Treating Venous Thromboembolism Without Lytic Medications?

Constantino S. Peña, FSIR, FSCCT, FAHA
Interventional Radiologist
Medical Director, Vascular Imaging
Miami Cardiac & Vascular Institute,
Radiology Associates of South Florida

Treating Venous Thromboembolism Without Lytic Medications?

Constantino S. Peña, FSIR, FSCCT, FAHA
Interventional Radiologist
Medical Director, Vascular Imaging
Miami Cardiac & Vascular Institute,
Radiology Associates of South Florida

Types of Percutaneous Thrombectomy Techniques

- Catheter-Directed Thrombolysis (CDT)
- Conventional vs. ultrasound-assisted
- Mechanical Techniques
  - Fragmentation (pigtail, balloons, rotating devices)
  - Rheolytic Thrombectomy
  - Vacuum Assisted Thrombectomy
  - Suction Devices
  - Extraction Devices

Why do we need Mechanical Techniques?

- Venous Thromboembolic (VTE) in patients with a contraindication/failure of thrombolysis
- Patients who do not have a contraindication but are high risk for thrombolysis
- Require a rapid response

Ideal Mechanical Device VTE

- Simple to use; easy set up
- Able to use with multiple passes without losing access
- Low Profile -- No puncture site complications
- Removes large amount of thrombus
- Minimize blood loss
- Does not traumatize vessel
- Easy to navigate through vessels/through heart safely
- Inexpensive
- Can be done with moderate sedation (no need for general anesthesia)
- Does not require long Fluoroscopy times (low radiation)
- Obtains consistent & reproducible results
- Does not require a large team

Mechanical Fragmentation: Limited Data

- Schmitz-Rode T (J Am Coll Cardiol. 2000;36(2):375)
  - Rapid and safe improvement of the hemodynamic compromise
  - Average recanalization of about 1/3
  - Useful especially in high-risk patients
  - Mortality was high at 20%
- Nakazawa (2008 B J Radiol)
  - Rapid and low cost
  - Widely available
  - May result in distal embolization and PAP
    - Then requiring additional technique in conjunction

Disclosures

- Advisory Board:
  - C. R. Bard
  - Boston Scientific
- Speaker/Teaching:
  - BTG
  - Cook Medical
  - Penumbra
  - Medtronic
  - C. R. Bard
Catheter-directed Therapy for the Treatment of Massive Pulmonary Embolism: Systematic Review and Meta-analysis of Modern Techniques

William T. Lee, MD, Michael K. Gould, MD, MS, John D. Lewis, MD, Jarrett K. Roachberg, MD, Daniel V. Tan, MD, PhD, and Lawrence V. Bodman, MD

J VIR Nov 2009

- 35 studies; 594 patients; Massive PE
- Cases primarily consisted:
  - pigtail catheter fragmentation (53%/ 16% in combination with other techniques)
  - rotation/aspiration thrombectomy
  - balloon fragmentation
  - rheolytic thrombectomy 11.4% - 68 pts
- Overall Pooled clinical success rate 86.5%

Mechanical Fragmentation:
- Pigtail catheter; (Balloons)

Historical Devices & Initial Iterations

Mechanical Fragmentation- Self Rotating Devices

Trerotola Device: Arrow Medical
Cleaner Device: Argon Medical

Off Label use of these devices.
Must be aware of potential damage to the pulmonary artery

Cleaner Device

Aspirex Catheter:
Archimedes screw aspirates thrombus into collection system

CDT – Techniques (Massive PE)
CDT – Techniques (Massive PE)

Helix Clot Buster

Impeller – Aspirates thrombus, fragments it (10um), then expels via sideports

Low profile 7Fr catheter with 75cm, 120cm lengths

Rheolytic Thrombectomy

• Rheolytic Thrombectomy (Angiojet system- Boston Scientific)

Rheolytic Thrombectomy Mechanism of Action

The Bernoulli Effect explains the relationship between velocity and pressure.

Pressurized saline jets travel backwards to create a low pressure zone causing a vacuum effect.

Cross-Stream® windows optimize the drawing action for more effective thrombus removal.

Thrombus is drawn into the catheter where it is fragmented by the jets and evacuated from the body.

JVIR Meta-Analysis: Catheter Directed Therapy for Massive PE

• AngioJet Rheolytic Thrombectomy (ART)

• 68 patients (11%)

• Major Complications = 19 (28%)

• Minor Complications = 27 (40%)

• 5 procedure-related deaths

• 19/25 (76%) of all major complications attributed to ART

• “...we believe the AngioJet device should not be used as the initial mechanical treatment in future CDT protocols for patients with acute massive PE.”

Kuo WT et al., JVIR 2009; 20:1431–1440

Suction Devices
Suction Devices

- Vacuum Assisted Thrombectomy
- Suction Cannula and Circuit
- Manual Aspiration and canister techniques
- Combinations

- Sheaths, catheters, hand suction, vacuum aided images

---

Manual Suction Devices

- Sheaths and catheters
- Limited by size of catheter/sheath lumen
- Limited by manual suction
- Likely only helpful for small amount of thrombus

---

Suction Catheter with Circuit: AngioVac/AngioDynamics VORTEX

- 22F device
- FDA approved for the removal of Undesirable Intravascular Material (UIM)
- Extracorporeal bypass circuit
- Can be inserted via 26F dry-seal sheath
- Suction to engage and remove clot
- Drainage, filtration and reinfusion of blood

---

Findings:

- Caval thrombosis to the level of the IVC filter
- Bilateral iliofemoral DVT
• Thrombus aspiration of IVC via the AngioVac catheter

Suction Catheter and Circuit system (Angio-Vac) Enhancement

Available with either a straight or 20 degree angled tip
Angled tip aids in navigation for potentially easier placement with the vasculature

• Y-Adapter with Touhy allows for over-the-wire capability the working side port and accommodates up to an 18F adjunctive device

Vacuum Assisted Thrombectomy

• Potential for single-setting management
• Small enough to make it an everyday procedure
• Large enough to handle clot burden
• Still have all other options open (Lysis, fragmentation), however, potential to reduce dosage
• Potential to reduce ICU and infusion costs

Indigo® System

Indication intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

Reinforced flexible catheters
Aspiration Catheters in 4 sizes – CAT-3, 5, 6 & 8
Continuous - 29mmHg vacuum
Clinical Presentation

- 45 y/o man who originally presented to the hospital with slurred speech and right sided weakness who was found to have a left basal ganglia hemorrhagic stroke.

Hospital Day #16

- Immediately after physical therapy, patient became diaphoretic, dyspneic with O2 saturation of 86% on room air, and systolic blood pressure dropped into the 80’s.
- Tachycardic with HR = 120’s
- O2 requirement continued to increase to 8L nonrebreather with O2 saturation of 94%.
- PF4 came back positive for heparin allergy

CTA

Initial Pulmonary Arteriogram

Initial Pulmonary Artery Pressure of 103 mmHg Systolic (Mean = 56 mmHg)

Vacuum assisted embolectomy

Patient had an immediate improvement in O2 saturation from 80% (intubated with 100% O2) to 94% (intubated with 100% O2)

Vacuum Assisted Embolectomy

Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA
Substantial Thrombus Removal

Post Procedure & FU
- Off all pressors by the end of the embolectomy procedure: (Epinephrine, Levophed, Vasopressin)
- PatiO2 saturation had increased to 100% from 80% initially; Extubated next day
- Heart rate from 120’s to 70’s
- PA pressure: from 103 mmHg systolic (mean = 56 mmHg) to 65 mmHg systolic (mean = 37 mmHg)
- 5 days post: HR 70s; normotensive; O2 sat 98% room air

CTA 48hrs post procedure

Thrombus Extraction Devices
- New technologies to capture and remove thrombus
- Example: FlowTriever from Inari

Patient with Submassive Pulmonary Embolism

Right Pulmonary Artery
Patient with Submassive Pulmonary Embolism

Announcement of FLARE Study

Inani Medical Announces IDE Approval To Study The FlowTriever System For The Treatment Of Pulmonary Embolism

FLARE: First-in-Human Trial to Investigate the Safety and Efficacy of the FlowTriever System in the Treatment of Submassive Pulmonary Embolism

Conclusion

Mechanical thrombectomy provides an alternative treatment strategy for the management of acute VTE

Catheter Directed Mechanical Therapy offers a more rapid therapeutic option

Data suggests procedures can be done safely

Many unknowns

No good prospective trials to date

All referenced studies consider short term outcomes

Ideal device does not exist

Extremely exciting frontier!