GORE® VIABAHN® endoprosthesis in complex SFA lesions

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Disclosure

Speaker name:
Markus Steinbauer

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
  - [x] Other(s): W.L. Gore

- [ ] I do not have any potential conflict of interest
The Evolution of Performance

The GORE® VIABAHN® Endoprosthesis is the leader among stent grafts. Decades of partnership with clinicians around the globe has resulted in unparalleled performance across multiple indications:

- Arteriovenous Access
- Superficial Femoral Artery
- In-stent Restenosis
- Iliac Artery
- Popliteal Artery Aneurysm

1996
Original GORE® HEMOGRAFT® Endoprosthesis introduced in Europe

2008
GORE® VIABAHN® Endoprosthesis with PROPAK® Bioactive Surface introduced in Europe

2003
TIPtoHUB deployment introduced on 4-8 mm devices

2009
Laser technology enables the new expanded edge at proximal end

9-13 mm devices introduced with 0.035” guidewire compatibility

2010
35 cm length: Longest stent-graft introduced in EUROPE

2011
GORE® VIABAHN® Endoprosthesis with PROPAK® Bioactive Surface 5-8 mm devices decreased in profile by one French size

2014
Receives CT mark for the treatment of symptomatic VHOCs

2016
Radiopaque markers introduced on 5-8 mm devices in Europe
Viabahn: Indications
PAA – Complex Iliac lesions

Results of hybrid procedures for treatment of aortoiliac Trans-Atlantic Inter-Society Consensus II D lesions with self-expanding covered heparin-bonded stent grafts.

Uhl C¹, Betz T², Weiss B², Töpel J², Steinbauer M².
Indications POD
Complex SFA / popliteal lesions

pAVK IIb:
- Following conservative treatment (e.g. after CFA-TEA)

pAVK III/IV (CLI)
- Bail-out after PTA/DEB/Stent
- Additional alternative to stenting and bypassing
- Stenoses / occlusions in patients unfit for surgery
Indications POD Bypass - Viabahn

Comparison of Long-term Outcomes of Heparin Bonded Polytetrafluoroethylene and Autologous Vein Below Knee Femoropopliteal Bypasses in Patients with Critical Limb Ischaemia

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Comparison of Long-term Outcomes of Heparin Bonded Polytetrafluoroethylene and Autologous Vein Below Knee Femoropopliteal Bypasses in Patients with Critical Limb Ischaemia

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N=151
N=270
N=108

Tibial and peroneal bypasses in octogenarians and nonoctogenarians with critical limb ischemia

Christian Uhl, MD,* Carolin Hock, MD,† Isabelle Ayx, MD,‡ Niels Zorger, MD,§ Markus Steinbauer, MD, and Ingolf Töpel, MD,¶ Regensburg, Germany

Background: Elderly patients with critical limb ischemia are increasingly treated through interventional therapy. The outcome of tibial and peroneal bypasses in octogenarians who were unsuitable for endovascular therapy remains unclear.

Methods: We conducted a retrospective analysis of all patients who underwent tibial or peroneal bypass surgery in our clinic between October 2007 and April 2015. In Group 1 we included all patients 80 years and older and in group 2 all patients under 80 years. Vein was used whenever possible (diameter not less than 3 mm, not more than two segments for sufficient length). Study end points were primary and secondary patency, limb salvage and survival after 3 years.

Results: Indications were rest pain in 32.2% and ulcer and gangrene in 67.8%. There were 92 cases in Group 1 (median age, 85 years) and 178 in group 2 (median age, 70 years). Risk factors and indications were similar in both groups except for gender, renal insufficiency and smoking. 30-day mortality was 9.7% in group 1 and 1.1% in group 2 (P = .001). There was no significant difference in 30-day graft failure and major amputation. At 3 years primary patency in group 1 was 88.9% vs 49.7% (P = .058), secondary patency was 73.5% vs 59.5% (P = .007). Limb salvage was 80.1% in group 1 vs 73.0% in group 2 (P = .446), survival was 44.0% vs 71.2% (P = .006).

Conclusions: Our analysis showed good results in octogenarians undergoing tibial and peroneal bypass surgery with regard to patency rates and limb salvage. However, octogenarians had a significantly higher perioperative mortality rate. (J Vasc Surg 2016;63:1555–62.)
pAVK IIb
Subintimal recanalization (out-back)

- pAVK II b rechts, SFA occlusion
- previous TEA/Patch right CFA
- 3 month excercise

Procedure:
- Puncture (8 F sheeth)
- Recanalization
- Viabahn (V3.18) 6 mm x 25 cm + 6 x 10 cm
pAVK IIb
Subintimal recanalization (out-back)
Viastar


<table>
<thead>
<tr>
<th>Patient Demographics</th>
<th>GORE® VIABAHN® Endoprosthesis</th>
<th>Bare Metal Stent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Age</td>
<td>69</td>
<td>69</td>
<td>0.69</td>
</tr>
<tr>
<td>Male</td>
<td>67%</td>
<td>75%</td>
<td>0.34</td>
</tr>
<tr>
<td>Smoker</td>
<td>69%</td>
<td>70%</td>
<td>0.87</td>
</tr>
<tr>
<td>Hypertension</td>
<td>83%</td>
<td>84%</td>
<td>0.91</td>
</tr>
<tr>
<td>Diabetes</td>
<td>35%</td>
<td>36%</td>
<td>0.99</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>68%</td>
<td>68%</td>
<td>0.86</td>
</tr>
<tr>
<td>Rutherford Category</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>18%</td>
<td>17%</td>
<td>0.72</td>
</tr>
<tr>
<td>3</td>
<td>68%</td>
<td>65%</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>3%</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>11%</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Baseline ABI</td>
<td>0.58</td>
<td>0.58</td>
<td>0.94</td>
</tr>
</tbody>
</table>

Only 14 % vs 19 % CLI patients
Lesion characteristics similar across treatment groups.

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>GORE® VIABAHN® Endoprostesis</th>
<th>Bare Metal Stent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Chronic Occlusions</td>
<td>79%</td>
<td>70%</td>
<td>0.21</td>
</tr>
<tr>
<td>Mean Lesion Length (mm)</td>
<td>190</td>
<td>173</td>
<td>0.13</td>
</tr>
<tr>
<td>TASC Classification</td>
<td></td>
<td></td>
<td>0.09</td>
</tr>
<tr>
<td>TASC II A</td>
<td>0%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>TASC II B</td>
<td>28%</td>
<td>42%</td>
<td></td>
</tr>
<tr>
<td>TASC II C</td>
<td>25%</td>
<td>23%</td>
<td></td>
</tr>
<tr>
<td>TASC II D</td>
<td>47%</td>
<td>32%</td>
<td></td>
</tr>
</tbody>
</table>

TASC C and D: Only 72 % vs 55 %
Viastar: 2 Year Results
Primary Patency, Intent-to-treat Analysis

P < 0.05

Viastar: 2 Year Results
Primary Patency, Intent-to-treat Analysis
Lesions > 20 cm

Lession length: 19.0 cm vs. 17.3 cm

Viabahn:

Barmherzige Brüder Regensburg 2010-2018

- 125 Patients with Viabahn
  - 32 PAA
  - 20 Aorto-Iliac
  - 11 Viabahn <25 cm

- 62 Patients included in retrospective study
  (prospective data assessment)

Median lesion length 25 cm (22.0 – 41.3 cm)

Table 1. Patient characteristics, risk factors and indications.

<table>
<thead>
<tr>
<th>Condition</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (median)</td>
<td>70.5</td>
<td>(52–94)</td>
</tr>
<tr>
<td>Men</td>
<td>45</td>
<td>(72.6%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>25</td>
<td>(40.3%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>35</td>
<td>(56.5%)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>15</td>
<td>(24.2%)</td>
</tr>
<tr>
<td>Coronary artery bypass</td>
<td>6</td>
<td>(9.7%)</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>18</td>
<td>(29.0%)</td>
</tr>
<tr>
<td>Dialysis</td>
<td>2</td>
<td>(3.2%)</td>
</tr>
<tr>
<td>Hyperlipidaemia</td>
<td>30</td>
<td>(48.4%)</td>
</tr>
<tr>
<td>Smoker</td>
<td>21</td>
<td>(33.9%)</td>
</tr>
<tr>
<td>Claudication</td>
<td>38</td>
<td>(61.3%)</td>
</tr>
<tr>
<td>Critical limb ischemia</td>
<td>24</td>
<td>(38.7%)</td>
</tr>
<tr>
<td>3 vessel run-off</td>
<td>27</td>
<td>(43.6%)</td>
</tr>
<tr>
<td>2 vessel run-off</td>
<td>19</td>
<td>(30.6%)</td>
</tr>
<tr>
<td>1 vessel run-off</td>
<td>16</td>
<td>(25.8%)</td>
</tr>
</tbody>
</table>

CLI 38.7 %
Viabahn:

Barmherzige Brüder Regensburg 2010-2018

Median lesion length 25 cm (22.0 – 41.3 cm)

Table 2. Procedure and stent graft details.

<table>
<thead>
<tr>
<th>Procedure and stent graft details</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stentgraft n = 1</td>
<td>37 (59.7%)</td>
</tr>
<tr>
<td>Stentgraft n &gt; 1</td>
<td>25 (40.3%)</td>
</tr>
<tr>
<td>Distal end of the stentgraft</td>
<td></td>
</tr>
<tr>
<td>above femoral condyles</td>
<td>39 (62.9%)</td>
</tr>
<tr>
<td>below femoral condyles</td>
<td>23 (37.1%)</td>
</tr>
<tr>
<td>Cut down</td>
<td>13 (20.9%)</td>
</tr>
<tr>
<td>Percutaneus</td>
<td>49 (79.1%)</td>
</tr>
<tr>
<td>Occlusions</td>
<td>85.5%</td>
</tr>
<tr>
<td>Subintimal recanalization</td>
<td>19.4%</td>
</tr>
</tbody>
</table>

More than 1 viabahn: 40.3%
Infragenual landing zone: 37.1%
Occlusions: 85.5%
Subintimal recanalization 19.4%

Real World Data:
More „Viabahn vs Bypass“ than „Viabahn vs Stent“
Postproedurales Procedere

- ASS 100 mg + Clopidogrel 75 mg for 6 month
- ASS 100 mg life long
- Duplex every 6 month
  - After successful treatment of viabahn occlusion
    - ASS 100 mg + Clopidogrel 75 mg life long
  - Eminence – No Evidence !!!!
20.9% general anesthesia, 79.1% local anesthesia,
7 x CFA TEA + viabahn (10.3%)

No local complications (infection, hematoma, pseudoaneurysm)
0% 30 Tage mortality (4 x ALI)

5 early occlusion (8.1%)
- 1x ALI patient with palliative colon carcinoma - major amputation
- 1 x conservative therapy
- 2 x successful lysis
- 1 x bypass (ALI)
Long-term results of the heparin-bonded Viabahn stent graft in femoropopliteal TASC C and D lesions with a covered stent length of minimum 25 cm

1 year *primary* patency: 61.1 %
5 year *primary* patency: 38.5 %

- More than 50 % of occluded viabahns could be treated successfully by lysis

1 year *secondary* patency: 83.0 %
5 year *secondary* patency: 52.4 %

- In case of critical ischemia: embolectomy or bypass
Long-term results of the heparin-bonded Viabahn stent graft in femoropopliteal TASC C and D lesions with a covered stent length of minimum 25 cm

pAVK II vs CLI (5 a)

- No difference concerning patency rates and limb salvage (independend of „Run off vessels“)

- Survival 82.3 vs. 46.7 % (independend risk factor: CAD)

Limb salvage
No differences:

• Lesion length – number of viabahns
  (independend risk factor: renal insufficiency)

• Suprarenal vs infrarenal
  – Patency rates and limb salvage
    (no difference concerning „Run off“)
  – Survival 82.5 % vs. 39.7 %

• Viabahn diameter: 5 mm vs > 5 mm
Comparison of Long-term Outcomes of Heparin Bonded Polytetrafluoroethylene and Autologous Vein Below Knee Femoropopliteal Bypasses in Patients with Critical Limb Ischaemia

C. Uhl, C. Grosch, C. Hock, I. Töpel, M. Steinbauer
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Secundary patency

Limb salvage
Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos, MD, PhD, MSc, EBIR; Stavros Spiliopoulos, MD, PhD; Panagiotis Kitrou, MD, PhD; Miltiadis Krokidis, MD, PhD; Dimitrios Kamabatidis, MD, PhD

Background—Several randomized controlled trials (RCTs) have already shown that paclitaxel-coated balloons and stents significantly reduce the rates of vessel restenosis and target lesion revascularization after lower extremity interventions.

Methods and Results—A systematic review and meta-analysis of RCTs investigating paclitaxel-coated devices in the femoral and/or popliteal arteries was performed. The primary safety measure was all-cause patient death. Risk ratios and risk differences were pooled with a random effects model. In all, 28 RCTs with 4663 patients (89% intermittent claudication) were analyzed. All-cause patient death at 1 year (28 RCTs with 4432 cases) was similar between paclitaxel-coated devices and control arms (2.3% versus 2.3% crude risk of death; risk ratio, 1.08; 95% CI, 0.72–1.61). All-cause death at 2 years (12 RCTs with 2316 cases) was significantly increased in the case of paclitaxel versus control (7.2% versus 3.8% crude risk of death; risk ratio, 1.68; 95% CI, 1.15–2.47; number-needed-to-harm, 29 patients [95% CI, 19–59]). All-cause death up to 5 years (3 RCTs with 863 cases) increased further in the case of paclitaxel (14.7% versus 8.1% crude risk of death; risk ratio, 1.93; 95% CI, 1.27–2.93; number-needed-to-harm, 14 patients [95% CI, 9–32]). Meta-regression showed a significant relationship between exposure to paclitaxel (dose-time product) and absolute risk of death (0.4±0.1% excess risk of death per paclitaxel mg-year; P<0.001). Trial sequential analysis excluded false-positive findings with 99% certainty (2-sided α, 1.0%).

Conclusions—There is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs. Further investigations are urgently warranted.
**RECOMMENDATIONS**

Based on the FDA's review of available data and the Advisory Panel conclusions, we recommend that health care providers consider the following recommendations:

- Continue diligent monitoring of patients who have been treated with paclitaxel-coated balloons and paclitaxel-eluting stents.

- Discuss the risks and benefits of all available PAD treatment options with your patients. For many patients, alternative treatment options to paclitaxel-coated balloons and paclitaxel-eluting stents provide a more favorable benefit-risk profile based on currently available information.

- For individual patients judged to be at particularly high risk for restenosis and repeat femoropopliteal interventions, clinicians may determine that the benefits of using a paclitaxel-coated device outweigh the risk of late mortality.

- In discussing treatment options, physicians should explore their patients' expectations, concerns and treatment preferences.

➢ Viabahn is an valid alternative to DEB/DES in complex SFA / politeal lesions
Summary
Viabahn in complex SFA / popliteal lesions

- Real Word Data (lesion length, ALI, CLI, infragenual)
- Patency rates lower than in the viastar study
- Secondary patency (5a) acceptable/good
- Patency independent of Viabahn length and infragenual landing zone

- Vein bypass is gold standard (long term data)
- Comparable results to PTFE bypasses below the knee
- Endoluminal therapy feasible in patients “unfit for surgery”
- Open question: “double platelet therapy” for “how long“
Save The Dates

137. Deutscher Chirurgen Kongress
CityCube, Berlin
Thank you for your attention
Viabahn

Ultra dünnwandige ePTFE Prothese

Befestigungsfilm

Nitinol-Stent

“Contoured Proximal Edge”

PROPATEN Bioaktive Oberfläche

Längen: 2,5, 5, 10, 15 und 25 cm

Durchmesser: 5 – 13 mm
pAVK IV:
Patient nicht narkosefähig

- pAVK IV re, nicht narkosefähig:
- AFC-Stenose, serielle AFS-Stenose + A. Fibularis-Verschluß, Z.n. AFS Stent

Prozedur:
- Offene TEA/Patch AFC in LA
- Viabahn 5mm x 25 cm
- Rekanalisierung A. fibularis
pAVK IV
Viabahn + PTA
GORE® VIABAHN® endoprosthesis in complex SFA lesions

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