What I am still learning with the GORE® VIABAHN® endoprosthesis

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Disclosure

Speaker name:
MMPJ Reijnen

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
Introduction

• **Development in stent design:**
  - Heparin-bonding technology
  - Contoured proximal edge
  - 25 cm long stents

• **Versatility in use:**
  - SFA occlusive disease
  - Popliteal artery aneurysm
  - Many other indications.....
Introduction

• Development in stent design:
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• Versatility in use:
  • SFA occlusive disease
  • Popliteal artery aneurysm
  • Many other indications.....
SFA occlusive disease

• Technical aspects
  • Entry, passing and re-entry

• Theoretical aspects
  • Positioning of the technique in the treatment algorithm of SFA occlusive disease
  • Covering of collateral arteries
  • Edge stenosis and thrombosis
Technical aspects

• Approach:
  • Percutaneous
  • Open introduction
  • Hybrid techniques

• Passing of the lesion:
  • Regular wires, catheters and balloons
  • Reekross balloon
  • Specific crossing devices

• Re-entry:
  • Re-entry devices
  • Popliteal approach
Outback catheter

• Useful tool to recanalize chronic femoropopliteal occlusions after failed guidewire re-entry
• Success rate 65-92%
• Moderate or severe calcification at the site of re-entry is a significant predictor of failure ($P = .01$)

Popliteal approach

- Combined ipsilateral antegrade-retrograde approach:
  - Cheap alternative to re-entry devices
  - ‘Re-entry’ point as proximal as possible thus preserving collaterals as much as possible

Place in the treatment algorithm of SFA occlusive disease?
Current practice Rijnstate Hospital

• Short lesions (<5cm): plain balloon angioplasty

• Intermediate lesions (5-15 cm): Drug-eluting balloon and BMS when indicated

• Long lesions (>15 cm): Viabahn® or surgery: SUPERB trial
SuperB trial interim analysis

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Surgical (n=58)</th>
<th>Endoluminal (n=56)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>67</td>
<td>69</td>
<td>0.20</td>
</tr>
<tr>
<td>Gender (male; %)</td>
<td>83</td>
<td>68</td>
<td><strong>0.07</strong></td>
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<tr>
<td><strong>Risk factors</strong></td>
<td></td>
<td></td>
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<tr>
<td>Tobacco use (%)</td>
<td>54</td>
<td>50</td>
<td>0.71</td>
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<tr>
<td>Hypertension (%)</td>
<td>73</td>
<td>70</td>
<td>0.68</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>34</td>
<td>36</td>
<td>0.84</td>
</tr>
<tr>
<td>Dyslipidemia (%)</td>
<td>66</td>
<td>71</td>
<td>0.54</td>
</tr>
<tr>
<td>Cardiac disease (%)</td>
<td>66</td>
<td>61</td>
<td>0.56</td>
</tr>
<tr>
<td>Pulmonary disease (%)</td>
<td>25</td>
<td>20</td>
<td>0.50</td>
</tr>
<tr>
<td>Renal insufficiency (%)</td>
<td>16</td>
<td>11</td>
<td>0.41</td>
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<tr>
<td><strong>Rutherford</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>70</td>
<td>55</td>
<td>0.23</td>
</tr>
<tr>
<td>4</td>
<td>14</td>
<td>27</td>
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<tr>
<td>5</td>
<td>14</td>
<td>18</td>
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</tr>
<tr>
<td>6</td>
<td>2</td>
<td>0</td>
<td></td>
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</tbody>
</table>

*Interim analysis; Data may be subjected to changes*
## SuperB trial interim analysis

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<thead>
<tr>
<th>Characteristic</th>
<th>Surgical (n=58)</th>
<th>Endoluminal (n=56)</th>
<th>P value</th>
</tr>
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<tbody>
<tr>
<td><strong>TASC=2 (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>5</td>
<td>4</td>
<td>0.60</td>
</tr>
<tr>
<td>C</td>
<td>15</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>80</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>Lesion length (cm)</td>
<td>23.9</td>
<td>24.0</td>
<td>0.99</td>
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<tr>
<td>Flush occlusion (%)</td>
<td>39</td>
<td>29</td>
<td>0.29</td>
</tr>
<tr>
<td>Diameter PA (mm)</td>
<td>5.6</td>
<td>5.2</td>
<td>0.02</td>
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<tr>
<td><strong>Number of patent outflow vessels (%)</strong></td>
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<td>0</td>
<td>3</td>
<td>8</td>
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<td>14</td>
<td>16</td>
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<tr>
<td>2</td>
<td>22</td>
<td>29</td>
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</tr>
<tr>
<td>3</td>
<td>57</td>
<td>46</td>
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<tr>
<td>Pre-procedural ABI</td>
<td>0.6</td>
<td>0.6</td>
<td>0.33</td>
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</tbody>
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*Interim analysis; Data may be subjected to changes*
SuperB trial interim analysis

<table>
<thead>
<tr>
<th>Patency</th>
<th>Surgical (n=58)</th>
<th>Endoluminal (n=56)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 MONTH (n=101)</strong></td>
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<tr>
<td>Primary patency</td>
<td>92,3%</td>
<td>95,8%</td>
<td>0,855</td>
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<tr>
<td>Primary assisted patency</td>
<td>92,3%</td>
<td>97,9%</td>
<td>0,672</td>
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<tr>
<td>Secondary patency</td>
<td>92,3%</td>
<td>97,9%</td>
<td>0,444</td>
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<tr>
<td><strong>3 MONTHS (n=75)</strong></td>
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<td></td>
<td></td>
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<tr>
<td>Primary patency</td>
<td>86,4%</td>
<td>91,6%</td>
<td>0,254</td>
</tr>
<tr>
<td>Primary assisted patency</td>
<td>86,4%</td>
<td>95,6%</td>
<td>0,354</td>
</tr>
<tr>
<td>Secondary patency</td>
<td>86,4%</td>
<td>95,6%</td>
<td>0,261</td>
</tr>
<tr>
<td><strong>6 MONTHS (n=81)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary patency</td>
<td>84,2%</td>
<td>89,1%</td>
<td>0,472</td>
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<tr>
<td>Primary assisted patency</td>
<td>86,4%</td>
<td>93,0%</td>
<td>0,377</td>
</tr>
<tr>
<td>Secondary patency</td>
<td>86,4%</td>
<td>95,6%</td>
<td>0,469</td>
</tr>
</tbody>
</table>

Interim analysis; 
Data may be subjected to changes
Focal edge stenosis
Edge stenosis and thrombosis

Avoidance by proper sizing, covering all disease and no post-dilation outside the endoprosthesis

Retrospective analysis of 115 edge stenosis in 88 patients

- 77% presented within the 1\textsuperscript{st} year
- 2/3 located at the proximal edge

\begin{tabular}{ |c|c| }
\hline
PTA & Extension \\
\hline
45\% & 43\% \\
81\% & 92\% \\
\hline
\end{tabular}

→ Role of PTX-based techniques?
Conflict of interests

Healthy to healthy: Minimalizes risk on occlusion

Preserving collaterals: Prevention of clinical deterioration in case of occlusion
Collateral arteries

• Retrospective analysis on outcome of failures over a 10-year period
• 449 patients of which 49 with definitive failure
• ABI significantly lower at the time of failure
  $(0.66 \pm 0.19$ versus $0.45 \pm 0.19$)
• Clinical consequences
  • Pre-treatment Rutherford $3.1 \pm 1.3$
  • Post-failure Rutherford $3.3 \pm 0.6$
  • 80% presented with the same or even an improved Rutherford category
• Amputation rate: 4.1% (n=2)

Collateral arteries

- Distal anastomosis mostly above P2
- Importance of collaterals of P2 and P3?
- Combination with GORE® TIGRIS®?

5x15 mm Tigris
6x250mm Viabahn
Conclusions

• The use of the Viabahn® for SFA occlusive disease is safe and related to an acceptable outcome
• Technical aspects continue to evolve
• Focus on patient selection and the treatment and prevention of edge stenosis
• The place in the treatment algorithm will remain under debate
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