Thai Venous Forum

Catheter based intervention for PE Indication & Technique

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15th August 2021

Disclosure

- Speaker name: **Nutsiri Kittitirapong**
- I have the following potential conflicts of interest to report:
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- ✓ I do not have any potential conflict of interest

Outline

How important?

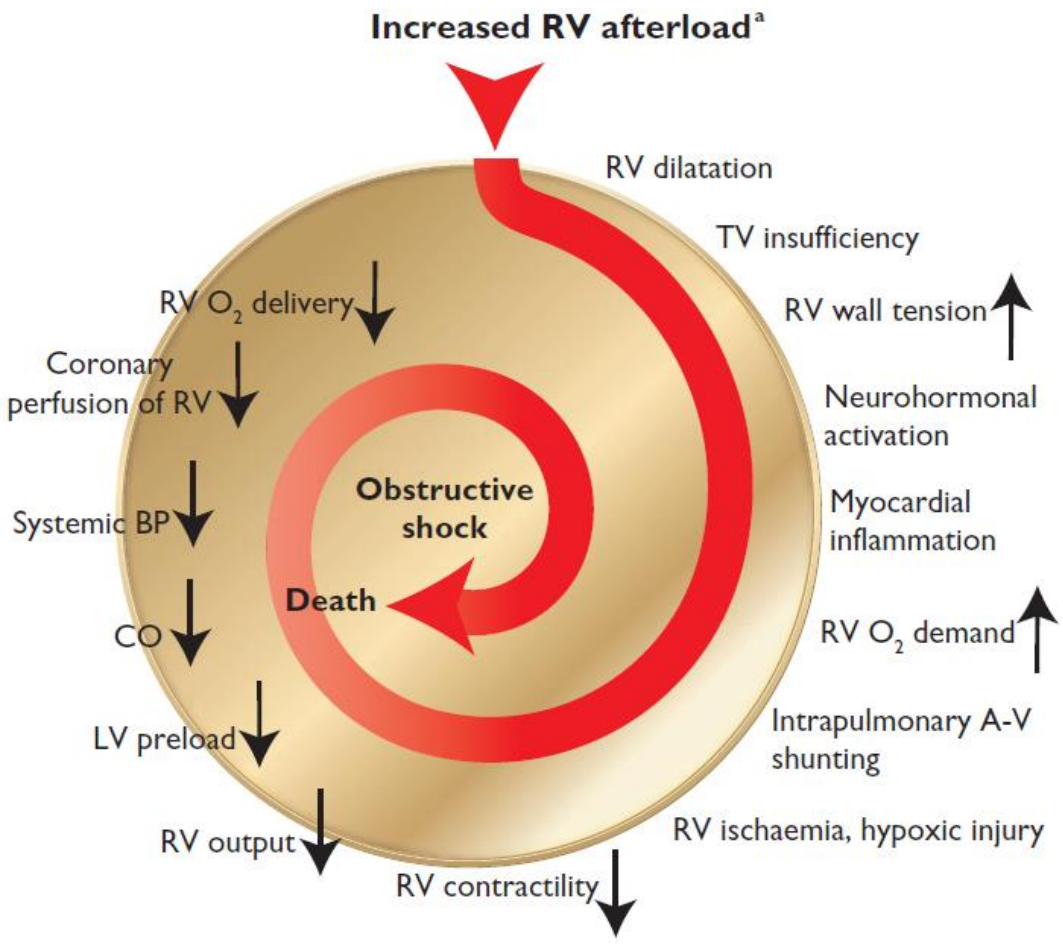
ESC guideline

Treatment modality

1. How important?

Pathophysiology

- Acute PE interferes with both **circulation** and **gas exchange**
- It is the **third most common cause of death** in hospitalized patients



ESC guideline 2019. European Heart Journal (2020) 41, 543–603

Who need intervention for acute PE ?

2. ESC Guideline

ESC European Society of Cardiology

European Heart Journal (2020) **41**, 543–603
doi:10.1093/eurheartj/ehz405

ESC GUIDELINES

2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS)

The Task Force for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology (ESC)

ESC guideline 2019. European Heart Journal (2020) 41, 543-603

Prognostic assessment strategy

Table 8 **Classification of pulmonary embolism severity and the risk of early (in-hospital or 30 day) death**

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

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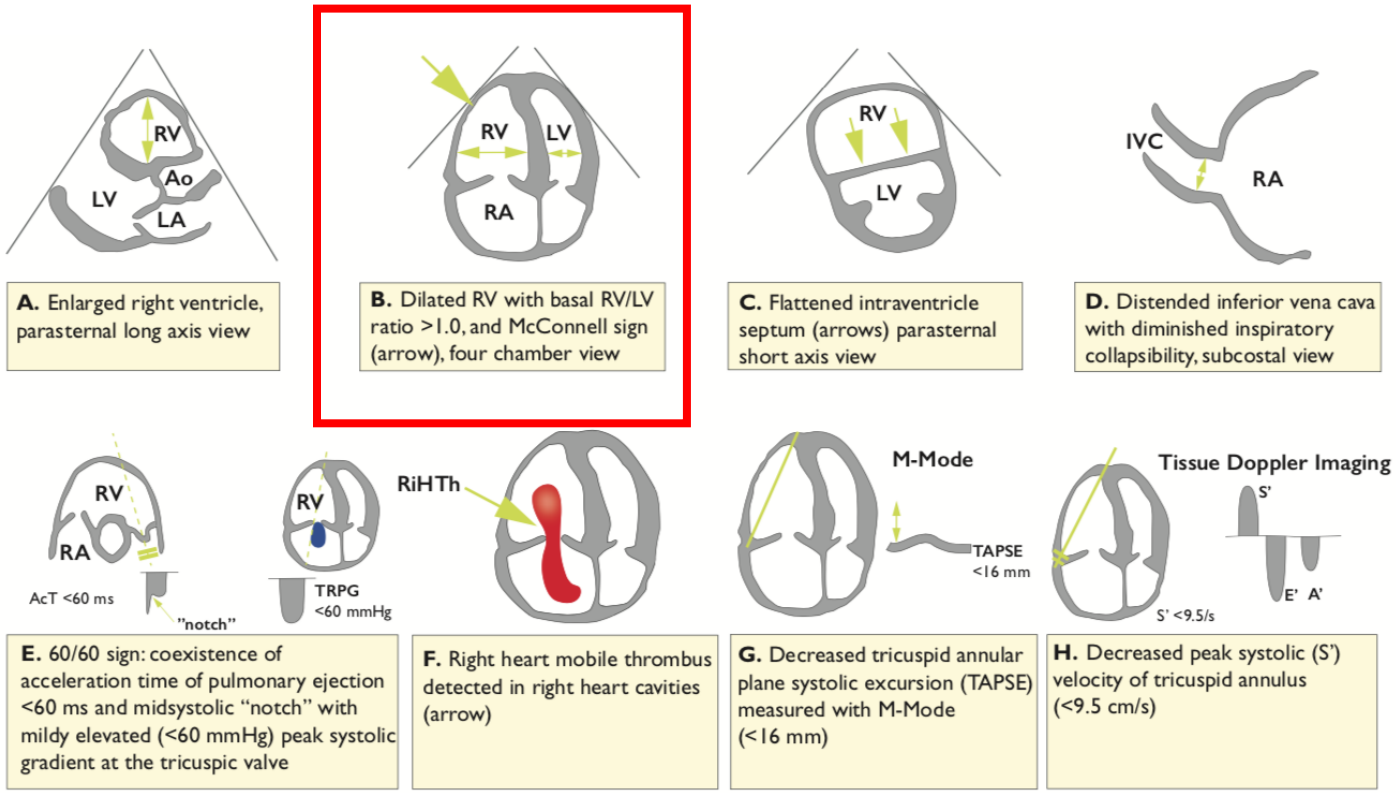
RV dysfunction on TTE or CTPA

Elevated cardiac troponin levels



A. Enlarged right ventricle, parasternal long axis view

B. Dilated RV with basal RV/LV ratio >1.0, and McConnell sign (arrow), four chamber view

C. Flattened intraventricle septum (arrows) parasternal short axis view

D. Distended inferior vena cava with diminished inspiratory collapsibility, subcostal view

E. 60/60 sign: coexistence of acceleration time of pulmonary ejection <60 ms and midsystolic "notch" with mildy elevated (<60 mmHg) peak systolic gradient at the tricuspic valve

F. Right heart mobile thrombus detected in right heart cavities (arrow)

G. Decreased tricuspid annular plane systolic excursion (TAPSE) measured with M-Mode (<16 mm)

H. Decreased peak systolic (S') velocity of tricuspid annulus (<9.5 cm/s)

- Elevation of further laboratory biomarkers
  - NT-proBNP ≥ 600 ng/L
  - H-FABP ≥ 6 ng/mL
  - copeptin ≥ 24 pmol/L

ESC guideline 2019. European Heart Journal (2020) 41, 543-603

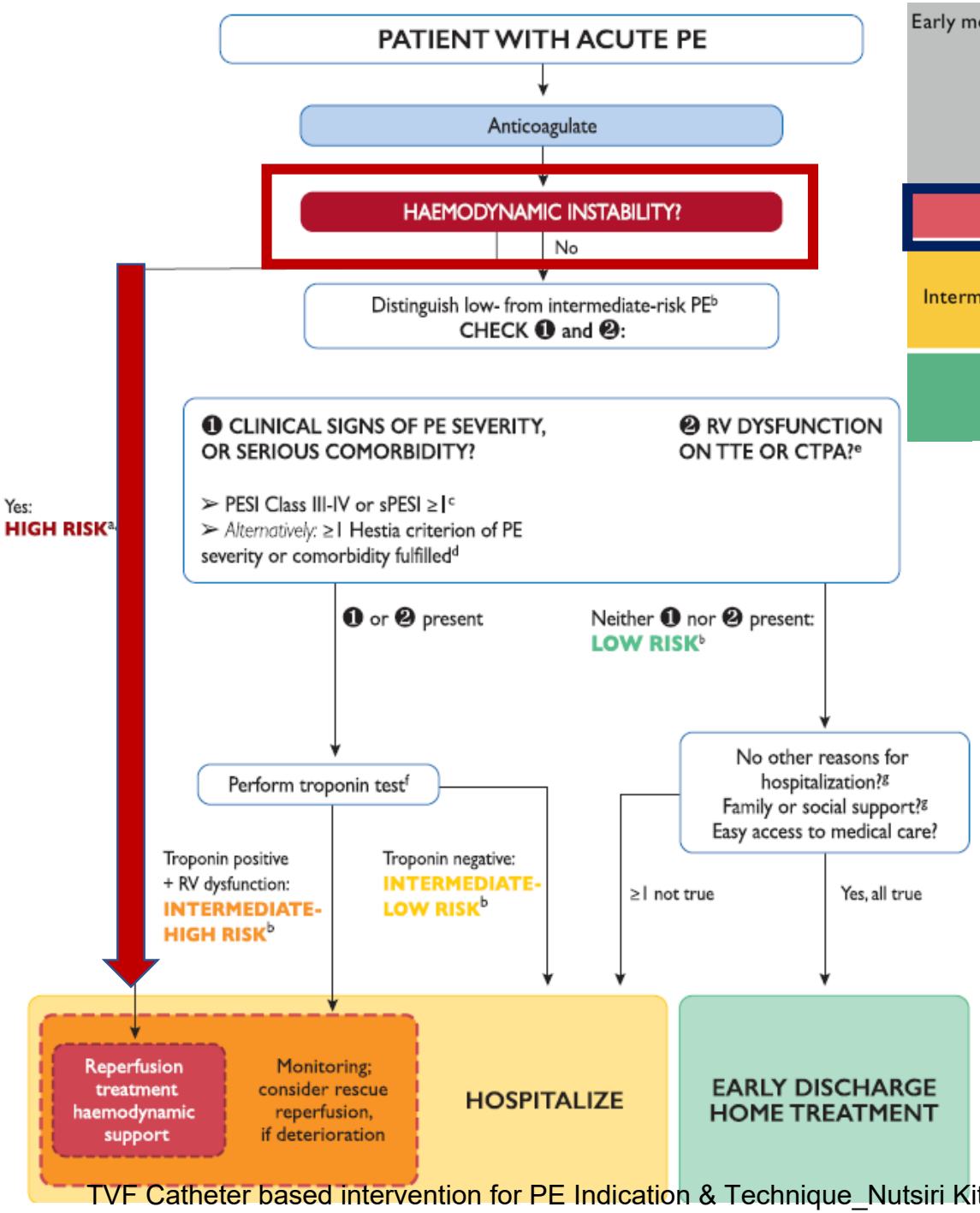


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Table 7 **Original and simplified Pulmonary Embolism Severity Index**

Parameter	Original version[226]	Simplified version[229]
Age	Age in years	1 point (if age >80 years)
Male sex	+10 points	–
Cancer	+30 points	1 point
Chronic heart failure	+10 points	1 point
Chronic pulmonary disease	+10 points	
Pulse rate ≥110 b.p.m.	+20 points	1 point
Systolic BP <100 mmHg	+30 points	1 point
Respiratory rate >30 breaths per min	+20 points	–
Temperature <36°C	+20 points	–
Altered mental status	+60 points	–
Arterial oxyhaemoglobin saturation <90%	+20 points	1 point

Parameter	Original version[226]	Simplified version[229]
	Risk strata[a]	
	Class I: ≤65 points very low 30 day mortality risk (0–1.6%) **Class II: 66–85 points** low mortality risk (1.7–3.5%)	**0 points =** 30 day mortality risk 1.0% (95% CI 0.0–2.1%)
	Class III: 86–105 points moderate mortality risk (3.2–7.1%) **Class IV: 106–125 points** high mortality risk (4.0–11.4%) **Class V: >125 points** very high mortality risk (10.0–24.5%)	**≥1 point(s) =** 30 day mortality risk 10.9% (95% CI 8.5–13.2%)

BP = blood pressure; b.p.m. = beats per minute; CI = confidence interval.
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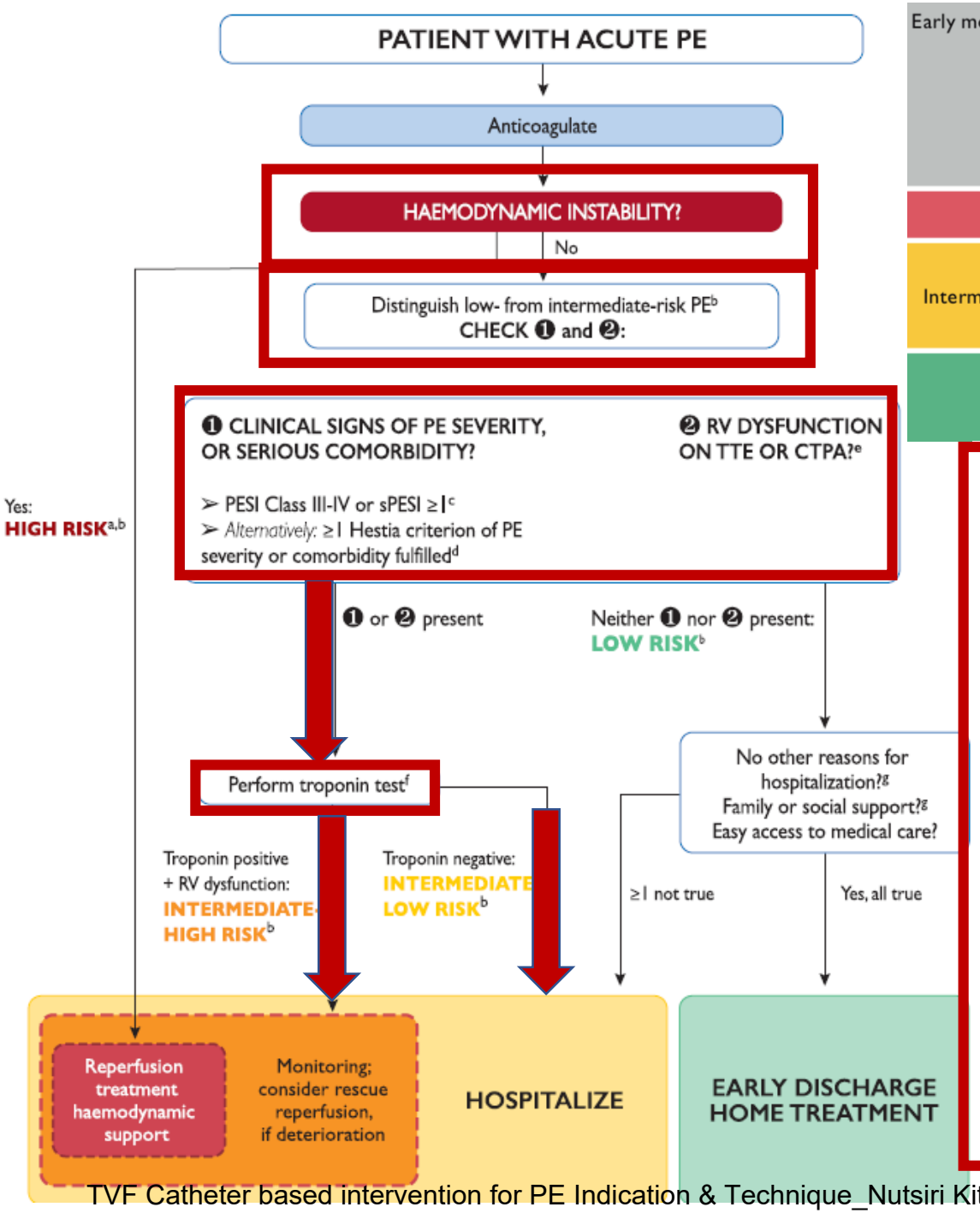

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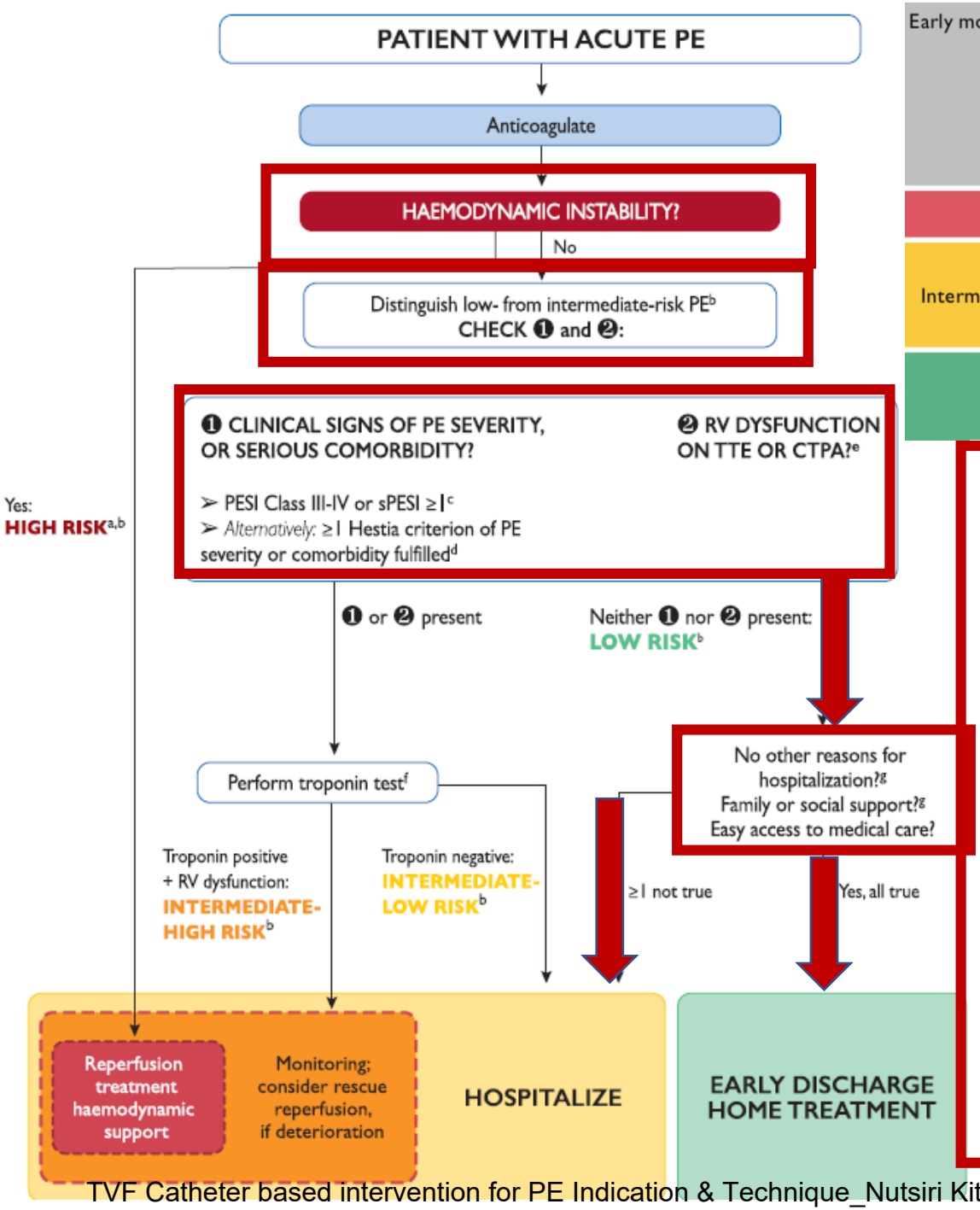

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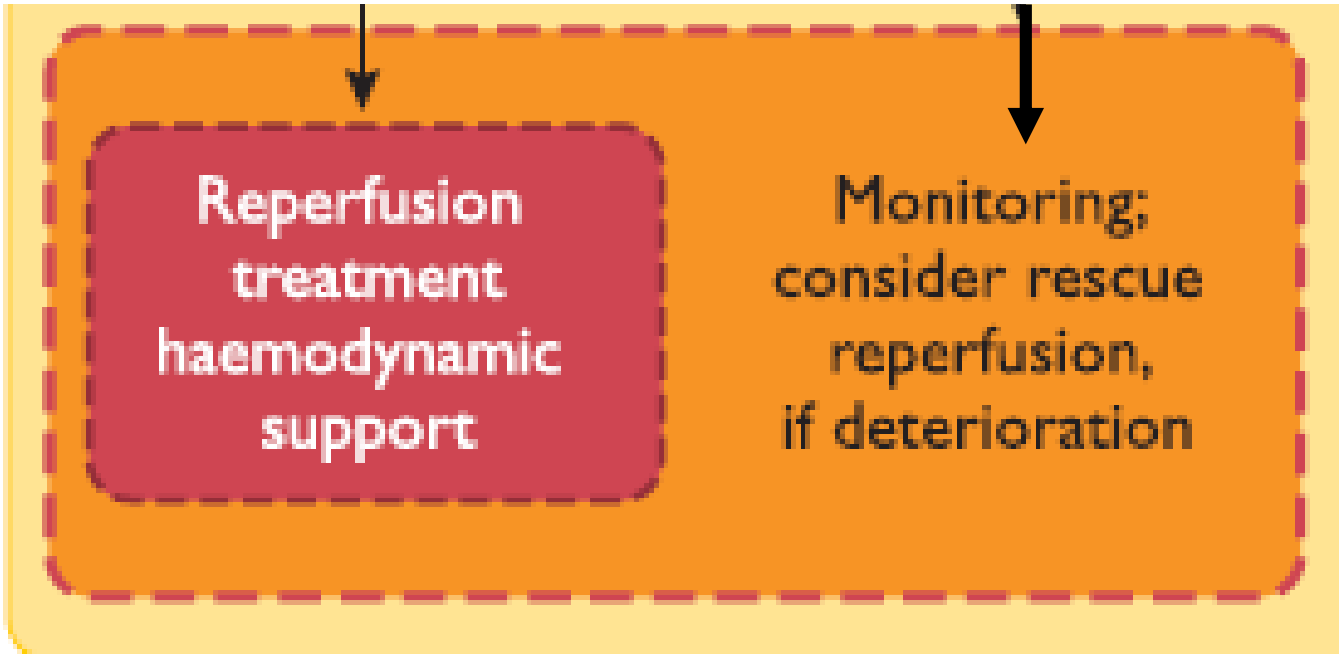
Who need intervention (catheter-based) ?

High risk PE

Intermediate, high risk PE

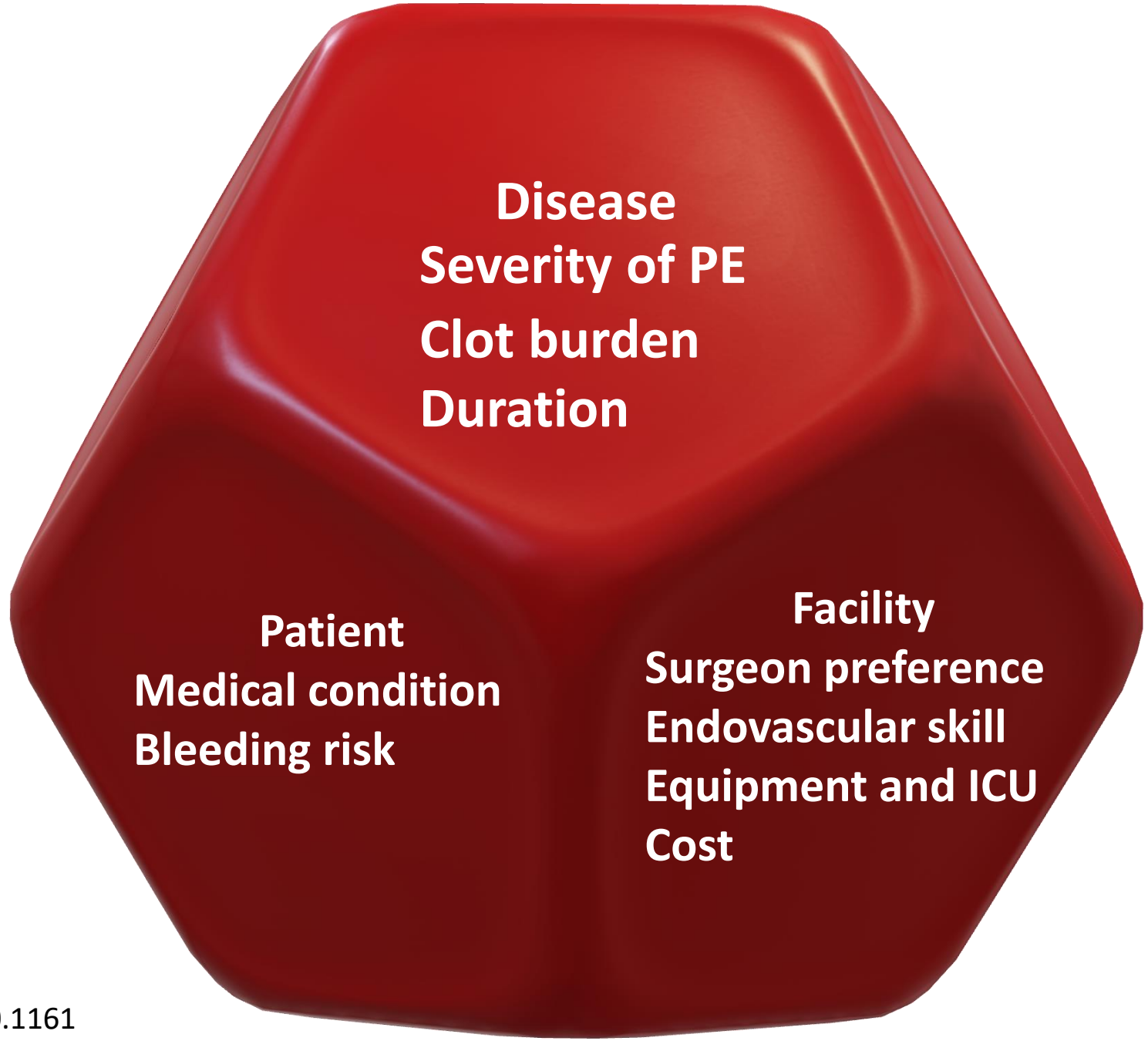


Reperfusion

- Surgical thrombectomy
- Systemic thrombolysis
- Catheter based

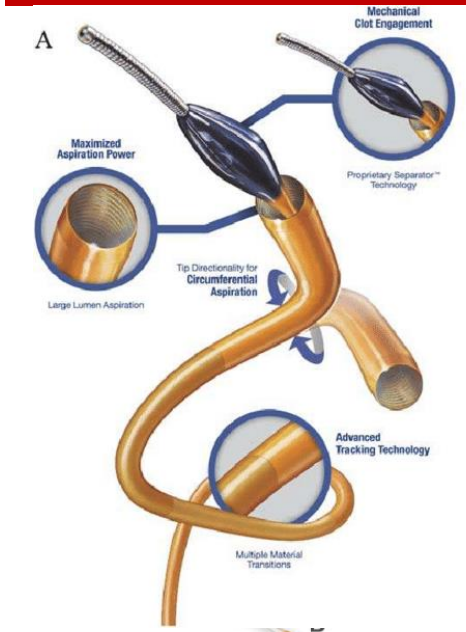
3. Treatment nodality

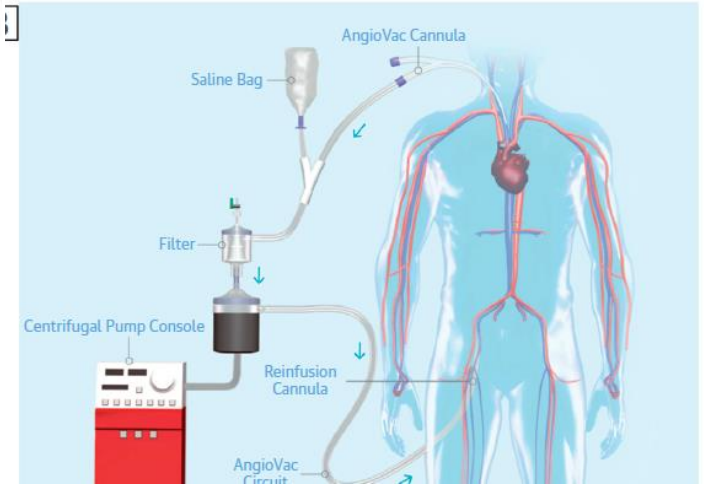
Factors Determine Treatment Options

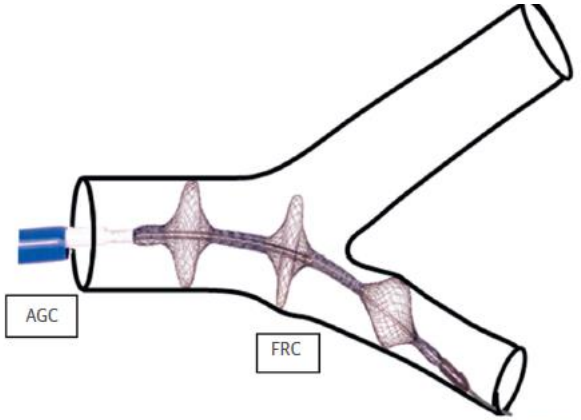


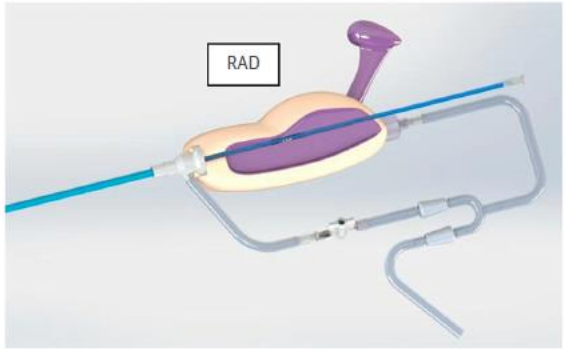
Giri J. Circulation. 2019;140:e774–e801. DOI: 10.1161

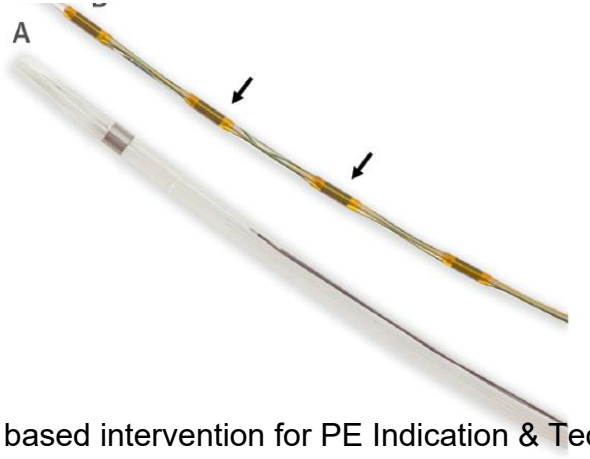
Technique for Percutaneous catheter-directed treatment



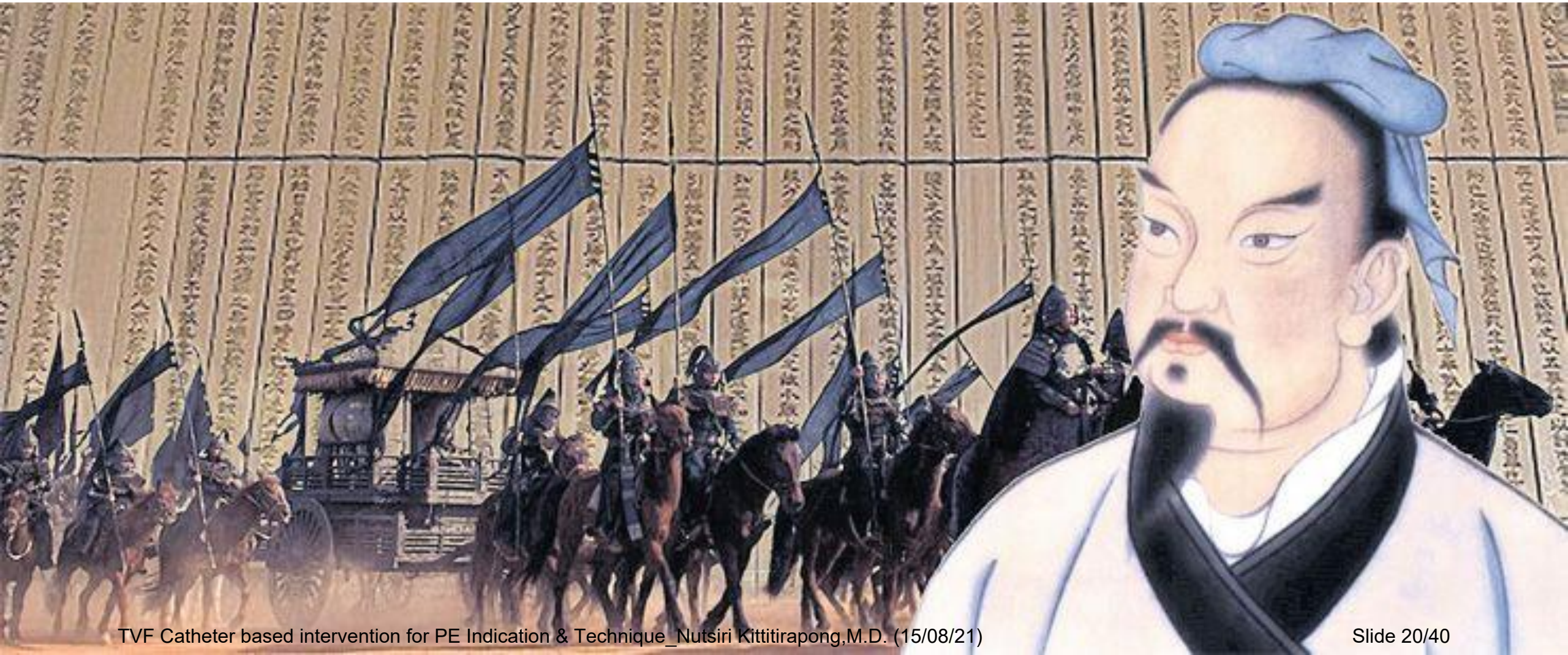








“รู้เขารู้เรา รบร้อยครั้งไม่แพ้ร้อยครั้ง
รู้เราไม่รู้เขา ชนะหนึ่งแพ้หนึ่ง
แต่ถ้าไม่รู้เขาไม่รู้เรา จะแพ้ทุกการรบ”



Known your patients

- Severity of PE
- Hemodynamic status
- Clot burden and duration
- Presence of DVT
- Cause of VTE
- C/I to thrombolysis
- C/I to anticoagulant
- C/I to PA catheterization

Known yourself

- Available facilities
- Available and suitable device including limitation
- Surgeon experience
- Team experience
  - PERT: pulmonary embolism response team
- Available ECMO
- ICU
- Cost

Absolute contraindications to pulmonary artery (PA) catheterization	• Tricuspid or pulmonary valve prosthesis or vegetation, • Recent myocardial infraction • Left bundle branch block
Relative contraindications	• Contrast allergy • History of ventricular irritability

Xi Xue. Tech Vasc Interventional Rad 21:78-84 C 2018

Characteristics of interventional pulmonary embolism devices

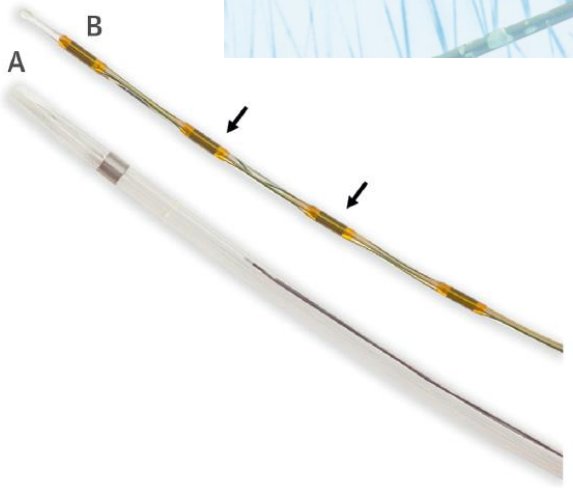
Device	Mechanism	Technical Considerations	Regulatory Status in United States
EKOSonic	USAT	5F catheter	510(k) Clearance for infusion for treatment of PE
Unifuse	CDL	4F–5F catheter	510(k) Clearance for treatment of peripheral vasculature
Cragg-McNamara	CDL	4F–5F catheter	510(k) Clearance for treatment of peripheral vasculature
Bashir Endovascular Catheter	Pharmacomechanical CDL	7F catheter with a nitinol-supported infusion basket that is expanded within the thrombus	510(k) Clearance for use in peripheral vasculature
AngioVac	Veno-veno bypass; funnel-shaped inflow tip to engage thrombi	26F access for inflow, 16F–20F access for outflow; requires perfusion team	510(k) Clearance for removal of undesirable intravascular material
FlowTreiver	Mechanical clot engagement with aspiration with adjunctive nitinol disks engage and mechanically retrieve clot	20F catheter; must manage blood loss associated with large-bore aspiration	510(k) Clearance for treatment of PE
Indigo System	Mechanical clot engagement with mechanized aspiration	8F catheter; large size of some proximal PE renders en bloc aspiration difficult with 8F device	510(k) Clearance for peripheral artery and venous systems
AngioJet	Rheolytic thrombectomy with option of thrombolytic vs saline spray	6F–8F catheters for venous thrombus; can cause hypotension and bradycardia	510(k) Clearance for peripheral thrombectomy; black-box warning against use in PAs
Aspire Max	Suction thrombectomy with specially designed handheld aspirator	5F–6F catheters	510(k) Clearance for removal of fresh, soft thrombi, and emboli from the peripheral and coronary vasculature

CDL indicates catheter-directed thrombolysis; PA, pulmonary artery; PE, pulmonary embolism; and USAT, ultrasound-assisted thrombolysis.

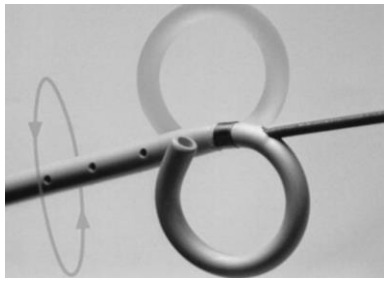
+ PE

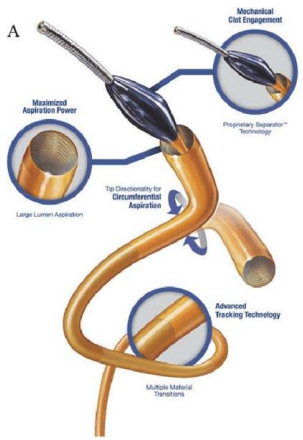
Catheter based treatment for PE

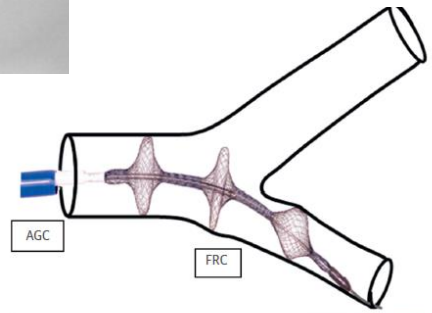
Catheter-directed thrombolysis

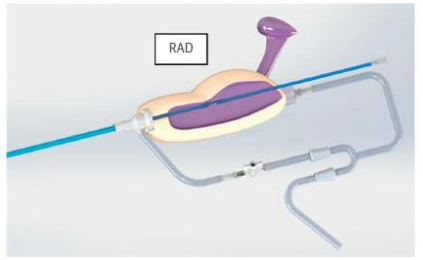


Catheter –based embolectomy









Catheter-based thrombolysis

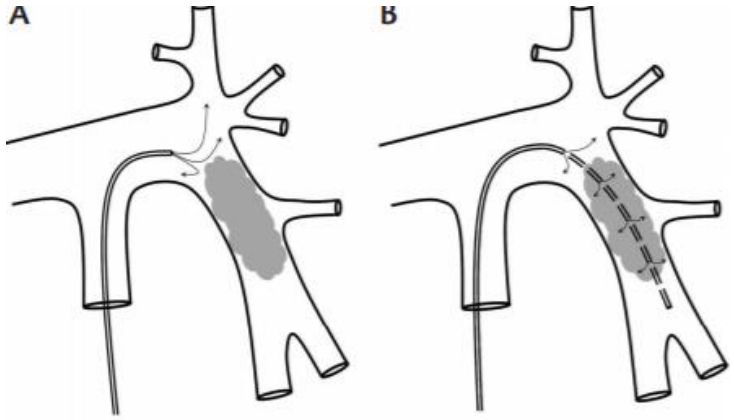
Catheter-based thrombolysis

Catheter-directed thrombolysis (CDL/CDT)	Infusion catheter
Uni-Fuse (AngioDynamics Inc, Latham, NY) catheters	
Cragg-McNamara (ev3 Inc, Plymouth, MN) catheters	
Ultrasound-assisted thrombolysis (USAT) with the EKOSonic endovascular system (EKOS Corp, Bothell, WA)	

Giri J. Circulation. 2019;140:e774–e801. DOI: 10.1161

Catheter-directed thrombolysis (CDL/CDT)

- The goals
  - Decrease the rate of major and intracranial bleeding



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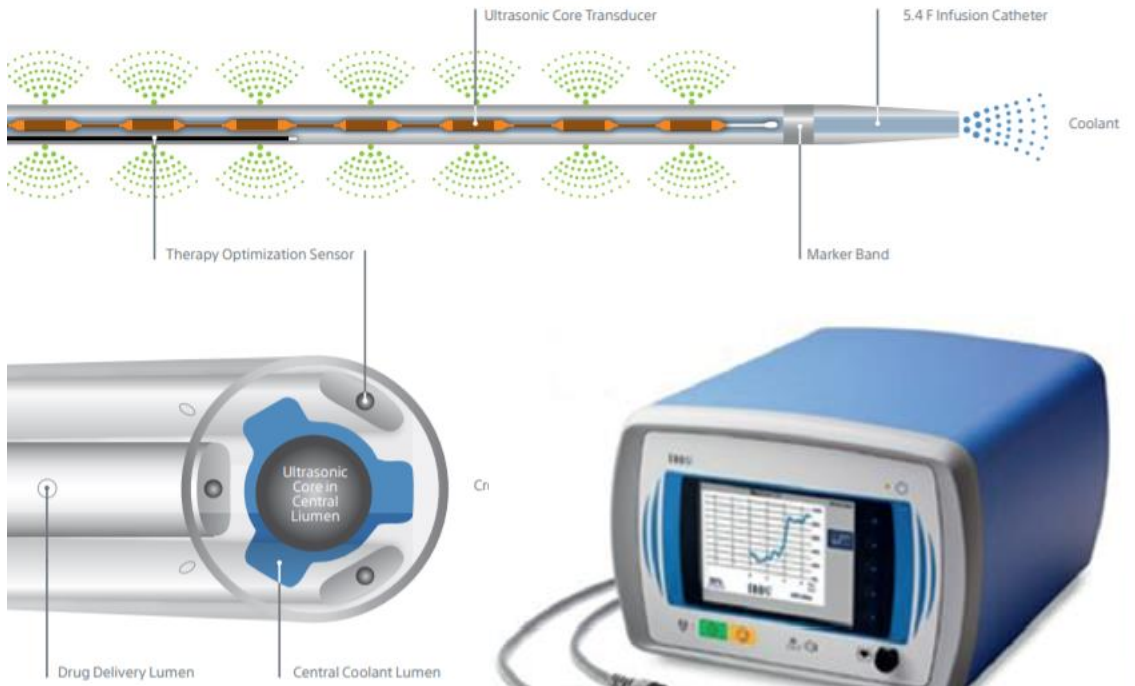
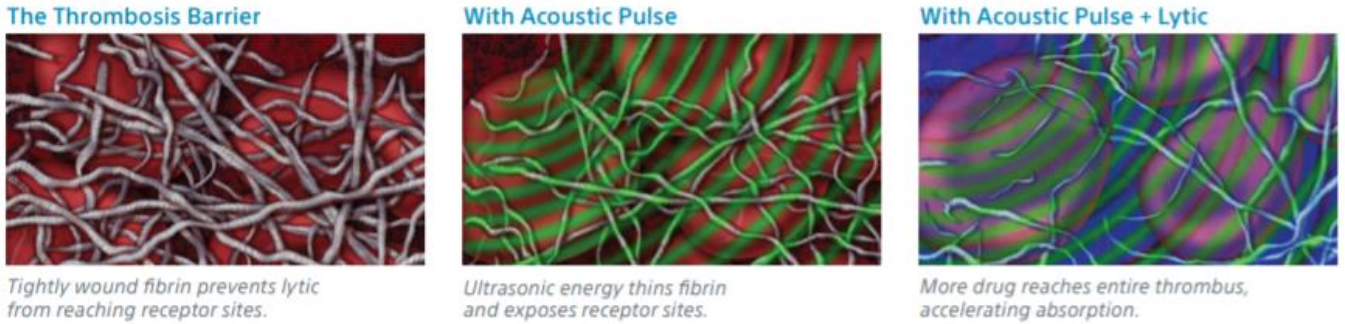
EKOS : EKOSonic endovascular system (EKOS Corp, Bothell, WA)

The EkoSonic™ Endovascular System includes an ultrasonic core within an infusion catheter, and control unit.



The EKOS System's targeted ultrasound waves accelerate thrombus dissolution by unwinding the fibrin matrix.[1]



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Catheter-based thrombolysis

CONCLUSION

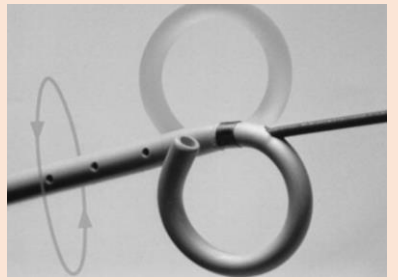
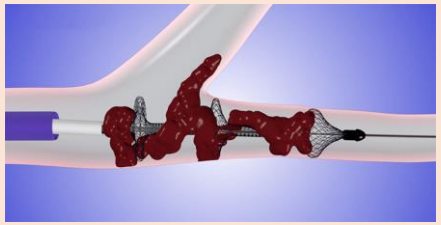
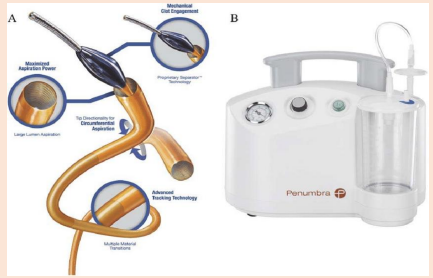
- Hemodynamically unstable PE (high-risk acute PE)
- Intermediate-high risk PE/ Hemodynamic deterioration

- Decrease bleeding risk compared to systemic thrombolysis

But still remain increased bleeding risk

Catheter-based embolectomy

Catheter-based embolectomy

Catheter-Based Thrombus Maceration	Catheter & guidewire	
Large-Bore Embolectomy	The Flow-Triever system (Inari Medical, Irvine, CA)	
Small-Bore Embolectomy	The Indigo Thrombectomy System (Penumbra, Inc, Alameda, CA)	

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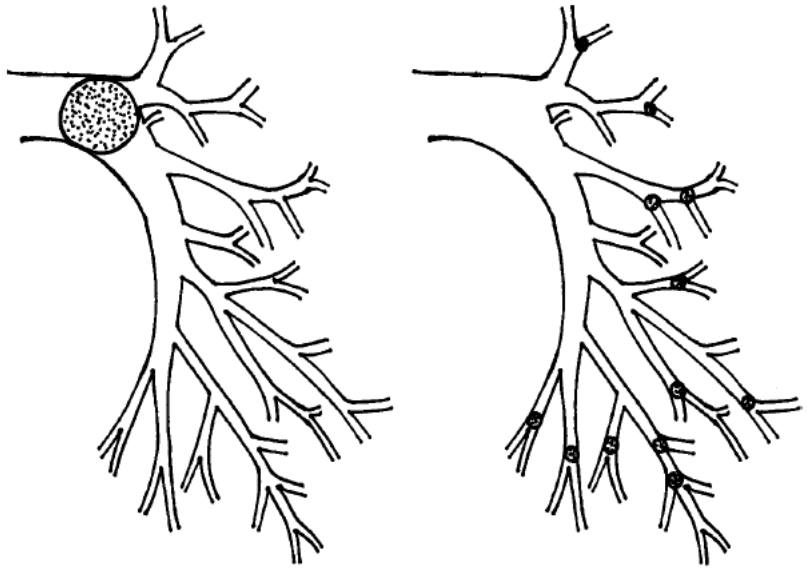
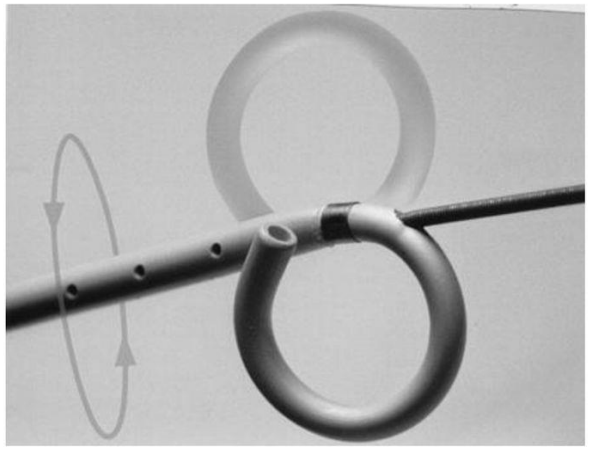
Catheter-Based Thrombus Maceration



Effect of mechanical fragmentation of a
total occlusive central thrombus in the pulmonary artery

- Reduce pulmonary artery pressure
- Increase total pulmonary perfusion

The fragmentation approach:
Pigtail Rotational Catheter



case reports and series

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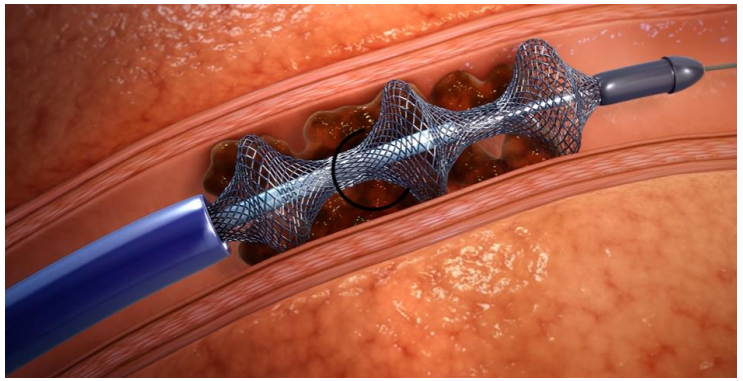
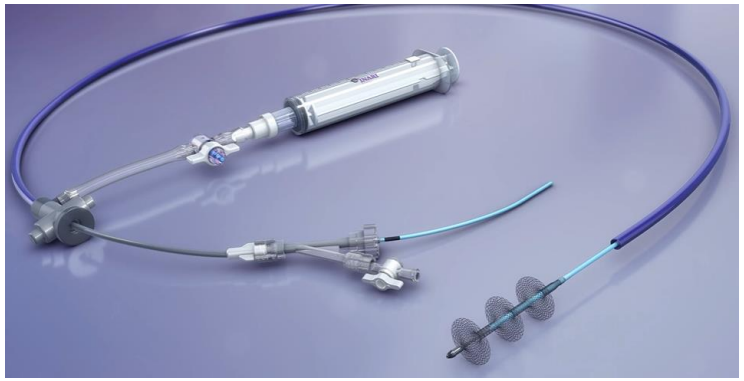
Large-Bore Embolectomy
The Flow-Triever system (Inari Medical, Irvine, CA)

20 F device with three self-expanding nitinol discs entrapping the thrombus with simultaneous aspiration





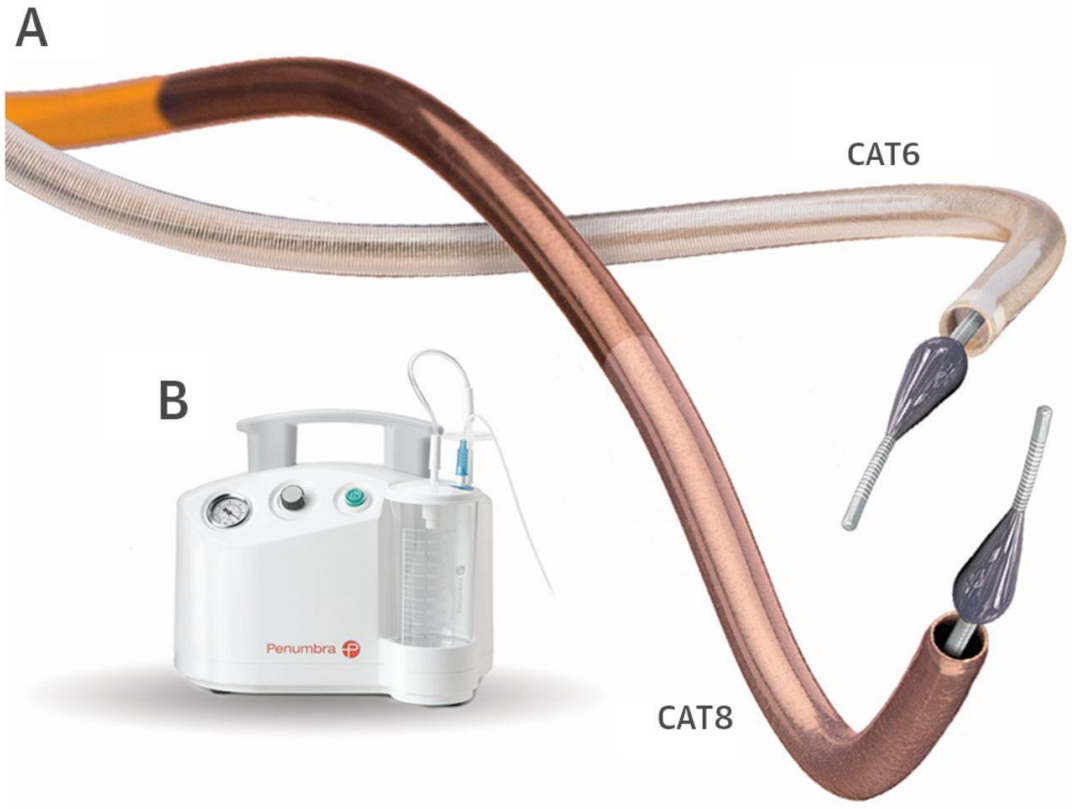
The FlowTriever is an over-the-wire system designed to:

- Capture and Remove large clot burden from big vessels
- Eliminate the need for thrombolytics
- Remove clot through both mechanical and aspiration mechanisms of action
- Treat in a single session
- Eliminate ICU Stay

Giri J. Circulation. 2019;140:e774–e801. DOI: 10.1161

Small-Bore Embolectomy

The Indigo Thrombectomy System (Penumbra, Inc, Alameda, CA)

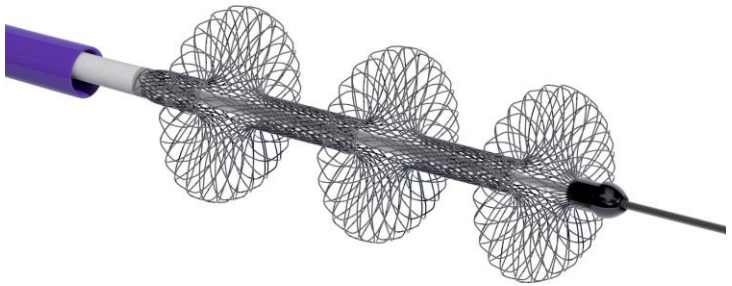


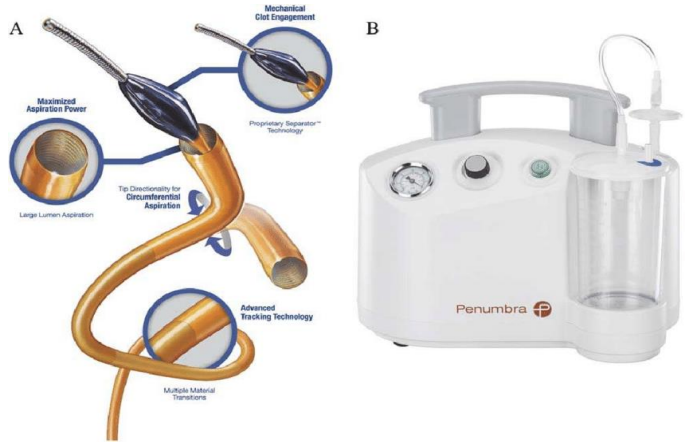
8 F vacuum assisted aspiration with mechanical clot engagement

Giri J. Circulation. 2019;140:e774–e801. DOI: 10.1161

The devices have been cleared by FDA for use in acute PE

- The EKOSonic endovascular system (SEATTLE II, 2014)
- The FlowTriever embolectomy device (FLARE, 2018)
- The Indigo Thrombectomy System (EXTRACT-PE, 2020)



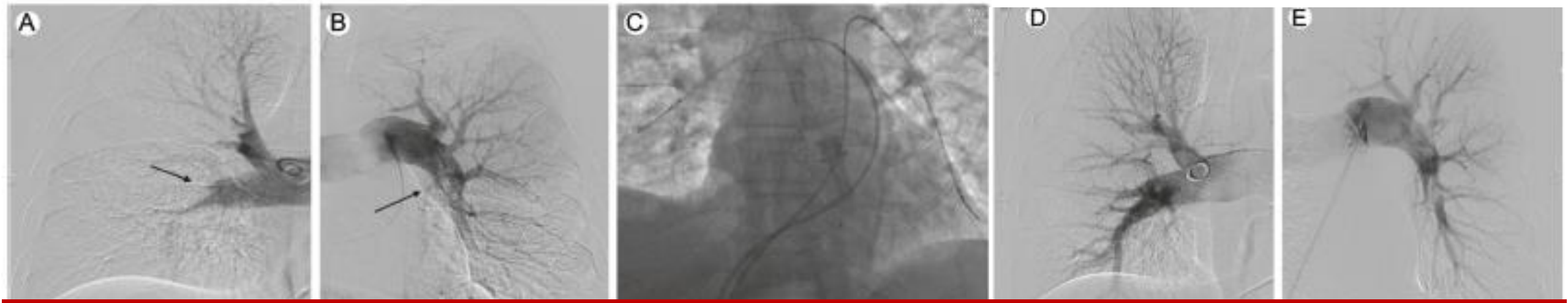


Giri J. Circulation. 2019;140:e774–e801. DOI: 10.1161

Comparison trials

	Extract PE (N 119), 2019	SEATTLE II[1] (N 150), 2015	FLARE[2] (N 106), 2019	PEITHO[3] Tenecteplase arm (N 506), 2014
Device, study design	Penumbra (single arm)	EKOS (single arm)	Flow Triever (single arm)	Systemic thrombolysis VS Anticoagulant (RCT)
PE risk	Intermediate risk	Intermediate+ high risk	Intermediate risk	Intermediate risk
Primary efficacy (Change in RV/LV ratio at 48 hr)	0.43; p<0.0001	0.42; p<0.0001	0.38; p<0.0001	N/A
Primary safety	Major Adverse Events within 48 hrs 1.7%	Major bleeding within 72 hrs 10%	Major Adverse Events within 48 hrs 3.8%	Death or hemodynamic decompensation within 7 d 2.6%
Major bleeding	Within 48 hrs, 1.7%	Within 72 hrs, 10%	Within 48 hrs, 1.0%	Within 7 d, 11.5%
All cause mortality (30 d)	2.5%	2.7%	1.0%	2.4%
Device time	37 min	12-24 hrs	57 min	NA

1. Piazza et al. JACC Cardiovasc Interv,2015. 8(10): 1382-922;2
2. Tu et al. JACC Cardiovasc Interv, 2019 May 13;12(9):859-869
3. Meyer et al. N Engl J Med. 2014 Apr 10;370(15):1402-11

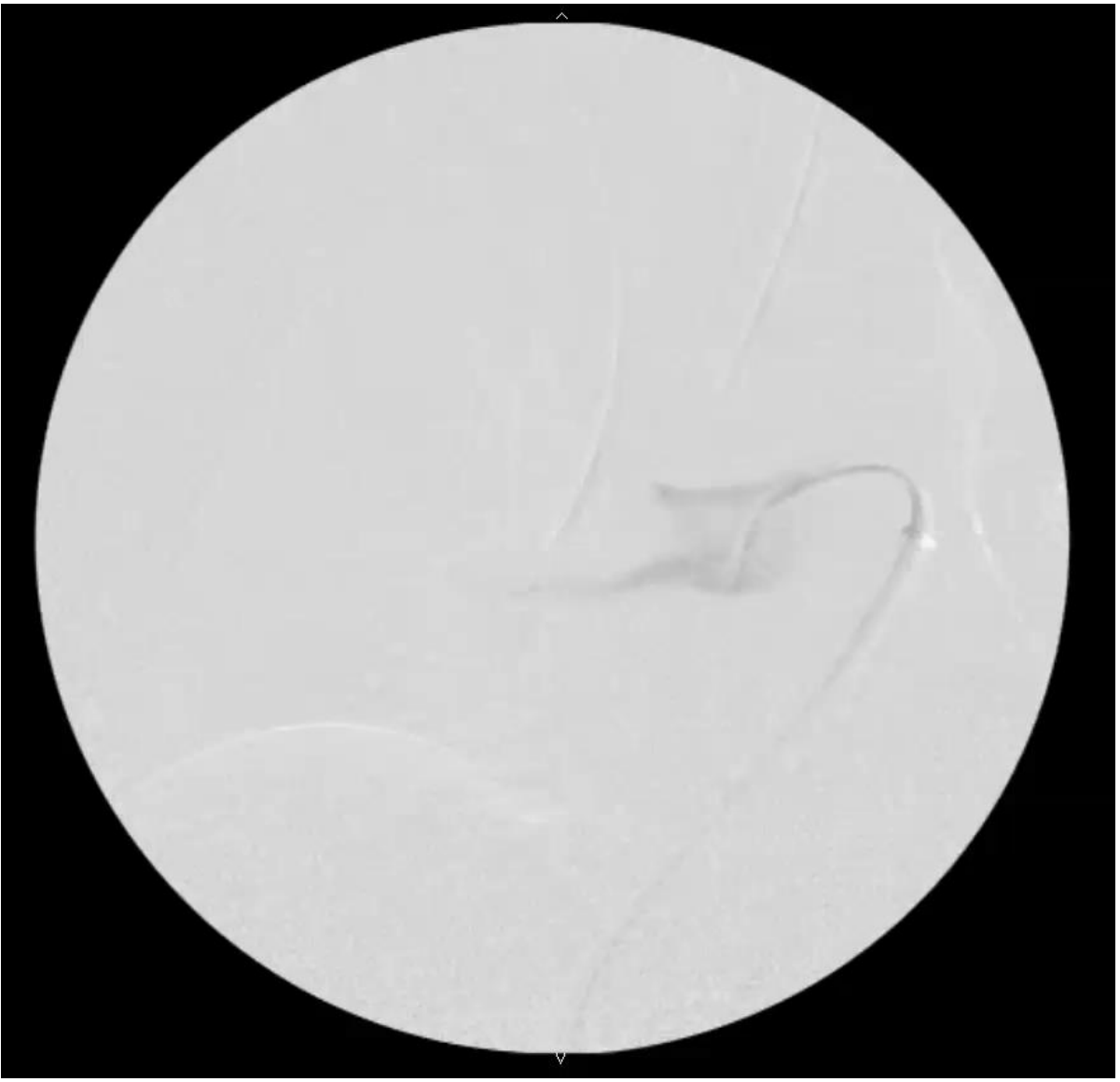


Technique

Procedural tips

"Clinical improvement doesn't correlate to angiographic result"

Pre



Post

Indigo system SEP 8

Conclusion

Understanding of pathophysiology of PE is the key to success.

Catheter-based intervention should be considered in pts with high risk or intermediate-high risk PE who are at risk for thrombolysis.

Determining the factors for the optimal treatment; patient, disease and utility, is important.

Thai Venous Forum

Catheter based intervention for PE Indication & Technique

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15th August 2021