Amsterdam UMC
University Medical Centers

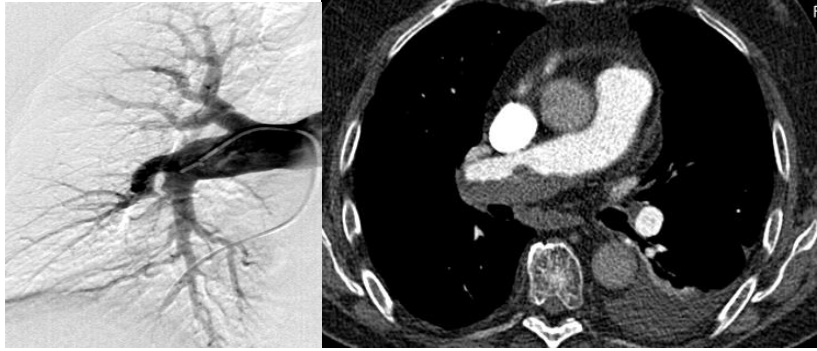
Intermediate high-risk longembolieën; how to treat?

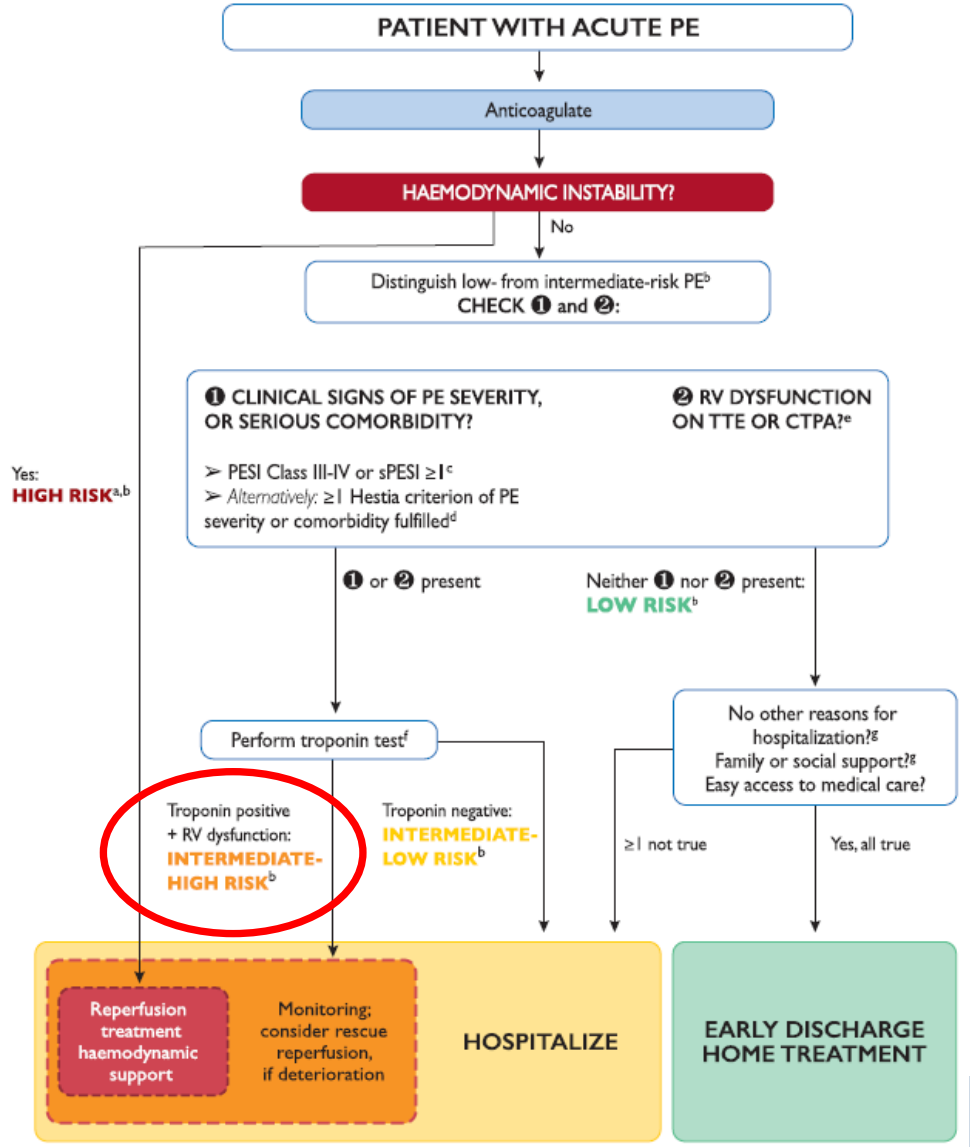
Esther J. Nossent, Longarts – Amsterdam UMC. Nederlands Trombose Congres 01-07-2022.

Disclosure belangen spreker: E.J. Nossent

Nederlands Trombose Congres 01-07-2022	
(potentiële) Belangenverstrengeling	
Voor bijeenkomst mogelijk relevante relaties met bedrijven	
Sponsoring of onderzoeksgeld	Astra Zeneca Janssen/Johnson & Johnson MSD Boehringer Ingelheim bv Chiesi GlaxoSmithKline BV Novartis Roche United Therapeutics/Ferrer/Therabel Pharma Nederland BV

De richtlijn





ESC European Society of Cardiology

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doi:10.1093/eurheartj/ehz405

ESC GUIDELINES

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)

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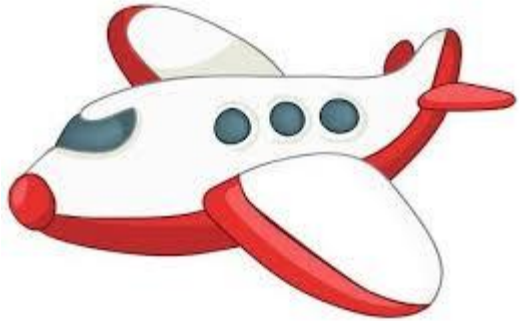
Casus



Vrouw, 71 jaar

Voorgeschiedenis:
Blanco

RX: -

Presentatie shockroom SEH via Schiphol

Anamnese:

Op Schiphol niet lekker geworden.

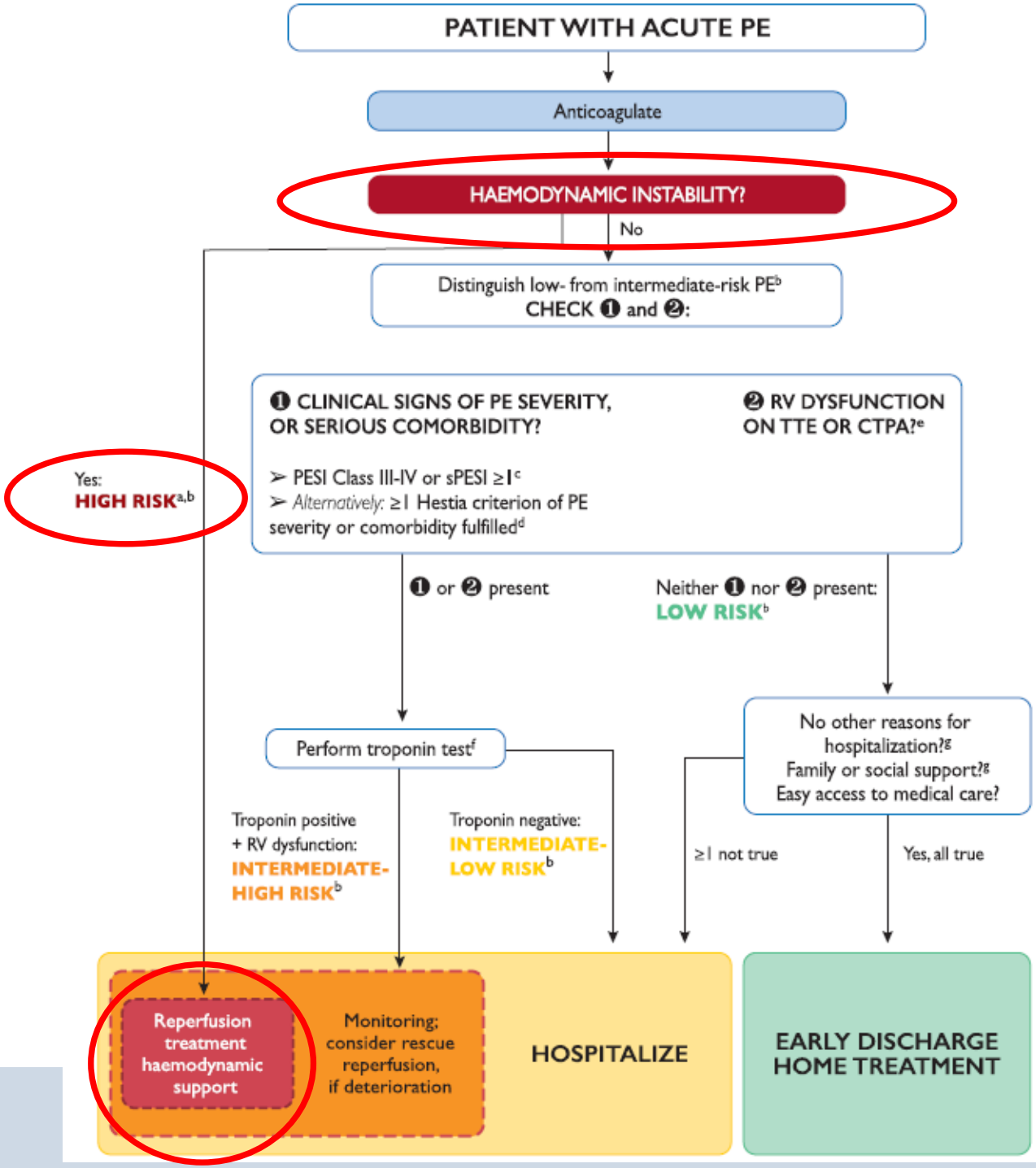
Komt net uit Bali terug gevlogen van vakantie.

Bij het uitstappen uit het vliegtuig zweterig, klam en “flauw gevallen”.

Gaat nu wel weer.

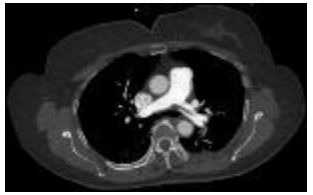
Geen pijn, niet echt kortademig.

Wat wilt u direct weten?

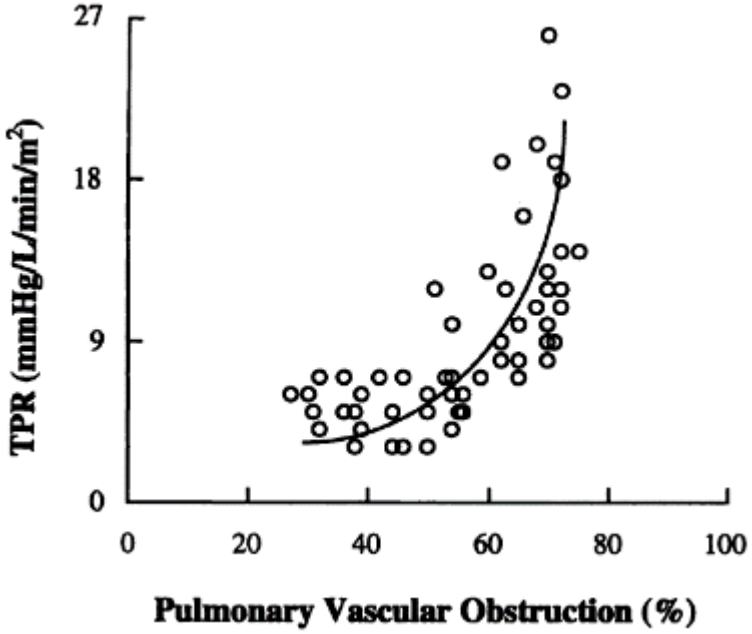


Committee TPS. Am Heart J 2012
Meyer et al. NEJM 2014
Klok et al. Thromb Haemost 2017
Barco et al. Eur Heart J 2019
Konstantinides et al. Eur Heart J 2020

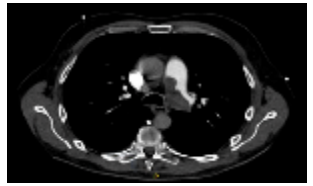
Obstructie pulmonale vasculaire bed; vaatweerstand ↑

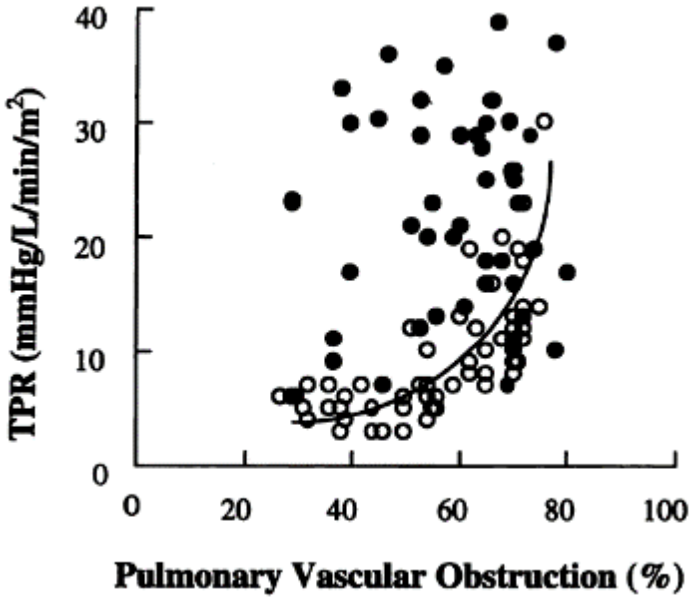


Acute PE



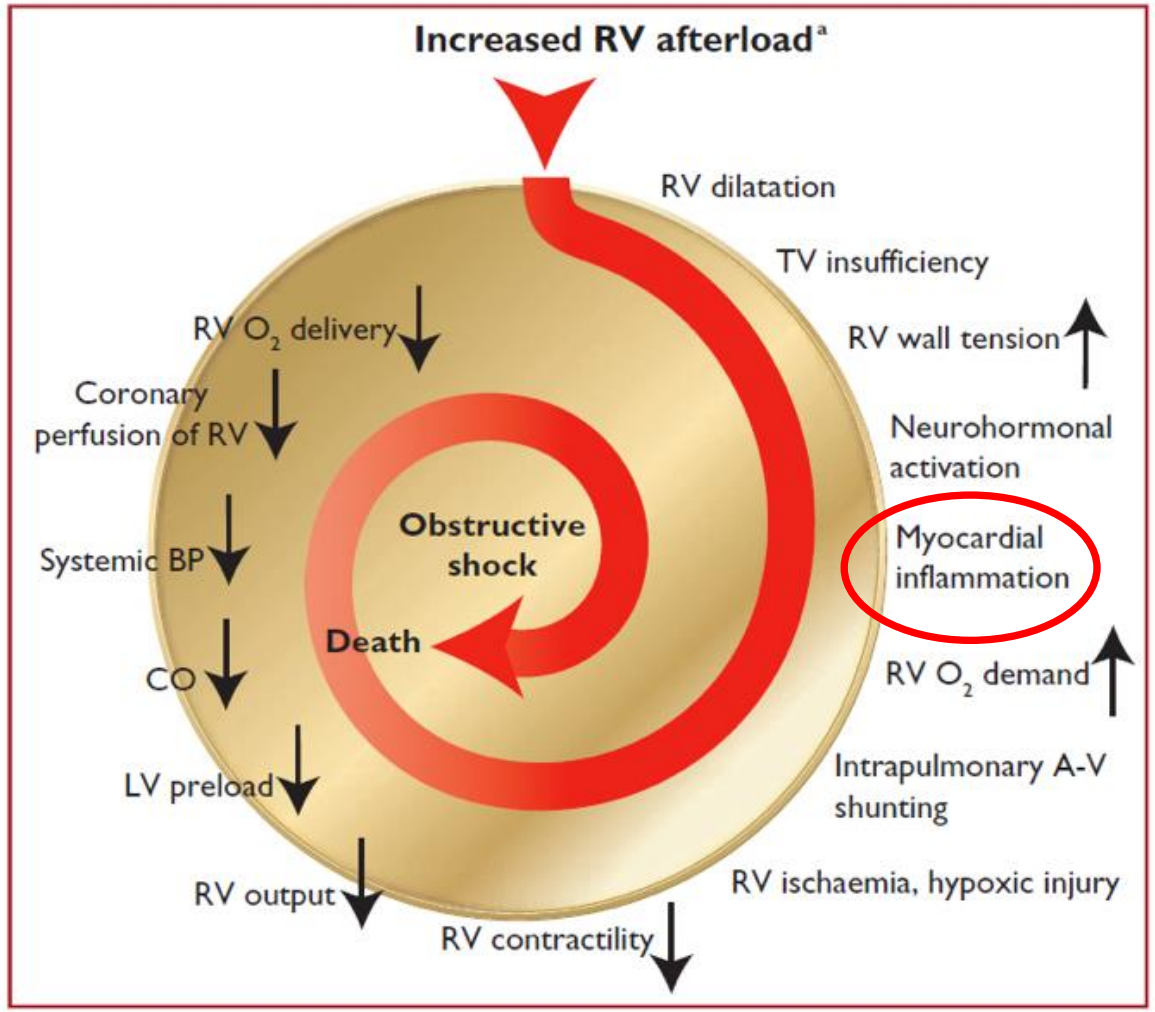
CTEPH





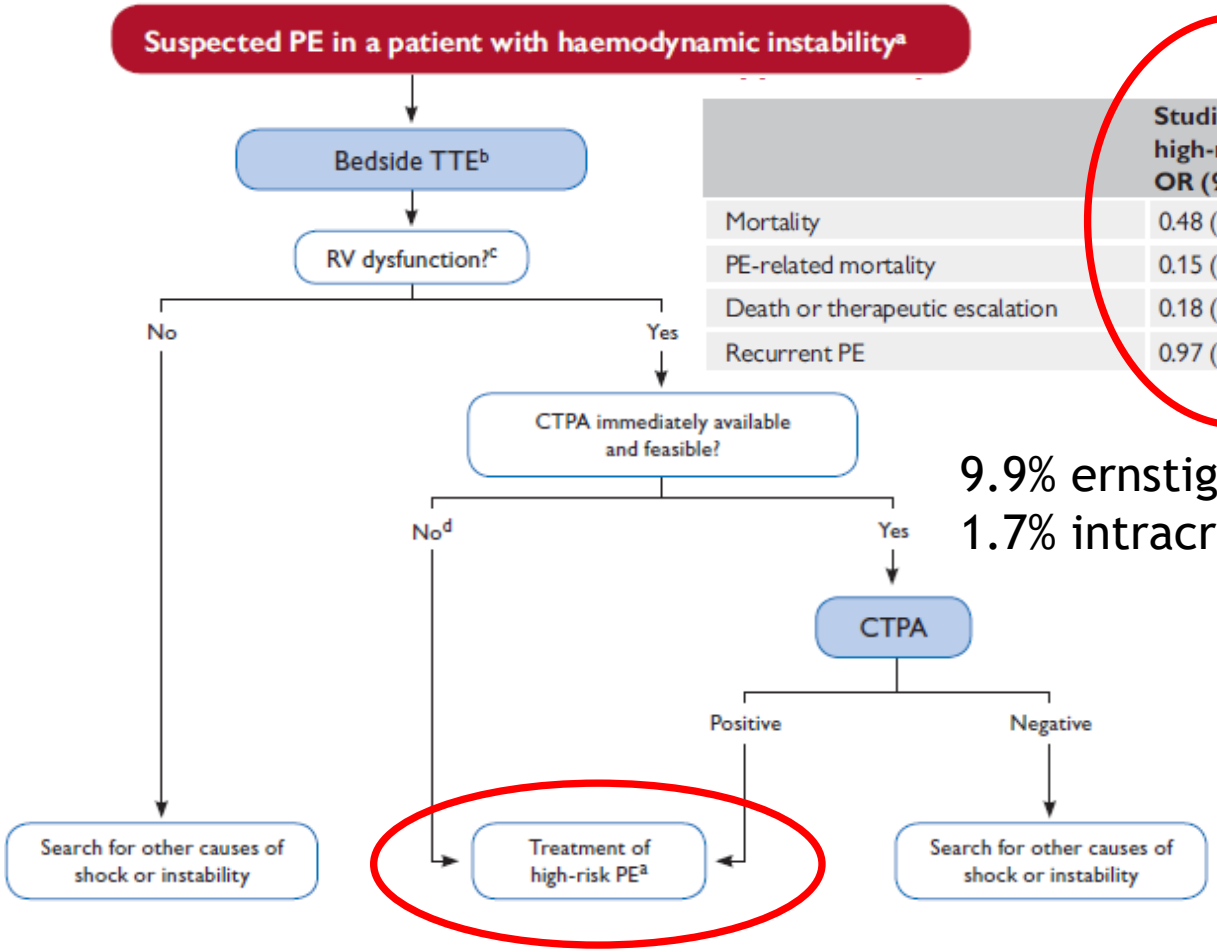
Azarian et al. J Nucl Med 1997

De rechter ventrikel



Patiënten met acute longembolieën overlijden aan **<u>rechter ventrikel falen.</u>**

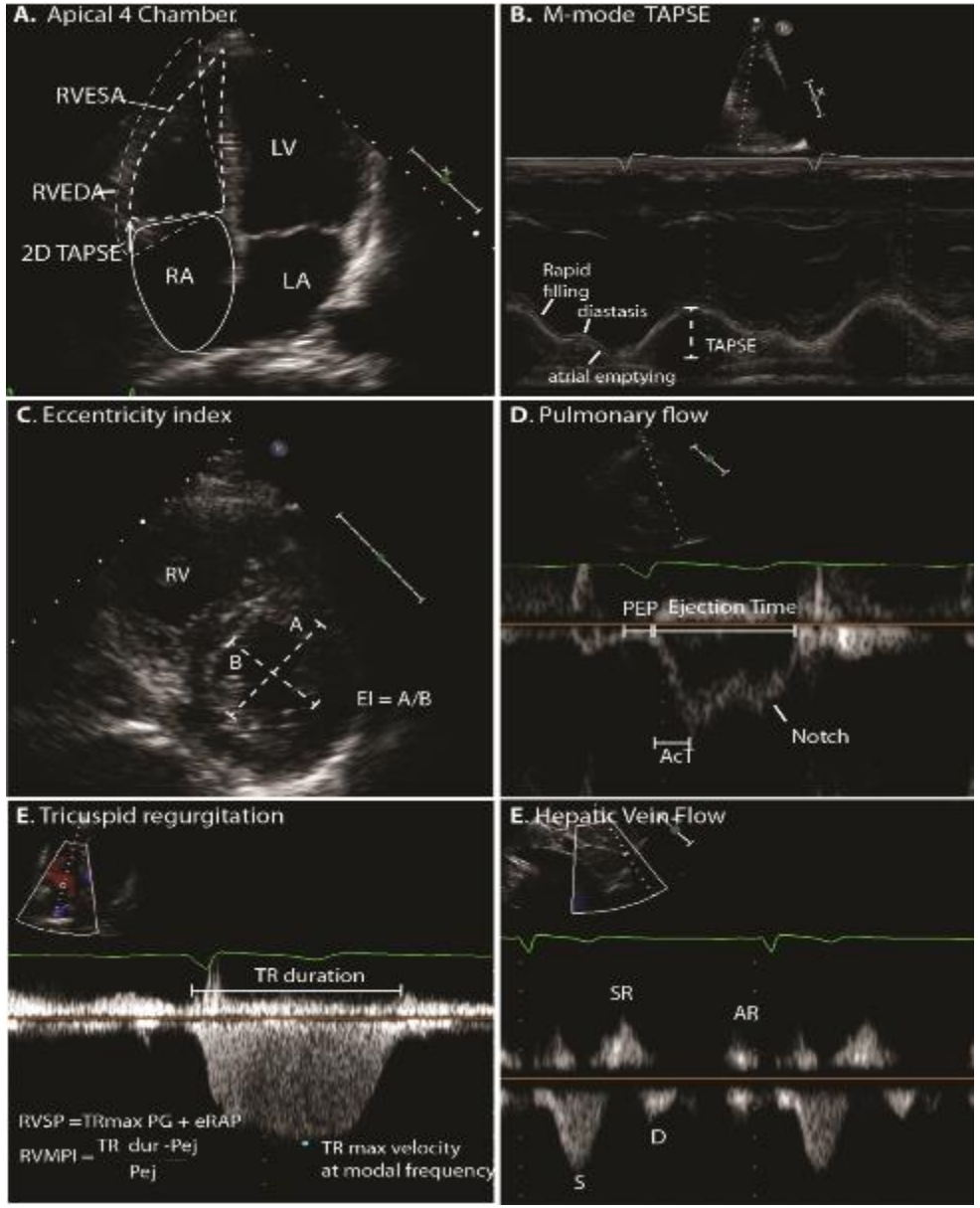
McIntyre et al. Am J Cardiol 1971
Smulders. Cardiovasc Res 2000
Begieneman et al. Heart 2008
Konstantinides et al. Eur Heart J 2020



	Studies including high-risk PE[a] OR (95% CI)
Mortality	0.48 (0.20–1.15)
PE-related mortality	0.15 (0.03–0.78)
Death or therapeutic escalation	0.18 (0.04–0.79)
Recurrent PE	0.97 (0.31–2.98)

9.9% ernstige bloeding;
1.7% intracranieel

Reperfusie therapie



Marti et al. Eur Heart J 2015
Konstantinides et al. Eur Heart J 2020

Reperfusie therapie

Table 10 **Thrombolytic regimens, doses, and contraindications**

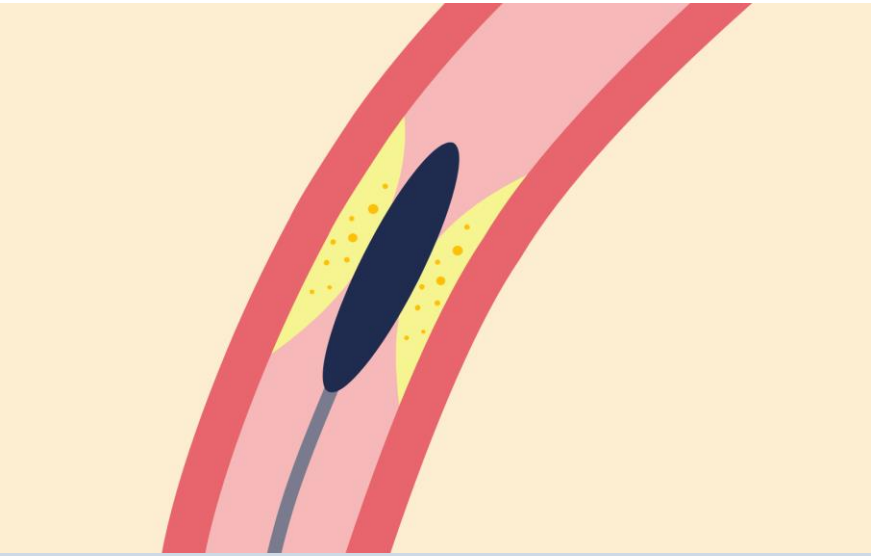
Molecule	Regimen	Contraindications to fibrinolysis
rtPA	100 mg over 2 h	**Absolute**
	0.6 mg/kg over 15 min (maximum dose 50 mg)[a]	History of haemorrhagic stroke or stroke of unknown origin
Streptokinase	250 000 IU as a loading dose over 30 min, followed by 100 000 IU/h over 12–24 h	Ischaemic stroke in previous 6 months
	Accelerated regimen: 1.5 million IU over 2 h	Central nervous system neoplasm
Urokinase	4400 IU/kg as a loading dose over 10 min, followed by 4400 IU/kg/h over 12–24 h	Major trauma, surgery, or head injury in previous 3 weeks
	Accelerated regimen: 3 million IU over 2 h	Bleeding diathesis
		Active bleeding
		Relative
		Transient ischaemic attack in previous 6 months
		Oral anticoagulation
		Pregnancy or first post-partum week
		Non-compressible puncture sites
		Traumatic resuscitation
		Refractory hypertension (systolic BP >180 mmHg)
		Advanced liver disease
		Infective endocarditis
		Active peptic ulcer

© ESC 2019

BP = blood pressure; IU = international units; rtPA, recombinant tissue-type plasminogen activator.
[a]This is the accelerated regimen for rtPA in pulmonary embolism; it is not officially approved, but it is sometimes used in extreme haemodynamic instability such as cardiac arrest.

Chirurgische embolectomie, VA-ECMO

Percutane katheter geleide interventie;
thrombus aspiratie, mechanische fragmentatie,
in situ gereduceerde dosis thrombolyse of een combi.



Konstantinides et al. Eur Heart J 2020

Presentatie SEH

LO:

Bij aankomst ambulance op Schiphol sat 86% zonder O2.

Bij binnenkomst SEH: RR 139/91 mmHg, pols 112/min, AF 20/min.

Bij klinische beoordeling sat 96% zonder O2, maar bij mobiliseren direct desaturatie naar 85%.

Pulmones: VAG, bijgeluiden -

Soepele kuiten bdz, omtrek gelijk.

Aanvullend onderzoek

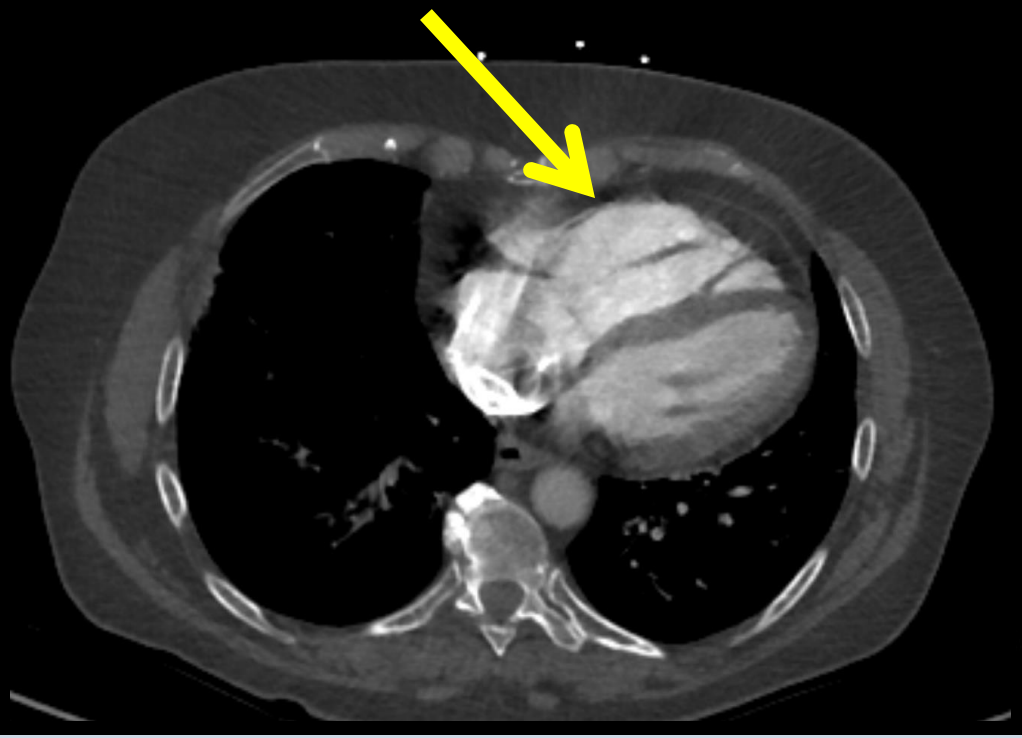
Lab: CRP 3, Hb 9.2, leuco's 12.5, creat 72

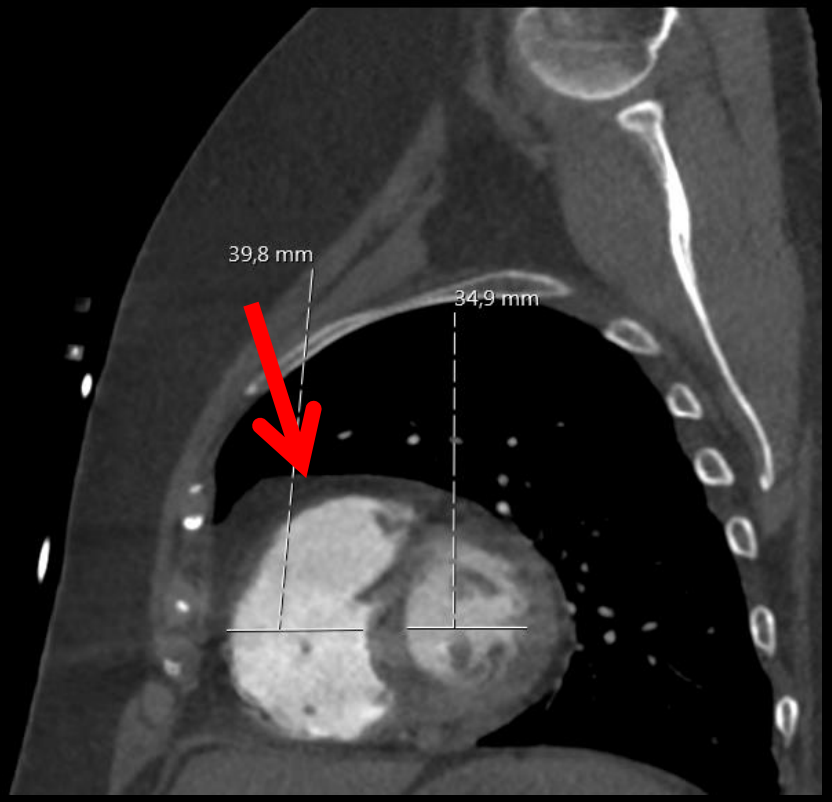
ECG: SR 112/min, rechter as, normale geleidingstijden, rechter bundeltak configuratie, hoge brede p-top in II, neg T V1-V3

Uw volgende stap?

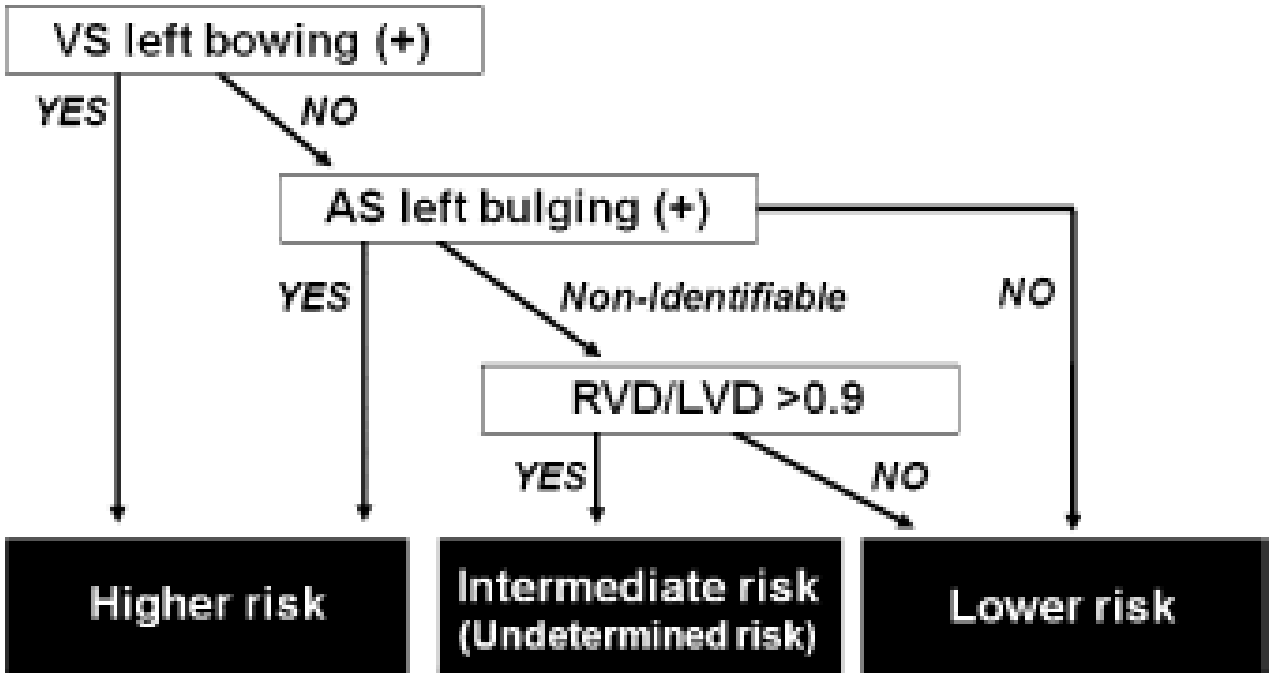
CTA-thorax

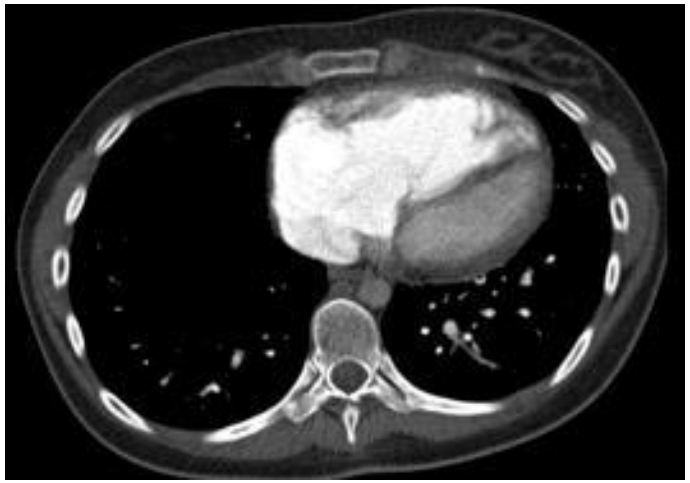
CTA thorax





Gratis en voor niets…





RDV/LDV > 1.0 geeft 5 x ↑ risico longembolie gerelateerde mortaliteit.

Becattini et al. Eur Heart J 2011
Kim et al. Int J Cardiovasc Imaging 2014
Meinel et al. Am J Med 2015
Barco et al. Eur Heart J 2019
Cote et al. Eur Respir J 2017

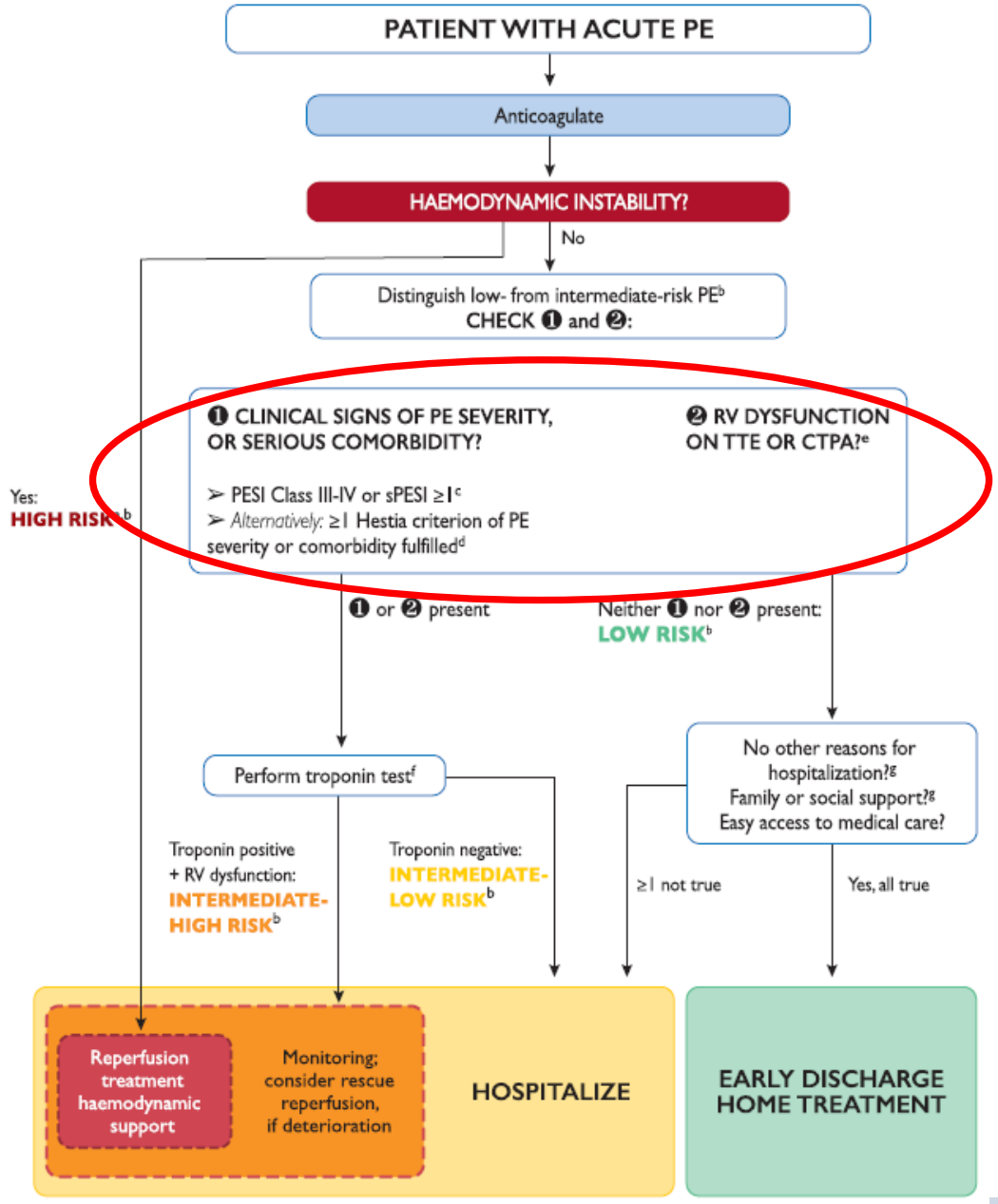
Diagnose

Bilaterale acute longembolieën, radiologisch RV dysfunctie

Hoe gevaarlijk is dit nu?

Behandeling?

Op welke afdeling in uw ziekenhuis neemt u patiënte op? Of mag patiënte naar huis?



Risicostratificatie

In welke risico groep valt onze patiënte?

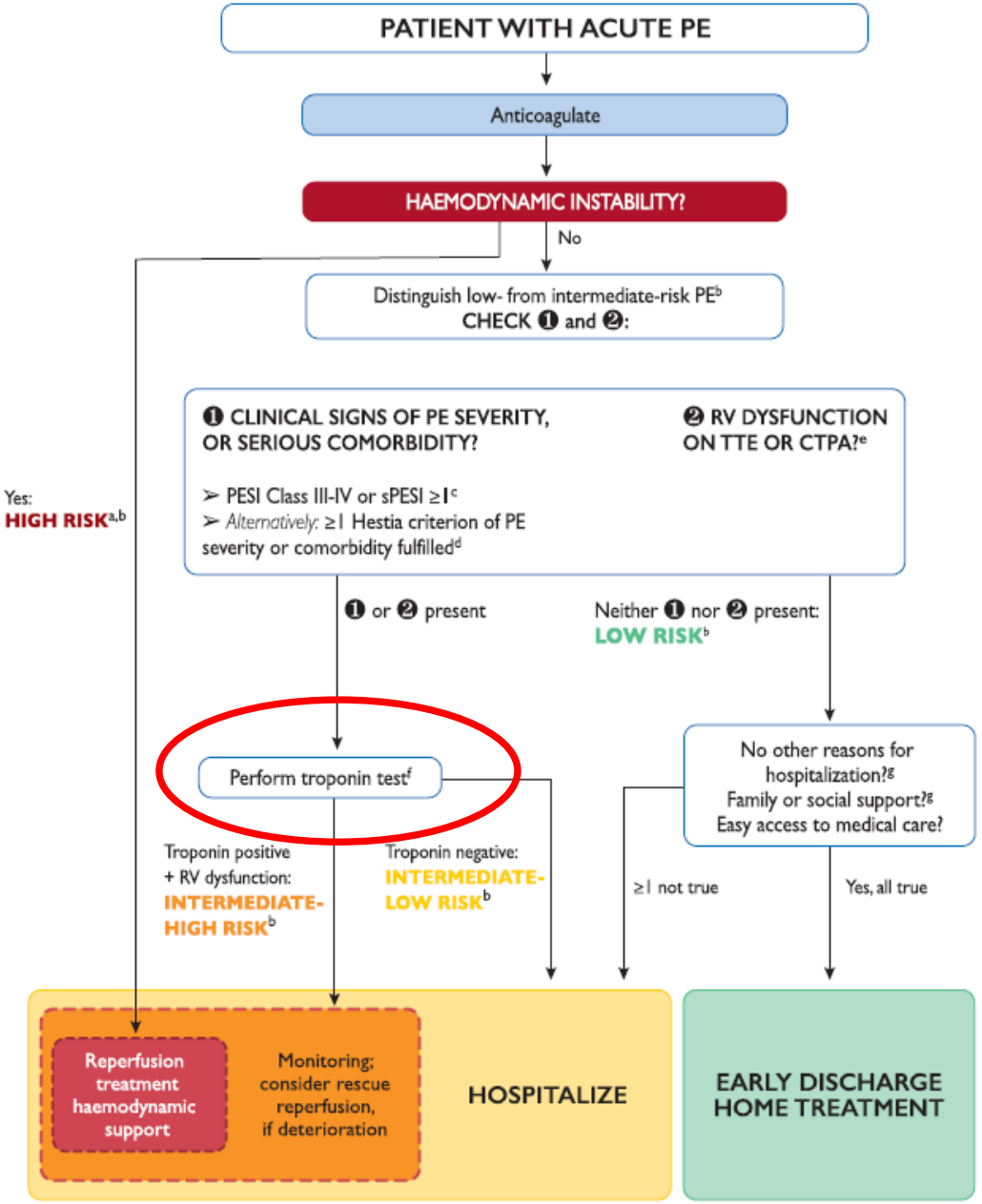
2019 ESC Guidelines on the diagnosis and management of acute pulmonary embolism. EHJ.

Pulmonary Embolism Severity Index

Table 7 **Original and simplified PESI**

Parameter	Original version[214]	Simplified version[218]
Age	Age in years	1 point (if age >80 years)
Male sex	+10 points	–
Cancer	+30 points	1 point
Chronic heart failure	+10 points	1 point
Chronic pulmonary disease	+10 points	
Pulse rate ≥110 b.p.m.	+20 points	1 point
Systolic blood pressure <100 mm Hg	+30 points	1 point
Respiratory rate >30 breaths per minute	+20 points	–
Temperature <36 °C	+20 points	–
Altered mental status	+60 points	–
Arterial oxyhaemoglobin saturation <90%	+20 points	1 point

2019 ESC Guidelines on the diagnosis and management of acute pulmonary embolism. EHJ.

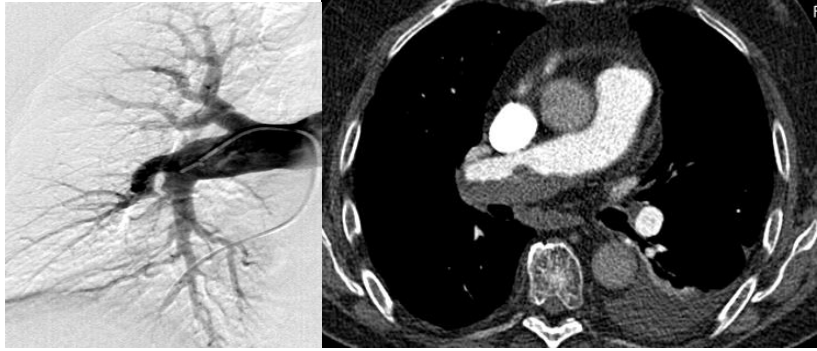


Risicostratificatie

In welke risico groep valt onze patiënte?

2019 ESC Guidelines on the diagnosis and management of acute pulmonary embolism. EHJ.

De richtlijn



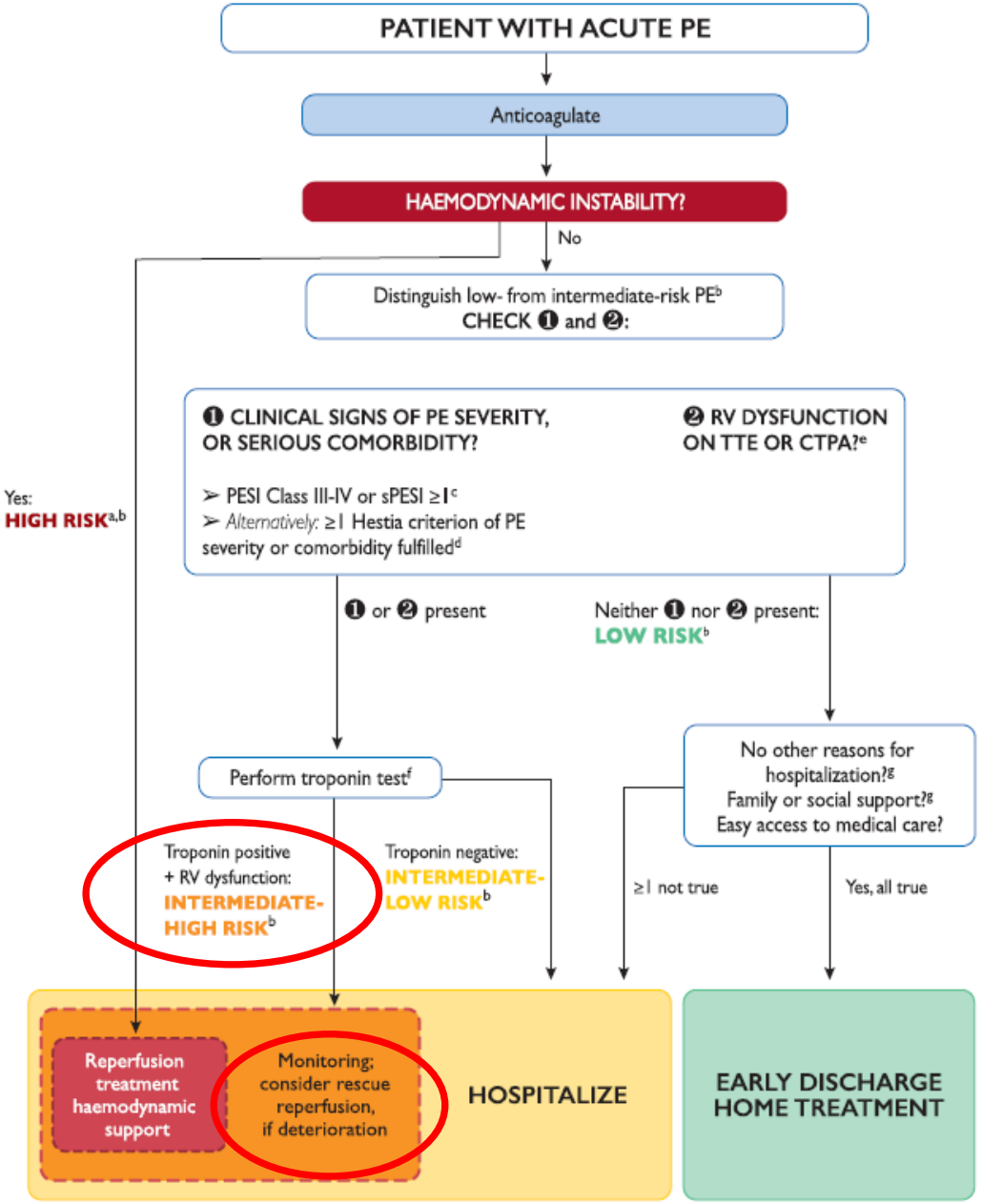
Early mortality risk		Indicators of risk			
		Haemodynamic instability[a]	Clinical parameters of PE severity and/ or comorbidity: PESI class III–V or sPESI ≥I	RV dysfunction on TTE or CTPA[b]	Elevated cardiac troponin levels[c]
High		+	(+)[d]	+	(+)
Intermediate	Intermediate–high	-	+[e]	+	+
	Intermediate–low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

Becattini et al. Eur Heart J 2011
Committee TPS. Am Heart J 2012
Barco et al. Eur Heart J 2019
Konstantinides et al. Eur Heart J 2020

Aanvullend onderzoek

	30-10-2017 10:55
BSE / CRP / PROCAL...	
CRP	3
HEMOCYTOMETRIE	
Hb	9,2
Leuco's	12,5 ▲
NIERFUNCTIE,ELECTR...	
Natrium	140
Kalium	4,5
Kreatinine	72
eGFR (CKD-EPI)	73 *
LEVERFUNCTIE,ENZYMEN	
TroponineT	0,176 ⇑
NT-proBNP	81
OVERIGE	
CTA LONGEMBOLIE	

In welke risico groep valt onze patiënte?



Risicostratificatie

In welke risico groep valt onze patiënte?

2019 ESC Guidelines on the diagnosis and management of acute pulmonary embolism. EHJ.

Welke medicamenteuze behandeling start u bij deze patiënt?

A. DOAC

B. Systemische thrombolyse full dose

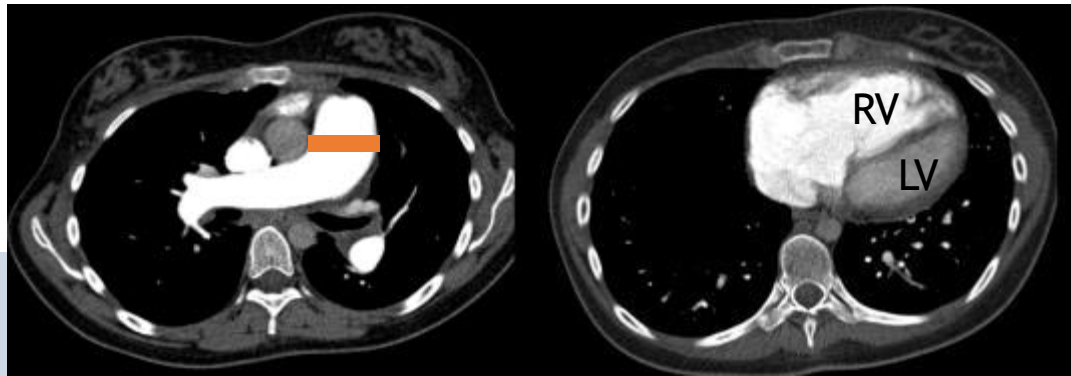
C. Systemische thrombolyse half dose

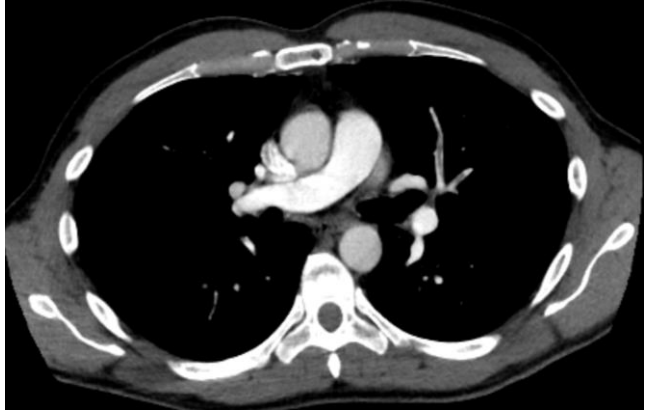
D. LMWH

E. UFH

F. Vit K antagonist

G. Anders, namelijk…



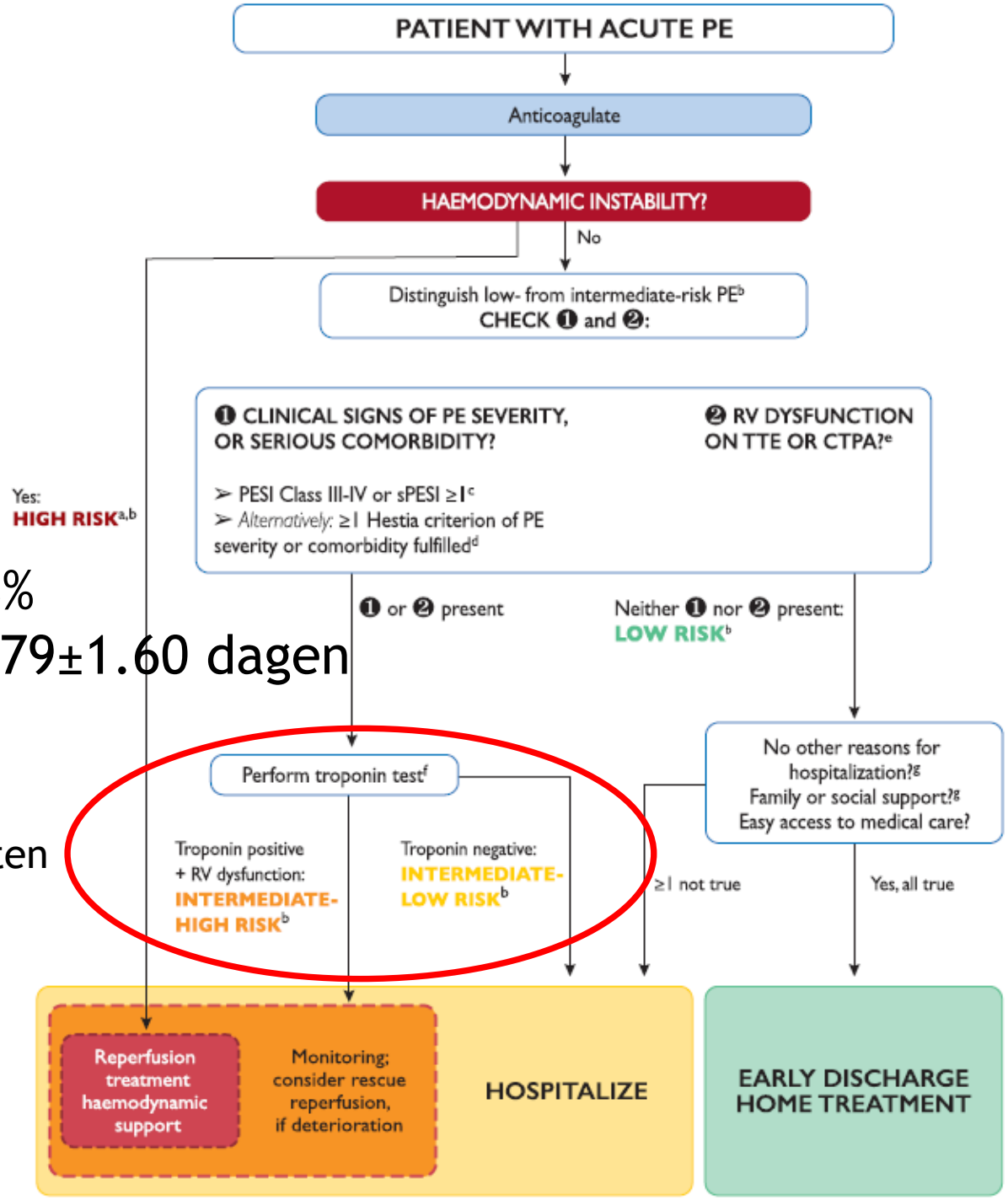


Intermediate-high risk

Vroege mortaliteit rond de 8%

5.6 % hemodynamische decompensatie 1.79±1.60 dagen

60% van alle LE patiënten



Committee TPS. Am Heart J 2012
Meyer et al. NEJM 2014
Klok et al. Thromb Haemost 2017
Barco et al. Eur Heart J 2019
Konstantinides et al. Eur Heart J 2020

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism

Guy Meyer, M.D., Eric Vicaut, M.D., Thierry Danays, M.D., Giancarlo Agnelli, M.D., Cecilia Becattini, M.D., Jan Beyer-Westendorf, M.D., Erich Bluhmki, M.D., Ph.D., Helene Bouvaist, M.D., Benjamin Brenner, M.D., Francis Couturaud, M.D., Ph.D., Claudia Dellas, M.D., Klaus Empen, M.D., Ana Franca, M.D., Nazzareno Galiè, M.D., Annette Geibel, M.D., Samuel Z. Goldhaber, M.D., David Jimenez, M.D., Ph.D., Matija Kozak, M.D., Christian Kupatt, M.D., Nils Kucher, M.D., Irene M. Lang, M.D., Mareike Lankeit, M.D., Nicolas Meneveau, M.D., Ph.D., Gerard Pacouret, M.D., Massimiliano Palazzini, M.D., Antoniu Petris, M.D., Ph.D., Piotr Pruszczyk, M.D., Matteo Rugolotto, M.D., Aldo Salvi, M.D., Sebastian Schellong, M.D., Mustapha Sebbane, M.D., Bozena Sobkowicz, M.D., Branislav S. Stefanovic, M.D., Ph.D., Holger Thiele, M.D., Adam Torbicki, M.D., Franck Verschuren, M.D., Ph.D., and Stavros V. Konstantinides, M.D., for the PEITHO Investigators*

PEITHO trial, NEJM 2014

PEITHO trial

Table 3. Efficacy Outcomes.*

Outcome	Tenecteplase (N=506)	Placebo (N=499)	Odds Ratio (95% CI)	P Value
Primary outcome — no. (%)	13 (2.6)	28 (5.6)	0.44 (0.23–0.87)	0.02
Death from any cause	6 (1.2)	9 (1.8)	0.65 (0.23–1.85)	0.42
Hemodynamic decompensation	8 (1.6)	25 (5.0)	0.30 (0.14–0.68)	0.002
Time between randomization and primary efficacy outcome — days	1.54±1.71	1.79±1.60		
Recurrent pulmonary embolism between randomization and day 7 — no. (%)	1 (0.2)	5 (1.0)	0.20 (0.02–1.68)	0.12
Fatal	0	3 (0.6)		
Nonfatal	1 (0.2)	2 (0.4)		
Other in-hospital complications and procedures — no. (%)				
Mechanical ventilation	8 (1.6)	15 (3.0)		
Surgical embolectomy	1 (0.2)	2 (0.4)		
Catheter thrombus fragmentation	1 (0.2)	0 (0.0)		
Vena cava interruption	5 (1.0)	1 (0.2)		
Thrombolytic treatment other than study medication	4 (0.8)	23 (4.6)		
Death from any cause between randomization and day 30 — no. (%)	12 (2.4)	16 (3.2)	0.73 (0.34–1.57)	0.42
Patient still hospitalized at day 30 — no. (%)	59 (11.7)	50 (10.0)		
Rehospitalization between randomization and day 30 — no. (%)	22 (4.4)	15 (3.0)		

* Plus–minus values are means ±SD. Odds ratios and P values are provided for efficacy outcomes that were prespecified in the trial protocol.

Intermediate-high risk

Vroege mortaliteit rond de 8%
5.6 % hemodynamische decompensatie 1.79±1.60 dagen

Primaire eindpunt behaald

Dood
of
hemodynamische decompensatie
< 7 dagen ↓

Meyer et al. NEJM 2014
Chatterjee et al. JAMA 2014
Marti et al et al. Eur Heart J 2015
Konstantinides et al. Eur Heart J 2020

PEITHO trial

Table 4. Safety Outcomes in the Intention-to-Treat Population.*

Outcome	Tenecteplase (N=506)	Placebo (N=499)	Odds Ratio (95% CI)	P Value
	no. (%)			
Bleeding between randomization and day 7				
Major extracranial bleeding	32 (6.3)	6 (1.2)	5.55 (2.3–13.39)	<0.001
Minor bleeding	165 (32.6)	43 (8.6)		
Major bleeding†	58 (11.5)	12 (2.4)		
Stroke between randomization and day 7	12 (2.4)	1 (0.2)	12.10 (1.57–93.39)	0.003
Ischemic stroke	2 (0.4)	0		
Hemorrhagic stroke‡	10 (2.0)	1 (0.2)		
Serious adverse events between randomization and day 30	55 (10.9)	59 (11.8)	0.91 (0.62–1.34)	0.63

* Odds ratios and P values are provided for efficacy and safety outcomes that were prespecified in the trial protocol.
† Major bleeding was defined according to the criteria of the International Society on Thrombosis and Haemostasis.
‡ Hemorrhagic stroke included hemorrhagic conversion of ischemic stroke.

Intermediate-high risk

Systemische trombolyse

Conform overige literatuur

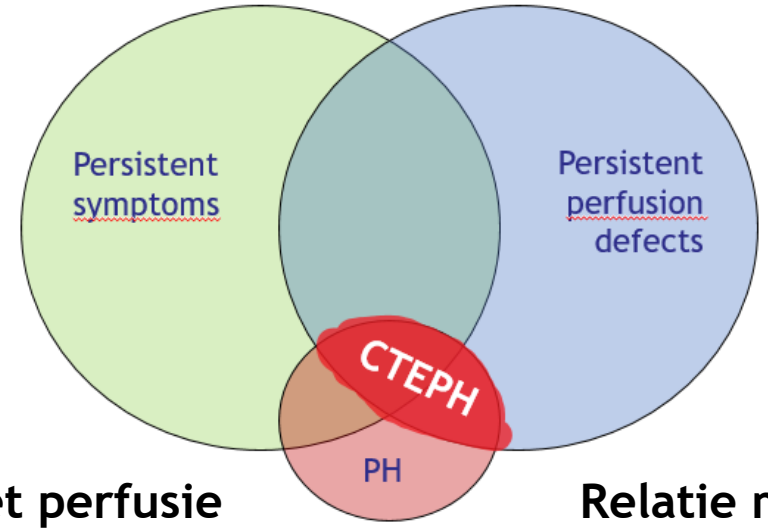
Nee

Meyer et al. NEJM 2014

Waarom de discussie nog niet gesloten is…

collapse.[179] Routine primary reperfusion treatment, notably full-dose systemic thrombolysis, is not recommended, as the risk of potentially life-threatening bleeding complications appears too high for the expected benefits from this treatment.[179] Rescue thrombolytic therapy or, alternatively, surgical embolectomy or percutaneous catheter-directed treatment should be reserved for patients who develop signs of haemodynamic instability. In the PEITHO trial, the

Post PE syndroom



Geen relatie met perfusie

- Onderliggend lijden
- Deconditionering
- Psychische gevolgen
- RV schade

Relatie met perfusie

- Recidief
- CTEPH
- CTEPD

Konstantinides et al. Eur Heart J 2020

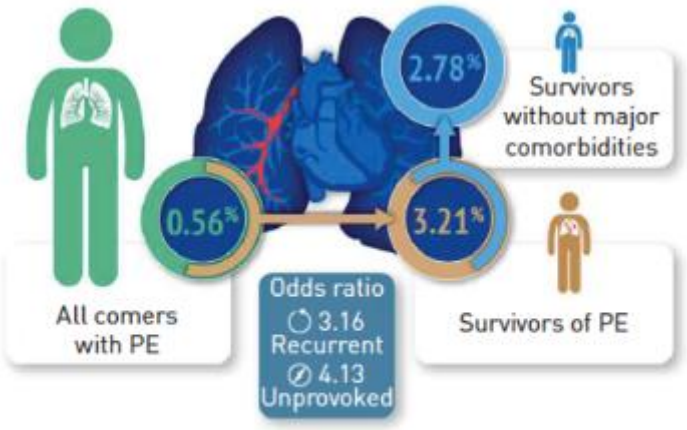
Na longembolieën: <4% van de patiënten ontwikkelt CTEPH

Definitie van CTEPH

1. Gemiddelde druk a. pulmonalis >20 mmHg met een wiggedruk ≤15 mmHg en PVR ≥3WU

2. Ten minste 1 (segmenteel) perfusie defect of passend pulmonalis angiogram

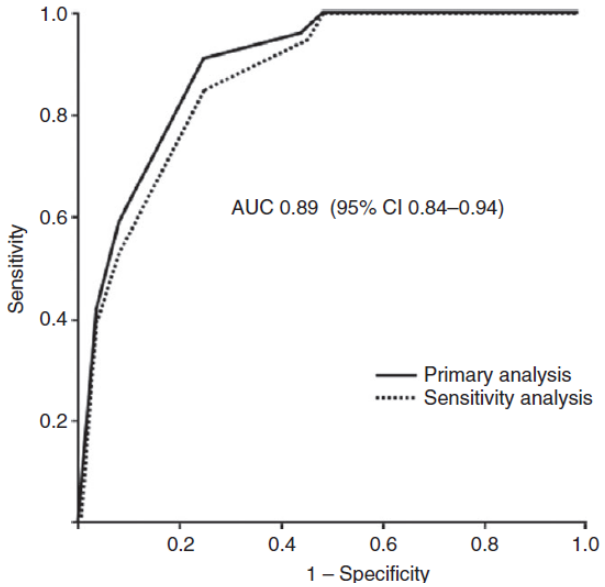
3. Ondanks 3 maanden adequate antistolling



16 studies - 4047 PE patients

Pengo et al. NEJM 2004
Klok et al. Haematologica 2010
Lang et al. Eur Respir J 2013
Ende-Verhaar et al. Eur Respir J 2017
Simonneau et al. Eur Respir J 2019

Kleinere kans op CTEPH bij score ≤ 6



	Points for score
Unprovoked PE	+ 6
Known hypothyroidism	+ 3
Symptom onset > 2 weeks before PE diagnosis	+ 3
Right ventricular dysfunction on CT or echocardiography	+ 2
Known diabetes mellitus	− 3
Thrombolytic therapy or embolectomy	− 3

Klok et al. J Throm Haem 2016.

PEITHO trial

Intermediate-high risk

Vroege mortaliteit rond de 8%
5.6 % hemodynamische decompensatie 1.79±1.60 dagen

Table 3. Efficacy Outcomes.*

Outcome	Tenecteplase (N=506)	Placebo (N=499)	Odds Ratio (95% CI)	P Value
Primary outcome — no. (%)	13 (2.6)	28 (5.6)	0.44 (0.23–0.87)	0.02
Death from any cause	6 (1.2)	9 (1.8)	0.65 (0.23–1.85)	0.42
Hemodynamic decompensation	8 (1.6)	25 (5.0)	0.30 (0.14–0.68)	0.002
Time between randomization and primary efficacy outcome — days	1.54±1.71	1.79±1.60		
Recurrent pulmonary embolism between randomization and day 7 — no. (%)	1 (0.2)	5 (1.0)	0.20 (0.02–1.68)	0.12
Fatal	0	3 (0.6)		
Nonfatal	1 (0.2)	2 (0.4)		
Other in-hospital complications and procedures — no. (%)				
Mechanical ventilation	8 (1.6)	15 (3.0)		
Surgical embolectomy	1 (0.2)	2 (0.4)		
Catheter thrombus fragmentation	1 (0.2)	0 (0.0)		
Vena cava interruption	5 (1.0)	1 (0.2)		
Thrombolytic treatment other than study medication	4 (0.8)	23 (4.6)		
Death from any cause between randomization and day 30 — no. (%)	12 (2.4)	16 (3.2)	0.73 (0.34–1.57)	0.42
Patient still hospitalized at day 30 — no. (%)	59 (11.7)	50 (10.0)		
Rehospitalization between randomization and day 30 — no. (%)	22 (4.4)	15 (3.0)		

* Plus–minus values are means ±SD. Odds ratios and P values are provided for efficacy outcomes that were prespecified in the trial protocol.

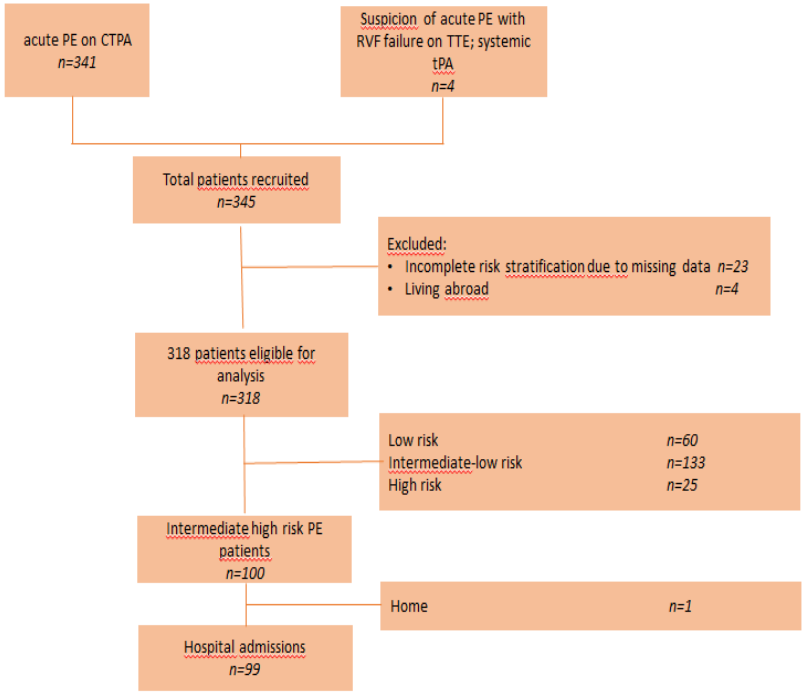
	Studies including high-risk PE[a] OR (95% CI)	Intermediate-risk PE
Mortality	0.48 (0.20–1.15)	0.42 (0.17–1.03)
PE-related mortality	0.15 (0.03–0.78)	0.17 (0.05–0.67)
Death or therapeutic escalation	0.18 (0.04–0.79)	0.37 (0.20–0.69)
Recurrent PE	0.97 (0.31–2.98)	0.25 (0.06–1.03)

Discrepantie ?
Lange termijn?

33% dyspneu

Meyer et al. NEJM 2014
Chatterjee et al. JAMA 2014
Marti et al et al. Eur Heart J 2015
Konstantinides et al. Eur Heart J 2020

Onze eigen klinische praktijk; ALERT database



Patients	Intermediate high risk acute PE n=99
Hospital admission	
Normal care unit; n (%)	17 (17)
High care unit; n (%)	82 (82)
Clinical outcome	
30-day all cause mortality; n (%)	10 (10)
30-day PE related mortality; n (%)	7 (7)
Reperfusion therapy; n (%)	*3 (3)**
Major bleeding; n (%)	7 (7)

* One patient survived

Impact niet te onderschatten…
Identificeren wij de patiënten adequaat?

Triaging acute pulmonary embolism for home treatment by Hestia or simplified PESI criteria: the HOME-PE randomized trial

Roy et al. Eur Heart J 2021
Overgaauw et al. Unpublished data

PEITHO trial

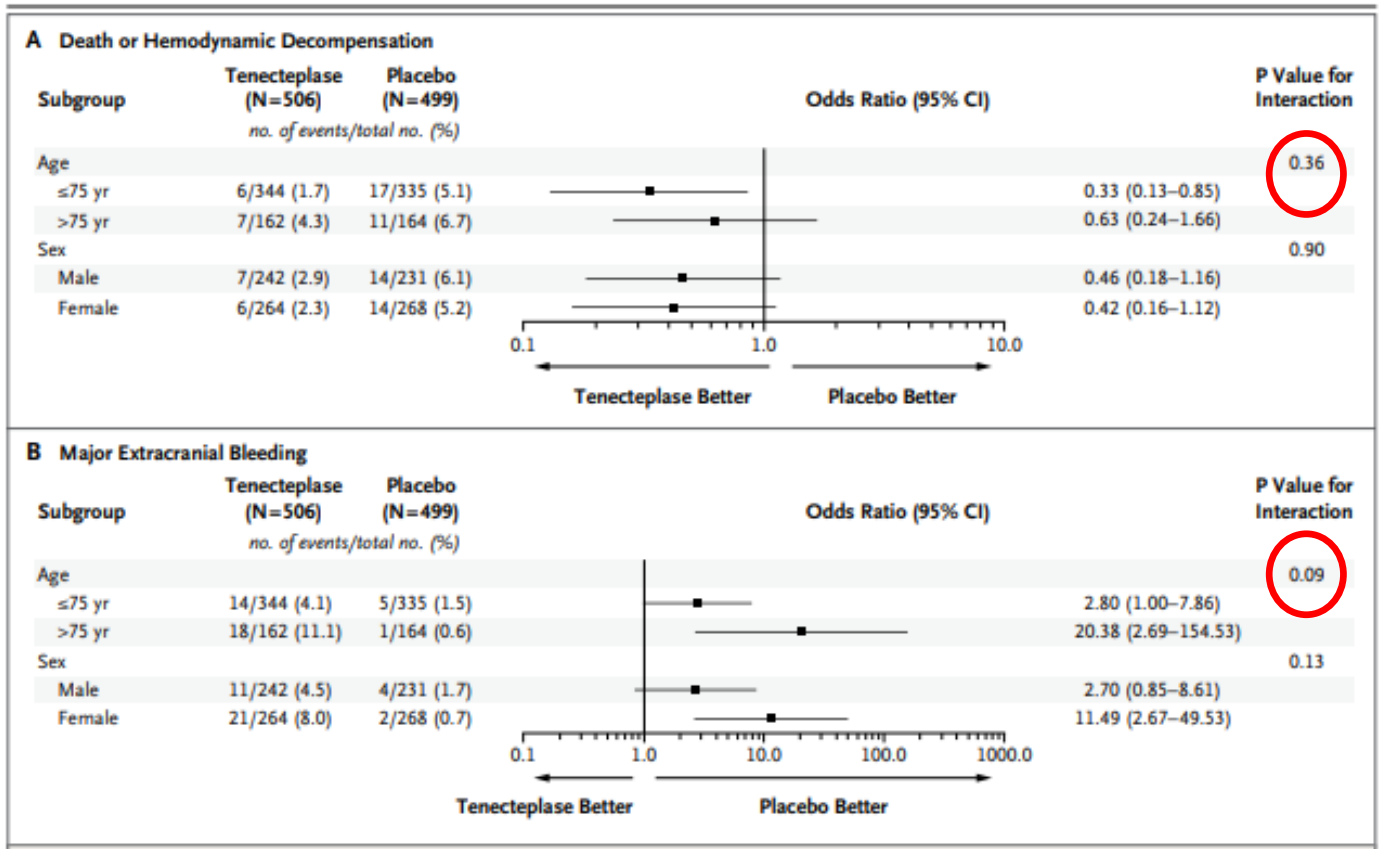


Figure 1. Efficacy and Safety Outcomes in Prespecified Subgroups.
Panel A shows the primary efficacy outcome (death or hemodynamic decompensation), and Panel B shows a safety outcome (major extracranial bleeding), both within 7 days after randomization.

Intermediate-high risk

Systemische trombolyse

Prespecified subgroep analyse:
> 75 jaar niet significant, maar…

Gereduceerde dosis?

Meyer et al. NEJM 2014

Toekomst

Reduced-dose intravenous thrombolysis for acute intermediate high-risk pulmonary embolism

Rationale and design of the Pulmonary Embolism International THrOmbolysis (PEITHO)-3 trial

Criteria clinical severity
RR ≤ 110 mmHg
Resp rate > 20/min
VG hartfalen

Gereduceerde dosis systemische thrombolyse versus standaard heparine

Primaire eindpunt: dood, hemodynamische decompensatie, recidief
Veiligheid
Lange termijn functionele beperkingen, RV dysfunctie, incidentie CTEPH

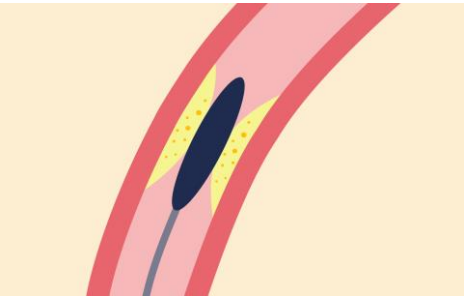
- ☐ Child (birth–17)
- ☐ Adult (18–64)
- ☐ Older Adult (65+)

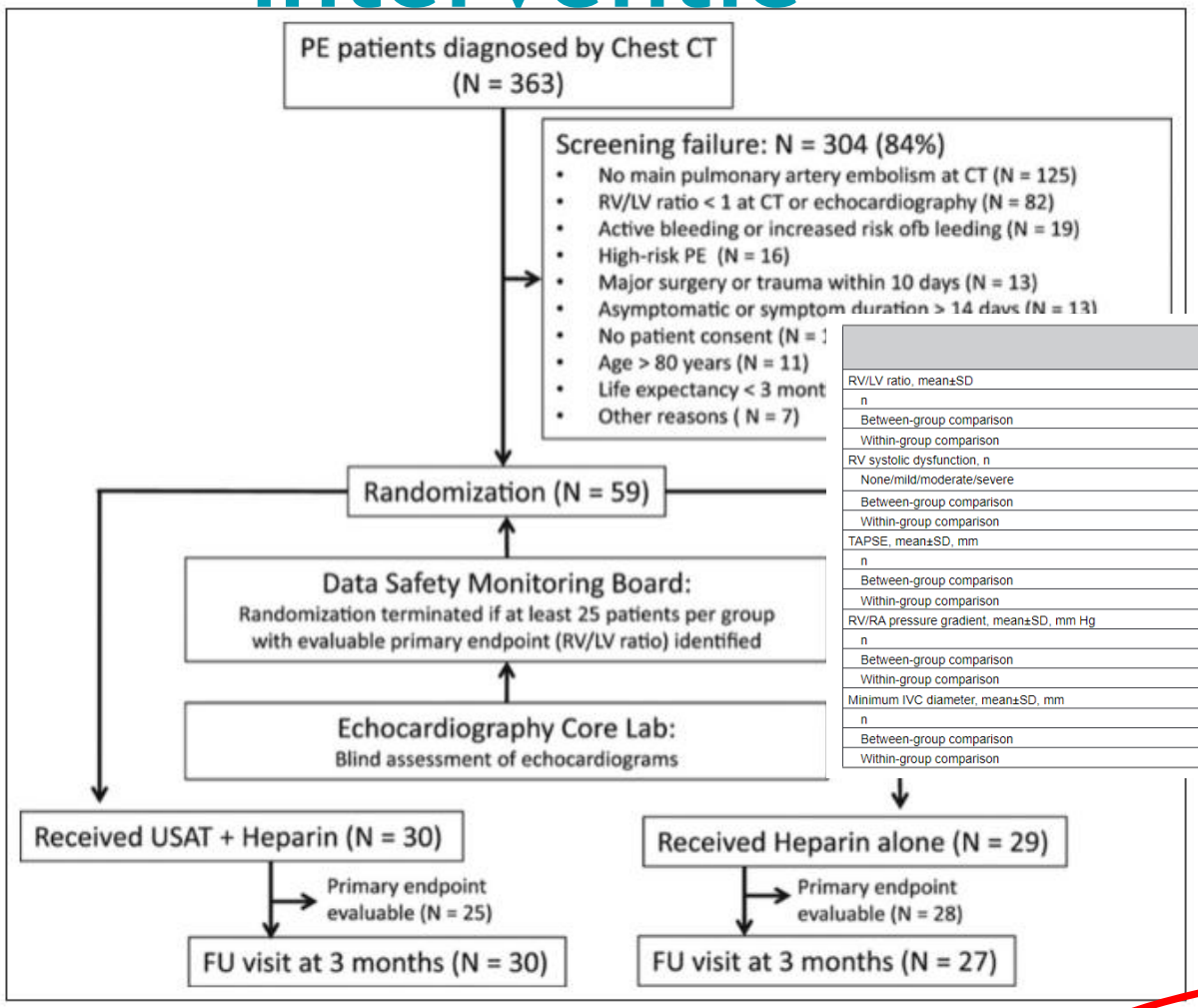
Sex :
- ◉ All
- ○ Female
- ○ Male

7	☐	Recruiting	Pulmonary Embolism International THrOmbolysis Study-3	• Pulmonary Embolism	• Drug: Alteplase • Drug: Placebo	• Graz, Mediz Universität Graz, Austria • UCL Brussels Bruxelles, Belgium • KU Leuven Leuven, Belgium • (and 94 more...)

clinicaltrials.gov

De katheter geleide interventie





	Baseline		24 h		90 days		Difference: Baseline vs 24 h		Difference: Baseline vs 90 d	
	USAT	Heparin	USAT	Heparin	USAT	Heparin	USAT	Heparin	USAT	Heparin
RV/LV ratio, mean±SD	1.28±0.19	1.20±0.14	0.99±0.17	1.17±0.20	0.92±0.15	0.96±0.16	0.30±0.19	0.03±0.16	0.35±0.22	0.24±0.19
n	26	29	28	28	26	27	25	28	23	27
Between-group comparison	*P*=0.07		*P*=0.001		*P*=0.36		*P*<0.001		*P*=0.07	
Within-group comparison	NA		NA		NA		*P*<0.001	*P*=0.31	*P*<0.001	*P*<0.001
RV systolic dysfunction, n										
None/mild/moderate/severe	0/4/5/16	0/5/11/13	5/10/10/2	1/9/7/11	19/5/0/0	10/15/1/1	1.1±0.8*	0.3±0.4*	2.2±0.9*	1.5±0.9*
Between-group comparison	*P*=0.37		*P*=0.01		*P*=0.003		*P*<0.001		*P*=0.01	
Within-group comparison	NA		NA		NA		*P*<0.001	*P*=0.02	*P*<0.001	*P*<0.001
TAPSE, mean±SD, mm	15.7±3.8	19.9±5.8	18.6±4.3	19.4±5.0	21.4±4.6	23.0±3.6	−3.1±4.4	0.9±4.9	−6.1±4.6	−3.4±5.4
n	20	20	20	23	19	23	16	18	13	18
Between-group comparison	*P*=0.01		*P*=0.56		*P*=0.21		*P*=0.02		*P*=0.16	
Within-group comparison	NA		NA		NA		*P*=0.014	*P*=0.43	*P*<0.001	*P*=0.02
RV/RA pressure gradient, mean±SD, mm Hg	42.8±16.6	42.2±16.3	33.9±13.2	40.2±13.3	33.1±13.1	29.9±17.7	9.8±9.9	0.3±10.9	12.3±12.8	11.6±15.1
n	17	22	14	21	12	13	11	17	10	11
Between-group comparison	*P*=0.91		*P*=0.18		*P*=0.62		*P*=0.03		*P*=0.91	
Within-group comparison	NA		NA		NA		*P*=0.01	*P*=0.91	*P*=0.01	*P*=0.03
Minimum IVC diameter, mean±SD, mm	15.5±6.2	14.4±4.3	10.8±3.4	17.4±6.8	9.4±3.6	9.9±5.2	7.2±3.9	0.7±5.0	4.0±9.1	6.1±5.4
n	10	10	8	10	8	13	6	7	4	7
Between-group comparison	*P*=0.65		*P*=0.02		*P*=0.80		*P*=0.02		*P*=0.69	
Within-group comparison	NA		NA		NA		*P*=0.01	*P*=0.72	*P*=0.44	*P*=0.02

Veilig
De RV functie herstelt sneller en beter op korte en lange termijn

Kucher et al. Circulation 2014

Toekomst

Ultrasound-facilitated, catheter-directed thrombolysis vs anticoagulation alone for acute intermediate-high-risk pulmonary embolism: Rationale and design of the HI-PEITHO study

Kathetergeleide lokale thrombolyse versus standaard anticoagulation

Primaire eindpunt: dood, hemodynamische decompensatie, recidief
Veiligheid
Lange termijn oa functionele beperkingen, kwaliteit van leven

20	☐	Recruiting	Ultrasound-facilitated, Catheter-directed, Thrombolysis in Intermediate-high Risk Pulmonary Embolism	• **Pulmonary Embolism**	• Drug: Anticoagulation with heparin • Device: EkoSonicTM Endovascular System	• University of Alabama at Birmingham Birmingham, Alabama, United States • Cedars - Sinai Medical Center Los Angeles, California, United States • University of California Davis Sacramento, California, United States • (and 60 more...)

clinicaltrials.gov

Op welke afdeling in uw ziekenhuis neemt u deze patiënt op?

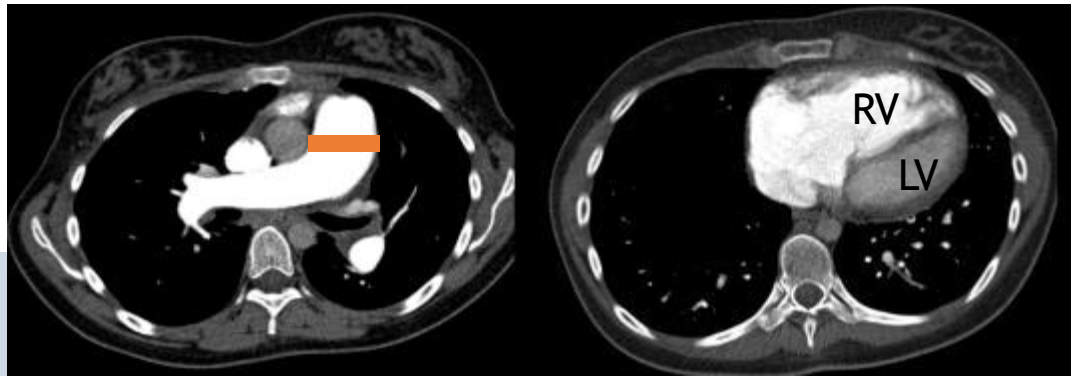
A. Verpleegafdeling

B. IC/MC

C. CCU

D. Verpleegafdeling met ritmebewaking

E. Anders, namelijk ….



Behandeling bij intermediate-high risk longembolieën

into an *intermediate-high-risk* category. As discussed in more detail in the following section, close monitoring is recommended in these cases to permit early detection of haemodynamic decompensation and the need for initiation of rescue reperfusion therapy.[253] On the

?

2019 ESC Guidelines on the diagnosis and management of acute pulmonary embolism. EHJ.

Beleid

Intermediate high-risk

Opname op MC, UFH iv

Blijft stabiel

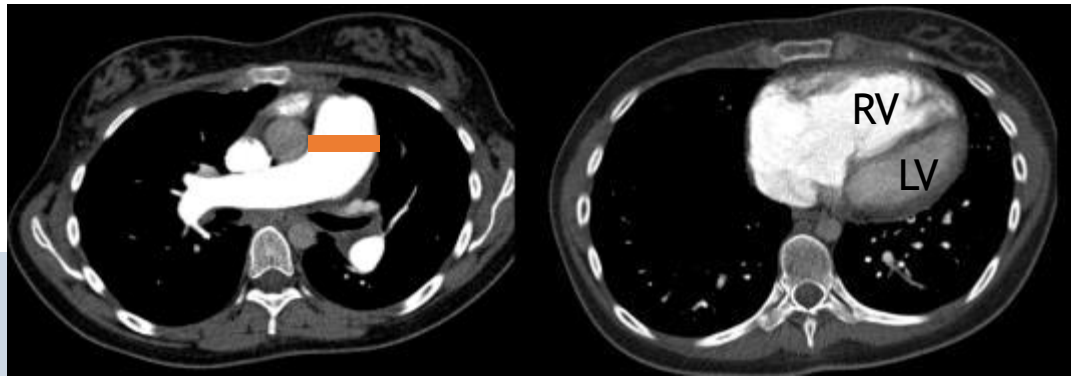
Na 48 uur overplaatsing verpleegafdeling, O2 snel kunnen afbouwen en ontslag naar huis met DOAC

Intermediate high-risk longembolieën.

Behandeling:

Geen plaats (full-dose) systemische thrombolyse

“ Wat als” plan

Toekomst:

- Betere herkenning van de patient die hemodynamisch zal verslechteren.
- Risico inschatting major bleeding.
- Lange termijn uitkomsten.