Vortex Strategy for Massive PE

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Faculty Disclosures

- I disclose the following financial relationships:
  - None

AHA Guidelines

Circulation 2011;123:1788-1830

High Risk PE

- 5% of patients
- Hypotension, shock
- 15% - 50% mortality
- Systemic thrombolysis recommended (1B)
  - Peripheral intravenous
  - Short infusion
- Less than half treated
  - 50% with contraindications
  - Environmental factors

CT Scan for Initial Diagnosis

CIT July/August 2014

PERT Team

Hospital Practice 2016;42:1,31-37
Guidelines for Surgical Embolectomy

- Massive PE and contraindications to fibrinolysis (Class IIa; Level of Evidence C).
- Massive PE who remain unstable after receiving fibrinolysis (Class IIa; Level of Evidence C).
- May be considered for submassive acute PE judged to have clinical evidence of adverse prognosis (new hemodynamic instability, worsening respiratory failure, severe RV dysfunction, or major myocardial necrosis) (Class IIb; Level of Evidence C).
- Not recommended for patients with low-risk PE or submassive acute PE with minor RV dysfunction, minor myocardial necrosis, and no clinical worsening (Class III; Level of Evidence C).

Indications for Transcatheter Procedures

- Alternative to lysis when contraindications or when emergency surgery is unavailable or contraindicated
- Failure of lysis to improve hemodynamics in acute setting
- Hybrid therapy includes both catheter-based clot fragmentation and local thrombolysis

Unresolved Problems

We lack good alternatives for the treatment of patients with massive PE/IVC and Iliofemoral DVT:

- Poor candidates for open pulmonary thromboembolectomy
- Who have contraindications to thrombolysis
- Who require urgent pharmacologic and mechanical thrombolysis due to phlegmasia/hemodynamic instability

Vortex Angiovac

- Large bore device for the removal of Undesirable Intravascular Material (UIM), fresh, soft thrombi, emboli, vegetation
- Emboli Trap
- Suction to engage and remove UIM
- Reinfusion of shed blood
AngioVac Cannula Generation 3

- Open or Percutaneous
- ID (20.2 Fr) Large bore OD (23Fr)
- Tracks over a .035" guidewire, kink resistant, collapse resistant
- Self-expanding funnel shaped tip
  - Remotely deployable
  - Engage and conform UIM
  - Maintain local blood flow
  - Prevent vessel collapse

AngioVac Initial Experience

<table>
<thead>
<tr>
<th>Patients</th>
<th>31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>52</td>
</tr>
<tr>
<td>Gender</td>
<td>55% Male, 45% Female</td>
</tr>
<tr>
<td>Primary Location of UIM™</td>
<td>RA 30%, PA 32%, IVC 29%</td>
</tr>
<tr>
<td>Material Aspirated</td>
<td>87%</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>75%</td>
</tr>
<tr>
<td>Conversion to Open</td>
<td>10%</td>
</tr>
<tr>
<td>Complications</td>
<td>6.4%</td>
</tr>
</tbody>
</table>
  - 1 Tamponade
  - 1 Urgent PE/TVP under CPB |
| Procedural Mortality | 3.2% |
  - 1 RA Perforation |
VORTEX ASPIRATION THROMBECTOMY
SVC→RA

- Percutaneous placement of a 24 F Vortex (inflow) cannula via right common femoral vein.
- Percutaneous placement of a 17F (outflow) cannula in left CFV
- TEE guided VORTEX aspiration (suction thrombectomy) of mobile mass in RA and SVC

PA Angiogram

VORTEX ASPIRATION THROMBECTOMY
RIGHT MAIN PA
### AngioVac® Clinical Experience (2009-2012)

<table>
<thead>
<tr>
<th>Patients</th>
<th>375</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>54</td>
</tr>
<tr>
<td>Gender</td>
<td>52% Male 48% Female</td>
</tr>
<tr>
<td>Primary Location of UIM™ PA</td>
<td>20%</td>
</tr>
<tr>
<td>RA</td>
<td>35%</td>
</tr>
<tr>
<td>Iliofem/IVC</td>
<td>43%</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
</tr>
<tr>
<td>Material Aspirated</td>
<td>97%</td>
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<tr>
<td>Procedural Success</td>
<td>80% - 90%</td>
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<tr>
<td>Conversion to Open</td>
<td>1.0%</td>
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<tr>
<td>Complications</td>
<td>0.6%</td>
</tr>
<tr>
<td></td>
<td>2 Tamponade*</td>
</tr>
<tr>
<td></td>
<td>*wire perfs prior to AngioVac insertion</td>
</tr>
<tr>
<td>Procedural Mortality</td>
<td>&lt; 1 %</td>
</tr>
<tr>
<td></td>
<td>1 RA Perforation</td>
</tr>
</tbody>
</table>

### Conclusions

- This device represents a novel option for the management of patients with extensive IVC and iliac vein thrombosis, pulmonary emboli, atrial thrombus, particularly those with contra-indications to thrombolysis
- The Vortex AngioVac represents a safe and effective device for the treatment of acute IVC and iliac vein thrombosis
- RAPID registry - The Rapid database will evaluate patterns of use, safety and effectiveness data for patients treated with the AngioVac system to remove fresh, soft thrombi or emboli

### Thank You