MASSIVE AND SUBMASSIVE PE: NEW TOOLS AND TECHNIQUES FOR CATHETER-DIRECTED AND PHARMACOMECHANICAL THERAPY

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Rationale for Catheter Directed Interventions (CDI)

• Increase number of patients that can be treated (massive and submassive)
• Improve safety profile
• Impact and lower M&M
• Other Invasive options are not widely available and carry a high risk


Catheter-Directed Therapy (CDT)

• Catheter directed thrombolysis
  • Convolutional; EKOS
  • Rheolytic Thrombectomy
  • Angiojet
  • Fragmentation
  • Pigtail, Cleaner
  • Aspiration and Suction
    • Syringe Devices, Penumbra, Angiovac
  • Clot entrapment and removal
    • Inari flowtriever
  • Pharmacomechanical combinations

Catheter-Directed Thrombolysis

• Multiple series have shown success in treating patients with acute PE with & without mechanical techniques
• Proven concept in the arterial and venous circulation: Embed catheter in clot –facilitate lytic efficacy

Disclosures

Consultant and MAB:
Penumbra
Gore
Endoshape
Scientia
Cordis
Abbott
MC 10

Royalties:
Penumbra
Stock:
Reverse Medical
Xablecath
Bridgewater

JVIR Meta-Analysis; Catheter Directed Therapy for Massive PE

• Meta-analysis of 35 studies with 594 patients treated for PE by catheter-based techniques
• Cases primarily consisted:
  • pigtail catheter fragmentation
  • rotation/aspiration thrombectomy
  • balloon fragmentation
  • rheolytic thrombectomy
• Overall clinical success rate 86.5%
  • 7.9% minor and 2.4% major procedural complications
  • bradycardia, heart blocks, hemoglobinuria, temporary renal insufficiency, hemoptysis, hemorrhage, product-related death

William T. Kuo, MD, Michael K. Gould, MD, MS, John D. Louie, MD, Jarrett K. Rosenberg, PhD, Daniel Y. Soo, MD, PhD, and Lawrence V. Hofmann, MD. JVIR 2009; 20:1431–1440
The PERFECT Multicenter Prospective Registry: fragmentation, embolectomy and catheter thrombolysis for acute PE

- N=101 with massive (N=28) or submassive (N=73) acute PE
- CD mechanical or pharmacomechanical thrombectomy/lysis
- Patient with a contraindication to or failure of fibrinolytic therapy
- MPE clinical success → 85.7% (24/28)
- SMPE clinical success → 97.3% (71/73)
- Mean PAP 51.2 ± 14.1 mmHg → 37.2 ± 15.8 mmHg, p<0.0001
- Improvement in RV strain by echo @ f/u → 89.1% (57/64)
- 2 in-hospital deaths; no major procedure-related complications; 2 → mild hemoptysis; 1 → mild cor pulmonale @ f/u in MPE pts

Mechanical Fragmentation

Rheolytic Thrombectomy

- Rheolytic Thrombectomy (Boston Scientific Angiojet)

Helix Device


- 7F device FDA-approved for dialysis grafts & fistulas
- Propelled by an air turbine @ 50 PSI & rotates @ 150,000 rpm
- Used with an 8-10 F guide sheath or 10F guide catheter
- Small case series
- Can see hemolysis and hemoptysis

Arrow-Trerotola Device

- FDA-approved for dialysis grafts & fistulas
- With or without a guidewire;
- 9/15 mm basket rotates @ 3000 rpm
- Use with an 8F guide sheath
- Fragments & redistributes clot
- Concern for vascular wall injury
- Case reports

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Cleaner Device

**Inari FlowTriever System**

- FDA-approved Feb. 2015 for removing emboli in the peripheral vasculature.
- Flexible 20F guide catheter with a centering balloon – advanced over an 0.035” guidewire.
- Self-expanding nitinol framework – designed to engage, disrupt and remove emboli.
- Retraction Aspirator provides a vacuum for aspiration during clot retrieval.

**Inari FlowTriever Device Insertion**

- FlowTriever is in collapsed state inside the delivery catheter
- FlowTriever delivery catheter advanced over guidewire and through guide catheter through the embolus

**FlowTriever Fully Expanded**

- FlowTriever fully self-expanded inside of the embolus as delivery catheter is retracted. Thrombus is entrapped within the wire mesh.

**Suction Devices**

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

- Inserted collapsed
- Expands upon removal of the dilator
**Massive PE-CDT**


- N = 14 patients; 15 treatments
- Massive PE +/- IVC or right heart thrombus
- AngioVac (FDA-approved 2009)
- Extra-corporeal circuit; TEE monitoring
  - 18F suction catheter via a 26F Gore Dry Seal sheath over a 0.035" stiff guidewire
  - 17F or 19F re-infusion catheter
- Need a perfusionist for ECMO; heparinized
- Flow rates up to 4L/min – centrifugal pump

**Penumbra Indigo System**

- Arterial and venous indication
- Limited experience with PE
- Mechanical clot extraction
- Continuous vacuum aspiration

**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/USAT), however, potential to reduce dosage

**CASE EXAMPLE**

Initial Pulmonary Arteriogram
Vacuum Assisted Embolectomy

CTA 48hrs post procedure

Pre  Post

Conclusion

- CDI provides an alternative treatment strategy for the management of acute massive and submassive PE and is safer than systemic lysis
- Catheter Directed Therapy offers a more rapid therapeutic option
- Good data suggests procedures can be done safely
- Some mechanical devices can be life saving in massive PE and can rapidly downstage severity of disease
- Many unknowns
  - All referenced studies consider short term outcomes
Massive and Submassive PE (Catheter Directed Thrombolysis)

Massive PE:
CDT or surgical embolectomy can be useful in patients who have:
- Contraindications to or failed thrombolysis
- Shock that is likely to cause death (before IV t-PA can work)
- If appropriate expertise and resources are available (Level IIC).

Submassive PE:
No formal ACCP recommendation for CDT and submassive PE

AHA says CDT may be considered if worsening hemodynamic instability, severe RV dysfunction or major myonecrosis (Level IIIC).

AHA: CDT or Surgical Thrombectomy not recommended for submassive PE with minor RV dysfunction, minor myonecrosis and no clinical worsening (Grade IIIC).