FlowTriever® as the first Choice treatment of Acute PE patients

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Disclosure

Speaker name:

I have the following potential conflicts of interest to report:

- [x] Consulting Inari Medical, Boston Scientific, W.L.Gore, Veryan Medical, Abbott
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Case 1

- 73 yo male patient with oropharyngeal carcinoma dismissed after long term hospital stay for radiation and chemotherapy, tracheostoma and PEG
- feeling unwell, dyspnea, low blood pressure, fell backwards hit his head w/o any injury
- sys. blood pressure 93 mmHg, HR 97/min, SPO2 95% (5l O2) (PESI 3)
- TnT elevated, RV strain, no TVR, PE confirmed in CT, Lactat 3.3 mmol/L
Case 2

- 59 yo male patient with 2 weeks of slow onset of dyspnea
- immobilisation due to back pain (disc prolapse)
- sys. blood pressure 160 mmHg, HR 74/min, SPO2 95% RA (sPESI 0)
- TnT elevated, no BNP, no strain in ultrasound
- TAPSE 22mm, ePAP 37mmHg plus CVP
PE treatment guidelines
PE mortality over decades

**All-Cause Mortality @ 30-days in PE Patients**

- **12.5%**
  - ICOPER '99
  - 2,454 patients
  - 95.6% Int-risk, 4.4% High-risk

- **11.8%**
  - MGH PERT '18
  - 338 patients
  - 86% Int-risk, 14% High-risk

- **15.7%**
  - Schultz et al. '19
  - 416 patients
  - 19% Low-risk, 36% Int-Low risk

- **10.2%**
  - PERT Registry '21
  - 5,048 patients
  - 18% Low-risk, 67% Int-risk, 15% High-risk

By risk level:

- **6-15%**
  - in submassive PE patients

- **25-50%**
  - in massive PE patients

**Nearly Half**

Of submassive 30-day all-cause mortality occurred **after the patient left the hospital** & **nearly 2/3** of 90-day all-cause mortality

Secemsky et al, Am J Med 2018
### Outcomes in Pulmonary Embolism

<table>
<thead>
<tr>
<th>Embolism Size</th>
<th>Severity</th>
<th>Cardiopulmonary Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemodynamically Stable – RV Normal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emboli in transit</td>
<td>Syncope</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shock</td>
</tr>
<tr>
<td>Sudden Death</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Arrest</td>
<td></td>
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</tr>
</tbody>
</table>

### Antikoagulation

<table>
<thead>
<tr>
<th>All cause mortality at 30 days</th>
<th>Thrombolytics</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 6-15% in submassive pts</td>
<td>Major bleeding</td>
</tr>
<tr>
<td>- 25-50% in massive pts</td>
<td>- 9-22%</td>
</tr>
<tr>
<td></td>
<td>- 1.5-3% intracranial</td>
</tr>
</tbody>
</table>

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Kucher et al, Circ 2006  
Secemsky et al Am J Med 2018  
Schultz et al Pulm Circ 2019  
PERT Database 10/2021  
Darki et al, EVT 2022  
Chatterjee et al JAMA 2014  
Goldhaber et al Lancet 1999  
Budaj-Fidecka et al Int J Cardiol 2013
Normotensive cardiogenic shock

“Our current definition and risk stratification tools may not be sufficient to identify these [patients at risk of hemodynamic decompensation] with submassive PE.”

~40% of normotensive PE patients are in cardiogenic shock (low CI)*

~20% of PE patients with sPESI=0 are in cardiogenic shock**

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*Low CI defined as <1.8 l/min/m²
**Low CI defined as <2.0 l/min/m²
Residual Pulmonary Vessel Obstruction

Adverse Events @ 6-months
Combined endpoint of death, recurrent PE, HF or worsening dyspnea

- 0-18%: 6.2%
- 19-26%: 9.4%
- 27-37%: 21.9%
- 38-64%: 62.5%

“RPVO as evaluated by V–Q scan at discharge in patients with intermediate- to high-risk PE is a powerful prognostic factor for outcomes at 6 months.”

“Rapid unloading of the right ventricle and increased thrombus clearance may prevent maladaptive cardiopulmonary remodeling.”

## PE risk stratification

<table>
<thead>
<tr>
<th>Clinical Predictors of Adverse Events</th>
<th>Traditional Risk Stratification Tool</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>sPESI/PESI</td>
</tr>
<tr>
<td><strong>Right Heart Dysfunction</strong> (RV/LV ratio ≥0.9)</td>
<td>1.14 odds for death for every 0.1 increase in RV/LV&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Large Clot Burden</strong></td>
<td>17.6X risk of mortality at 6 months&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Central Clot Location</strong></td>
<td>&gt;2X risk of PE-related mortality&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Concomitant DVT</strong></td>
<td>&gt;4X risk of 90-day PE-related mortality &amp; recurrent VTE&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Residual Obstruction</strong> (RPVO)</td>
<td>Increased risk of death, pulmonary hypertension, heart failure or worsening dyspnea, and decreased QOL</td>
</tr>
</tbody>
</table>

Optimizing PE risk stratification

1. HR cut-off value 110/min vs. 80/min. increase sensitivity sPESI Score from 93% to 98%
   (identify low risk vs. Intermediate risk)

2. HR cut-off value 140/min increase specificity BOVA-Score from 93% to 98%
   (identify intermediate risk vs. High risk)

3. Plasma/venous lactat level 2 mmol/l or 3.3 mmol/l to identify pts with higher mortality risk

Jaureguizar et al, CHEST 2022
Large bore thrombectomy for PE treatment

- Designed to extract large volumes of clot
- Blood can be returned with FlowSaver®
- Single session
- Lytic-free approach
- Avoid consequent ICU stay
- Rapid symptom relief
Case 1

- sPA dropped from 46mmHg to 32mmHg
- 1 further night on ICU
- no RV strain, no TVR
- Referral for further surgical cancer treatment
Case 2

- sPAP dropped 50mmHg to 36mmHg
- no ICU stay, hospital stay 5 days, direct referral to orthopedics rehab
- after 3 month he came on a bike
<table>
<thead>
<tr>
<th>Real World Patients</th>
<th>Excellent Safety Outcomes</th>
<th>Immediate Clinical Improvement</th>
<th>Minimum Hospital Resource Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>85% Intermediate-high or high-risk patients</td>
<td>1.8% Major Adverse Events (MAEs) at 48-hours</td>
<td>-7.6 mmHg Mean PAP decrease</td>
<td>62.6% Did not need overnight ICU stay</td>
</tr>
<tr>
<td>32% Lytics contraindication</td>
<td>0 Device related deaths</td>
<td>12 bpm Decrease in heart rate</td>
<td>2.4% Required adjunctive PE therapy</td>
</tr>
<tr>
<td>65% Concomitant DVT</td>
<td>&lt;1.0% All-cause mortality at 30-day follow-up</td>
<td>+19% Increase in cardiac index</td>
<td>3 Hospital overnights post-procedure</td>
</tr>
</tbody>
</table>

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<thead>
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<th>Antikoagulation</th>
<th>Large bore thrombectomy</th>
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<tbody>
<tr>
<td>All cause mortality at 30 days</td>
<td>Lytic-free thrombectomy</td>
</tr>
<tr>
<td>- 6-15% in submassive pts</td>
<td>Fast and safe procedure</td>
</tr>
<tr>
<td>- 25-50% in massive pts</td>
<td>&lt; 1% mortality after 30 days</td>
</tr>
<tr>
<td>Long-term functional impairment</td>
<td>Large Clot removal</td>
</tr>
<tr>
<td>Long term RPVO impact</td>
<td>Immediate hemodyn. Improv.</td>
</tr>
<tr>
<td>24% all cause readmission</td>
<td>6.2% all cause readmission</td>
</tr>
</tbody>
</table>

Pert Database 10/2021
Darki et al, EVT 2022
Schultz et al Pulm Circ 2019
Secemsky et al Am J Med 2018
Kucher et al, Circ 2006
Sista et al, Vasc Med 2017
Meneveau Eur Heart J 2013
Toma et al, EuroInterv 2022
Tu et al JACC Card Int 2019
Primary Endpoint Components

In-hospital mortality

- FlowTriever Arm (n = 53)
- Performance Goal (Literature-based)
- Context Arm (n = 61)

1.9% (FlowTriever Arm) vs. 29.5% (Context Arm)
Summary

• mechanical – large bore – thrombectomy is a safe and effective alternative to „standard“ therapy for patients mit HR or IHR PE
• RCTs for IHR comparing against CDT (PEERLESS) and OAK (PEERLESS-2) are enrolling/planned
• RCT for HR pts?
How does a lytic-free, bloodless approach advance the treatment of Venous Thromboembolism?

Dr Steven Abramowitz
Vascular Surgery (USA)
How do DEFIANCE and CLOUT answer critical questions about the management of DVT?

Dr Michael Piorkowski
Internal Medicine, Cardiology and Angiology (Germany)
FlowTriever® System as the first-choice treatment of acute PE patients

Dr Michael Lichtenberg
Angiology & Vascular Medicine (Germany)
Why doesn't existing clinical data initiate a change in the current DVT treatment guidelines?

Visit us after for a hands-on workshop in the Inari Hospitality Suite