Angiovac Strategy for the Treatment of Massive PE

Christopher J. Kwolek, M.D, MBA, DFSVS, FACS
Chief Medical Officer
The Vascular Care Group
Mass General Brigham
NEWTON-WELLESLEY HOSPITAL

Faculty Disclosures

- *I disclose the following financial relationships:*
- Amsel Medical, Endologix, Philips, Silk Road, Vasorum

Category of PE

Table. Clinical Definitions of Pulmonary Embolism.(20)

	Definition	Mortality
Massive PE	Sustained hypotension (systolic blood pressure	Up to 65%
Submassive PE	Right ventricular dysfunction (elevated BNP or ECG changes) or myocardial necrosis (elevated troponin) without hypotension	5%–15%
Low-Risk PE	Normotensive and no markers of adverse prognosis	1%–2%

PERT Team

Hospital Practice
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/thop20

The Massachusetts General Hospital Pulmonary Embolism Response Team (MGH PERT): Creation of a Multidisciplinary Program to Improve Care of Patients With Massive and Submassive Pulmonary Embolism

Tim Provias MD, MPH[a], David M Dudzinski MD, JD[a], Michael R Jaff DO, FACC, FAHA[a], Kenneth Rosenfield MD, MHCDS[a], Richard Channick MD[b], Joshua Baker MD[a], Ido Weinberg MD[b], Cameron Donaldson MD[a], Rajeev Narayan MD[a], Andrew N Rassl MD[a] & Christopher Kabrhel MD, MPH[c]
[a] The Massachusetts General Hospital Institute for Heart, Vascular, and Stroke Care
[b] Division of Pulmonary and Critical Care
[c] Center for Vascular Emergencies, Department of Emergency Medicine, Boston, MA
Published online: 13 Mar 2015.

Hospital Practice 2015;42:1,31-37

Summary of PE Trials

TABLE 1. A COMPARISON OF TRIALS FOR PE TREATMENT

	EXTRACT PE[1] (N = 119)	SEATTLE II[2] (N = 150)	FLARE[3] (N = 106)	PEITHO[4] (tenecteplase arm, n = 506)
Treatment method	Indigo aspiration system	EkoSonic endovascular system	FlowTriever system	Fibrinolytic therapy
Primary efficacy (reduction in RV/LV ratio at 48 h)	0.43; *P* < .0001	0.42; *P* < .0001	0.38; *P* < .0001	NA
Primary safety	Major adverse events within 48 h, 1.7%	Major bleeding within 72 h, 10%	Major adverse events within 48 h, 3.8%	Death or hemodynamic decompensation within 7 d, 2.6%
Major bleeding	1.7% within 48 h	10% within 72 h	1% within 48 h	11.5% within 7 d
All-cause mortality (30 d)	2.5%	2.7%	1%	2.4%
Device time	37 min	12-24 h	57 min	NA

Abbreviations: NA, not available; LV, left ventricular; RV, right ventricular.

Guidelines for Surgical Embolectomy

- Massive PE and contraindications to fibrinolysis (Class IIa; Level of Evidence C).
- Massive PE who remain unstable after receiving fibrinolysis (Class IIa; Level of Evidence C).
- *May be considered* for submassive acute PE judged to have clinical evidence of adverse prognosis (new hemodynamic instability, worsening respiratory failure, severe RV dysfunction, or major myocardial necrosis) (Class IIb; Level of Evidence C).
- Not recommended for patients with low-risk PE or submassive acute PE with minor RV dysfunction, minor myocardial necrosis, and no clinical worsening (Class III; Level of Evidence C)

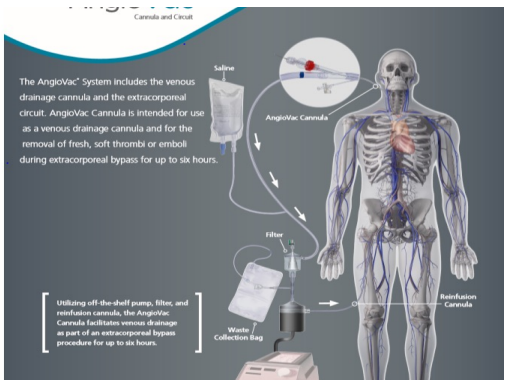
Suction Thrombectomy

Suction Thrombectomy			
Indigo	4, 6, 8 Fr	High-velocity vacuum suction catheter	EXTRACT PE (Evaluating the Safety and Efficacy of the Indigo® Aspiration System in Acute Pulmonary Embolism) • 0.43 reduction (in the RV/LV ratio after 48 hours • Small caliber
FlowTriever	20 Fr	Large aspiration guide catheter, device has 3 self-expanding nitinol disks unsheathed to disrupt and aspirate clot	FLARE (FlowTriever Pulmonary Embolectomy Clinical Study)[22] • No tPA required • Major bleeding rate 0.9%

Tu T, Toma C, Tapson VF, et al. A Prospective, Single-Arm, Multicenter Trial of Catheter-Directed Mechanical Thrombectomy for Intermediate-Risk Acute Pulmonary Embolism: The FLARE Study. *JACC Cardiovasc Interv* 2019;12:859-69

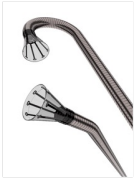
Indications for Transcatheter Procedures

- Alternative to lysis when contraindications or when emergency surgery is unavailable or contraindicated
- Failure of lysis to improve hemodynamics in acute setting
- Hybrid therapy includes both catheter – based clot fragmentation and local thrombolysis



AngioVac Cannula Generation 3

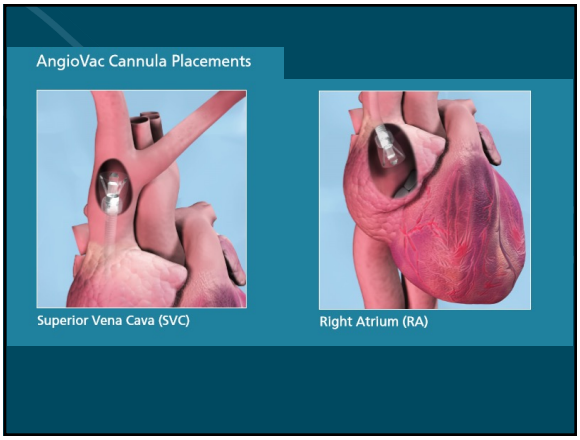
- Open or Percutaneous
- ID (20.2 Fr) Large bore OD (23Fr)
- Tracks over a .035” guidewire, kink resistant, collapse resistant
- 16 Fr Venous Return Cannula
- Self-expanding funnel shaped tip
  - Remotely deployable
  - Engage and conform UIM
  - Maintain local blood flow
  - Prevent vessel collapse

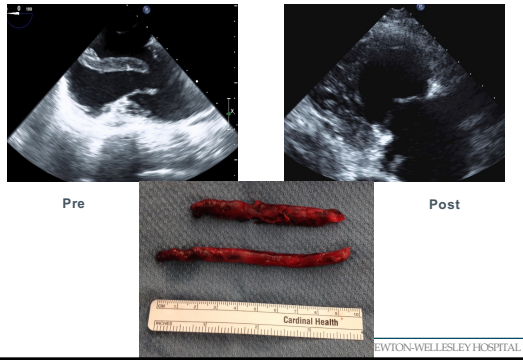


AngioVac™

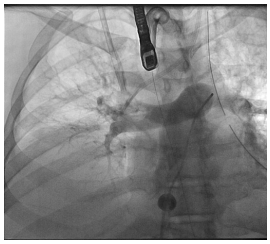
AngioVac Initial Experience

Patients	31
Mean Age	52
Gender	55% Male 45% Female
Primary Location of UIM™	PA 39% RA 32% IVC 29%
Material Aspirated	87%
Procedural Success	71%
Conversion to Open	10%
Complications	6.4% 1 Tamponade 1 Urgent PE/TVP under CPB
Procedural Mortality	3.2% 1 RA Perforation

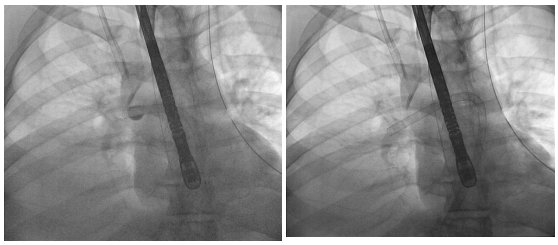




PA Angiogram



Angiovac Thrombectomy Right Main PA



AngioVac® Clinical Experience (2009-2012)

Patients	375
Mean Age	54
Gender	52% Male 48% Female
Primary Location of UIM™	PA 20% RA 35% Iliofem/IVC 43% Other 2%
Material Aspirated	97%
Procedural Success	80% - 90%
Conversion to Open	1.0%
Complications	0.6% 2 Tamponade* *wire perfs prior to AngioVac insertion
Procedural Mortality	< 1 % 1 RA Perforation

RAPID Angiovac Registry

JVIR
Journal of Vascular and Interventional Radiology

CLINICAL STUDY | VOLUME 32, ISSUE 4, P549-557.E3, APRIL 01, 2021

Endovascular Removal of Thrombus and Right Heart Masses Using the AngioVac System: Results of 234 Patients from the Prospective, Multicenter Registry of AngioVac Procedures in Detail (RAPID)

John M. Moriarty, MD, FSIR • Victoria Rueda, MPH • Millie Liao, DO • Grace Hyun J. Kim, PhD • Paul J. Rochon, MD • Mohamed A. Zayed, MD, PhD • David Lasorda, DO • Yosef S. Golowa, MD • David M. Shavelle, MD • David J. Dexter, MD • Show less

Published: January 29, 2021 • DOI: https://doi.org/10.1016/j.jvir.2020.09.012 • Check for updates

NEWTON-WELLESLEY HOSPITAL

RAPID Registry

234 Patients – 21 Centers

March 2016 – August 2019

Patient	%	Indication	Success
84	35.9%	Caval Thrombus	73.6%
113	48.3%	Right Heart Mass	59%
20	8.5%	Cath Related Thrombus	60%
4	1.7%	Pulmonary Embolus	57%

1. Moriarty JM, Rueda V, Liao M, et al. J Vasc Interv Radiol. 2021;32(4):549-557.e3

RAPID Registry

234 Patients – 21 Centers

March 2016 – August 2019

Extracorporeal Bypass < 1 hour	75.2%
EBL < 250 ml	76.5%
Transfusion	25%
Mortality	1/234 (<1%)

1. Moriarty JM, Rueda V, Liao M, et al. J Vasc Interv Radiol. 2021;32(4):549-557.e3

New 18 Fr Cannula

AngioDynamics Receives FDA Breakthrough Device Designation for the AngioVac System for the Non-Surgical Removal of Right Heart Vegetation

August 15, 2023

PDF Version

Pivotal Milestone Accelerates Pathway to Specific Indication

LATHAM, N.Y.--(BUSINESS WIRE)--Aug. 15, 2023-- AngioDynamics, Inc. (NASDAQ: ANGO), a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options and improving quality of life for patients, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation for the Company's AngioVac System for the proposed indications for use to include the non-surgical removal of vegetation from the right heart.

Conclusions

- The Angiovac Device represents a novel option for the management of
  - extensive IVC and Iliac vein thrombosis,
  - atrial thrombus
  - valvular vegetations,
  - ?PE,

  particularly in pts with contra-indications to thrombolysis
- The AngioVac device is a safe and effective device for the removal of undesirable intravascular material from the venous system

NEWTON-WELLESLEY HOSPITAL

Conclusions

- Lack of prospective randomized data for comparing different modalities
- Team based approach offers best way to balance risks/benefits
- Optimal treatment in your institution will depend on experience, what technology you have available!