Thromboseforum - Update 2026:

Risikoadaptierte Behandlung der Lungenembolie

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Interessenkonflikte

- Honoraria für Beratung, Vorträge: Daiichi Sankyo, Boston Scientific, Inari Medical/Stryker, MSD, Novartis, Penumbra Inc.
- Forschungsförderung (an die UM Mainz): Daiichi Sankyo, Boston Scientific, Inari Medical/Stryker, Penumbra Inc., Getinge AB

Übersicht

- Leitlinienempfehlungen: aktueller Stand

Risikostratifizierung in den ESC-Leitlinien (2019)

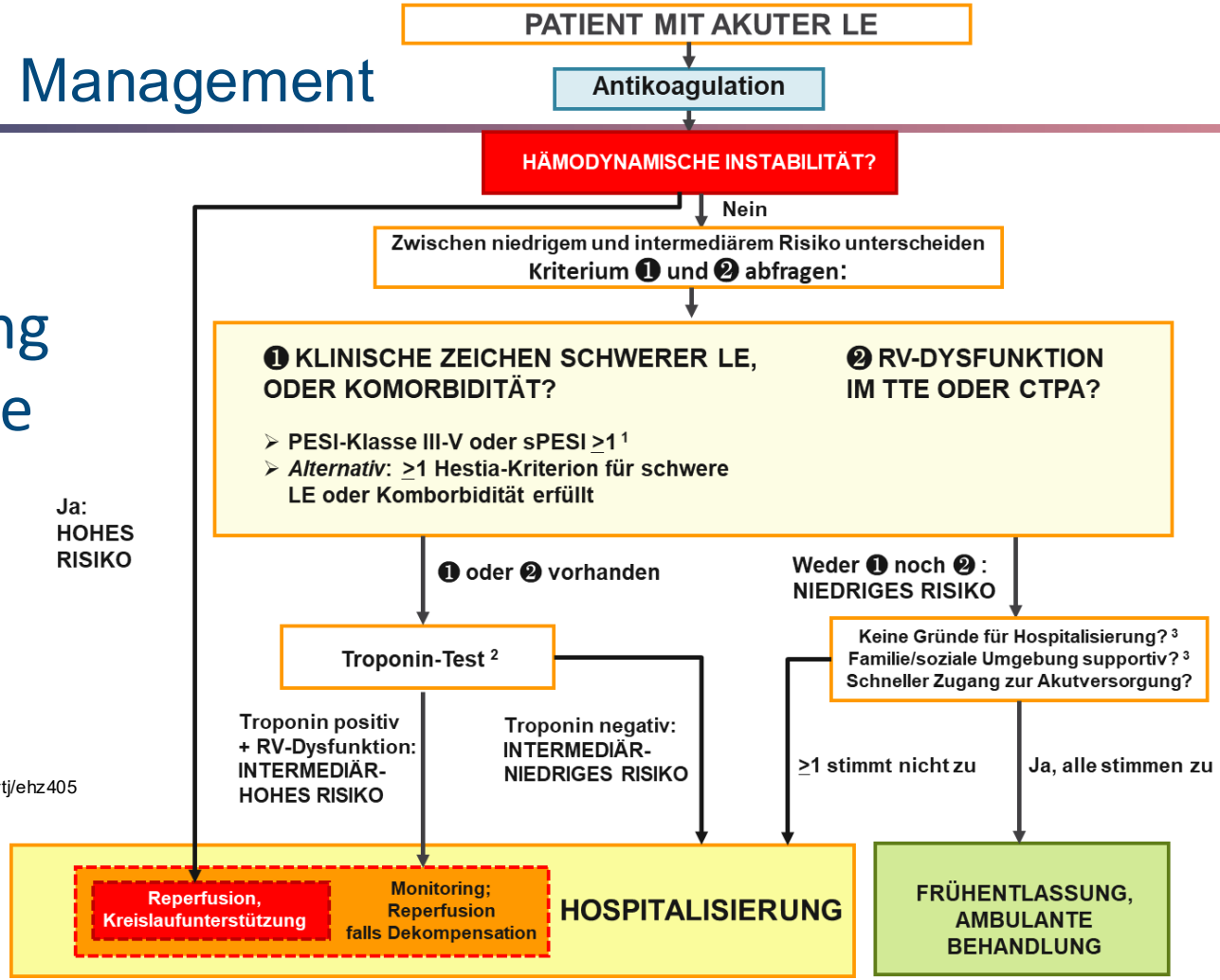
Klinische (In)stabilität, RV-Bildgebung, Komorbiditäten, Labormarker

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

2019 ESC Guidelines on the diagnosis and management of acute pulmonary embolism. *Eur Heart J* 2019 - doi/10.1093/eurheartj/ehz405

Risiko-adaptiertes Management

Akutbehandlung Lungenembolie (Status 2019)



ESC Guidelines. *Eur Heart J* 2019; doi:10.1093/eurheartj/ehz405

DGK Pocket-Leitlinie Lungenembolie 2020

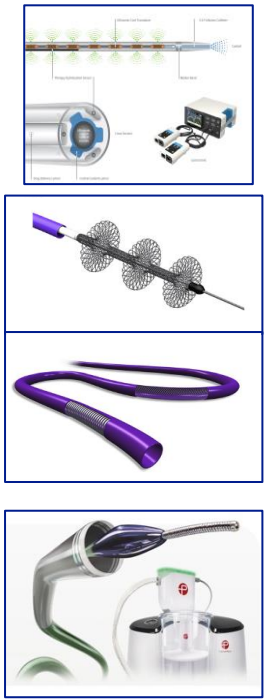
Wirksamkeit vs. Sicherheit einer systemischen Lyse – PEITHO

	Tenecteplase (n=506)		Placebo (n=499)		*P* value
	n	(%)	n	(%)	
Primary efficacy endpoint					
All-cause mortality or hemodynamic collapse within 7 days of randomization	13	(2.6)	28	(5.6)	0.015
Strokes by day 7	**12**	**(2.4)**	**1**	**(0.2)**	**0.003**
Hemorrhagic	10		1		
Ischemic	2		0		

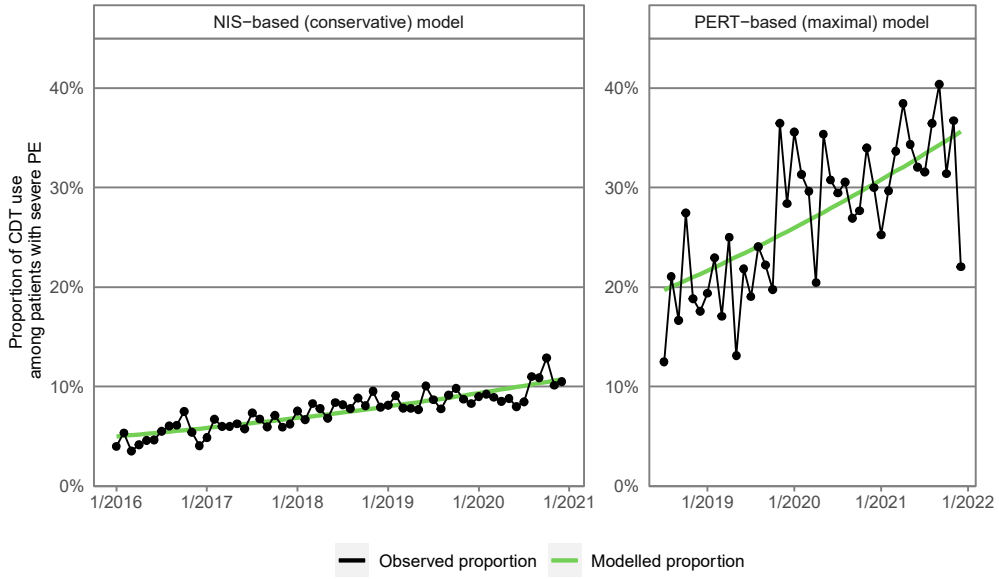
Meyer G *et al*, for the PEITHO Investigators. *N Engl J Med* 2014;370:1402-11

Zunehmend Fokus auf Katheter-gestützte Interventionen

Lokale Thrombolyse, mechanische Thrombektomie



Konservatives (NIS) und maximales (PERT) Modell des Wachstums der CDT-Einsätze in Deutschland in den kommenden Jahren (2025 bis 2030) auf der Basis von US-Daten (2016-2022)



Mohr K, et al. *Eur Heart J Acute Cardiovasc Interv* 2024. doi: 10.1093/ehjacc/zuae019

Neueste nordamerikanische Empfehlungen 2026

AHA/ACC PE Risk Outcomes Category	Systemic Lysis	CDL	MT	Surgery
A-C1	3-Harm A	3-NB C-EO	3-NB C-EO	3-NB C-EO
C2	3-Harm B-R	2B C-LD (unclear)	2B C-LD (unclear)	3-NB C-EO
C3	2B C-LD (unclear)	2B C-LD (unclear)	2B C-LD (unclear)	3-NB C-EO
D1-2	**2B C**-LD (may be considered)	**2B B**-NR (may be considered)	**2B B-NR** (may be considered)	**2B C**-LD (unclear)
E1	2A C-LD	2A C-LD	2A B-NR	2A B-NR
E2	2A C-LD	N/A	N/A	3-NB B-NR

Creager MA, et al. 2026 AHA/ACC/ACCP/ACEP/CHEST/SCAI/SHM/SIR/SVN Guideline for the Evaluation and Management of Acute Pulmonary Embolism in Adults. *J Am Coll Cardiol* 2026. DOI:10.1016/j.jacc.2025.11.005

Übersicht

- ✓ Leitlinienempfehlungen: aktueller Stand
- ➢ Was haben wir in den vergangenen 12 Monaten gelernt?

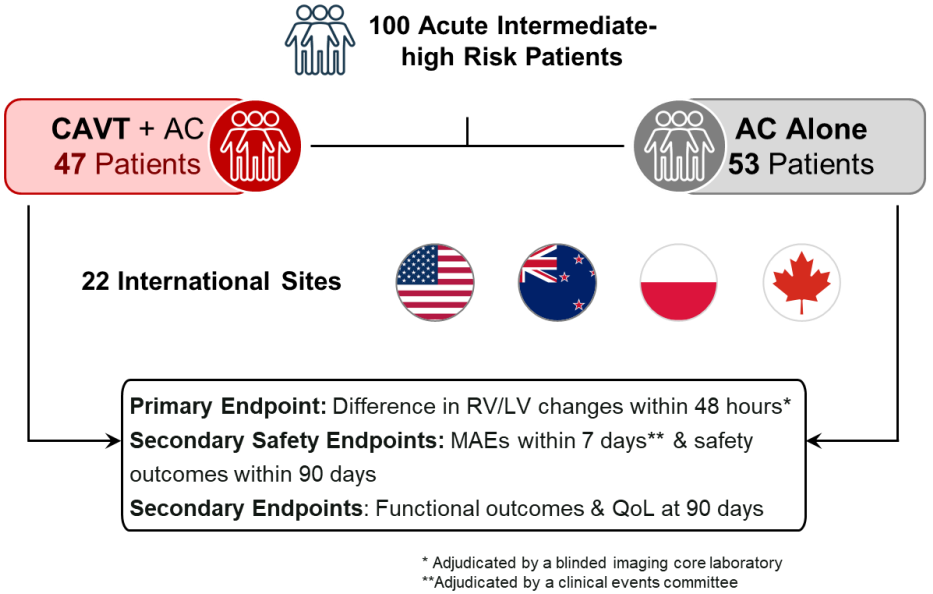
STORM-PE – Mechanische Thrombektomie vs. Antikoagulation

Inclusion

- ✓ Clinical signs & symptoms of acute PE (≤ 14 days)
- ✓ CTPA showing filling defect in ≥ 1 main or proximal lobar pulmonary artery
- ✓ RV/LV ratio ≥ 1.0 on CTPA
- ✓ Elevated cardiac biomarkers

Exclusion

- × Hemodynamic instability or on ECMO
- × CTEPH or CTED findings
- × Primary brain or metastatic brain cancer
- × Life expectancy < 90 days
- × **NEWS2 ≥ 9**

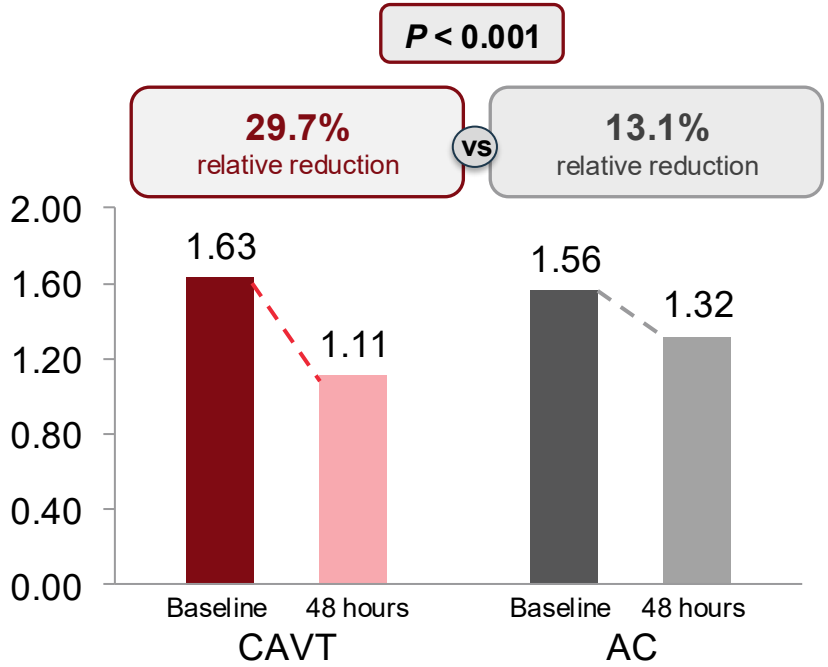


Lookstein R, et al. *Circulation* 2025. doi: 10.1161/CIRCULATIONAHA.125.077232

STORM-PE - Änderung der RV/LV-Ratio binnen 48 Stunden

RV/LV Ratio	CAVT (N=46)	AC (N=52)	*P* value
Baseline	1.63 ± 0.36	1.56 ± 0.35	0.397
48 Hours	1.11 ± 0.28	1.32 ± 0.31	<0.001
Absolute Reduction*	**0.52 ± 0.37**	**0.24 ± 0.40**	**<0.001**
Between-group difference (95% CI) in reduction: Δ 0.27 (0.12, 0.43)			

*Paired data
One patient in each arm had a 0 change in RV/LV ratio assigned



Lookstein R, et al. *Circulation* 2025. doi: 10.1161/CIRCULATIONAHA.125.077232

STORM-PE: Major Adverse Events binnen 7 Tagen

MAE Composite, Components, & Additional Details	CAVT (N = 47)	AC (N = 53)	*P* value
Composite MAE ≤ 7 Days	**2 (4.3%)**	**4 (7.5%)**	**0.681**
Clinical Deterioration Requiring Rescue Therapy	1 (2.1%)	3 (5.7%)	0.620
PE-related Mortality	2 (4.3%)	0 (0.0%)	0.218
Major Bleeding*	1 (2.1%)	1 (1.9%)	>0.999
Major Bleeding Requiring Transfusion	1 (2.1%)	1 (1.9%)	NA
AC-related MAEs	0 (0.0%)	2 (3.8%)	NA
Device- or Procedure-related MAEs	0 (0.0%)	NA	NA

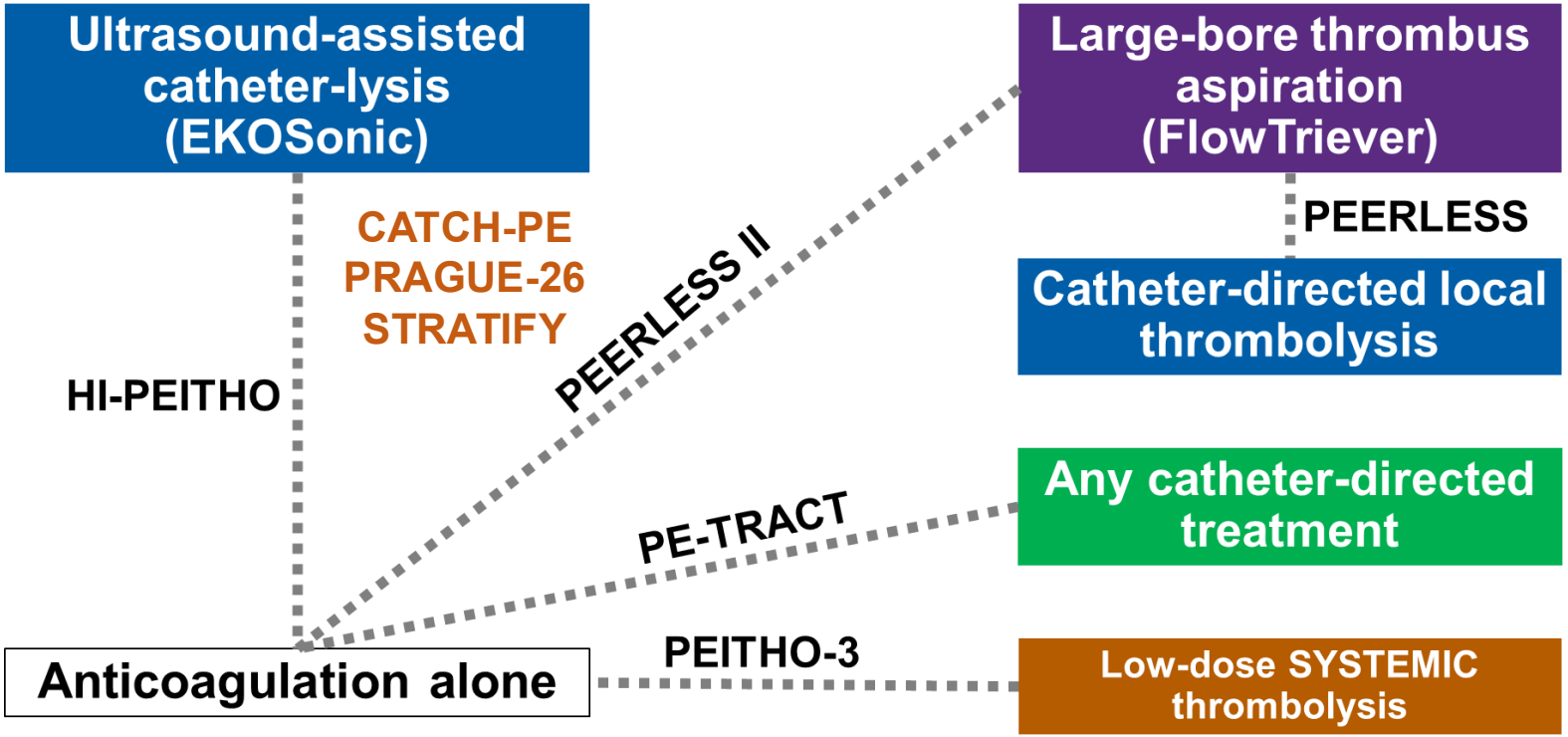
*Death, clinical deterioration, and major bleeding all occurred in the same CAVT patient.

Lookstein R, et al. *Circulation* 2025. doi: 10.1161/CIRCULATIONAHA.125.077232

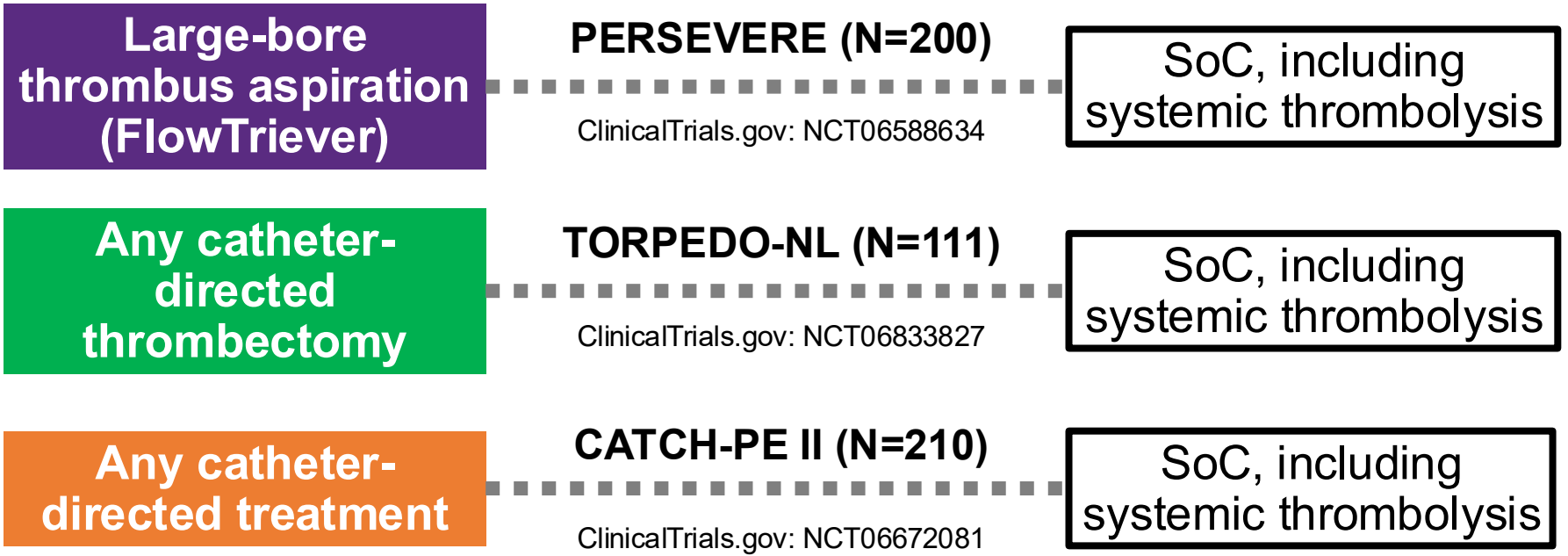
Übersicht

- ✓ Leitlinienempfehlungen: aktueller Stand
- ✓ Was haben wir seit den letzten Leitlinien gelernt?
- ➢ Was erwarten wir in diesem und im nächsten Jahr?

Große laufende Studien: intermediäres Risiko



Große laufende Studien: hohes Risiko



Überblick der laufenden randomisierten Studien

HI-PEITHO (NCT04790370)

- Standardized protocol of ultrasound
  standard of care (anticoag
- 544 patients, int
- FU: 12
- ath *or* clinical decompensation
  (7 d)
- dary: Safety, functional outcomes, CTEPH

First late-breaking clinical trial presentation at ACC congress, March 28, 09:30 a.m.

PE-TRACT (NCT05591118)

- Pharmaco-mechanical (w lysis) or purely mechanical CDT ***vs*** SoC
- 500 patients, intermediate risk & RV dysfunction
- FU: 12 months
- Primary EP: Peak VO_2 (3m) *or* NYHA class (12m)
- Secondary: Decompensation, 6MWD, SF-36

PEERLESS II (NCT06055920)

- Large-bore mechanical thrombectomy ***vs*** SoC
- 1200 patients, intermediate-risk PE
- FU: 3 months
- Primary EP: Death (30d) → decompensation (30d) → rehospitalization (30d) → Tx escalation (30d) → Dyspnea (mMRC scale; 2d)
- Secondary: Readmissions, QoL, post-PE impairment

PERSEVERE (NCT05684796)

- Large-bore mechanical thrombectomy ***vs*** SoC
- 200 patients, high-risk PE
- FU: 3 months
- Primary EP: All-cause death *or* cardiac arrest or bailout *or* major bleeding BARC *or* ECMO (7d)
- Secondary: Days outside hosp, QoL, PPEI (3m)

Große akademische randomisierte Studie zur Lyse

A reduced dose (0.6 mg/kg; max, 50 mg) of **thr** **olytic** treatment (alteplase) for patients with intermediate ute pulmonary emb

The Pulmonary Embo HrOmbolysis trial - 3 O-3)

LATEST update: 790 (98.8%) out of 800 patients enrolled as of 24th February 2026 - LPI expected March 2026

HÔPITAUX DE PARIS

UNIVERSITÄTSmedizin. MAINZ

CTH Centrum für Thrombose und Hämostase Mainz

ClinicalTrials.gov Identifier: NCT04430569

Die systemische Thrombolyse ist kein „Auslaufmodell“!

Als Alternative zu oder in Kombination mit Intervention

- ☑ Funktioniert bei Allen
- ☑ Standardisiert
- ☑ Sofort anwendbar, schnell wirkend
- ☑ (Fast) überall vorhanden und verfügbar
- ☑ (Relativ) kostengünstig

- ➢ Wirksamkeit und Sicherheit müssen noch durch eine große RCT bestätigt werden

Übersicht

- ✓ Leitlinienempfehlungen: aktueller Stand
- ✓ Was haben wir seit den letzten Leitlinien gelernt?
- ✓ Was erwarten wir im kommenden Jahr?
- ➢ Neue Management-Strategien, nicht nur neue Interventionen!

Risikostratifizierung überdenken

Klinische (In)stabilität, RV-Bildgebung, Komorbiditäten, Labormarker

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

Eur Heart J 2019; doi:10.1093/eurheartj/ehz405

Intermediäres Risiko überdenken: zusätzliche Kriterien

1) Age 18-80 years
2) Objectively confirmed acute PE, based on computed tomography pulmonary angiography (CTPA) involving at least one main or proximal lobar pulmonary artery
3) Erhöhtes Risiko von Tod/Kreislaufkollaps: **≥ 2 Kriterien**:
   a) Tachykardie: ≥100/min (dokumentiert) OHNE Hypovolämie, Arrhythmie, Sepsis;
   b) Hypotension: SBP ≤ 110 mm Hg over at least 15 min;
   c) Tachypnoe/Hypoxämie: AF >20/min, oder SpO_2 <90% (PO_2 <60 mmHg) unter RL
4) Right-to-left ventricular (RV/LV) diameter ratio ≥ 1.0 on CTPA
5) Serum troponin I or T levels above the upper limit of normal (measured by high sensitivity assay)

Am Heart J 2022;251:43-53. doi: 10.1016/j.ahj.2022.05.011

Fokus auf die Hypoperfusion - mehr als auf den Blutdruck

Ann Emerg Med. 2013 Mar;61(3):330-8. doi: 10.1016/j.annemergmed.2012.10.022. Epub 2013 Jan 7.

Prognostic value of plasma lactate levels among patients with acute pulmonary embolism: the thrombo-embolism lactate outcome study

Simone Vanni [1], Gabriele Viviani, Michele Baioni, Giuseppe Pepe, Peiman Nazerian, Filippo Socci, Maurizio Bartolucci, Marco Bartolini, Stefano Grifoni

Results: Of the 270 patients included in the study, the mean age was 73 years (SD 12.7 years) and 151 (55.9%) were women. Twelve patients (4.4%) showed shock or hypotension (shock or systolic arterial pressure <100 mm Hg) at presentation, 109 (40.4%) had right-sided ventricular dysfunction, 93 (34.4%) showed troponin I level greater than or equal to 0.10 ng/mL, and 81 (30%) showed lactate level greater than or equal to 2 mmol/L. Seventeen patients (6.3%) died, 12 (4.4%) because of pulmonary embolism, and 37 (13.7%) reached the composite endpoint. Patients with lactate level greater than or equal to 2 mmol/L showed higher mortality (17.3%; 95% confidence interval [CI] 11.9% to 20%) than patients with a lower level (1.6%; 95% CI 0.8% to 1.9%). Plasma lactate level was associated with all-cause death (hazard ratio 11.67; 95% CI 3.32 to 41.03) and the composite endpoint (hazard ratio 8.14; 95% CI 3.83 to 17.34) independent of shock or hypotension, right-sided ventricular dysfunction, or elevation of troponin I values.

ELSEVIER

European Journal of Internal Medicine

journal homepage: www.elsevier.com/locate/ejim

Original article

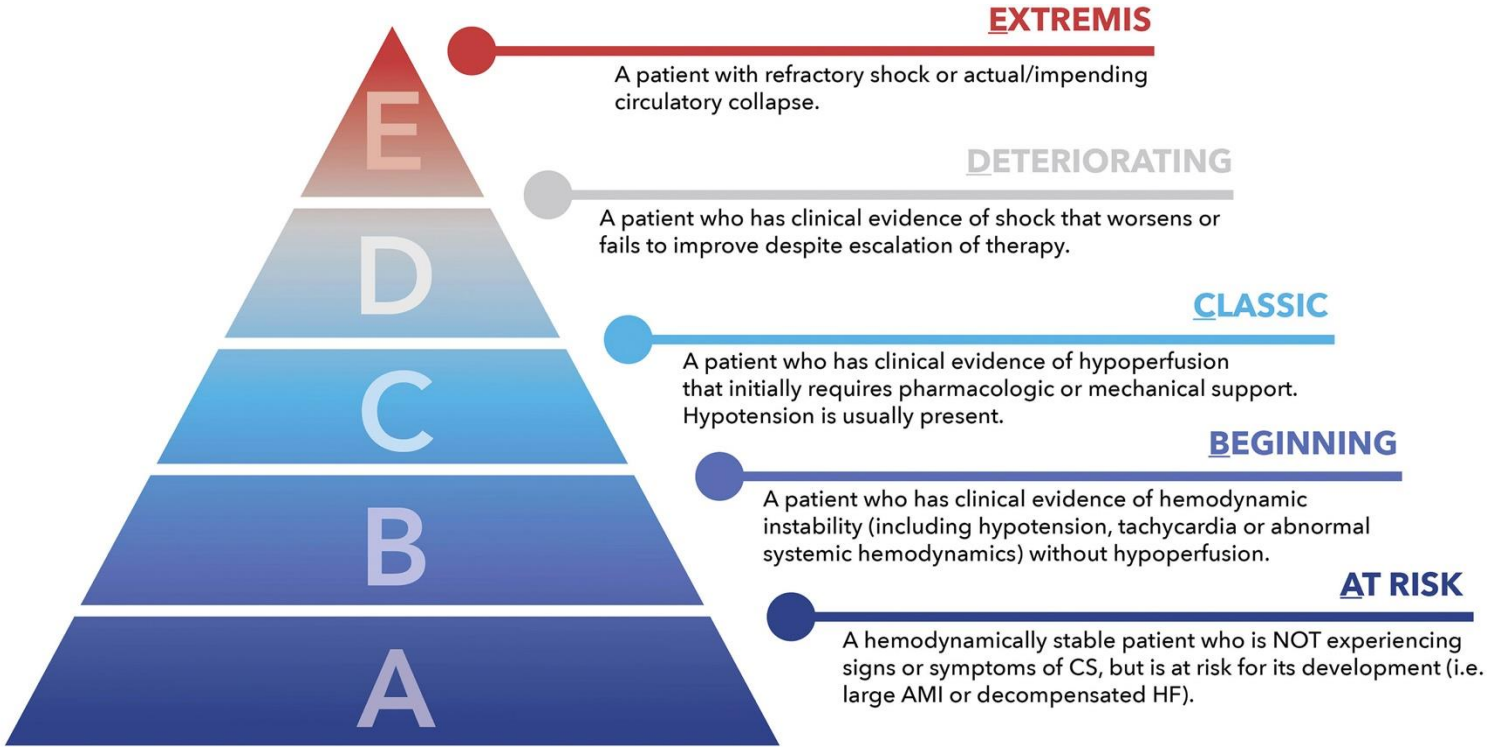
Venous lactate improves the prediction of in-hospital adverse outcomes in normotensive pulmonary embolism

Matthias Ebner [a,b], Charlotta F. Pagel [c], Carmen Sentler [c], Veli-Pekka Harjola [d], Héctor Bueno [e,f,g], Markus H. Lerchbaumer [h], Karl Stangl [a], Burkert Pieske [b,i,j], Gerd Hasenfuß [c,k], Stavros V. Konstantinides [l,m], Mareike Lankeit [b,c,i,l,*]

Results: An optimised venous lactate cut-off value of 3.3 mmol/l predicted both, in-hospital adverse outcome (OR 11.0 [95% CI 4.6–26.3]) and all-cause mortality (OR 3.8 [95%CI 1.3–11.3]). The established cut-off value for

Conclusion: Venous lactate above the upper limit of normal was associated with increased risk for adverse outcomes and an optimised cut-off value of 3.3 mmol/l predicted adverse outcome and mortality. Adding venous lactate to the 2019 ESC algorithm may improve risk stratification. Importantly, the established cut-off value for arterial lactate has limited specificity in venous samples and should not be used.

Harmonisierung der Schock-Definition



Naidu S *et al*, SCAI SHOCK Stage Classification Expert Consensus Update. *J Am Coll Cardiol.* 2022;79:933-946

Dynamischen Verlauf der Vitalzeichen integrieren

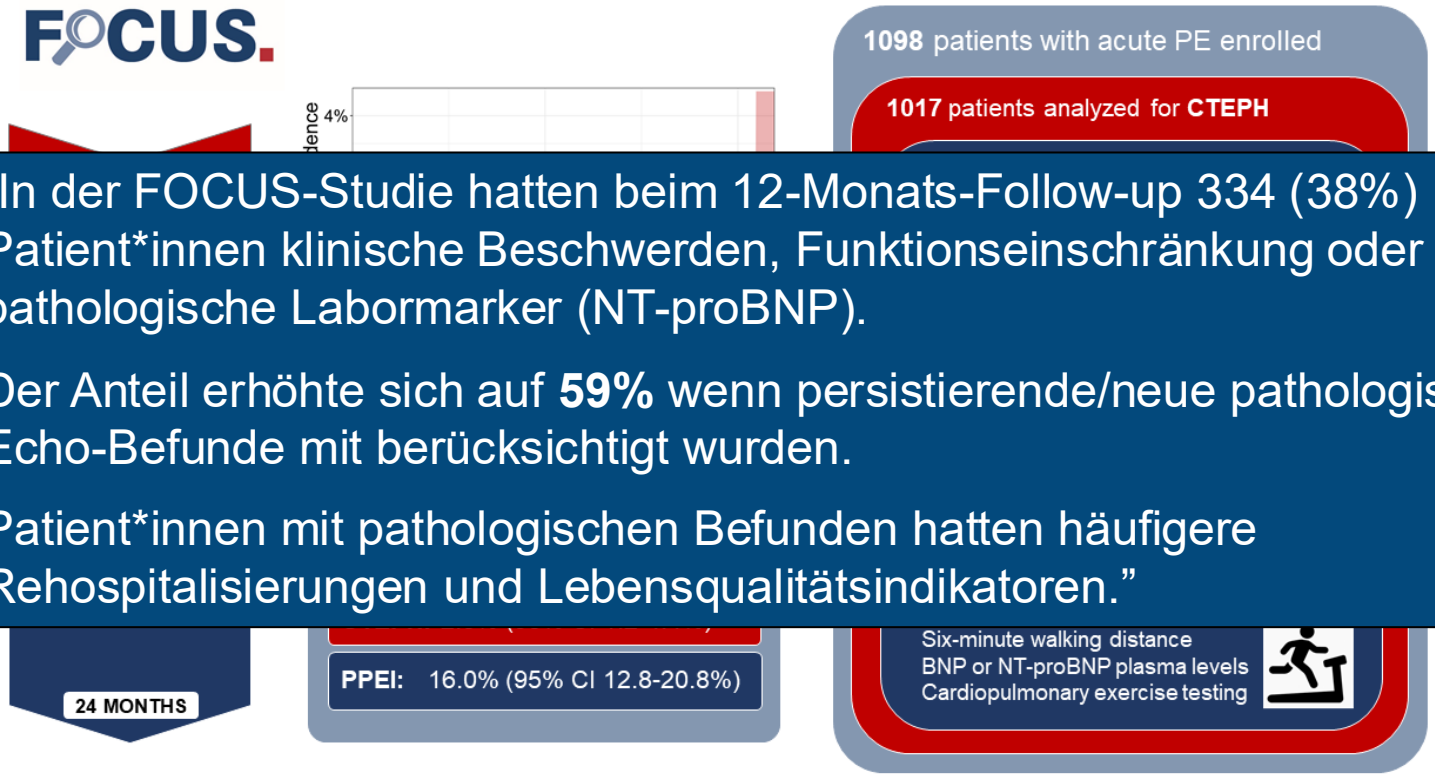
Kriterium für die Wahl - und den Erfolg - der Therapie

PHYSIOLOGICAL PARAMETERS	3	2	1	0	1	2	3
Respiration Rate	≤8		9 - 11	12 - 20		21 - 24	≥25
Oxygen Saturations	≤91	92 - 93	94 - 95	≥96			
Any Supplemental Oxygen		Yes		No			
Temperature	≤35.0		35.1 - 36.0	36.1 - 38.0	38.1 - 39.0	≥39.1	
Systolic BP	≤90	91 - 100	101 - 110	111 - 219			≥220
Heart Rate	≤40		41 - 50	51 - 90	91 - 110	111 - 130	≥131
Level of Consciousness				A			V, P, or U

- Currently being validated in HI-PEITHO, STORM-PE TRIAL

https://www.mdcalc.com/national-early-warning-score-news

Können Interventionen den Langzeitverlauf verbessern?



- "In der FOCUS-Studie hatten beim 12-Monats-Follow-up 334 (38%) Patient*innen klinische Beschwerden, Funktionseinschränkung oder pathologische Labormarker (NT-proBNP).
- Der Anteil erhöhte sich auf **59%** wenn persistierende/neue pathologische Echo-Befunde mit berücksichtigt wurden.
- Patient*innen mit pathologischen Befunden hatten häufigere Rehospitalisierungen und Lebensqualitätsindikatoren."

BNP = brain natriuretic peptide; CI = confidence interval; CTEPH = chronic thromboembolic pulmonary hypertension; LV = left ventricular; NT-proBNP = N-terminal pro-brain natriuretic peptide; PE = pulmonary embolism; PPEI = post-pulmonary embolism impairment; RA = right atrial; RV = right ventricular; TAPSE = tricuspid annular plane systolic excursion; WHO = World Health Organization

Valerio L, et al. *Eur Heart J* 2022. doi:10.1093/eurheartj/ehac206

Wann sind Katheterthерapien der LE kosteneffektiv?

Acute intermediate- and high-risk PE:

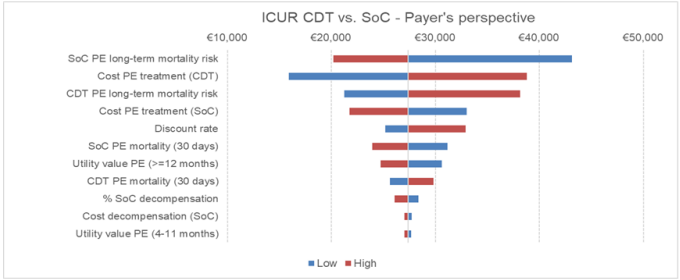
CDT or SoC ?

- **CDT for PE has higher upfront costs, but possible long-term benefits and cost savings**
- **Usage of CDT rising, socio-economic impact unclear**

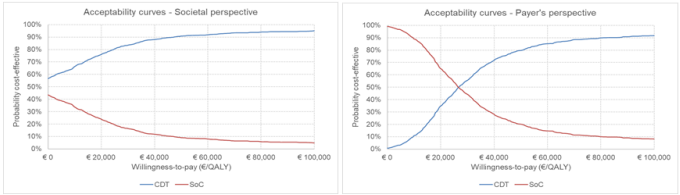
Cost-effectiveness and cost-utility analysis
(German healthcare system; 5-year horizon)

4.13 LY 3.58 QALY Mean cost per patient: • €11,657 (payer's perspective) • €33,313 (societal perspective)	3.90 LY 3.38 QALY Mean cost per patient: • €6087 (payer's perspective) • €37,501 (societal perspective)

- **Payer's perspective: ICUR €27,349 per QALY gained**
- **Societal perspective: CDT "dominant" (less costly than SoC)**



One-way sensitivity analysis: ICUR of CDT changes across each parameter's higher (red bars) and lower (blue bars) values, but remains below €45,000/QALY



Probabilistic sensitivity analysis: CDT becomes cost-effective at willingness to pay of €28,000/QALY *(payer's perspective)*; CDT remains cost effective at any threshold *(societal perspective)*

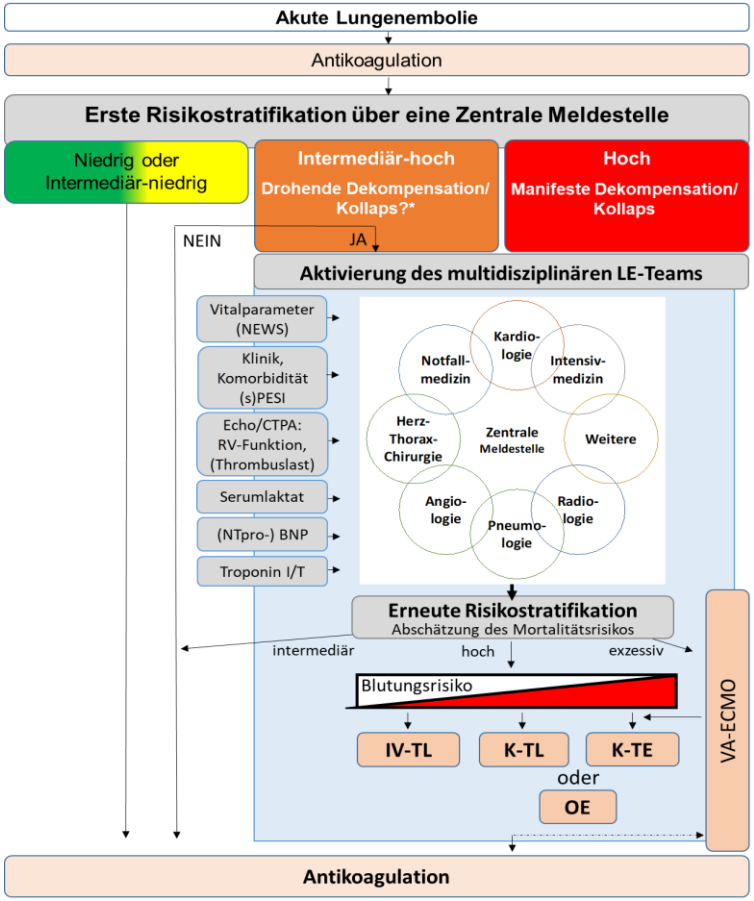
- **CDT may be cost-effective for selected patients with acute PE**
- **CDT may improve patient outcomes while remaining within the acceptable cost-effectiveness threshold**

CDT, catheter-directed thrombolysis; ICUR, incremental cost-utility ratio; LY, life-years; PE, pulmonary embolism; QALY, quality-adjusted life-years; SoC, standard of care

Mohr K, et al. *Eur Heart J Qual Care Clin Outcomes* 2026. doi:10.1093/ehjqcco/qcag003

Multidiziplinäres LE-Management im 5-Jahes-Horizont

- Ein Prozess in Evolution: mehrere Ebenen des hohen Risikos
- Optimierte klinische, laborchemische und Bildgebungskriterien für die Definition einer bevorstehenden Dekompensation
- Rechtzeitige Identifizierung der Kanditat*innen für eine Intervention
- Übergang zur ambulanten LE-Nachsorge



Ghanem A, [...], Konstantinides S. *Kardiologie* 2023;17:141–159.
https://doi.org/10.1007/s12181-023-00610-7