Intravascular Stenting and Angiographic Results: Randomized Comparison of STenting, Stenting after Paclitaxel-eluting balloon and ATherectomy in patients with symptomatic Peripheral Artery Disease
- Results at 6 months -

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on behalf of ISAR-STATH Investigators
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Potential conflicts of interest

Speaker’s name: Massimiliano Fusaro

☐ I have the following potential conflicts of interest to report:
  ☐ Research contracts
  ☐ 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
Background

- Paclitaxel-eluting balloon (PEB) is superior to conventional balloon for patients with PAD involving superficial femoral artery (SFA)

- The possible synergic anti-restenotic efficacy of PEB plus stent therapy still remains uncertain

- The comparative efficacy of stent or PEB plus stent against debulking (atherectomy) has not been evaluated in RCTs
Study Objective

To compare the anti-restenotic efficacy of:

- **Stent**
- **versus**
- PEB plus Stent
- **versus**
- Directional atherectomy (DA)

(SMART Control - Cordis/Johnson & Johnson, Warren, NJ, US)
(In.PACT - Medtronic Inc., Santa Rosa, CA, US)
(SilverHawk/TurboHawk - Covidien, Plymouth, MN, US)
**Design**

**DESIGN:**
Prospective, randomized, active controlled, clinical trial

**INCLUSION CRITERIA:**
- Symptomatic ≥70% stenosis of the SFA (Rutherford Class 2-5)
- Written informed consent

**EXCLUSION CRITERIA:**
- Acute ischemia and/or acute thrombosis of the SFA
- Untreated ipsilateral iliac artery stenosis >70%
- Previous stenting of the SFA
- Popliteal stenosis >70%
- Severe renal insufficiency

155 patients with de novo lesions of SFA enrolled between July 2009 and June 2014 at 2 centers in Germany

- Stent (N=52)
- PEB+Stent (N=48)
- DA (N=55)

Clinical, angiographic and Duplex follow-up at 6-8 months (N=116, 75%)

Clinical and Duplex follow-up at 24 months

ClinicalTrials.gov identifier
NCT00986752
Design

PRIMARY ENDPOINT:
% Diameter stenosis (DS) at follow-up angiography at 6-8 months

SECONDARY ENDPOINTS:
- Death at 6 and 24 months
- Major adverse peripheral events [MAPE, acute thrombosis of SFA or ipsilateral amputation or revascularization (TLR - PTA or bypass surgery), at 6 and 24 months]
- Binary restenosis at 6-8 months
- Rutherford Class at 6 months

TEST HYPOTHESIS:
Superiority-design based on these assumptions: %DS of 20% for PEB+Stent versus 28% for DA versus 36% for Stent, SD of 20%, 2-sided alpha level of 0.017 (Bonferroni adjustment for 3 comparisons), power of 80%; 43 patients/group to be enrolled
## Baseline Characteristics – Patients

<table>
<thead>
<tr>
<th></th>
<th>Stent N=52</th>
<th>PEB+Stent N=48</th>
<th>DA N=55</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>69.2</td>
<td>69.7</td>
<td>68.8</td>
</tr>
<tr>
<td>Female, %</td>
<td>29</td>
<td>31</td>
<td>25</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>29</td>
<td>21</td>
<td>30</td>
</tr>
<tr>
<td>Smoking, %</td>
<td>65</td>
<td>75</td>
<td>56</td>
</tr>
<tr>
<td>Rutherford Class, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>7.7</td>
<td>14.6</td>
<td>9.1</td>
</tr>
<tr>
<td>III</td>
<td>84.6</td>
<td>79.2</td>
<td>87.3</td>
</tr>
<tr>
<td>IV</td>
<td>5.8</td>
<td>2.0</td>
<td>3.6</td>
</tr>
<tr>
<td>V</td>
<td>1.9</td>
<td>4.2</td>
<td>-</td>
</tr>
<tr>
<td>ABI</td>
<td>0.58*</td>
<td>0.69</td>
<td>0.73</td>
</tr>
</tbody>
</table>

* *p<0.001; no other significant differences across groups*
## Baseline Characteristics – Lesions

<table>
<thead>
<tr>
<th></th>
<th>Stent N=52</th>
<th>PEB+Stent N=48</th>
<th>DA N=55</th>
</tr>
</thead>
<tbody>
<tr>
<td>DS, %</td>
<td>93.5</td>
<td>93.3</td>
<td>86.7</td>
</tr>
<tr>
<td>RVD, mm</td>
<td>4.0</td>
<td>3.8</td>
<td>4.6</td>
</tr>
<tr>
<td>Length, mm</td>
<td>68</td>
<td>73</td>
<td>60</td>
</tr>
<tr>
<td>Occlusions, %</td>
<td>67.4</td>
<td>58.3</td>
<td>43.6</td>
</tr>
<tr>
<td>Stent/treated vessel, n</td>
<td>1.4</td>
<td>1.3</td>
<td>0.3*</td>
</tr>
<tr>
<td>Stent diameter, mm</td>
<td>7.1</td>
<td>6.9</td>
<td>6.9</td>
</tr>
<tr>
<td>Acute success</td>
<td>100</td>
<td>98</td>
<td>100</td>
</tr>
</tbody>
</table>

*bail-out only, *p*<0.001; no other significant differences across groups; acute success was defined as <30% postprocedural DS
Results
Angiographic endpoints at 6-8 month follow-up

**% Diameter Stenosis**

- **Stent** versus **PEB+Stent**, p<0.01
- **PEB+Stent** versus **DA**, p<0.01
- **Stent** versus **DA**, p=0.99

**Binary restenosis**

p for trend=0.02
## Clinical endpoints at 6-month follow-up

<table>
<thead>
<tr>
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<th>DA N=55</th>
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</thead>
<tbody>
<tr>
<td>Death, %</td>
<td>-</td>
<td>2.1 ‖</td>
<td>-</td>
</tr>
<tr>
<td>MAPE, % ‡</td>
<td>10.9</td>
<td>8.7</td>
<td>19.7</td>
</tr>
<tr>
<td>TLR</td>
<td>10.9</td>
<td>6.8</td>
<td>19.7</td>
</tr>
<tr>
<td>Acute thrombosis</td>
<td>-</td>
<td>-</td>
<td>2.2</td>
</tr>
<tr>
<td>Amputation</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Rutherford Class, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>35.4</td>
<td>29.1</td>
<td>23.1</td>
</tr>
<tr>
<td>III</td>
<td>25</td>
<td>10.9</td>
<td>21.2</td>
</tr>
<tr>
<td>IV</td>
<td>2.1</td>
<td>20</td>
<td>23.1</td>
</tr>
<tr>
<td>V</td>
<td>-</td>
<td>-</td>
<td>1.9</td>
</tr>
</tbody>
</table>

for death and MAPE percentages derive from Kaplan-Meier estimates; ‖postprocedural retroperitoneal bleeding; ‡p=0.33; no other significant differences across groups
Limitations

• The trial is powered only for angiographic endpoints
• The validity of these results is confined to SFA treatment
• Lack of a group with isolated PEB
• Lack of the comparison with drug-eluting stent
In patients with PAD of the SFA, PEB followed by stenting is superior in terms of anti-restenotic efficacy to both stenting alone and directional atherectomy.
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