Successful recanalisation of venous thrombotic occlusions with Aspirex mechanical thrombectomy

Michael K. W. Lichtenberg
Disclosure

Speaker name:
Michael Lichtenberg

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [x] 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>
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<tr>
<td>Deep vein thrombosis</td>
<td>200.482</td>
<td>265.233</td>
<td>465.715</td>
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<tr>
<td>Pulmonary embolism</td>
<td>86.511</td>
<td>209.471</td>
<td>295.982</td>
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<tr>
<td><strong>VTE associated death</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Patient on anticoagulation</td>
<td>8.124</td>
<td>18.349</td>
<td>26.473</td>
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<tr>
<td>Patient not on anticoag.</td>
<td>63.541</td>
<td>153.853</td>
<td>217.394</td>
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<td>Sudden death</td>
<td>36.870</td>
<td>89.275</td>
<td>126.145</td>
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<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>395.673</td>
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<td>Pulm. Hypertension</td>
<td>1.173</td>
<td>2.961</td>
<td>4.135</td>
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</table>

\(^b\) Postthrombotic Syndrome

Indication for proximal venous thrombectomy

Young and active patient
Descending ileofemoral thrombosis
**May-Thurner Syndrome**

Phlegmasia, descending IVC thrombosis
**Bowel cancer**

Stenosis of right iliac vein
With thrombus
**Lymphocele compression**
50 % of patients develop PTS after proximal DVT

The overall relative risk of developing PTS was 1.58 (95% confidence intervals: 1.24-2.02) in patients suffering from asymptomatic DVT as compared to patients without DVT (p<0.0005)

Primary four-level DVT, calf vein thrombosis, recurrence of ipsilateral DVT and a non-sufficient oral anticoagulation are of prognostic significance for developing clinically relevant PTS within 10 to 20 years after first DVT

Proximal DVT is associated with PTS in every second case (Akesson, J Vasc Surg 1990)
Mechanical Thrombectomy
Rotational thrombectomy (Aspirex®)

6 – 10 French

8 F: blood volume aspiration up to 75 ml/min
10 F: blood volume aspiration up to 130 ml/min
Two center experiences for DVT thrombectomy with the Aspirex® catheter

- 26 Aspirex thrombectomy procedures
- 23 DVTs lower limb
- 3 DVTS upper limb

- 24 Aspirex thrombectomy procedures
- 20 DVTs lower limb
- 4 DVTs upper limb

Technical success analysis
Safety analysis
6 month follow up patency analysis
• 26 patients (14 male)
• Mean age: 50
• 21 ileofemoral DVT
• 2 descending IVC thrombosis
• 3 subclavian thrombosis (only Aspirex)

• Stent rate: 95 %
• Technical success = ready in cath lab : 96 % (22/23 patients)
• No SAE (bleeding, perforation, pulmonary embolism)
Mechanical thrombus fragmentation
<table>
<thead>
<tr>
<th>m/f</th>
<th>Age</th>
<th>Reason</th>
<th>Phlegm.</th>
<th>Location</th>
<th>Access</th>
<th>Aspirex</th>
<th>Stent</th>
<th>Ready in lab</th>
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<td>f</td>
<td>52</td>
<td>May-Thurner</td>
<td>no</td>
<td>IVC/VIE</td>
<td>VFC</td>
<td>8 F</td>
<td>Yes</td>
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<td>VPOP</td>
<td>8 F</td>
<td>Yes</td>
<td>yes</td>
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<td>IVC-VPOP</td>
<td>VPOP</td>
<td>8 F</td>
<td>Yes</td>
<td>yes</td>
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<tr>
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<td>CIV-VPOP</td>
<td>VPOP</td>
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<td>yes</td>
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<td>10 F</td>
<td>Yes</td>
<td>yes</td>
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<td>VFS</td>
<td>8 F</td>
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<td>yes</td>
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<td>VPOP</td>
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<td>VPOP</td>
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<tr>
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<td>CIV-VFS</td>
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<td>m</td>
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<td>3 rd. DVT</td>
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<td>CIV-VPOP</td>
<td>VSM</td>
<td>10 F</td>
<td>Yes</td>
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</tbody>
</table>
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: 100 % (24/24 patients)
- No prolonged lytic therapy, just r-tPa bolus in 2 patients
- Stent rate 100 % in 20 patients
- Stent rate 1,25 / patient
- Complications: No bleeding, PE
  - 2 small perforations in the CIV stent
  - 1 wire loss snared
81 y, female, descending thrombosis
TIS, 23 y, female: 6 F Aspirex
Technical Tips for Aspirex usage

• No local anticoagulation – systemic anticoagulation !!!
• Flushing very important during the procedure
• Always take care of the guidewire
• Interrupt procedure for flushing the catheter
• The larger the Aspirex catheter the more avoid friction and curved angels
• Post treatment: Asprin 100 mg plus OAC
Therapy strategies for endovascular DVT treatment

**Aspirex®**
- 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
Conclusion

DVT thrombectomy with the Aspirex PMT

• 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
Peripheral Vascular Disease

Ultrasound-Assisted Versus Conventional Catheter-Directed Thrombolysis for Acute Iliofemoral Deep Vein Thrombosis

Rolf P. Engelberger, MD; David Spirk, MD; Torsten Willenberg, MD; Adriano Alatri, MD; Dai-Do Do, MD; Iris Baumgartner, MD; Nils Kucher, MD

Background—For patients with acute iliofemoral deep vein thrombosis, it remains unclear whether the addition of intravascular high-frequency, low-power ultrasound energy facilitates the resolution of thrombosis during catheter-directed thrombolysis.

Methods and Results—In a controlled clinical trial, 48 patients (mean age 50±11 years, 52% women) with acute iliofemoral deep vein thrombosis were randomized to receive ultrasound-assisted catheter-directed thrombolysis (N=24) or conventional catheter-directed thrombolysis (N=24). Thrombolysis regimen (20 mg r-tPA over 15 hours) was identical in all patients. The primary efficacy end point was the percentage of thrombus load reduction from baseline to 15 hours according to the length-adjusted thrombus score, obtained from standardized venograms and evaluated by a core laboratory blinded to group assignment. The percentage of thrombus load reduction was 55±27% in the ultrasound-assisted catheter-directed thrombolysis group and 58±27% in the conventional catheter-directed thrombolysis group (P=0.91). Adjunctive angioplasty and stenting was performed in 19 (80%) patients and in 20 (83%) patients, respectively (P>0.99). Treatment-related complications occurred in 3 (12%) and 2 (8%) patients, respectively (P>0.99). At 3-month follow-up, primary venous patency was 100% in the ultrasound-assisted catheter-directed thrombolysis group and 96% in the conventional catheter-directed thrombolysis group (P=0.33), and there was no difference in the severity of the post-thrombotic syndrome (mean Villalta score: 3.0±3.9 [range 0–15] versus 1.9±1.9 [range 0–7]; P=0.21), respectively.

Conclusions—In this randomized controlled clinical trial of patients with acute iliofemoral deep vein thrombosis treated with a fixed-dose catheter thrombolysis regimen, the addition of intravascular ultrasound did not facilitate thrombus resolution.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01482273.
(Circ Cardiovasc Interv. 2015;8:e002027. DOI: 10.1161/CIRCINTERVENTIONS.114.002027.)
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- Herzzenrum Bad Krozingen, Bad Krozingen, Germany
- Vascular Center, Arnsberg Clinic, Arnsberg, Germany

Faculty:
Prof. Marianne Brodmann, Prof. Thomas Zeller
Dr. Michael Lichtenberg, Dr. Wilhelm Stahlhoff
PD Dr. Andrej Schmidt, Prof. Giovanni Torsello
Prof. Karl-Ludwig Schulte

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Dr. Michael Lichtenberg
Dr. Wilhelm Stahlhoff
Klinikum Arnsberg, Karolinen-Hospital
Stolte Ley 5, D-59759 Arnsberg

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the interactive cardiovascular channel
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