Covered Stents

Matthias Ulrich
Covered Stents – Available Devices

- Balloon expandable covered stents
- Self-expanding covered stents
- Stent-grafts
ADVANTA® (Atrium)

- Advanta™ V12 ePTFE covered balloon expandable stainless steel stent, OTW
- Ø 5 mm – 16 mm
- Length 16 – 61 mm
- Shaft 80 and 120 cm
- Sheath: 5 - 11 Fr
- Self-expanding ePTFE-covered nitinol-stent
- Ø 5-8, 10, 12, 13.5 mm
- Length 20, 30, 40, 60, 80, 100, 120 mm
- Sheath: 8-9 (12) Fr
Stent-grafts for use in the SFA

- Viabahn Endoprosthesis (Gore)
  Nitinol + ePTFE
  Ø 5-13mm, length 2.5 – 25 cm
  Sheath: 7-12 Fr
  Katheter: 75 & 120 cm
- Heparin coating
  PROPATEN Bioactive Surface
Potential Indications for Covered Stents

- Traumatic vascular lesions, Vessel perforations
- Aneurysmatic Lesions
- Atherosclerotic obstructive lesions
  - Complex aorto-iliac obstructions ?
  - Long lesions in the SFA ?
  - In-stent restenosis ?
Rupture during recanalization of External Iliac Occlusion

After stenting and postdilatation with a 5 mm-balloon
Rupture during recanalization of External Iliac Occlusion after implantation of 8 / 60 Fluency
Multiple trauma with rupture of a profunda artery branch

Implantation of 5/50 Viabahn
Popliteal aneurysm

- 7 cm x 3 cm
- partially thrombosed
- distal embolization
Popliteal aneurysm

- Viabahn
  8 x 100 mm
Popliteal aneurysm

Result after postdilatation
Endovascular Treatment of popliteal artery aneurysm

- Hemobahn for pop. aneurysm treatment (n=15) versus open surgical repair (n=15)

- Randomized single center trial

Stentgraft-Implantation for Popliteal Aneurysms

Primary patency

Stentgraft-Implantation for Popliteal Aneurysms

Secondary patency

Endovascular Pop. Aneurysm Repair

25 patients with pop. aneurysms > 20mm or 1.5/1 Ø aneurysm/reference vessel

Mohan, Bray et al. *Eur J Endovasc Surg* 2006
Hemobahn 5 years after Implantation
Atherosclerotic obstructive lesions

Potential indications:

- Long lesions in the SFA?
- Complex aorto-iliac obstructions?
- In-stent restenosis?
Viabahn for Treatment of SFA-Obstructions

Viabahn Weighted Primary Patency

Primary Patency

0% 20% 40% 60% 80% 100%

0 1 2 3 4

Years

Jahnke Saxon
Bleyn Railo
Bauermeister Lammer
Tarantini Turicchia
Weighted Average Fischer

Not included:
- Deutshmann 2003: ballooned entire SFA, spot stented with Viabahn
- Bray 2003: Suboptimal anti-platelet therapy
- Fischer 2004: 1 center placed device in heavily calcified lesions (partial deployment) and in patients with little or no runoff (0 or < 1 vessel)
<table>
<thead>
<tr>
<th>Poor*</th>
<th>Good**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>Secondary</td>
</tr>
<tr>
<td>40%</td>
<td>67%</td>
</tr>
<tr>
<td>• Poor runoff</td>
<td>• Straight line runoff</td>
</tr>
</tbody>
</table>

* Fischer et al Zentralbi Chir 2001;126:138-143
** Jahnke et al JVIR 2003;14:41-51
Vibrant-Study

Viabahn versus bare Nitinol stent

- Viabahn vs. bare nitinol-stent
- Randomized, multi-center
- SFA-lesions with length > 8 cm
- 3-year surveillance via ultrasound
- 143 Patients (72 Viabahn / 76 Bare Nitinol)
### Vibrant-Study

**VlāBahn vs Are Nitinol stent**

#### Lesion characteristics

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>GORE VIABAHN® Endoprosthesis</th>
<th>Bare Nitinol Stent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TREATED OCCLUSIONS</strong></td>
<td>59.7%</td>
<td>56.6%</td>
<td>0.74</td>
</tr>
<tr>
<td><strong>TARGET LESION LENGTH (cm)</strong></td>
<td></td>
<td></td>
<td>0.87</td>
</tr>
<tr>
<td>Mean (Std Dev)</td>
<td>19 (8)</td>
<td>18 (7)</td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>20 (8 – 40)</td>
<td>16 (8 – 36)</td>
<td></td>
</tr>
<tr>
<td><strong>LESION CALCIFICATION</strong></td>
<td></td>
<td></td>
<td>0.01</td>
</tr>
<tr>
<td>None – Mild</td>
<td>37.5%</td>
<td>57.9%</td>
<td></td>
</tr>
<tr>
<td>Moderate – Severe</td>
<td>62.5%</td>
<td>42.1%</td>
<td></td>
</tr>
<tr>
<td><strong>TIBIAL RUNOFF</strong></td>
<td></td>
<td></td>
<td>0.10</td>
</tr>
<tr>
<td>1 Vessel</td>
<td>15.3%</td>
<td>22.4%</td>
<td></td>
</tr>
<tr>
<td>2 Vessel</td>
<td>50.0%</td>
<td>32.9%</td>
<td></td>
</tr>
<tr>
<td>3 Vessel</td>
<td>34.7%</td>
<td>44.7%</td>
<td></td>
</tr>
</tbody>
</table>
Vibrant-Study
VIaBahn veRsus bAre NItinol stenT

One Year Results

<table>
<thead>
<tr>
<th></th>
<th>GORE VIABAHN® Endoprosthesis</th>
<th>Bare Nitinol Stent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>97%</td>
<td>97%</td>
<td>1.00</td>
</tr>
<tr>
<td>Primary Patency (PSVR 2.5)</td>
<td>53%</td>
<td>58%</td>
<td>0.58</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>73%</td>
<td>69%</td>
<td>0.69</td>
</tr>
<tr>
<td>Assisted Primary Patency</td>
<td>84%</td>
<td>91%</td>
<td>0.41</td>
</tr>
<tr>
<td>Secondary Patency</td>
<td>93%</td>
<td>98%</td>
<td>0.19</td>
</tr>
</tbody>
</table>
Vibrant-Study

VIaBahn veRsus bAre Nitinol stenT

Patterns of restenosis

- **GORE VIABAHN® Endoprosthesis**
  - Focal edge stenosis comprised 87% GORE VIABAHN® Endoprosthesis failures
    - 50% isolated proximal edge
    - 30% both proximal and distal edges
    - 6% isolated distal edge

- **Bare Nitinol Stent**
  - In-stent stenosis comprised 93% bare nitinol stent failures
Diffuse Restenosis in Bare Nitinol Stent

Edge Restenosis in Stent-Graft Patient
Atherosclerotic obstructive lesions

Potential indications:
- Long lesions in the SFA?
- Complex aorto-iliac obstructions?
- In-stent restenosis?
Cobest - Trial

Aorto iliac lesion

• Prospective, Multicenter, Advanta covered stent versus bare stent, 123 Patients (83 V12 vs. 84 BMS)

• Objektive
  - Binary Restenosis (DU / CTA / DAS) at 1, 6, 12, and 18 month
  - Freedom From Stent Occlusion

Mwipatayi, Patrice LINC 2010
Cobest - Trial

Kaplan-Meier Curves For Freedom From Binary Restenosis

The development of binary restenosis between the two groups was statistically different. Hazard Ratio For Binary Restenosis (V12 vs BMS): 0.38 (CI: 0.1756 to 0.8333)
Cobest - Trial

COBEST - Clinical Improvement - Binary Restenosis

Percentage

Time (months)

- V12 Patency
- Bare Patency
- V12 Clin Imp
- Bare Clin Imp
Cobest - Trial

Subgroup analysis regarding TASC

- For TASC C/D Aorto-iliac occlusive disease, there is a difference in restenosis / freedom for occlusion between Covered stents and Bare metal stent at 12/18 months. **Recommend covered stent in TASC D/C as 1st choice?**

- There is no difference between Covered stents and Bare Metal stents for TASC B lesions. There is no patency difference or no difference in restenosis.

Kaplan-Meier curves for Freedom From Binary Restenosis for the type of stent used according to the TASC C/D group.
Leriche - Syndrome
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Leriche Syndrome

Balloon expandable covered stents

Bare Nitinol Stent
Atherosclerotic obstructive lesions

Potential indications:
- Long lesions in the SFA?
- Complex aorto-iliac obstructions?
- In-stent restenosis?
Atherosclerotic obstructive lesions

ISR Study

- “The GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface versus Plain Old Balloon Angioplasty (POBA) for the Treatment of Superficial Femoral Artery (SFA) In-Stent Restenosis “

- Prospective, randomized controlled trial
- 80 patients, 6 EU Centers, core lab
- PI’s: Dr. Bosiers, Dr. Peeters
- Primary endpoint: primary patency @ 12mo (f/u to 24mo)
Conclusion

- Covered stents necessary for traumatic lesions
- Comparable results for open surgery and covered stents in aneurysmatic lesions
- Advantage of covered stents in complex iliac lesions
- Maybe a role in SFA and restenotic lesions