Analysis of Outcomes for Bioresorbable Vascular Scaffold Use for the Treatment of Peripheral Vascular Disease

Mohammad Ansari, MD
and
Daniel Garcia, MD
Disclosure

Speaker name:
Mohammad Ansari, MD

I do not have any potential conflict of interest
Introduction

• Endovascular treatment for PAD:

  1. Percutaneous balloon angioplasty

  2. Provisional stent implantation: stabilization of the vessel wall and prevention of re-occlusion

• Novel stents made of bioresorbable vascular scaffold (BVS) are currently approved for coronary use

• Expanding its use for PAD
Objective

• We investigated BVS use for the treatment of symptomatic PAD patients
Methods

- Systematic search through Pub Med and Cochrane database using all clinical data
- Reports of outcomes of BVS use for the treatment of femoropopliteal disease and infra-popliteal disease
- Performed in accordance with established methods for systematic reviews in cardiovascular medicine
Methods

• The following medical subject heading terms were included for a MEDLINE search:

1. “BVS”
2. “Bioresorbable vascular scaffold”
3. “Peripheral vascular disease”
4. “Peripheral balloon angioplasty”

• There was neither language nor patient population size restriction for the search
Methods

• Data extraction and quality assessment were independently completed by the two authors (DCG and MMA)

• Project coordinator (DCG) reviewed all the studies to ensure that they met the inclusion criteria

• Disagreements were resolved by consensus (10% of the time) and by the senior author of the study (MMA)
Methods

• Inclusion criteria:

1. Studies that compared traditional POBA to BVS
2. Patients treated for symptomatic PAD and eligible to antiplatelet therapy
3. Reports of the primary and/or secondary outcomes
Methods

• Exclusion criteria:

1. Reports of BVS only, without comparison to POBA and vice-versa

2. Overlapping patient population, identified by studies developed over the same period of time, with common authors or common study centers. In that case, only the study with a greater number of patients was included.
Primary Endpoints

1. Target lesion revascularization (TLR)
2. Target vessel revascularization (TVR)
3. Primary and secondary lesion patency
Secondary Endpoints

1. Binary restenosis

2. Scaffold thrombosis

3. Leg amputation

4. Mortality
Statistical Analysis

• Pooled treatment effects were estimated using odd-ratio (OR) with the Mantel–Haenszel risk ratio in a random-effects model.

• Heterogeneity was assessed using chi-square tests and I² statistic.

• We defined $I^2 < 50\%$ as low heterogeneity according to the Cochrane Handbook of Systematic Reviews.

• We performed fixed effect analysis when $I^2$ up to 50% and $P$ at least 0.10, otherwise we used random effect.

• We used Fixed or Random Effect analysis using the Cochrane Handbook of Systematic Reviews and RevMan 5.2 for statistical analysis.
# Femoro-Popliteal Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Follow up (months)</th>
<th>BVS</th>
<th>Patients (n)</th>
<th>Primary Patency</th>
<th>Secondary Patency</th>
<th>TLR</th>
<th>TVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lammer.2016</td>
<td>12</td>
<td>Espirit</td>
<td>34</td>
<td>NA</td>
<td>NA</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Werner.2014</td>
<td>12</td>
<td>Igaki-Tamal</td>
<td>28</td>
<td>9</td>
<td>25</td>
<td>16</td>
<td>NA</td>
</tr>
<tr>
<td>Total n (%)</td>
<td>142</td>
<td></td>
<td>52 (51%)</td>
<td>86 (87%)</td>
<td>45 (32%)</td>
<td>29 (25%)</td>
<td></td>
</tr>
</tbody>
</table>
## Femoro-Popliteal Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Amputation</th>
<th>Death</th>
<th>Binary Restenosis</th>
<th>Scaffold Thrombosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bontinck.2016</td>
<td>3/78</td>
<td>2/76</td>
<td>NA</td>
<td>1</td>
</tr>
<tr>
<td>Lammer.2016</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Werner.2014</td>
<td>0</td>
<td>1</td>
<td>19</td>
<td>8</td>
</tr>
<tr>
<td>Total n (%)</td>
<td>3(2%)</td>
<td>3(2%)</td>
<td>21(33%)</td>
<td>9(6%)</td>
</tr>
</tbody>
</table>
# Infra-Popliteal Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Follow up (months)</th>
<th>BVS</th>
<th>Patients (n)</th>
<th>Primary Patency</th>
<th>Secondary Patency</th>
<th>TLR</th>
<th>TVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giordano.2016</td>
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<td>NA</td>
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<td>NA</td>
<td>NA</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Peeter.2005</td>
<td>3</td>
<td>Biotronik</td>
<td>20</td>
<td>NA</td>
<td>NA</td>
<td>1</td>
<td>NA</td>
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<tr>
<td>Varcoe.2016</td>
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<td>Absrob</td>
<td>15</td>
<td>13</td>
<td>15</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Total n (%)</td>
<td></td>
<td></td>
<td>91</td>
<td>13</td>
<td>15 (14)</td>
<td>13</td>
<td>13</td>
</tr>
</tbody>
</table>
## Infra-Popliteal Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Amputation</th>
<th>Death</th>
<th>Binary Restenosis</th>
<th>Scaffold thrombosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giordano.2016</td>
<td>1</td>
<td>0</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Peeter.2005</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Varcoe.2016</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total n (%)</strong></td>
<td>1(1)</td>
<td>1(1)</td>
<td>2(5.7)</td>
<td>3(8.5)</td>
</tr>
</tbody>
</table>
Discussion

• BVS might be safe and efficacious for the endovascular treatment of symptomatic PAD

• Scaffold thrombosis rate were very low

• An in-depth analysis to determine the clinical application of this modality compared to the current standard therapy
Future

• Critical limb ischemia treatment

• Dual anti-platelet therapy duration

• Long-term patency

• Cost and availability of new technologies
Thank you
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