Recanalization of venous occlusions with Aspirex®S mechanical thrombectomy – The effective one-session treatment, which largely replaces the need of thrombolysis!

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LINC, 26.01.2016, Leipzig
Disclosure

Speaker name: Thomas Heller

I have the following potential conflicts of interest to report:

- 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 in 2004**

<table>
<thead>
<tr>
<th></th>
<th>acute</th>
<th>Outpatient</th>
<th>During hospital stay</th>
<th>total</th>
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</thead>
<tbody>
<tr>
<td><strong>VTE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>200.482</td>
<td>265.233</td>
<td></td>
<td>465.715</td>
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<tr>
<td>Pulmonary embolism</td>
<td>86.511</td>
<td>209.471</td>
<td></td>
<td>295.982</td>
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<tr>
<td><strong>VTE associated death</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient on anticoagulation</td>
<td>108.535</td>
<td>261.477</td>
<td></td>
<td>370.012</td>
</tr>
<tr>
<td>Patient not on anticoag.</td>
<td>8.124</td>
<td>18.349</td>
<td></td>
<td>26.473</td>
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<td>Sudden death</td>
<td>63.541</td>
<td>153.853</td>
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<td>217.394</td>
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<td></td>
<td>36.870</td>
<td>89.275</td>
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<td>126.145</td>
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</tbody>
</table>

Epidemiology US 2007

80 / 100,000
200,000 cases/y
50,000 PE
25,000 death´s to PE

NCHS 2007

Venous thromboembolism: annualised United States models for total, hospital-acquired and preventable costs utilising long-term attack rates

For VTE in the base model, annual cost ranges in 2011 US dollars for total, hospital- acquired, and hospital-acquired "preventable" costs and were $13.5-$27.2, $9.0-$18.2, and $4.5-$14.2. The second sensitivity analysis with long-term attack rates (LTAR) for recurrent events and post-thrombotic syndrome and chronic pulmonary thromboembolic hypertension demonstrated annual US total, hospital-acquired and hospital-acquired "preventable" VTE costs ranging from $15.4-$34.4, $10.3-$25.4, and $5.1-$19.1.

Ratio behind the treatment

Therapy of acute symptoms / phlegmasia
Prevention of post thrombotic syndrom
Protection against pulmonary embolism
Prevention of chronic thrombembolic pulmonary hypertension
Management of Massive and Submassive Pulmonary Embolism, Iliofemoral Deep Vein Thrombosis, and Chronic Thromboembolic Pulmonary Hypertension: A Scientific Statement From the American Heart Association


European Heart Journal Advance Access published August 29, 2014

ESC GUIDELINES

2014 ESC Guidelines on the diagnosis and management of acute pulmonary embolism

The Task Force for the Diagnosis and Management of Acute Pulmonary Embolism of the European Society of Cardiology (ESC)

Endorsed by the European Respiratory Society (ERS)
DVT / VT - what do we need?

Endovascular revascularisation system

- effective
- fast
- easy to use
- no or little side effects
- one session use (definitively)
- no lysis drug
- no ICU-stay
DVT / VT what do we have?

Conservative medical treatment (eg. LMWH, OAC, DOAC)

Systemic thrombolyis

Local thrombolysis

Endovascular approaches

- Thrombus fragmentation and removal by Ballon-PTA, Basket, Aspiration
- Pharmacomechanical thrombolysis & CDT (Trellis (Covidien))
  AngioJet (Boston Sc. (Medrad))
  EkoSonic (BTG)
- Mechanical thrombectomy devices
  Aspirex (Straub)
  Angiovac (Argon)
  Tretorola (Teleflex)
  Cleaner 15 / XT
# mechanical thrombectomy - Aspirex®S

<table>
<thead>
<tr>
<th>Size</th>
<th>Length cm</th>
<th>GW</th>
<th>OD mm</th>
<th>rVD mm</th>
<th>Rotation rpm</th>
<th>MAC ml/min</th>
<th>Head</th>
</tr>
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<tr>
<td>6 F</td>
<td>110</td>
<td>0,018</td>
<td>2,0</td>
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<td>60.000</td>
<td>45</td>
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<td>8 F</td>
<td>85</td>
<td>0,018</td>
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<td>5 - 8</td>
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<td>75</td>
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<td>3,3</td>
<td>7 - 12</td>
<td>40.000</td>
<td>130</td>
<td>8-shape</td>
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</table>

GW-Guidewire, OD-outer diameter, rVD-recommended Vessel Diameter, MAC-maximum aspiration capacity
primary clinical indications

symptomatic Iliofemoral Vein Thrombosis
symptomatic Cervicobrachial Vein Thrombosis
Vena Cava Thrombosis
symptomatic Portal Vein Thrombosis
(Pulmonary Embolism)

No controindication against pharmocological lysis or endovascular intervention

(age of thrombus < 21 d)
primary clinical indications
primary clinical indications

age of thrombus 21 d

Over time, thrombus organization begins with the infiltration of inflammatory cells into the clot. This results in a fibroelastic intimal thickening at the site of thrombus attachment in most patients and a fibrous synechiae in up to 11%. In many patients, this interaction between vessel wall and thrombus leads to valvular dysfunction and overall vein wall fibrosis. Histological examination of vein wall remodeling after venous thrombosis has demonstrated an imbalance in connective tissue matrix regulation and a loss of regulatory venous contractility that contributes to the development of chronic venous insufficiency.


87 year old female patient, iliofemoral DVT left

Thrombus head in the common femoral vein
87 year old female patient, iliofemoral DVT left
14 year old female patient, iliofemoral IVC DVT right
14 year old female patient, iliofemoral IVC DVT right
after 24 month
59 y m, MTS, desc. Iliofemoral DVT left
59 y m, MTS, desc. Iliofemoral DVT left
59 y m, MTS, desc. Iliofemoral DVT left
mechanical thrombectomy – underlaying pathology
Two center experiences for DVT thrombectomy with the Aspirex® catheter

- 24 Aspirex thrombectomy procedures
- 20 DVTs lower limb
- 4 DVTs upper limb
- 26 Aspirex thrombectomy procedures
- 23 DVTs lower limb
- 3 DVTs upper limb

Technical success analysis
Procedural details analysis
Safety analysis
12 month follow up patency analysis
Data from Rostock

- 26 patients (12 female = 46%), Mean age: 50
- Duration of symptoms: 1 day – 6 months (and longer)
- 21 iliofemoral DVT (5 r, 14 l, 12 b)
- 2 descending IVC thrombosis (?, m 9 y, f 27 y)
- 3 subclavian vein thrombosis (2 Port, 1 idiop.)
- Technical success = ready in cath lab: 96 % (25/26 patients)
- Stent rate: 23 pts. = 89 %
- No SAE (bleeding, hematoma, pulmonary embolism)

- 2 perforations (brachial vein, CFV) no therapy
- 1 wire-tip loss → snare
Iliofemoral DVT Data from Arnsberg

- 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: 100% (24/24 patients)
- No prolonged lytic therapy, just r-tPa bolus in 2 patients
- Stent rate 100%
- Complications: No bleeding, PE
  - 2 small perforations in the CIV stent
  - 1 wire loss snared

Klinikum Arnsberg
Akademisches Lehrkrankenhaus
Westfälische Wilhelms-Universität Münster
Iliofemoral DVT combined Data

• Technical Success: 49/50, 98%
• Major complication: 0/50
• Minor complication: 4/50, 8% perforation
  2/50, 4% wire loss
  6/50, 12%
• 6 / 12 month patency: 45/50, 90%
63 y w, SVT r after Port - AspirexS
63 y w, SVT r after Port - AspirexS
63 y w, SVT r after Port - AspirexS
63 y w, SVT r after Port - AspirexS
forced flushing of the sheath during procedure in any approach (6F Aspirex®S aspirates approximately 45 ml/min, the 8F 75ml/min and the 10F 180ml/min) with a introducer sheath + 1F systemic not local (side port) administration of heparin and ACT-measurement

pause action, remove and rinse the catheter

early replacement of the GW – spare wire

take care of the GW

choose the appropriate Size

avoid friction and narrow curves

„What´s in my Bag?“

Post treatment: Asprin 100 mg plus OAC
Aspirex – Competitors

AngioJet: time limitation, finish as local lysis
systemic irritation due to cell destruction

Trellis: time-consuming,
 rtPa,
not for IVC

EkoSonic: lysis drug,
 ICU-stay
no single session


Jackson et l, Catheter-directed thrombolysis and/or thrombectomy with selective endovascular stenting as alternative to systemic anticoagulation for treatment of acute deep venous thrombosis, j.am.surg 190 (2005): 871-876

Venous recanalisation is a complex process
three stages

1. **pre-intervention-examination/treatment**
   - medical history / physical examination
duplex ultrasound, if needed more modalities
how old, how long, how acute
to determine the optimal individual strategy
to plan the intervention access site, material
(GW, Balloon, Stent, Infusion)
to set / optimize the anticoagulation
to secure the bailout procedure
2. intervention

in every case under anticoagulation: heparin-perfusion
ACT-measurement
ultrasound guidance
tranquilizer / sedativa / anaesthesia
saline +/- contrast pressure-infusion
place the guidewire in a free lumen
far away from the tip, not too far
and take care of it
never introduce it from the handle
spare GW, spare collection bag
correct position of the handle
somebody observe the blood-flow, hear the noise
react, if there is something unexpected
(check 1: catheter, 2: chamber, 3: connection coll. Bag)
3. post-intervention

take care of the anticoagulation therapy:
Heparin / VitK-Antagonists / NOAK / ASS

compression tape / stockings
pneumatic compression / movement !!!!!!!!!!!!!!!

control at next day, at admission, within 7 days, within 2 weeks - reintervention!
Conclusion

PMT with a mechanical thrombectomy device (Aspirex®S)

- restores vein patency fast and effective
- preserves valvular function
- able to prevent PTS, PE, CTEPH
- low risk, less adverse effects
- no lysis-time and lysis-drug
- no need for ICU stay
Thank you

Rostock beach
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