Intervenční léčba plicní embolie

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NEMOCNICE PARDUBICKÉHO KRAJE

Venous thromboembolism (VTE), clinically presenting as DVT or PE, is globally the third most frequent acute cardiovascular syndrome behind myocardial infarction and stroke.

European Heart Journal (2020) 41, 543603

VTE: the Most Recent Example of Vascular Evolution to Catheter-Based Treatments

Development of new tools and supporting data continue to drive treatment away from thrombolytic drugs to definitive endovascular mechanical interventions

Myocardial Infarction

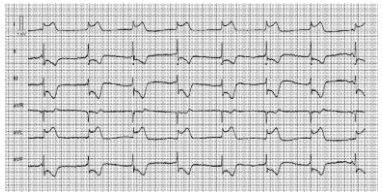
Thrombolysis → Balloon Angioplasty, Bare Metal Stent, Drug-Eluting Stents → Primary Angioplasty in Acute Myocardial Infarction (PAMI), Stent PAMI

Stroke

Systemic Thrombolysis → Stentriever, Aspiration Thrombectomy → REVASCAT, ESCAPE, MR CLEAN, EXTEND-IA, SWIFT PRIME

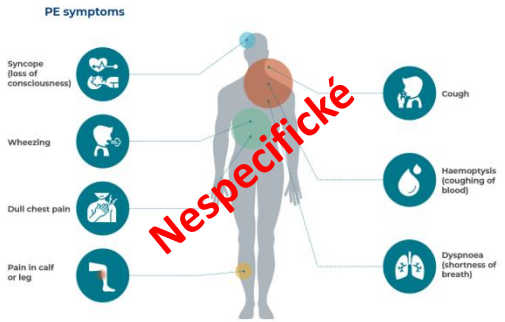
Expected Path for Venous Thromboembolism (DVT and PE)

Catheter Directed Thrombolysis, Pharmaco-mechanical Thrombolysis → ClotTriever FlowTriever → FLARE, CLOUT, FLASH, FLAME



PCI

Trombektomie/Systémová trombolýza



Evidence pro CDT

Study	Devices	Design	Sample	Population	Intervention	Control	Efficacy outcome	Safety outcomes	Follow-up
ULTIMA[53] (NCT01166997), 2013	EkoSonic	Randomised, open-label	59	Intermediate-risk PE	Anticoagulation plus tPA-USAT (10 mg)	Anticoagulation monotherapy	ΔRV/LV ratio at 24 h: 0.30±0.20 vs 0.03±0.16 (p<0.001)	0 deaths, 0 major bleeds, 3 minor bleeds at 90 days	90 days
SEATTLE II[51] (NCT01513759), 2015	EkoSonic	Single-arm	150	Intermediate-high-risk PE	Anticoagulation plus tPA-USAT (12-24 mg)	-	ΔRV/LV ratio at 48 h: 0.42±0.36 (p<0.0001)	7 deaths, 15 major bleeds at 30 days	30 days
OPTALYSE PE[54] (NCT02396758), 2018	EkoSonic	Randomised, open-label	101	Intermediate-risk PE	Anticoagulation plus tPA-USAT (4 mg, 6 mg, or 12 mg)	Compared 4 tPA regimens*	RV/LV ratio reduced in all arms at 48±6 h	5 major bleeds at 72 h	365 days
SUNSET sPE[84] (NCT02758574), 2021	EkoSonic vs Cragg-McNamara or Uni-Fuse	Randomised, single-blind	81	Intermediate-risk PE	Anticoagulation plus tPA-USAT (4-8 mg)	Anticoagulation plus CDT	ΔRV/LV ratio at 48 h: 0.37±0.34 vs 0.59±0.42 (p=0.01)	2 major bleeds, 3 minor bleeds and 1 in-hospital death	90 days
CANARY[85] (NCT05172115), 2022	Cragg-McNamara	Randomised, open-label	94	Intermediate-high-risk PE	Anticoagulation plus CDT (12-24 mg)	Anticoagulation monotherapy	ΔRV/LV ratio reduced at 3 months: 0.7 vs 0.8 (p=0.01)	1 BARC Type 3a major bleed	90 days
RESCUE[50] (NCT04248868), 2022	BASHIR	Single-arm	109	Intermediate-risk PE	Anticoagulation plus CDT (7-14 mg)	-	ΔRV/LV ratio at 48 h: 0.56±0.41 (p<0.0001)	1 death, 3 major bleeds at 30 days	30 days
Kroupa et al[86] (pilot study), 2022	Cragg-McNamara	Randomised, open-label	23	Intermediate-high-risk PE	Anticoagulation plus CDT (20 mg)	Anticoagulation monotherapy	ΔRV/LV ratio at 48 h: 0.88±0.16 vs 1.42±0.44 (p=0.01)	0 BARC Type 5 or 3c major bleeds	30 days

Evidence pro aspirační embolektomii

Trial	Devices	Design	Sample	Population	Intervention	Control	Efficacy outcome	Safety outcomes	Follow-up
FLARE[74] (NCT02692586), 2019	FlowTriever	Single-arm	106	Intermediate-risk PE	Anticoagulation plus FlowTriever	-	ΔRV/LV ratio at 48 h: 0.41±0.05 (p<0.0001)	All-cause death: 0; major bleeding: 0.9% at 48 h	30 days
EXTRACT-PE[75] (NCT03218566), 2021	Indigo	Single-arm	119	Intermediate-risk PE	Anticoagulation plus Indigo	-	ΔRV/LV ratio at 48 h: 0.43±0.26 (p<0.0001)	All-cause death: 1.1%; major bleeding: 1.6% at 48 h	30 days
FLAME[89] (NCT04795167), 2023	FlowTriever	Prospective, non-randomised	104	High-risk PE	Anticoagulation plus FlowTriever	Other therapies	Composite of all-cause mortality, clinical deterioration, bailout, and major bleeding: 17% vs 63.9%	All-cause death: 1.9% vs 29.5%; major bleeding: 11.3% vs 24.6%	In hospital

Up to date 2024

EuroIntervention
2024;20:e408-e424
published online e-edition April 2024
DOI: 10.4244/EIJ-D-23-00895

State-of-the-Art
by EuroIntervention

Percutaneous interventions for pulmonary embolism

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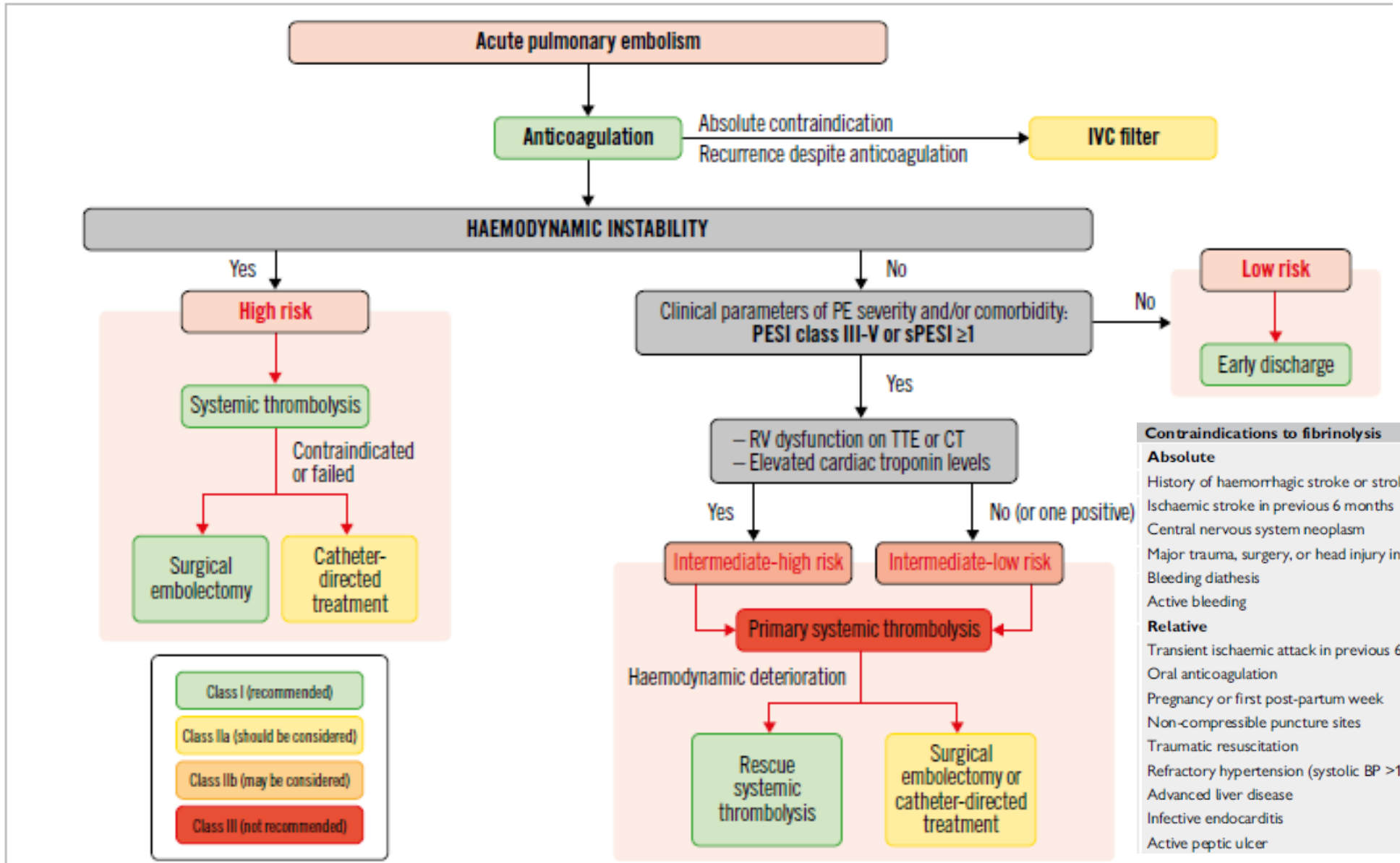
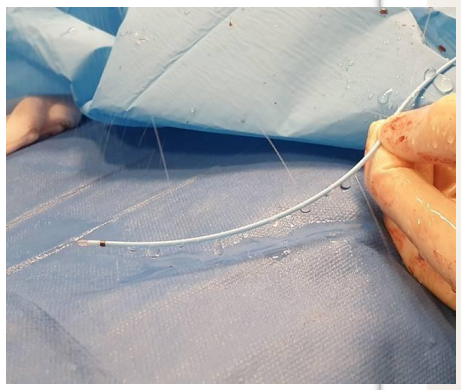
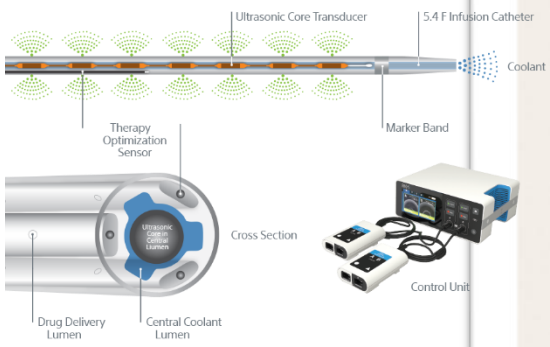
This paper also includes supplementary data published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-23-0089



Contraindications to fibrinolysis
Absolute
History of haemorrhagic stroke or stroke of unknown origin
Ischaemic stroke in previous 6 months
Central nervous system neoplasm
Major trauma, surgery, or head injury in previous 3 weeks
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

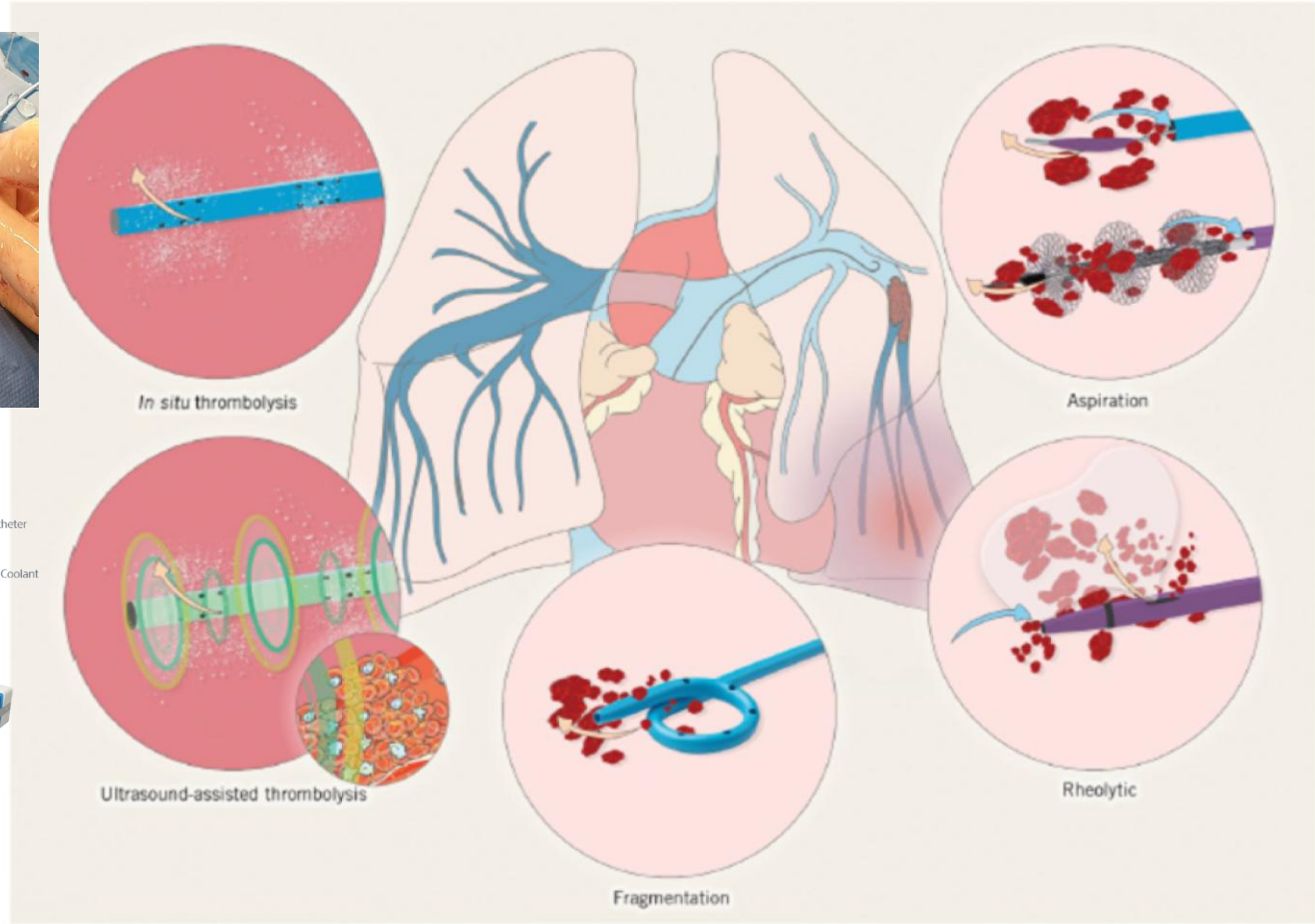




NEW FlowTriever2

EuroIntervention — Central Illustration

Interventional options for the treatment of acute pulmonary embolism.



Simone Finocchiaro *et al.* • *EuroIntervention* 2024;20:e408-e424 • DOI: 10.4244/EIJ-D-23-00895

Běžící studie intervenční léčby plicní embolie

Trial	Design	Sample	Population	Intervention	Control	Primary outcomes	Follow-up
HI-PEITHO (NCT04790370)	Single-blind, phase 4	406	Intermediate-high-risk PE	USAT	Standard anticoagulation	All-cause death, haemodynamic decompensation, recurrent PE	7 days
NCT05612854	Open-label, phase 1	200	Intermediate-high-risk PE	Fragmentation, aspiration	Standard anticoagulation	MACE	2 years
PE-TRACT (NCT05591118)	Open-label, phase 3	500	Intermediate-high-risk PE	CDT or mechanical thrombectomy	Standard anticoagulation	Peak oxygen consumption, NYHA FC, major bleeding	7 days, 3 months, 12 months
PEERLESS (NCT05111613)	Open-label	550	Intermediate-high-risk PE	Aspiration embolectomy (FlowTriever system)	CDT	All-cause death, intracranial haemorrhage, major bleeding, haemodynamic decompensation	7 days
PEERLESS II (NCT06055920)	Open-label	1,200	Intermediate-high-risk PE	Aspiration embolectomy (FlowTriever system)	Standard anticoagulation	Haemodynamic decompensation, all-cause hospital readmission, bailout therapy	30 days
PRAGUE-26 (NCT05493163)	Open-label, phase 4	558	Intermediate-high-risk PE	CDT	Standard anticoagulation	All-cause death, haemodynamic decompensation, recurrent PE	7 days
STORM-PE (NCT05684796)	Open-label	100	Intermediate-high-risk PE	Aspiration embolectomy (Indigo system)	Standard anticoagulation	Change in right ventricle/ left ventricle ratio	48 hours
STRATIFY (NCT04088292)	Single-blind, phase 3, 1:1:1	210	Intermediate-high-risk PE	USAT or low-dose thrombolysis	Standard anticoagulation	Miller score	96 hours

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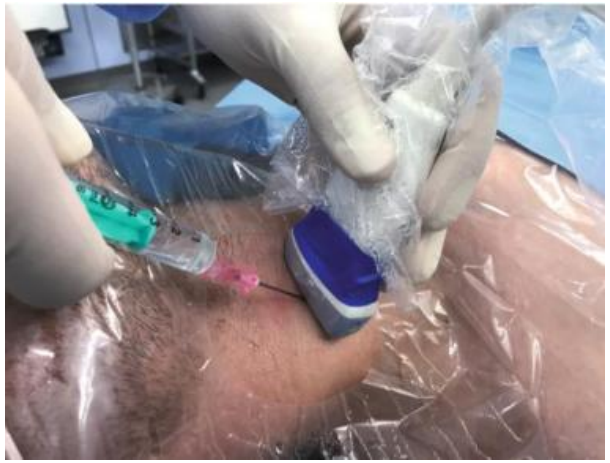
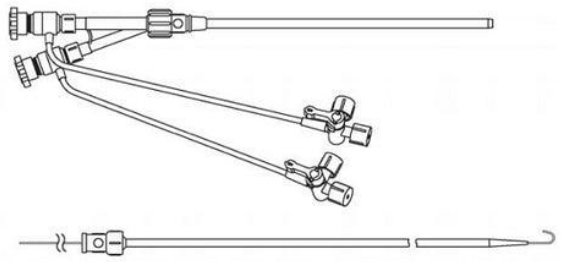
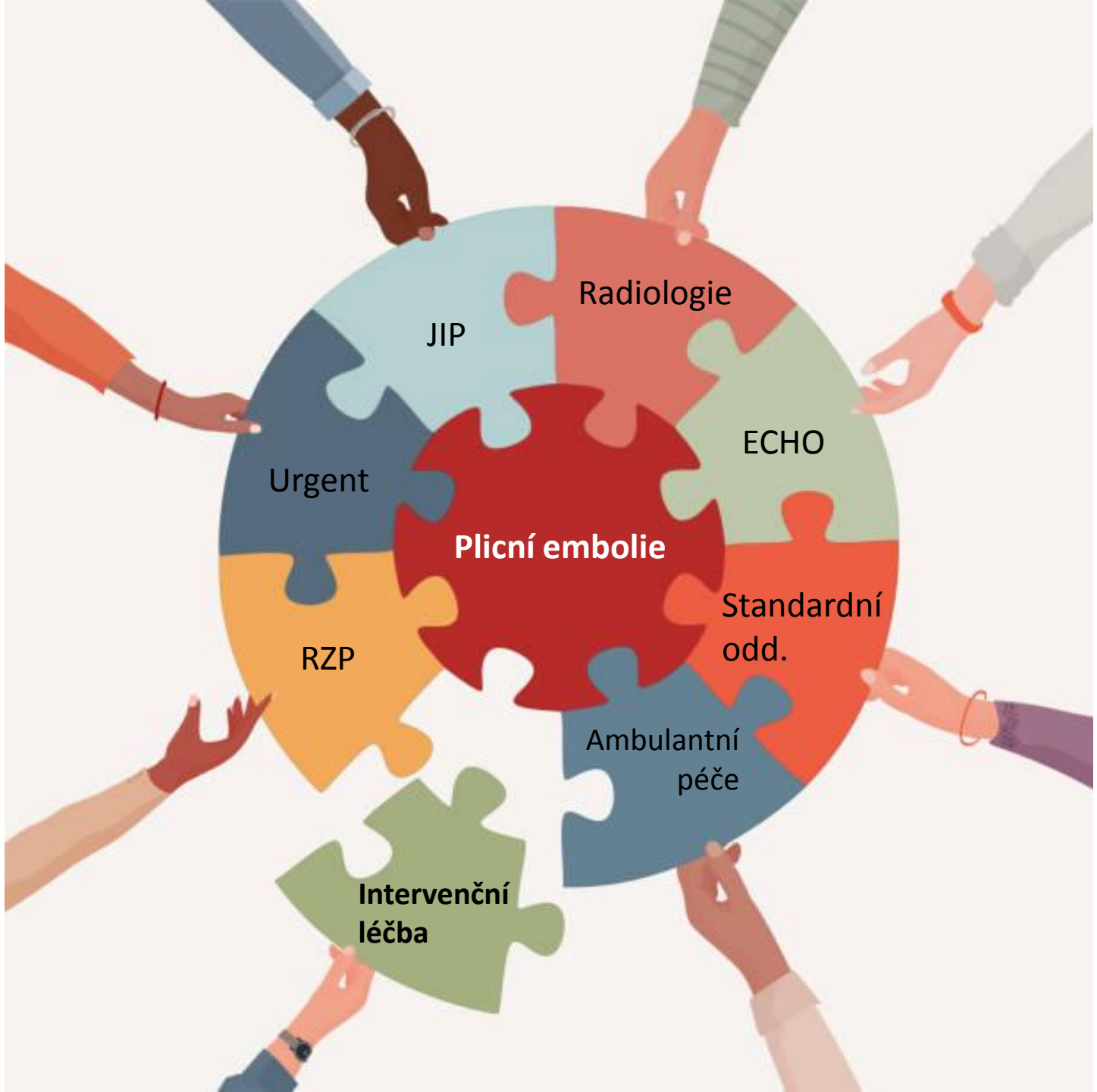
Naše zkušenosti s CDT včetně Prague 26

- 8x iHR PE v rámci studie Prague 26
- 3x HR PE a refrakterním šokem - CDT včetně 3x po napojení na ECMO
- periprocedurální komplikace - 0
- velká krvácení v souvislosti s výkonem – 0



Radiologie
JIP
ECHO
Urgent
Plicní embolie
Standardní odd.
RZP
Ambulantní péče
Intervenční léčba

I don't UNDERSTAND, having a pulmonary embolism isn't on his 'To Do' list!