Disclosure

• Speaker name:
  • Jorge Fernández Noya

• I have the following potential conflicts of interest to report:
  • Consulting: GORE
    • Employment in industry
    • Stockholder of a healthcare company
    • Owner of a healthcare company
    • Other(s)
  • I do not have any potential conflict of interest
ENDOLUMINAL BY-PASS

Planning with Duplex-Scan or CT.

Usually ipsilateral approach.

Angiogram: Looking for healthy vessel proximal and distal (1 cm).

Don’t cover genicular arteries.

Avoid Oversizing (< 20%).

Single long stent is better.

Post-dilatation inside the device.

Follow-up is critical.
ENDOLUMINAL BY-PASS

Planning with Duplex-Scan or CT.
Avoid Oversizing (<20%)

Effects of Device Sizing: Proximal

- % Free from Loss of Patency
- p<0.05
- Oversized <=20%: 91%
- Oversized > 20%: 70%

Effects of Device Sizing: Distal

- % Free from Loss of Patency
- p=0.09
- Oversized <=20%: 87%
- Oversized > 20%: 72%

VIPER TRIAL
ENDOLUMINAL BY-PASS

Avoid Oversizing (<20%)

15.8%

6 mm Viabahn

9%
Angiogram: Looking for proximal and distal (1 cm) healthy vessel
Angiogram: Looking for proximal and distal (1 cm) healthy vessel
HYBRID TECHNIQUE

GORE® VIABAHN® ENDOPROSTHESIS: BEST PRACTICE FOR DURABLE RESULTS
HYBRID TECHNIQUE

Viabahn
GORE® VIABAHN® ENDOPROSTHESIS: BEST PRACTICE FOR DURABLE RESULTS
GORE® VIABAHN® ENDOPROSTHESIS: BEST PRACTICE FOR DURABLE RESULTS

COLATERALS
<table>
<thead>
<tr>
<th>Lesions</th>
<th>GORE VIABAHN® Endoprosthesis</th>
<th>Bare Nitinol Stent</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated Occlusions</td>
<td>59.7%</td>
<td>56.6%</td>
<td>0.74</td>
</tr>
<tr>
<td>Mean Lesion Length [cm] (Std Dev)</td>
<td>19 (8)</td>
<td>18 (7)</td>
<td>0.87</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Safety Endpoint</th>
<th>GORE VIABAHN® Endoprosthesis</th>
<th>Bare Nitinol Stent</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Enrolled Subject</td>
<td>72</td>
<td>79</td>
<td></td>
</tr>
<tr>
<td>Access / Treatment Site Complications</td>
<td>1**</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Acute Renal Insufficiency</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Study Limb Amputation</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interim Performance Endpoint</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>

<table>
<thead>
<tr>
<th>Device Occlusion</th>
<th>GORE VIABAHN® Endoprosthesis</th>
<th>Bare Nitinol Stent</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Occlusion</td>
<td>9</td>
<td>6</td>
<td>0.18</td>
</tr>
<tr>
<td>Acute Limb Ischemia</td>
<td>2</td>
<td>4</td>
<td>0.14</td>
</tr>
<tr>
<td>Chronic Limb Ischemia</td>
<td>7</td>
<td>2</td>
<td>0.14</td>
</tr>
<tr>
<td>Intervention &lt; 24 hours</td>
<td>1</td>
<td>4</td>
<td>0.09</td>
</tr>
<tr>
<td>Intervention &gt; 24 hours</td>
<td>7</td>
<td>1</td>
<td>0.04</td>
</tr>
</tbody>
</table>

* Not approved for SFA use
** The single access site complication was thrombosis in the non-treatment leg that was resolved with subsequent treatment.
ENDOLUMINAL BY-PASS

Don’t cover genicular arteries
OUR EXPERIENCE

LENGTH

<table>
<thead>
<tr>
<th>LENGTH</th>
<th>PRIMARY PATENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10 cm</td>
<td>86.2%</td>
</tr>
<tr>
<td>10-20 cm</td>
<td>89.4%</td>
</tr>
<tr>
<td>&gt;20 cm</td>
<td>69.6%</td>
</tr>
</tbody>
</table>

1 year

- <10 cm: 86.2%
- 10-20 cm: 89.4%
- >20 cm: 69.6%

2 years

- <10 cm: 76.6%
- 10-20 cm: 89.4%
- >20 cm: 58%

LENGTH>20 Cm

<table>
<thead>
<tr>
<th>STENT</th>
<th>Primary patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 STENT</td>
<td>79%</td>
</tr>
<tr>
<td>2 STENT</td>
<td>64.7%</td>
</tr>
<tr>
<td>3 STENT</td>
<td>66.7%</td>
</tr>
</tbody>
</table>
Post-dilatation inside the device.
GORE® VIABAHN® ENDOPROSTHESIS: BEST PRACTICE FOR DURABLE RESULTS
GORE® VIABAHN® ENDOPROSTHESIS: BEST PRACTICE FOR DURABLE RESULTS
GORE® VIABAHN® ENDOPROSTHESIS: BEST PRACTICE FOR DURABLE RESULTS
Vast majority of Viabahn failures are a focal (short and local) edge stenosis (Type I)

- 50% isolated proximal edge.
- 30% both proximal and distal edges
- 5% isolated distal edge
Follow-up is critical
Male 69 years old Diabetes Dislypemia
Hypertension Myocardial revascularization using right Saphenous vein

RESUME EXAMPLE
- Rest Pain in the right foot
- ABI 0.38
- Good Flow in CFA
- Multiple lesions in SFA
- Short occlusion in popliteal artery
GORE® VIABAHN® ENDOPROSTHESIS: BEST PRACTICE FOR DURABLE RESULTS
GORE® VIABAHN® ENDOPROSTHESIS: BEST PRACTICE FOR DURABLE RESULTS
Ipsilateral approach → Intraluminal technique → Tibioperoneal trunk lesion → Viabahn stent graft without angioplasty → Post-dilatation inside the device
6*250 mm GORE® VIABAHN® ENDOPROSTHESIS
RESULT

- Duplex showed open stent-Graft
- ABI: 0.71
- No rest pain
- Discharged: 24 hours
- Plavix and ASA
4 days later…

- Acute rest pain
- Moderate sensitive loss
- No popliteal pulse
- Urgent Angiography
4 days later…
4 days later…

**WHY ????

- Oversizing
- Untreated distal lesions
- Insufficient distal coverage
- Insufficient proximal coverage
- Others
WHY ???

- Oversizing
- Untreated distal lesions
- Insufficient distal coverage
- Insufficient proximal coverage
- Others
Oversizing
Untreated distal lesions
Insufficient distal coverage
Insufficient proximal coverage
Others
WHY ????

- Oversizing
- Untreated distal lesions
- Insufficient distal coverage
- Insufficient proximal coverage
- Others
WHY ????

- Oversizing
- Untreated distal lesions
- Insufficient distal coverage
- Insufficient proximal coverage
- Others
4 days later...

PROCEDURE

- Contralateral approach
- Fibrinolysis (24 hours)
- Stent in the tibioperoneal trunk
- Proximal stent graft
RESULT

3*40 mm Abbott® Xpert Self-Expanding Stent
6*100 mm GORE® VIABAHN® ENDOPROSTHESIS
RESULT
GORE R VIABAHN R ENDOPROSTHESIS: BEST PRACTICE FOR DURABLE RESULTS

RESULT
<table>
<thead>
<tr>
<th><strong>RESULT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duplex showed open stent-Graft</strong></td>
</tr>
<tr>
<td><strong>ABI: 0.68</strong></td>
</tr>
<tr>
<td><strong>Popliteal pulse</strong></td>
</tr>
<tr>
<td><strong>No rest pain</strong></td>
</tr>
<tr>
<td><strong>Discharged: 48 hours</strong></td>
</tr>
<tr>
<td><strong>Plavix and ASA</strong></td>
</tr>
<tr>
<td>TAKE HOME MESSAGES</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td>Avoid oversizing</td>
</tr>
<tr>
<td>Cover all the lesion</td>
</tr>
<tr>
<td>Calcificated lesions are dangerous</td>
</tr>
<tr>
<td>Post-dilatation inside the device</td>
</tr>
<tr>
<td>Try to achieve a straight line flow to the foot with the less number of stent grafts</td>
</tr>
<tr>
<td>Good option for in-stent re-stenosis</td>
</tr>
<tr>
<td>Surveillance is critical</td>
</tr>
<tr>
<td>Look backwards to improve the results</td>
</tr>
</tbody>
</table>
“You can't connect the dots looking forward; you can only connect them looking backwards. So you have to trust that the dots will somehow connect in your future.”
THANK YOU !!!