Single-session revascularization of acute iliofemoral DVT

A pure mechanical approach

Michael K. W. Lichtenberg, MD, FESC
Vascular Centre Arnsberg, Germany
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)
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

I do not have any potential conflict of interest
# VTE Impact Assessment Group in Europe (VITAE)

**Estimation for Europe in 2004**

<table>
<thead>
<tr>
<th></th>
<th>Outpatient</th>
<th>During hospital stay</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VTE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>200.482</td>
<td>265.233</td>
<td>465.715</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>86.511</td>
<td>209.471</td>
<td>295.982</td>
</tr>
<tr>
<td><strong>VTE associated death</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient on anticoagulation</td>
<td>108.535</td>
<td>261.477</td>
<td>370.012</td>
</tr>
<tr>
<td>Patient not on anticoag.</td>
<td>8.124</td>
<td>18.349</td>
<td>26.473</td>
</tr>
<tr>
<td>Sudden death</td>
<td>63.541</td>
<td>153.853</td>
<td>217.394</td>
</tr>
<tr>
<td></td>
<td>36.870</td>
<td>89.275</td>
<td>126.145</td>
</tr>
<tr>
<td><strong>Chronic complications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postthrombotic Syndrome(^b)</td>
<td>177.236</td>
<td>218.437</td>
<td><strong>395.673</strong></td>
</tr>
<tr>
<td>Pulm. Hypertension</td>
<td>1.173</td>
<td>2.961</td>
<td>4.135</td>
</tr>
</tbody>
</table>

Proactive Endovascular Treatment

• Eliminates the thrombus
• Early treatment increases probability of
  – Maintaining normal valve function
  – Maintaining vein function
• Decreases risk of post-thrombotic syndrome
• 2. Indications for early thrombus removal

2.1. We suggest a strategy of early thrombus removal in selected patients meeting the following criteria:

• (a) a first episode of acute iliofemoral deep venous thrombosis
• (b) symptoms <14 days in duration
• (c) a low risk of bleeding
• (d) ambulatory with good functional capacity and an acceptable life expectancy (Grade 2C)
Venous Thrombus Treatment Options: Proactive Endovascular Treatment

- Anticoagulation & Compression Stockings only
- Catheter Directed Thrombolysis (CDT) • Enhanced CDT (eg, ultrasound)
- Mechanical Thrombectomy
- Pharmacomechanical Thrombectomy (PMT)
<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Design</th>
<th>Limbs Treated</th>
<th>Pathology</th>
<th>Arms</th>
<th>Agent</th>
<th>Short-Term Patency</th>
<th>Long-Term Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bjarnason et al.</td>
<td>Institution series</td>
<td>87</td>
<td>Acute iliofemoral DVT</td>
<td>CDT (87) ± angioplasty ± stent ± PMT</td>
<td>Urokinase</td>
<td>Immediate: 69 (79%), iliac, 86%; femoral, 63%</td>
<td>1 year: iliac, 63% primary, 78% secondary; femoral, 40% primary, 51% secondary</td>
</tr>
<tr>
<td>Mewissen et al.</td>
<td>National registry data</td>
<td>303</td>
<td>Acute and chronic suprapopliteal</td>
<td>PMT</td>
<td>Urokinase</td>
<td>Immediate: grade III in 96 (31%), II in 162 (52%), I in 54 (17%)</td>
<td>1 year: 181 (60%)</td>
</tr>
<tr>
<td>Gandini et al.</td>
<td>Institution series</td>
<td>8</td>
<td>Iliovisceral thrombosis</td>
<td>None</td>
<td>None</td>
<td>Immediate: 6 (75%)</td>
<td>2 years: 6 (75%)</td>
</tr>
<tr>
<td>Elsharawy et al.</td>
<td>Single blind RCT</td>
<td>35</td>
<td>Iliofemoral DVT &lt;10 days</td>
<td>CDT + (18), Anticoagulation alone (17)</td>
<td>Streptokinase</td>
<td>1 week: CDT 11 (61%), control 0 (0%)</td>
<td>6 months: CDT, 2 (13%); control, 2 (12%)</td>
</tr>
<tr>
<td>Jackson et al.</td>
<td>Institution series</td>
<td>28</td>
<td>Acute supra popliteal DVT (4 had symptoms &gt;14 days)</td>
<td>CDT + stenting ± PMT</td>
<td>Urokinase</td>
<td>Immediate: 5 (18%) complete lysis, 20 (72%) partial</td>
<td>1 year: 22 (80%)</td>
</tr>
<tr>
<td>Lin et al.</td>
<td>Retrospective comparison of CDT and PMT</td>
<td>98</td>
<td>Acute symptomatic lower limb DVT</td>
<td>CDT (46), PMT (52)</td>
<td>Urokinase</td>
<td>Immediate: grade III and III lysis in 41 (95%)</td>
<td>1 year: CDT, 29 (64%); PMT, 35 (68%)</td>
</tr>
<tr>
<td>Protack et al.</td>
<td>Institution series</td>
<td>69</td>
<td>Lower extremity DVT</td>
<td>CDT (27), PMT (12), both (30)</td>
<td>r-TPA</td>
<td>Immediate: grade III in 46 (67%), II in 19 (26%), I in 4 (0%)</td>
<td>2 years: 57 (83%) freedom from rethrombosis</td>
</tr>
<tr>
<td>Rao et al.</td>
<td>Institution series</td>
<td>43</td>
<td>Symptomatic iliofemoral DVT (19, &gt;14 days)</td>
<td>CDT + PMT (12), both (30)</td>
<td>None</td>
<td>Immediate: grade III and III lysis in 14 (89%), I in 2 (11%)</td>
<td>Follow-up: 12 (75%)</td>
</tr>
<tr>
<td>Shi et al.</td>
<td>Institution series</td>
<td>16</td>
<td>Massive lower limb DVT</td>
<td>CDT + PMT + NC filter</td>
<td>r-TPA</td>
<td>Immediate: grade III in 24, II in 20 for CDT group</td>
<td>6 years: 84 (82%) mean follow-up 50 months</td>
</tr>
<tr>
<td>Baekgaard et al.</td>
<td>Institution series</td>
<td>103</td>
<td>DVT &lt;14 days, open distal popliteal vein</td>
<td>CDT + stockings (103) ± stent (57)</td>
<td>r-TPA</td>
<td>1 week: 95/103 (92%)</td>
<td>6 months: 32 (64%) of CDT group vs 19 (36%) of control</td>
</tr>
<tr>
<td>Enden et al.</td>
<td>Open multicenter RCT: short-term report</td>
<td>103</td>
<td>Iliofemoral DVT &lt;21 days and symptoms</td>
<td>CDT + anticoagulation (50), anticoagulation alone (53)</td>
<td>r-TPA</td>
<td>Immediate: grade III in 24, II in 20 for CDT group</td>
<td>Follow-up: 12 (75%)</td>
</tr>
</tbody>
</table>

ca. 900 patients

> 70% patency after 1 year

Arterioscler Thromb Vasc Biol. 2010;30:669-674
### Additional catheter-directed thrombolysis (n=90) vs. Standard treatment only (n=99)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Additional catheter-directed thrombolysis</th>
<th>Standard treatment only</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-thrombotic syndrome at 24 months†</td>
<td>37 (41.1% (31.5-51.4))</td>
<td>55 (55.6% (45.7-65.0))</td>
<td>0.047</td>
</tr>
<tr>
<td>Iliofemoral patency at 6 months†‡</td>
<td>58 (65.9% (55.5-75.0))</td>
<td>45 (47.4% (37.6-57.3))</td>
<td>0.012</td>
</tr>
<tr>
<td>Post-thrombotic syndrome at 6 months§</td>
<td>27 (30.3% (21.8-40.5))</td>
<td>32 (32.2% (23.9-42.1))</td>
<td>0.77</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**

**Lancet. 2012 Jan 7;379(9810):31-8.**
PMT reduces the need for CDT and therefore bleeding complication
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

May-Thurner Syndrome

Bowel cancer

Lymphocele compression
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

Postthrombotic Syndrome; Patricia E. Thorpe, MD, FSIR; October 2007; Endovascular Today
Early Clot Removal
Many Choices – None Perfect!

EKOS® Peripheral Infusion System

Trellis™ System

AngioJet®

Aspirex® (Rotational thrombectomy)

Indigo System® (Penumbra)

6 – 10 French

Therapy strategies for endovascular DVT treatment

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

**EKOS®, Trellis®, Angiojet®**
- Time consuming
- Additional thrombolitics
- 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
17 y, female, swelling of left leg and back pain for 1 day
Penumbra – Indigo System
Two center retrospective data analysis for DVT thrombectomy with the Aspirex® catheter

Dr. Thomas Heller
Dr. Michael Lichtenberg

43 Aspirex thrombectomy procedures for iliofemoral DVT

Technical success analysis
Safety analysis
23 y, female: Back pain for 14 days, persistent swelling
Ileofemoral DVT therapy with Aspirex catheter

- May-Thurner syndrome: 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
Arnsberg Pathway in Patients with Iliofemoral DVT

**Iliofemoral DVT**

**Indication for endovascular treatment**

**Yes**
- DVT < 21 days
- Young, active pt.
- Phlegmasia
- Mechanical thrombectomy (Aspirex 10 F, Indigo 8 F)
- Transpopliteal access
- Optional full anaesthesia
- Thrombolysis just for bail out
- IVUS
- Stenting underlying reason
- No IVC filter

**No**
- Old, immobile pt.
- Low compliance
- DVT > 21 days
- Anticoagulation
- Stockings

Optional diagnostic approach in each case:
- CT-Venography
- MR-Venography
Post-market 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>
</tr>
</thead>
<tbody>
<tr>
<td>NUMBER OF SUBJECTS</td>
<td>In total: up to 120</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INVESTIGATORS AND RELATED STUDY SITES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. med. Thomas Heller</td>
<td>Institut für Diagnostische und Interventionelle Radiologie</td>
</tr>
<tr>
<td></td>
<td>Zentrum für Radiologie</td>
</tr>
<tr>
<td></td>
<td>Universitätsklinik Rostock</td>
</tr>
<tr>
<td></td>
<td>Schillingallee 35</td>
</tr>
<tr>
<td></td>
<td>18057 Rostock</td>
</tr>
<tr>
<td>Dr. med. Michael Lichtenberg</td>
<td>Klinik für Angiologie</td>
</tr>
<tr>
<td></td>
<td>Klinikum Arnsberg</td>
</tr>
<tr>
<td></td>
<td>Goethestr. 15</td>
</tr>
<tr>
<td></td>
<td>59755 Arnsberg</td>
</tr>
<tr>
<td>Dr. Gerard J. O’Sullivan, Galway</td>
<td>University Hospitals, Newcastle Road, Galway, H91 YR71, Ireland</td>
</tr>
</tbody>
</table>

**Inclusion criteria**

- Acute thrombotic or thromboembolic occlusion (onset of pain < 14 days)
- Age > 18 years
- Written informed consent form

<table>
<thead>
<tr>
<th>Planned Start of Clinical Phase</th>
<th>Nov 2015</th>
</tr>
</thead>
<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>
DVT thrombectomy with a pure mechanical approach

• 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 (safe)
  • No ICU stay
  • „End it in the Angiolab“
• Prevention of post thrombotic syndrome
THANK YOU FOR YOUR ATTENTION
Single-session revascularization of acute iliofemoral DVT
A pure mechanical approach

Michael K. W. Lichtenberg, MD, FESC
Vascular Centre Arnsberg, Germany