

INTERVENTIONELLE THERAPIE BEI PE - FUTILE OR LIFE-SAVING? KATHETERGESTÜTZTE THROMBOLYSE

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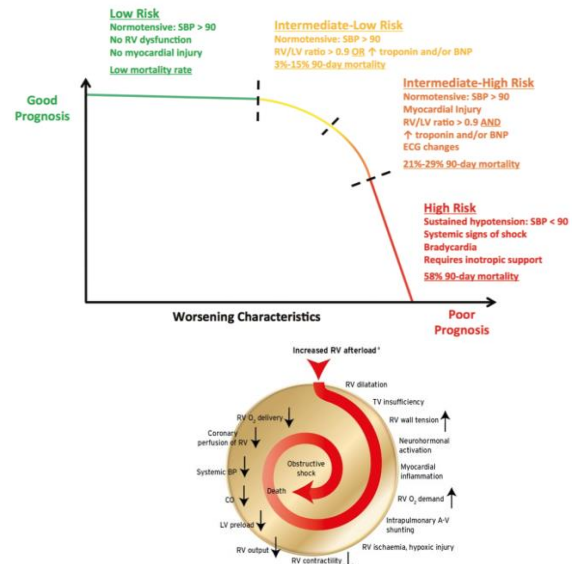
IFIMP 2025

Potentielle Interessenskonflikte
Teilnahme HI PEITHO Studie



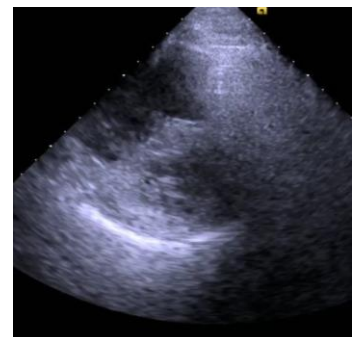
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D-sign



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Recommendations high risk PE	Class	Level
Percutaneous catheter directed treatment should be considered for patients with high-risk PE, in whom thrombolysis is contraindicated or has failed .	Ila	C

Bei **Kontraindikationen** gegen eine indizierte **systemische Thrombolyse** oder bei **Versagen** einer systemischen Thrombolyse sollen **endovaskuläre oder chirurgische Reperfusionenverfahren** als therapeutische Alternative erwogen werden. (Empfehlungsstärke: ↑↑, starker Konsens).

Recommendations intermediate high risk PE	Class	Level
As an alternative to rescue thrombolytic therapy, surgical embolectomy or percutaneous catheter-directed treatment should be considered for patients with haemodynamic deterioration on anticoagulation treatment.	Ila	C

Hämodynamisch stabile Patienten mit Lungenembolie und intermediärem Risiko sollen **primär eine therapeutische Antikoagulation erhalten** und innerhalb der ersten (meist 2-3) Tage stationär überwacht werden, um bei klinischer Verschlechterung eine Therapieeskalation (z.B. Reperfusionstherapie) rechtzeitig einleiten zu können. (Empfehlungsstärke: ↑↑, starker Konsens)

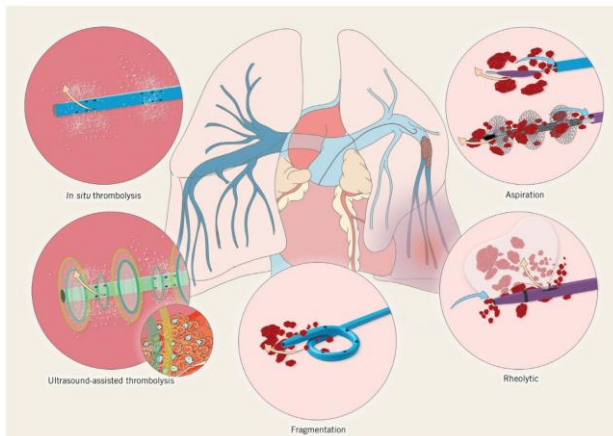
Linnemann et al., Diagnostik und Therapie der tiefen Venenthrombose und Lungenembolie – AWMF-S2k-Leitlinie

S. V. Konstantinides et al., 2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS), European Heart Journal (2019) 00, 1-61



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Anatomical Complexity

Disease-Related

Patient-Related

Technical Issues

S. Finocchiaro et al., Percutaneous interventions for pulmonary embolism, EuroIntervention 2024;20:e408-e424

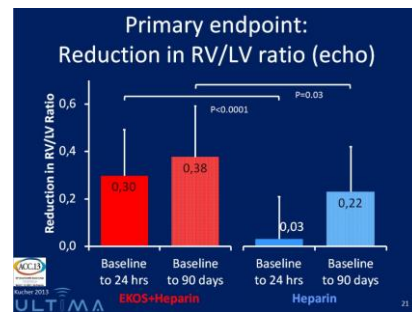
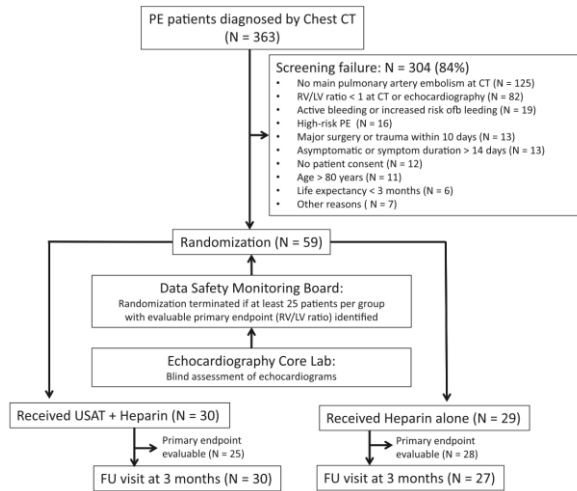
M. Zuñin et al., Innovation in Catheter-Directed Therapy for Intermediate-High-Risk and High-Risk Pulmonary Embolism, JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 17, NO. 19, 2024



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ULTIMA



Secondary endpoint analysis

Clinical outcomes at 90 days	EKOS + Heparin N = 30	Heparin N = 29	p-value
Death	0	1*	0.49
Recurrent venous thromboembolism	0	0	1.00
Major bleeding	0	0	1.00
Minor bleeding	3**	1 [§]	0.61

*: rehospitalization and death from advanced pancreatic cancer.
 **: two patients with transient mild hemoptysis without medical intervention, one patient with groin hematoma requiring manual compression, one patient with transient anal bleeding following endoscopic removal of colon polyp.

Kucher N. et al., Randomized, Controlled Trial of Ultrasound-Assisted Catheter-Directed Thrombolysis for Acute Intermediate-Risk Pulmonary Embolism, Circulation. 2014;129:479-486



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ULTIMA

Table 3. Invasive Hemodynamic Measurements in Patients From the Ultrasound-Assisted Catheter-Directed Thrombolysis Group

	Baseline	Follow-Up*	Difference: Baseline vs Follow-Up	P Value
Pulmonary artery systolic pressure, mm Hg	52.0±11.5 (n=27)	39.7±10.3 (n=26)	12.3±10.0 (n=26)	<0.001
Pulmonary artery diastolic pressure, mm Hg	19.6±8.1 (n=27)	16.2±5.4 (n=26)	3.2±7.8 (n=26)	0.049
Pulmonary artery mean pressure, mm Hg	30.2±9.1 (n=27)	24.1±6.7 (n=26)	5.7±7.6 (n=26)	<0.001
Right atrial mean pressure, mm Hg	12.5±6.0 (n=24)	8.8±4.1 (n=21)	4.5±7.3 (n=19)	0.015
Cardiac index, L/min per m ²	2.5±0.5 (n=16)	3.9±2.3 (n=15)	-0.7±0.6 (n=10)	0.005

*Follow-up hemodynamic data were obtained at 18±3 h after initiation of therapy.

Kucher N. et al., Randomized, Controlled Trial of Ultrasound-Assisted Catheter-Directed Thrombolysis for Acute Intermediate-Risk Pulmonary Embolism, Circulation. 2014;129:479-486



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SEATTLE II

- 150 Patienten
- multizentrisch, single-arm
- EKOS
- massive und submassive Pulmonalembolie



Baseline demographics and clinical characteristics	N=150 No. (%)
Age, years	59±16.1
Female	77 (51.3)
Immobility within 30 days of PE	45 (30)
Previous DVT	30 (20)
Previous PE	15 (10)
Active infectious illness within 30 days of PE	20 (13.3)

PE characteristics and anticoagulation	N=150 No. (%)
Duration of symptom ≤ 14 days	149 (99.3)
Submassive PE	119 (79.3)
Massive PE	31 (20.7)
Previous DVT	30 (20)
Previous PE	15 (10)
Pre procedure UFH	76 (50.7)

Piazza G. et al., A Prospective, Single-Arm, Multicenter Trial of Ultrasound-Facilitated, Catheter-Directed, Low-Dose Fibrinolysis for Acute Massive and Submassive Pulmonary Embolism, The SEATTLE II Trial, Am Coll Cardiol Intv 2015;8:1382–92



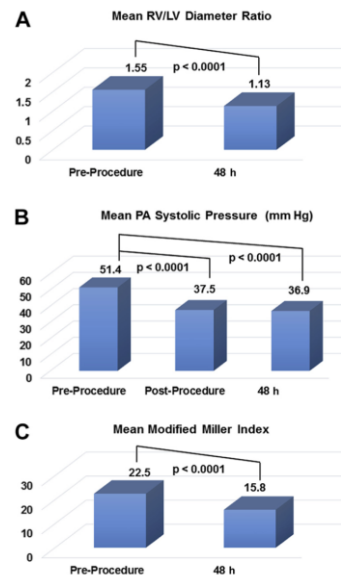
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SEATTLE II

Procedure characteristics	N=150
Total dose of t-Pa, mg	23.7±2.9
Successful device placement, no. (%)	278 (97.5)
2 devices implanted, no. (%)	129 (86)

Safety outcomes	N=150
Length of stay, SD, days	8.8±5
In hospital death, no. (%)	3 (2)
30 day mortality,, no. (%)	4 (2.7)
Major bleeding within 30 days, no. (%)	15 (10)
Intracranial hemorrhage	0 (0)



Piazza G. et al., A Prospective, Single-Arm, Multicenter Trial of Ultrasound-Facilitated, Catheter-Directed, Low-Dose Fibrinolysis for Acute Massive and Submassive Pulmonary Embolism, The SEATTLE II Trial, Am Coll Cardiol Intv 2015;8:1382–92

Sterling et al., Prospective Multicenter International Registry of Ultrasound-Facilitated Catheter-Directed Thrombolysis in Intermediate-High and High-Risk Pulmonary Embolism, Circ Cardiovasc Interv. 2024;17:e013448



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OPTALYSE

- RV/LV Ratio ≥ 0.9 (n=101; 17 Zentren)
- optimale Dauer und Dosis von r-tPA
- EKOS
- Änderung der RV/LV ratio in der CT nach 48 Stunden
- Major bleeding innerhalb von 72 Stunden

Randomization			
Cohort 1	Cohort 2	Cohort 3	Cohort 4
26 Patients 2 (h) EKOS™ 4/8 mg r-tPA*	26 Patients 4 (h) EKOS™ 4/8 mg r-tPA*	27 Patients 6 (h) EKOS™ 6/12 mg r-tPA*	18 Patients 6 (h) EKOS™ 12/24 mg r-tPA*



Tapson V. et al., Optimum Duration and Dose of r-tPA with the Acoustic Pulse Thrombolysis Procedure for Submassive Pulmonary Embolism: OPTALYSE PE; presented at the American Thoracic Society meeting, Washington D.C., May 2017



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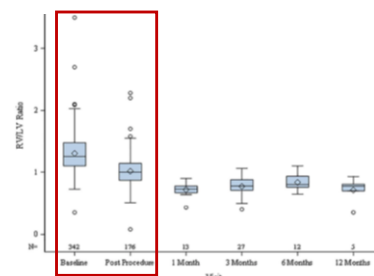
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KNOCOUT PE

- Prospektives, multizentrisches, internationales Register (03/2018-06/2020)
- Dosierung, VTE Rezidiv, RV/LV ratio major bleeding
- Patienten mit intermediate high risk and high risk Pulmonalembolie definiert nach ESC Guidelines
- Beschwerdebeginn < 14 Tage

	Bleeding events within 30 days
total	8 (1.6%)
Gastrointestinal hemorrhage	2 (0.4%)
Head laceration	1 (0.2%)
Vascular access site hematoma	4 (0.8%)
SDH (preexisting)	1 (0.2%)

	Prospective cohort N=489
Age	63 (20-81)
BMI>30kg/m ²	319 (65.2%)
Catheter placement time, h, mean	0.67 (0.37)
Duration thrombolytic therapy, h, mean	10.5 (5.37)
Total r-tPA dose mg, mean	18.1 (7.4)
12.01-20 mg	184 (38.5%)
4-12 mg	147 (30.8%)
Successful placement of catheter	488 (99.8%)



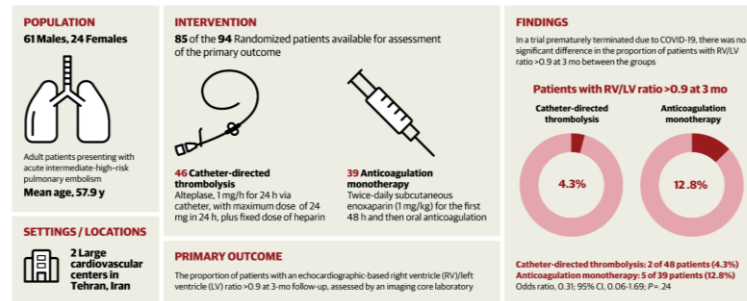
Sterling et al., Prospective Multicenter International Registry of Ultrasound-Facilitated Catheter-Directed Thrombolysis in Intermediate-High and High-Risk Pulmonary Embolism, Circ Cardiovasc Interv. 2024;17:e013448



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CANARY

RCT: Catheter-Directed Thrombolysis vs Anticoagulation in Patients With Acute Intermediate-High-Risk Pulmonary Embolism

	CDT+anticoagulation, n=46	Anticoagulation, n=39	P-value
Baseline hs troponin ng/L	169.9	168.1	
RV/LV ratio	1.2	1.2	
Obstruction score	55.1	55.2	
72h RV/LV ratio>0.9	13/48 (27%)	24/46 (52.1%)	0.01
3 month unrecovered RV	3/46 (6.2%)	11/39 (28.2%)	0.009
PE related mortality 3 month	0	2/46 (4.3%)	0.34

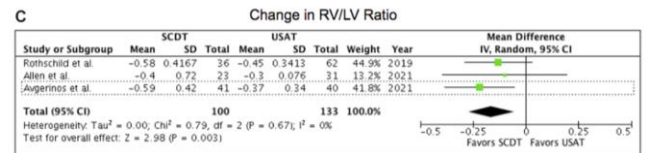
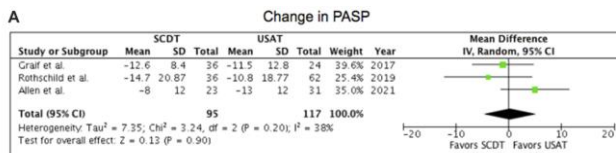
Sadeghipour et al., Catheter-Directed Thrombolysis vs Anticoagulation in Patients With Acute Intermediate-High-risk Pulmonary Embolism The CANARY Randomized Clinical Trial, JAMA Cardiol. 2022;7(12):1189-1197



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Reference, year	Group	No. of patients	Massive	Submassive	Age, y	Male sex	Thrombolytic dose, mg	Infusion time, h
Lin et al. ⁸ 2009	SCDT	14/25 (56)	14/25 (56.0)	0/25 (0.0)	62.0 ± 16.0	7/14 (50.0)	25.4 ± 5.3	26.7 ± 8.6
	USAT	11/25 (44)	11/25 (44.0)	0/25 (0.0)	59.0 ± 17.0	5/11 (45.5)	17.2 ± 2.4	17.4 ± 5.2
Kuo et al. ⁹ 2015	SCDT	63/92 (69)	28/92 (27.7)	35/92 (38.0)	60.3 ± 14.9	53/92 (52.5)	25.6 ± 11.7	20.8 ± 11.5
	USAT	29/92 (31)	0/92 (0.0)	29/92 (31.5)	57.1 ± 17.5	10/27 (37.0)	30.3 ± 9.1	23.2 ± 8.1
Liang et al. ⁹ 2016	SCDT	27/63 (42.9)	6/63 (9.5)	21/63 (33.3)	57.1 ± 17.5	10/27 (37.0)	23.2 ± 13.7	23.7 ± 13.9
	USAT	36/63 (57.1)	2/63 (3.2)	34/63 (54.0)	40.6 ± 12.8	17/36 (47.2)	27.5 ± 12.9	15.4 ± 5.3
Graif et al. ¹⁰ 2017	SCDT	36/60 (60.0)	5/60 (8.3)	31/60 (51.7)	59.1 ± 11.4	20/36 (55.6)	33.6 ± 13.9	30.4 ± 12.6
	USAT	24/60 (40.0)	3/60 (5.0)	21/60 (35.0)	53.3 ± 18.0	11/24 (45.8)	27.1 ± 11.3	23.9 ± 8.8
Rao et al. ¹¹ 2019	SCDT	33/70 (47.1)	6/70 (8.6)	25/70 (35.7)	57.4 ± 12.7	15/33 (45.5)	24.7 ± 12.2	13.3 ± 3.9
	USAT	37/70 (52.9)	5/70 (7.1)	34/70 (48.6)	65.2 ± 12.8	22/37 (59.5)	25.1 ± 6.3	13.3 ± 3.2
Rothschild et al. ¹² 2019	SCDT	36/98 (36.7)	4/98 (4.1)	32/98 (32.7)	60.4 ± 15.7	17/36 (47.2)	28.7 ± 14.0	22.9 ± 14.5
	USAT	62/98 (63.3)	3/98 (3.1)	59/98 (60.2)	57.7 ± 15.4	30/62 (48.4)	34.4 ± 17.3	31.5 ± 17.3
Allen et al. ¹³ 2021	SCDT	23/54 (42.6)	0/54 (0.0)	23/54 (42.6)	60.0 ± 2.3	11/23 (47.8)	23.0 ± 0.8	12.0 ± 0.4
	USAT	31/54 (57.4)	0/54 (0.0)	31/54 (57.4)	59.0 ± 2.5	15/31 (48.4)	20.0 ± 0.8	11.0 ± 0.5
Avgerinos et al. ¹⁵ 2021	SCDT	41/81 (50.6)	0/81 (0.0)	41/81 (50.6)	55.0 ± 14.0	20/41 (48.8)	18.0 ± 7.0	14.0 ± 5.0
	USAT	40/81 (49.4)	0/81 (0.0)	40/81 (49.4)	52.0 ± 13.0	23/40 (57.5)	19.0 ± 7.0	14.0 ± 6.0
Combined	SCDT	273/543 (50.3)	63/273 (23.1)	210/273 (76.9)	58.7 ± 13.6	100/273 (47.6)	25.3 ± 10.8	20.5 ± 10.1
	USAT	270/543 (49.7)	24/270 (8.9)	246/270 (91.1)	58.1 ± 13.9	123/270 (51.0)	25.1 ± 9.8	19.7 ± 8.2



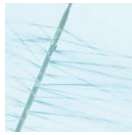
Bruno et al., A Meta-analysis of Standard Versus Ultrasound-Assisted Catheter-Directed Thrombolysis in the Management of Acute Pulmonary Embolism, Journal of the Society for Cardiovascular Angiography & Interventions 2 (2023) 100514



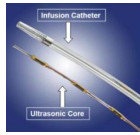
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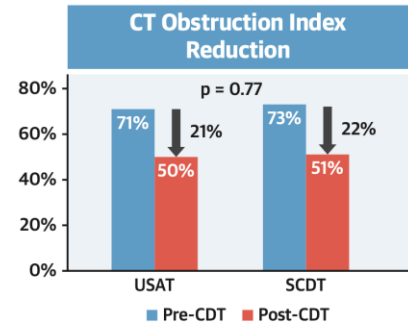
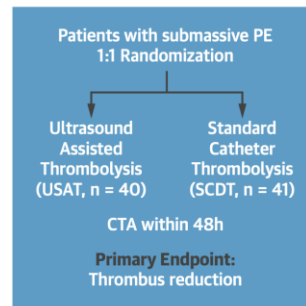
SUNSET PE



VS.



- 81 Patienten
- prospektiv, randomisiert, multizentrisch
- RV/LV Ratio > 1
- USAT vs. SCDT
- intermediate high risk Pulmonalembolie



Avgerinos, E.D. et al. J Am Coll Cardiol Interv. 2021;14(12):1364–73.

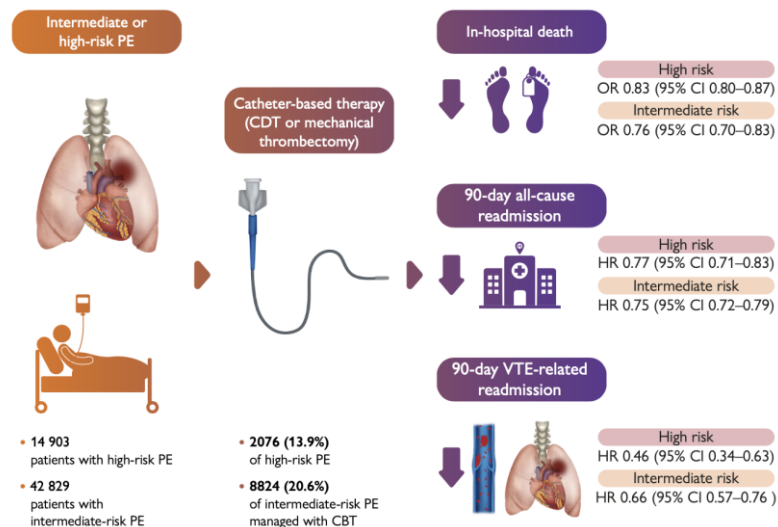
	USAT n=40	SCDT n=41	P-value
Secondary outcomes			
RV/LV ratio reduction	0.37±0.34	0.59±0.42	0.01

Avgerinos E. et al., Randomized Trial Comparing Standard Versus Ultrasound-Assisted Thrombolysis for Submassive Pulmonary Embolism, VOL. 14, NO. 12, 2021



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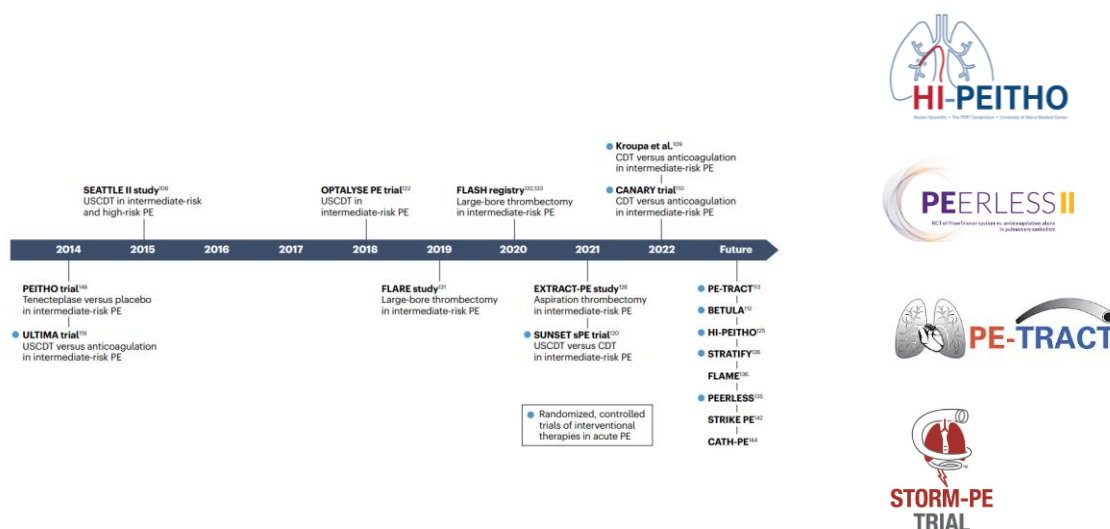


Leiva et al., Catheter-based therapy for high-risk or intermediate-risk pulmonary embolism: death and re-hospitalization, European Heart Journal (2024) 00, 1–11



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Pruszczyk et al., 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, EuroIntervention 2022;18:e623-e638

Gahnem et al., Interventionelle Therapie und multidisziplinäre Managementstrategien für die akute Lungenembolie, Kardiologie, <https://doi.org/10.1007/s12181-023-00610-7>

Kopeck et al., Role of catheter-directed therapies in the treatment of acute pulmonary embolism. Expert opinion of the Polish PERT Initiative, Working Group on Pulmonary Circulation, Association of Cardiovascular Interventions, and Association of Intensive Cardiac Care of the Polish Cardiac Society, Kardiologia Polska, DOI: 10.33963/KP.a2023.0075

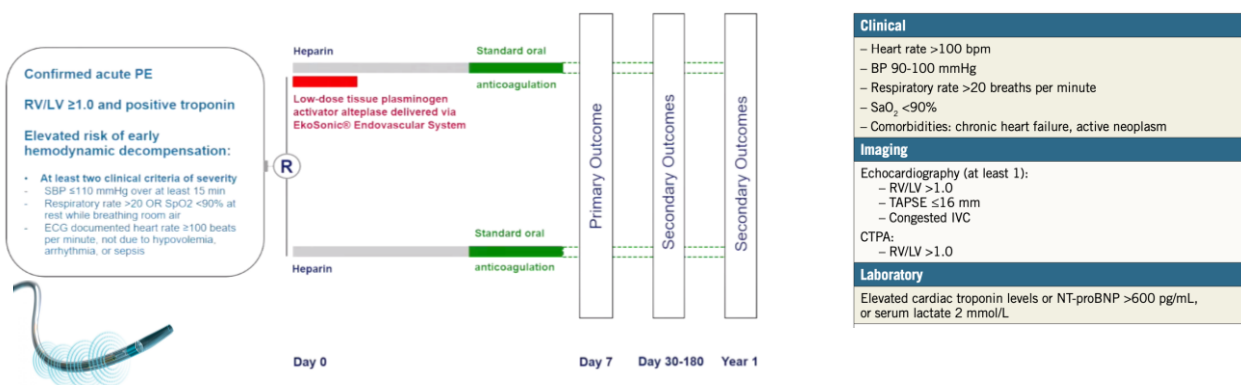


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HI-PEITHO: Study flow



Trial Flow Chart übernommen aus Boston Scientific Webinar Panel Discussion „HI PEITHO: Are you ready?, <https://www.youtube.com/watch?v=QHKX6V-1UIk> am 3.3.2021

Pruszczyk et al., 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, EuroIntervention 2022;18:e623-e638



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48 a



- Dyspnoe seit 2 Tagen
- 1 Stock möglich
- Heute Synkope



- HF 112/min, AF 27, RR 117/82 mmHg, Sättigung 89% bei RL
- Einseitige Beinschwellung
- NEWS 8 Punkte
- CPES Score 6 Punkte

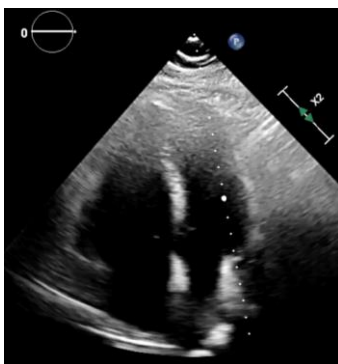


- Lactat: 32 mg/dl
- Troponin T 34.8 ng/l

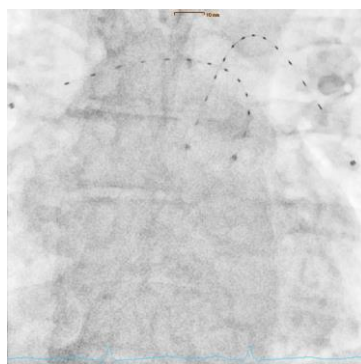
Physiological Parameters	3	2	1	0	1	2	3
Respiration rate (BPM)	≤ 8		9-11	12-20		21-24	≥ 25
Oxygen saturation (%)	≤ 91	92-93	94-95	≥ 96			
Supplemental Oxygen		Yes		No			
Temperature (°C)	≤ 35		35.1-36	36.1-38	38.1-39	≥ 39.1	
Systolic RR (mmHg)	≤ 90	91-100	101-110	111-219			≥ 220
Heart rate (BPM)	≤ 40		41-50	51-90	91-110	111-130	≥ 131
Level of consciousness (AVPU)				Alert			Voice, Pain, Unresponsive



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vor Intervention



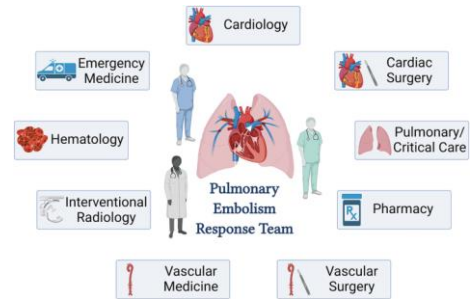
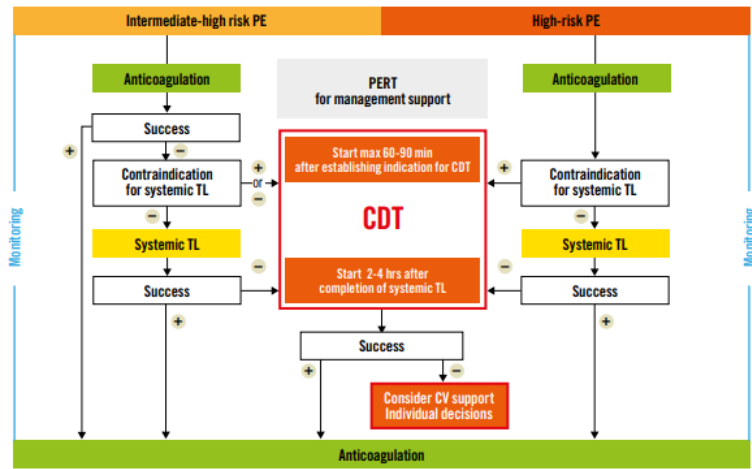
48h nach Intervention

Kathetergestützte Lyse mit 18 mg Actilyse (9 mg/Seite) noch am selben Tag



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Gahnem et al., Interventionelle Therapie und multidisziplinäre Managementstrategien für die akute Lungenembolie, *Kardiologie*, <https://doi.org/10.1007/s12181-023-00610-7>

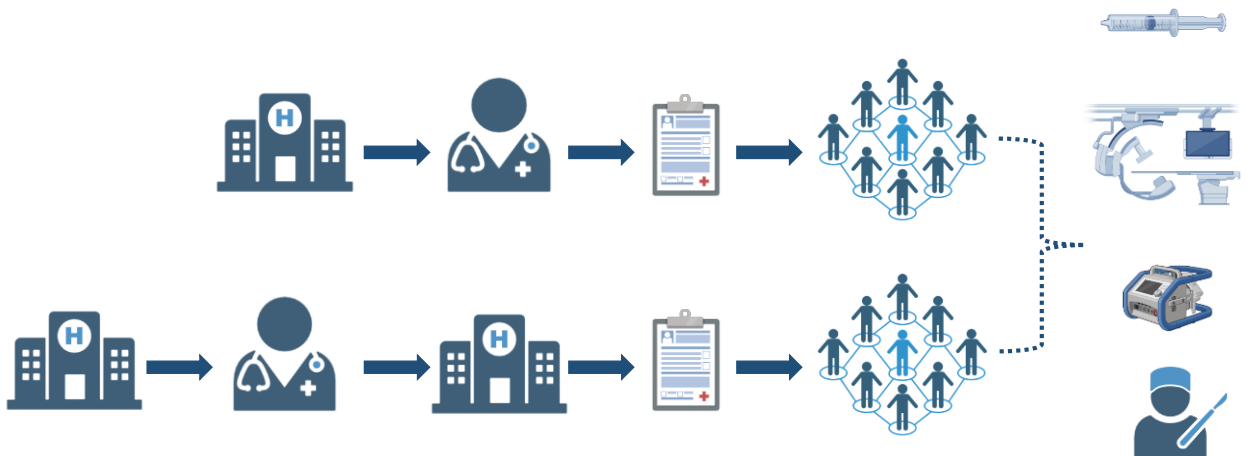
Kopec et al., Role of catheter-directed therapies in the treatment of acute pulmonary embolism. Expert opinion of the Polish PERT Initiative, Working Group on Pulmonary Circulation, Association of Cardiovascular Interventions, and Association of Intensive Cardiac Care of the Polish Cardiac Society, *Kardiologia Polska*, DOI: 10.33963/KP.a2023.0075



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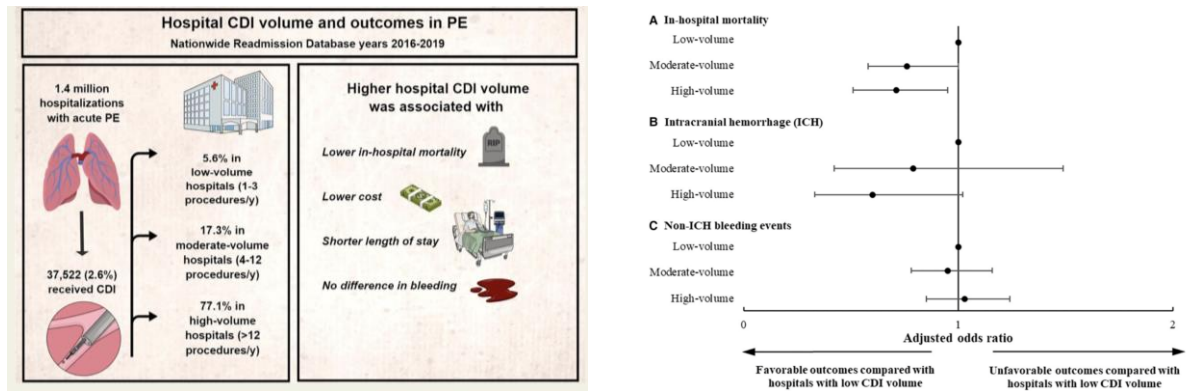
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Mini PERT



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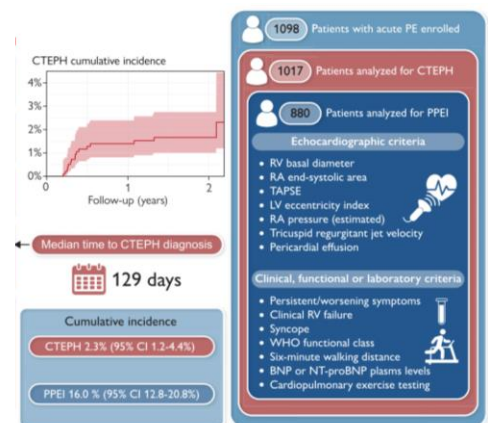
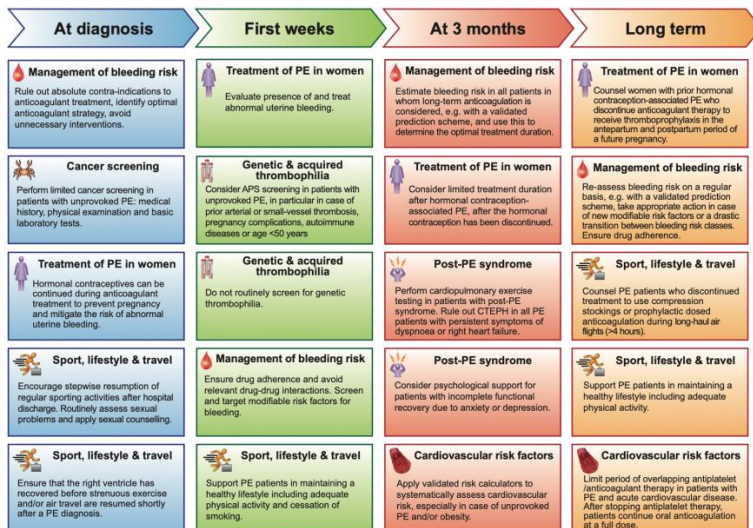


Sedhom et al., Hospital procedural volume and outcomes with catheter-directed intervention for pulmonary embolism: a nationwide analysis, *European Heart Journal: Acute Cardiovascular Care* (2022) 11, 684–692



IFIMP 2025-Kathetergestützte Thrombolyse

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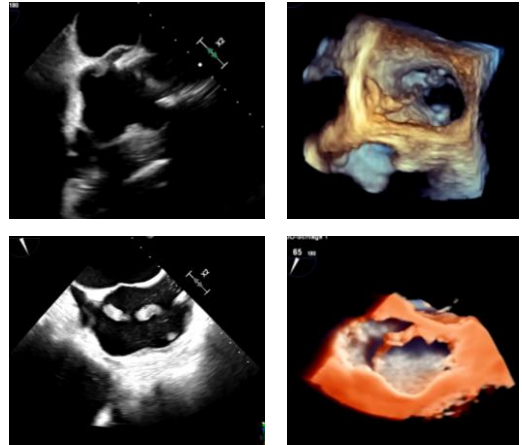


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Zusammenfassung

- kathetergestützte Lyse als additive Therapie
- gutes Sicherheitsprofil
- kein Benefit USAT vs. SCDT
- prospektive, randomisierte Studien notwendig
- Zeitfaktor entscheidend
- „gaps in evidence“
- PERT → komplexe Lungenembolien (NEWS, CPES)
- Nachsorge



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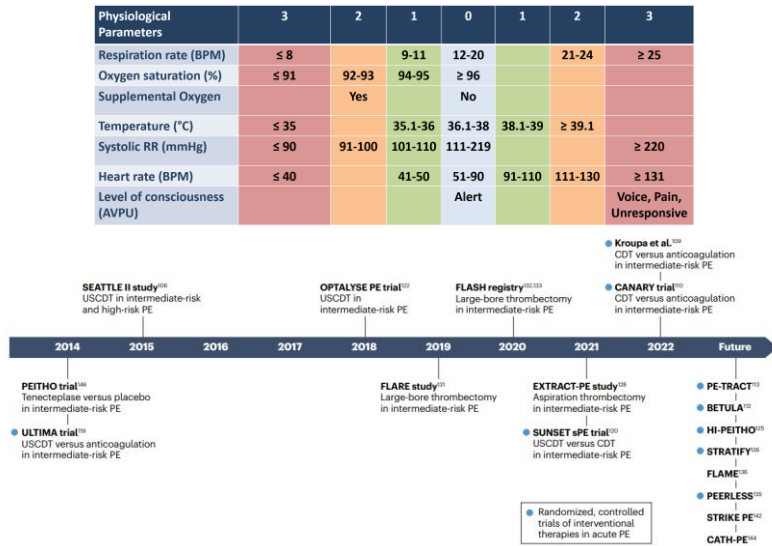
DANKE FÜR DIE AUFMERKSAMKEIT !

Markus.Theurl@tirol-kliniken.at



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Pruszczyk et al., 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, *EuroIntervention* 2022;18:e623-e638

Gahnem et al., Interventionelle Therapie und multidisziplinäre Managementstrategien für die akute Lungenembolie, *Kardiologie*, <https://doi.org/10.1007/s12181-023-00610-7>

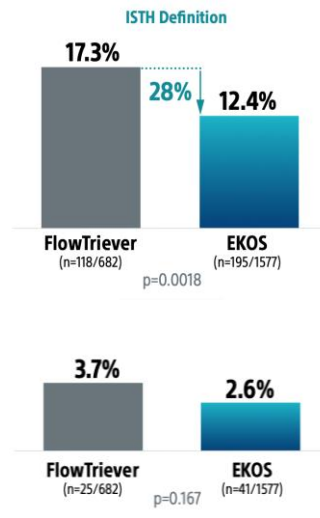
Kopeck et al., Role of catheter-directed therapies in the treatment of acute pulmonary embolism. Expert opinion of the Polish PERT Initiative, Working Group on Pulmonary Circulation, Association of Cardiovascular Interventions, and Association of Intensive Cardiac Care of the Polish Cardiac Society, *Kardiologia Polska*, DOI: 10.33963/KP.a2023.0075



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REAL PE



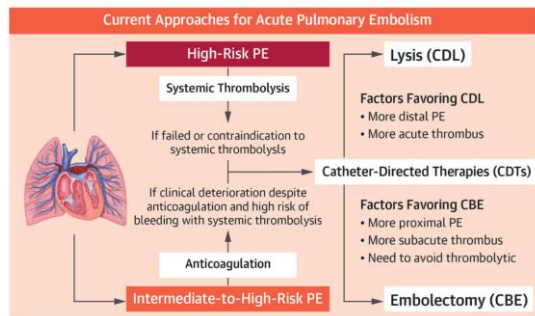
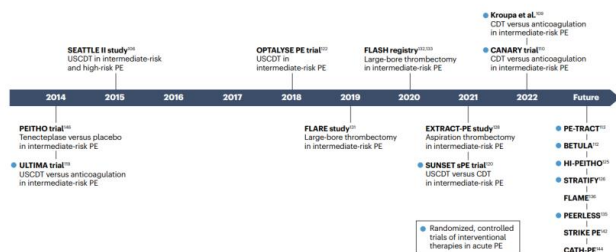
Monteleone P. et al., Modern Treatment of Pulmonary Embolism (USCDT vs MT): Results From a Real-World, Big Data Analysis (REAL-PE), *Journal of the Society for Cardiovascular Angiography & Interventions* 3 (2024) 101192



Kardiologie Kongress Innsbruck 2024

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Physiological Parameters	3	2	1	0	1	2	3
Respiration rate (BPM)	≤ 8		9-11	12-20		21-24	≥ 25
Oxygen saturation (%)	≤ 91	92-93	94-95	≥ 96			
Supplemental Oxygen		Yes		No			
Temperature (°C)	≤ 35		35.1-36	36.1-38	38.1-39	≥ 39.1	
Systolic RR (mmHg)	≤ 90	91-100	101-110	111-219			≥ 220
Heart rate (BPM)	≤ 40		41-50	51-90	91-110	111-130	≥ 131
Level of consciousness (AVPU)				Alert			Voice, Pain, Unresponsive



Pruszczyk et al., 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, *EuroIntervention* 2022;18:e623-e638

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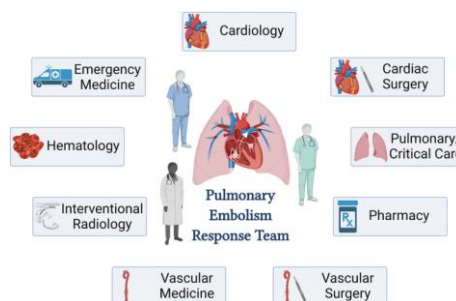
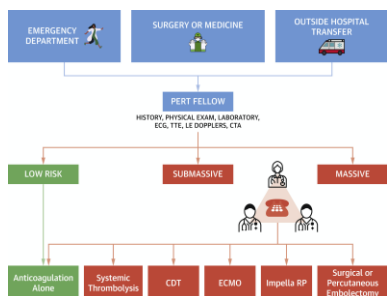
Sallersymposium Graz 2024

M. Theurl
Universitätsklinik für Innere Medizin, Kardiologie und Angiologie**Recommendations high risk PE**

Set-up of a multidisciplinary team and a pro-gramme 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.

Class**Ila****Level****C**

Die Festlegung der optimalen Therapiestrategie bei Patienten mit akuter Lungenembolie und hohem Risiko sollte individualisiert und im interdisziplinären Konsens erfolgen. (Empfehlungsstärke: ↑, starker Konsens)



Brailowsky et al., Pulmonary Embolism Response Team: Additional Call Burden or a Valuable Learning Opportunity?, *JACC*. 2021 Apr, 77 (13) 1691-1696

Hobohm et al., Pulmonary embolism response team (PERT) implementation and its clinical value across countries: a scoping review and meta-analysis, *Clinical Research in Cardiology* (2023) 112:1351-1361

PERT Consortium Handbook of Pulmonary Embolism 2025



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Fall #1



32 a



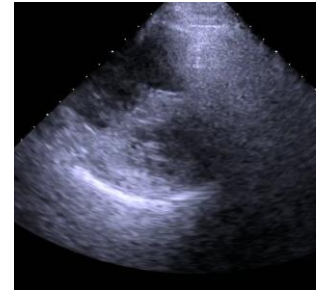
- Transferierung an den Schockraum der Notaufnahme "schockierter Patient"
- Vor 3 Tagen Rückflug aus den USA
- Keine Komorbiditäten, positive Familienanamnese hinsichtlich venöser Thromboembolie



- HF 126/min, AF 27, RR 85/52 mmHg, Sättigung 6l O₂ 93%
- Einseitige Beinschwellung
- NEWS Score 12 Punkte



- Lactat: 32 mg/dl
- Troponin T 34.8 ng/l



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Fall #2



72 a



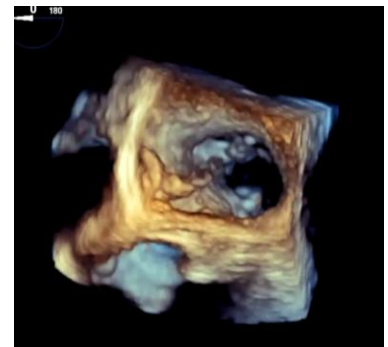
- Progrediente Dyspnoe seit einer knappen Woche, heute Synkope
- 8 stündige Busreise vor 10 Tagen
- Subst. Hypothyreose, DM II



- NT-pro BNP 5295 ng/l
- Troponin T 32 ng/l

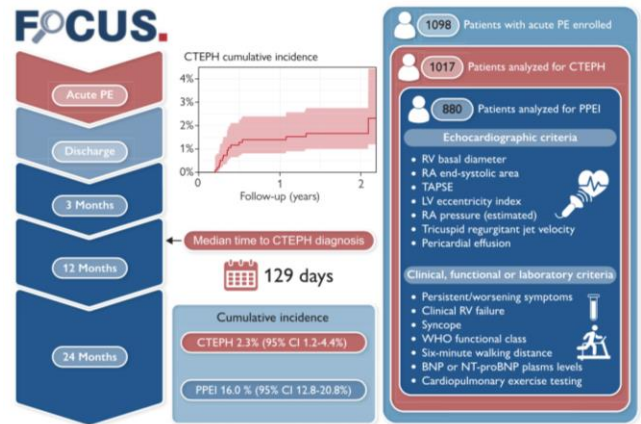
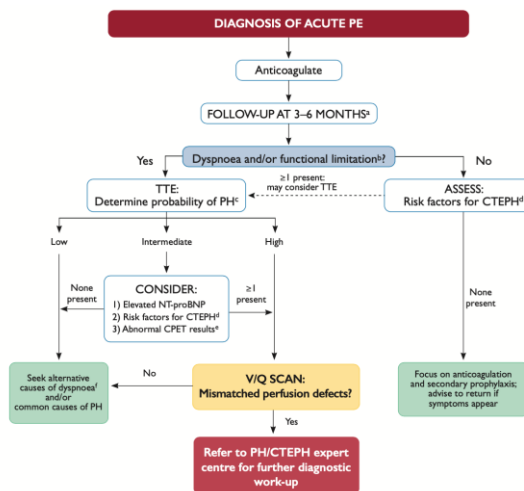


- HF 103/min, AF 22, Sättigung bei RL 88%, RR 87/56 mmHg
- Lactat 22 mg/dl
- NEWS Score 9 Punkte



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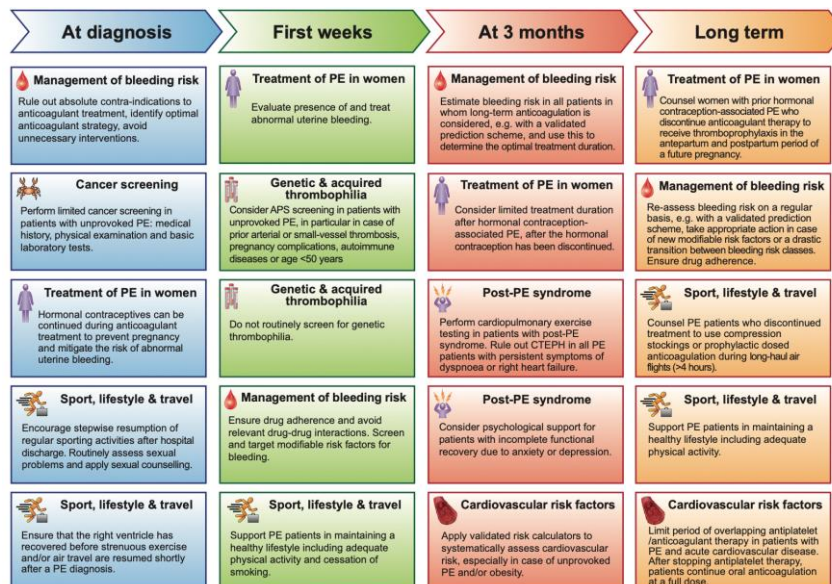


S. V. Konstantinides et al., 2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS), European Heart Journal (2019) 00, 1-61
 Valerio et al., Chronic thromboembolic pulmonary hypertension and impairment after pulmonary embolism: the FOCUS study, European Heart Journal (2022) 43, 3387-3398



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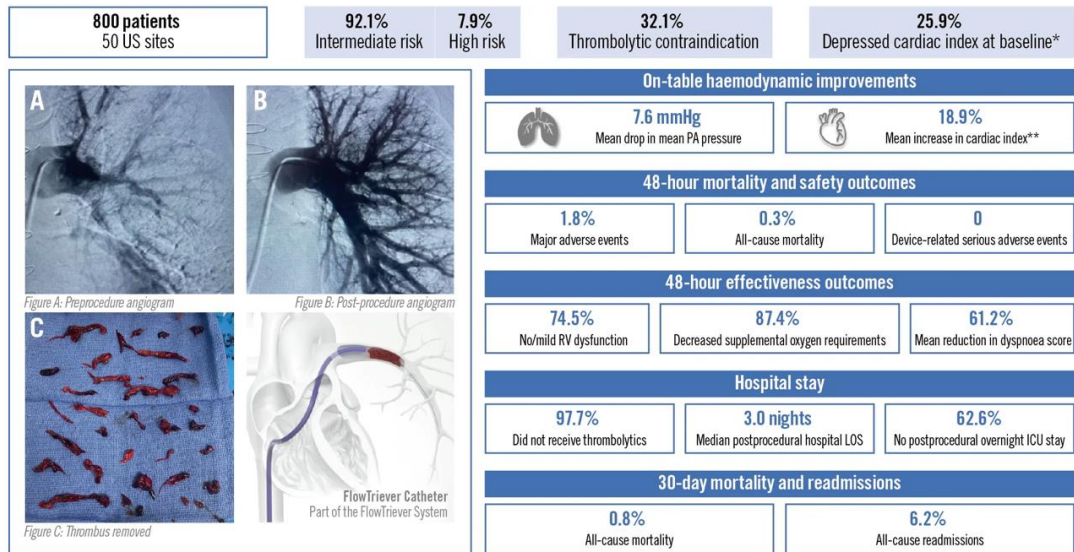
Klok et al., Optimal follow-up after acute pulmonary embolism: a position paper of the European Society of Cardiology Working Group on Pulmonary Circulation and Right Ventricular Function, in collaboration with the European Society of Cardiology Working Group on Atherosclerosis and Vascular Biology, endorsed by the European Respiratory Society, European Heart Journal (2022) 43, 183-189



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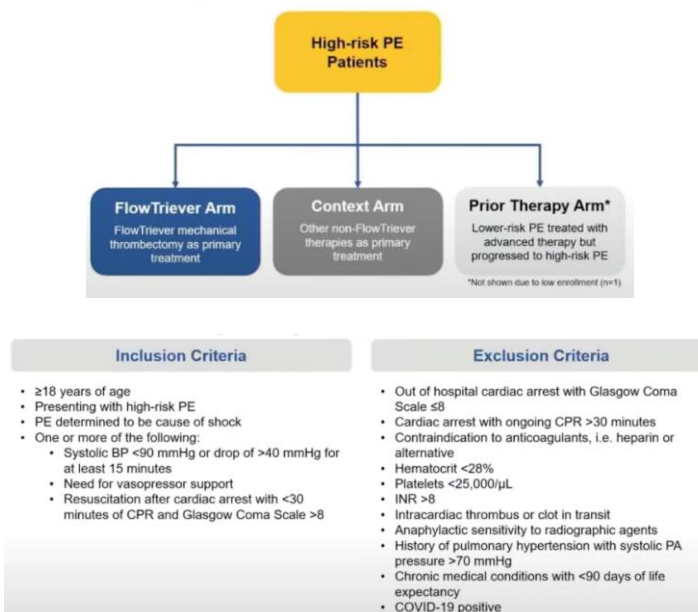
FLASH REGISTRY: Real-world PE patient population



Toma et al., Acute outcomes for the full US cohort of the FLASH mechanical thrombectomy registry in pulmonary embolism, EuroIntervention 2023;18:1201-1212



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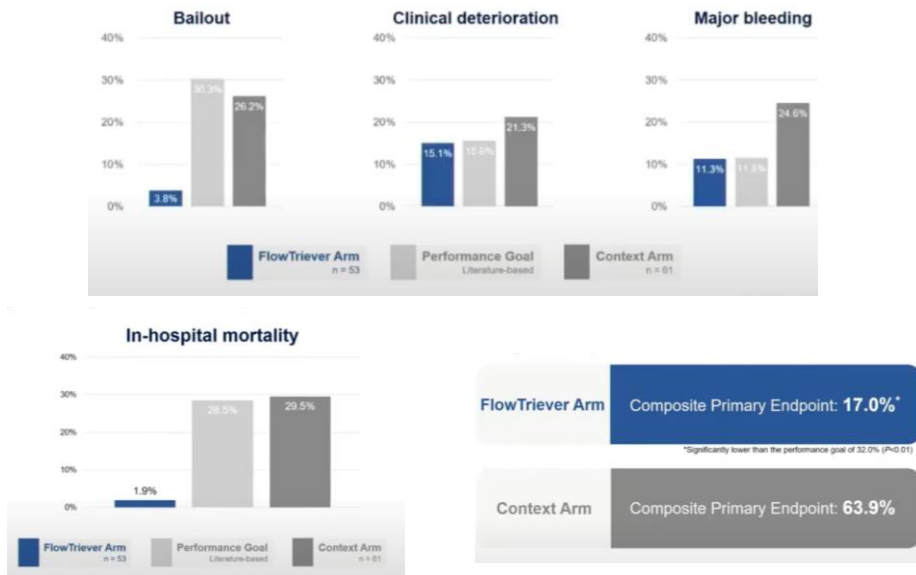
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Silver et al., Outcomes in High-Risk Pulmonary Embolism Patients Undergoing FlowTrievers Mechanical Thrombectomy or Other Contemporary Therapies: Results From the FLAME Study, Circ Cardiovasc Interv. 2023;16:e013406



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Silver et al., Outcomes in High-Risk Pulmonary Embolism Patients Undergoing FlowTriever Mechanical Thrombectomy or Other Contemporary Therapies: Results From the FLAME Study, *Circ Cardiovasc Interv.* 2023;16:e013406



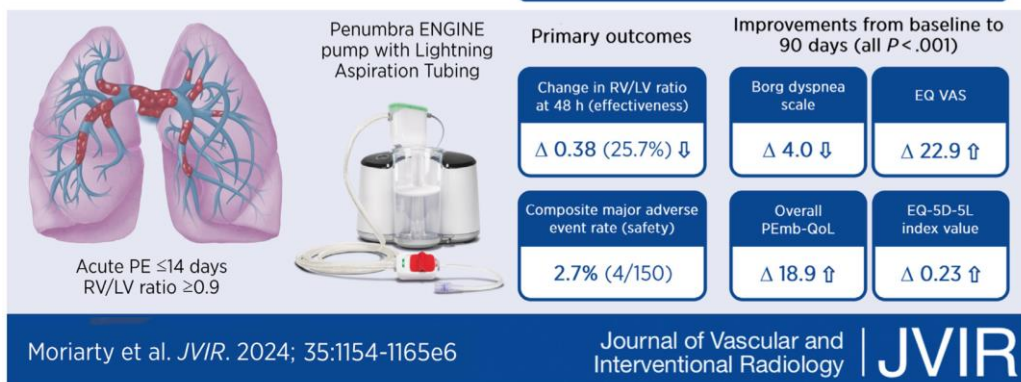
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Clinical, Functional, and Quality of Life Outcomes After Computer Assisted Vacuum Thrombectomy for Pulmonary Embolism: Interim Analysis of the STRIKE-PE Study

STRIKE-PE: Prospective, international, multicenter study to enroll 600 patients

Interim analysis of 150 patients
92.7% with high-risk or intermediate-high-risk PE



Moriarty et al., Clinical, Functional, and Quality-of-Life Outcomes after Computer Assisted Vacuum Thrombectomy for Pulmonary Embolism: Interim Analysis of the STRIKE-PE Study, *J Vasc Interv Radiol* 2024; 35:1154–1165

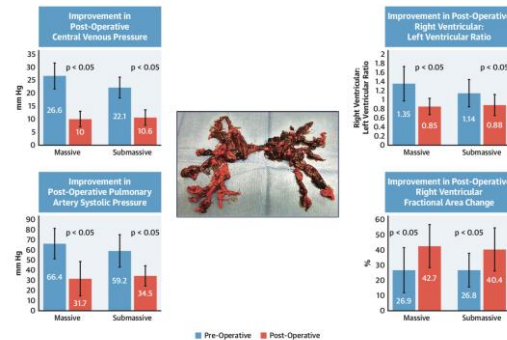


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Recommendations high risk PE	Class	Level
Surgical pulmonary embolectomy is recommended for patients with high-risk PE, in whom thrombolysis is contraindicated or has failed.	Ila	C

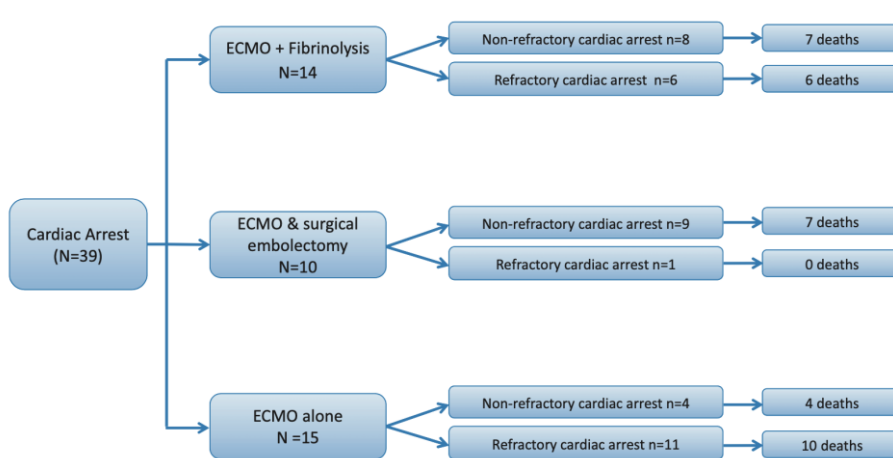
Bei Kontraindikationen gegen eine indizierte systemische Thrombolyse oder bei Versagen einer systemischen Thrombolyse sollen endovaskuläre oder chirurgische Reperusionsverfahren als therapeutische Alternative erwogen werden. (Empfehlungsstärke: ↑↑, starker Konsens).



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Recommendations high risk PE	Class	Level
ECMO may be considered, in combination with surgical embolectomy or catheter-directed treatment, in patients with PE and refractory circulatory collapse or cardiac arrest.	Iib	C

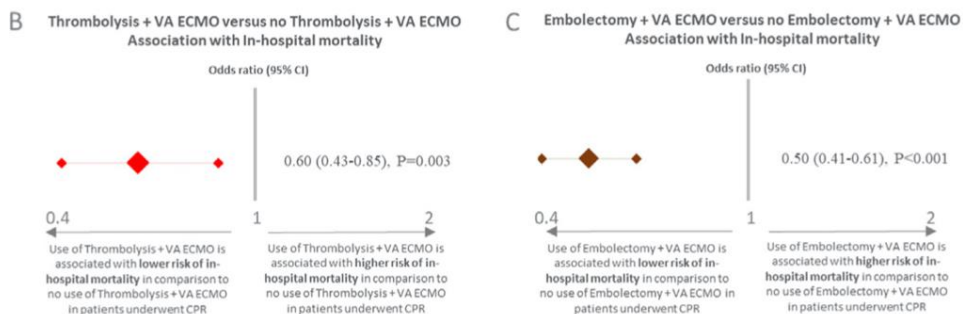


Meneveau et al., Outcomes after extracorporeal membrane oxygenation for the treatment of high-risk pulmonary embolism: a multicentre series of 52 cases, European Heart Journal (2018) 39, 4196–4204



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Davis et al., Current status of ECMO for massive pulmonary embolism, *Front. Cardiovasc. Med.* 10:1298686

George et al., Extracorporeal membrane oxygenation for large pulmonary emboli, *PROC (BAYL UNIV MED CENT)* 2023;36(3):314–317

Hobohm et al., Clinical use and outcome of extracorporeal membrane oxygenation in patients with pulmonary embolism, *RESUSCITATION* 170(2022)285–292



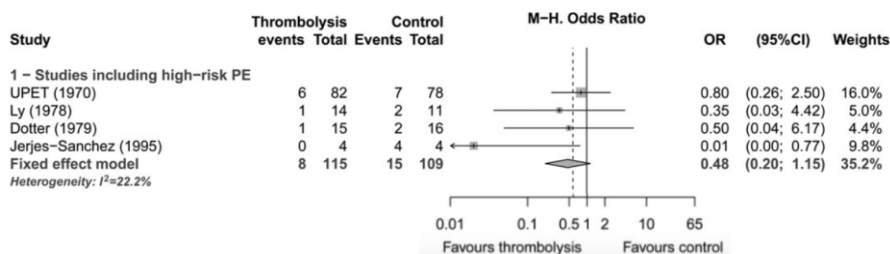
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Recommendations high risk PE	Class	Level
It is recommended that anticoagulation with UFH, including a weight-adjusted bolus injection, be initiated without delay in patients with high-risk PE.	I	C
Systemic thrombolytic therapy is recommended for high-risk PE.	I	B

Patienten mit Lungenembolie und hohem Risiko bzw. hämodynamischer Instabilität sollen ohne zeitlichen Verzug einer Reperfusionstherapie – vorzugsweise einer systemischen Thrombolyse – zugeführt werden. (Empfehlungsstärke: ↑↑, starker Konsens)

- 10 mg Actilyse als Bolus, 90 mg über 2 h
- 0.6 mg/kg KG (max. 50 mg) über 15 min.



Jerjes-Sanchez C et al., Streptokinase and heparin versus heparin alone in massive pulmonary embolism: a randomized controlled trial. *J Thromb. Thrombolysis* 1995;2:227–229.

Marti et al., Systemic thrombolytic therapy for acute pulmonary embolism: a systematic review and meta-analysis, *European Heart Journal* (2015) 36, 605–614



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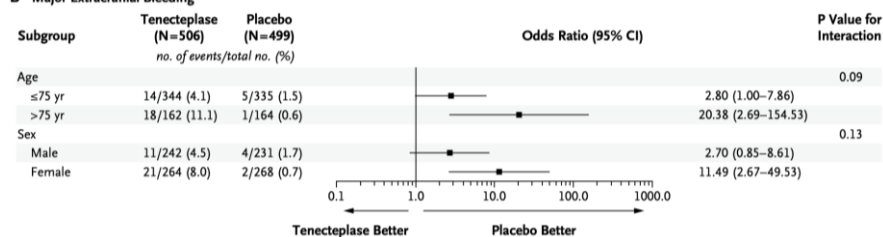
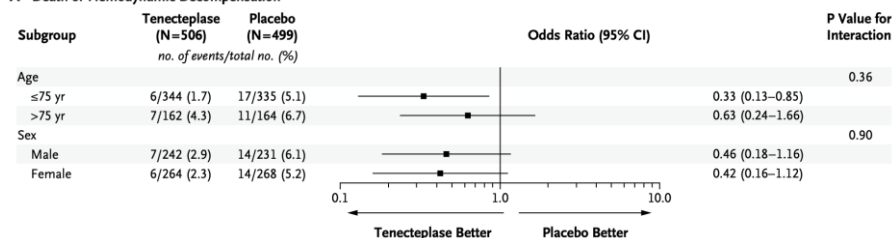
	Tenecteplase (N=506)	Placebo (N=499)	Odds Ratio (95% CI)	
Outcome	No. (%)	No. (%)		P Value
Primary outcome	13 (2.6)	28 (5.6)	0.44 (0.23-0.87)	0.02
Death from any cause	6 (1.2)	9 (1.8)	0.65 (0.23-1.85)	0.42
Hemodynamic decompensation	8 (1.6)	25 (5.0)	0.3 (0.14-0.68)	0.002

	Tenecteplase (N=506)	Placebo (N=499)	Odds Ratio (95% CI)	
Outcome	No. (%)	No. (%)		P Value
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)		

Meyer et al., Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism, NEJM 370:15, 2014



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Universitätsklinik für Innere Medizin, Kardiologie und Angiologie**B Major Extracranial Bleeding****A Death or Hemodynamic Decompensation**

Meyer et al., Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism, NEJM 370:15, 2014



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Table

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	FlowTrier Arm (n = 53)	Context Arm (n = 61)
Reason for high-risk PE:		
• Systolic BP <90 mmHg or decrease of >40 mmHg for 15 minutes	34 (64.2%)	31 (50.8%)
• Need for vasopressor support	32 (60.4%)	46 (75.4%)
• Resuscitation after cardiac arrest with <30 minutes of CPR and Glasgow Coma Scale >8	11 (20.8%)	20 (32.8%)
SCAI shock stage		
A	2 (3.8%)	1 (1.6%)
B	11 (20.8%)	6 (9.8%)
C	29 (54.7%)	22 (36.1%)
D	5 (9.4%)	12 (19.7%)
E	6 (11.3%)	20 (32.8%)
PE Location		
• Central	49 (92.5%)	40/53 (75.5%)
• Lobar	36 (67.9%)	36/53 (67.9%)
• Segmental	27 (50.9%)	25/53 (47.2%)
	11 (20.8%)	6 (9.8%)
	29 (54.7%)	22 (36.1%)

Poor Candidates for
Mechanical Thrombectomy

largest interventional trial in high-risk PE

ombectomy with FlowTrier was associated with
ence of meaningful in-hospital adverse clinical

In-hospital composite:

- All-cause mortality
- Bailout to alternate thrombus removal strategy
- Clinical deterioration
- Major bleeding

Secondary Endpoints

Safety:

- Primary endpoint components, stroke, device-related complications, and access site injury

Utility measures:

- Hospital and ICU stay, ECMO use, time to extubation, and discharge location

ilout, clinical deterioration, major bleeding
d with remarkably low mortality

.9%

.5%

29.5%

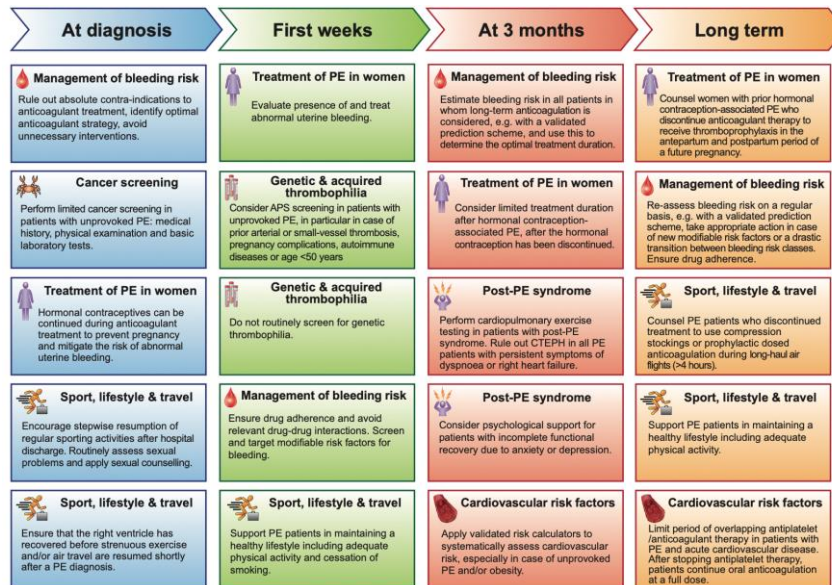
B

C

Poor Candidates for
Mechanical Thrombectomy

11 (20.8%)
29 (54.7%)

6 (9.8%)
22 (36.1%)



Klok et al., Optimal follow-up after acute pulmonary embolism: a position paper of the European Society of Cardiology Working Group on Pulmonary Circulation and Right Ventricular Function, in collaboration with the European Society of Cardiology Working Group on Atherosclerosis and Vascular Biology, endorsed by the European Respiratory Society, European Heart Journal (2022) 43, 183–189



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Recommendations high risk PE	Class	Level
Surgical pulmonary embolectomy is recommended for patients with high-risk PE, in whom thrombolysis is contraindicated or has failed.	I	C
Bei Kontraindikationen gegen eine indizierte systemische Thrombolyse oder bei Versagen einer systemischen Thrombolyse sollen endovaskuläre oder chirurgische Reperfuersverfahren als therapeutische Alternative erwogen werden. (Empfehlungsstärke: ↑↑, starker Konsens).		



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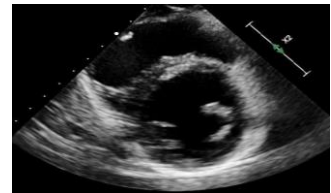
Absolute	Relative
Intrakranielle Blutung in der Vorgeschichte - Ischämischer Schlaganfall innerhalb der letzten 6 Monate - ZNS-Neoplasie mit erhöhtem Blutungsrisiko - Schweres Trauma, Operation oder Kopfverletzung innerhalb der letzten 3 Monate - Hämorrhagische Diathese - Aktive, nach Lyse potenziell bedrohliche Blutung - Allergie gegen Thrombolytikum	TIA innerhalb der letzten 6 Monate - Orale Antikoagulation - Schwangerschaft oder Entbindung innerhalb der letzten 7 Tage - Reanimation mit Herzdruckmassage - Unkontrollierte Hypertonie (RRsyst > 180 mmHg) - Schwere Lebererkrankung - Infektiöse Endokarditis oder Perikarditis - Ösophagusvarizen - Aktive gastroduodenale Ulzera - Akute Pankreatitis - Arterielle Aneurysmata - Kürzlich erfolgte Punktion an nicht komprimierbarer Punktionsstelle



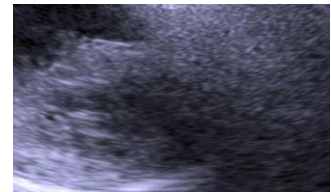
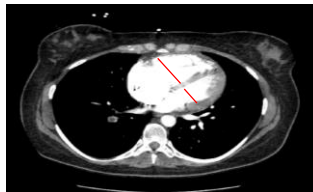
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Fall #1



Fall #2



Fall #3



Abteilungsfortbildung BKH St. Johann – Innere Medizin

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Recommendations high risk PE	Class	Level
Systemic thrombolytic therapy is recommended for high-risk PE.	I	B
Percutaneous catheter directed treatment should be considered for patients with high-risk PE, in whom thrombolysis is contraindicated or has failed .	IIa	C
It is recommended that anticoagulation with UFH, including a weight-adjusted bolus injection, be initiated without delay in patients with high-risk PE.	I	C
ECMO may be considered, in combination with surgical embolectomy or catheter-directed treatment, in patients with PE and refractory circulatory collapse or cardiac arrest.	IIb	C
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

Surgical treatment

Ecmo

Impeall

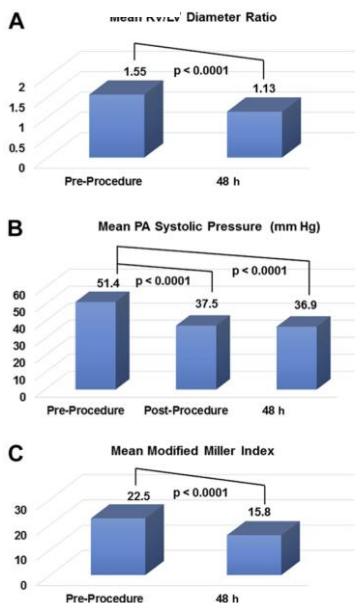
Jerjes-Sanchez C, Ramirez-Rivera A, Lourdes Garcia M, Arriaga-Nava R, Valencia S, Rosado-Buzzo A, Pierzo JA, Rosas E. Streptokinase and heparin versus heparin alone in massive pulmonary embolism: a randomized controlled trial. J Thromb Thrombolysis 1995;2:227–229.

*adapted from S. V. Konstantinides et al., 2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS), European Heart Journal (2019) 00, 1–61 c



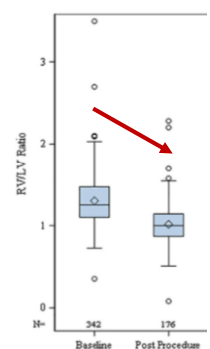
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	Bleeding events within 30 days
total	8 (1.6%)
Gastrointestinal hemorrhage	2 (0.4%)
Head laceration	1 (0.2%)
Vascular access site hematoma	4 (0.8%)
SDH (preexisting)	1 (0.2%)

	Prospective cohort N=489
Age	63 (20-81)
BMI > 30 kg/m ²	319 (65.2%)
Catheter placement time, h, mean	0.67 (0.37)
Duration thrombolytic therapy, h, mean	10.5 (5.37)
Total r-tPA dose mg, mean	18.1 (7.4)
12.01-20 mg	184 (38.5%)
4-12 mg	147 (30.8%)
Successful placement of catheter	488 (99.8%)

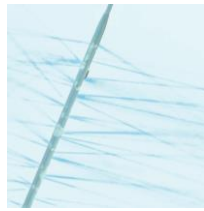


Sterling et al., Prospective Multicenter International Registry of Ultrasound-Facilitated Catheter-Directed Thrombolysis in Intermediate-High and High-Risk Pulmonary Embolism, Circ Cardiovasc Interv. 2024;17:e013448

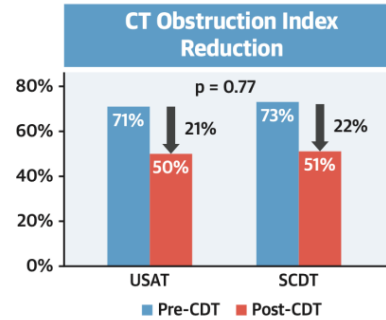
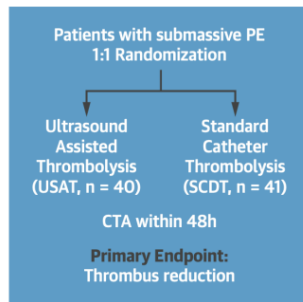
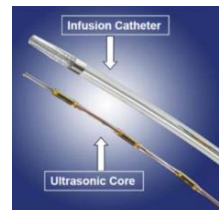


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VS.



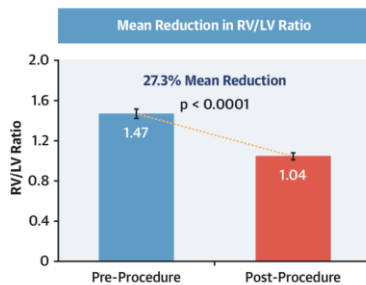
Avgerinos, E.D. et al. J Am Coll Cardiol Interv. 2021;14(12):1364-73.



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CENTRAL ILLUSTRATION Primary Efficacy and Safety Endpoint Results of the EXTRACT-PE Trial



Primary Safety Endpoint Analysis	All Patients (N = 119)	95% CI
Major adverse events within 48 h Clinical Events Committee, a composite of:	1.7% (2/119)	0.0%–4.0%
Device-related death within 48 h	0.8% (1/119)	0.0%–2.5%
Major bleeding within 48 h	1.7% (2/119)	0.0%–4.0%
Device-related serious adverse events within 48 h Clinical Events Committee, a composite of:	0.8% (1/119)	0.0%–2.5%
Clinical deterioration within 48 h	0.8% (1/119)	0.0%–2.5%
Pulmonary vascular injury within 48 h	0.8% (1/119)	0.0%–2.5%
Cardiac injury within 48 h	0.0%	N/A



Sista, A.K. et al. J Am Coll Cardiol Interv. 2021;14(3):319-29.

CI = confidence interval; LV = left ventricular; N/A = not applicable; RV = right ventricular.

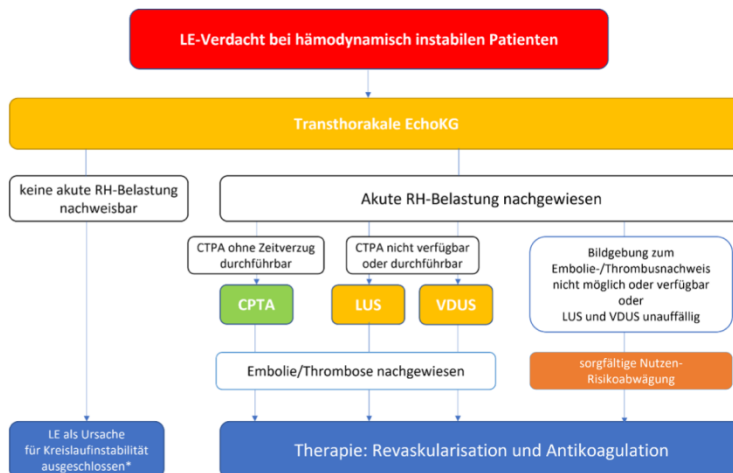


<https://evtoday.com/articles/2023-feb/lightning-flash-the-most-powerful-and-advanced-mechanical-thrombectomy-system-for-pe-and-venous-thrombus>



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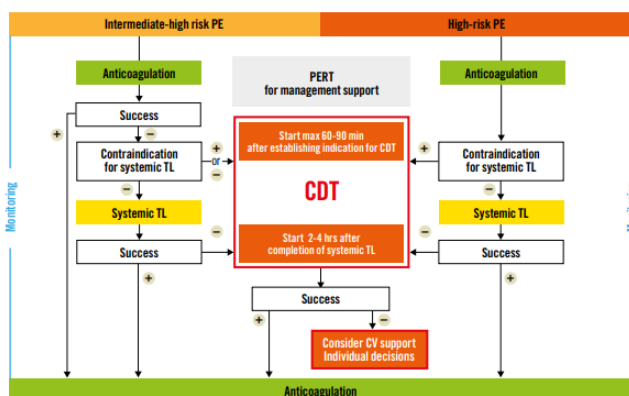
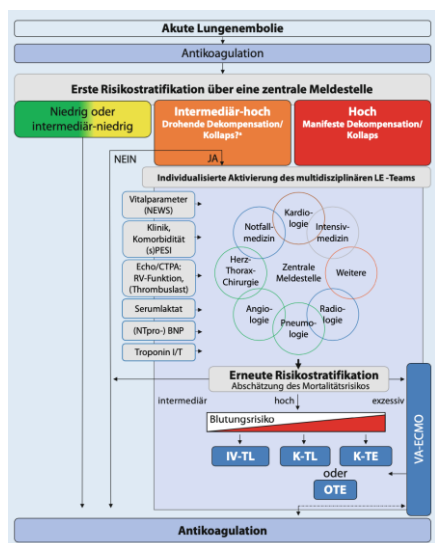
* Eine fehlende RH-Belastung kann lediglich das Vorliegen einer hämodynamisch relevanten LE ausschließen. Kleinere Embolien sind weiterhin möglich.
Abk.: CTPA = CT-Pulmonalisangiografie; LE = Lungenembolie; LUS = Lungenultraschall; RH = Rechter Herz; VDUS = venöse Duplexsonografie

Linnemann et al., Diagnostik und Therapie der tiefen Venenthrombose und Lungenembolie – AWMF-S2k-Leitlinie
* Mit Genehmigung der Universitätsklinik für Radiologie (Innsbruck)



ÖGIA Jahrestagung

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Pruszczyk et al., 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, EuroIntervention 2022;18:e623-e638

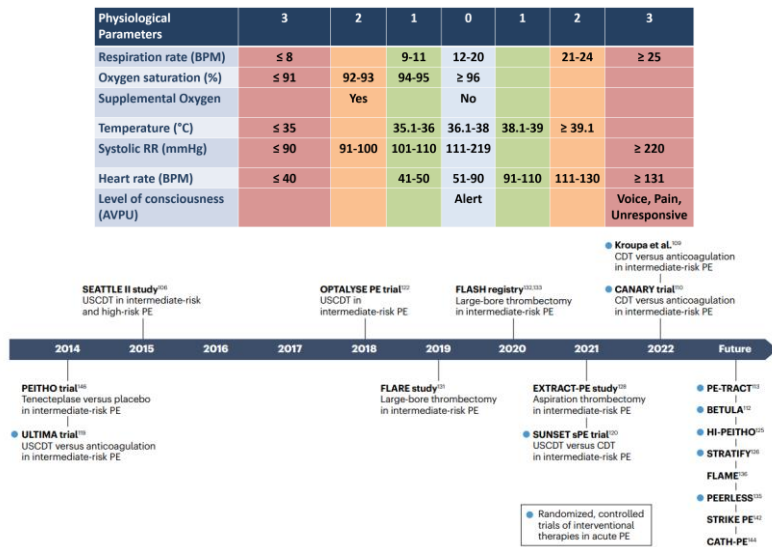
Gahlem et al., Interventionelle Therapie und multidisziplinäre Managementstrategien für die akute Lungenembolie, Kardiologie, <https://doi.org/10.1007/s12181-023-00610-7>

Kopeck et al., Role of catheter-directed therapies in the treatment of acute pulmonary embolism. Expert opinion of the Polish PERT Initiative, Working Group on Pulmonary Circulation, Association of Cardiovascular Interventions, and Association of Intensive Cardiac Care of the Polish Cardiac Society, Kardiologia Polska, DOI: 10.33963/KP.a2023.0075



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Pruszczyk et al., 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, *EuroIntervention* 2022;18:e623-e638

Gahnem et al., Interventionelle Therapie und multidisziplinäre Managementstrategien für die akute Lungenembolie, *Kardiologie*, <https://doi.org/10.1007/s12181-023-00610-7>

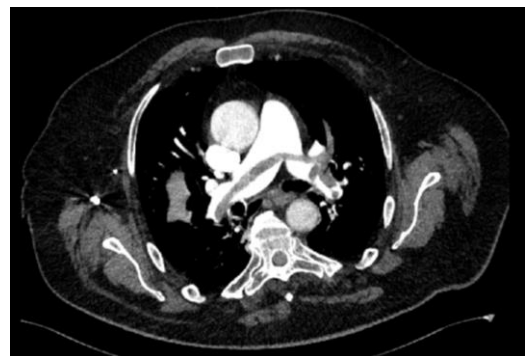
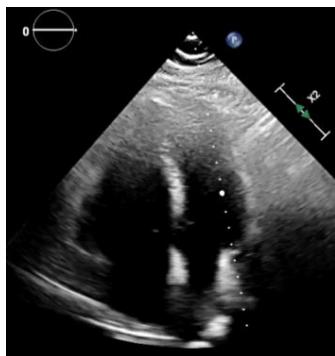
Kopec et al., Role of catheter-directed therapies in the treatment of acute pulmonary embolism. Expert opinion of the Polish PERT Initiative, Working Group on Pulmonary Circulation, Association of Cardiovascular Interventions, and Association of Intensive Cardiac Care of the Polish Cardiac Society, *Kardiologia Polska*, DOI: 10.33963/KP.a2023.0075



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- 48 a, männlich
- Dyspnoe seit 2 Tagen, 1 Stockwerk möglich, Synkope
- RR: 117/82 mmHg, HF: 107/min, Sättigung 89% bei RL, AF 24/min
- Lactat: normal, Troponin: 34 ng/ml, NT-proBNP 2147 ng/l
- CT: bilaterale zentrale Pulmonalembolie



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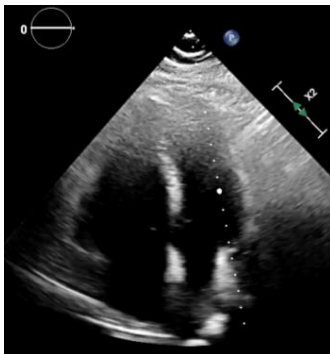
Please download and install the Slido app on all computers you use



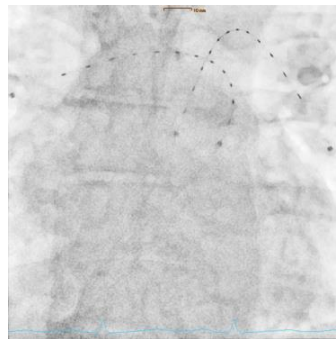
Für welche Therapie würden Sie sich entscheiden?

① Start presenting to display the poll results on this slide.

- 48 a, männlich
- Dyspnoe seit 2 Tagen, 1 Stockwerk möglich, Synkope
- RR: 117/82 mmHg, HF: 107/min, Sättigung 89% bei RL, AF 24/min
- Lactat: normal, Troponin: 34 ng/ml, NT-proBNP 2147 ng/l
- CT: bilaterale zentrale Pulmonalembolie



vor Intervention



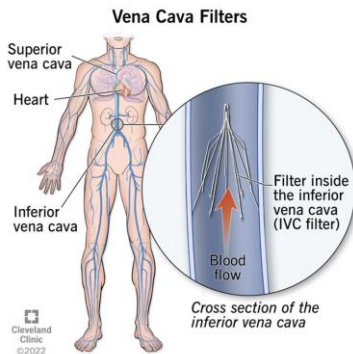
48h nach Intervention

Kathetergestützte Lyse mit 18 mg Actilyse (9 mg/Seite) noch am selben Tag



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Kelkar et al., Inferior vena cava filters: a framework for evidence-based use, *NONANTICOAGULANT INTERVENTIONS IN VENOUS THROMBOEMBOLISM*, Hematology 2020
 Young et al, Vena caval filters for the prevention of pulmonary embolism, Cochrane Database of Systematic Reviews 2020, Issue 10. Art. No.: CD006212.
<https://my.clevelandclinic.org/health/treatments/17609-vena-cava-filters>



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Haben Sie in den letzten 5 Jahren die
 Implantation eines Vena cava Filter indiziert?

i Start presenting to display the poll results on this slide.

Kathtergestützte Verfahren: Lungenembolie mit intermediär-hohem und hohem Risiko

Etablierung eines Pulmonary Embolism Response Teams

Indikation durch kardiovaskuläre Mediziner:innen

Gaps in evidence (u.a. clots in transit)

Andere interventionelle Verfahren mit schlechter Datenlage (Einzelfallentscheidungen)

Randomisierte prospektive Studien

Kelkar et al., Inferior vena cava filters: a framework for evidence-based use, *NONANTICOAGULANT INTERVENTIONS IN VENOUS THROMBOEMBOLISM*, Hematology 2020
 Young et al, Vena caval filters for the prevention of pulmonary embolism, *Cochrane Database of Systematic Reviews* 2020, Issue 10. Art. No.: CD006212.
<https://my.clevelandclinic.org/health/treatments/17609-vena-cava-filters>



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DANKE FÜR DIE AUFMERKSAMKEIT !

Markus.Theurl@i-med.ac.at



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FLAME: Trial Design

attached correct at

Dr. Jay Giri

Prospective, multicenter, non-randomized, parallel group, observational study of high-r

Trial Details

- Specific treatment not dictated (physician discretion)
- Concurrent, non-randomized enrollment
- Patients followed through discharge 45 days
- **Designed to capture all high-risk patients:**
 - Waiver of consent for unbiased enrollment
 - Chart review to ensure no high patients were missed

Poor Candidates for Mechanical Thrombectomy

- Distal or low clot burden
- Minor PE
- Patients with prior chest irradiation – Possible risk of perforation



Prior Thera

Lower-risk PE
advanced the
progressed to

Table 3. Efficacy Outcomes.*

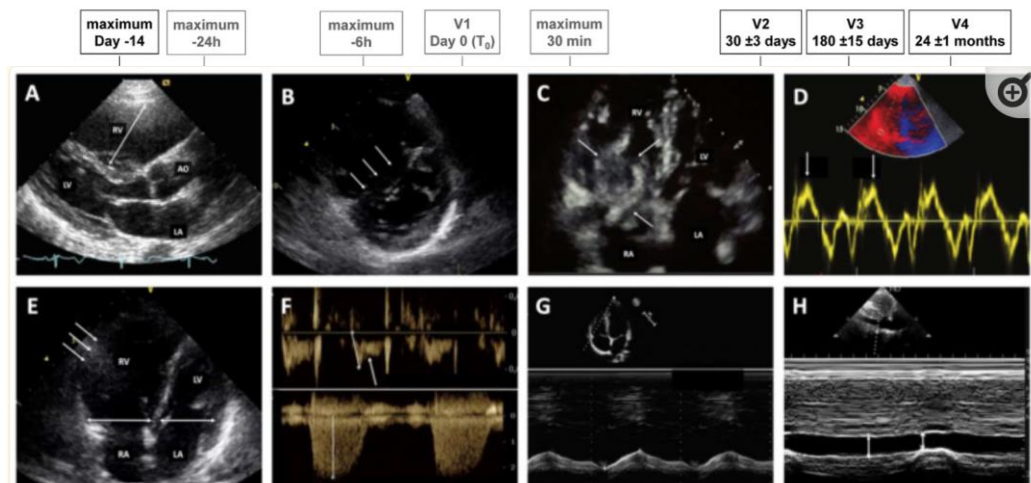


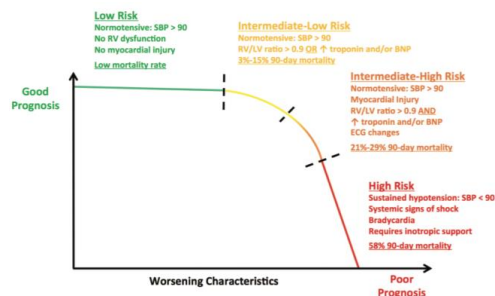
Fig. 1 Overview of design of the Pulmonary Embolism International Thrombolysis (PEITHUS)-3 trial. AEs, adverse events; PE, pulmonary embolism; RV, right ventricular; i.v., intravenously; V, visit.



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Cardiac arrest	Obstructive shock	Persistent hypotension
Need for cardiopulmonary resuscitation	Systolic BP <90 mmHg, or vasopressors required to achieve a BP $\geq$ 90 mmHg despite adequate filling status and End-organ hypoperfusion (altered mental status; cold, clammy skin; oliguria/ anuria; increased serum lactate)	Systolic BP <90 mmHg, or systolic BP drop $\geq$ 40 mmHg, either lasting longer than 15 minutes or not caused by new-onset arrhythmia, hypovolaemia, or sepsis
	And RV dysfunction (TTE/CT)	
At least one of the clinical manifestations indicate high-risk PE.		
BP: blood pressure; CTPA: computed tomography pulmonary angiography; RV: right ventricular; TTE: transthoracic echocardiography		



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	Systolic blood pressure, mm Hg	129.1 (3.3)	122.9 (2.6)
	Heart rate, beats/min	102.6 (2.7)	105.0 (3.2)
	Coexisting conditions		
	Diabetes	6 (13)	9 (23)
	Hypertension	13 (28)	14 (36)
	Dyslipidemia	5 (11)	7 (18)
	Coronary artery disease	8 (17)	8 (21)
	Obstructive airway disease	2 (4)	3 (8)
	Previous cerebrovascular accident	1 (2)	0
	Previous history of PE	1 (2)	1 (2)
	Active malignancy	0	0
	Immobility $\geq$ 3 d	10 (23)	9 (22)
	Surgery within prior 4 wk	3 (7)	3 (8)
	Anemia ^a	6 (13)	5 (13)
	Previous statin therapy	3 (7)	6 (15)
Subgroup (total No.)			
Age, y			
<65 (53)			
$\geq$ 65 (32)			
Sex			
Female (24)			
Male (61)			
Baseline CTPA indices, mean (SEM)			
Right-to-left ventricle ratio ^b	1.2 (0.11)	1.2 (0.3)	

Favors
control

Table 2. Study Outcomes in the Study Population

Outcome	No. (%)	cCDT + anticoagulation	Anticoagulation monotherapy	Odds ratio (95% CI)	Risk ratio (95% CI)	P
Primary outcome ^a						
3-mo Echocardiographic RV/LV ratio >0.9	2/46 (4.3)	5/39 (12.8)		OR, 0.31 (0.06 to 1.69)	0.33 (0.07 to 1.65)	.2
Other efficacy outcomes						
72-h RV/LV ratio >0.9 ^c	13/48 (27.0)	24/46 (52.1)		OR, 0.34 (0.14 to 0.80)	0.52 (0.30 to 0.89)	.0
3-mo Unrecovered RV ^{b,d}	3/46 (6.2)	11/39 (28.2)		OR, 0.18 (0.06 to 0.77)	0.23 (0.07 to 0.77)	.0
3-mo All-cause mortality ^e	0/48	3/46 (6.5)		-6.50 (-13.06 to 6.14)		.4
Composite of 3-mo all-cause mortality or the primary outcome	2/48 (4.2)	8/46 (17.3)		OR, 0.20 (0.04 to 1.03)	0.24 (0.05 to 1.07)	.0
PE-related mortality ^f	0 ^g	2/46 (4.3)		-4.35 (-11.34 to 2.66)	0.34 (0.07 to 1.65)	.3
Hospital length of stay, median (IQR), d ^h	6 (5-8)	6 (5-8)		NA	NA	.4
3-mo 6-min Walk test, median (IQR), m ⁱ	415 (339-455)	368 (270-442)		NA	NA	.3
Safety outcomes ^k						
BARC type 3 or 5	1/48 (2.1)	0		2.1 (-1.9 to 6.52)		.8
CRNMB	3/48 (6.2)	0 ^g		6.25 (-1.53 to 14.03)		.4
Major or nonmajor bleeding	4/48 (8.3)	0 ^g		8.33 (-0.27 to 16.94)	NA	.2
				1.53 to 14.03)		.4
						.4
						.4

mbolism Thrombolysis (PEITHO) definition for cRV recovery was used as follows: (1) RV size (in the per view) less than 35 mm, (2) pulmonary artery pre (3) an RV/LV ratio less than 0.9, and (4) the norm ysis. The fulfillment of all the criteria, some criteria, is was defined as complete, partial, and no recovery

incidence in 1 group, only absolute risk difference

est was only evaluated in 1 center and tested in patie a follow-up visit and were able to exercise (14 patien) patients in the anticoagulation-monotherapy grou it counts less than 20×10^3 /L (20×10^3 /L).

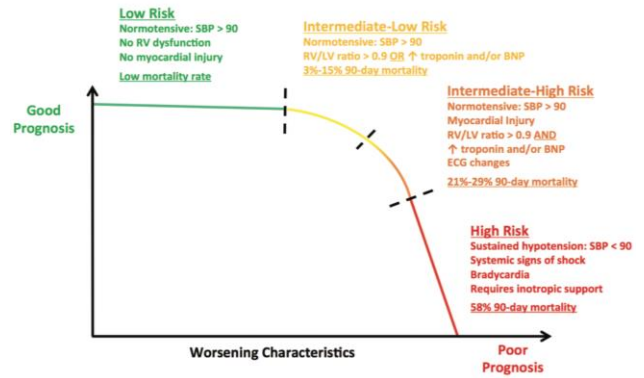
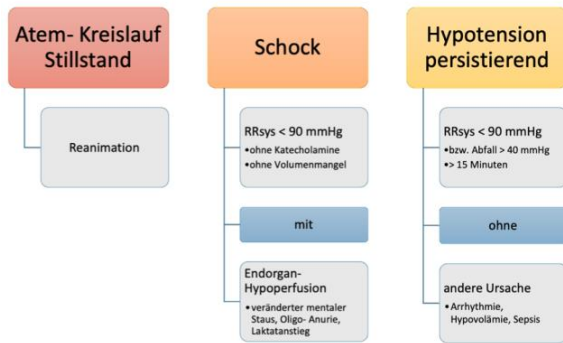
	CDT+anticoagulation n	Anticoagulation	P-value
Baseline hs troponin ng/L (SEM)	169.9	168.1	
NT-proBNP pg/L (SEM)	1804.2	1762.4	
RV/LV ratio	1.2	1.2	
Obstruction score	55.1	55.2	
72h RV/LV ratio >0.9	13/48 (27%)	24/46 (52.1%)	0.01

Avgerinos E. et al., Randomized Trial



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Kardiologie und Angiologie



Linnemann et al., Diagnostik und Therapie der tiefen Venenthrombose und Lungenembolie – AWMF-S2k-Leitlinie

Jaff M., Endovascular Today, Oktober 2020, Vol. 19, No. 10, Advanced Endovascular Interventions With Ultrasound-Accelerated Thrombolysis in Intermediate-Risk Pulmonary Embolism



IFIMP 2025-Kathetergestützte Thrombolysen

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