Endovascular treatment of severe TASC C and D external iliac artery occlusive disease

SAINT-LEBES Bertrand
Toulouse – FRANCE
Disclosure

Speaker name:
SAINT-LEBES

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)

I do not have any potential conflict of interest
### External iliac artery obstructive disease

<table>
<thead>
<tr>
<th>TASC C</th>
<th>TASC D</th>
</tr>
</thead>
</table>
| • Bilateral EIA stenoses 3-10 cm long not extending into the CFA  
• Unilateral EIA stenosis extending into the CFA  
• Unilateral EIA occlusion that involves the origins of internal iliac and/or CFA | • Diffuse disease involving the aorta and both iliac arteries  
• Diffuse multiple stenoses involving the unilateral CIA, EIA and CFA  
• Unilateral occlusions of both CIA and EIA  
• Bilateral occlusions of EIA |
• Between July 2009 and September 2010

Endovascular therapy may be considered the preferred first-line treatment option of iliac lesions irrespectively of TASC lesion category.

• 24M primary patency rate
  – TASC C: 91.9%
  – TASC D: 84.8%
Vascular stent design matters

- Stent design should accommodate natural anatomic forces
- Goal: allow arteries to maintain as much natural behavior and function
- Dynamic forces of the EIA require a compliant stent to minimize chronic vessel injury and stresses on stent that can lead to fracture
Stent fractures significantly influenced the patency of the stented segment.

Unique Dual-Component Stent Design

Designed to:

• Maximize flexibility while minimizing risk of stent fracture
• Allow axial compression while resisting stent elongation
• Naturally conforms and allows vessel movement

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Dual-Component Stent Design (Nitinol+ePTFE)

Carmedia bioactive surface (Heparin Bonding)
Device information

Unlocking the delivery system

- When unlocking the catheter will advance 0.5cm
- Reposition before deployment

<table>
<thead>
<tr>
<th>Device Sizing</th>
<th>Labeled Device Diameter (mm)</th>
<th>Recommended Vessel Diameter (mm)</th>
<th>Introducer Sheath Size (Fr)</th>
<th>Guidewire Diameter</th>
<th>Recommended Balloon Diameter for Device Touch-up (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5</td>
<td>4.0 – 4.7</td>
<td>6</td>
<td>0.035&quot; (0.889 mm)</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>4.8 – 5.5</td>
<td>6</td>
<td>0.035&quot; (0.889 mm)</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>5.6 – 6.5</td>
<td>6</td>
<td>0.035&quot; (0.889 mm)</td>
<td>7.0</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>6.6 – 7.5</td>
<td>7</td>
<td>0.035&quot; (0.889 mm)</td>
<td>8.0</td>
</tr>
</tbody>
</table>

Recommended stent compression within the vessel is approximately 5 – 20%.

Lengths: 30, 40, 60, 80, 100mm
Catheter Lengths: 80, 120cm
CLINICAL CASES
Case 1

• Mr P
  – 55 Y, Male
  – Risk Factors: Tobacco use, Dyslipidemia, obesity
  – Rutherford III, ABI 0,71
  – TASC D
  – Ttt 25/06/2014
Case 2

- Mr A
  - 60 Y, Male
  - Risk Factors: Tobacco use, Dyslipidemia
  - Rutherford III, ABI 0,6
  - TASC C
  - Ttt 07/01/2014
Case 3

• Mr H
  – 47 Y, Male
  – Risk Factors: Tobacco use, Obesity, HT
  – Rutherford III, ABI 0.61
  – TASC D
  – Ttt 27/02/2014
Case 4

• Mr P
  – 75 Y, Male
  – Risk Factors: Tobacco stopped, Obesity, dyslipidemia
  – Rutherford III, ABI 0.68
  – TASC C
  – Ttt 09/04/2014
Case 5

• Mrs M
  – 78 y old, Female
  – Risk factors: Dyslipidemia, Obesity, Diabetes
  – CLI, Rutherford IV, ABP 0.6
  – Long Occlusion of EIA after IIA
CLINICAL DATA
# Our Results

## From 10/2012 to 12/2015

<table>
<thead>
<tr>
<th>Total</th>
<th>N patients</th>
<th>98</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limbs</td>
<td>106</td>
<td></td>
</tr>
<tr>
<td>Sex ratio</td>
<td>76 – 22 (77.6%)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>66 (46 – 92)</td>
<td></td>
</tr>
<tr>
<td>Lesions length average</td>
<td>80mm (40 – 120mm)</td>
<td></td>
</tr>
<tr>
<td>TASC C</td>
<td>57 (58%)</td>
<td></td>
</tr>
<tr>
<td>TASC D</td>
<td>41 (42%)</td>
<td></td>
</tr>
<tr>
<td>8 bilateral-11 double stenting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rutherford II</td>
<td>20 (19%)</td>
<td></td>
</tr>
<tr>
<td><strong>Rutherford III</strong></td>
<td><strong>67 (63%)</strong></td>
<td></td>
</tr>
<tr>
<td>Rutherford IV</td>
<td>15 (14%)</td>
<td></td>
</tr>
<tr>
<td>Rutherford V</td>
<td>4 (4%)</td>
<td></td>
</tr>
</tbody>
</table>

## Risk Factors

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tabacco</strong></td>
<td><strong>93 (95%)</strong></td>
</tr>
<tr>
<td>Diabetis</td>
<td>25 (26%)</td>
</tr>
<tr>
<td>Obesity</td>
<td>46 (47%)</td>
</tr>
<tr>
<td>HTA</td>
<td>37 (38%)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>60 (61%)</td>
</tr>
<tr>
<td>ABI</td>
<td>0,63</td>
</tr>
<tr>
<td>ABI Rutherford II</td>
<td>0,73</td>
</tr>
<tr>
<td>ABI Rutherford III</td>
<td>0,65</td>
</tr>
<tr>
<td>ABI Rutherford IV</td>
<td>0,48</td>
</tr>
<tr>
<td>ABI Rutherford V</td>
<td>0,34</td>
</tr>
</tbody>
</table>

**B. Saint-lebes and M. Sibe, JVS submission process**
Results n=106

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures completed</td>
<td>100%</td>
</tr>
<tr>
<td>FU</td>
<td>16.8 months (13 to 51)</td>
</tr>
<tr>
<td>Perioperative death</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Late Mortality (&gt; M6)</td>
<td>2 (1.8%)</td>
</tr>
<tr>
<td>Thombosis</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>Stenosis</td>
<td>4 (3.8%)</td>
</tr>
<tr>
<td>Amputation</td>
<td>0</td>
</tr>
</tbody>
</table>

98% at 24 M
98% at 36 M
88% at 36 M

B. Saint-lebes and M. Sibe, JVS submission process
Conclusions

Tigris is a good option treatment
- Flexibility, conformability and accuracy: EIA

CBAS
- Avoid early thrombosis

Disadvantages
- Only short lengths (30-100mm)
- No extremity markers

Required clinical results
- FU, long term results
- RCT
Thanks for your attention

bsl@saintlebes.com
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