Outcome of DCB and PTA post stenting in occluded versus stenotic lesions – subgroup analysis of the randomized Freeway Stent Study

J. Tacke, K.A. Hausegger, H. Schröder, J. Dambach, S. Stahnke,

S. Müller-Hülsbeck, MD, EBIR, FCIRSE, FICA, FSIR

ACADEMIC HOSPITALS Flensburg
of Kiel University – Faculty of Medicine
Ev.-Luth. Diakonissenanstalt zu Flensburg
Knuthstraße 1, 24939 FLENSBURG

Dept. of Diagnostic and Interventional Radiology / Neuroradiology
Disclosure

I have the following potential conflicts of interest to report:

- [x] Consulting: Terumo, BSCI, Eurocor Tech
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Aim of the Study

- Evaluation of the inhibition of restenosis

Post stent PTA with paclitaxel-eluting balloon

*versus*

Post stent PTA with standard balloon

in stenotic or occluded femoropopliteal lesions.
Study Material & Methods

- Multicenter, prospective randomized (1:1) study
- Patients with stenotic lesions or occlusions of the femoropopliteal artery
- Material: FREEWAY™ DCB (Eurocor Tech), commercially available Nitinol stents and PTA balloons
- 13 German & Austrian centers
- Independent, blinded corelab (Bad Krozingen)
Endpoints

**Primary endpoint**
- Clinical driven TLR at 6 months

**Secondary endpoints**
- Primary patency rate at 6 and 12 months
- Clinical driven TLR at 12 months
- Rutherford at 6 and 12 months
- ABI at 6 and 12 months
- MAE at 6 and 12 months
Main Study Criteria

**Inclusion criteria**
- SFA and PI lesion or occlusion
- Rutherford 2 – 6
- Lesion length 4 to ≤ 15 cm, RVD 4 to 7 mm

**Exclusion criteria**
- Previous bypass or stenting of target vessel
- Significant inflow disease or inflow disease to target vessel treated in last 6 months
- No patent outflow vessel
Study Flow Chart *

204 Patients

Randomization 1:1

Nitinolstent + FREEWAY™ DCB Postdilatation
Occluded (N=67) / Stenotic (N=38)

12 Months follow up
Occluded (N=55) / Stenotic (N=34)

Nitinolstent + PTA Postdilatation
Occluded (N=63) / Stenotic (N=36)

12 Months follow up
Occluded (N=51) / Stenotic (N=28)

* Subgroup analysis Occluded versus Stenotic lesions
## Baseline Demographics & Clinical Status

<table>
<thead>
<tr>
<th></th>
<th>FREEWAY DCB + Stent</th>
<th>PTA + Stent</th>
<th>p-value (ns &gt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Occluded (67)</td>
<td>Occluded (63)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stenotic (38)</td>
<td>Stenotic (36)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>80.6 %</td>
<td>77.8 %</td>
<td>ns / ns</td>
</tr>
<tr>
<td>Age (years)</td>
<td>64.3 ± 10.1</td>
<td>63.0 ± 9.7</td>
<td>ns / ns</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>23.9 %</td>
<td>28.6 %</td>
<td>ns / ns</td>
</tr>
<tr>
<td>History of PAD</td>
<td>29.9 %</td>
<td>39.7 %</td>
<td>ns / ns</td>
</tr>
<tr>
<td>History of CAD</td>
<td>20.9 %</td>
<td>19.0 %</td>
<td>ns / ns</td>
</tr>
<tr>
<td>Smoking</td>
<td>89.6 %</td>
<td>85.7 %</td>
<td>ns / ns</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>64.2 %</td>
<td>58.7 %</td>
<td>ns / ns</td>
</tr>
<tr>
<td>Hypertension</td>
<td>71.6 %</td>
<td>76.2 %</td>
<td>ns / ns</td>
</tr>
<tr>
<td>Rutherford</td>
<td>2.88 ± 0.74</td>
<td>2.73 ± 0.51</td>
<td>ns / ns</td>
</tr>
<tr>
<td></td>
<td>2.87 ± 0.47</td>
<td>2.78 ± 0.82</td>
<td></td>
</tr>
</tbody>
</table>
Baseline Lesion Characteristics*

<table>
<thead>
<tr>
<th></th>
<th>FREEWAY DCB + Stent</th>
<th>PTA + Stent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Occluded (N = 67)</td>
<td>Stenotic (N = 38)</td>
<td>Occluded (N = 63)</td>
</tr>
<tr>
<td>Lesion location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SFA prox</td>
<td>7.5 %</td>
<td>5.3 %</td>
<td>4.8 %</td>
</tr>
<tr>
<td>SFA mid</td>
<td>47.8 %</td>
<td>47.4 %</td>
<td>42.9 %</td>
</tr>
<tr>
<td>SFA dist</td>
<td>43.3 %</td>
<td>44.7 %</td>
<td>52.4 %</td>
</tr>
<tr>
<td>PI</td>
<td>1.5 %</td>
<td>2.6 %</td>
<td>0 %</td>
</tr>
<tr>
<td>Lesion length</td>
<td>8.6 ± 4.3 cm</td>
<td>6.1 ± 3.7 cm</td>
<td>9.3 ± 3.9 cm</td>
</tr>
<tr>
<td>Diameter stenosis</td>
<td>100 %</td>
<td>76.7 %</td>
<td>100%</td>
</tr>
<tr>
<td>Ref. vessel diameter</td>
<td>4.6 ± 0.7 mm</td>
<td>4.8 ± 1.0 mm</td>
<td>4.6 ± 0.9 mm</td>
</tr>
<tr>
<td>Vessel Calcification</td>
<td>1.39 ± 1.04</td>
<td>1.55 ± 1.14</td>
<td>1.21 ± 1.04</td>
</tr>
<tr>
<td>Infrapopliteal run-off vessels</td>
<td>2.15 ± 0.88</td>
<td>2.47 ± 0.74</td>
<td>2.24 ± 0.79</td>
</tr>
</tbody>
</table>

* Determined by an independent, blinded corelab (Bad Krozingen)
## Results at 12 Months FU

<table>
<thead>
<tr>
<th></th>
<th>FREEWAY DCB + Stent</th>
<th>PTA + Stent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% (n)**</td>
<td>% (n)**</td>
<td>(ns &gt; 0.05)</td>
</tr>
<tr>
<td>Occluded</td>
<td>(54)</td>
<td>(47)</td>
<td></td>
</tr>
<tr>
<td>12 Months</td>
<td>77.8</td>
<td>59.6</td>
<td></td>
</tr>
<tr>
<td>Stenotic</td>
<td>(30)</td>
<td>(29)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>76.7</td>
<td>65.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Δ 18.2 %</td>
<td>Δ 11.2 %</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>FREWAY DCB + Stent</th>
<th>PTA + Stent</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% (n)**</td>
<td>% (n)**</td>
<td>(ns &gt; 0.05)</td>
</tr>
<tr>
<td>Occluded</td>
<td>(55)</td>
<td>(51)</td>
<td></td>
</tr>
<tr>
<td>12 Months</td>
<td>7.3</td>
<td>17.6</td>
<td></td>
</tr>
<tr>
<td>Stenotic</td>
<td>(34)</td>
<td>(28)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8.8</td>
<td>17.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Δ 10.3 %</td>
<td>Δ 9.1 %</td>
<td></td>
</tr>
</tbody>
</table>

* Determined by an independent, blinded corelab (Bad Krozingen)

** n= number of evaluated patients
### Results Rutherford at 12 Months FU

<table>
<thead>
<tr>
<th>Shift in Rutherford from baseline ≥ 1</th>
<th>FREEWAY DCB + Stent % (n)**</th>
<th>PTA + Stent % (n)**</th>
<th>p-value (ns &gt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occluded</td>
<td>96.3 (54)</td>
<td>78.4 (51)</td>
<td>0.007</td>
</tr>
<tr>
<td>Stenotic</td>
<td>94.1 (34)</td>
<td>82.1 (28)</td>
<td>0.228</td>
</tr>
</tbody>
</table>

**Δ 17.9 %**

**Δ 12.0 %**

**n= number of evaluated patients**
## MAE at 12 Months in the overall population

<table>
<thead>
<tr>
<th>MAE</th>
<th>FREEWAY DCB + Stent</th>
<th>PTA+ Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12 Months N = 90</td>
<td>12 Months N = 81</td>
</tr>
<tr>
<td>MAE</td>
<td>2.2 % (2)</td>
<td>3.8 % (3)</td>
</tr>
<tr>
<td>Death</td>
<td>1.1 %* (1)</td>
<td>2.5 %* (2)</td>
</tr>
<tr>
<td>Study related amputation</td>
<td>0.0 % (0)</td>
<td>0.0 % (0)</td>
</tr>
<tr>
<td>Thrombosis of target lesion</td>
<td>1.0 % (1)</td>
<td>1.3 % (1)</td>
</tr>
</tbody>
</table>

[no significant differences between both arms]

*death not related to study
**Cases of death**

<table>
<thead>
<tr>
<th>DCB arm</th>
<th>PTA (Control arm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Case 1:</strong> ischemic cardiomyopathy: cardiac decompensation (LVEF &lt;15%), 3-vessel disease, valve insufficiency, TIA, progressive sepsis and decreasing general condition</td>
<td><strong>Case 1:</strong> myocardial infarction, arrest of cardiac cycle and respiratory system</td>
</tr>
<tr>
<td><strong>medical history:</strong> PAD both legs, amputation right forefoot, CAD, stroke, diabetic patient for 30 years, wound healing disorder</td>
<td><strong>Case 2:</strong> Renal failure, anemia, aspiration pneumonia</td>
</tr>
</tbody>
</table>
Conclusions

- **Highly favored** patency rate for the FREEWAY™ over PTA arm in the occluded and stenotic lesions subgroup underlines the overall outcome at 12 months (Occluded Δ 18.2 %, Stenotic Δ 11.2%)

- **Highly favored** TLR rate at 12 months for the FREEWAY™ over PTA arm (Occluded Δ 10.3 %, Stenotic Δ 9.1 %)

- TLR at 12 months is **independent of lesion type** but only depends on the treatment

- **Advantage** of DCB vs. PTA treatment in patency rate and Rutherford seems to be **higher in** patients with occluded lesions compared to stenotic patients.

- **Significant better improvement** of ≥1 of Rutherford clinical category in the FREEWAY™ over PTA arm at 12 months in the occluded (Occluded Δ 17.9 %, Stenotic Δ 12.0 %)
CIRSE 2019

Barcelona, Spain
September 7-11

Featuring IDEAS
Interdisciplinary Endovascular Aortic Symposium

www.cirse.org

Featuring an extensive endovascular programme, join us for multidisciplinary discussions on advancements in vascular treatment.

- Focus sessions
- Hands-on Device training workshops
- Round table and case-based discussions and much more...
Outcome of DCB and PTA post stenting in occluded versus stenotic lesions – subgroup analysis of the randomized Freeway Stent Study

J. Tacke, K.A. Hausegger, H. Schröder, J. Dambach, S. Stahnke,

S. Müller-Hülsbeck, MD, EBIR, FCIRSE, FICA, FSIR

ACADEMIC HOSPITALS Flensburg
of Kiel University – Faculty of Medicine
Ev.-Luth. Diakonissenanstalt zu Flensburg
Knuthstraße 1, 24939 FLENSBURG

Dept. of Diagnostic and Interventional Radiology / Neuroradiology