4 year results of IN.PACT SFA RCT comparing the IN.PACT Admiral DCB vs POBA in femoral-popliteal lesions: the benefits persist with various lesions in different patient groups

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Disclosure
Peter A. Schneider
Enter patients in studies sponsored by: Gore, Cordis, Medtronic, Silk Road, Bard, NIH, Limflow
Modest royalty: Cook
Scientific Advisory Board (non-compensated): Abbott, Medtronic, Boston Scientific
Chief Medical Officer: Intact Vascular, Cagent

IN.PACT SFA Trial Overview

Objective: Assess safety and efficacy of IN.PACT Admiral DCB vs standard PTA for treatment of superficial femoral and proximal popliteal artery disease due to claudication and rest pain.

IN.PACT SFA I

150 subjects enrolled at 13 EU sites Sep 2010-Apr 2011

Prospective, multicenter EU and US, randomized (2:1), single-blinded trial

Primary Efficacy Endpoint
Primary Patency within 12 months

Secondary Endpoints
Freedom from Target Lesion Revascularization (TLR)
Freedom from Clinically Driven TLR
Freedom from Amputation
Freedom from Clinically Driven Target Vessel Revascularization (TVR)

4-Year Follow-Up Assessment
Clinically driven TLR was adjudicated by an independent Clinical Event Committee, blinded to the assigned treatment based on any re-intervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared to post-procedure baseline ABI
Conducted via telephone interview

IN.PACT SFA Trial Investigators and Sites

IN.PACT SFA I
150 subjects enrolled at 13 EU sites Sep 2010-Apr 2011

IN.PACT SFA II
101 subjects enrolled at 13 US sites Apr 2012-Jan 2013

Baseline Characteristics

<table>
<thead>
<tr>
<th>IN.PACT</th>
<th>PTA</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Age, Y±SD</td>
<td>67.5±9.5</td>
<td>68.0±9.2</td>
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<tr>
<td>Male, %</td>
<td>65.0% (143/220)</td>
<td>67.0% (171/251)</td>
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<tr>
<td>Diabetes, %</td>
<td>40.5% (90/220)</td>
<td>40.5% (89/220)</td>
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<tr>
<td>Current smoker, %</td>
<td>36.6% (85/231)</td>
<td>38.0% (88/111)</td>
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<tr>
<td>Rutherford class, %</td>
<td>27.7% (63/220)</td>
<td>27.7% (61/220)</td>
</tr>
<tr>
<td>3</td>
<td>57.3% (126/220)</td>
<td>55.9% (122/218)</td>
</tr>
<tr>
<td>4</td>
<td>8.6% (19/220)</td>
<td>5.4% (12/220)</td>
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<tr>
<td>Lesion length (mm±SD)</td>
<td>8.9±4.49</td>
<td>8.8±3.12</td>
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<tr>
<td>Total occlusions, %</td>
<td>25.5% (57/220)</td>
<td>19.3% (22/113)</td>
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<tr>
<td>Severe calcification, %</td>
<td>8.1% (18/220)</td>
<td>6.2% (7/113)</td>
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<td>Proximal stenting, %</td>
<td>7.3% (16/220)</td>
<td>12.6% (14/113)</td>
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IN.PACT SFA: Investigators and Sites

IN.PACT SFA I

IN.PACT SFA II
IN.PACT SFA Trial
Primary Patency Through 3 Years

IN.PACT SFA Trial
Freedom From CD-TLR Through 4 Years

IN.PACT SFA Trial
Effectiveness Outcomes Through 4 Years

IN.PACT SFA Trial
Safety Outcomes Through 4 Years

IN.PACT SFA Trial
Independent Predictors of CD-TLR in All ITT Patients Cox Regression Multivariate Analysis

IN.PACT SFA Trial
Conclusion

Data show that female gender, longer lesion length, severe calcium, and PTA treatment are predictive of higher risk of CD-TLR through 4-years.