Endovascular Therapy for Acute Pulmonary Embolism

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Disclosures:
In the past 12 months, my spouse or myself have engaged in financial relationships as follows:

- Consultant:
  - Boston Scientific, Medtronic, Abbott Vascular
- Advisory Board: Boston Scientific, Medtronic
- Clinical Events Committee: INTACT Vascular, Shockwave
- Speakers Bureau:
  - Boston Scientific, Penumbra, Medtronic, Cook, Endologix
- Research Support
  - Philips Healthcare, Spectranetics, Terumo, BTG, Boston Scientific

Catheter-Based Thrombus Removal for the Initial Treatment of PE

24. In patients with acute PE who are treated with a thrombolytic agent, we suggest systemic thrombolytic therapy using a peripheral vein over CDT (GRADE 2C).

Remarks: Patients who have a higher risk of bleeding with systemic thrombolytic therapy and who have access to the expertise and resources required to do CDT are likely to choose CDT over systemic thrombolytic therapy.

25. In patients with acute PE associated with hypotension and who have (i) a high bleeding risk, (ii) failed systemic thrombolysis, or (iii) shock that is likely to cause death before systemic thrombolysis can take effect (eg, within hours), if appropriate expertise and resources are available, we suggest catheter-assisted thrombus removal over no such intervention (GRADE 2C).

Remarks: Catheter-assisted thrombus removal refers to mechanical interventions, with or without catheter directed thrombolysis.

Mechanical Thrombectomy

What is the Rationale for Pharmacomechanical Thrombectomy for Acute Pulmonary Embolism?

- What if there was a single session/single device therapy for acute PE that could:
  - Avoid high dose lytic infusion
  - Avoid overnight lytic infusion
  - Acutely lower PA pressure
  - Acutely improve RV function
  - Rapidly remove PA thrombus/clot
  - Excellent safety profile

Would that change practice?

What if.....

- This concept had largely been realized for:
  - STEMI
  - Stroke
  - Acute DVT
  - Why not Pulmonary Embolism?
Therapeutic Alternatives in Acute PE

- **Anticoagulation**
  - Unfractionated Heparin
  - Continuous Intravenous
  - Full-Dose Subcutaneous
  - Low-Molecular-Weight Heparin
  - Synthetic Pentasaccharide
  - Direct Thrombin Inhibitors
  - Xa Antagonist
  - Warfarin

- **Thrombolytic Therapy**
  - Systemic (full or half-dose)
  - Catheter Directed (CDT)
  - Pharmacomechanical Catheter-Directed Thrombolysis (P-CDT)

- **Mechanical**
  - Surgical Thrombectomy
  - Thrombo-aspiration
  - Endovascular
  - Adjunct Rx
    - Extracorporeal support (ECMO)
    - RVAD
    - IVC Filter

**Pulmonary Embolectomy**

**Embolic Material**

**WHAT IS THE ROLE OF THROMBOASPIRATION?**

- Potential to debulk Acute Pulmonary Embolism in intermediate risk PE?
  - Reduce/eliminate the need for overnight lysis
- Potential to replace surgical embolectomy in high risk patients?
  - Reduce the morbidity of open surgery
  - Expand thrombo-embolectomy to patients considered high-risk?
AngioVac® Basics

CASE: Early Experience with AngioVac Aspiration in the Pulmonary Arteries

Ramsey Al-Hakim, MD, Jonathan Park, MD, Anahuman Bansal, MD, Scott Genshaft, MD, and John M. Moriarty, MD

Abstract

FIT case: First case in which the AngioVac® aspiration catheter was used for the management of pulmonary embolism (PE) was successfully completed. Four cases (80%) were performed with success, and two (40%) were technically successful (ClinicalTrials.gov identifier: NCT03704707). A total of 24 patients (30%) were successfully treated with a mean of 5 days after the procedure, including one death related to right ventricular failure. Although the AngioVac® aspiration catheter has shown promise in a variety of clinical situations, early experience in the pulmonary arteries has been limited. Further study and careful patient selection are required.

"...early experience in the pulmonary arteries has shown limited success, and further study and careful patient selection are required."

TABLE 2: Pre- and Intra-procedural Variables

<table>
<thead>
<tr>
<th>Indication</th>
<th>Pre-intraprocedural Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep venous thrombosis involving vena cava</td>
<td>11 (7%)</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>5 (33%)</td>
</tr>
<tr>
<td>Involving pulmonary trunk or main pulmonary artery</td>
<td>3 (20%)</td>
</tr>
<tr>
<td>Right atrial mass</td>
<td>11 (73%)</td>
</tr>
<tr>
<td>Right ventricular mass</td>
<td>3 (21%)</td>
</tr>
<tr>
<td>Catheter-associated thrombus</td>
<td>2 (13%)</td>
</tr>
</tbody>
</table>

Case successfully completed at St. Luke’s 2017 for “Clot In Transit”
The FlowTriever System consists of the Flow Restoration Catheter, Aspiration Guide Catheter and Retraction Aspirator Device. The FlowTriever System is indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion and/or aspiration of contrast media and other fluids into or from a blood vessel.

The FlowTriever System is intended for use in the peripheral vasculature system.

**Inari FlowTriever™ Infusion Aspiration System**

20 French

**FlowTriever Versatility and Compliance**

Disk nominally compressed when deployed in “in range” vessel

Disk uncompressed

Disk over-compressed when deployed in an undersized vessel

**Percutaneous Pulmonary Embolus Mechanical Thrombectomy**

Deepali Nivas Tukaye, MBBS, FAAC, Michael McNeill, MB, Henry Liberman, MD

**FlowTriever Pulmonary Embolectomy Clinical Study**

**FLARE Study (NCT02692586)**

Prospective, single-arm, controlled, multicenter study

**Study Design**

- Up to 158 patients / 20 sites
- Age ≥ 18 and ≤ 75 years
- Acute PE < 14 days
- No lytic therapy 30 days prior to treatment
- Upcoming procedure not required but allowed

**Study Endpoints**

- Safety: Major Adverse Events
- Effectiveness: Reduction in RV/LV ratio from baseline to 48 hours

**Enrollment Status**

- Open clinical sites: 3
- Patients enrolled: 4

**Completed enrollment**

**FDA Clears FlowTriever, First Device to Pull Blood Clots from Lungs**

May 15, 2018
Penumbra CAT8

MECHANICAL CLOT ENGAGEMENT

8 French

Large Lumen Aspiration

TIP DIRECTIONALITY

Penumbra CAT8 Thromboaspiration system

Penumbra CAT8 Thromboaspiration system

Before

After

Horacio D’Agostino and Chaitanya Ahuja, M.D.
LSU Shreveport, LA

Penumbra

Continuous Aspiration Mechanical Thrombectomy for the Management of Submassive Pulmonary Embolism: A Single-Center Experience

Husayen A. Alshibli, MD, Joel Blodgett, MS, Patricia M. Philips, MD, and James T. Rosenthal, MD

Welcome! A message from Dr. Abhilash 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 Penumbra® Thromboaspiration System in Acute Submassive Pulmonary Embolism.” It is my honor to lead this trial along with an accomplished Steering Committee. Drs. Jim Rosenthal, Veerag, and Jim Harnett. We are also fortunate to have advanced PE experts on both the Clinical Events and Data Safety Monitoring Board (DSMB) Committees to ensure the safety and efficacy of the trial.
AngioJet® System Components

- AngioJet Catheters
- AngioJet Console

Published data

- Early and Long-Term Clinical Results of AngioJet Rheolytic Thrombectomy in Patients With Acute Pulmonary Embolism
- Use of Rheolytic Thrombectomy in Treatment of Acute Mass Pulmonary Embolism

Attributes/Characteristics

- ASPIRATION
- STENT-TRIEVER
- VEIN-VEIN BYPASS
- LARGE BORE
- SMALL BORE

In summary

- Numerous Devices currently exist for aspiration of pulmonary embolism
- All devices have been used clinically and have demonstrated feasibility at being able to be delivered to the pulmonary circulation and aspirate pulmonary embolus
- At present, there is no consensus regarding appropriate use and which device is most appropriate for which clinical presentation
- Prospective studies are desperately needed to demonstrate safety and clinical benefit
- We need a single session therapy------there is a lot of work yet to do