What is the role for directional atherectomy in infrainguinal vessels

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Clinical Limitations & Unmet Needs

Calcium as a Barrier

**Calcium Limits Vessel Expansion**

Significant difference in vessel compliance leads to overstretch in non-diseased tissue causing dissections, recoil, excessive injury, and poor outcomes.

![Figure 12.1. Elastic Recoil After PTCA of Calcified Lesions](Calcification_attenuation.jpg)

**Calcium May Limit Drug Effect**

Increased lesion length is an independent predictor of decreased patency.

1 F. Freed, Manual of Interventional Cardiology, Ch. 10, 245-254
2 Fanelli, DEBELLUM, 3 Laird, CCI, June 2010
3 SMART Control IFU
4 Matusumura, DURABILITY II JVS, July 2013
If you consider to perform atherectomy there will be...

- ...almost no dissections
- ...no need for stents
- ...ideal vessel preparation for DEB
- ...ability to treat Ca^{++}
- ...effective treatment for in-stent-restenosis
- ...ideal treatment for non-stenting-lesions (e.g. CFA, popliteal)
- ...ideal for ostial lesions
- ...but
  
  ...you will increase your costs
Jetstream (Boston Scientific®)
LINC Live Case 2016 (Atherectomy plus DEB)
Hawk-one (Covidien/Medtronic®)
Distal Popliteal occlusion in a Rutherford 4 Patient
BASELINE: CLINICAL AND ANATOMICAL DESCRIPTION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>67</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td>Diabetes</td>
<td>No</td>
</tr>
<tr>
<td>Rutherford Class</td>
<td>4</td>
</tr>
<tr>
<td>ABI/TBI</td>
<td>0.55</td>
</tr>
<tr>
<td>Lesion Length (cm)</td>
<td>9</td>
</tr>
<tr>
<td>Pre-procedure Stenosis</td>
<td>100%</td>
</tr>
<tr>
<td>Severe Calcium</td>
<td>NO</td>
</tr>
</tbody>
</table>
PROCEDURE

Post 1st cut Silverhawk MS-M

Post 2nd cut Silverhawk MS-M

LAO 30
FINAL RESULT

12 Month F/U Assessment
Rutherford Class 2
ABI/TBI 0.85
Primary Patency (PSVR <2.4) Yes

Provisional Stent No
Pantheris (Avinger®)

Atherectomy plus OCT
Study Design – Definitive AR

General and Angiographic Criteria Assessment

Lesion Severely Calcified*?

- **NO**
  - Randomization
    - DAART (n=48)
    - DCB (n=54)

- **YES**
  - DAART (n=19)

*Defined as: dense circumferential calcification extending > 5 cm
**STUDY DESIGN - DEFINITIVE AR**

**Inclusion Criteria**
- RCC Score of 2, 3 or 4
- ≥70% stenosis, restenosis or occlusion in the SFA and/or popliteal artery
- Target lesion(s) length is 7-15 cm
- Target vessel diameter is ≥ 4 mm and ≤ 7 mm

**Exclusion Criteria**
- In-stent restenosis
- Aneurysmal target vessel
- 2 or more lesions that require treatment in the target limb

*Defined as: dense circumferential calcification extending > 5 cm*
Study Devices

Covidien’s SilverHawk™ & TurboHawk™ peripheral plaque excision systems

Bayer HealthCare’s Peripheral Paclitaxel-coated angioplasty catheter with Paccocath® Technology

**Baseline Lesion Characteristics**

*Per Core Lab*

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>DAART (N= 48)</th>
<th>DCB (N = 54)</th>
<th>p-Value*</th>
<th>DAART Severe Ca++ Arm (N=19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (cm)</td>
<td>11.2</td>
<td>9.7</td>
<td>0.05</td>
<td>11.9</td>
</tr>
<tr>
<td>Diameter Stenosis</td>
<td>82%</td>
<td>85%</td>
<td>0.35</td>
<td>88%</td>
</tr>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>4.9</td>
<td>4.9</td>
<td>0.48</td>
<td>5.1</td>
</tr>
<tr>
<td>Minimum lumen diameter (mm)</td>
<td>1.0</td>
<td>0.8</td>
<td>0.34</td>
<td>0.7</td>
</tr>
<tr>
<td>Calcification</td>
<td>70.8%</td>
<td>74.1%</td>
<td>0.82</td>
<td>94.7%</td>
</tr>
<tr>
<td>Severe calcification</td>
<td>25.0%</td>
<td>18.5%</td>
<td>0.48</td>
<td>89.5%</td>
</tr>
</tbody>
</table>

* p-value for DAART and DCB groups
### Periprocedural Outcomes (per CEC)

**Higher Technical Success and Lower Incidence of Flow-Limiting Dissection in DAART RCT Arm**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>DAART (N= 48)</th>
<th>DCB (N = 54)</th>
<th>(p)-Value (DAART vs. DCB)</th>
<th>DAART Severe Ca++ Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>89.6%</td>
<td>64.2%</td>
<td>0.004</td>
<td>84.2%</td>
</tr>
<tr>
<td>Distal Embolization</td>
<td>6% (3/48)</td>
<td>0% (0/54)</td>
<td>0.101</td>
<td>5.3% (1/19)</td>
</tr>
<tr>
<td>No Intervention</td>
<td>1</td>
<td>0</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Endovascular Intervention</td>
<td>2</td>
<td>0</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Bail-Out Stent</td>
<td>0% (0/48)</td>
<td>3.7% (2/54)</td>
<td>0.50</td>
<td>5.3% (1/19)</td>
</tr>
<tr>
<td>Dissection (flow-limiting, Grade C/D)</td>
<td>2% (1/48)</td>
<td>19% (10/54)</td>
<td>0.01</td>
<td>0% (0/19)</td>
</tr>
<tr>
<td>No Intervention</td>
<td>1</td>
<td>6</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Endovascular Intervention</td>
<td>0</td>
<td>4</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Perforation</td>
<td>4% (2/48)</td>
<td>0% (0/54)</td>
<td>0.22</td>
<td>0% (0/19)</td>
</tr>
<tr>
<td>No Intervention</td>
<td>0</td>
<td>0</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Endovascular Intervention</td>
<td>2</td>
<td>0</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

Technical success defined as achieving ≤30% residual stenosis following protocol-defined treatment and before adjunctive therapy (ie post-dilatation). No surgical interventions were required for any patient.
Key Study Outcome at 12 Months

DUS Patency - Potential Advantage Emerging in Long and Severely Calcified Lesions

Per Core Lab Assessment. “All Severe Ca++ “ group includes all patients treated with DAART therapy including randomized and non-randomized patients with severe calcium.
Key Study Outcome at 12 Months

Angiographic Patency shows similar pattern

Results for all patients who returned for angiographic follow-up
## Major Adverse Events at 1 Year

*Similar Rates Observed Across Groups*

<table>
<thead>
<tr>
<th>Major Adverse Events</th>
<th>DAART</th>
<th>DCB</th>
<th>p-Value*</th>
<th>DAART Severe Ca++ Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically-driven TLR</td>
<td>7.0% (3/43)</td>
<td>7.8% (4/51)</td>
<td>1.00</td>
<td>0.0% (0/17)</td>
</tr>
<tr>
<td>Death</td>
<td>4.7% (2/43)**</td>
<td>2.0% (1/51)**</td>
<td>0.59</td>
<td>5.9% (1/17)</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>0.0% (0/48)</td>
<td>0.0% (0/54)</td>
<td>NA</td>
<td>0.0% (0/17)</td>
</tr>
<tr>
<td>Total</td>
<td>11.6% (5/43)</td>
<td>9.8% (5/51)</td>
<td>1.00</td>
<td>5.9% (1/17)</td>
</tr>
</tbody>
</table>

* p-value for DAART and DCB groups; **Non device-related – CHF & Cancer
DAART resulted in a significantly larger minimum lumen diameter (MLD) following the protocol-defined treatment in DEFINITIVE AR.
Conclusions

- **DEFINITIVE AR** was a *pilot study* designed to assess the effect of treating lesions with DA followed by DCB (DAART).

- Results suggested trends favoring DAART:
  - Added benefit of DA in lesions ≥10 cm (RCT)
    - DUS Patency: DAART 96.8%; DCB 85.9% (KM)
    - Angiographic patency: DAART 90.9%; DCB 68.8%

  - Added benefit of DA in severely calcified lesions (All DAART)
    - DAART 70.4%; DCB 62.5%

- Added benefit with increased post-procedure MLD

- **24-month follow-up** is on-going to assess long-term effect of DAART. Larger, statistically-powered, randomized studies are needed to further validate the benefits of DAART.
Thank You For Your Attention!

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