Value of stent-graft placement in hemodialysis patients with dysfunctional arteriovenous fistulas and grafts

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Conflict of interest

Speaker’s name: Gianmarco de Donato

I have the following potential conflicts of interest to report:

- Research contracts
- Travel & educational grants (Endologix, Gore, Penumbra)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest


19 Authors
12 ESVS Guidelines members
3 ESVS Guidelines Reviewers
<table>
<thead>
<tr>
<th>Chapter VII</th>
<th>Later vascular access complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.</td>
<td>Late vascular access complications</td>
</tr>
<tr>
<td>7.1</td>
<td>True and false access aneurysms</td>
</tr>
<tr>
<td>7.2</td>
<td>Infection</td>
</tr>
<tr>
<td>7.3</td>
<td>Stenosis and recurrent stenosis</td>
</tr>
<tr>
<td>7.3.1</td>
<td>Inflow arterial stenosis</td>
</tr>
<tr>
<td>7.3.2</td>
<td>Juxta-anastomotic stenosis</td>
</tr>
<tr>
<td>7.3.3</td>
<td>Venous outflow stenosis</td>
</tr>
<tr>
<td>7.3.4</td>
<td>Cephalic arch stenosis</td>
</tr>
<tr>
<td>7.4</td>
<td>Thrombosis</td>
</tr>
<tr>
<td>7.4.1</td>
<td>Treatment of arteriovenous fistula thrombosis</td>
</tr>
<tr>
<td>7.4.2</td>
<td>Treatment of arteriovenous graft thrombosis</td>
</tr>
<tr>
<td>7.5</td>
<td>Central venous occlusive disease</td>
</tr>
<tr>
<td>7.5.1</td>
<td>Haemodialysis associated venous thoracic outlet syndrome</td>
</tr>
<tr>
<td>7.6</td>
<td>Vascular access induced limb ischaemia and high flow vascular access</td>
</tr>
<tr>
<td>7.7</td>
<td>Neuropathy</td>
</tr>
<tr>
<td>7.8</td>
<td>Non-used vascular access</td>
</tr>
</tbody>
</table>

Eur J Vasc Endovasc Surg. 2018 Jun;55(6):757-818
7. LATE VASCULAR ACCESS COMPLICATIONS
7.3 Stenosis and recurrent stenosis

**Stenosis and restenosis**
- Inflow arterial stenosis
- Juxta-anastomotic stenosis
- Venous outflow stenosis
- Cephalic arch stenosis

7. LATE VASCULAR ACCESS COMPLICATIONS
7.3 Stenosis and recurrent stenosis

Stenosis and restenosis

Inflow arterial stenosis
Juxta-anastomotic stenosis
Venous outflow stenosis
Cephalic arch stenosis

PTA can be used as the primary approach for juxta-anastomotic stenosis, however, the recurrent stenosis rate is higher than after surgery, and in those patients where early recurrence occurs, surgical revision is indicated.

If surgical revision is expected to shorten the usable length of the AVF for cannulation PTA is justified as the primary tool.

7. LATE VASCULAR ACCESS COMPLICATIONS
7.3 Stenosis and recurrent stenosis

**Stenosis and restenosis**

*Inflow arterial stenosis*

*Juxta-anastomotic stenosis*

**Venous outflow stenosis**

*Cephalic arch stenosis*

PTA is the first treatment option in the outflow veins (cephalic/basilic), especially when the lesion is short (<2 cm).

For long segment stenoses (>2 cm), treatment is controversial.

*For stenting the venous anastomosis and venous stenoses, stent grafts may be superior to bare stents*

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**Recommendation 62**

Balloon angioplasty is recommended for the treatment of venous outflow stenosis.

**Recommendation 63**

Endovascular treatment with stent grafts should be considered for the treatment of cephalic arch stenosis.

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- Rajan DK, Falk A. A randomized prospective study comparing outcomes of angioplasty versus VIABAHN stent-graft placement for cephalic arch stenosis in dysfunctional hemodialysis accesses. JVIR 2015;26:1355e61

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Pre-angioplasty

Angioplasty (9/40mm)

Post-angioplasty

30% residual stenosis

>50% elastic recoil

After 20 min
BMS: fracture & restenosis issue

![Image showing an AV graft occluded on day 291 after repeated PTA attempts.]

![Image showing a graph with data on the primary patency of BMS in treating dysfunctional AVGs between 2004 and 2013.]

<table>
<thead>
<tr>
<th>Citation</th>
<th>Author</th>
<th>n</th>
<th>Study type</th>
<th>6 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney Int. 2006;69(5):934-937.</td>
<td>Maya and Alion</td>
<td>14</td>
<td>Prospective</td>
<td>19%</td>
</tr>
</tbody>
</table>

Weighted Average: 33%
RESTENOSIS / BARE METAL STENT / STENT GRAFT

Re-lining with Viabahn
Stent-Graft for vascular access

**Stent grafts**
- mimic open surgical revision of a graft
- prevent elastic recoil
- avoiding trans-stent growth of neointimal tissue (barrier)


VIABAHN®: Conformability to tortuosity

J Vasc Interv Radiol 2013; 24:1280–1287
Cardiovasc Intervent Radiol 2012; 36:133-9
FLUENCY® Device: conformability

Cephalic arch

Central vein

J Vasc Interv Radiol 2013; 24:1280–1287

J Vasc Surg 2008; 48:1524-31
Flexibility to Conform with the Anatomy

Arm Position

GORE® VIABAHN® Endoprosthesis

Other Stent-Graft

Straight Arm

GORE® VIABAHN® Endoprosthesis

BARD® FLAIR® Device

Bent Arm

GORE® VIABAHN® Endoprosthesis

BARD® FLAIR® Device

Images courtesy of Marc Webb, MD
CLINICAL CASE

Male Patients

AVG on September 2015

Gore Hybrid graft

Re-stenosis (distal edge HYBRID graft)

Nitinol reinforced section 5 cm

Viabahn 10 cm
Male Patients
AVG on September 2015
Gore Hybrid graft

Viabahn 10 cm

20 months of primary patency after Viabahn deployment
The Gore REVISE Clinical Study reported quality outcomes when outflow wall apposition was not achieved.

**Table 1. Patency Results of the Gore REVISE Clinical Study for the Target Lesions and the Entire Dialysis Access Circuit**

<table>
<thead>
<tr>
<th>Outcomes Effectiveness-per-protocol group</th>
<th>GORE® VIABAHN® Endoprosthesis (N = 138)</th>
<th>Angioplasty (N = 138)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target lesion primary patency (TLP)</td>
<td>52.9%</td>
<td>35.5%</td>
<td>.008</td>
</tr>
<tr>
<td>Month 6</td>
<td>52.9%</td>
<td>35.5%</td>
<td></td>
</tr>
<tr>
<td>Month 12</td>
<td>30.2%</td>
<td>18.2%</td>
<td></td>
</tr>
<tr>
<td>Month 24</td>
<td>9.6%</td>
<td>6.8%</td>
<td></td>
</tr>
<tr>
<td>Median days to loss of TLP</td>
<td>285</td>
<td>750</td>
<td></td>
</tr>
<tr>
<td>Vascular access circuit primary patency (CPP)</td>
<td>43.4%</td>
<td>29.4%</td>
<td>.035</td>
</tr>
<tr>
<td>Month 6</td>
<td>43.4%</td>
<td>29.4%</td>
<td></td>
</tr>
<tr>
<td>Month 12</td>
<td>21.4%</td>
<td>15.2%</td>
<td></td>
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<tr>
<td>Month 24</td>
<td>9.6%</td>
<td>6.8%</td>
<td></td>
</tr>
<tr>
<td>Median days to loss of CPP</td>
<td>126</td>
<td>91</td>
<td></td>
</tr>
</tbody>
</table>

**Outcomes when the Outflow Vein Diameter is 1 mm Greater than the GORE® VIABAHN® Device Diameter (n = 49)**

- **Patency**
  - 3 months: 77%
  - 6 months: 62%
  - 12 months: 44%
  - 24 months: 22%
- **Circuit Primary Patency**
  - 3 months: 69%
  - 6 months: 48%
  - 12 months: 34%
  - 24 months: 16%
- **Access Secondary Patency**
  - 3 months: 98%
  - 6 months: 94%
  - 12 months: 89%
  - 24 months: 77%

**Figure 2. Cost curves for the Gore REVISE clinical study showing average total cumulative costs per patient.**

- **2. Reintervention & total cost**
- **3. Sub-groups & Technical notes**
Primary Effectiveness Endpoint:

- The GORE® VIABAHN® Device group demonstrated **statistical superiority** over the PTA group in **target lesion primary patency** as determined by Kaplan-Meier estimates ($p = 0.008$).

Greater patency for both thrombotic and non-thrombotic patients

Despite the reduced patency outcomes for thrombotic patients, no statistical difference was detected in terms of treatment effect of the GORE® VIABAHN® Device relative to PTA (p = 0.792)

The Gore REVISE Clinical Study

2. Reintervention & total cost

Mean Cumulative Interventions per Subject over 24 Months

Reduced interventions per subject

Cost Analysis at 24 Months

2. Reintervention & total cost

Primary or *de novo* treatment with the GORE® VIABAHN® Endoprosthesis reduced costs by ~$2000 per patient over 24 months

<table>
<thead>
<tr>
<th></th>
<th>VIABAHN n=131</th>
<th>PTA n=138</th>
<th>Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Procedure Costs</td>
<td>$7,820</td>
<td>$3,440</td>
<td>($4,380)</td>
<td>&lt;.01</td>
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<tr>
<td>Repeat Intervention Costs at 24-Months</td>
<td>$16,585</td>
<td>$23,022</td>
<td>$6,436</td>
<td>0.02</td>
</tr>
</tbody>
</table>

DECIDING ON OUTFLOW WALL APPPOSITION

The Gore REVISE Clinical Study reported quality outcomes when outflow wall apposition was not achieved.

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</tr>
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<td>3 months</td>
</tr>
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<td>Target Lesion Primary Patency</td>
</tr>
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</tr>
</tbody>
</table>
Tips & tricks
Stent graft in venous outflow stenosis
Durability to Last Under Mechanical Strain

No reported fractures the two year study period in the Gore REVISE Clinical Study

In hemodialysis patients with dysfunctional AVF & AVG

Stent graft is more durable than venoplasty alone and is undoubtedly preferable to BMS placement.

The crucial technical points for stent graft placement include:
- ensuring all disease is effectively ballooned prior to stent placement with no residual waisting
- selecting the correct stent diameter and length to ensure all disease is treated while not introducing new points of angulation (conformability with the natural anatomy)
Piazza del Campo, Siena – Italy
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