Impact of revascularization strategies in femoropopliteal lesions – Results from the REVIVE study

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Department of Cardiac, Vascular and Endovascular Surgery, Paracelsus Medical University, Salzburg, Austria;
Department of Surgery, Rijnstate, Arnhem, the Netherlands;
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Disclosure

Speaker name: Serdar Farhan

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
Introduction

• REVIVE study:

  Literature research PUBMED, EMBASE and websites (clinicaltrials.gov, tctmd.com, leipzig-interventional-course.com)

  Search for RCTs comparing endovascular intervention with use of scaffolds vs. vascular bypass surgery

  6 RCTs were identified

  Principal investigators of 5 RCTs agreed to pool the data

Farhan et al. J Am Coll Cardiol 2023;81:358–370
Revascularization strategies for femoropopliteal artery lesions range from endovascular techniques using drug-eluting stents (DES) and non-DES to surgical bypass utilizing polytetrafluorethylene (PTFE) as well as autologous vein grafts (AVG). None of the existing studies were adequately powered to compare these techniques.
Study endpoints and groups

• Primary endpoint
  • Major adverse limb events (MALE): Composite of all-cause death, major amputation or target limb revascularization

• Secondary endpoints
  • included amputation free survival (AFS), target-limb revascularization (TLR) and primary patency.

• Patient groups:
  • Autologous vein graft
  • Prosthetic graft (PTFE/dacron)
  • DES
  • Non-DES (bare metal stents and covered stents).
### Baseline and procedural characteristics

**AVG**: autologous vein graft; **PTFE**: polytetrafluoroethylene; **DES**: drug-eluting stent, **BMS**: bare metal stent, **CFA**: common femoral artery

#### Lesion type

<table>
<thead>
<tr>
<th>Category</th>
<th>GRAF N= 148 (23.2%)</th>
<th>PTFE/Dacron N= 166 (26.0%)</th>
<th>DES N= 136 (21.3%)</th>
<th>Non-DES N= 189 (29.6%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stenotic</td>
<td>21 (14.3%)</td>
<td>6 (3.6%)</td>
<td>9 (6.6%)</td>
<td>36 (19.4%)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Occlusive</td>
<td>126 (85.7%)</td>
<td>159 (96.4%)</td>
<td>127 (93.4%)</td>
<td>150 (80.6%)</td>
<td></td>
</tr>
</tbody>
</table>

#### Lesion length, cm

<table>
<thead>
<tr>
<th>Category</th>
<th>GRAF N= 148</th>
<th>PTFE/Dacron N= 166</th>
<th>DES N= 136</th>
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</tr>
</thead>
<tbody>
<tr>
<td>AVG</td>
<td>26.4±7.0</td>
<td>22.2±8.9</td>
<td>22.3±7.6</td>
<td>23.5±8.5</td>
<td>&lt;.001</td>
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#### Angiographic runoff

<table>
<thead>
<tr>
<th>Category</th>
<th>GRAF N= 148</th>
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<th>DES N= 136</th>
<th>Non-DES N= 189</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 vessel</td>
<td>3 (2.1%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>3 (1.7%)</td>
<td>0.152</td>
</tr>
<tr>
<td>1 vessel</td>
<td>24 (17.1%)</td>
<td>6 (11.8%)</td>
<td>7 (30.4%)</td>
<td>39 (21.7%)</td>
<td></td>
</tr>
<tr>
<td>2 vessels</td>
<td>65 (46.4%)</td>
<td>16 (31.4%)</td>
<td>8 (34.8%)</td>
<td>67 (37.2%)</td>
<td></td>
</tr>
<tr>
<td>3 vessels</td>
<td>48 (34.3%)</td>
<td>29 (56.9%)</td>
<td>8 (34.8%)</td>
<td>71 (39.4%)</td>
<td></td>
</tr>
</tbody>
</table>

#### Concomitant CFA treatment

<table>
<thead>
<tr>
<th>Category</th>
<th>GRAF N= 148</th>
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<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>47 (31.8%)</td>
<td>3 (1.8%)</td>
<td>0 (0.0%)</td>
<td>24 (12.7%)</td>
<td>&lt;.001</td>
<td></td>
</tr>
</tbody>
</table>

#### Technical failure

<table>
<thead>
<tr>
<th>Category</th>
<th>GRAF N= 148</th>
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<th>DES N= 136</th>
<th>Non-DES N= 189</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>2 (1.5%)</td>
<td>21 (11.1%)</td>
<td>&lt;.001</td>
<td></td>
</tr>
</tbody>
</table>

#### Length of hospital stay, in days

<table>
<thead>
<tr>
<th>Category</th>
<th>GRAF N= 148</th>
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</tr>
</thead>
<tbody>
<tr>
<td>8.0±4.3</td>
<td>6.8±5.4</td>
<td>2.9±1.2</td>
<td>3.3±1.3</td>
<td>&lt;.001</td>
<td></td>
</tr>
</tbody>
</table>

#### Medications at discharge

<table>
<thead>
<tr>
<th>Category</th>
<th>GRAF N= 148</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Anticoagulants</td>
<td>43 (29.1%)</td>
<td>18 (30.5%)</td>
<td>3 (13.6%)</td>
<td>38 (20.1%)</td>
<td>0.102</td>
</tr>
<tr>
<td>Aspirin</td>
<td>115 (78.2%)</td>
<td>51 (86.4%)</td>
<td>19 (86.4%)</td>
<td>150 (80.2%)</td>
<td>0.560</td>
</tr>
<tr>
<td>P2y12 inhibitor</td>
<td>34 (23.3%)</td>
<td>21 (35.6%)</td>
<td>20 (90.9%)</td>
<td>150 (80.2%)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Lipid lowering</td>
<td>111 (75.5%)</td>
<td>27 (71.1%)</td>
<td>11 (47.8%)</td>
<td>127 (77.9%)</td>
<td>0.019</td>
</tr>
</tbody>
</table>

#### Insulin use

<table>
<thead>
<tr>
<th>Category</th>
<th>GRAF N= 148</th>
<th>PTFE/Dacron N= 166</th>
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<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 (13.2%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>8 (7.8%)</td>
<td>0.261</td>
<td></td>
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### Lesion type

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#### Occlusive

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### Lesion length, cm

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<td>23.5±8.5</td>
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</tr>
</tbody>
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### Angiographic runoff

- **0 vessel**: 3 (2.1%)
- **1 vessel**: 24 (17.1%)
- **2 vessels**: 65 (46.4%)
- **3 vessels**: 48 (34.3%)

### Concomitant CFA treatment

- **47 (31.8%)**: 3 (1.8%)
- **0 (0.0%)**: 24 (12.7%)

### Technical failure

- **0 (0.0%)**: 0 (0.0%)
- **2 (1.5%)**: 21 (11.1%)

### Length of hospital stay, in days

- **8.0±4.3**: 6.8±5.4
- **2.9±1.2**: 3.3±1.3

### Medications at discharge

- **Anticoagulants**: 43 (29.1%)
- **Aspirin**: 115 (78.2%)
- **P2y12 inhibitor**: 34 (23.3%)
- **Lipid lowering**: 111 (75.5%)
- **Insulin use**: 14 (13.2%)

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### Presentation

- **Critical limb ischemia or acute limb ischemia**
- **72 (48.6%)**: 55 (33.1%)
- **39 (28.7%)**: 81 (42.9%)

### Interruption of claudication

- **76 (51.4%)**: 111 (66.9%)
- **97 (71.3%)**: 108 (57.1%)

### TASC classification

- **<.001**

### B

- **2 (1.4%)**: 15 (9.2%)
- **9 (6.6%)**: 19 (10.2%)

### C

- **52 (35.4%)**: 19 (11.7%)
- **18 (13.2%)**: 63 (33.9%)

### D

- **93 (63.3%)**: 129 (79.1%)
- **109 (80.1%)**: 104 (55.9%)
Results: Primary endpoint MALE

Death, amputation, or re-intervention at 24m

Log-rank P value = 0.6122

Cumulative incidence (%) vs Days after randomization

Number at risk
- GRAF: 148, 120, 103, 93, 79
- PTFE: 166, 138, 118, 97, 84
- DES: 133, 122, 92, 73, 63
- Non-DES: 168, 136, 107, 99, 80

Legend:
- Red: GRAF
- Blue: PTFE
- Green: DES
- Orange: Non-DES
Results: AFS
### Results: TLR

#### TLR

<table>
<thead>
<tr>
<th></th>
<th>N (%)</th>
<th>HR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVG</td>
<td>50 (34.8%)</td>
<td>Ref.</td>
<td></td>
</tr>
<tr>
<td>PTFE/Dacron</td>
<td>42 (27.8%)</td>
<td>0.75 (0.50 - 1.13)</td>
<td>0.164</td>
</tr>
<tr>
<td>DES</td>
<td>31 (26.8%)</td>
<td>0.66 (0.42 - 1.04)</td>
<td>0.072</td>
</tr>
<tr>
<td>Non-DES</td>
<td>66 (38.0%)</td>
<td>1.11 (0.77 - 1.60)</td>
<td>0.578</td>
</tr>
</tbody>
</table>

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**Reintervention at 24m**

![Graph showing cumulative incidence of reintervention over time](image)

- Log-rank P-value = 0.0476

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**Number at risk**

- GRAF: 148, 120, 103, 93, 80
- PTFE: 165, 138, 116, 97, 84
- DES: 135, 124, 96, 76, 65
- Non-DES: 106, 147, 116, 105, 85

---

**Days after randomization**

- Days range from 0 to 720
## Results: Primary Patency

### Loss of primary patency

<table>
<thead>
<tr>
<th>Group</th>
<th>N (%)</th>
<th>HR (95% CI)</th>
<th>P-value</th>
<th>aHR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVG</td>
<td>64 (44.5%)</td>
<td>Ref.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTFE/Dacron</td>
<td>49 (33.2%)</td>
<td>0.65 (0.45 - 0.94)</td>
<td>0.023</td>
<td>0.54 (0.36 - 0.81)</td>
<td>0.003</td>
</tr>
<tr>
<td>DES</td>
<td>45 (39.0%)</td>
<td>0.72 (0.49 - 1.05)</td>
<td>0.092</td>
<td>0.58 (0.37 - 0.89)</td>
<td>0.012</td>
</tr>
<tr>
<td>Non-DES</td>
<td>97 (55.9%)</td>
<td>1.40 (1.02 - 1.92)</td>
<td>0.037</td>
<td>1.28 (0.93 - 1.77)</td>
<td>0.135</td>
</tr>
</tbody>
</table>

AVG: autologous vein graft; PTFE: polytetrafluoroethylene; DES: drug eluting stent.

*Model adjusted for CKD, intermittent claudication, TASC D, lesion type occlusive, lesion length, and concomitant CFA treatment.*
Conclusion:

• Endovascular intervention with DES and non-DES is associated with similar risk of MALE, compared to AVG or prosthetic grafts.

• Secondary endpoints:
  • Utilization of prosthetic grafts or DES was associated with highest primary patency followed by AVG, and non-DES.
  • EVT with DES was associated with the lowest risk for TLR compared to AVG and non-DES implantation.
  • Unmeasured confounders might have contributed to these findings.

• The importance of medical therapy must be emphasized.