Revising dysfunctional and thrombosed dialysis access: My experiences and clinical outcome

Christian Hohl, EBIR
Disclosure

Speaker name: Christian Hohl

I have the following potential conflicts of interest to report:

- [x] Consulting for WL Gore and COOK Medical
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Typical location of graft stenoses

From 156 PROSTHETIC GRAFTS

L. Turmel-Rodrigues et al.  
Typical location of fisutula stenoses

From 209 FOREARM AVFs
- 1%: 7%
- 6%: 55%
- 49%: 22%
- 19%
- 18%

From 74 UPPER ARM AVFs
- 6%: 17%
Access stenoses

- PTA as the standard therapy for venous stenoses
Failing PTA

- Scoring balloon
- Drug eluting balloon
- Drug eluting stent
- Viabahn-Endoprosthesis
Failing PTA

- Scoring balloon
- Drug eluting balloon
- Drug eluting stent
- Viabahn-Endoprosthesis
Neointimale venous hyperplasia
Stent-Grafts to avoid neointimal hyperplasia

Mechanical barrier

Stent Graft (VIABAHN)

- Eliminating the stimulus for restenosis
- Porosity avoids ingrowth of neointima
Viabahn®

- Contoured edge design
- CBAS® Heparin-surface
- Ultrathin ePTFE wall
- Unique endofilm
- Polished nitinol scaffold
- Length: 2.5, 5, 10, 15, 25 cm
- Diameter: 5 – 13 mm

CBAS® are trademarks of Carmeda AB, a wholly owned subsidiary of W. L. Gore & Associates.
Viabahn in central venous stenosis

Cardiovasc Intervent Radiol (2013) 36:133–139
DOI 10.1007/s00270-012-0433-x

CLINICAL INVESTIGATION

VENOUS INTERVENTIONS

Cephalic Arch Stenosis in Autogenous Haemodialysis Fistulas: Treatment With the Viabahn Stent-Graft

Andrew Shawyer · Nicos I. Fotiadis · Girish Namagondu · Arun Iyer · Mark Blunden · Martin Raftery · Magdi Yaqoob
Viabahn in central venous stenosis
Viabahn in central stenosis

Fig. 2 Kaplan–Meier primary access patency after percutaneous cephalic arch Viabahn stent-graft placement to salvage autogenous haemodialysis fistulas
Further indications for Viabahn?

- Anastomosis?
- Venous outflow tract?
- Graft stenosis?
Anastomosis

Re-Re-occlusion
Treatment accessory vein
post embolization
Viabahn 5/50
Patent since 01.09.13
Venous outflow post PTA
Venous outflow
Venous outflow

Viabahn 5/50
Venous outflow
Graft stenosis
Graft stenosis
Graft stenosis

Post PTA
Graft stenosis

Viabahn 7/100 mm
Graft stenosis
Revise-Studie

- Multicenter, randomized-controlled trial
- VIABAHN® Endoprosthesis in treating stenosis or thrombotic occlusions of a synthetic arteriovenous (AV) access graft at the venous anastomosis
## SUBJECT PRE-ENROLLMENT CHARACTERISTICS

<table>
<thead>
<tr>
<th></th>
<th>GORE® VIABAHN® Device Group</th>
<th>PTA Group</th>
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</thead>
<tbody>
<tr>
<td>Intent-to-Treat Population</td>
<td>n = 145</td>
<td>n = 148</td>
</tr>
<tr>
<td>Age (Years)</td>
<td>62 ± 13</td>
<td>61 ± 15</td>
</tr>
<tr>
<td>Ethnicity (Hispanic)</td>
<td>11%</td>
<td>21%</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>51%</td>
<td>54%</td>
</tr>
<tr>
<td>White or Caucasian</td>
<td>42%</td>
<td>38%</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>52%</td>
<td>51%</td>
</tr>
<tr>
<td><strong>Physical Characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height (cm)</td>
<td>167 ± 12</td>
<td>165 ± 13</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>84 ± 29</td>
<td>81 ± 26</td>
</tr>
<tr>
<td>BMI</td>
<td>30 ± 9</td>
<td>30 ± 9</td>
</tr>
<tr>
<td><strong>Medical History</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of Diabetes</td>
<td>65%</td>
<td>66%</td>
</tr>
<tr>
<td>History of Hypertension</td>
<td>99%</td>
<td>97%</td>
</tr>
<tr>
<td>Duration of Time Since Starting Hemodialysis (Years)</td>
<td>3.6 ± 3.9</td>
<td>4.1 ± 4.2</td>
</tr>
<tr>
<td>Age of Vascular Access Graft (Years)</td>
<td>1.9 ± 1.9</td>
<td>2.3 ± 2.6</td>
</tr>
<tr>
<td>Mean Number of Prior Interventions at the Target Lesion</td>
<td>1.9 ± 2.2</td>
<td>1.8 ± 2.3</td>
</tr>
</tbody>
</table>

No statistical values less than 0.05 were detected unless otherwise specified. Means include ± Standard Deviation.

* a. Statistical comparison between the two treatment groups reported a p-value of 0.036.
* b. Subjects may select multiple races.
Primary Effectiveness Endpoint

Target lesion primary patency (p = 0.008)
Target Lesion Primary Patency at 6 Months

- PTA Group
- GORE® VIABAHN® Device Group

Non-Thrombotic Subjects:
- n = 74, 46%
- n = 77, 65%

Thrombotic Subjects:
- n = 64, 24%
- n = 54, 36%
Stents/Stent grafts were necessary to produce the secondary patency outcomes of the PTA group.
Reduced interventions per subject

At the Target Lesion  \( p = 0.009 \)

In the Access Circuit  \( p = 0.053 \)
Prior interventions did not affect outcomes for GORE® VIABAHN® Device group but did for the PTA group.
Summary

• FDA approved for VA since Dec 2013
• CE mark for VA since Dec 2014
• Exacte dimensioning!
• No tapered Viabahn yet.
• Candy-wrapper but no neo-intima
• Ready for cannulating after 4 weeks – off label!
See you in Barcelona!
Tabaksbeutelnäht
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