FlowTriever embolectomy for acute pulmonary embolism

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High-risk Pulmonary Embolism

• Mortality in high-risk PE is >25%, largely unchanged over 20 years
  • ICOPER 1999: 52% 90d mortality\(^1\)
  • MGH PERT 2018: 41% 90d mortality\(^2\)
• Mortality is driven by RV failure\(^3\):
  • Acute elevations in RV afterload from PE are not well-tolerated by the RV
  • RV failure is what leads to the obstructive shock death spiral...
• Unpredictable Need For Accelerated Care in Submassive elevated risk

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\(^1\)Kucher et al. Circulation. 2006;113
\(^2\)Secemky et al. Am J Med. 2018;131
\(^3\)Piazza and Goldhaber. Circulation. 2010; 122:1124
Early Data: Normotensive Patients are Often Sicker Than They Appear?

- With hemodynamic assessment, 43% of normotensive sub-massive PE patients were found to be in cardiogenic shock (C.I. < 2.2 l/min)

- Should we be doing more hemodynamic assessments in the catheterization lab?

Why A Mechanical Device for Acute PE

? Mimic the Success of Surgical Embolectomy Without a Sternotomy
Surgical Embolectomy

**TABLE 2. Indications for surgical embolectomy (n = 47)**

<table>
<thead>
<tr>
<th>Indication</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contraindications to thrombolysis</td>
<td>21 (45%)</td>
</tr>
<tr>
<td>Recent surgical intervention</td>
<td>10 (21%)</td>
</tr>
<tr>
<td>Active bleeding</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>4 (9%)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (9%)</td>
</tr>
<tr>
<td>Failed medical treatment</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Failure of thrombolytics</td>
<td>4 (9%)</td>
</tr>
<tr>
<td>Failure of catheter embolectomy</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Large RA-RV thrombus</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>RV hemodynamic dysfunction</td>
<td>15 (32%)</td>
</tr>
<tr>
<td>Large PFO</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

*RA-RV, Right atrium–right ventricle; PFO, patent foramen ovale.*

- Survival at 1 and 3 years 86% and 83%
- 6% periop. mortality and most deaths in FU due to Malignancy (5 of 6 pts)

**Surgical embolectomy requires a median sternotomy and cardiopulmonary bypass.**

The Device Evolution
(Potential Benefits of Bleeding, LOS, COST)

- PE intervention without thrombolysis Potential Benefits
  - Reduced bleeding risk
  - Reduced length of stay
  - Reduced cost of hospitalization
    - Thrombolytic drug $4,000.00 to $8,000.00 per vial
    - ICU Bed $3,500.00 per day
  - The patient with thrombolytic contraindications!!

- Does device thrombectomy result in less residual pulmonary vascular obstruction (RPVO) then low dose short duration lytic strategies?
  - Remains to be determined no randomized trials to date
# Why A Mechanical Device for Acute PE

## Current Treatment Needs
- Fewer contraindications
- Rapid clot debulking to unload right heart
- Remove acute and subacute thrombus consistently
- Faster, on table results like STEMI
- Lower mortality
- Less ICU use with less risk of clinical deterioration
- Early discharge
- Early symptomatic improvement

## How FlowTriever Answers the Needs
- No need for Thrombolysis
- Effectively removes large clot burden present
- High level of procedural success
- See Trial Results
The Inari FlowTriever
Inari FlowTriever

Generations of Improvements
INARI FLOWTRIEVER STEPS

1) Large bore femoral or internal jugular access and secondary venous
2) Traverse right heart and place 0.35 wire (balloon catheter or shaped catheter)
3) Crossing catheter if need for wire optimization
4) Advance FlowTriever catheter with dilator
5) Start aspiration just proximal to clot
6) Transfuse blood removed via FlowSaver
7) Consider Mech Discs for resistant clot
8) Place wire in next branch and repeat, image with dilute contrast
9) For left side typically utilize mesh discs or curved catheter to create more favorable angle
10) Measure hemodynamics as needed
11) Figure of 8 purse string suture for sheath removal
Optimizing Clot Retrieval: Aspiration

Perhaps the single most important variable in maximizing clot retrieval is POSITION of the T20/T24 relative to the clot.

Optimal position is 1-5mm proximal to clot for whoosh technique.
FLAME STUDY: Outcomes

In-hospital mortality:
- FlowTrierer Arm: 1.9%
- Performance Goal: 28.5%
- Context Arm: 29.5%

Bailout:
- FlowTrierer Arm: 3.8%
- Performance Goal: 30.3%
- Context Arm: 26.2%

Clinical deterioration:
- Control: 15.1%
- Literature-based: 15.6%
- Context: 21.3%

Major bleeding:
- Control: 11.3%
- Literature-based: 11.5%
- Context: 24.6%
Case

- 70 y/o male without hx of prior VTE and no known risk factors
- Syncope at home
- Brought to ER by EMS
- CTA chest reveals large PE with RV strain
Course

- SBP 70 mmHg, O2 Sat 72% on non re-breather
- Intubated in ER and given full dose lytics without improvement in hemodynamics.
- Norepinephrine initiated in the ER, dialing up.
- How long do you wait?...
- Brought to the cath lab emergently.
Pre/Post
Course

• PA pressure 54/23 mmHg → 40/20 mmHg. Norepinephrine discontinued in the cath lab.

• Extubated 24 hours later.

• No end-organ dysfunction

• Venous duplex revealed popliteal vein residual.

• Discharged home on DOAC.
THANK YOU