PE patients pathway at La Timone hospital - Marseille





THM

Il Rischio Intermedio rappresenta una variabile altamente dinamica e pericolosa

La stratificazione del R all'esordio é cruciale per il destino del paziente con EP acuta

L'attivazione del PERT è determinante per il corretto e veloce percorso del paziente

L'utilizzo di tecniche interventistiche è sicura ed efficace

A mio parere la Trombectomia dovrebbe essere estesa a tutti i pz **SINTOMATICI** con R > Basso





Grazie per l'attenzione....

domenico.tavella@aovr.veneto.it









2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS)

The Task Force for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology (ESC)

Authors/Task Force Members: Stavros V. Konstantinides* (Chairperson) (Germany/Greece), Guy Meyer* (Co-Chairperson) (France), Cecilia Becattini (Italy), Héctor Bueno (Spain), Geert-Jan Geersing (Netherlands), Veli-Pekka Harjola (Finland), Menno V. Huisman (Netherlands), Marc Humbert[†] (France), Catriona Sian Jennings (United Kingdom), David Jiménez (Spain), Nils Kucher (Switzerland), Irene Marthe Lang (Austria), Mareike Lankeit (Germany), Roberto Lorusso (Netherlands), Lucia Mazzolai (Switzerland), Nicolas Meneveau (France), Fionnuala Ní Ainle (Ireland), Paolo Prandoni (Italy), Piotr Pruszczyk (Poland), Marc Righini (Switzerland), Adam Torbicki (Poland), Eric Van Belle (France), and José Luis Zamorano (Spain)

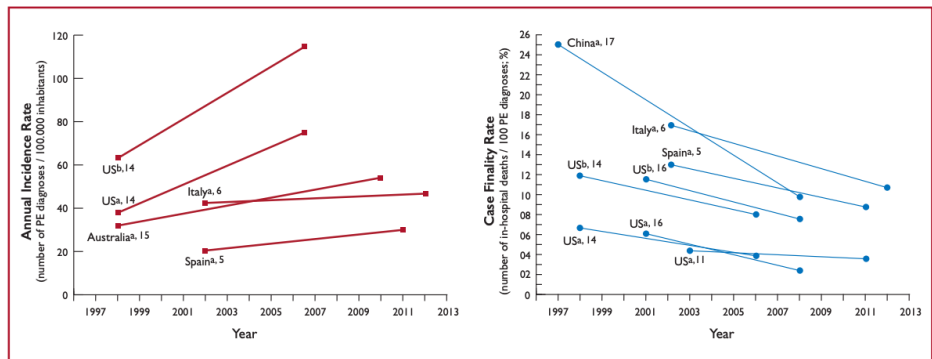


Figure 1 Trends in annual incidence rates (left panel) and case fatality rates (right panel) of pulmonary embolism around the world, based on data retrieved from various references.^{5,6,11,14–17} Reproduced with permission from JACC 2016;67:976–90. PE = pulmonary embolism; US = United States.

[†]PE listed as principal diagnosis.

^aAny listed code for PE was considered.

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Table 8 Classification of pulmonary embolism severity and the risk of early (in-hospital or 30 day) death

Early mortality risk		Indicators of risk			
		Haemodynamic instability ^a	Clinical parameters of PE severity and/or comorbidity: PESI class III–V or sPESI $\geq$ I	RV dysfunction on TTE or CTPA ^b	Elevated cardiac troponin levels ^c
High		+	(+) ^d	+	(+)
Intermediate	Intermediate–high	–	+ ^e	+	+
	Intermediate–low	–	+ ^e	One (or none) positive	
Low		–	–	–	Assesment optional; if assessed, negative

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CLINICAL PRACTICE GUIDELINES

2026 AHA/ACC/ACCP/ACEP/CHEST/SCAI/SHM/SIR/SVM/SVN Guideline for the Evaluation and Management of Acute Pulmonary Embolism in Adults: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

La principale novità riguarda la collocazione delle terapie avanzate. Trombolisi sistemica, trombolisi catetere-diretta, trombectomia meccanica ed embolectomia chirurgica sono raccomandate soprattutto nei pazienti in Categoria E1 e considerate nei pazienti in Categoria D1-D2.

La nuova classificazione tenta così di superare i limiti delle categorie di rischio tradizionali — ad esempio nei pazienti a rischio intermedio-alto, spesso caratterizzati da un decorso benigno con la sola anticoagulazione — e di identificare meglio quell'area grigia rappresentata dai pazienti in **shock normoteso** o da quelli in **prevedibile o attuale rapido deterioramento**, frequentemente sottotrattati o gestiti in modo eterogeneo.

Inevitabile conseguenza di questa nuova "grammatica" dell'EP acuta è la **conferma del ruolo strategico dei PERT** (Pulmonary Embolism Response Teams). L'EP viene definitivamente riconosciuta come una **patologia multidisciplinare**, che coinvolge pronto soccorso, medicina interna, pneumologia, cardiologia, radiologia interventistica, terapia intensiva e chirurgia. In questo contesto, l'esito clinico dipende non solo dalla terapia, ma dalla capacità del sistema di organizzare tempestivamente l'appropriato percorso assistenziale.

4.1.4. Pulmonary Embolism Response Team

Recommendation for PERT Referenced studies that support the recommendation are summarized in the Evidence Table.		
COR	LOE	Recommendations
1	B-NR	1. In patients with acute PE who are at increased risk of adverse outcomes (ie, AHA/ACC PE Categories C-E)*, a multidisciplinary PERT assessment is recommended to improve in-hospital clinical care delivery. ¹⁻¹⁸

Le nuove categorie

Le nuove categorie includono:

Categoria A: embolia incidentale e asintomatica

Categoria B: pazienti sintomatici a basso rischio (B1: EP subsegmentaria; B2: EP segmentaria)

Categoria C: pazienti sintomatici con elevata severità clinica (C1: normale funzione del ventricolo destro e biomarcatori negativi; C2: disfunzione del ventricolo destro o ≥ 1 biomarcatore alterato; C3: disfunzione del ventricolo destro e ≥ 1 biomarcatore alterato; per tutti con o senza modificatore respiratorio)

Categoria D: insufficienza cardiopolmonare incipiente (D1: ipotensione transitoria; D2: shock normoteso; per tutti con o senza modificatore respiratorio)

Categoria E: insufficienza cardiopolmonare conclamata (E1: ipotensione persistente o ricorrente con shock cardiogeno; E2: shock cardiogeno refrattario o arresto cardiaco; per tutti con o senza modificatore respiratorio)



PESI (Pulmonary Embolism Severity Index): Prevede 11 variabili cliniche (età, sesso, patologie concomitanti, parametri vitali). Le classi I e II identificano un basso rischio, mentre le classi dalla III alla V indicano un rischio via via maggiore

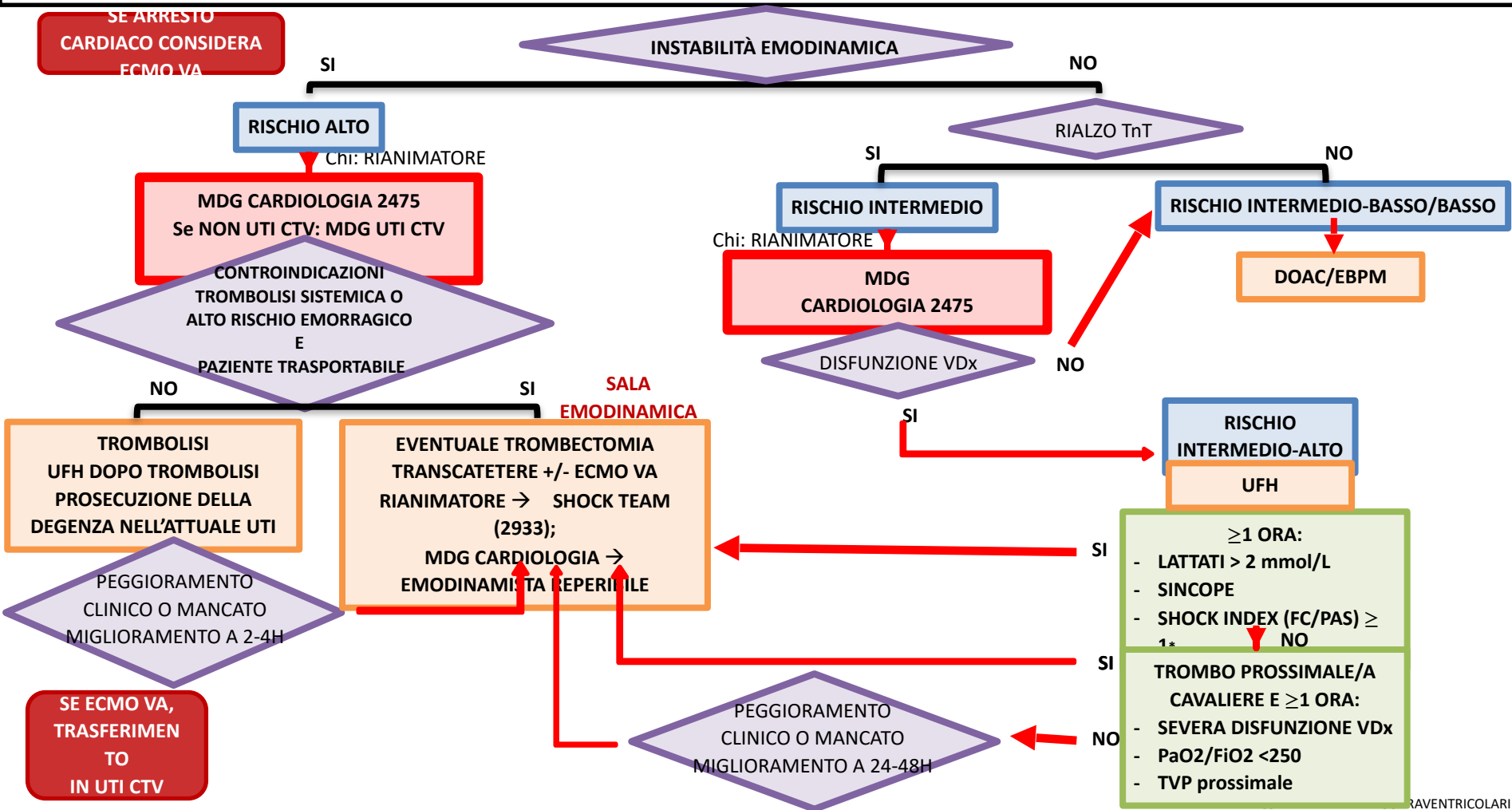
sPESI (simplified PESI): Una versione semplificata che considera 6 parametri (tra cui età > 80 anni, frequenza cardiaca, pressione arteriosa e saturazione) per definire rapidamente i pazienti a basso rischio (0 punti) o ad alto rischio (≥ 1 punto).







DIAGNOSI DI EP ACUTA CON TROMBO PROSSIMALE IN TERAPIA INTENSIVA



DIAGNOSI DI EP ACUTA CON TROMBO PROSSIMALE IN REPARTO

