PLICNÍ EMBOLII JE MOŽNÉ LÉČIT POUZE FARMAKOLOGICKY

Mýtus či realita?

Viktor Kočka, Josef Kroupa *za celý PERT tým*

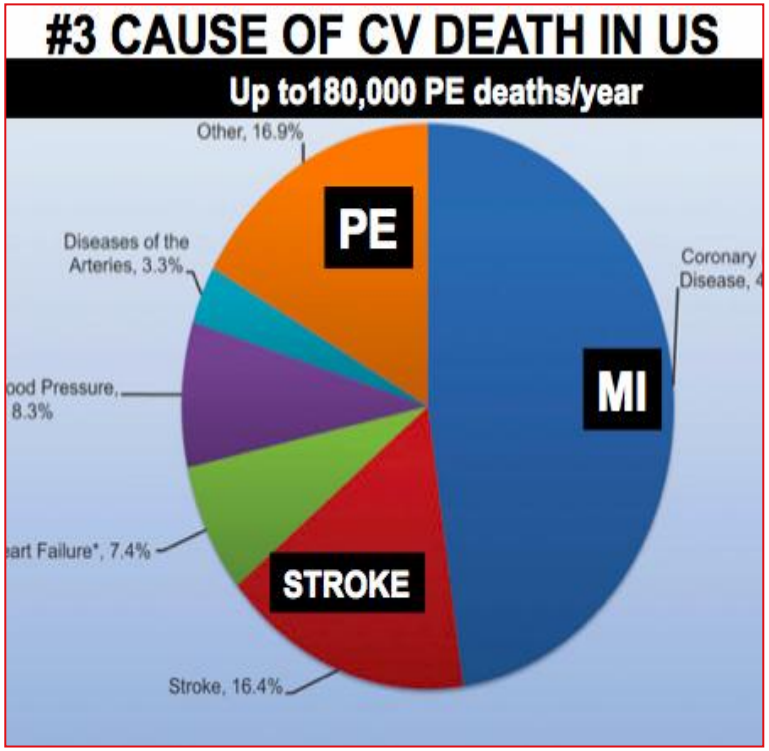
Kardiocentrum

Fakultní nemocnice Královské Vinohrady a

3.lékařská fakulta UK v Praze

Plicní embolie za 25 let

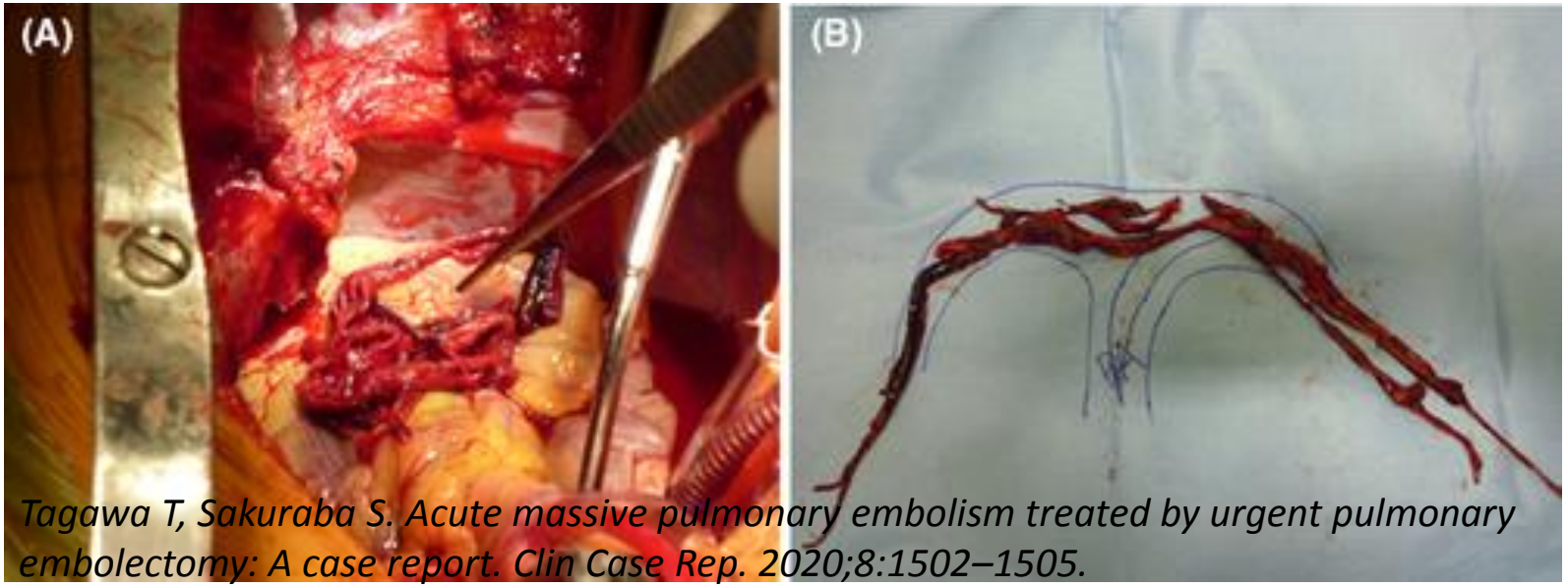
- CT AG plicnice….již od 1997 v Jablonci na Nisou
- Trombolýza pro pacienty v šoku….již od 1995
- Debaty o trombolýze pro méně nemocné pacienty….2001



Jerjes-Sanchez C, Ramirez-Rivera A, de Lourdes GM, et al. Streptokinase and heparin versus heparin alone in massive pulmonary embolism: a randomized controlled trial. *J Thromb Thrombolysis.* 1995; *2*: 227–229.
Goldhaber SZ. Thrombolysis in pulmonary embolism: a debatable indication. *Thromb Haemost.* 2001; *86*: 444–451.

Plicní embolectomie pro PE

- Malé serie pacientů či kasuistiky
- Prováděna vzácně, vysoké riziko operace



Tagawa T, Sakuraba S. Acute massive pulmonary embolism treated by urgent pulmonary embolectomy: A case report. Clin Case Rep. 2020;8:1502–1505.

Centra excellence – 89% přežití za 1 rok.
Aklog L, Williams CS, Byrne JG, et al, Acute pulmonary embolectomy: a contemporary approach. *Circulation*. 2002; **105**: 1416- 1419.

Katetrizační intervence pro PE

Recommendations for acute-phase treatment of high-risk PE (2)

ESC European Society of Cardiology

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

ECMO = extracorporeal membrane oxygenation.

Recommendations for acute-phase treatment of intermediate- or low- risk PE (3)

ESC European Society of Cardiology

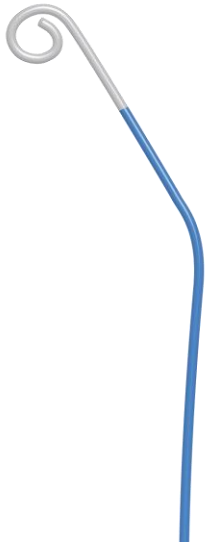
Recommendations	Class	Level
Reperfusion treatment		
Rescue thrombolytic therapy is recommended for patients with haemodynamic deterioration on anticoagulation treatment.	I	B
As an alternative to rescue thrombolytic therapy, surgical embolectomy or percutaneous catheter- directed treatment should be considered for patients with haemodynamic deterioration on anticoagulation treatment.	IIa	C
Routine use of primary systemic thrombolysis is not recommended in patients with intermediate- or low-risk PE.	III	B

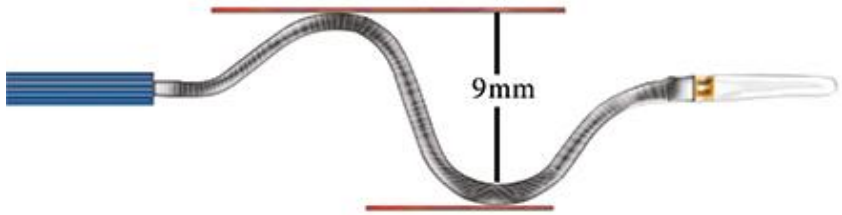
Jaké jsou intervenční možnosti?

- **Mechanická fragmentace**
- **Lokální trombolýza** (včetně ultrazvukem facilitované)
- **Mechanická embolektomie**
- **Kombinované metody (mechanické + farmakologické)**

•K DOSAŽENÍ HEMODYNAMICKÉ STABILITY NENÍ NUTNÉ ODSTRANĚNÍ VŠECH TROMBOTICKÝCH HMOT!!!

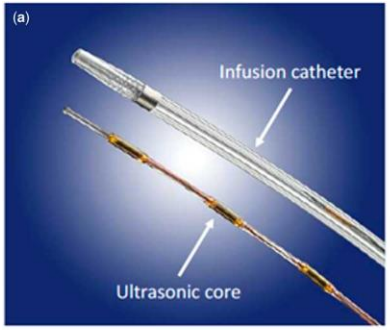
Mechanická fragmentace 4F-10F

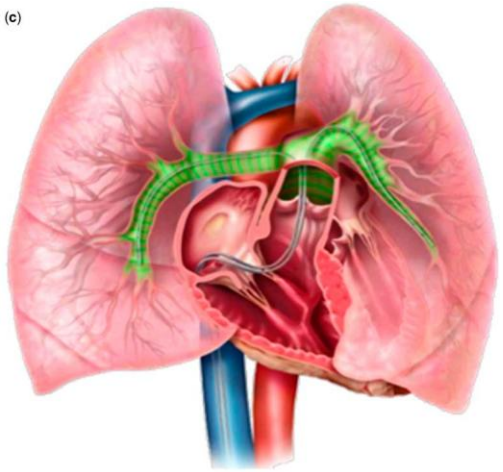


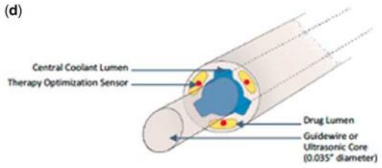


CLEANER™ rotational thrombectomy system

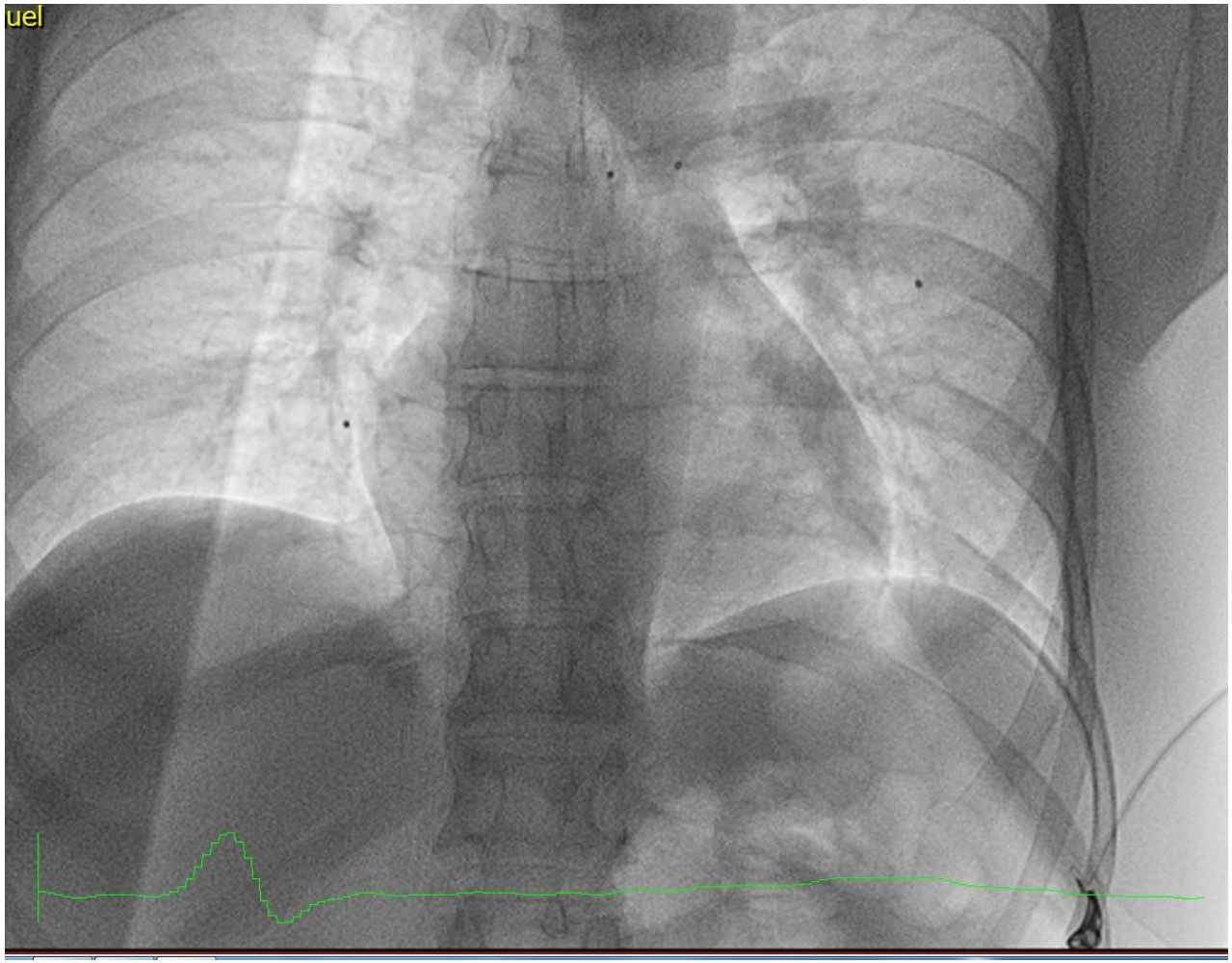
Lokální trombolýza 4F-10F







Lokální trombolýza



Katetrizační intervence ve FNKV

EuroIntervention 2022; 18:e639-e646. DOI: 10.4244/EIJ-D-

A pilot randomised trial of catheter-directed thrombolysis or standard anticoagulation for patients with intermediate-high risk acute pulmonary embolism

Josef Kroupa[1]*, MD, PhD; Michal Buk[2], MD; Jiri Weichet[2], MD, PhD; Hana Malikova[2], MD, PhD; Lucie Bartova[1], MSc; Hana Linkova[1], MD, PhD; Oana Ionita[1], MD; Martin Kozel[1], MD, PhD; Zuzana Motovska[1], MD, PhD; Viktor Kocka[1], MD, PhD

Abstract

Background: Intermediate-high risk acute pulmonary embolism (PE) remains associated with substantial mortality despite anticoagulation therapy.

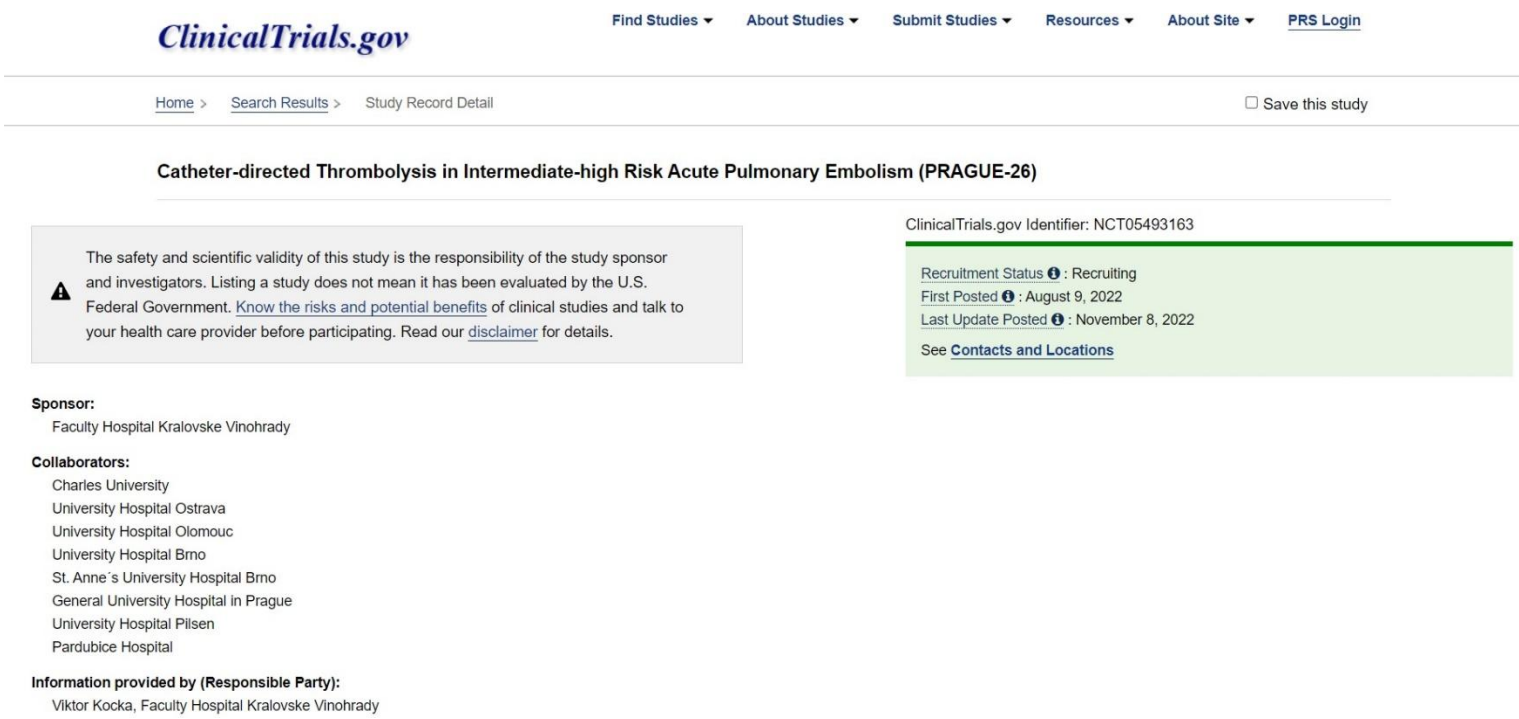
Aims: The aim of this randomised pilot study was to compare catheter-directed thrombolysis to standard anticoagulation therapy.

Methods: Intermediate-high risk acute PE patients were admitted to a tertiary care centre (November 2019 to April 2021) and randomised in a 1:1 ratio to catheter-directed thrombolysis (CDT) or standard anticoagulation. Two catheters were used for the infusion of Alteplase (1 mg/hr/catheter; total dose 20 mg) in the CDT group. The primary efficacy endpoint targeted improvement of right ventricular (RV) function, a decrease in pulmonary pressure, and a reduction of thrombus burden.

Results: Twenty-three patients were included (12 in the CDT group and 11 in the standard care group). The primary efficacy endpoint was achieved more frequently in the CDT group than in the standard care group (7 of 12 patients vs 1 of 11 patients, p=0.0004). An RV/left ventricular ratio reduction ≥25% (evident on computed tomography angiography) was achieved in 7 of 12 patients in the CDT group vs 2 of 11 patients in the standard care group (p=0.03). A systolic pulmonary artery pressure decrease of ≥30% or normotension at 24 hrs after randomisation was present in 10 of 12 patients in the CDT group vs 2 of 11 patients in the standard care group (p=0.001). There was no intracranial or life-threatening bleeding (type 5 or 3c bleeding, according to the Bleeding Academic Research Consortium classification).

Conclusions: CDT for intermediate-high risk acute PE appears to be safe and effective. Further research is warranted to assess clinical endpoints.

PRAGUE-26



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Catheter-directed Thrombolysis in Intermediate-high Risk Acute Pulmonary Embolism (PRAGUE-26)

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT05493163

Recruitment Status ⓘ : Recruiting
First Posted ⓘ : August 9, 2022
Last Update Posted ⓘ : November 8, 2022
See Contacts and Locations

Sponsor:
Faculty Hospital Kralovske Vinohrady

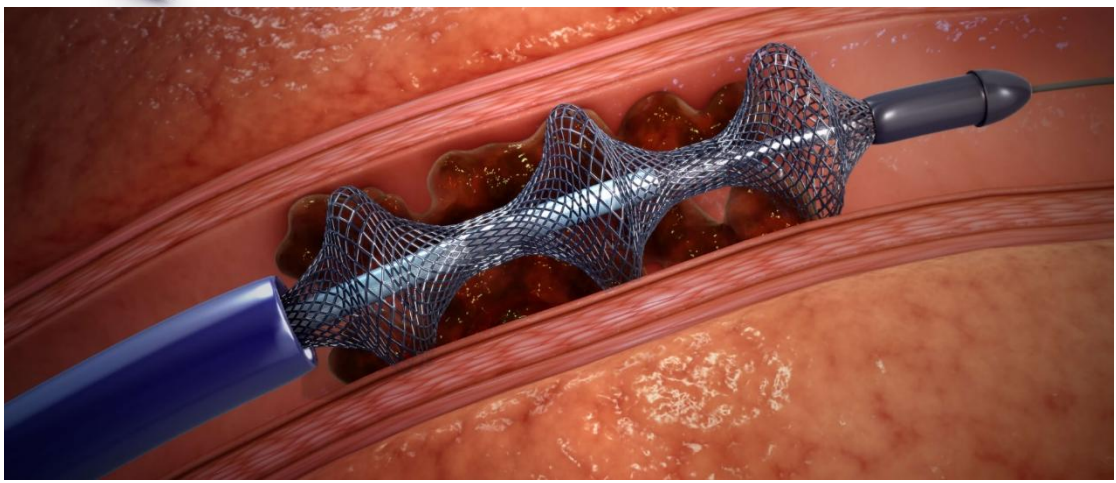
Collaborators:
Charles University
University Hospital Ostrava
University Hospital Olomouc
University Hospital Brno
St. Anne´s University Hospital Brno
General University Hospital in Prague
University Hospital Pilsen
Pardubice Hospital

Information provided by (Responsible Party):
Viktor Kocka, Faculty Hospital Kralovske Vinohrady

- 8 intervenčních center v České republice, **558 pacientů**

- **Cíl →** porovnat klinický outcome pacientů (intermediate-high risk) podstupujících katetrizační intervenci oproti standardní antikoagulační léčbě

Aspirační embolektomie 16F-24F

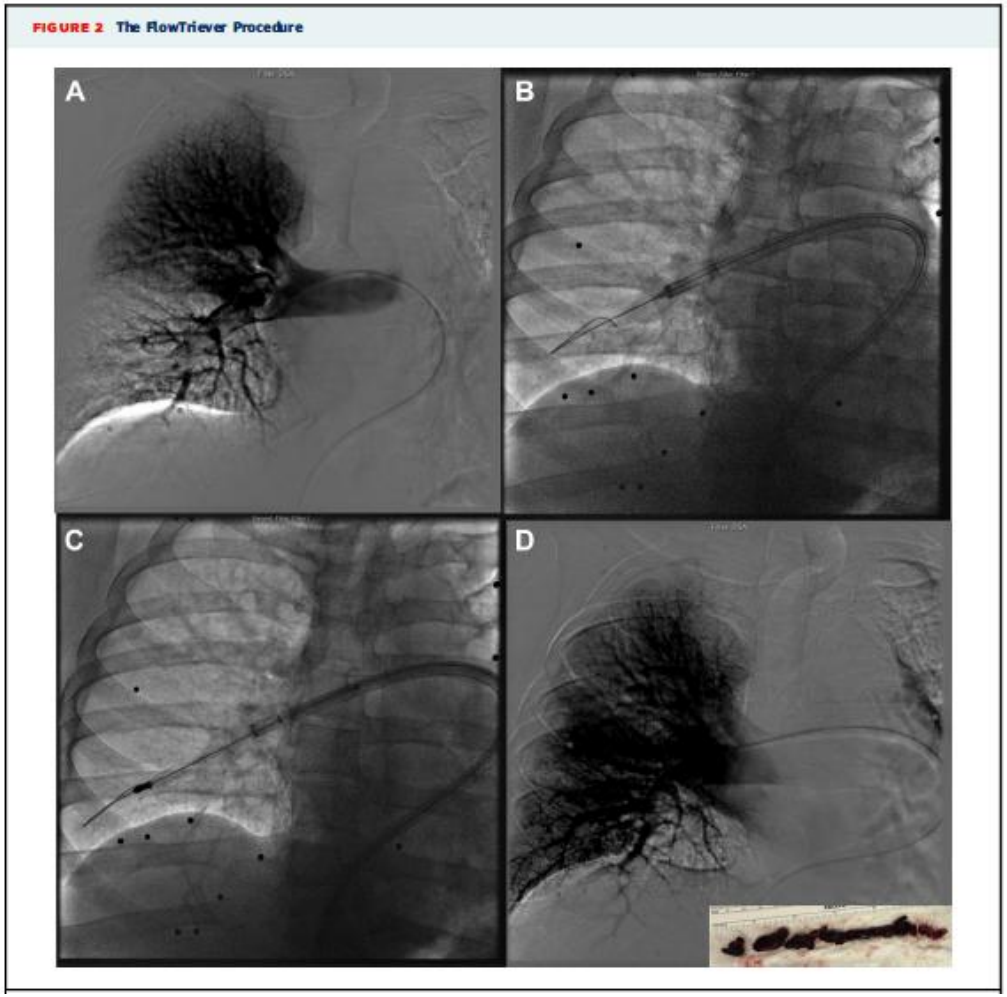


The FlowTriever system (Inari Medical)

Aspirační embolektomie 16F-24F

TABLE 2 Procedural Characteristics (n = 104)

Local anesthesia	100 (96.2)
Femoral access	104 (100)
Number of devices introduced	1.7 ± 0.7
1	43 (41.3)
2	48 (46.2)
3	13 (12.5)
Device size used	
Small	36.9%
Medium	39.7%
Large	23.4%
Number of passes attempted	3.9 ± 1.7*
Number of passes with clot retrieved	3.2 ± 1.6
Number with clot retrieved on no passes	3 (2.9)
Number with clot retrieved on all passes	66 (63.5)†
Technical complications	2 (1.9)‡
Anticoagulation before procedure	
UFH	86 (82.7)
LMWH	22 (21.2)
VKA	1 (1.0)
DOAC	5 (4.8)
Procedure time, min (n = 100)	93.8 ± 29.6
AGC time, min (n = 99)	57.1 ± 24.2
Length of ICU stay, days	1.5 ± 2.1
Length of hospital stay, days (n = 103)	4.1 ± 3.5



FLARE study: JACC Cardiovasc Interv 2019 May 13;12(9):859-869.

The FlowTriever system (Inari Medical)

Aspirační embolektomie 8F-12F

FIGURE 2 Indigo Aspiration Catheter and Penumbra Aspiration Pump

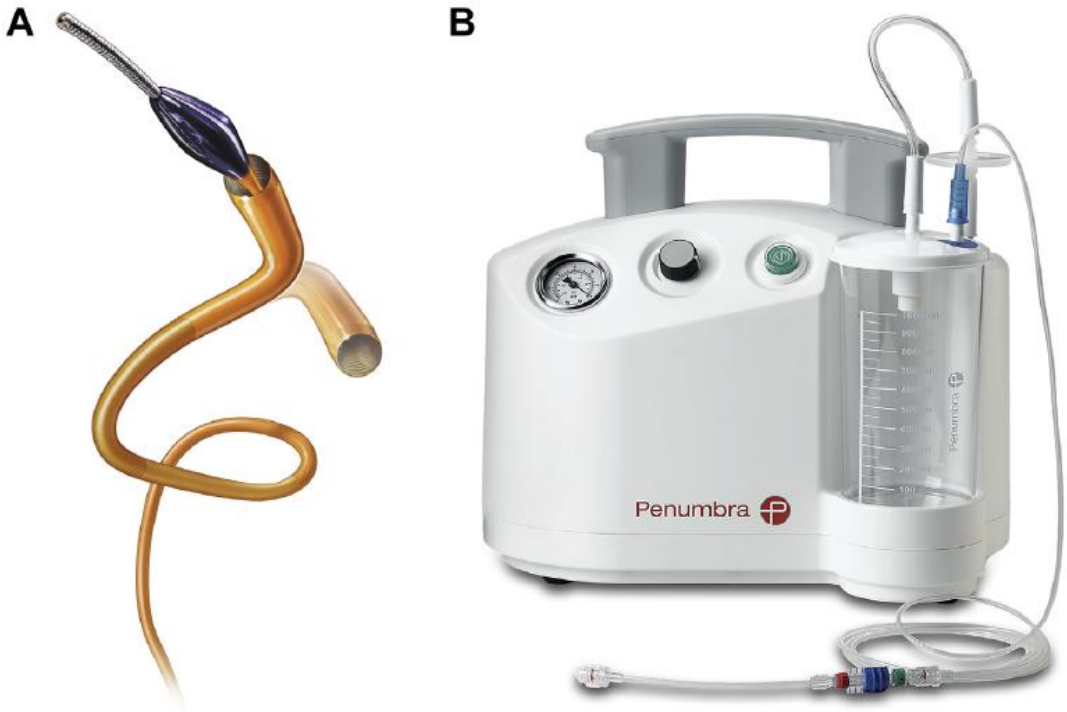
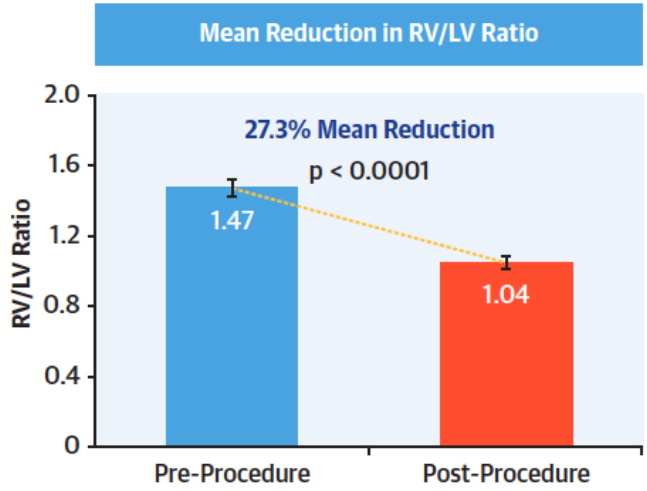


Illustration of components of the device system. **(A)** An enlarged image of the Indigo aspiration catheter; **(B)** the Indigo aspiration pump producing sustained aspiration power at -28.5 mm Hg.

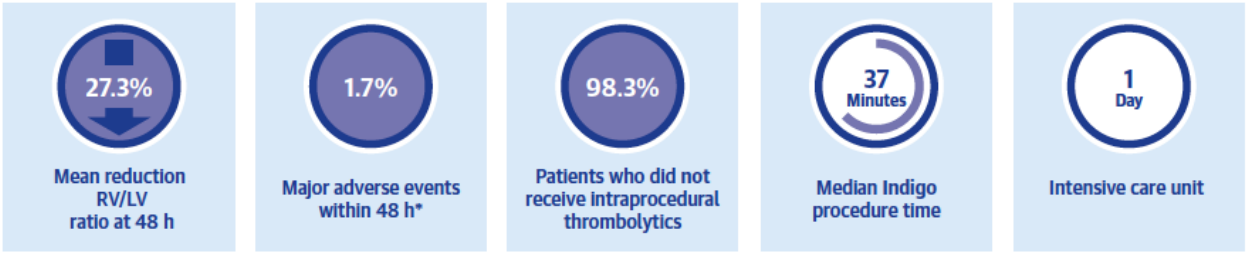
The Indigo mechanical thrombectomy system Penumbra

Aspirační embolektomie 8F-12F

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 Intv. 2021;14(3):319–29.

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

The Indigo mechanical thrombectomy system Penumbra

ESC position paper (2022)

PERIPHERAL INTERVENTIONS
EXPERT CONSENSUS

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

Piotr Pruszczyk[1], MD, PhD, FESC; Frederikus A. Klok[2,3], MD, PhD, FESC; Nils Kucher[4], MD, FESC; Marek Roik[1]*, MD, PhD; Nicolas Meneveau[5], MD, PhD; Andrew S.P. Sharp[6], MD; Jens Erik Nielsen-Kudsk[7], MD, DMSc; Slobodan Obradović[8], MD, PhD, FESC; Stefano Barco[3,4], MD, PhD, FESC; Francesco Giannini[9], MD; Giulio Stefanini[10,11], MD, PhD; Giuseppe Tarantini[12], MD, FESC; Stavros Konstantinides[3,13], MD, FESC; Dariusz Dudek[9,14], MD, FESC

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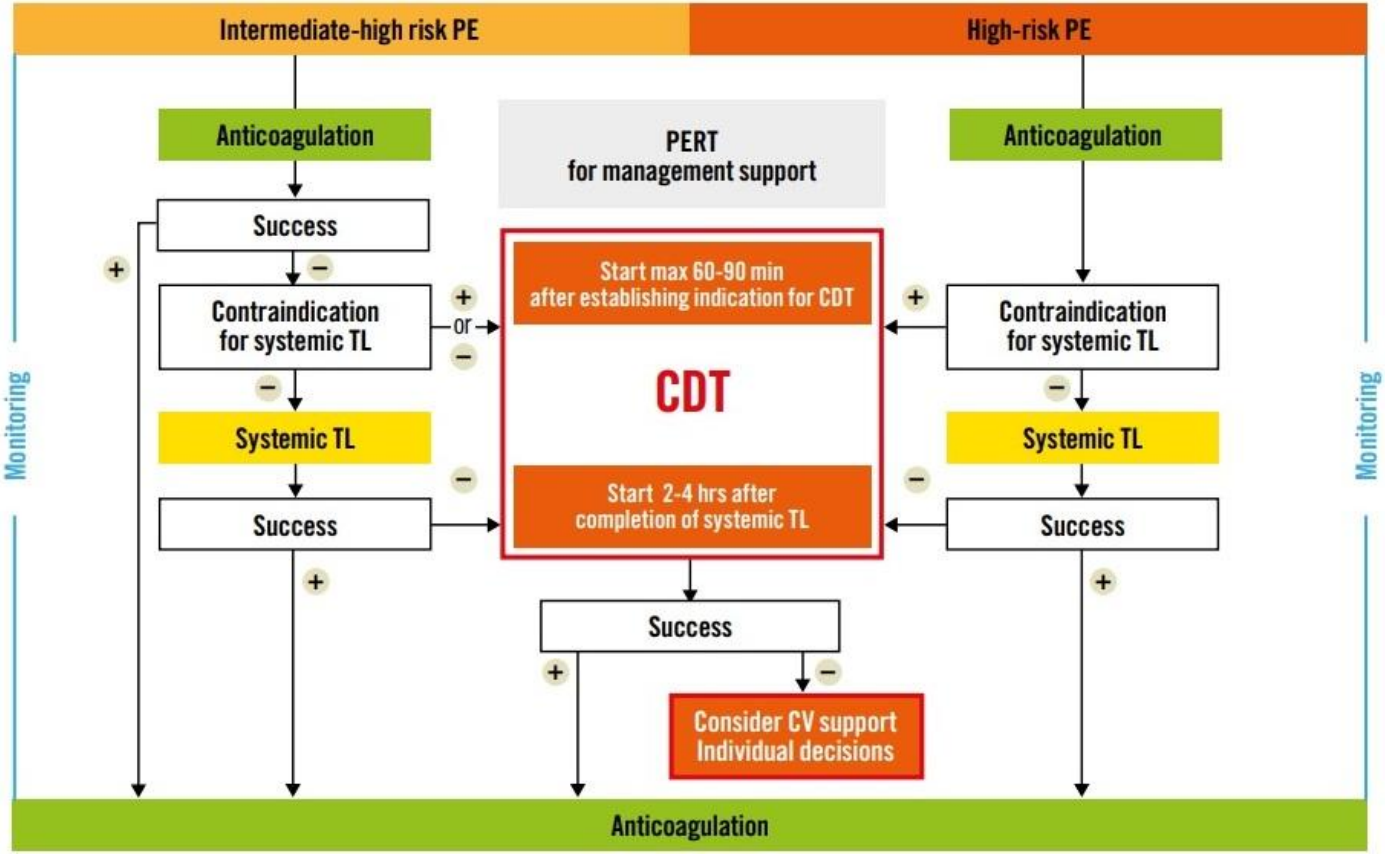
EuroIntervention 2022;18:e623-e638 published online ahead of print September 2022 published online

ESC position paper (2022)

EuroIntervention

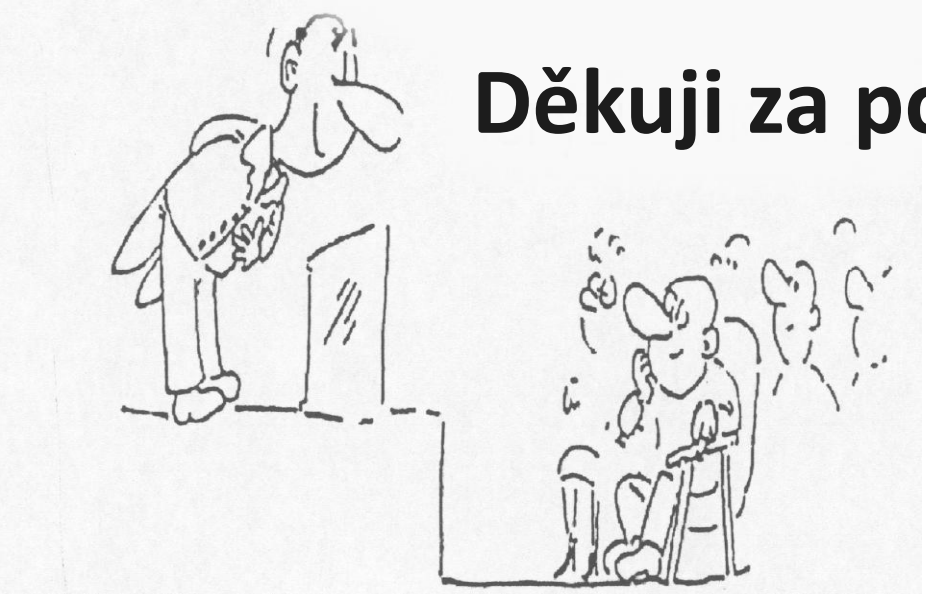
CENTRAL **ILLUSTRATION** Proposed algorithm and timelines of catheter-directed therapies (CDT) in high-risk and intermediate-high risk pulmonary embolism (PE).



CV: cardiovascular; PERT: Pulmonary Embolism Response Team; TL: thrombolysis

Závěr

- Možnosti katetrizačních intervencí pro pacienty s PE se rozšiřují
- Lokální trombolýzu pro pacienty s vyšším středním rizikem zkoumá randomizovaná studie PRAGUE 26 – díky
- Agresivnější a snad i účinnější přístupy jsou potřeba pro pacienty v šoku
- Ve FNKV již vznikl PERT tým!!



Děkuji za pozornost