The Vortex Strategy for Management of Massive PE

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Faculty Disclosures

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VTE Epidemiology

- Common
  - PE 300-600K cases/year
  - 150 K deaths/year
  - DVT 1-2M cases/year
- Increasing Incidence
  - Better diagnosis (CT’s in ED)
  - Age dependent

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

Intermediate Risk PE

- 40-60% patients
- Stable patient impaired RV function
  - Imaging
  - Biochemical marker
  - 3-15% mortality
- 10% progress to hemodynamic compromise
- Thrombolysis recommended selected patients (2B)

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
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).

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)
- Emboli Trap
- Suction to engage and remove UIM
- Reinfusion of shed blood

AngioVac Cannula

- Open or Percutaneous
- Large bore (22F)
- Tracks over a .035" guidewire, kink resistant, collapse resistant
- Specialized funnel shaped tip
  - Remotely deployable
  - Engage and conform UIM
  - Maintain local blood flow
  - Prevent vessel collapse

AngioVac Circuit

- Simple partial venous bypass circuit without reservoir
- Create maximal safe suction levels
- Manage large UIM/blood volume
- Inline filter
  - Transparent provide immediate visual feedback
- Real-time reinfusion of shed blood
  - Ensure hemodynamic stability
- Large safety operating window
  - Minimal risk air embolism
  - Pre-load and after-load independent
• Percutaneous placement of a 22 F Vortex catheter right CFV & 17F (outflow) cannula left CFV
• TEE guided VORTEX aspiration (suction thrombectomy) of mobile mass in RA
• Attempted aspiration of PA clot
• IVC filter

Pre
Post

Course continued
• Large mobile thrombus in SVC extending into RA with evidence of distal embolization into right main PA
• Likely catheter-associated
• Poor candidate for lysis or surgical removal in the OR
• Percutaneous approach considered
VOXET 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.

VOXET ASPIRATION THROMBECTOMY RIGHT MAIN PA

AngioVac® Clinical Experience (2009-2012)

- Patients: 375
- Mean Age: 54
- Gender: 52% Male, 48% Female
- Primary Location of UIM™: PA 20%, RA 35%, Iliofem/IVC 43%, Other 2%
- Material Aspirated: 97%
- Procedural Success: 80% - 90%
- Conversion to Open: 1.0%
- Complications: 0.6%
  - 2 Tamponade*
  - wire perforation prior to AngioVac insertion
- Procedural Mortality: < 1 %
  - 1 RA Perforation

PA Angiogram
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.