Which Mechanical Device To Use For PE

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Disclosures

- Penumbra: consultant and stockholder
- Endologix: speaker
- Sirtex: speaker

BACKROUND

- Mechanical devices represent a new treatment option for massive and sub-massive PE
- Data does exist to support their use
- These devices and techniques are still in their infancy
- Mechanical devices provide an alternative treatment option for patients who are not good lytic candidates
- Allows a previously untreated subset of patients to be treated

Ideal Mechanical Device For PE

- Simple to use; easy set up
- Able to use with multiple passes without losing access to PA
- Low Profile — No puncture site complications
- Removes large amount of thrombus
- Minimize blood loss
- Doesn’t traumatize vessel
- Crosses through heart safely
- Inexpensive
- Can be done with moderate sedation (no need for general anesthesia)
- Doesn’t require long fluoros times (low radiation)
- Obtains consistent & reproducible results
- Can be done by single specialty or single physician

Therapeutic Options?

55 yr male recovering from recent stroke with high risk submassive PE

JVIR Meta-Analysis

- Meta-analysis of 35 studies with 594 patients treated for PE by catheter-based techniques
- Cases primarily consisted of:
  - 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
  - bradyarrhythmia, heart block, hemoglobinuria, temporary renal insufficiency, hemoptysis, hemorrhage, product-related deaths

William T. Kuo, MD, Michael K. Gould, MD, MS, John D. Louie, MD, Jerzy K. Rosenberg, PhD, Daniel Y. Sun, MD, PhD, and Lawrence V. Hofmann, MD; JVIR 2009; 20:1431–1440
JVIR Meta-Analysis

- AngioJet Rheolytic Thrombectomy (ART)
- 68 patients (11%)
  - Minor Complications = 27 (40%)
  - Major Complications = 19 (28%)
  - 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.”
- FDA has issued a black box warning for use of AngioJet in acute massive PE

William T. Kuo, MD, Michael K. Gould, MD, MS, John D. Louie, MD, Jaret R. Brownberg, PhD, Daniel Y. Sue, MD, PhD, and Lawrence V. Holman, MD; JVIR 2009; 20:1431–1440

FLARE FlowTriever® Clinical Study

Investigational trial for patients with acute intermediate-risk PE were treated with the FlowTriever Retrieval/Aspiration System (Inari Medical, Irvine, California)

Endpoints: Effectiveness in reducing RV/LV ratio at 48 hours and safety in minimizing major adverse event rate

Over-the-wire stent retriever that uses both mechanical and aspiration mechanisms

106 patients, 18 sites

Results

- Effectiveness:
  0.38 (25.1%) reduction in RV/LV ratio from 1.53 at baseline to 1.15 (p<0.0001)
  Only 2 of 106 patients were given thrombolytics

- Safety:
  - 3.8% Major Adverse Events (4/106)

- Aspiration guide catheter duration
  - 57.1 minutes

FlowTriever Fully Expanded

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

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.

Right Pulmonary Artery

Patient with Submassive Pulmonary Embolism
AngioVac® by AngioDynamics

- Cardiopulmonary veno-venous bypass circuit indicated for the removal of fresh, soft clot
- Alternative to anticoagulation and thrombolytic therapy.

Technical difficulties in limited maneuverability of device from stiffness and restricted steerability.

Bypass not recommended for patients with hemodynamic instability.

Findings:
- Caval thrombosis to the level of the IVC filter
- Bilateral iliofemoral DVT

• AngioVac device advanced through 26 Fr DrySeal sheath placed via right IJV
• Pt is on extracorporeal bypass with reinfusion cannula in the left IJV

Perfusionist - Need feedback regarding flow rates

Final Venogram

Outcome
- Significant thrombus removed
- Minimal blood loss
- Clinical resolution of symptoms
Early Experience with AngioVac Aspiration in the Pulmonary Arteries
Ramsey Al-Hakim, MD, Jonathan Park, MD, Anshuman Bansal, MD, Scott Genshaft, MD, and John M. Moriarty, MD

ABSTRACT

Five consecutive cases in which the AngioVac aspiration system was used for the management of pulmonary embolism (PE) were retrospectively reviewed. Four cases (80%) presented with acute PE; and one (20%) was incidentally discovered in a patient who presented with atrial fibrillation (AF). The pronounced clinical improvement after AngioVac aspiration was deemed to be due to the combination of high aspiration pressure, rapid aspiration rate, and large aspiration volume. Although the AngioVac aspiration system has shown clinical promise in a variety of clinical applications, only experience in the pulmonary arteries has shown limited success, and further study and careful selection are required.

J Vasc Interv Radiol 2018; 27:730–734
http://dx.doi.org/10.1016/j.jvir.2016.01.012

Constraints with Syringe Based Aspiration

• Aspiration:
  – Inefficiency with syringe based aspiration

Interventional Therapies for Acute Pulmonary Embolism: Current Status and Principles for the Development of Novel Evidence: A Scientific Statement From the American Heart Association

- Catheter size:
  – Reports of hemodynamic and respiratory decompensation
  – Right sided heart and PA injury

Interventional Therapies for Acute Pulmonary Embolism: Current Status and Principles for the Development of Novel Evidence: A Scientific Statement From the American Heart Association

- Aspiration:
  – Inefficiency with syringe based aspiration

Interventional Therapies for Acute Pulmonary Embolism: Current Status and Principles for the Development of Novel Evidence: A Scientific Statement From the American Heart Association

- Aspiration:
  – Inefficiency with syringe based aspiration

- Catheter sizes, shapes and aspiration power
A Prospective, Multicenter Trial to Evaluate the Safety and Efficacy of the Indigo® Aspiration System in Acute Pulmonary Embolism

**Objectives:** Determine the safety and efficacy of the Indigo® Aspiration System for aspiration mechanical thrombectomy in patients with acute pulmonary embolism (PE)

**Inclusion Criteria**
Clinical signs and symptoms consistent with acute PE with duration of 14 days or less; Evidence of PE must be from CTA; Systolic BP >90 mmHg with evidence of dilated RV with an RV/LV ratio >0.9; Patient is 18 years of age or older

### Primary Endpoints
- Change in RV/LV ratio from baseline to 48 hours assessed by CTA
- Major Adverse Events, a composite of:
  - Device-related death within 48 hours
  - Major bleeding within 48 hours
  - Device-related SAEs within 48 hours, a composite of:
    - Clinical deterioration
    - Pulmonary vascular injury
    - Cardiac injury

### Procedural Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Patients (N=119)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedation, % (n/N)</td>
<td>97.5% (116/119)</td>
</tr>
<tr>
<td>Conscious</td>
<td>97.5% (116/119)</td>
</tr>
<tr>
<td>Access Site, % (n/N)</td>
<td>85.7% (102/119)</td>
</tr>
<tr>
<td>Femoral</td>
<td>85.7% (102/119)</td>
</tr>
<tr>
<td>Right internal jugular</td>
<td>14.3% (17/119)</td>
</tr>
<tr>
<td>Intraprocedural tPA, % (n/N)</td>
<td>1.7% (2/119)</td>
</tr>
<tr>
<td>Procedure Time (Minutes), Median [IQR]</td>
<td>66.0 [46.0, 94.0]</td>
</tr>
<tr>
<td>First Indigo Device Insertion to Last Device Removal (Minutes), Median [IQR]</td>
<td>37.0 [23.5, 60.0]</td>
</tr>
<tr>
<td>Hospital ICU Length of Stay (days), Median [IQR]</td>
<td>1.0 [1.0, 2.0]</td>
</tr>
</tbody>
</table>

### Primary Efficacy Endpoint (ITT)
- Reduction of 0.43 (95% CI 0.38-0.47) 27.3% Reduction

### Systolic Pulmonary Artery Pressure
- Reduction of 4.7 mmHg (95% CI 3.0-6.4)

### Primary Safety Endpoint
- Major Adverse Events within 48 Hours (CEC) 1.7% (2/119)*

*2 patients experienced 3 events (Grom access site bleeding, Hemoptysis, death due to Sustained Ventricular Tachycardia post-procedure)
Expansion of the basket:

- Immediately restores blood flow
- Activates patient’s own endogenous lytics
- Infusion of fluids enables synergistic lysis

Thrombolex

- The BASHIR™ Endovascular Catheter is a device intended for the localized infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

French size: 7 F (2.3 mm)
Effective length: 92.5 cm (36.44 in)
Infusion segment length: 12.50 cm (4.92 in)
Expanded infusion segment: 2.3 mm (.09 in) diameter ranges to 45 mm (1.57 in)

Continuous Aspiration Mechanical Thromboectomy for the Management of Submassive Pulmonary Embolism: A Single-Center Experience
Ramsey Al-Hakim, MD, Alok Bhatt, MD, and James F. Benenati, MD

Abstract

The BASHIR Mechanical Thromboectomy System (Rom Medical Inc., Alameda, California) was used to treat 12 patients with submassive pulmonary embolism (SPE). A comprehensive analysis revealed significant clinical benefits with no procedural complications. Complete thrombus retrieval was achieved in 9/12 patients, with a significant reduction in D-dimer levels (1.44 ng/mL; P < 0.01), and overall mortality rates in the intervention group were significantly lower than in the control group. This study supports the use of mechanical thrombectomy as a viable option for the management of SPE.

J Vasc Interv Radiol 2017; 28:1348–1352
http://dx.doi.org/10.1016/j.jvir.2017.06.025
Limitations with Current Treatment Options

- Inefficient in clot removal and dissolution
- Maude database reports of adverse events

### Comparison of Current Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Primary Efficacy (change in RV/LV ratio at 48 hrs)</th>
<th>Primary Safety</th>
<th>Device Time</th>
<th>All Cause Mortality (30 d)</th>
<th>Major Bleeding Within 48 hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXTRACT II</td>
<td>0.45; p &lt;0.0001</td>
<td>1.7%</td>
<td>37 min</td>
<td>2.5%</td>
<td>1.0%</td>
</tr>
<tr>
<td>SEA TTLE II</td>
<td>0.42; p &lt;0.0001</td>
<td>10%</td>
<td>12-24 hrs</td>
<td>2.7%</td>
<td>3.8%</td>
</tr>
<tr>
<td>FLARE</td>
<td>0.38; p &lt;0.0001</td>
<td>10%</td>
<td>57 min</td>
<td>1.5%</td>
<td>3.4%</td>
</tr>
</tbody>
</table>

### Ideal Mechanical Device for PE

<table>
<thead>
<tr>
<th>Device</th>
<th>Size</th>
<th>Blood loss</th>
<th>Heart Cath</th>
<th>Ease of use</th>
<th>Cost</th>
<th>Clot removal</th>
<th>Safety</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Row trower</td>
<td>20+ f</td>
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<td>pulmonary</td>
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<td>Angio vac</td>
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<td>+++</td>
<td>+</td>
<td>+SSSS</td>
<td>++++</td>
<td>+</td>
<td>vascular</td>
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</tr>
<tr>
<td>Indigo</td>
<td>5-10f</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>S</td>
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<td>++</td>
<td>Vascularity angiography trial compared</td>
</tr>
<tr>
<td>AngiJet</td>
<td>W</td>
<td>++</td>
<td>+</td>
<td>+++</td>
<td>SS</td>
<td>++</td>
<td>++</td>
<td>vascular</td>
</tr>
</tbody>
</table>

### Conclusion

- High risk sub massive PE and massive PE can be treated with more than anticoagulation
- Thrombectomy is a viable option for patients who may be at increased risk for thrombolytic therapy
- Thrombectomy may be a viable option even when thrombolytic is indicated in order to stabilize or downstage patients
- Choices of device depends on trade offs for size, safety and volume of clot removed
- Newer iterations and newer devices will drive this forward