A New ICD-10-PCS Code For Extracorporeal Removal of Thrombi and Emboli from Venous System

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Presented to: ICD-10-CM/PCS Coordination and Maintenance Committee Meeting
Centers for Medicare & Medicaid Services

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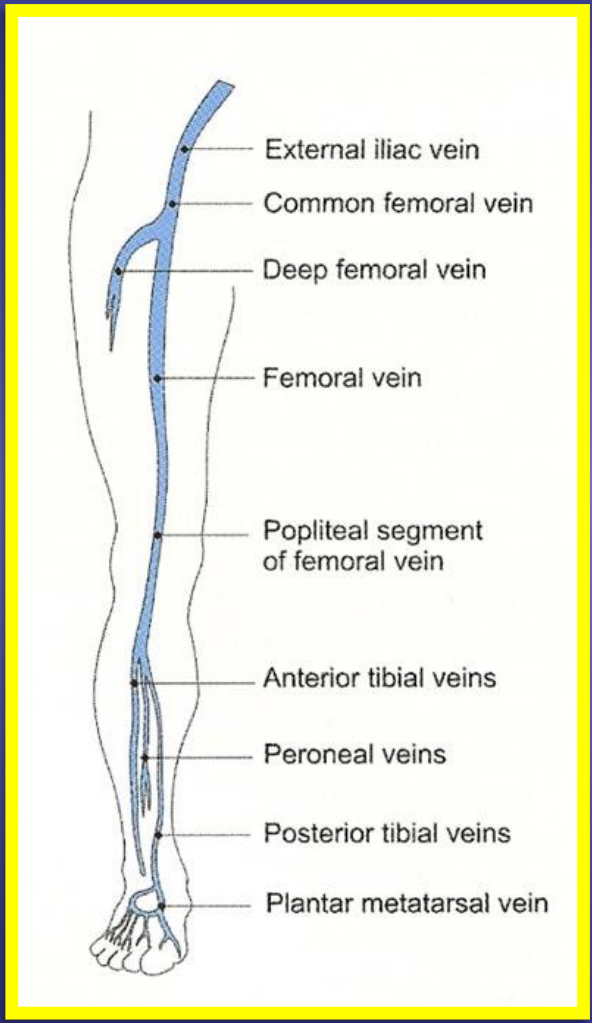
Agenda

- Coding Issue: Currently no ICD-9 or ICD-10 code to describe this unique intervention
- About Deep Vein Thrombosis
- Traditional Treatments
- Extracorporeal Removal of Thrombi & Emboli
- Rational for ICD-10-PCS
- ICD-10-PCS Code Options
- New Technology Add on Payment
- Questions and Answers

Venous Blood Clots

- Blood clots (thrombus) that form within a vein
  - DVT: Deep Vein Thrombosis
  - PTS: Post Thrombotic Syndrome
  - VTE: Venous Thromboembolism

Deep Vein Thrombosis (DVT)



DVTs occur in large venous structures:

- Superior Vena Cava (SVC)
- Inferior Vena Cava (IVC)
- Right Atrium (RA)
- Iliofemoral venous system

DVTs occur as a result of:

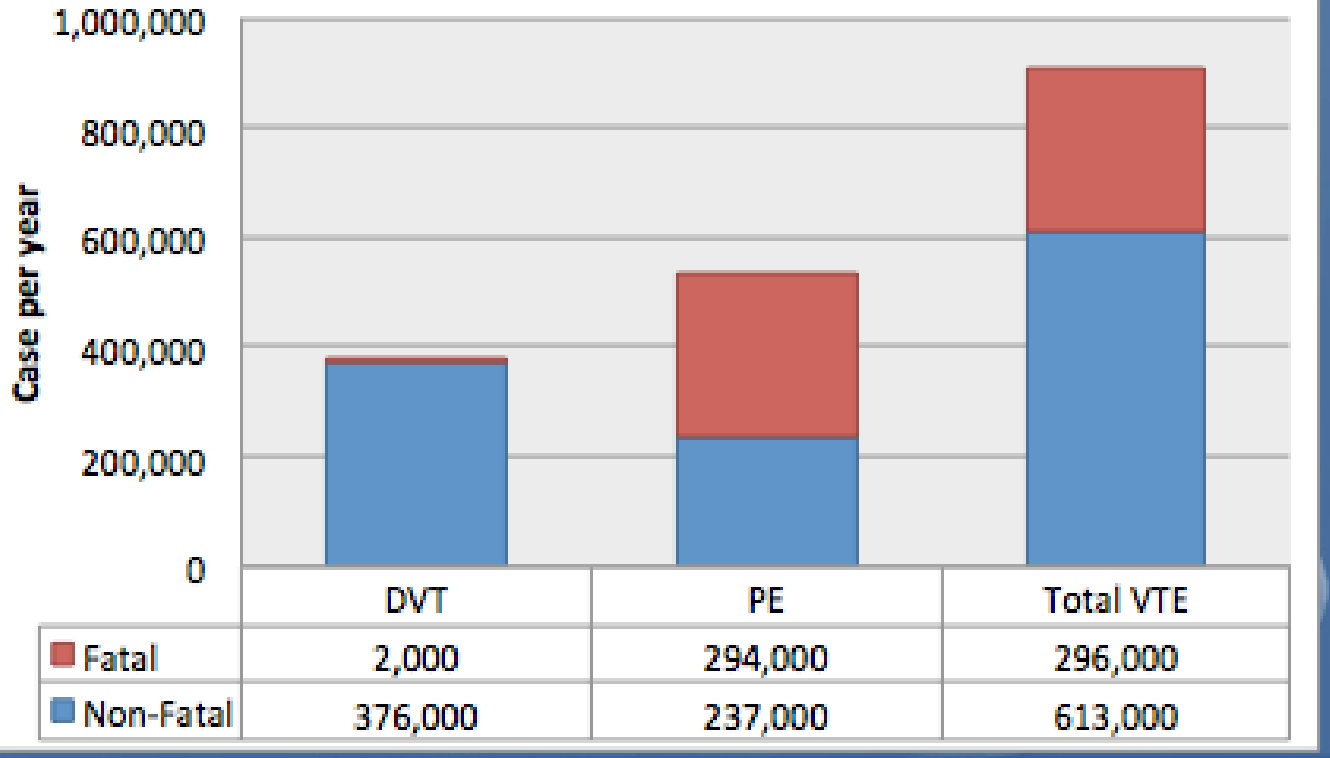
- Venous stasis (low or no blood flow)
- Vascular injury
- Hypercoagulable state (cancer, protein C or S deficiency)

VTE Statistics

- 1 to 3 per 1000 in general population per year
- 900,000-1,000,000 events in US per year
- Third most common cause of cardiovascular mortality
- 20% mortality at 1 year
- In-hospital VTE fatality is 12%, rising to 21% in elderly population

VTE Incidence

Overall ~1 Million VTE Events per Year in US



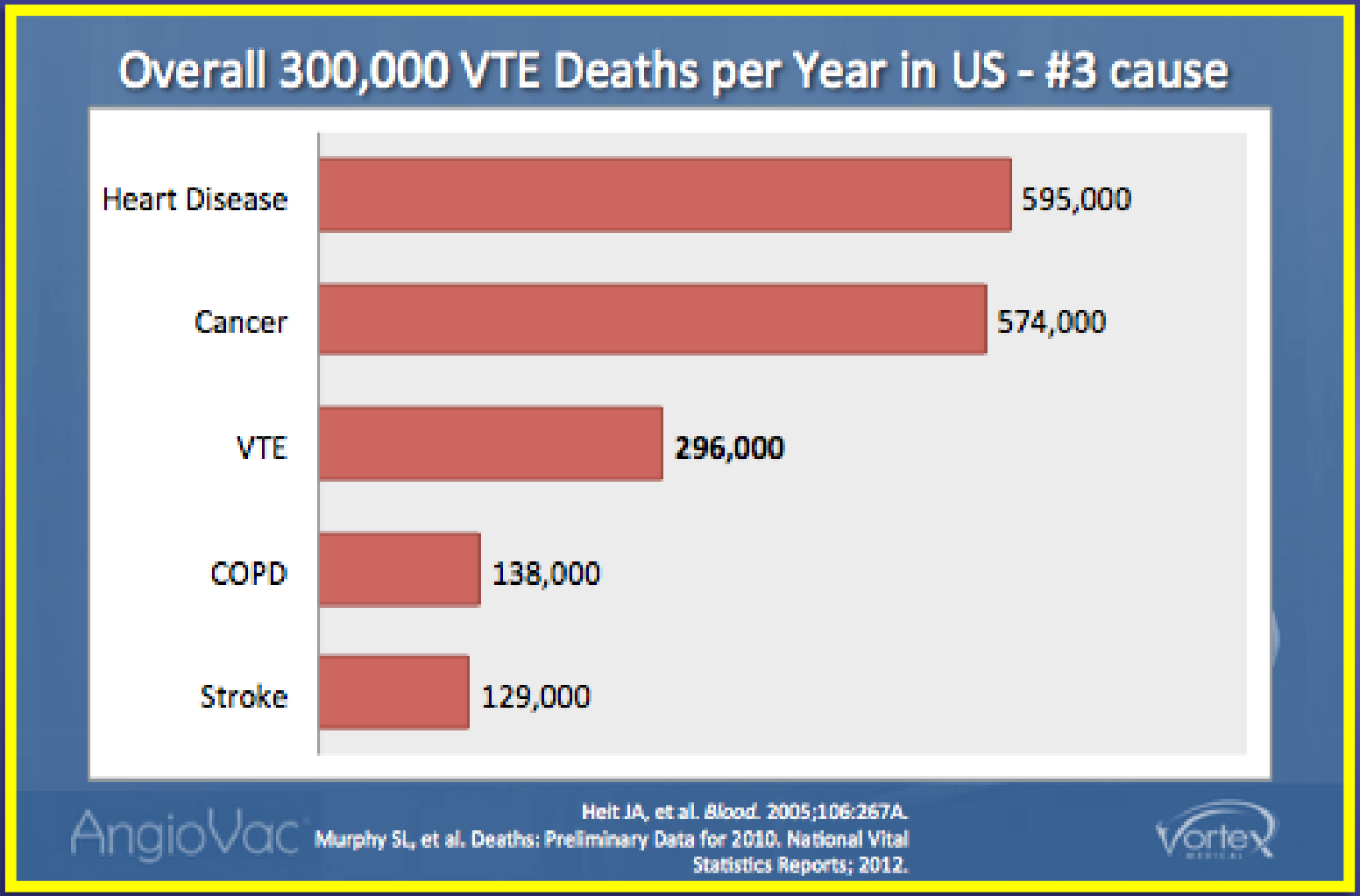
	DVT	PE	Total VTE
Fatal	2,000	294,000	296,000
Non-Fatal	376,000	237,000	613,000

AngioVac

Helt JA, et al. *Blood*. 2005;106:267A.

Vortex

VTE Mortality



VTE in 2015

- DVT is very common
- Post Thrombotic Syndrome (PTS) is the most common complication of DVT
- PTS causes large scale:
  - Morbidity
  - Societal cost
  - Reduction in patient QOL
- PTS is inadequately prevented and treated by current regimes

Post Thrombotic Syndrome (PTS)

- Leg swelling
- Limb pain
- Edema
- Skin Changes
- Leg Ulceration

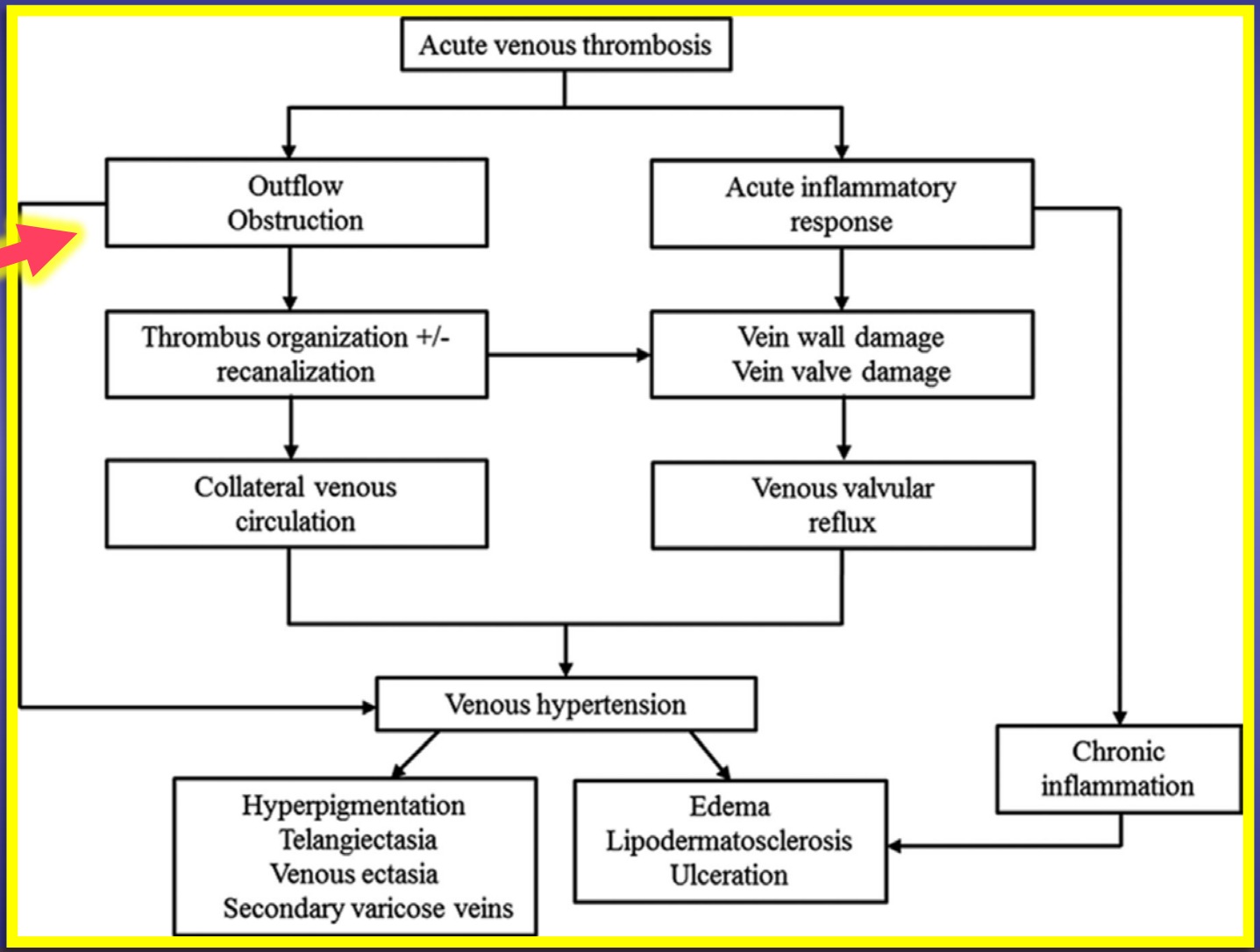
Extremely Common

- 20 – 50% of patients with DVT develop PTS despite optimal anticoagulation
  - In most cases, within 12 months
  - Cumulative incidence 10 – 20 years post
- 5 – 10% develop severe PTS…ulcers

- **Probability of developing venous ulcer over 10 years following DVT = 5%**

Kahn, Circ, 2014
Zidane, Arch Int Med, 2000
Kahn, Ant Int Med, 2008
Hencke, J Vac Surg, 2011

Causes of PTS



Extreme Societal Cost

- 2 million workdays lost per year in US as a result of leg ulcers
- QOL impairment = COPD, HF
- 2 year initial total per-patient cost of PTS was Canadian $4527
  - X2 if DVT without PTS
- Estimate mean adjusted annualized cost of developing PTS…**$11,667**
  - AF $6697
  - MI $9716

Bergen, NEJM, 2006
Guanella, JTH, 2011
McDougal, AMJHT, 2006

Current Treatments for VTE

- Systemic anticoagulation
- Surgical thrombectomy/embolectomy
- Systemic thrombolysis
- Catheter-directed thrombolysis (CDT)

Anticoagulation

- Glucosaminoglycans (GAGs)
  - Heparin/heparin sulfate
- Vitamin K Agonists (VKAs)
  - Coumadin/warfarin
- Low Molecular Weight Heparin (LMWH)
  - enoxaparin (Lovenox)
- New Oral Anticoagulants (NOACs) approved for:
  - Reduction of recurrent DVT
  - Prevention of PE
    - dabigatran (Pradaxa)
    - rivaroxaban (Xarelto)
    - apixaban (Eliquis)

Prandoni, Ann Intern Med, 2009
Shulman, NEJM, 1997
Schulman, NEJM, 2009

New Oral Anticoagulants (NOACs)

- **DVT Prophylaxis**
  - 2008: RECORD 1,2,3 (rivaroxaban: knee, hip, hip) → superior, fewer bleeds (knees)
  - 2008-10: ADVANCE 1,2,3 (apixaban: knee, knee, hip) → superior with EU dosing, inferior with US dosing
- **VTE (DVT/PE)**
  - 2010 EINSTEIN (rivaroxaban) → noninferior
  - 2012: EINSTEIN-PE (rivaroxaban) → noninferior, fewer bleeds in PE trial
  - 2013: EINSTEIN-EXTEND (rivaroxaban) → superior, more bleeds than placebo
  - AMPLIFY (apixaban) → noninferior, fewer bleeds
  - AMPLIF-EXT (apixaban) → superior, 2.5 mg dose equal placebo bleeds

Open Vein Hypothesis

- Rapid thrombus elimination and restoration of unobstructed deep venous flow may prevent valvular damage, reflux, venous obstruction and PTS.
  - Meissner (1993): venous segments that developed valvular reflux had longer (2.3 to 7.3 times) endogenous clot clearance than segments that did not ($P<0.04$)
  - Prandoni (2005): PTS developed more frequently in proximal DVT patients who had residual venous thrombus or popliteal valvular reflux at 6-mo follow-up (n=180, 47% vs. 23%, $P<0.01$)
  - Hull (20056): metaanalysis of 11 randomized DVT treatment trials and found a strong correlation between the amount of residual trhombus after a course of anticoagulant therapy and the subsequent incidence of recurrent VTE

Systemic Thrombolysis

Significant (18%) or complete clot lysis (45%) can be achieved by giving systemic lysis, but with an unacceptably high risk of bleeding complications (14%)

Goldhaber, Am J med, 1984
Elliot, BJS, 1979,
Turpie, Chest, 1990

Catheter-Directed Thrombolysis (CDT)

- CDT allows higher intrathrombus drug concentration, enhancing drug concentration and reducing total dose
- "CDT has been consistently successful in the removal of thrombus in acute iliofemoral DVT, with approximately 90% of patients experiencing significant thrombolysis."

Vedantham, JVIR, 2006

Catheter-Directed Thrombolysis (CDT)

- Urokinase – N/A
- tPA (alteplase)
- rtPA (reteplase)
  - 0.5mg/hr

Semba, JVIR, 2000
Sugimoto, Jvasc Surg, 2003
Bladwin, vasc Endo Surg, 2004

PRE

POST

What else apart from lysis?

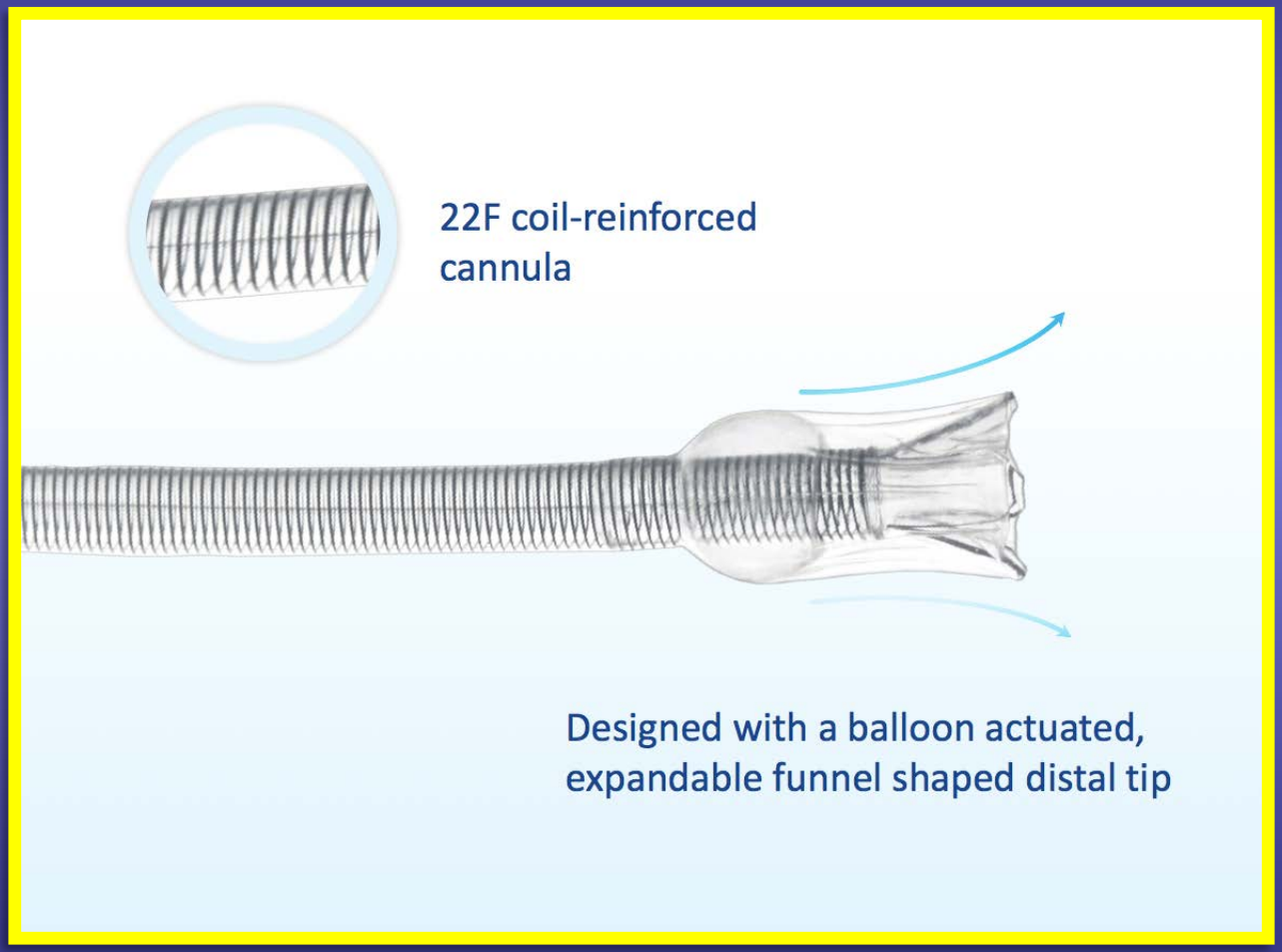
- Lysis doesn't work
- Lysis contraindicated
- Acute limb threat

? Faster, Cheaper

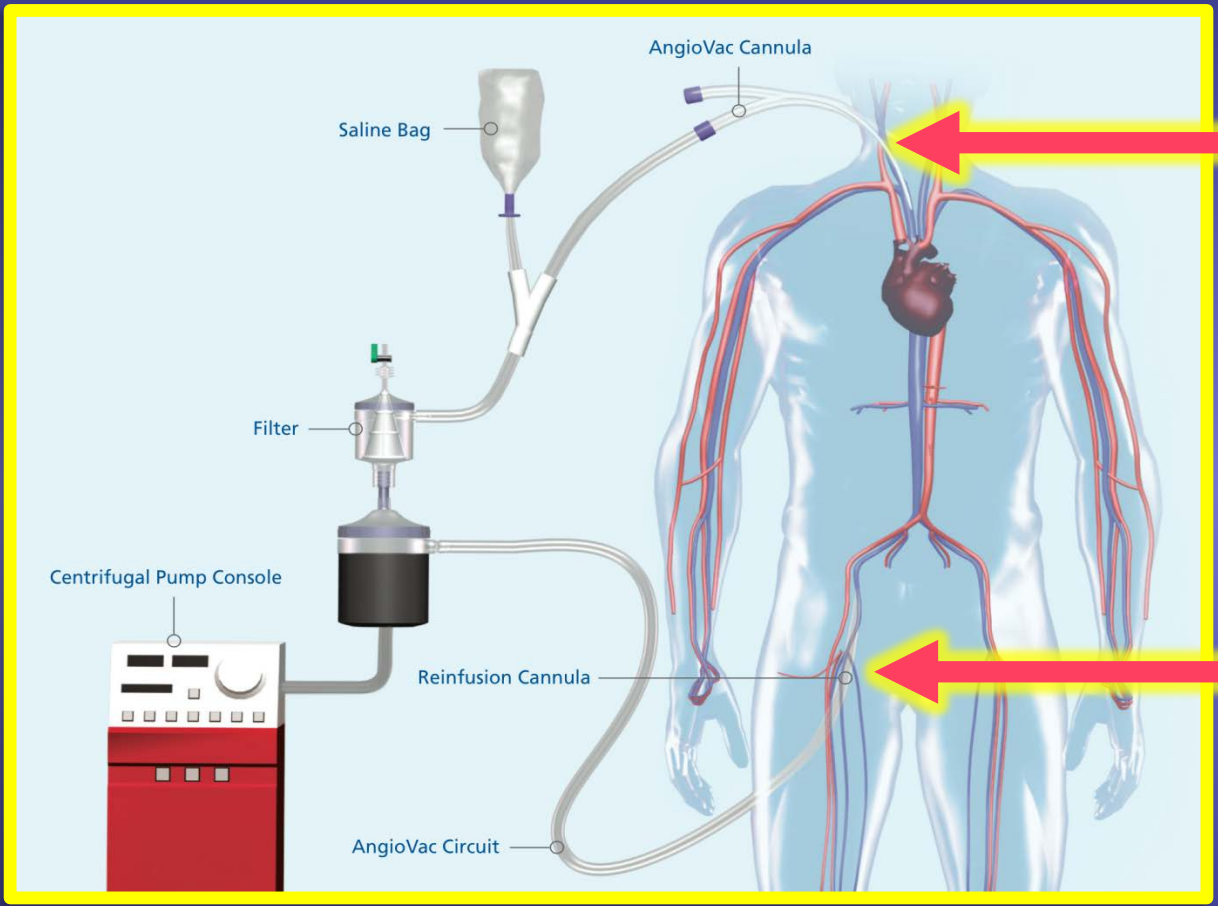
Extracorporeal Removal of Thrombi and Emboli: the AngioVac Procedure

- Typically performed in inpatient hospital setting
- General anesthesia
- Percutaneous procedure with real-time fluoroscopy
- Multidisciplinary team:
  - Interventionalist
  - Surgeon
  - Anesthesiologist
  - Perfusionist

AngioVac


22F coil-reinforced
cannula
Designed with a balloon actuated,
expandable funnel shaped distal tip

Standard AngioVac Cannula and Set Up



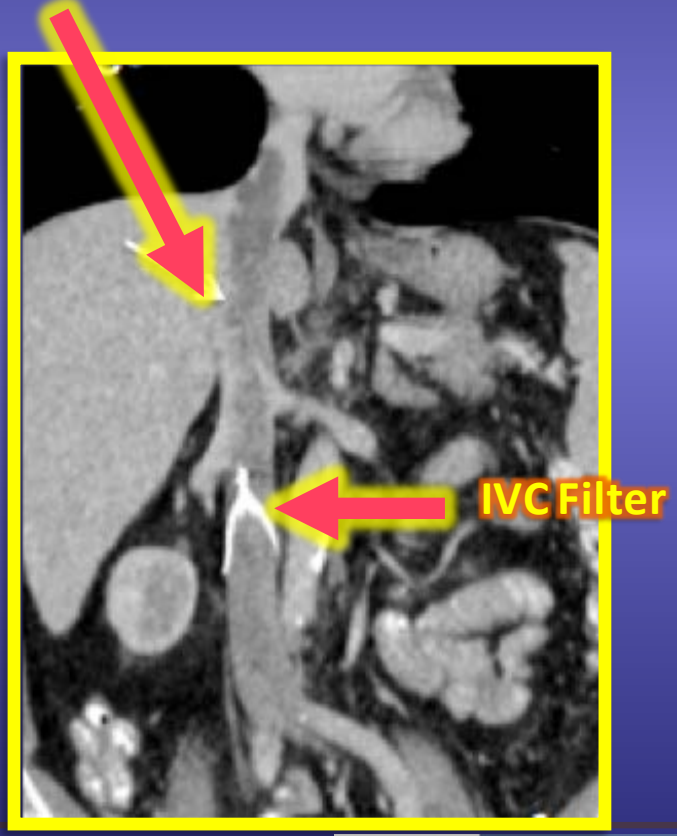
Access points are any combination of internal jugular (IJ) or common femoral vein (CFV). The above illustrates AngioVac (right IJ), reinfusion cannula (right CFV).

RA Thrombus

Right Atrial (RA) thrombus as indicated by the arrow

IVC Thrombus

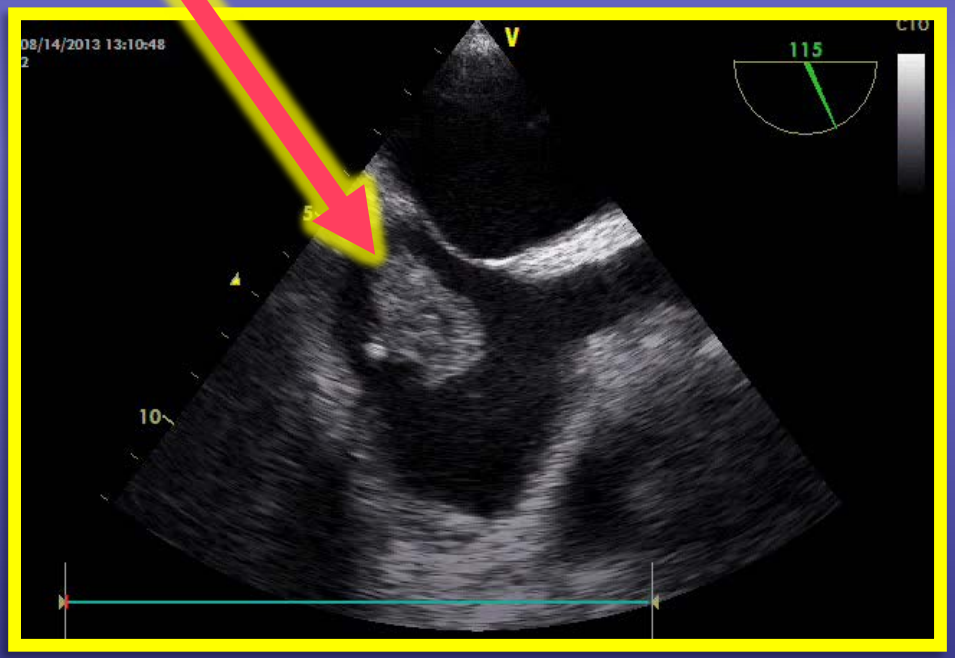
Extensive thrombus in the IVC both above and below the IVC filter



RA Thrombus Removed with AngioVac

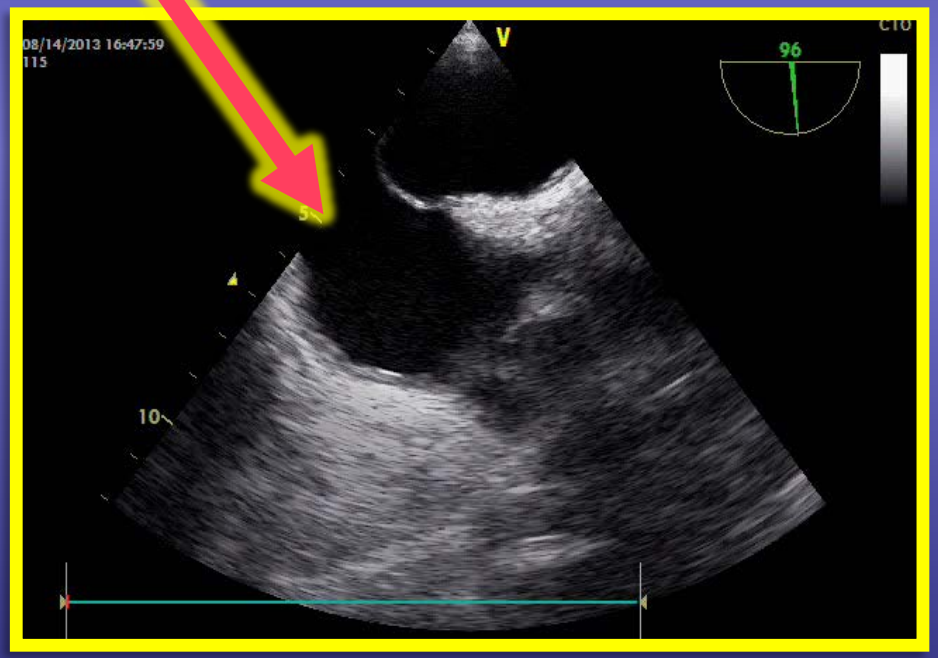
PRE AngioVac

Right Atrial (RA) thrombus as indicated by the arrow



POST AngioVac

Thrombus removed with AngioVac



Material Removed with AngioVac

Note the presence of both dark (fresh) thrombus…

…And the lighter, more chronic material

Evidence

CASE REPORT

Hybrid Minimally Invasive Extraction of Atrial Clot Avoids Redo Sternotomy in Jehovah's Witness

Jain Bhaskara Pillai, FRCS(CTh), FRCSC, Edward R. DeLaney, MS, CCP, Nirav C. Patel, MD, and Valavanur A. Subramanian, MD

Initial Use of a Large Bore Suction Thrombectomy Cannula for the Treament of Massive Inferior Vena Cava (IVC) and Iliofemoral Deep Venous Thrombosis (DVT)

Shirling Tsai*, Mark F. Conrad, Virendra Patel, Christopher J. Kwolek

Massachusetts General Hospital, Boston, MA

Vacuum-assisted Debulking of a Prohibitively Large Tricuspid Valve Vegetation Prior to Percutaneous Laser Lead Extraction

[1]JOHN MORIARTY, MD, [2]KOMAL PATEL, MD and [3]JASON BRADFIELD, MD

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Cardiovasc Intervent Radiol
DOI 10.1007/s00270-014-0953-7

CASE REPORT

AngioVac Aspiration for Paradoxical Emboli Protection through a Fenestrated Fontan During Central Venous Thrombus Manipulation

Ramsey Al-Hakim · Komal Patel · John M. Moriarty

Cardiovasc Intervent Radiol. 2014 Sep 5. [Epub ahead of print]

A Novel Technique for Endovascular Removal of Large Volume Right Atrial Tumor Thrombus.

Nickel B[1], McClure T, Moriarty J.

Catheter Cardiovasc Interv. 2014 Jun 27. doi: 10.1002/ccd.25583. [Epub ahead of print]

Thrombectomy using suction filtration and veno-venous bypass: Single center experience with a novel device.

Donaldson CW[1], Baker JN, Narayan RL, Provias TS, Rassi AN, Giri JS, Sakhuja R, Weinberg I, Jaff MR, Rosenfield KA.

Patient Selection Criteria

- When extracorporeal removal of thrombus should be considered:
  - Large thrombus burden not amenable to standard therapy – i.e. thrombolysis or rheolytic therapy (AngioJet)
  - Patient is contraindicated for thrombolytic therapy – i.e. recent surgery, history of stroke (CVA)
  - Patient is a high-risk or non-surgical candidate – decision made by the treating or consulting physician

FDA Status

- Original clearance March, 2009 (K091304, K092486).
- Subsequent clearance March 2014 (K133445).
- Intended for use as a venous drainage cannula during extracorporeal bypass for up to 6 hours and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours.
- It is for the cannula's expanded indication for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours that the request for ICD-10-PCS code is made.

Rationale for New ICD-10-PCS Code

- Procedure code needed to describe extracorporeal bypass with removal of thrombi and emboli from venous system
  - When used with prophylactic filtering during bypass surgery
  - When used as stand alone, destination procedure

ICD-10-PCS Code Options

Description	Comment
Do not create new codes for removal of thrombi and emboli that use cardiopulmonary bypass	This option does nothing to improve the fact that there are no ICD 9 or ICD 10 codes to describe this procedure
Create new codes to capture the prophylactic filtering during cardiopulmonary bypass in section 5A1 and removal of thrombus in the Medical Surgical tables 02C,05C and 06C	If the procedure to remove the thrombus can be coded independent of the prophylactic filtering this option is acceptable. If not, this option does not provide a means of identifying the destination stand alone removal of thrombus.
Create new codes in section X New Technology to identify removal of thrombus using the extracorporeal suction technique	We tentatively support this option but require more detail on this New Technology code section
Create new codes in section X New Technology to identify prophylactic filtering using the extracorporeal suction technique, during surgery that uses cardiopulmonary bypass	We do not support this option because it does not provide a means to code the procedure when performed as a destination therapy

Conclusion

- This is a novel approach to treat a serious condition
- Not currently coded, not currently forecast for coding under ICD-10-PCS
- Hospitals need code for identification of procedure:
  - Data Capture
  - Economic Analysis
  - Outcomes
  - Application for NTAP will be made
  - We request consideration of new code(s) for 2017 or as soon as code freeze is lifted

Questions/Answers/Discussion