Techniques for thrombus removal in acute DVT

Benefits of an Endovascular Approach for Rapid Flow Restoration in DVT

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Disclosure

Speaker name:

Michael Lichtenberg

I have the following potential conflicts of interest to report:

- [x] Consulting (CR Bard, Veniti, Volcano, Biotronik, Terumo, Boston, Straub Medical, Veryan, TVA medical, Spectranetics, Cook)
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

I do not have any potential conflict of interest
Indication for proximal venous thrombectomy

- 23 y female patient: Young and active patient descending ileofemoral thrombosis - May-Thurner Syndrome
- 65 y male patient: Phlegmasia, descending IVC thrombosis - Bowel cancer
- 80 y male patient: Stenosis of right iliac vein With thrombus - Lymphocele compression
Proactive Endovascular Treatment

• Eliminates the thrombus
• Early treatment increases probability of
  – Maintaining normal valve function
  – Maintaining vein function
• Decreases risk of post-thrombotic syndrome
Venous Thrombus Treatment Options: Proactive Endovascular Treatment

- Anticoagulation & Compression Stockings only
- Catheter Directed Thrombolysis (CDT)
  - Enhanced CDT (eg, ultrasound)
- Mechanical Thrombectomy
- Pharmacomechanical Thrombectomy (PMT)
Enden T, et al: CaVenT Study
– Follow-Up 24 months:
– Number needed to treat: 7

<table>
<thead>
<tr>
<th></th>
<th>Additional catheter-directed thrombolysis (n=90)</th>
<th>Standard treatment only (n=99)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%   (95% CI)</td>
<td>n</td>
</tr>
<tr>
<td>Post-thrombotic syndrome at 24 months†</td>
<td>37</td>
<td>41.1% (31.5–51.4)</td>
<td>55</td>
</tr>
<tr>
<td>Iliofemoral patency at 6 months†‡</td>
<td>58</td>
<td>65.9% (55.5–75.0)</td>
<td>45</td>
</tr>
<tr>
<td>Post-thrombotic syndrome at 6 months§</td>
<td>27</td>
<td>30.3% (21.8–40.5)</td>
<td>32</td>
</tr>
</tbody>
</table>

Post-thrombotic syndrome defined as Villalta score of 5 points or higher. *χ² test. †Co-primary outcomes. ‡Five patients had inconclusive patency assessments and one was lost to follow-up at 6 months. §Secondary outcome.

Table 2: Short-term and long-term outcomes


22 bleeding complications
All patients with patent veins and normal valve function showed no sign of dermal pigmentation, ulceration or venous claudication at follow-up.
Catheter-Directed Thrombolysis (CDT)

Advantages
- Technologically simple
- Minimally invasive
- Resolves thrombus
- Low equipment expense

Limitations
- Extensive exposure to thrombolytics
- Extended ICU stay
- Post-treatment care can be complicated
- Logistically challenging (ICU, Labs, Nursing)
- Requires specialized skills
- Multiple visits to the procedure lab

Endovascular placement of infusion catheter into affected area
Thrombolytic drug migrates into clot
Indication for proximal venous thrombectomy

23 y female patient
Descending ileofemoral thrombosis

65 y male patient
Phlegmasia, descending IVC thrombosis

80 y male patient
Stenosis of right iliac vein With thrombus

Young and active patient

May-Thurner Syndrome

Bowel cancer

Lymphocele compression
Early Clot Removal
Many Choices – None Perfect!

EKOS® Peripheral Infusion System

Trellis™ System

AngioJet®

Aspirex® (Rotational thrombectomy)

Indigo System ® (Penumbra)

6 – 10 French
CDT vs PMT Results: Lin et al

“When compared to CDT, [PMT] provides similar treatment success with reduced ICU, total hospital length of stay, and hospital costs”

<table>
<thead>
<tr>
<th></th>
<th>PMT (N=52 limbs)</th>
<th>CDT (N=46 limbs)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete thrombus removal</td>
<td>75%</td>
<td>70%</td>
<td>NS</td>
</tr>
<tr>
<td>Partial success (residual thrombus)</td>
<td>25%</td>
<td>30%</td>
<td>NS</td>
</tr>
<tr>
<td>Immediate clinical improvement</td>
<td>81%</td>
<td>72%</td>
<td>NS</td>
</tr>
<tr>
<td>Hemorrhagic complication</td>
<td>4%</td>
<td>6%</td>
<td>NS</td>
</tr>
<tr>
<td>PRBC transfusion (U)</td>
<td>0.2±0.3</td>
<td>1.2±0.7</td>
<td>&lt;.05</td>
</tr>
<tr>
<td>No. of venograms</td>
<td>0.4±0.2</td>
<td>2.5±0.7</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mean ICU stay (days)</td>
<td>0.6±0.3</td>
<td>2.4±1.2</td>
<td>&lt;.04</td>
</tr>
<tr>
<td>Overall hospital length of stay (days)</td>
<td>4.6±1.3</td>
<td>8.4±2.3</td>
<td>&lt;.02</td>
</tr>
</tbody>
</table>

*a decrease in pain/swelling within 24 h

- PMT and CDT groups had similar treatment effectiveness and complication rates
- Significantly reduced number of venograms, mean ICU and overall hospital stay duration for PMT vs CDT
- 18 h CDT thrombolytic infusion time vs 76 min PMT procedure time

CDT, catheter-directed thrombolysis; ICU, intensive care unit; PMT, pharmacomechanical thrombectomy; PRBC, packed red blood cell
### PEARL Comparison: Treatment of Lower Extremity DVT

<table>
<thead>
<tr>
<th></th>
<th>PEARL*</th>
<th>Venous Registry†</th>
<th>CaVenT‡</th>
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<tbody>
<tr>
<td></td>
<td>CDT</td>
<td>Standard</td>
<td></td>
</tr>
<tr>
<td><strong>Onset of DVT Symptoms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>67% (≤14 days)</td>
<td>66% (≤10 Days)</td>
<td>100% ≤21 days</td>
</tr>
<tr>
<td>Chronic</td>
<td>33% (&gt;14 days)</td>
<td>16% (&gt;10 Days)</td>
<td>NA</td>
</tr>
<tr>
<td>Acute &amp; Chronic</td>
<td>NA</td>
<td>19%</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Primary Lytic</strong></td>
<td>TPA</td>
<td>Urokinase</td>
<td>TPA</td>
</tr>
<tr>
<td><strong>CDT Drip Times (mean)</strong></td>
<td>17 hrs</td>
<td>48 hrs</td>
<td>57.6 hrs (2.4 days)</td>
</tr>
<tr>
<td><strong>Procedure Times</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDT (N=29)</td>
<td>40.9 hrs</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>CDT+PPS/RL (N=172)</td>
<td>22.0 hrs</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>PPS/RL (N=115)</td>
<td>2.0 hrs</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Bleeding Complications</strong></td>
<td>4.5% (major &amp; minor combined)</td>
<td>11% (major); 16% (minor)</td>
<td>22% (major &amp; minor combined)</td>
</tr>
</tbody>
</table>

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†Mewissen MW, Seabrook GR. Radiology 1999:211:39-49
ATTRACTION Trial (ongoing)

**Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis**

- Comparative effectiveness study
- NHLBI-funded, Phase III, open-label, multicenter RCT
- Objective:
  - Determine if the initial use of adjunctive Pharmacomechanical Catheter Directed Thrombolysis (PCDT) in symptomatic patients with proximal deep vein thrombosis (DVT) reduces the occurrence of Post-Thrombotic Syndrome (PTS) over 24 months follow-up
- PCDT + standard therapy vs standard therapy alone
- Study Drug is recombinant tPA (IND 103462)
- 692 patients with symptomatic, acute proximal DVT
Pure mechanical approach

**Aspirex® / Indigo®**
- Pure mechanical thrombectomy, no thrombolytics
- Age of thrombus not so relevant
- Chance to finish in the Angiolab
- No RCT date, only registry data

**EKOS®, Trellis®, Angiojet®**
- Time consuming
- Additional thrombolytics
- Bleeding risks
- Re-angio after finishing treatment for stent placement etc. (EKOS)
- Organized thrombus > 4 weeks = possible ineffectiveness
- Additional ICU stay in EKOS
- RCT data for EKOS and Angiojet
Two center retrospective data analysis for DVT thrombectomy with the Aspirex® catheter

43 Aspirex thrombectomy procedures for iliofemoral DVT

Technical success analysis
Safety analysis
21 y, female, descending DVT in May – Thurner syndrome. Transpopliteal access, 8 F Aspirex®
Ileofemoral DVT therapy with Aspirex catheter

- May-Thurner syndrom: 43.1 years, 66 % female
- Cancer patients with more phlegmasia symptoms
- Duration of symptoms: 1 day – 3 months
- Hemodynamic technical success in cath lab with Aspirex and stent implantation: 97 % (42/43 patients)
- No prolonged lytic therapy
- Stent rate 100 % in Arnsberg patients / 95 % Rostock
- Stent rate 1,25 / patient
- Complications: No bleeding, PE
  - 2 small perforations in the CIV stent
  - 1 wire loss snared
Clinical follow-up study with the ASPIREX®S Endovascular System to investigate the safety and effectiveness in the treatment of DVT patients and special patient groups

<table>
<thead>
<tr>
<th>STUDY DESIGN</th>
<th>Open, multicentric, international, prospective, post-market clinical follow-up study</th>
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<tbody>
<tr>
<td>NUMBER OF SUBJECTS</td>
<td>In total: up to 120</td>
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**Inclusion criteria:**
Acute thrombotic or thromboembolic occlusion (onset of pain < 14 days)

**FU:** up to 24 months

**Endpoints:**
Assessment of the effectiveness and safety of the ASPIREX®S catheter
MAE, QoL, CEAP, VCSS

<table>
<thead>
<tr>
<th>Planned Start of Clinical Phase</th>
<th>Nov 2015</th>
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<tbody>
<tr>
<td>Planned End of Recruitment</td>
<td>Oct 2016</td>
</tr>
<tr>
<td>Planned End of Clinical Phase</td>
<td>Apr 2017</td>
</tr>
<tr>
<td>Planned Availability of Draft Final Report</td>
<td>Jul 2017</td>
</tr>
</tbody>
</table>
Conclusion

DVT thrombectomy

- Is effective in venous thrombus removal
  - Even in more organized thrombus
- Restores vein patency in upper and lower limb
- Preserves valvular function
- Has low risk and less side effects with PMT
  - No ICU stay
  - „End it in the Angiolab“
- PMT will be the standard treatment
THANK YOU FOR YOUR ATTENTION
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