



VASCUPEDIA



# Catheter Interventions for pulmonary embolism: From Directed tPA Drips to Suction Thrombectomy

**Efthymios Avgerinos, MD**

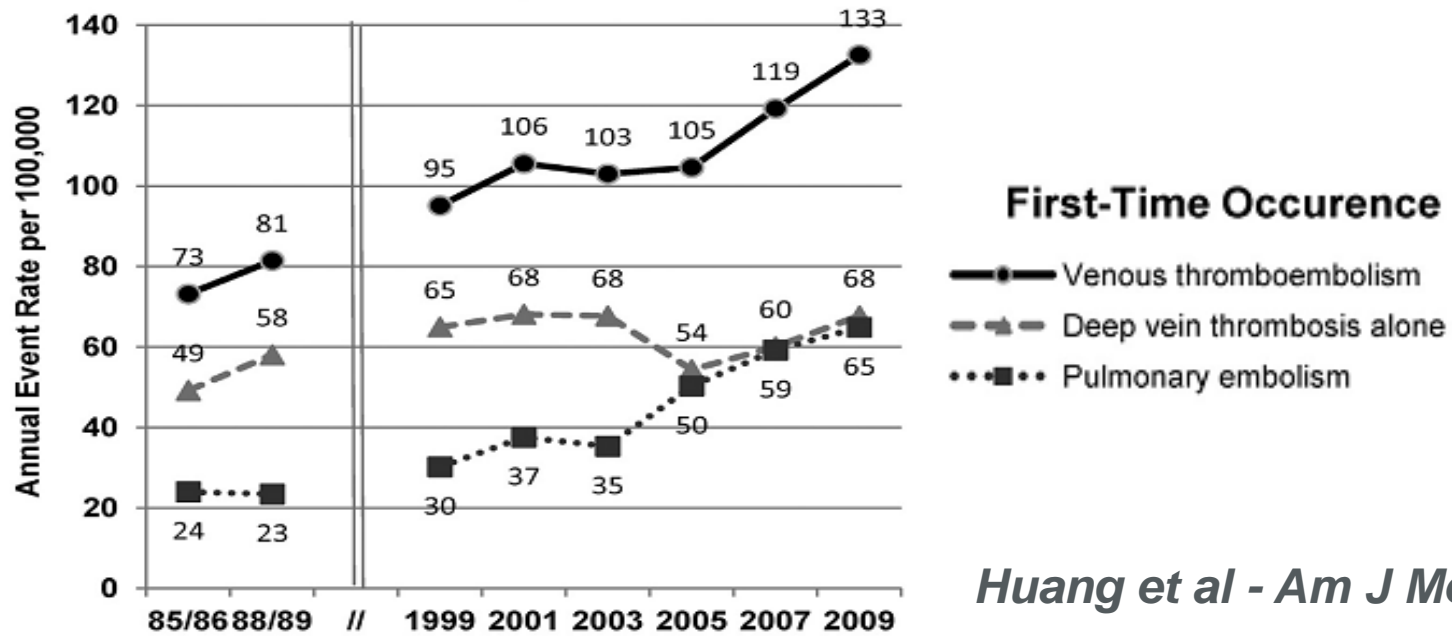
Associate Professor of Surgery

Division of Vascular Surgery

University of Pittsburgh Medical Center

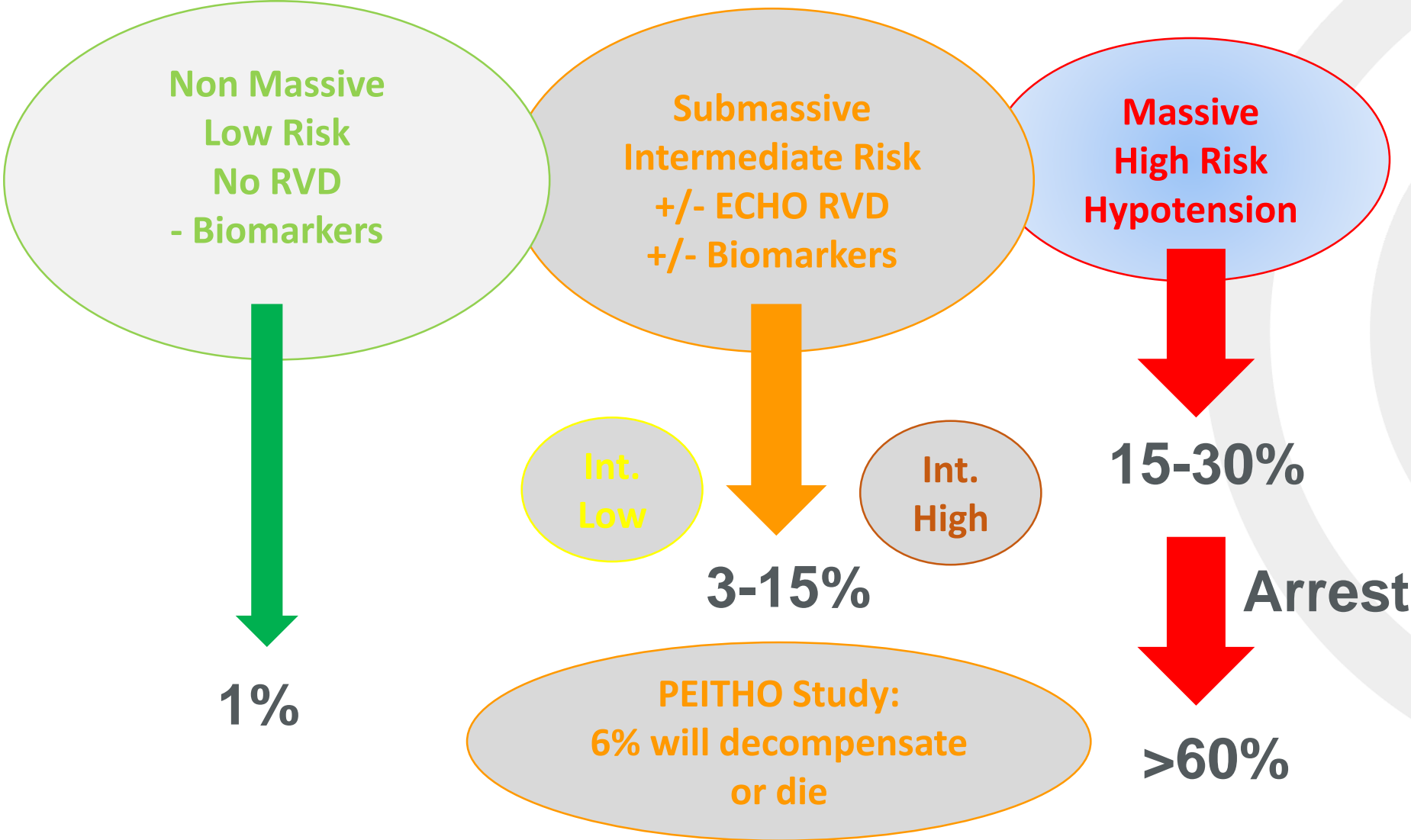
**UPMC** LIFE  
CHANGING  
MEDICINE

# PE - Increasing Incidence

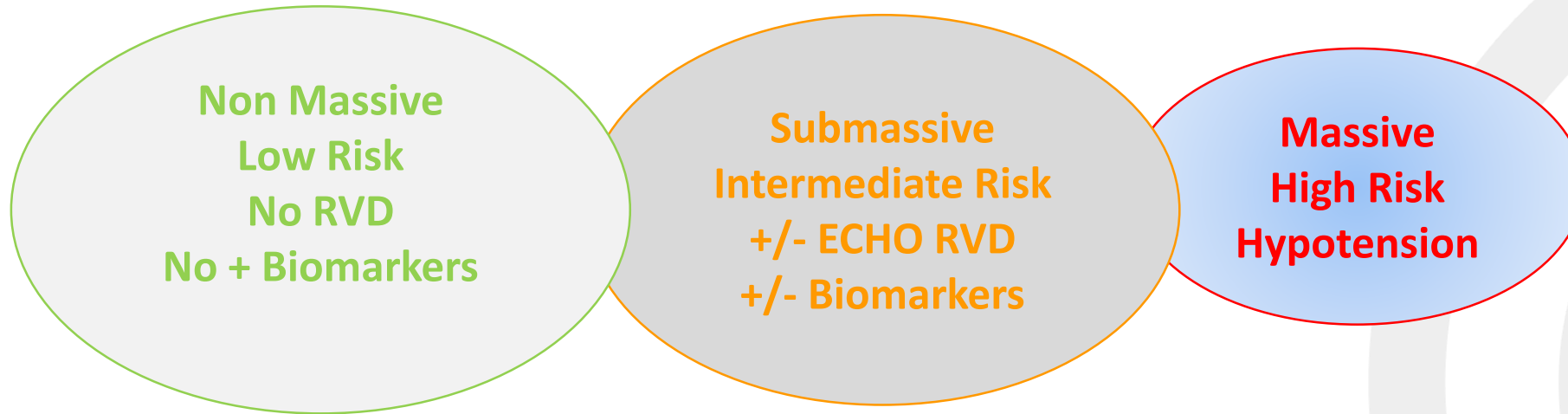


- Most common preventable cause of in-hospital death
- 50% have exercise limitation at 1 year
- 4% will develop Pulmonary Hypertension at 2-3 years

# PE Clinical Presentation & Risk of Death



# PE Clinical Presentation & Risk of Death



**Anticoagulation**

**Systemic Thrombolysis**

# Systemic vs Catheter Thrombolysis

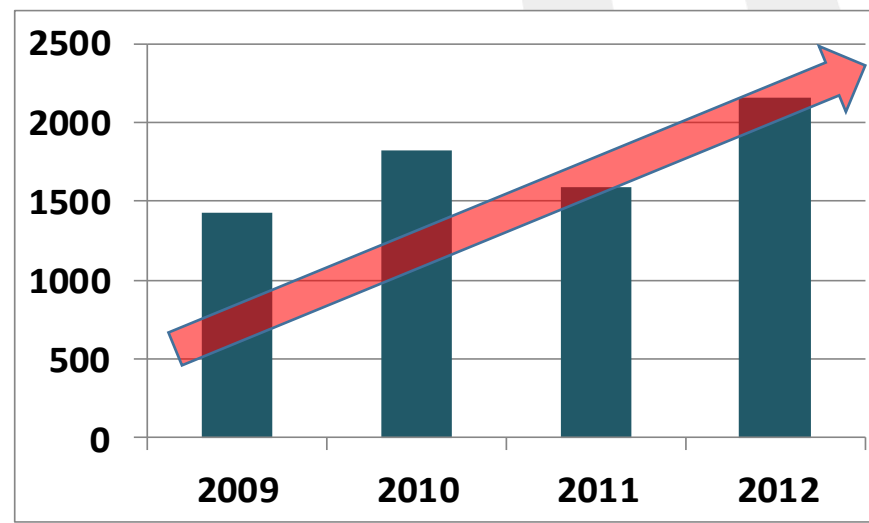
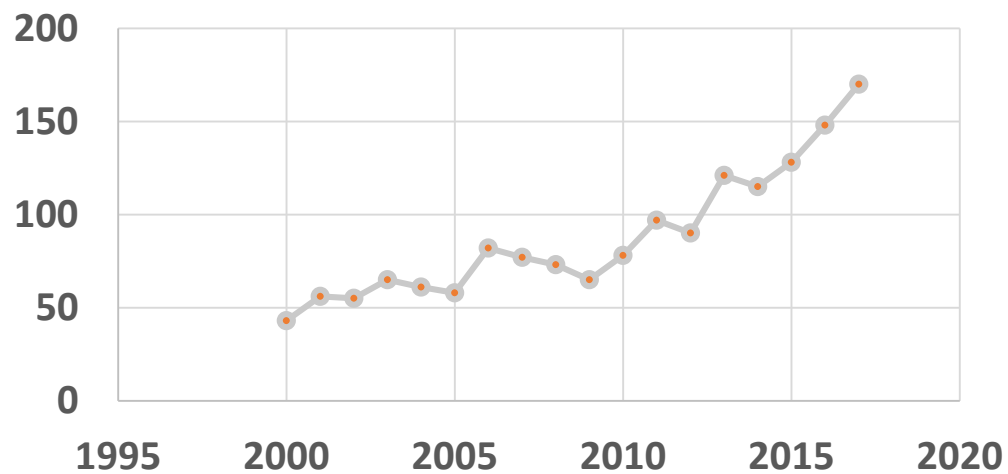
*“Systemic thrombolysis vs. AC is associated with a 47% mortality risk reduction ... but also high major bleeding rates (9.2% - 1.5% Stroke)”*

*Chatterjee et al JAMA 2014*

*“In intermediate risk PE us-assisted catheter directed thrombolysis is superior to heparin alone in reversing RV dilatation at 24 hours, without an increase in bleeding events”*

*Kucher et al Circulation 2014*

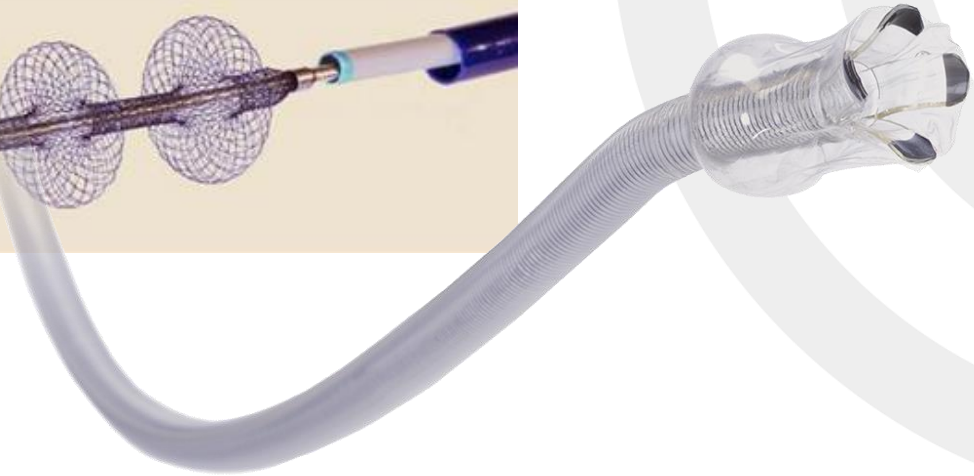
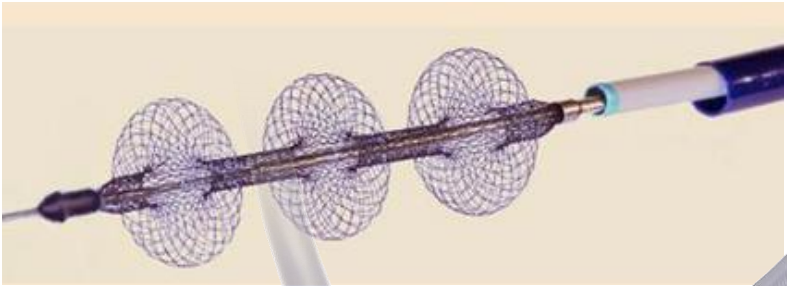
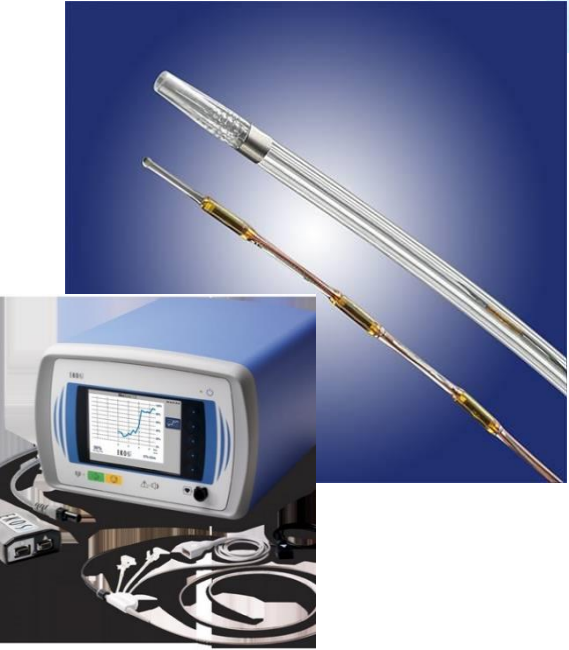
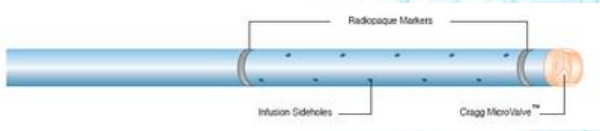
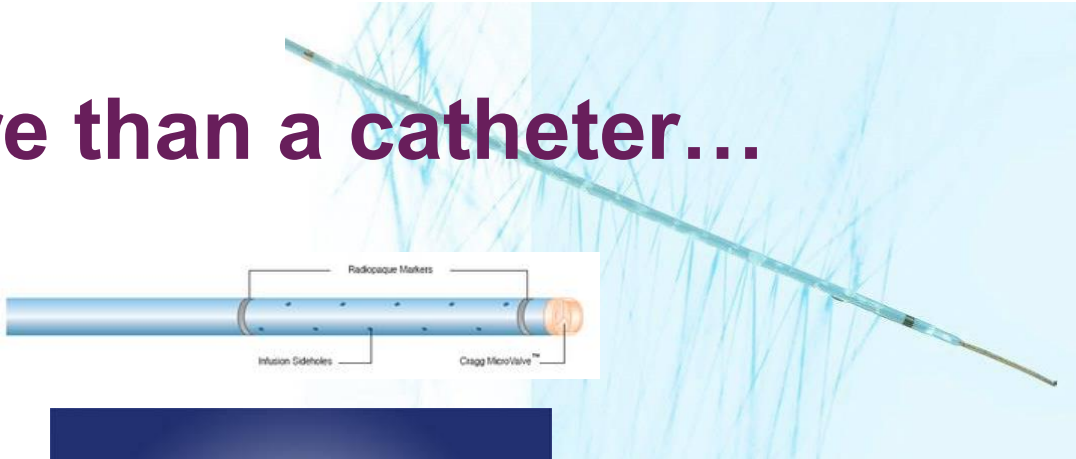
Pubmed Search Citations  
"Pulmonary Embolism AND Catheter"



*US National Inpatient Sample*

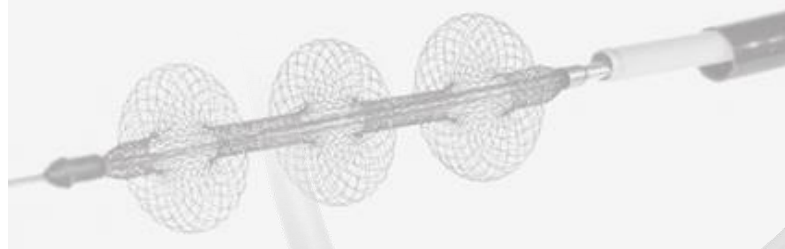
# Catheter Interventions for PE

It is more than a catheter...



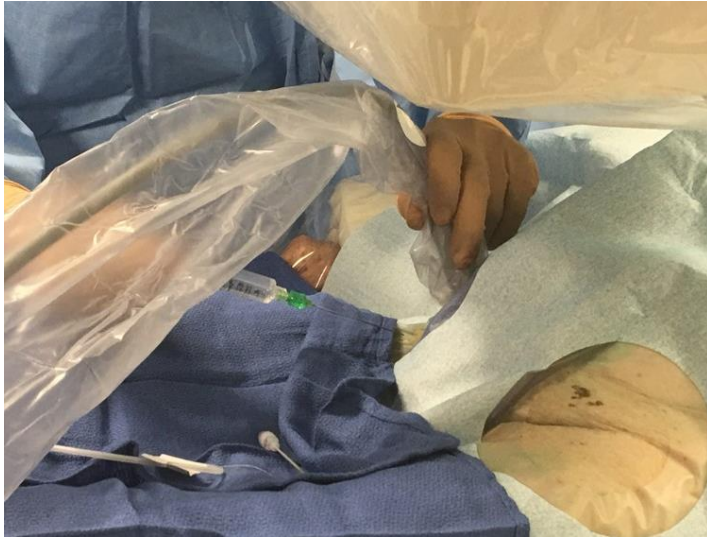
# Catheter Interventions for PE

- Standard Catheter Thrombolysis
- Ultrasound Assisted Thrombolysis
- Percutaneous clot extraction





# Catheter Interventions for PE

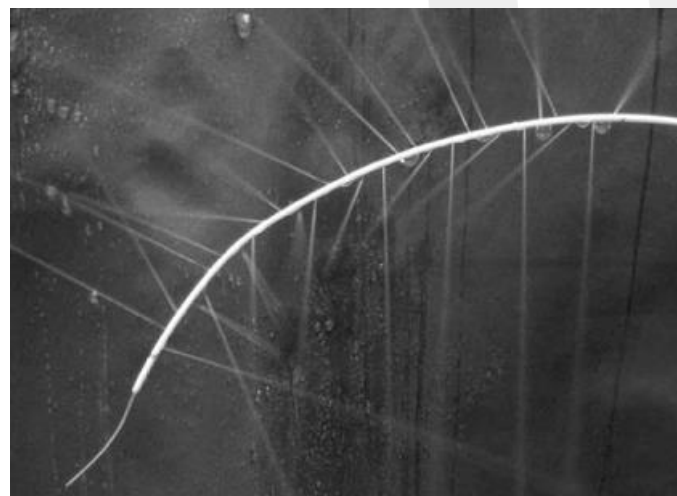
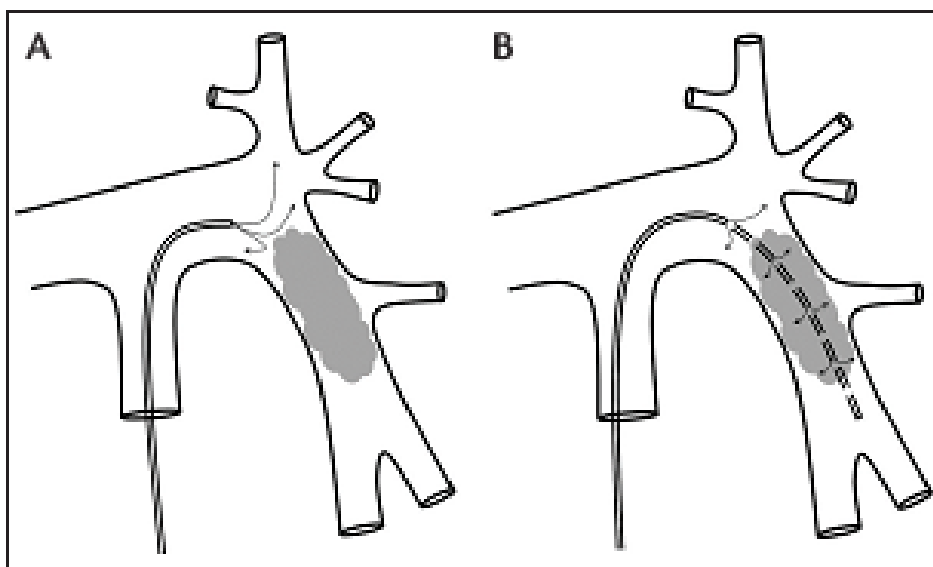




# Interventions for PE – Thrombolysis

## Standard Catheter Thrombolysis

- Multisidehole catheter introduced within the clot
- 12-24 hour tpa infusion 0.5-2mg/hour
- tPA penetrates & “softens” clot particles



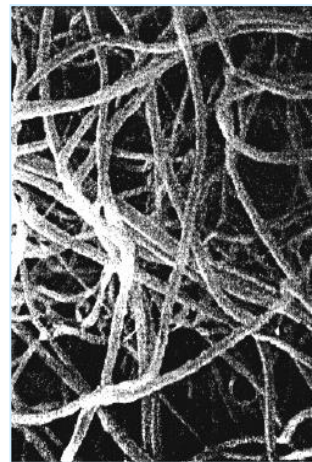
# Interventions for PE – Thrombolysis

## Ultrasound Assisted Thrombolysis (EKOS)

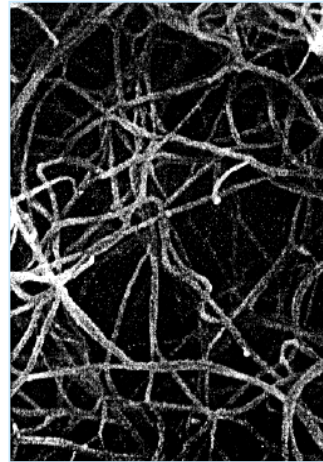
- Technically similar to catheter directed dripping

Fibrin Separation

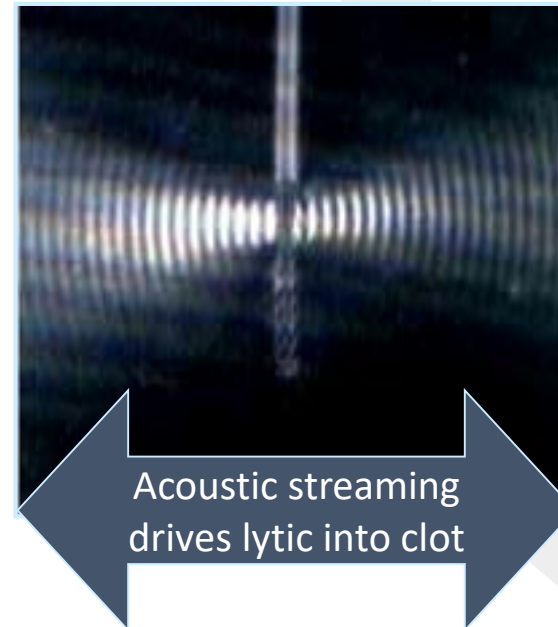
Active Drug Delivery



Fibrin without  
Ultrasound



Fibrin With  
Ultrasound



Acoustic streaming  
drives lytic into clot

**Acoustic Pulse Lysis can in-Vitro increase thrombus clearance by 50%**

# Interventions for PE – Thrombolysis

## Ultrasound Assisted Thrombolysis (EKOS)

- Technically similar to standard catheter dripping
- Ultrasound may reduce dripping time & tPA dose (?)
- Most literature supporting it – FDA approved
  - **ULTIMA RCT**
  - **SEATTLE II Registry**
  - **Multiple small series**
  - **OPTALYSE PE**
- No evidence of superiority over standard catheters

# Interventions for PE – Thrombolysis

## Ultrasound Assisted Thrombolysis (EKOS)

- Technically similar to standard catheter dripping
- Ultrasound may reduce dripping time & tPA dose (?)
- Most literature supporting it – FDA approved

Design and rationale of a randomized trial comparing standard versus ultrasound-assisted thrombolysis for submassive pulmonary embolism

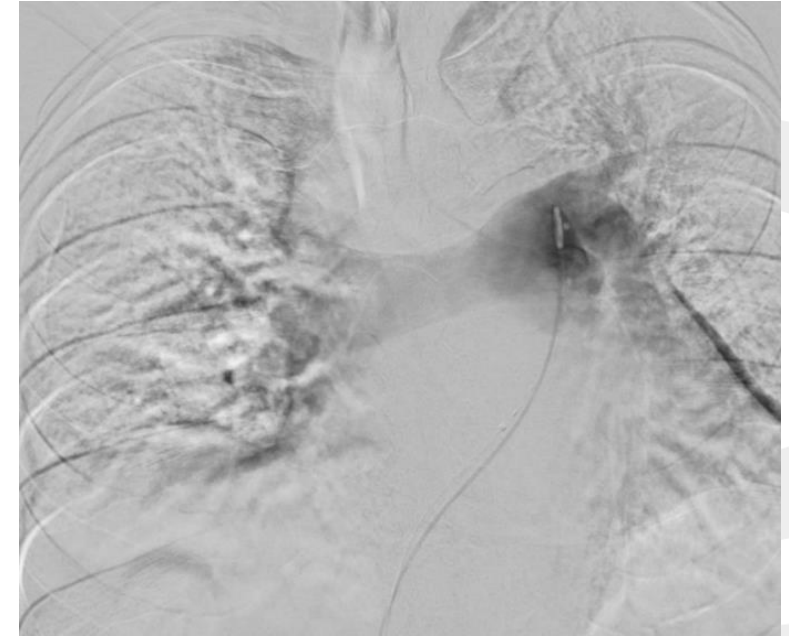
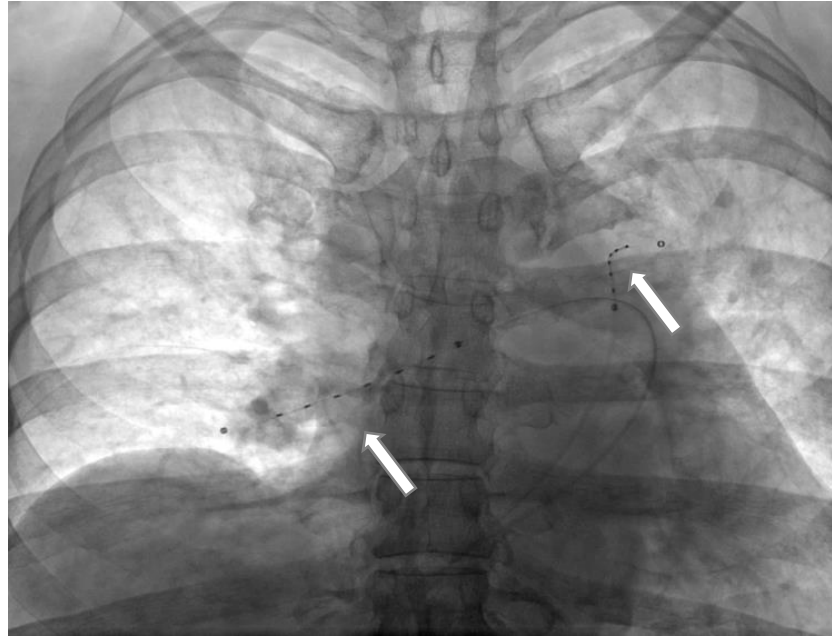


Efthymios D. Avgerinos, MD,<sup>a</sup> Abhisekh Mohapatra, MD,<sup>a</sup> Belinda Rivera-Lebron, MD,<sup>b</sup> Catalin Toma, MD,<sup>c</sup> Christopher Kabrhel, MD,<sup>d</sup> Larry Fish, PhD,<sup>a</sup> Joan Lacomis, MD,<sup>e</sup> Iclal Ocak, MD,<sup>e</sup> and Rabih A. Chaer, MD, MSc,<sup>a</sup> in collaboration with the PERT Consortium, *Pittsburgh, Pa; and Boston, Mass*

J Vasc Surg: Venous and Lym Dis 2018;6:126-32.

# Interventions for PE – Thrombolysis

## Ultrasound Assisted Thrombolysis (EKOS)



**Recommended Treatment Time: 2, 4, 6, 12 Hours**

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# Interventions for PE - Clot Extraction

## Thrombectomy Devices (no need for lytics)

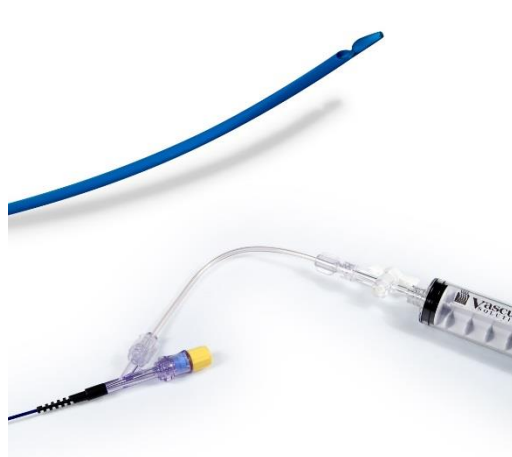
- **Small bore Aspiration Catheters/Systems**
- **Large bore Aspiration Catheters/Systems**



# Interventions for PE - Clot Extraction

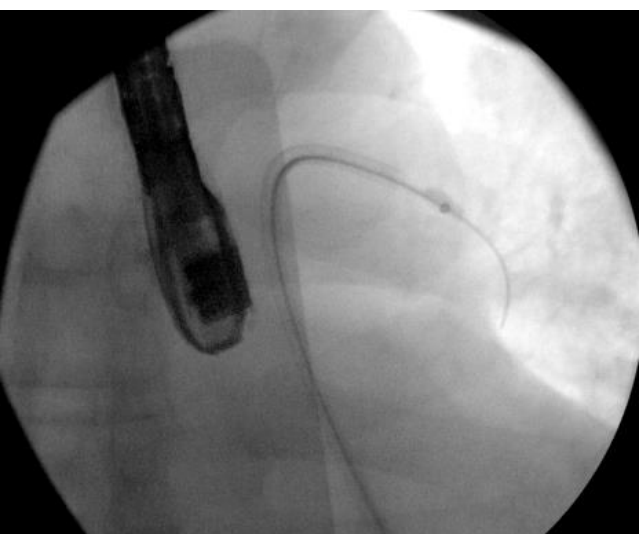
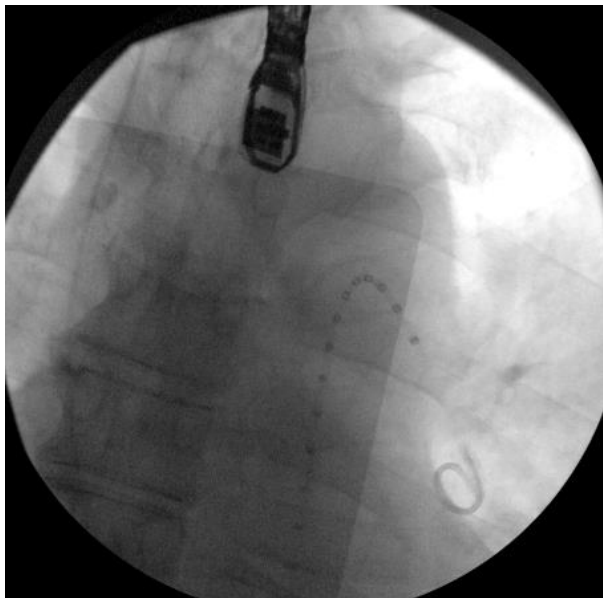
## Thrombectomy Devices

- **Small bore Aspiration Catheters/Systems**
  - Any catheter
  - Pronto Catheter (Vascular Solutions)
  - Aspire (Control Medical Technology)



# Manual Fragmentation and Aspiration

Pronto Catheter



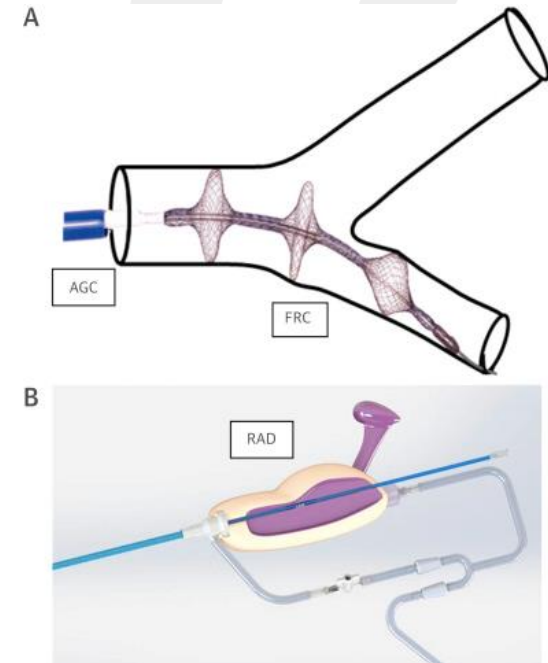
Courtesy: E. Avgerinos  
Univ. of Pittsburgh

# Interventions for PE – Suction Thrombectomy

## Thrombectomy Devices

- Large bore Aspiration Catheters  
(Rapid debulking of proximal thrombus)

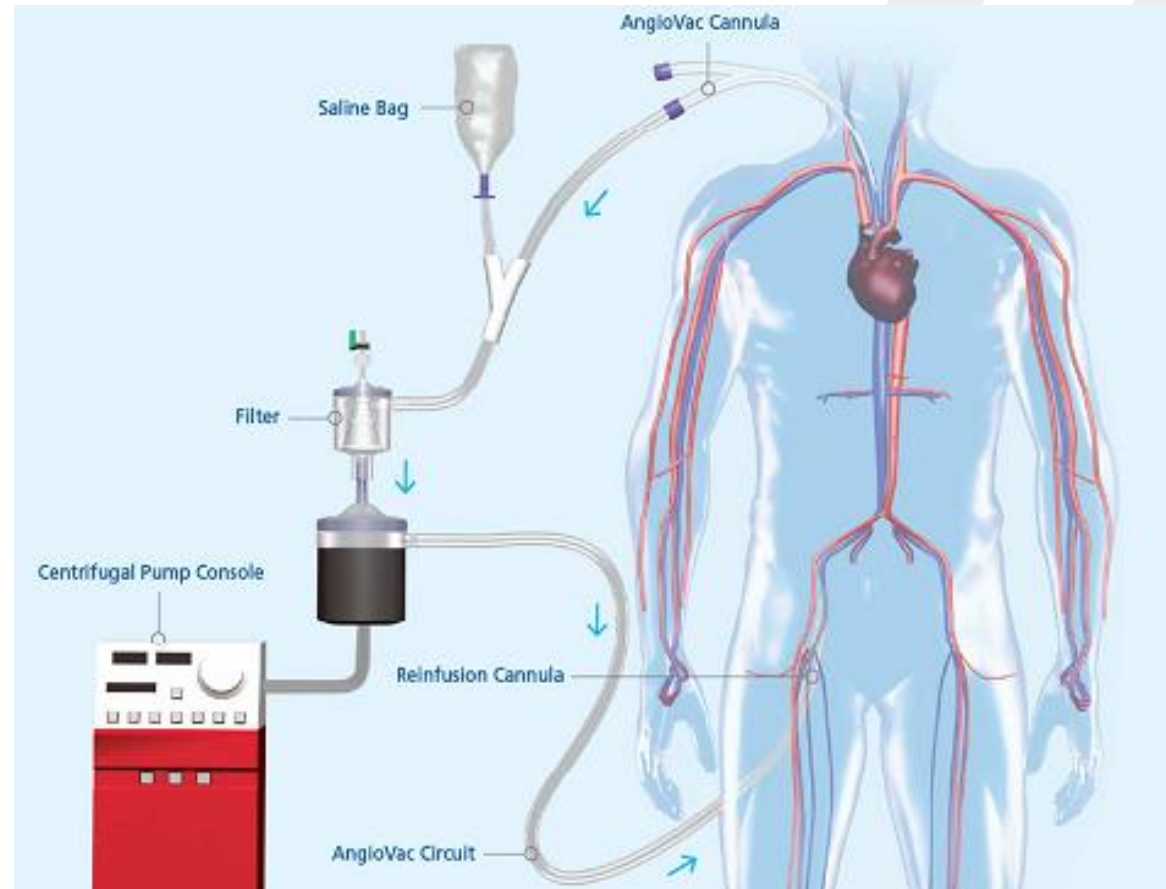
- ~~Trerotola (Teleflex)~~
- ~~Angiojet (Boston Scientific)~~
- ~~Angiovac (Angiodynamics)~~
- Indigo (Penumbra Inc)
- Flowtriever (Inari medical)



# Interventions for PE – Suction Thrombectomy

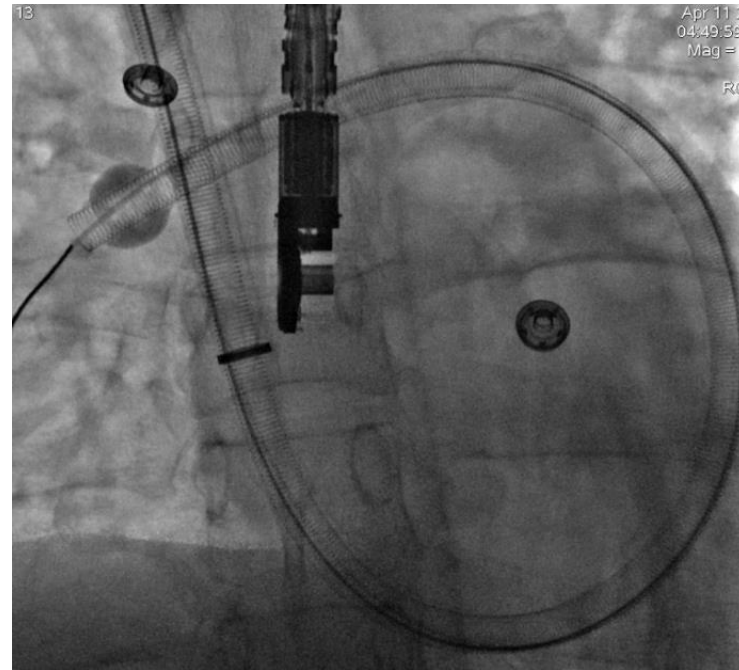
## Thrombectomy Devices

- Angiovac





# Interventions for PE – Suction Thrombectomy

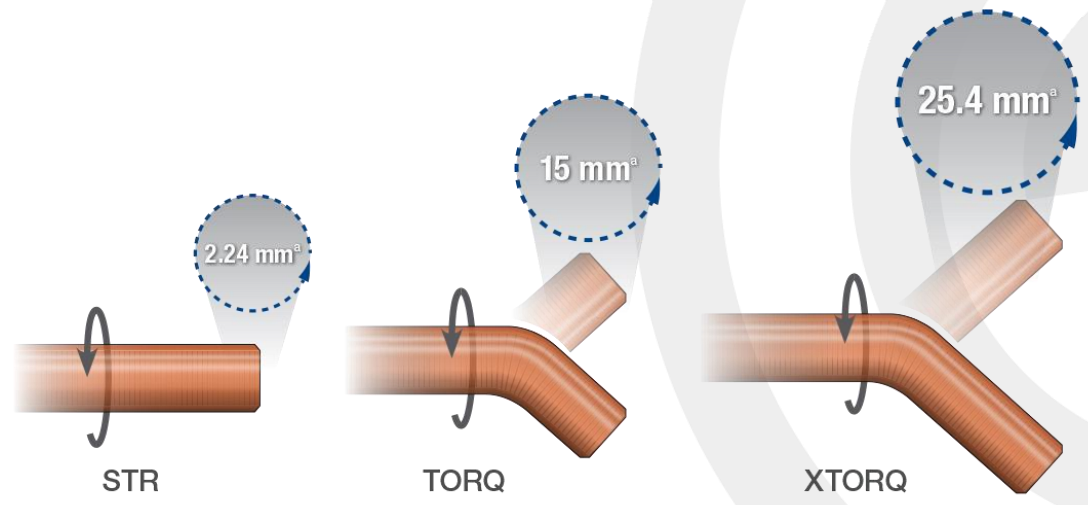


Courtesy: R. Chaer  
Univ. of Pittsburgh

# Interventions for PE – Suction Thrombectomy

## Thrombectomy Devices

- Indigo Penumbra

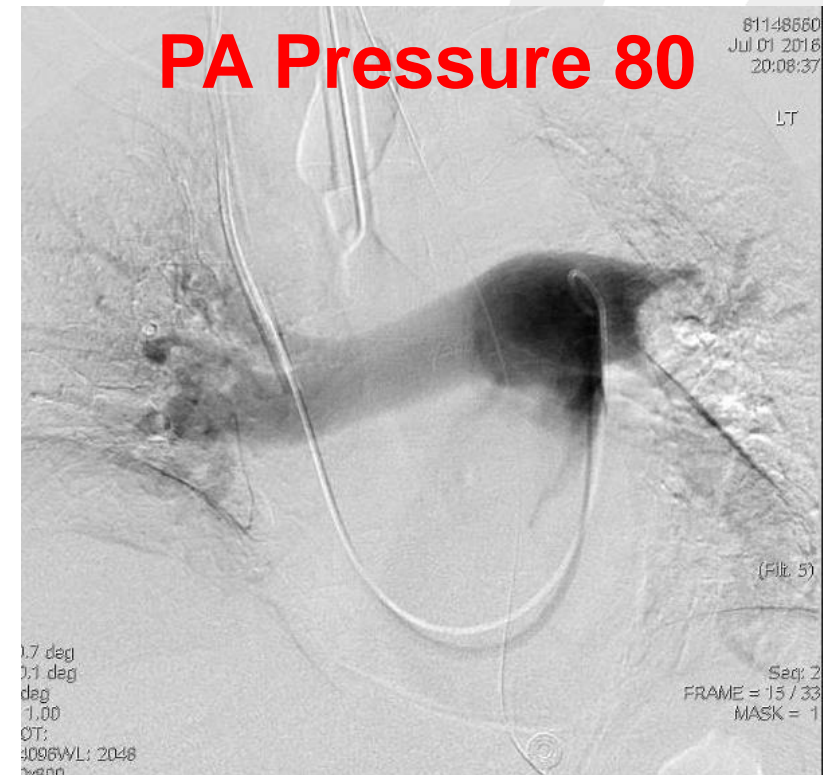
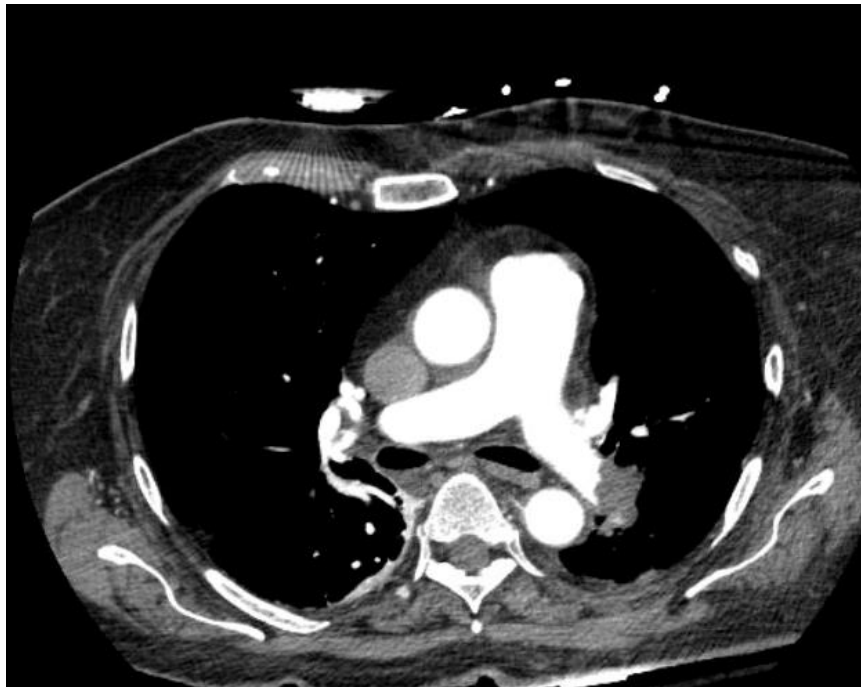


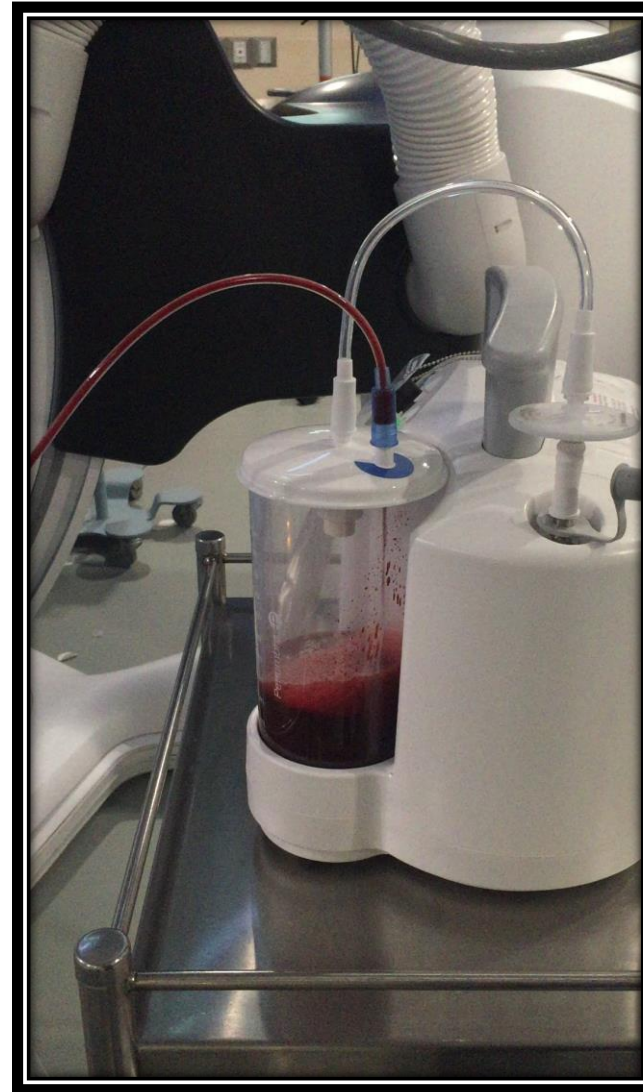
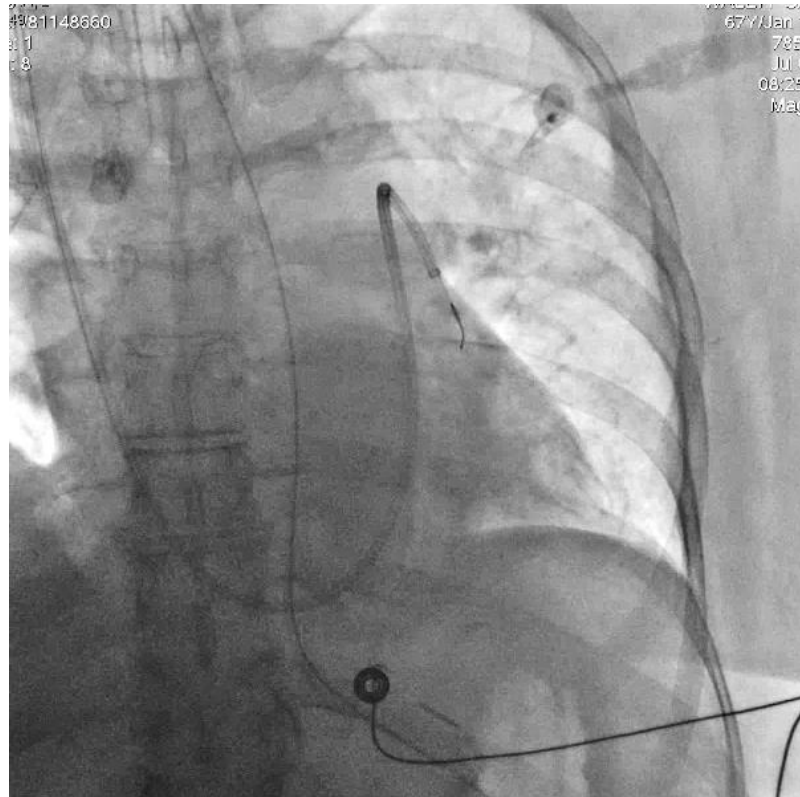


# Interventions for PE – Suction Thrombectomy

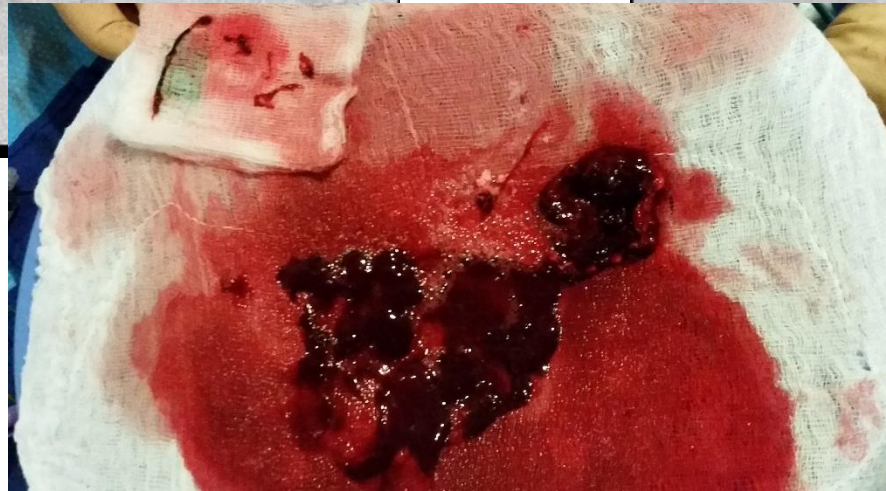
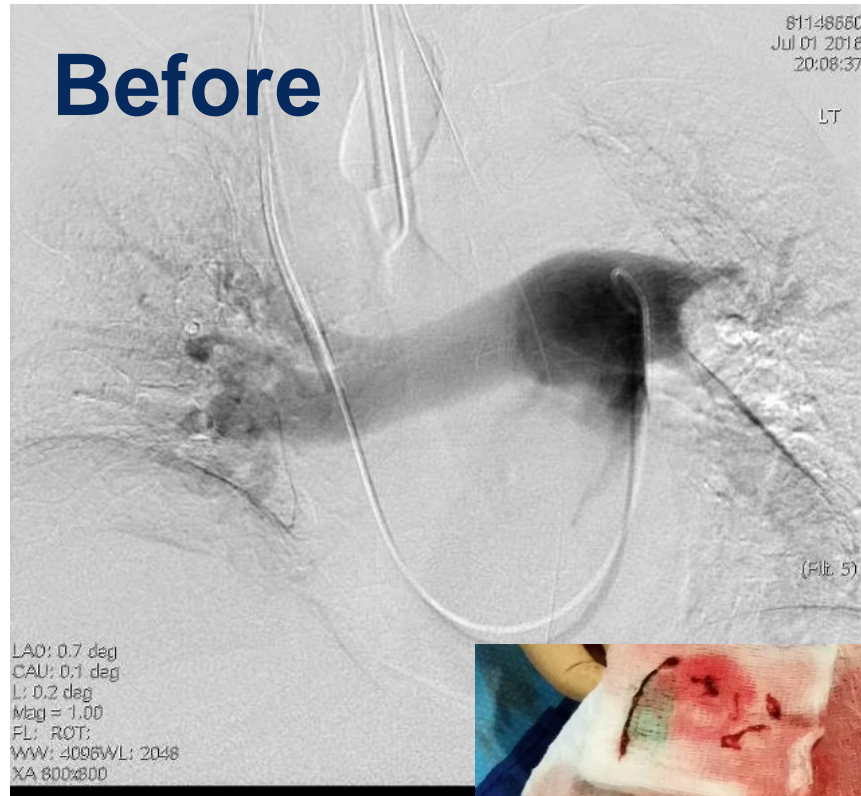
## Thrombectomy Devices

- Indigo Penumbra









Courtesy: E. Avgerinos  
Univ. of Pittsburgh

**Welcome!** A message from Dr. Akhilesh Sista, National Principal Investigator:



Dear EXTRACT-PE Clinical Site,

Welcome to this exciting trial: "A Prospective, Multicenter Trial to Evaluate the Safety and Efficacy of the Indigo<sup>®</sup> Aspiration System in Acute Submassive Pulmonary Embolism." It is my honor to lead this trial along with an accomplished Steering Committee: Drs. Jim Benenati, Vic Tapson, and Jim Horowitz. We are also fortunate to have esteemed PE experts on both the Clinical Events and Data Safety Monitoring Board (DSMB) Committees to oversee the safety and efficacy of the trial.

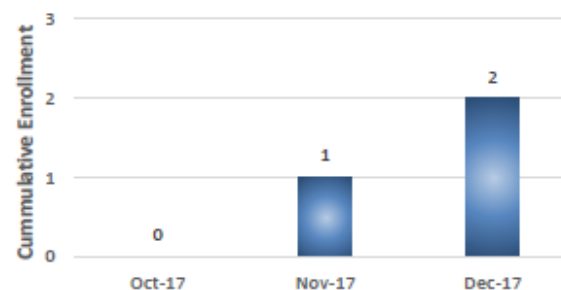
We have individually seen how the Indigo Aspiration System has can remove thrombus; it is now time to evaluate it in a prospective and rigorous fashion. The Indigo Aspiration System has the potential to remove thrombus with no or minimal thrombolytic drug use, a feature that could improve options for patients.

Thank you for participating in this important trial, and for your hard work in getting your sites up and running. Please feel free to email or call me with any study related questions. My cell is 410-908-1406, and my email is [Akhilesh.Sista@nyumc.org](mailto:Akhilesh.Sista@nyumc.org). I look forward to working with you.

### Steering Committee Members

- James Benenati, MD, FSIR  
*Medical Director, Noninvasive Vascular Laboratory  
Program Director, Vascular/Interventional  
Radiology Fellowship Baptist Cardiac & Vascular  
Institute Baptist Hospital of Miami*
- James Horowitz, MD, FACC  
*Clinical Assistant Professor, Department of Medicine  
NYU Critical Care Associates*
- Victor Tapson, MD  
*Director of Pulmonary and Critical Care Medicine*

### Subject Enrollment

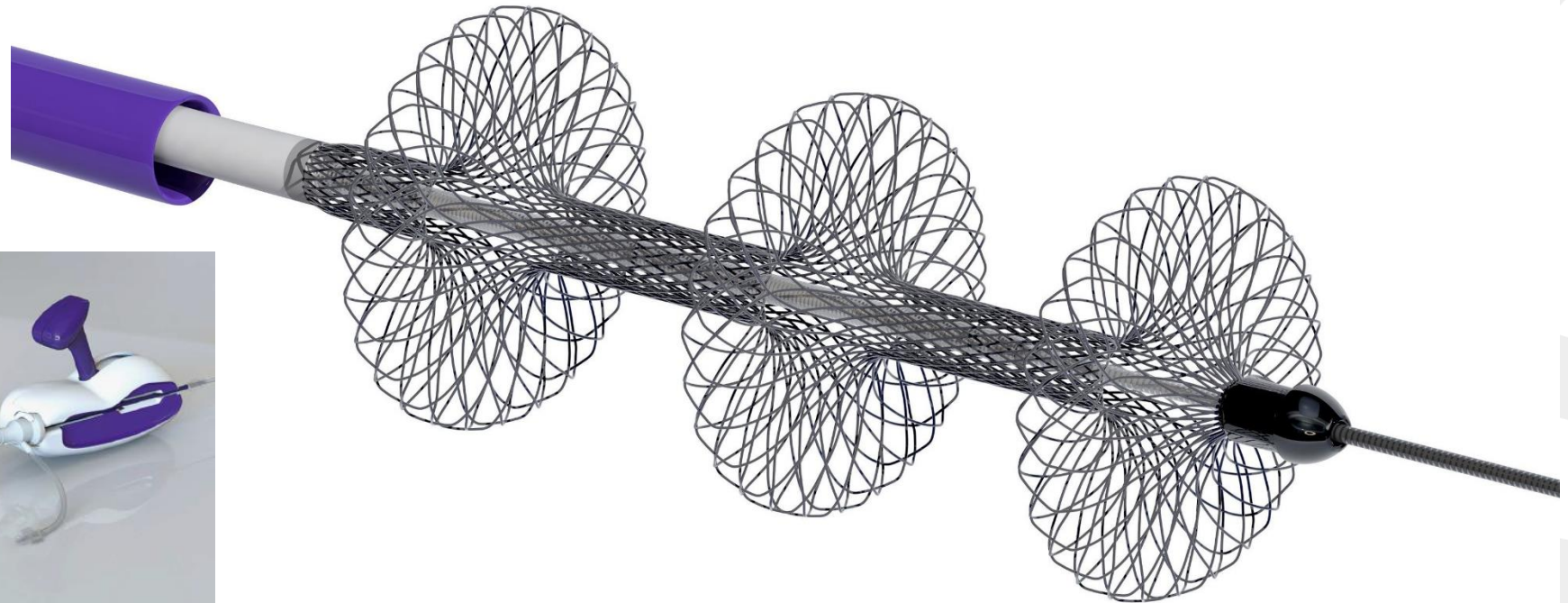


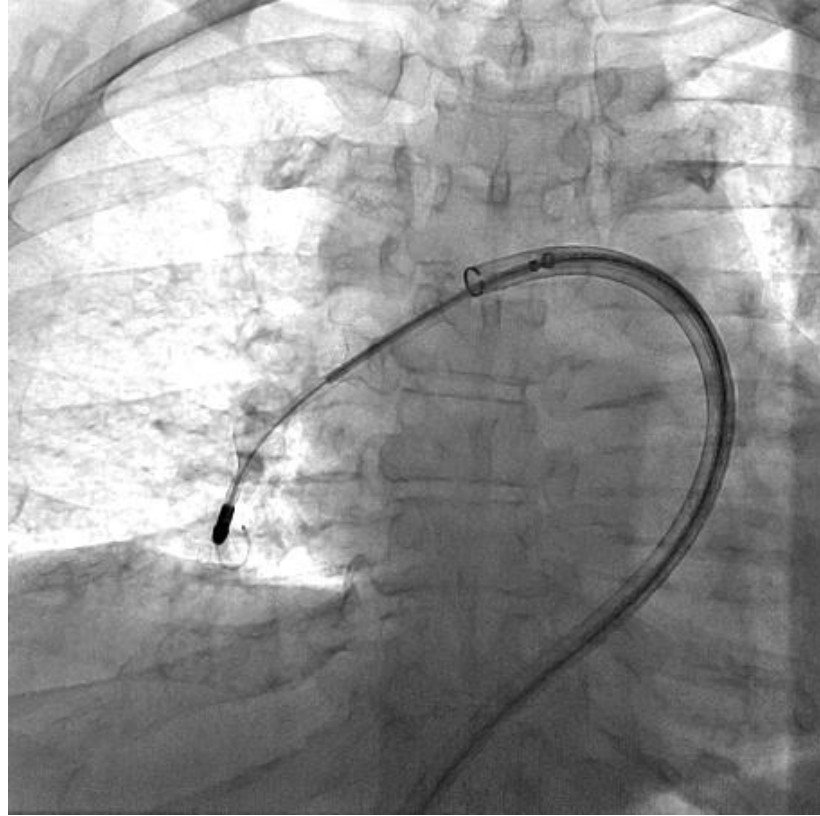


# Interventions for PE – Suction Thrombectomy

## Thrombectomy Devices

- Flowtriever Inari





Courtesy: C. Toma  
Univ. of Pittsburgh

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# FLARE

**FlowTriever<sup>®</sup>**  
Percutaneous Pulmonary Embolectomy  
Clinical Study

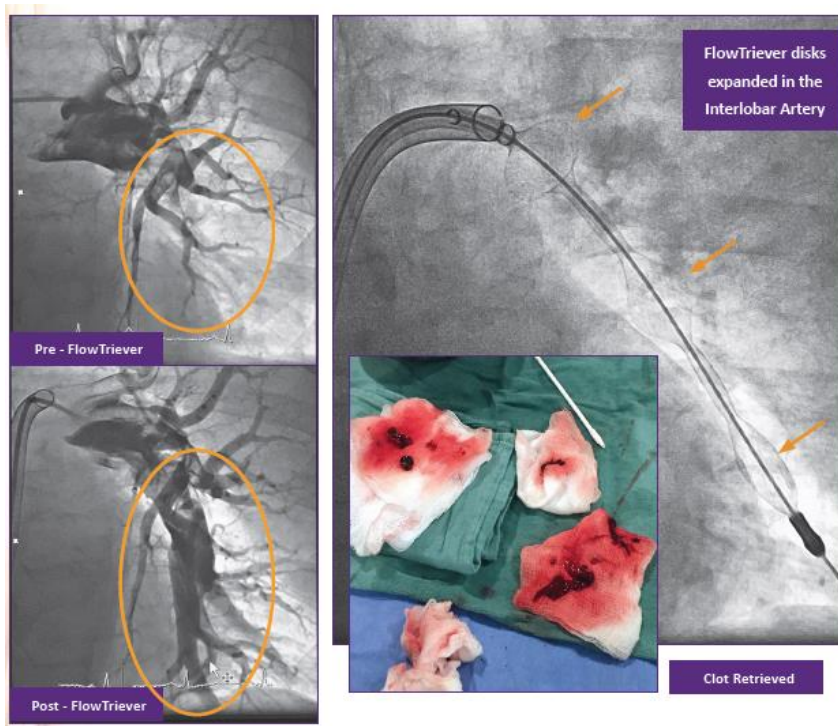


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## FLARE Enrollment by Investigator

Investigator	Site	Total
Tom Tu	Baptist Health	27
Chris Adams	Charleston Area MC	27
Wissam Jaber	Emory University	9
Rohit Bhatheja	Florida Hospital	8
Mitch Silver	OhioHealth	8
Sameer Khandhar	Penn Presbyterian MC	6
Rohit Amin	PRC / Sacred Heart	5
Mitch Weinberg	North Shore / Lenox Hill	3
Tod Engelhardt	East Jefferson GH	2
Eric Peden	Houston Methodist	2
Robert Maholic	UPMC Hamot	2
David Holmes	East Alabama MC	1
Scott Lilly	OSU/Wexner MC	1
Catalin Toma	UPMC Presbyterian	1
Hussam Hamdalla	Ephraim McDowell	1
Glenn Hoots	Tampa General	1
Victor Tapson	Cedars-Sinai	1
Monica Hunter	CRA / Birmingham Heart	1
<b>TOTAL ENROLLED</b>		<b>106</b>



# Safety of Catheter Interventions

**RCT**



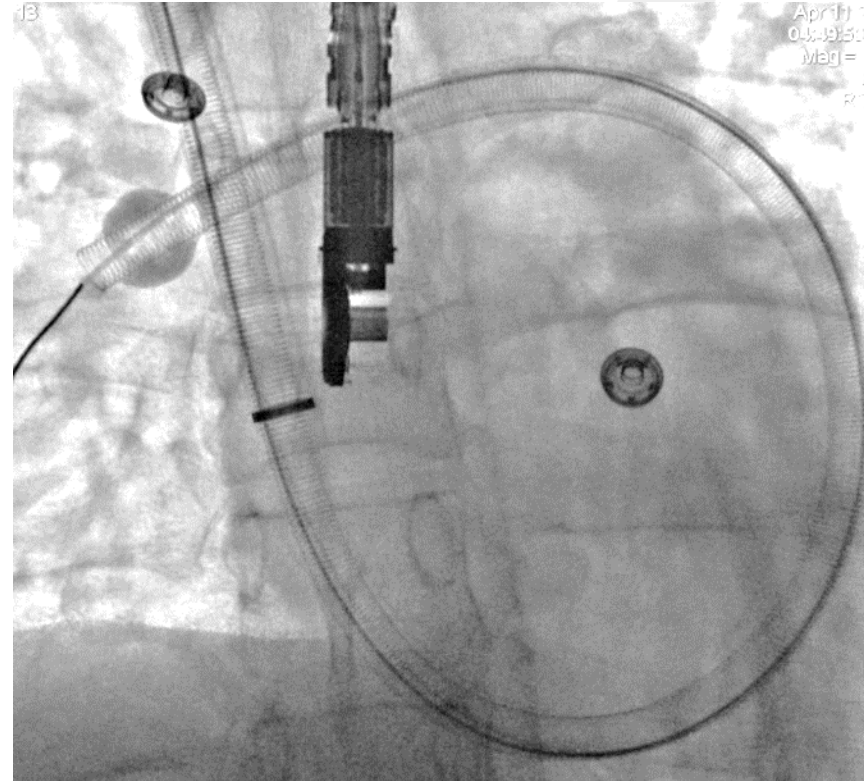
Trial	Type of Intervention	Pts	Major Bleed	ICH
Kuo et. al 2009	Various	594	~3.2%	0.1%
<b>ULTIMA-2014</b>	EKOS (Lysis)	30	0%	0%
<b>PERFECT 2015</b>	sCDT EKOS (Lysis)	101	0%	0%
<b>SEATTLE II 2015</b>	EKOS (Lysis)	150	10%	0%
NIS Data 2015	Various	352	~3.7%	0.3%

# Major Complications EXIST

Coronary Sinus Perforation



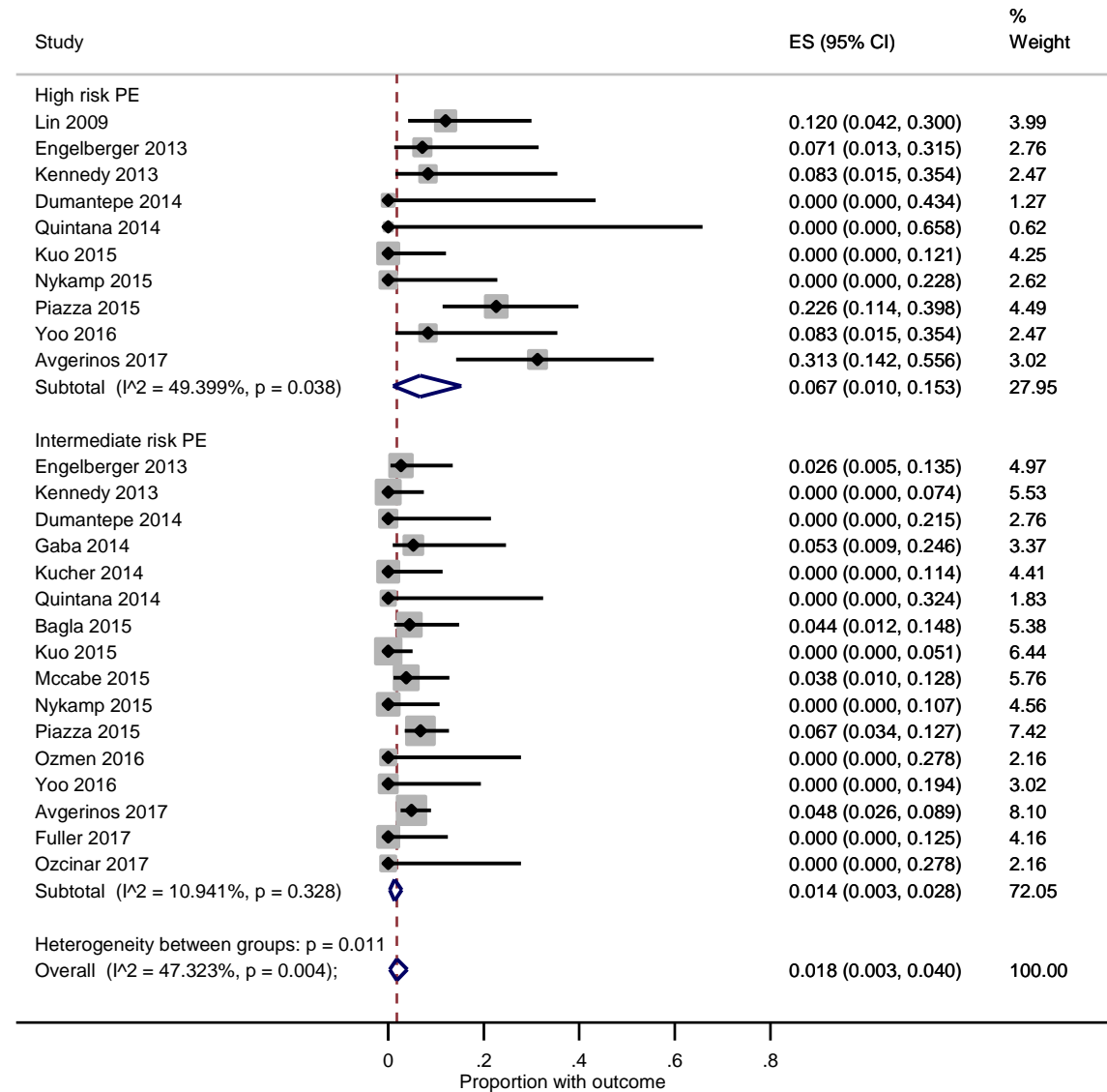
Tricuspid Rupture



Avgerinos et al, J Vasc Surg 2018 in press

- Metaanalysis of 20 Studies of Catheter Thrombolysis (2009-2017)
- 1,168 patients
- Massive PE
  - 8% Mortality
  - 6.7% Major Bleeding
- Submassive PE
  - <1% Mortality
  - 1.4% Major Bleeding

## Major Bleeding (by PE Severity)



# UPMC Algorithm

**High Risk**

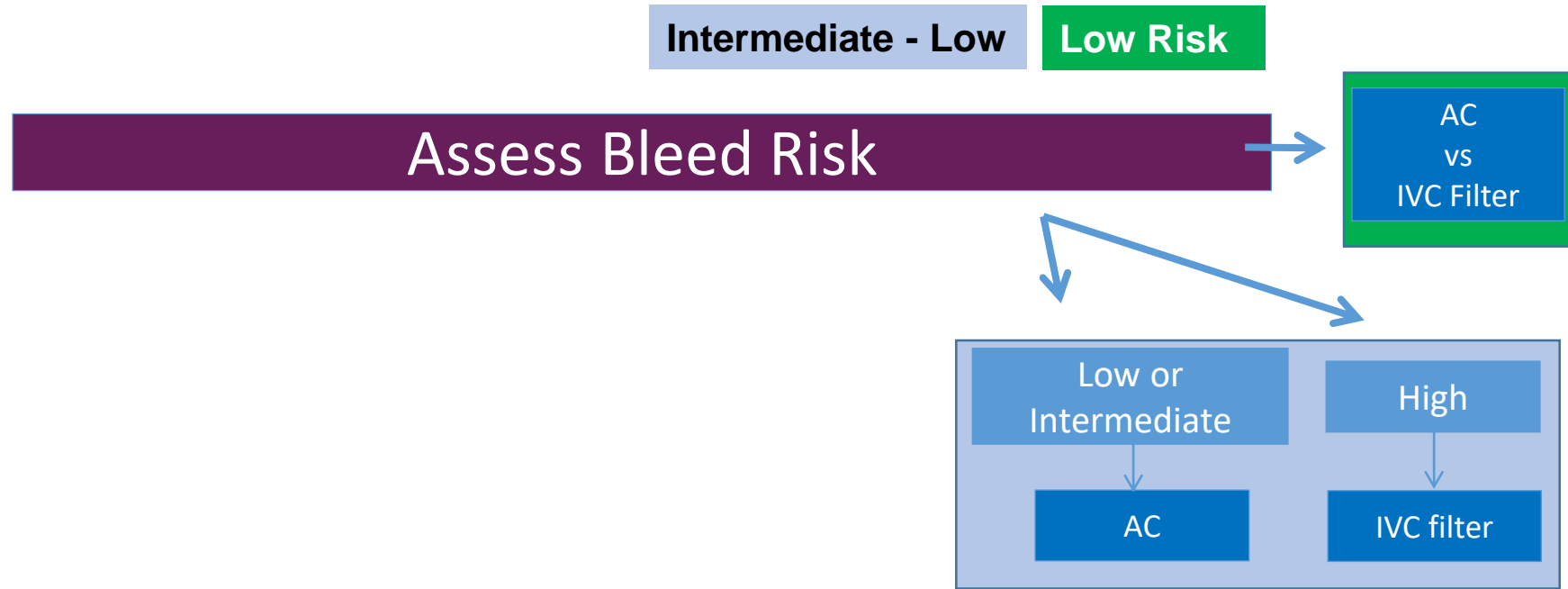
**Intermediate - High**

**Intermediate - Low**

**Low Risk**

**Assess Bleed Risk**

# UPMC Algorithm

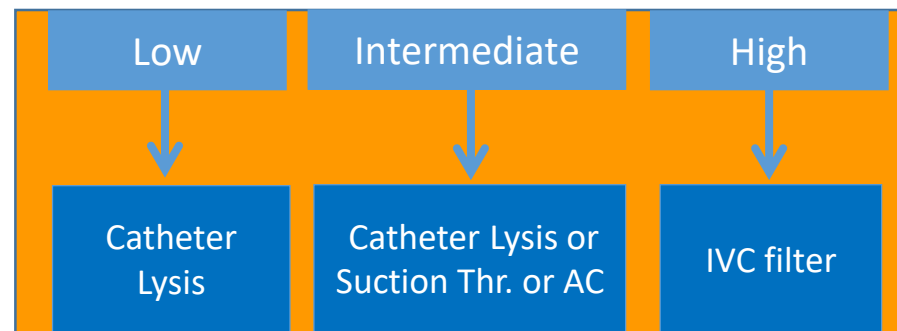




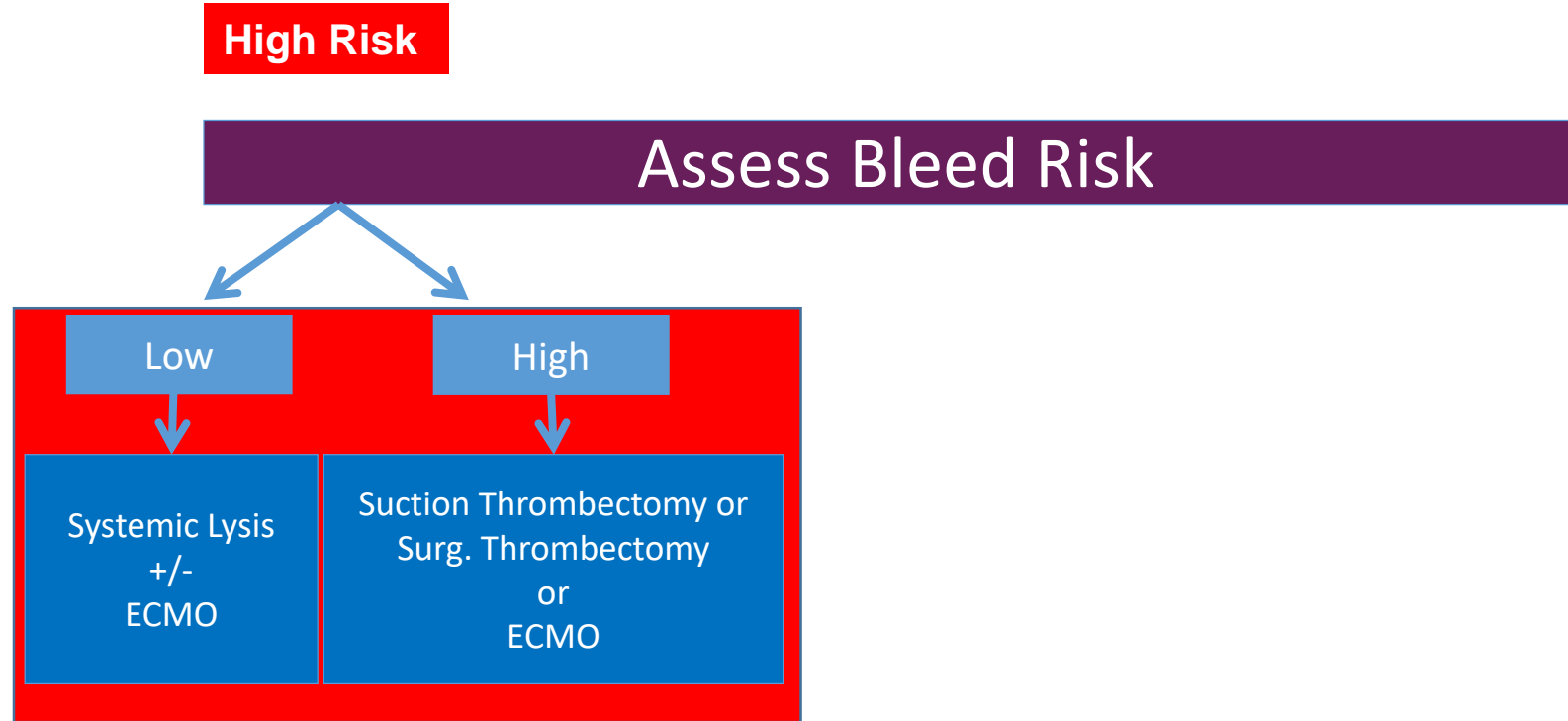
# UPMC Algorithm

Intermediate - High

Assess Bleed Risk



# UPMC Algorithm



# Take Home Messages

- Catheter Interventions for PE are here to stay
  - Catheter Lysis vs Catheter Thrombectomy are complimentary
- Faster Clot removal & RV function recovery
- Prevention of RV failure / decompensation
- Prevention of Pulmonary Hypertension (?)
- They are not complication-free procedures but complications are less than those of systemic lysis
- Careful patient selection in high-volume centers with appropriate expertise is essential till larger studies are available.