Improved clinical outcomes – Evidence on thrombectomy followed by stenting

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Disclosure

Speaker name:

Michael Lichtenberg

I have the following potential conflicts of interest to report:

- Consulting (CR Bard, Veniti, Volcano, Biotronik, Terumo, Boston, Straub Medical, Veryan, TVA medical, Spectranetics, Cook, Optimed)
- 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</td>
<td>177.236</td>
<td>218.437</td>
<td>395.673</td>
</tr>
<tr>
<td>Pulm. Hypertension</td>
<td>1.173</td>
<td>2.961</td>
<td>4.135</td>
</tr>
</tbody>
</table>

May-Thurner Syndrome

It causes between **two and five percent** of lower-extremity venous disorders. May–Thurner syndrome is often **unrecognized**; however, current estimates are that this condition is three times more common in women than in men. The classical syndrome typically presents in the second to fourth decades of life. In the 21st century in a broader disease profile, the syndrome acts as a **permissive lesion and becomes symptomatic when something else happens such as**, following trauma, a change in functional status such as swelling following orthopaedic joint replacement.

Venous outflow obstruction

webs, spurs, chords
C6, 58 year female with chronic outflow obstruction = Chronic DVT
Sinus XL Stent (22 x 80 mm)
4 x Sinus venous stents
Stent options!

- Off label use in venous system
- Good radial force
- Expensive
- High flexibility

Boston Wallstent

Optimed

Cook Zilver Vena

Veniti Vici

- Good radial force
- Expensive
- High flexibility

- Low radial force
- Expensive
- High flexibility

- High flexibility
- Good radial force
sinus-
Obliquus
Indication for proximal venous thrombectomy

23 y female patient
Young and active 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
Standard Treatment vs. CDT

Enden T, et al: CaVenT Study
- Follow-up at 24 months:
  - Number needed to treat: 7

[Lancet. 2012 Jan 7;379(9810):31-8.]

Long-term outcome after additional catheter-directed thrombolysis versus standard treatment for acute iliofemoral deep vein thrombosis (the CaVenT study): a randomised controlled trial

Tone Enden, Ylle Meiga, Nils-Einar Klouw, Carl-Erik Stølevold, Leiv Sandvik, Waidei Ghanaimo, Gorm Meijahl, Per Andre Holme, Lars Olaf Holmen, Anne Mette Hjerpsted, Gunnar Sandvik, Per Morten Sandvik, on behalf of the CaVenT Study Group.

**STENT RATE**

Only 17%

= Patients still a have hemodynamic outflow obstruction

Table 2: Short-term and long-term outcomes
All patients with patent veins and normal valve function showed no sign of dermal pigmentation, ulceration or venous claudication at follow-up.
# PEARL Comparison
## Treatment of Lower Extremity DVT

<table>
<thead>
<tr>
<th></th>
<th>PEARL*</th>
<th>Venous Registry†</th>
<th>CaVenT‡</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># of Patients</td>
<td>329</td>
<td>287</td>
<td>90</td>
</tr>
<tr>
<td># of Sites</td>
<td>32</td>
<td>63</td>
<td>20</td>
</tr>
<tr>
<td>Prior DVT</td>
<td>40%</td>
<td>31%</td>
<td>10%</td>
</tr>
<tr>
<td>Primary Treatment</td>
<td>AngioJet Thrombectomy With or Without PMT</td>
<td>CDT</td>
<td>CDT</td>
</tr>
<tr>
<td>Stent Placement</td>
<td>35%</td>
<td>33%</td>
<td>17%</td>
</tr>
<tr>
<td>Primary access</td>
<td>Popliteal</td>
<td>Popliteal</td>
<td>Popliteal</td>
</tr>
<tr>
<td>Male</td>
<td>57%</td>
<td>48%</td>
<td>64%</td>
</tr>
<tr>
<td>Age (mean)</td>
<td>52.2 yrs</td>
<td>47.5 yrs</td>
<td>53.3 yrs</td>
</tr>
<tr>
<td>Treatment Location</td>
<td>Iliofemoral – femoral pop</td>
<td>Iliofemoral – femoral pop</td>
<td>CFV or iliofemoral</td>
</tr>
<tr>
<td>Limbs Involved</td>
<td>Left=62%; Right=38%</td>
<td>Left=61%; Right=39%</td>
<td>Left=60%; Right=40%</td>
</tr>
</tbody>
</table>

†Mewissen MW, Seabrook GR. Radiology 1999:211:39-49

CDT, catheter-directed thrombolysis; CFV, common femoral vein; LMWH, low molecular weight heparin; PMT, pharmacomechanical thrombolysis
# PEARL Comparison
## Treatment of Lower Extremity DVT

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<tbody>
<tr>
<td></td>
<td></td>
<td>Overall % Thrombus Removal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Overall % Thrombus Removal</td>
<td>96%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CDT (N=28)</td>
<td>93%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CDT+PPS/RL (N=167)</td>
<td>97%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PPS/RL (N=113)</td>
<td>95%</td>
</tr>
<tr>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute: % Thrombus Removal</td>
<td>97%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chonic: % Thrombus Removal</td>
<td>95%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Primary Patency</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Freedom from Rethrombosis</td>
<td>6 Mon=87%; 12 Mon=83%</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

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†Mewissen MW, Seabrook GR. Radiology 1999;211:39-49
Fixed low-dose ultrasound-assisted catheter-directed thrombolysis followed by routine stenting of residual stenosis for acute ilio-femoral deep-vein thrombosis.

Engelberger RP, Fahmi J, Willenberg T, Baumann F, Spirk D, Diehm N, Do DD, Baumgartner I, Kucher N.

Abstract

Patients with ilio-femoral deep-vein thrombosis (DVT) are at high risk of developing the post-thrombotic syndrome (PTS). In comparison to anticoagulation therapy alone, extended venography-guided catheter-directed thrombolysis without routine stenting of venous stenosis in patients with ilio-femoral DVT is associated with an increased risk of bleeding and a moderate reduction of PTS. We performed a prospective single-centre study to investigate safety, patency and incidence of PTS in patients with acute ilio-femoral DVT treated with fixed-dose ultrasound-assisted catheter-directed thrombolysis (USAT; 20 mg rt-PA during 15 hours) followed by routine stenting of venous stenosis, defined as residual luminal narrowing >50%, absent antegrade flow, or presence of collateral flow at the site of suspected stenosis. A total of 87 patients (age 46 ± 21 years, 60% women) were included. At 15 hours, thrombolysis success ≥50% was achieved in 67 (77%) patients. Venous stenting (mean 1.9 ± 1.3 stents) was performed in 70 (80%) patients, with the common iliac vein as the most frequent stenting site (83%). One major (1%; 95% CI, 0-6%) and 6 minor bleedings (7%; 95% CI, 3-14%) occurred. Primary and secondary patency rates at 1 year were 87% (95% CI, 74-94%) and 96% (95% CI, 88-99%), respectively. At three months, 88% (95% CI, 78-94%) of patients were free from PTS according to the Villalta scale, with a similar rate at one year (94%, 95% CI, 81-99%). In conclusion, a fixed-dose USAT regimen followed by routine stenting of underlying venous stenosis in patients with ilio-femoral DVT was associated with a low bleeding rate, high patency rates, and a low incidence of PTS.

Stent rate 80 %
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)

5.1. We recommend the use of self-expanding metallic stents for treatment of chronic iliofemoral compressive or obstructive lesions that are uncovered by any of the thrombus removal strategies (Grade 1C).
Early Clot Removal
Many Choices – None Perfect!

EKOS® Peripheral Infusion System

Trellis™ System

AngioJet®

Aspirex® (Rotational thrombectomy)

Indigo System ® (Penumbra)

6 – 10 French
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, 10 F Aspirex®

8 F: blood volume aspiration up to 75 ml/min
10 F: blood volume aspiration up to 130 ml/min
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
Conclusion

DVT thrombectomy

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

Treat the underlying reason with a dedicated iliac vein stent
THANK YOU FOR YOUR ATTENTION
Improved clinical outcomes – Evidence on thrombectomy followed by stenting

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