PESTO-CFA

TRIAL

INTERIM ANALYSIS

Aljoscha Rastan
DISCLOSURE

Aljoscha Rastan

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☒ Speaker`s honoraria: Medtronic, BD
☒ Study support: Medtronic
DESIGN
Prospective, randomized, multi-center clinical evaluation of endovascular therapy vs. surgery in CFA treatment (non-inferiority of the treatment groups).

OBJECTIVE
To evaluate the acute and mid-term safety, and performance of Atherectomy + DCB vs. Surgery.

PRINCIPAL INVESTIGATORS
Aljoscha Rastan, MD, Lucerne Cantonal Hospital, Switzerland
Thomas Zeller, MD, University Heart Center, Freiburg - Bad Krozingen, Germany.

PESTO-CFA Trial Design

306 patients to be enrolled
13 sites in Germany + 2 sites in Switzerland

Colloquium consensus
Randomization 1:1

Endovascular
Atherectomy + DCB

Surgery
Endarterectomy

6-, 12-, and 24-months follow-up
- ABI-measurement
- Duplex sonography examinations
- Walking-impairment Questionnaire
- Treadmill test (optional)
PESTO-CFA Main Eligibility Criteria

Inclusion Criteria

- Age ≥ 21 years
- *De-novo* stenosis (>70%) or occlusion of the Common Femoral Artery
- LEAD Rutherford-Becker class 2 – 5
- At least one patent vessel outflow (BTK) to the foot

Exclusion Criteria

- Previous surgery or endovascular therapy of the CFA
- Thrombotic stenosis or occlusion of the CFA
- Aneurysm of the ipsilateral common-, external iliac artery, or CFA (TL)
- Life expectancy < 24 months
- Patients on dialysis
Primary Endpoint (efficacy)
Primary patency at 1 year (defined as absence of TL-Restenosis >50%, without the need of TLR).

Primary Endpoint (safety)
Death, myocardial infarction, minor-major amputation, and procedural complications at 30 days.

Main Secondary Endpoints
- Primary Patency at 6 and 24 months
- Secondary patency at 6, 12, and 24 months
- Change in WIQ and RBC at 6, 12, and 24 months
- CD-TLR at 6, 12, and 24 months
- MAE at 6, 12, and 24 months
PESTO-CFA Independent Data Analysis

Data Processing
Statconsult GmbH, Magdeburg, D

Clinical Research Organisation
Vascuscience GmbH, Leipzig, D

Core Laboratory
CoreLab Black Forest GmbH, Bad Krozingen, D
## PESTO-CFA Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Endovascular Therapy (n=44)</th>
<th>Vascular Surgery (n=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, yr</strong></td>
<td>69.1 ±7.8</td>
<td>69.4 ±7.3</td>
</tr>
<tr>
<td><strong>Male sex</strong></td>
<td>33 (76.7%)</td>
<td>32 (80%)</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td>27.8 ±5.1</td>
<td>27.2 ±4.8</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>39 (92.9%)</td>
<td>38 (95%)</td>
</tr>
<tr>
<td><strong>Diabetes mellitus</strong></td>
<td>21 (48.8%)</td>
<td>16 (40%)</td>
</tr>
<tr>
<td><strong>Hyperlipidemia</strong></td>
<td>39 (92.9%)</td>
<td>33 (82.5%)</td>
</tr>
<tr>
<td><strong>Smoking</strong></td>
<td>15 (34.9%)</td>
<td>15 (37.5%)</td>
</tr>
<tr>
<td><strong>Congestive Heart Failure</strong></td>
<td>5 (11.6%)</td>
<td>4 (10%)</td>
</tr>
<tr>
<td><strong>Coronary Artery Disease</strong></td>
<td>20 (47.6%)</td>
<td>19 (47.5%)</td>
</tr>
<tr>
<td><strong>Myocardial Infarction</strong></td>
<td>8 (18.6%)</td>
<td>7 (17.5%)</td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td>4 (9.3%)</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td><strong>Renal Insufficiency</strong></td>
<td>11 (25.6%)</td>
<td>5 (12.5%)</td>
</tr>
<tr>
<td><strong>Claudication (RBC 2+3)</strong></td>
<td>38 (88.4%)</td>
<td>37 (92.5%)</td>
</tr>
<tr>
<td><strong>CLI (RBC 4+5)</strong></td>
<td>5 (11.7%)</td>
<td>3 (7.5%)</td>
</tr>
</tbody>
</table>

*CLI, critical limb ischemia
*RBC, Rutherford-Becker class
*defined as clearance <60ml/min
**Target Lesion Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Endovascular Therapy (n=44)</th>
<th>Vascular surgery (n=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left CFA</td>
<td>24 (55.8%)</td>
<td>20 (50%)</td>
</tr>
<tr>
<td>CFA</td>
<td>19 (44.2%)</td>
<td>8 (20%)</td>
</tr>
<tr>
<td>CFA/SFA</td>
<td>13 (30.2%)</td>
<td>7 (17.5%)</td>
</tr>
<tr>
<td>CFA/DFA</td>
<td>6 (14%)</td>
<td>11 (27.5%)</td>
</tr>
<tr>
<td>CFA/SFA/DFA</td>
<td>5 (11.6%)</td>
<td>14 (35%)</td>
</tr>
<tr>
<td><strong>Occlusion</strong></td>
<td>7 (15.9%)</td>
<td>11 (27.5%)</td>
</tr>
<tr>
<td><strong>Length (mm)</strong></td>
<td>32.0 (±12.0)</td>
<td>34.1 (±21.4)</td>
</tr>
<tr>
<td><strong>Calcification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None/Mild</td>
<td>2 (4.6%)</td>
<td>3 (7.5%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>12 (27.9%)</td>
<td>12 (30%)</td>
</tr>
<tr>
<td>Severe</td>
<td>29 (67.5%)</td>
<td>25 (62.5%)</td>
</tr>
</tbody>
</table>

- CFA, common femoral artery
- SFA, superficial femoral artery
- DFA, deep femoral artery
## PESTO-CFA Results

### Length of Hospital Stay (Index Procedure)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Length (Mean ± SD, Median)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endovascular Therapy (n=44)</td>
<td>3.4 days ± 2.1 SD (Median 3.0)</td>
</tr>
<tr>
<td>Vascular Surgery (n=40)</td>
<td>8.2 days ± 3.5 SD (Median 6.0)</td>
</tr>
</tbody>
</table>

### Freedom from Major Adverse Events at 30 days

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Freedom (95%-CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endovascular Therapy (n=34)</td>
<td>95.3% (95%-CI: 84.2 - 99.4)</td>
</tr>
<tr>
<td>Vascular Surgery (n=26)</td>
<td>92.5% (95%-CI: 79.6 – 98.4)</td>
</tr>
</tbody>
</table>
**PESTO-CFA Clinical Results at 6-Month and 1-Year**

### Rutherford-Becker Class (RBC)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6-Month</th>
<th>1-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endovascular Therapy</strong></td>
<td>3.0 ±1.5</td>
<td>1.2 ±1.3</td>
<td>1.1 ±1.1</td>
</tr>
<tr>
<td><strong>Vascular Surgery</strong></td>
<td>2.6 ±1.4</td>
<td>1.0 ±1.4</td>
<td>0.9 ±1.1</td>
</tr>
</tbody>
</table>

### Ankle-Brachial Index (ABI)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6-Month</th>
<th>1-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endovascular Therapy</strong></td>
<td>0.6 ±0.3</td>
<td>1.0 ±0.3</td>
<td>1.0 ±0.4</td>
</tr>
<tr>
<td><strong>Vascular Surgery</strong></td>
<td>0.7 ±0.4</td>
<td>0.9 ±0.2</td>
<td>1.0 ±0.3</td>
</tr>
</tbody>
</table>
### PESTO-CFA 1-Year Primary Patency

#### Primary Patency

- **Endovascular Therapy (n=34):** 73.5% (95%-CI: 55.6 - 87.1)
- **Vascular Surgery (n=26):** 69.2% (95%-CI: 48.2 - 85.7)

#### Target Lesion Revascularization

- **Endovascular Therapy (n=34):** 17.5% (n=6)
- **Vascular Surgery (n=26):** 11.5% (n=3)
Because of the small number of patients, no reliable conclusion can be made about the performance of endovascular therapy and vascular surgery in the treatment of CFA lesions.

However, according to the results available to date, the 1-year primary patency rates of both procedures are lower than previously published data from randomized and nonrandomized studies.
PESTO-CFA Investigators

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