

IX CONGRESSO NAZIONALE ECOCARDIOCHIRURGIA 2017

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Il trattamento delle urgenze cardiorespiratorie time-dipendenti

*Perché implementare il trattamento della TEP a rischio
intermedio con Trattamento Farmaco Meccanico ?*

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I have the following potential conflicts of interest to report:

Consulting: Boston Scientific – EKOS -

- Interventional “Cardiologist”

Acute MI 

Acute Aortic Syndrome 

High Risk PE 

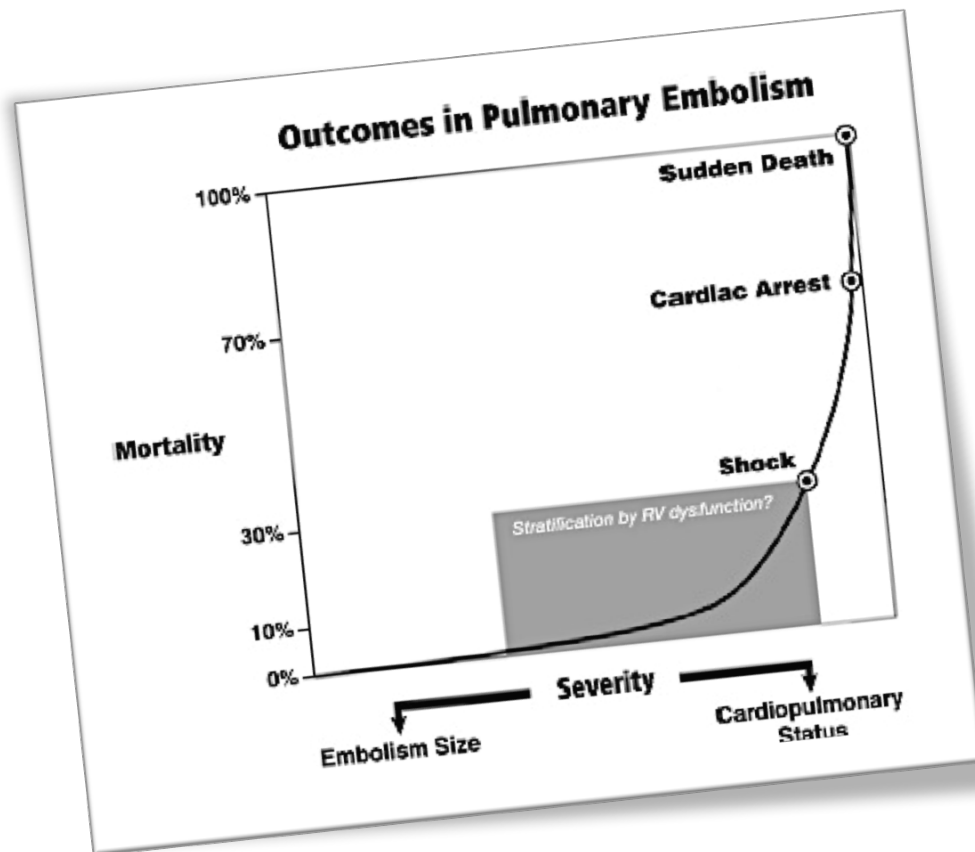
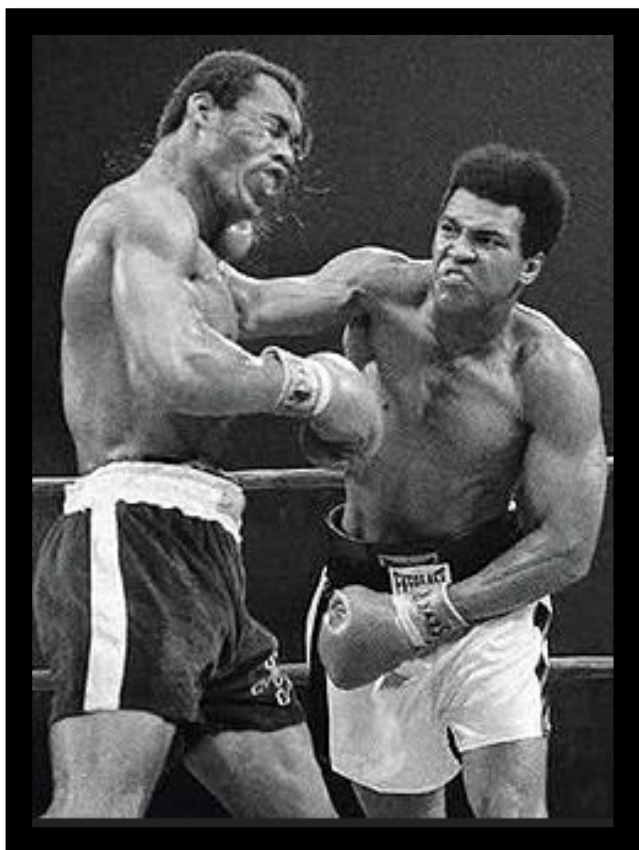
Intermediate/High risk PE ?

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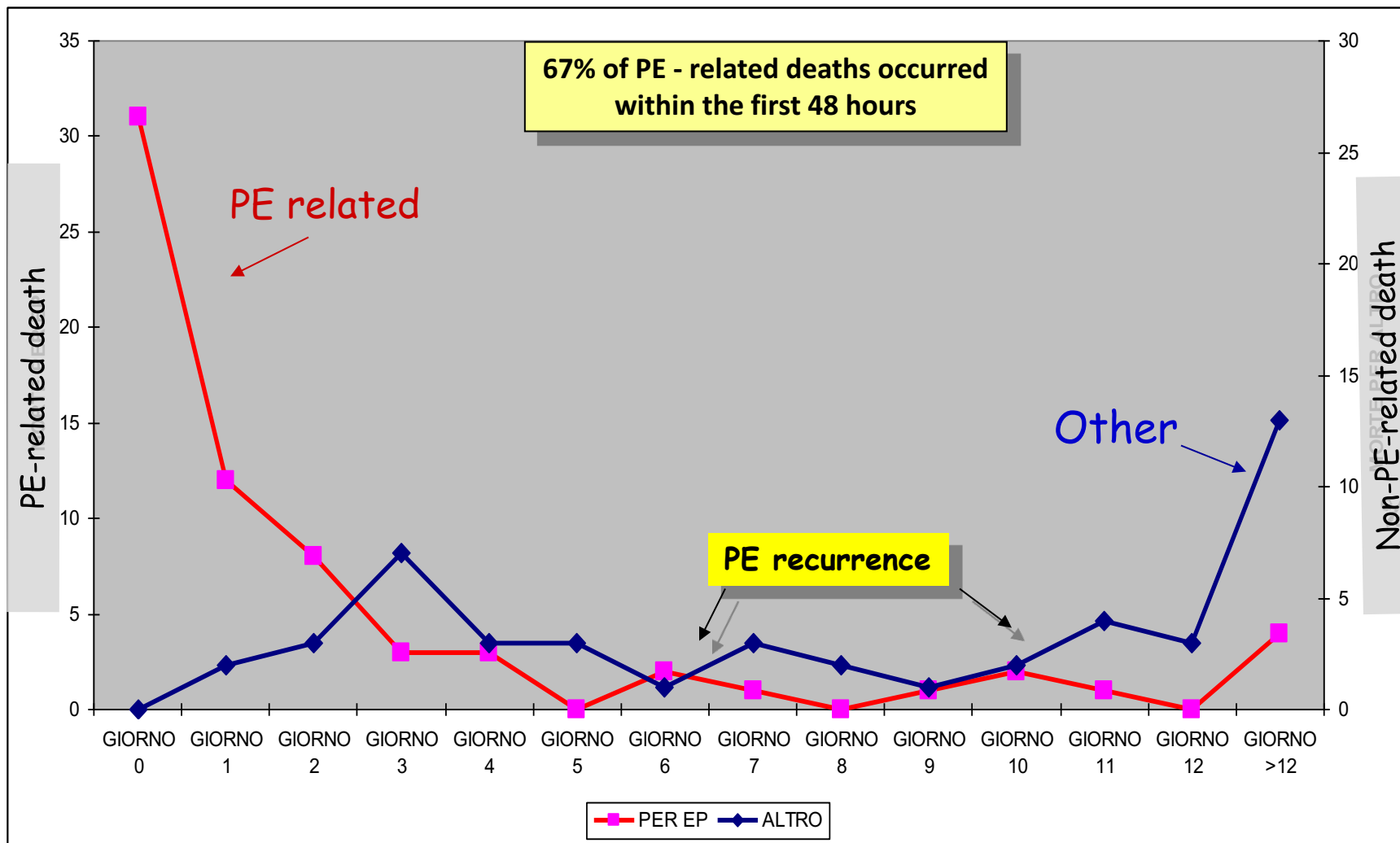


Challenges in diagnosis and treatment of Pulmonary Embolism

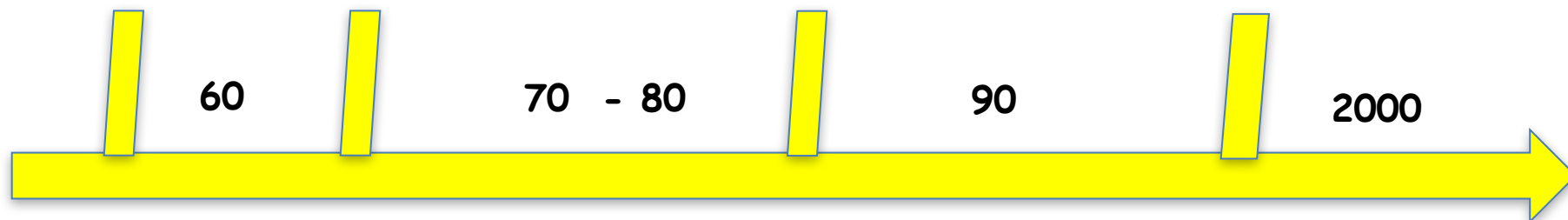


Wood, Chest 2002

Cause of death in the first days and over time



Management of acute PE



Eparin

Thrombolysis

Thrombolysis
Surgical therapy

Interventional



Era of observation

Era of interventional

Management of acute PE

Early mortality risk		Risk parameters and scores			
		Shock or hypotension	PESI class III-V or sPESI ≥ 1 ^a	Signs of RV dysfunction on an imaging test ^b	Cardiac laboratory biomarkers ^c
High		+	(+) ^d	+	(+) ^d
Intermediate	Intermediate-high	-	+	Both positive	
	Intermediate-low	-	+	Either one (or none) positive ^a	
Low		-	-	Assessment optional; if assessed, both negative ^a	



Interaction between specialists in diagnostic and therapeutic strategy of the PE

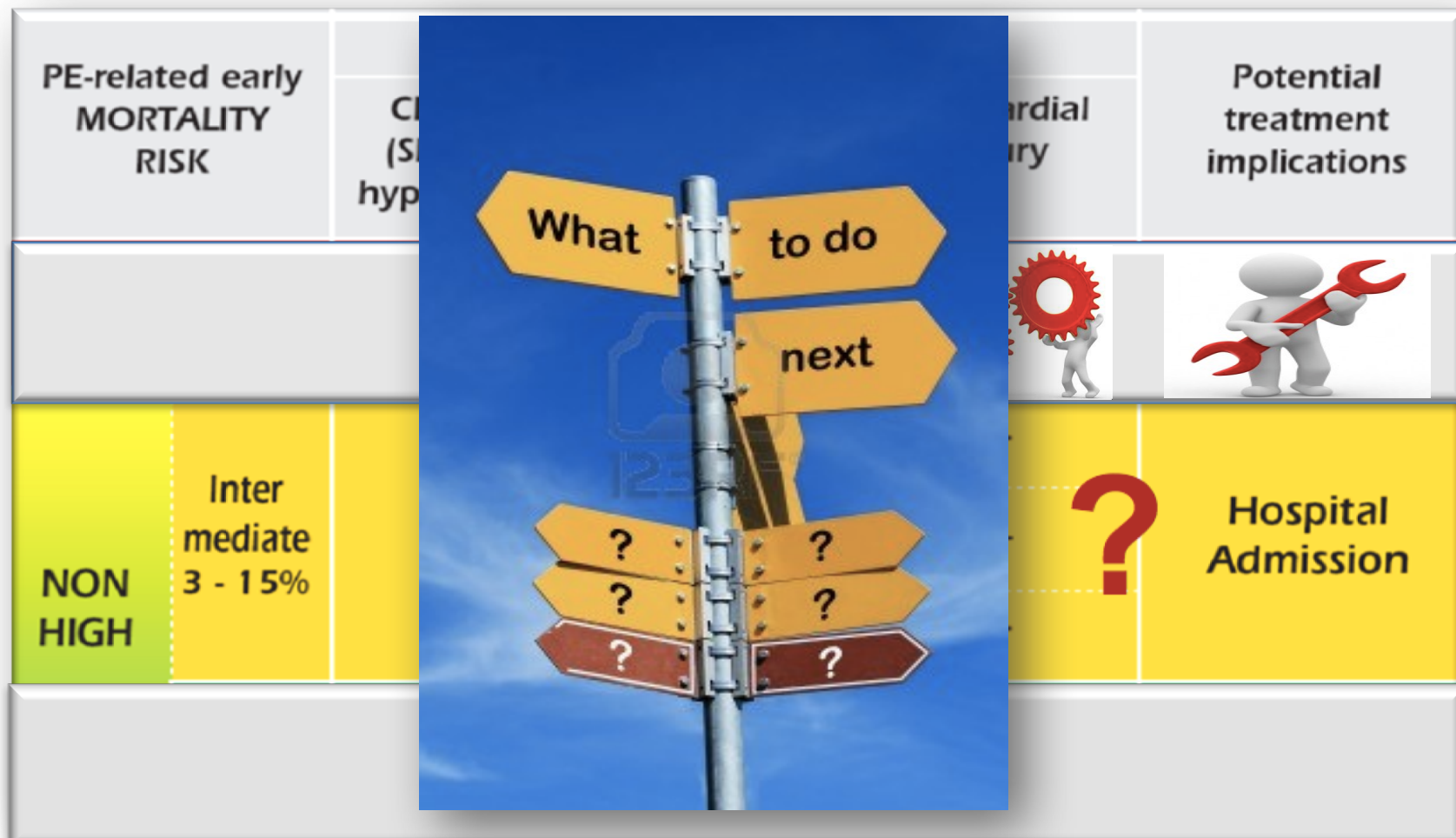
PE-related early MORTALITY RISK	RISK MARKERS			Potential treatment implications
	CLINICAL (Shock or hypotension)	RV Dysfunction	Myocardial injury	
Low <1%	—	—	—	Early discharge or home treatment



PE-related early MORTALITY RISK	RISK MARKERS			Potential treatment implications
	CLINICAL (Shock or hypotension)	RV Dysfunction	Myocardial injury	
HIGH > 15%	+	(+)*	(+)*	Thrombolysis or Embolectomy

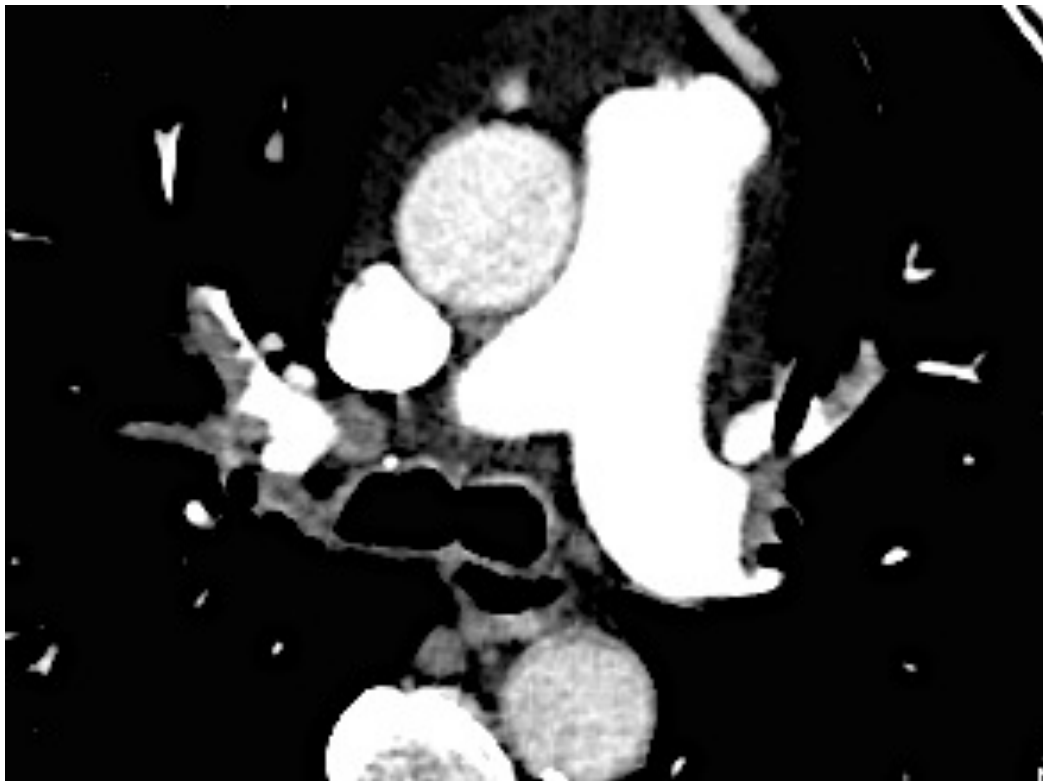


Interaction between specialists in diagnostic and therapeutic strategy of the PE



Intermediate-high risk patient

- 45 years old male
- Dispnea
- BP 120
- FC 95
- Sat 95%
- VD +/-
- Biomarkers -



ORIGINAL ARTICLE

Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism

ABSTRACT

BACKGROUND

The role of fibrinolytic therapy in patients with intermediate-risk pulmonary embolism is controversial.

METHODS

In a randomized, double-blind trial, we compared tenecteplase plus heparin with placebo plus heparin in normotensive patients with intermediate-risk pulmonary embolism. Eligible patients had right ventricular dysfunction on echocardiography or computed tomography, as well as elevated troponin I or troponin T or hemodynamic decompensation (or other criteria). Major safety outcomes were major extracranial hemorrhage and stroke within 7 days after randomization.

CONCLUSIONS

In patients with intermediate-risk pulmonary embolism, fibrinolytic therapy prevented hemodynamic decompensation but increased the risk of major hemorrhage and stroke. (Funded by the Programme Hospitalier de Recherche Clinique in France and others; PEITHO EudraCT number, 2006-005328-18; ClinicalTrials.gov number, NCT00639743.)

RESULTS

Of 1006 patients who underwent randomization, 506 were assigned to receive tenecteplase plus heparin and 499 to receive placebo plus heparin. Death or hemodynamic decompensation occurred in 32 patients (6.3%) in the tenecteplase group and 6 patients (1.2%) in the placebo group ($P<0.001$). Stroke occurred in 12 patients (2.4%) in the tenecteplase group and was hemorrhagic in 10 patients; 1 patient (0.2%) in the placebo group had a stroke, which was hemorrhagic ($P=0.003$). By day 30, a total of 12 patients (2.4%) in the tenecteplase group and 16 patients (3.2%) in the placebo group had died ($P=0.42$).

N ENGL J MED 370;15 NEJM.ORG APRIL 10, 2014

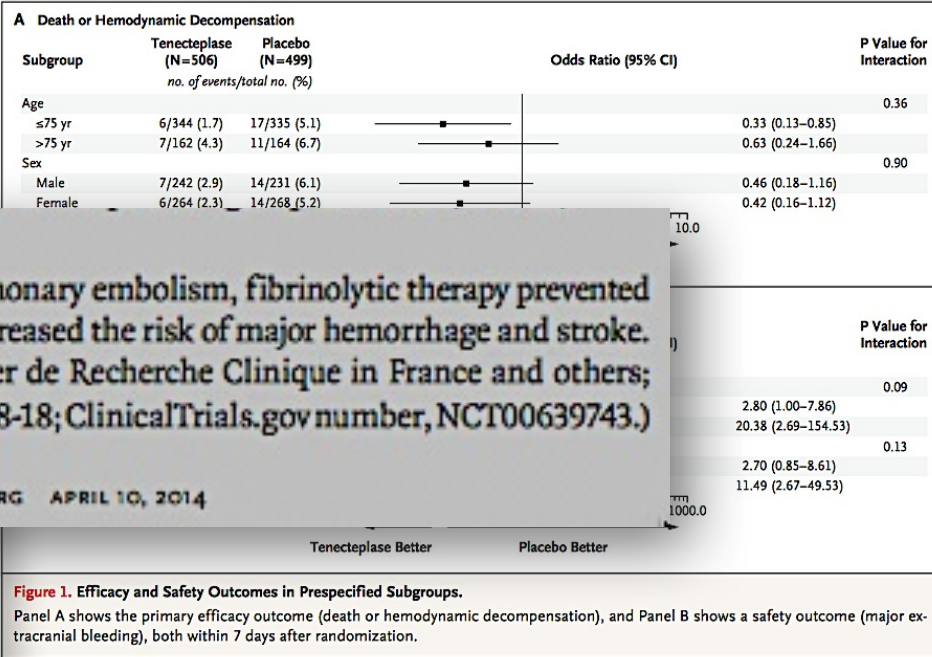


Figure 1. Efficacy and Safety Outcomes in Prespecified Subgroups. Panel A shows the primary efficacy outcome (death or hemodynamic decompensation), and Panel B shows a safety outcome (major extracranial hemorrhage), both within 7 days after randomization.



Thrombolysis for acute intermediate-risk pulmonary embolism: A meta-analysis.

Gao GY¹, Yang P², Liu M³, Ding M⁴, Liu GH⁵, Tong YL⁶, Yang CY⁷, Meng FB⁸.

⊕ Author information

Abstract

BACKGROUND: The use of thrombolytic therapy in patients with intermediate-risk pulmonary embolism is controversial. To compare with anticoagulation alone, no analysis before has determined whether thrombolytic therapy is associated with improved survival or lower incidence of adverse clinical outcomes for intermediate-risk pulmonary embolism.

OBJECTIVE: This meta-analysis was performed to assess mortality benefits, bleeding and recurrent pulmonary embolism risks associated with thrombolytic therapy compared with anticoagulation in patients with intermediate-risk pulmonary embolism.

METHODS: The Web of Science, PubMed, Embase, EBSCO, and the Cochrane Library databases were searched for randomized

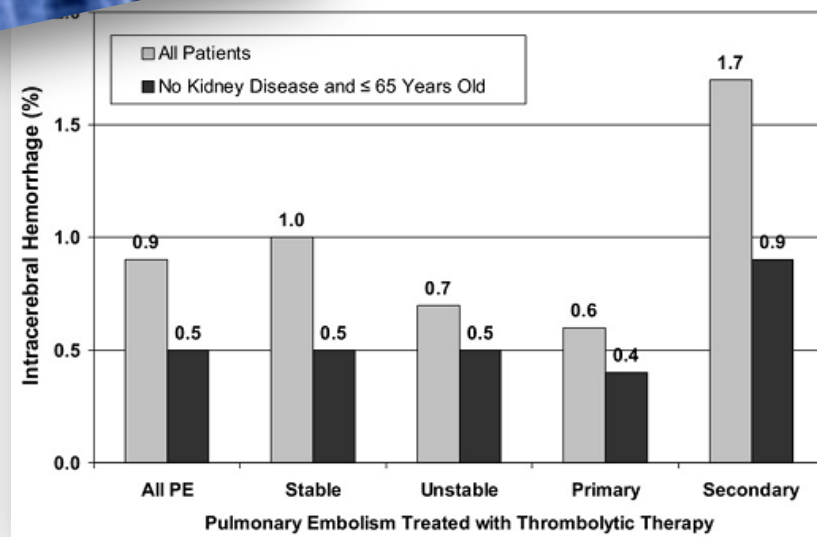
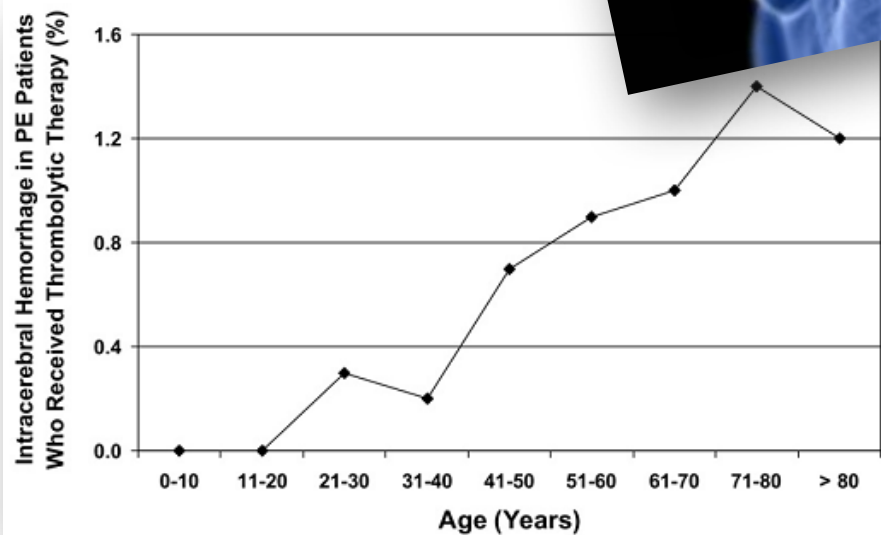
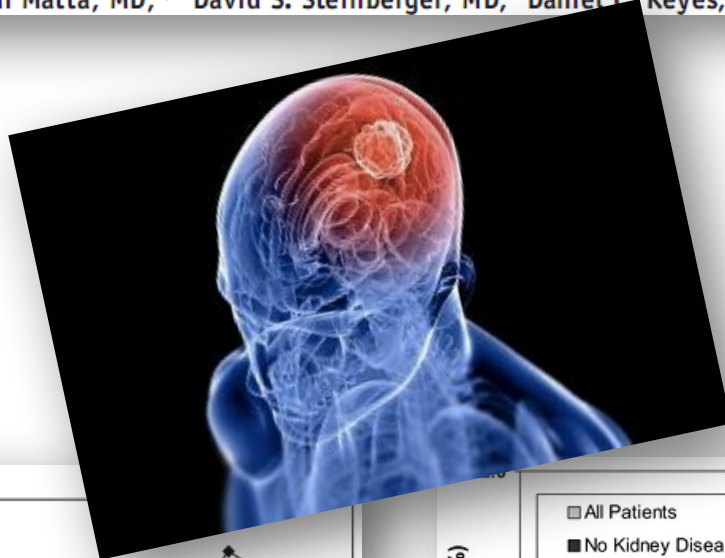
Conclusion

Compared with anticoagulation, thrombolytic therapy in patients with intermediate-risk pulmonary embolism is associated with lower all-cause mortality and recurrent pulmonary embolism risk despite increased major and minor bleeding risks.

1.39% [12/866] vs. 2.92% [26/889]). Compared with anticoagulation, thrombolytic therapy was associated with a higher risk of major (RR, 3.35; 95% CI, 2.03-5.54; 7.80% [64/820] vs. 2.28% [19/834]) and minor (RR, 3.66; 95% CI, 2.77-4.84; 32.78% [197/601] vs. 8.94% [53/593]) bleeding. Furthermore, thrombolytic therapy was associated with a lower incidence of recurrent pulmonary embolism (RR, 0.33; 95% CI, 0.15-0.73; 0.73% [6/826] vs. 2.72% [23/846]).

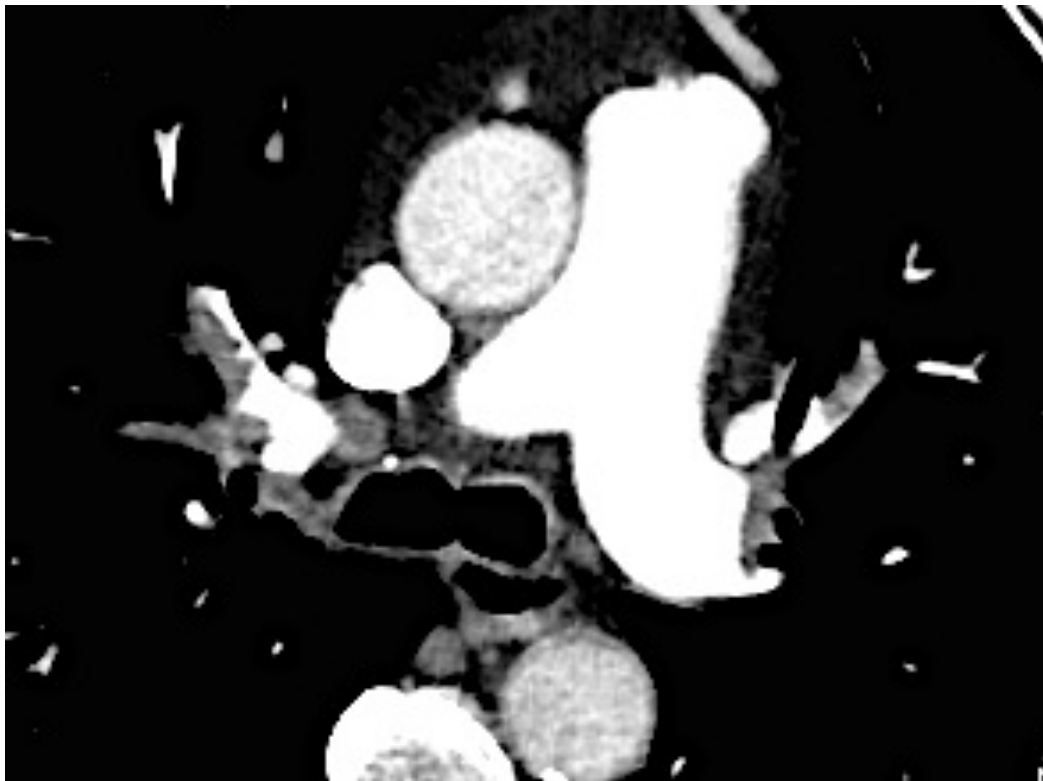
Intracerebral Hemorrhage with Thrombolytic Therapy for Acute Pulmonary Embolism

Paul D. Stein, MD,^{a,b} Fadi Matta, MD,^{a,b} David S. Steinberger, MD,^c Daniel C. Keyes, MD^{d,e}



Intermediate-high risk patient

- 45 years old male
- Dispnea
- BP 120
- FC 95
- Sat 95%
- VD +/-
- Biomarkers -



Catheter-based technique in Intermediate-high-risk patients

“Pharmacomechanical” Therapy



Mechanical Fragmentation



Hydrodynamic



Ultrasound-Accelerated
Fibrinolysis



Suction Embolectomy

PMT in Intermediate-high-risk patients

Ultrasound assisted thrombolysis

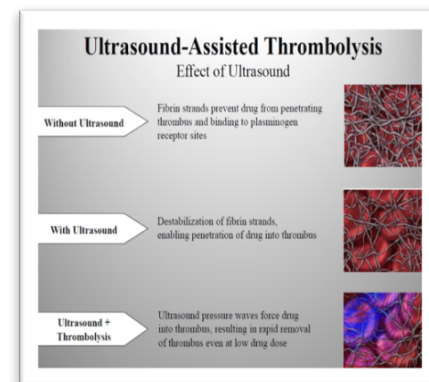
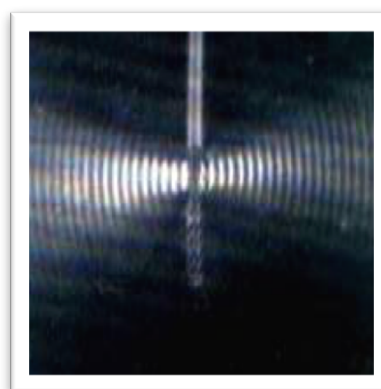
Ekosonic Control Unit



Endovascular device



Active Drug Delivery
Drug is actively driven into clot
by "Acoustic Streaming"



PMT in Intermediate-high-risk patients



European Heart Journal (2014) 35, 758–764
doi:10.1093/eurheartj/ehu029

REVIEW

20th cardiology update

Ultrasound-assisted thrombolysis for acute pulmonary embolism: a systematic review

Rolf P. Engelberger¹ and Nils Kucher^{1,2*}

Table 1 Summary of published studies on ultrasound-assisted thrombolysis for acute pulmonary embolism

First author and year of publication	No. of patients	Patients with high-risk PE	Total rt-PA dose (mg)	Total thrombolysis duration (h)	RV/LV ratio		Mean pulmonary artery pressure (mmHg)		Cardiac index (l/min/m ²)		Relative reduction in pulmonary occlusion score (%)	Bleeding complications		Mortality at 3 months
					Before	After	Before	After	Before	After		Minor	Major	
Chamsuddin et al. (2008) ²⁶	10	NA	21.8	24.8 ± 8.4	NA	NA	NA	NA	NA	NA	NA	2 (20)	0 (0) ^a	0 (0)
Lin et al. (2009) ²⁵	11	2 (18)	17.2 ± 2.4	17.4 ± 5.2	NA	NA	NA	NA	NA	NA	69.0 ^b	0 (0)	0 (0) ^c	1 (9)
Engelhardt et al. (2011) ²⁹	24	5 (21)	33.5 ± 15.5	19.7 ± 8.1	1.33 ± 0.24 ^d	1.0 ± 0.13 ^d	NA	NA	NA	NA	51.1 ^e	2 (8)	4 (17) ^f	0 (0)
Quintana et al. (2013) ²⁷	10	2 (20)	18 (7–38) ^g	20.8 (12–49) ^g	NA	NA	NA	NA	NA	NA	41.9 ^h	2 (20)	0 (0) ⁱ	0 (0)
Kennedy et al. (2013) ²⁸	60	12 (20)	35.1 ± 11.1	19.6 ± 6.0	NA	NA	27 ± 9	20 ± 6	NA	NA	32.0 ^b	1 (2)	1 (2) ^a	4 (7)
Engelberger et al. (2013) ²¹	52	14 (27)	21.0 ± 5.7	15.2 ± 1.7	1.42 ± 0.21 ⁱ	1.06 ± 0.23 ^j	37 ± 9	25 ± 8	2.0 ± 0.7	2.7 ± 0.9	NA	11 (21)	2 (4) ^k	2 (4)
Kucher et al. (2013) ³⁰	30	0 (0)	20.8 ± 3.0	15.0 ± 1.0	1.28 ± 0.19 ^l	0.99 ± 0.17 ^l	30 ± 9	24 ± 7	2.5 ± 0.5	3.9 ± 2.3	NA	3 (10)	0 (0) ^k	0 (0)
Total ^l	197	35 (18)	26.9 ^m	17.8 ^m	1.36 ± 0.21	1.03 ± 0.20	31.3 ± 9.0	22.7 ± 6.9	2.2 ± 0.7	3.1 ± 1.3	41.2	21 (10.7)	7 (3.6)	7 (3.6)

PMT in Intermediate-high-risk patients

Optimum Duration of Acoustic Pulse Thrombolysis Procedure in Acute Pulmonary Embolism (OPTALYSE PE)

Active Comparator: 2 hours APT Procedure and 4/8 mg rtPA

Active Comparator: 4 hours APT Procedure and 4/8 mg rtPA

Active Comparator: 6 hours APT Procedure and 6/12 mg rtPA

Active Comparator: 6 hours APT Procedure and 12/24 mg rtPA

Active Comparator: tbd x hr treatment with EkoSonic Endovascular

RV dysfunction



Basal



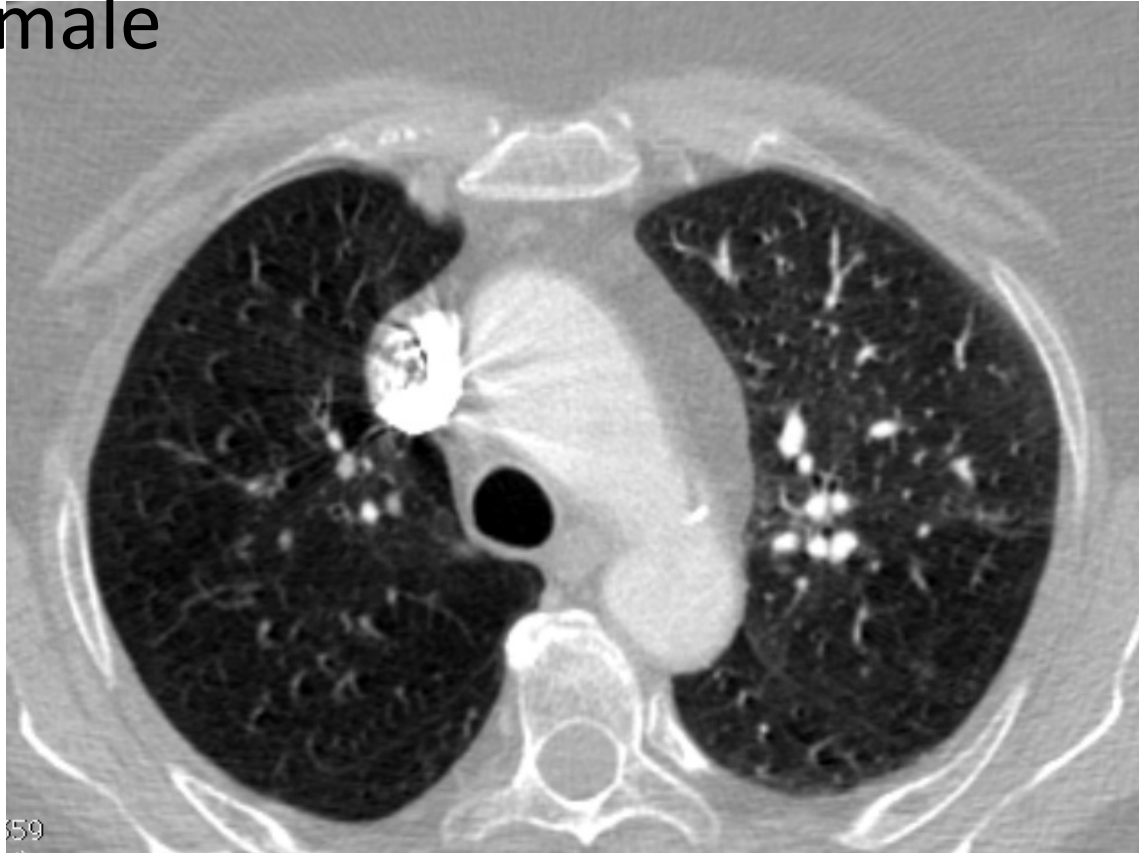
5 days



21 days

Intermediate-high-risk patients

- 79 years old female
- Dispnea
- BP 110
- FC 95
- Sat 93%
- VD ++
- Biomarkers +

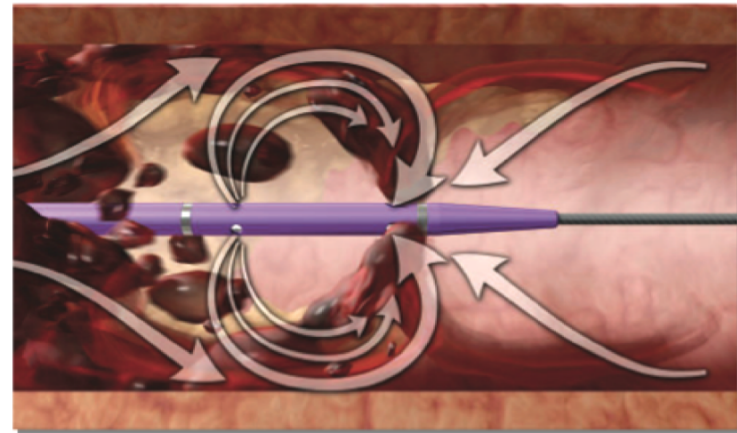


PMT in Intermediate-high-risk patients

➤ Rheolytic:

- **Rheo** from the Greek *rheo* (to flow)
- **Lytic** from the Greek *lytikos* (able to loosen)

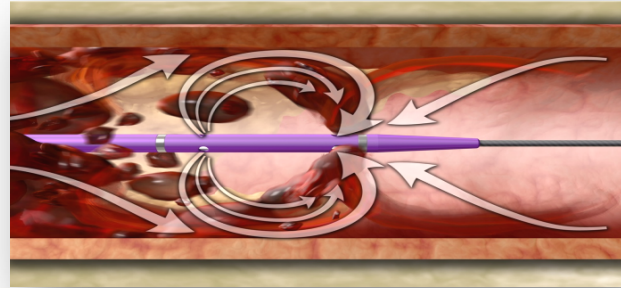
➤ AngioJet = Rheolytic Thrombectomy



Pharmaco-Mechanical Treatment

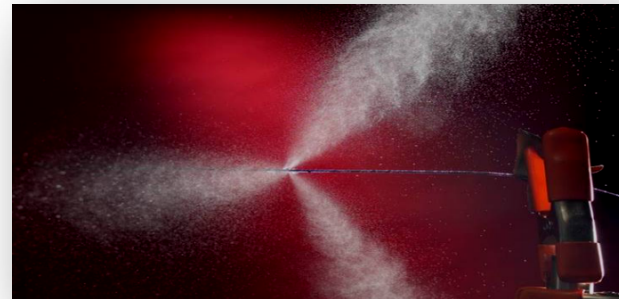
- ☑ **Rapidlysis** (5-10 mg Actilyse added to 250/500ml saline)

Cardiac Arrest – Shock



- ☑ **Power pulse technique** (20mg Actilyse added to 50ml saline power pulse spray, then 15-20 minutes wait and after that thrombectomy)

High/intermediate risk



PMT in Intermediate-high-risk patients

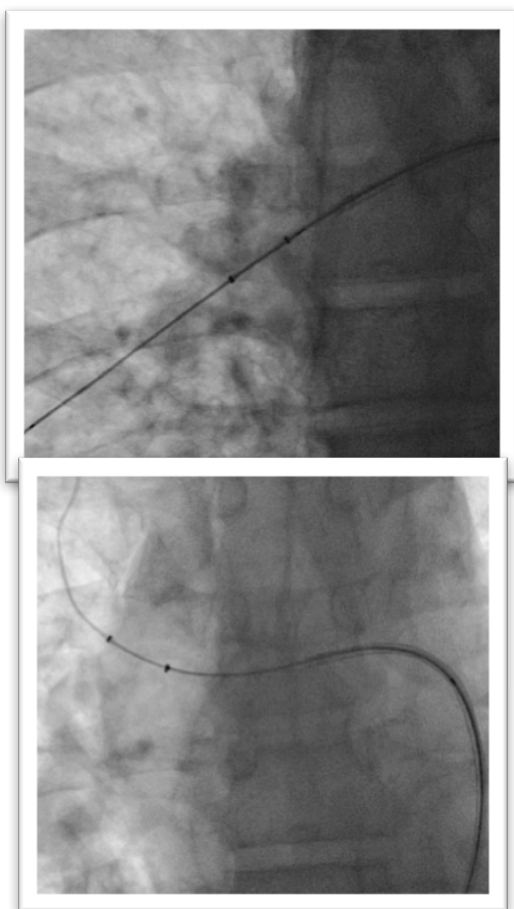
Right 30° PA angio
Pre Angiojet

8+8 cc contrast
Manual injection

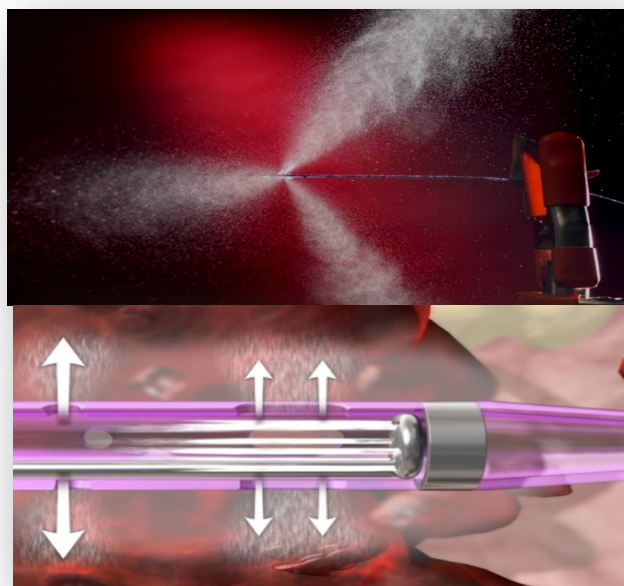
Left 25° PA angio
Pre Angiojet

SBP 110 mmHg
PAPm 45 mmHg
CF 103 mb
Sat 93%

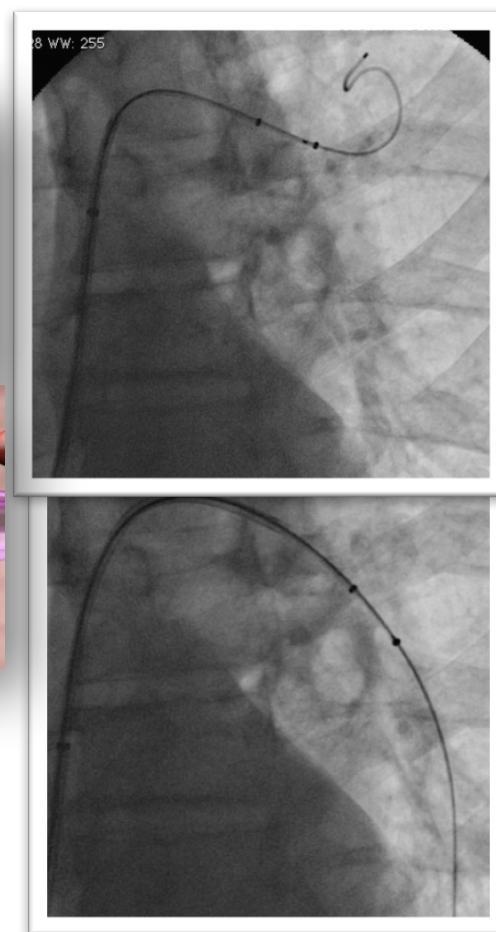
PMT in Intermediate-high-risk patients



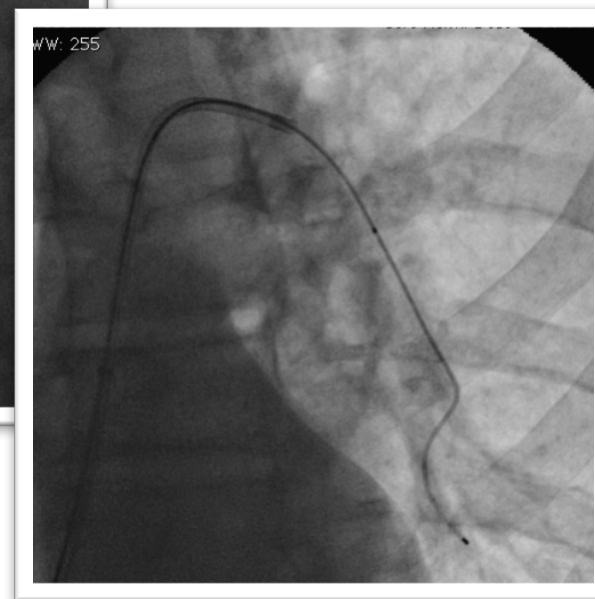
Power pulse technique



10mg Actilyse added to 50ml saline power pulse spray, then 15-20 minutes wait and after that thrombectomy



PMT in Intermediate-high-risk patients

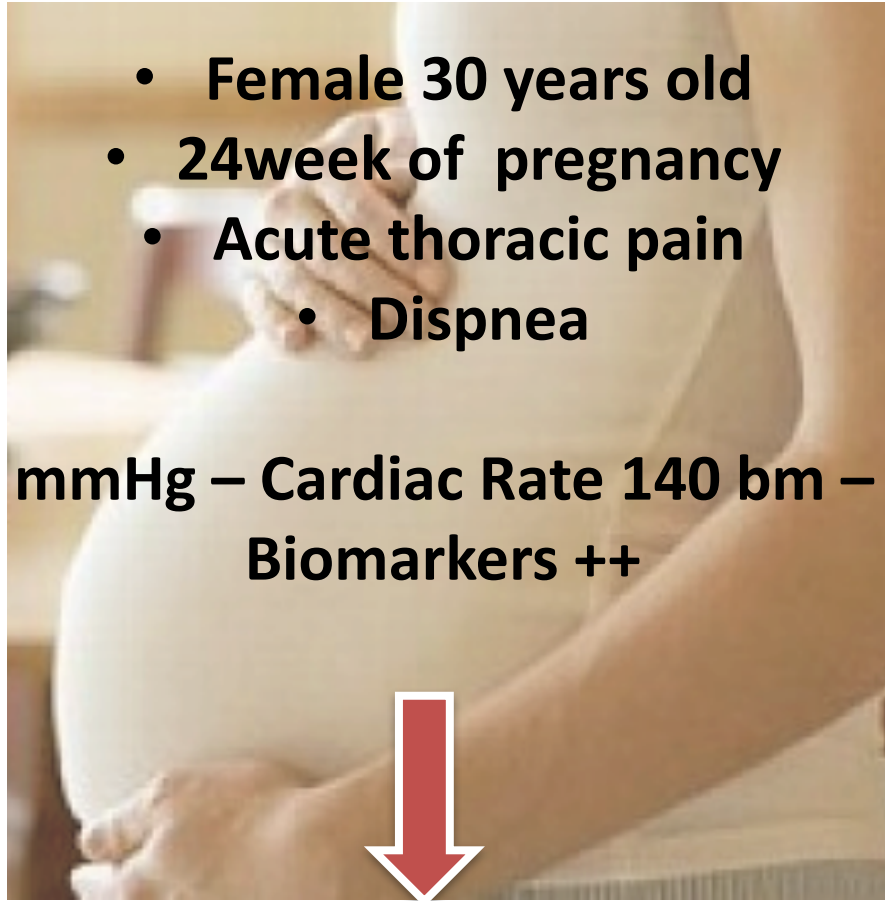


**SBP 110 mmHg
PAPm 45 mmHg
CF 103 mb
Sat 93%**



**SBP 135 mmHg
PAPm 28 mmHg
CF 90 mb
Sat 99%**

Intermediate-high risk patient



- Female 30 years old
- 24week of pregnancy
- Acute thoracic pain
 - Dispnea

SBP 105 mmHg – Cardiac Rate 140 bpm – Sat 90%
Biomarkers ++

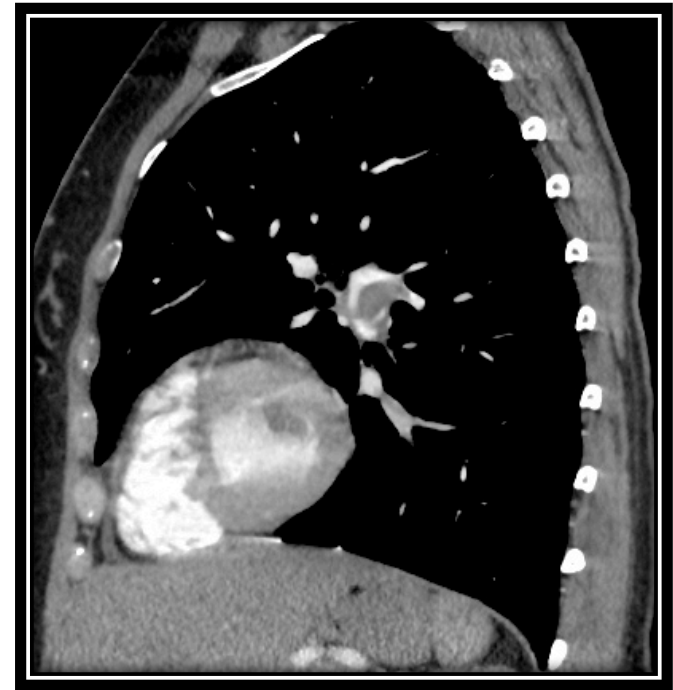
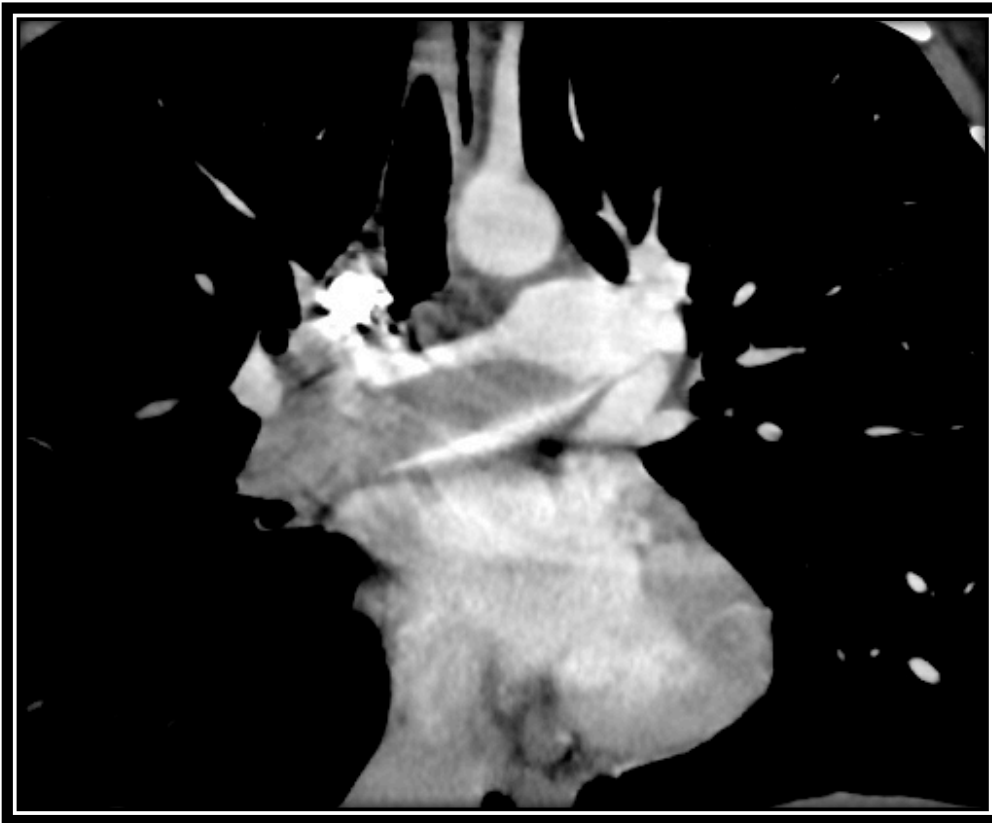


CT scan

Combined PMT in Intermediate-high-risk patients



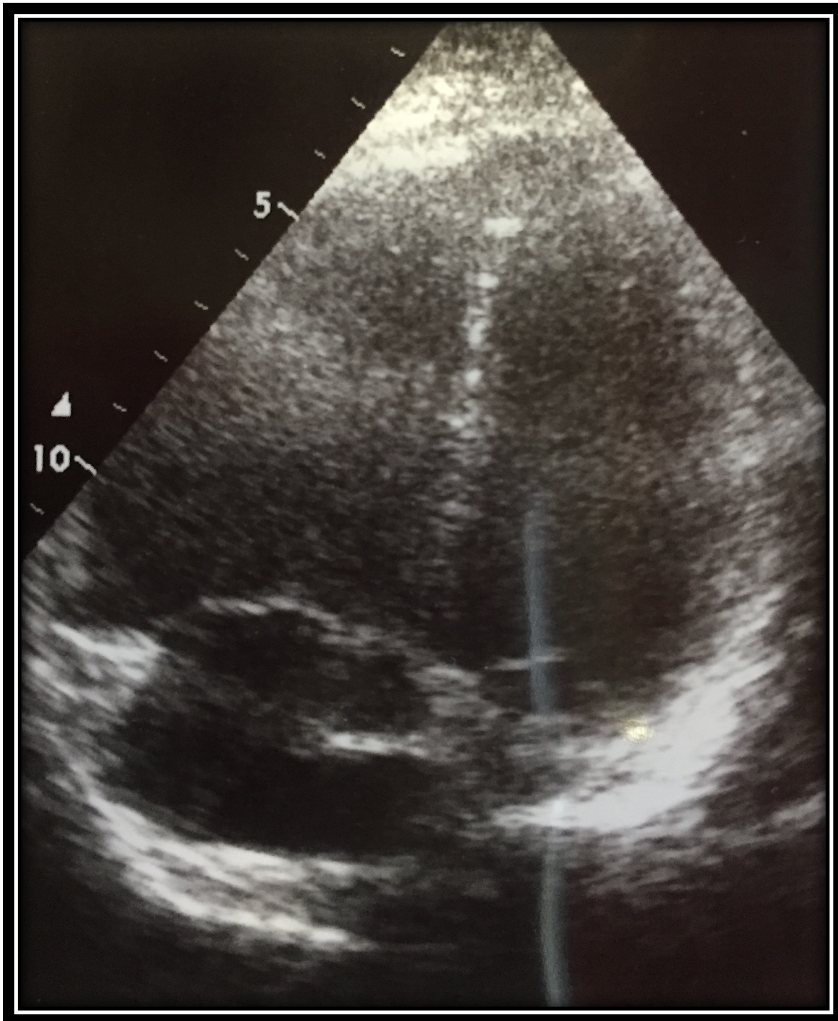
Combined PMT in Intermediate-high-risk patients







Combined PMT in Intermediate-high-risk patients



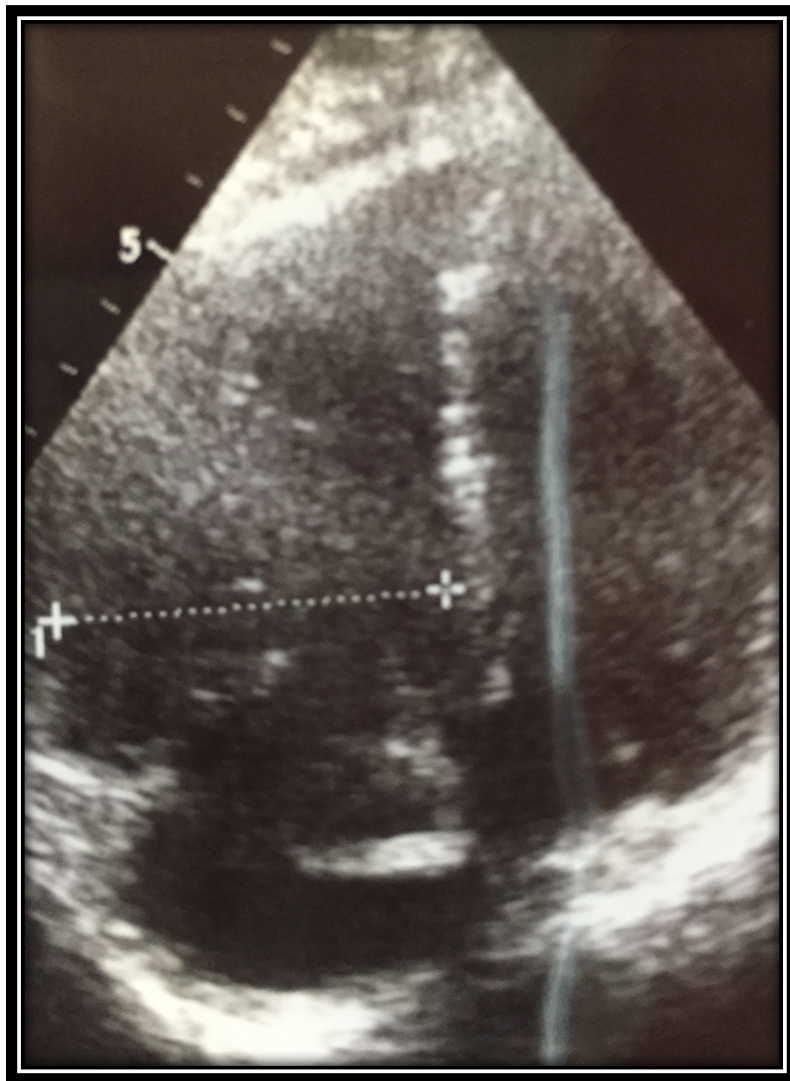
SBP 105 mmHg
PAPm 45 mmHg
CF 140 mb
Sat 91%



Power pulse technique

10 mg Actilyse added to 50ml saline
power pulse spray

Combined PMT in Intermediate-high-risk patients

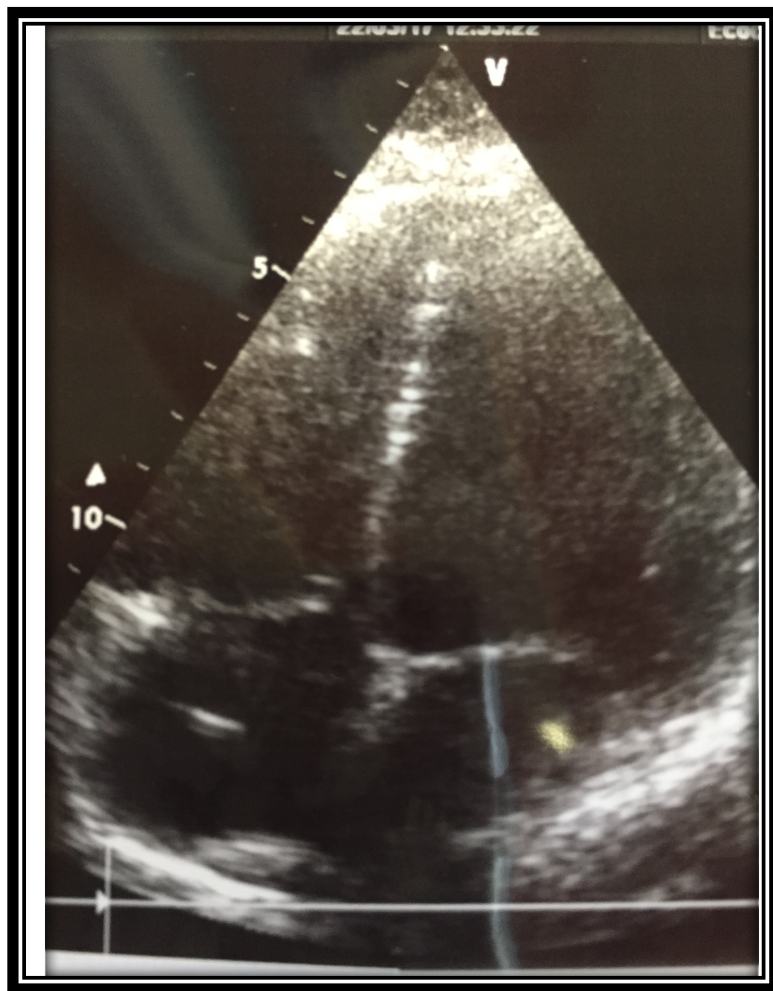


SBP 115 mmHg
PAPm 30 mmHg
CF 95 mb
Sat 99%



rtPa 1 mg /h x 12 h

Combined PMT in Intermediate-high-risk patients



Mobilizzazione in 24 h
EBPM 0.8 x 2
ECOcardio pre dimissione



Perché implementare il trattamento della TEP a rischio intermedio con Trattamento Farmaco Meccanico?

- Riduzione dosaggio trombolitico
- Riduzione complicanze emorragiche
- Efficacia terapia trombolitica

- Aumento pazienti eleggibili al trattamento
- Migliore outcome clinico
- Riduzione costi



BRAIN

IL CERVELLO

ISTRUZIONI PER L'USO

