Dedicated Venous Stents make sense for Iliofemoral Vein Obstructions

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Conflict of Interest - Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship Company
1. Honoraria for lectures: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan
2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific
3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow
4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica

Iliofemoral Venous Disease

Central Peripheral Collateral
Obstruction
Venous hypertension
Microvascular pathology
Leg pain/swelling/LDS/ulceration

Iliofemoral Outflow Obstruction – Western Europe

Country: Western Europe
Population ≥ 18 Years Age

Incidence
Annual Patients
Annual Treatable Patients

<table>
<thead>
<tr>
<th>CEAP Classification</th>
<th>Prevalence</th>
<th>Affected Population</th>
<th>% Obstructive Component</th>
<th>Treatable Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>C0</td>
<td>9.7%</td>
<td>32.396.246</td>
<td>N/A</td>
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</tr>
<tr>
<td>C1</td>
<td>59.0%</td>
<td>196.643.879</td>
<td>N/A</td>
<td>0</td>
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<tr>
<td>C2</td>
<td>14.3%</td>
<td>47.627.814</td>
<td>22.00%</td>
<td>10.478.119</td>
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<tr>
<td>C3</td>
<td>13.4%</td>
<td>44.694.821</td>
<td>21.80%</td>
<td>9.743.471</td>
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<tr>
<td>C4</td>
<td>2.9%</td>
<td>9.532.229</td>
<td>21.80%</td>
<td>2.078.026</td>
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<tr>
<td>C5</td>
<td>0.6%</td>
<td>2.066.427</td>
<td>21.80%</td>
<td>450.481</td>
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<tr>
<td>C6</td>
<td>0.1%</td>
<td>333.295</td>
<td>60.00%</td>
<td>199.977</td>
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<tr>
<td>CVD (C2-C6)</td>
<td>104.254.585</td>
<td>23.458.348</td>
<td></td>
<td>23.458.348</td>
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</tbody>
</table>

Days of hospitalisation

C6, 58 year female with chronic outflow obstruction

Sinus XL Stent (22 x 80 mm)
4 x Veniti Stent (16 x 120 mm + 14 x 60 mm)
Stent options!

Boston Wallstent
Cook Zilver Vena
Optimed Sinus Obliquus
Cook Zilver Vena
Veno
Optimed Sinus Obliquus
VIRTUS Trial
Vivo (EU) Trial
 Vernici Vici

"Choose wisely"

Radial Force and Crush Resistance

This was a 16 x 100 mm venous stent. It is compressed to 16 x 60 mm

Radial Force and Crush Resistance

Stent Flexibility
Arnsberg Prospective Venous Registry
VENITI VICI VENOUS STENT® System

Objective
Assess safety & effectiveness in achieving patency of target venous lesion through 36 months post stent placement (VENITI VICI Stent)

Effectiveness
Primary Patency @ 12-M

Principal Investigators
- Dr. Michael Lichtenberg
- Dr. Rick de Graaf

Study Design
Ongoing prospective, single arm, single center non-randomized registry (Start 1/2015)

Patient Population
Subjects with clinically significant chronic non-malignant obstruction of the iliofemoral venous segment

Demographics N=82
- Age in years (mean ± SD [range]): 56.5 ± 16.7 [19-84]
- Gender: Male 45.1% (N=37), Female 54.9% (N=45)
- Ethnicity: Caucasian 100% (N=82)

Medical history N=82
- Coagulation disorder: 4.9% (N=4)
- Pulmonary embolism: 24.4% (N=20)
- Deep vein thrombosis: 46.3% (N=38)
- History of cancer: 13.4% (N=11)

Lesion location(s) Reported (N=82)
- Sides treated:
  - Both: 8.5% (N=7)
  - Left: 75.6% (N=62)
  - Right: 15.9% (N=13)

- Lesion location(s):
  - Left:
    - Common iliac vein
    - External iliac vein
    - Common femoral vein
    - Common iliac vein, external iliac vein
    - Common iliac vein, external iliac vein, common femoral vein
    - External iliac vein, common femoral vein
  - Right:
    - Common iliac vein
    - External iliac vein
    - Common femoral vein
    - Common iliac vein, external iliac vein
    - Common iliac vein, external iliac vein, common femoral vein
    - External iliac vein, common femoral vein
  - Both:
    - External iliac (R), common iliac (L) vein
    - External iliac (R), common iliac (L), external iliac (L) vein
    - Common iliac (R+L), external iliac (L) vein
    - Common iliac (R+L), external iliac (R+L), common femoral (L) vein
    - Common iliac (R+L), external iliac (R+L), common femoral (R+L) vein

60 / 82 (73 %) patients: Postthrombotic
22 / 82 (27%) patients: NIVL

Effectiveness analysis

Mean VCSS score (tSD)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>FU1</th>
<th>FU2</th>
<th>FU3</th>
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<td>5.8</td>
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</table>

Mean CEAP score (tSD)

<table>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>2.6</td>
<td>2.8</td>
<td>2.5</td>
<td>2.0</td>
</tr>
</tbody>
</table>

Effectivity Classification
100% (N=82)

Medical History
- Age
- Gender
- Coagulation disorder
- Pulmonary embolism
- Deep vein thrombosis
- History of cancer
- Venous insufficiency
• Think obstruction! – an obstructive component in venous disease is common
• Patients considered for stenting should have pertinent symptoms & signs
• Treatment based on >50% area/diameter stenosis on morphological studies
• Use dedicated venous stents!

THANK YOU FOR YOUR ATTENTION