Atherectomy: is it still worth it?

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Why Atherectomy?

• Atherectomy Goals
  • to reduce the plaque burden without affecting the rest of the vessel wall
  • Debulks and removes atherosclerotic plaque by cutting, pulverizing, sanding or shaving – using catheter deliverable devices
  • Atherectomy offers the theoretical advantages of eliminating stretch injury on arterial walls, limiting acute dissection (and the need adjunctive stenting), and reducing elastic recoil, thereby potentially reducing the rate of restenosis.
Atherectomy Addresses Clinical Challenges

- Lesion characteristics
  - Calcium
  - In-stent restenosis
  - Chronic total occlusions (CTOs)
  - Soft plaque
  - Thrombus (thrombectomy)

- Procedural goals
  - Avoid stenting
  - Vessel preparation
    - Drug elution
    - Modify vessel compliance

Scenario:
Guidewire crosses lesion but device fails to follow
Why Remove Calcium?

- Calcium is heavily present in peripheral lesions
- Presence of calcium necessitates greater balloon pressures
- Calcium might influence drug-coated balloon efficacy
- Plaques associated with arterial dissections commonly have significant calcium deposits

Calcium Increases Arterial Resistance to Balloon Dilation
(Rabbit Model of Atherosclerosis)

Calcium Reduces Drug-coated Balloon Efficacy

- 60 patients with SFA stenosis or occlusion treated with DCB
- CTA, DSA, and IVUS used to quantify the calcium burden
- At 1 year, greater calcification was associated with:
  - Lower patency
    - 50% for 270°-360° vs 100% for 0°-90°
  - Lower ankle-brachial index
  - Greater late lumen loss and TLR rate

CTA, computed tomography angiography; DCB, drug-coated balloon; DSA, digital subtraction angiography; IVUS, intravascular ultrasound; SFA, superficial femoral artery; TLR, target lesion revascularization.

Atherectomy and Drug-Coated Balloon Efficacy: Clinical Evidence

- DEFINITIVE AR: directional atherectomy + DCB vs DCB alone
  - Third non-randomized arm for directional atherectomy + DCB for severely calcified lesions
- Results suggest that adjunctive atherectomy may improve procedural and clinical outcomes following DCB treatment of the SFA and/or popliteal artery, particularly for longer or severely calcified lesions

**Procedural Results**

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>Atherectomy + DCB</th>
<th>Atherectomy + DCB (Severe Ca²⁺)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>64.2%</td>
<td>89.6%</td>
<td>84.2%</td>
</tr>
<tr>
<td>Bail-out Stent</td>
<td>3.7%</td>
<td>0%</td>
<td>5.3%</td>
</tr>
<tr>
<td>Flow-limiting Dissection</td>
<td>19%</td>
<td>2%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**12-Month Results**

- Lesions >10 cm
  - DUS Patency: 97% (DCB), 86% (Atherectomy + DCB)
  - DUS Stenosis: 31% (DCB), 70% (Atherectomy + DCB)

- All Severe Ca²⁺
  - DUS Patency: 63% (DCB), 50% (Atherectomy + DCB)
  - DUS Stenosis: 47% (DCB), 47% (Atherectomy + DCB)
Types of Atherectomy

- **Laser**
  - uses light to vaporize plaque
  - Modifies lesion at the molecular level
  - Works at the tip
- **Directional**
  - SilverHawk
- **Orbital**
  - CSI Diamondback and Stealth
- **Rotational**
  - Jetstream
  - Rotablator
<table>
<thead>
<tr>
<th></th>
<th>Thrombus</th>
<th>Soft Plaque</th>
<th>In-Stent Restenosis(^b)</th>
<th>Mild Calcification</th>
<th>Moderate Calcification</th>
<th>Severe Calcification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diamondback 360(^a)</td>
<td>--</td>
<td>+</td>
<td>-</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Excimer laser</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>TurboHawk</td>
<td>--</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Jetstream Navitus</td>
<td>++</td>
<td>++</td>
<td>Not FDA approved</td>
<td>++</td>
<td>--</td>
<td>+</td>
</tr>
<tr>
<td>Phoenix atherectomy</td>
<td>--</td>
<td>++</td>
<td>Not known</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Crosser recanalization</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
</tbody>
</table>

+, effective; ++, very effective; --, less effective; ---, ineffective.

\(^a\)This table represents the opinion of the author based on personal experience and does not necessarily reflect data from clinical trials.

\(^b\)Some of these devices may be contraindicated for the treatment of in-stent restenosis.
DIRECTIONAL ATERECTOMY MAXIMIZES LUMEN GAIN UNLIKE OTHER THERAPIES\textsuperscript{1}

\textbf{DeNovo Lesion} (60 mm length)

\begin{itemize}
  \item Average Area of Lumen 7.0 mm\textsuperscript{2}
\end{itemize}

\textbf{After Initial Rotational Modality} (DiamondBack 360° 2.25 mm crown)

\begin{itemize}
  \item Average Area of Lumen 8.2 mm\textsuperscript{2}, 17% gain
\end{itemize}

\textbf{After Subsequent Directional Modality} (60 mm length)

\begin{itemize}
  \item Average Area of Lumen 15.0 mm\textsuperscript{2}, 114% gain
\end{itemize}
DEFINITIVE AR Study Overview

- Prospective, multicenter, randomized (DAART vs DCB alone); plus
  non-randomized DAART registry arm for severely calcified lesions
- 121 subjects enrolled at 10 investigational sites
- Primary Outcome
  
  **Target Lesion Percent Stenosis at 1 Year:** Defined as the
  narrowest point of the target lesion divided by the estimated
  native vessel diameter at that location as determined by the
  Angiographic Core Laboratory.

- Clinical follow-up at pre-discharge, 30 days, 6 months and 1 year post-procedure
- Independent CEC, Angiographic and DUS Core laboratory analyses
Key Inclusion and Exclusion Criteria

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

Exclusion Criteria
1. In-stent restenosis
2. Aneurysmal target vessel
3. 2 or more lesions that require treatment in the target limb

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## 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>
### 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></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Intervention</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endovascular Intervention</td>
<td>2</td>
<td>0</td>
<td></td>
<td></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></td>
</tr>
<tr>
<td>Endovascular Intervention</td>
<td>0</td>
<td>4</td>
<td></td>
<td></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></td>
</tr>
<tr>
<td>Endovascular Intervention</td>
<td>2</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Key Study Outcome at 12 Months

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

- All Patients: DAART 93.4%, DCB 89.6%
- Lesions > 10 cm: DAART 96.8%, DCB 85.9%
- All Severe Ca++: DAART 70.4%, DCB 62.5%

N = 48, N = 54
N = 31, N = 23
N = 27, N = 8

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Jacksonville Clinic

First Coast Cardiovascular Institute
Key Study Outcome at 12 Months

Angiographic Patency shows similar pattern

- All Patients: 82.4% DAART, 71.8% DCB
- Lesions > 10 cm: 90.9% DAART, 68.8% DCB
- All Severe Ca++: 58.3% DAART, 42.9% DCB

N = 34, N = 39
N = 22, N = 16
N = 24, N = 7

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Key Study Outcome at 12 Months
Angiographic Patency shows similar pattern

All Patients: DAART 82.4% vs. DCB 71.8%
Lesions > 10 cm: DAART 90.9% vs. DCB 68.8%
All Severe Ca++: DAART 58.3% vs. DCB 42.9%

N = 34 DAART, N = 39 DCB
N = 22 DAART, N = 16 DCB
N = 24 DAART, N = 7 DCB
12-Month Patency: DAART RCT Patients
Is it Important to Achieve ≤30% Residual Stenosis with Directional Atherectomy Post-Procedure?

DAART resulted in a significantly larger minimum lumen diameter (MLD) following the protocol-defined treatment in DEFINITIVE AR.

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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 $\geq 10$ 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.
Study Design

Primary Objective:
To evaluate the intermediate and long-term effectiveness of stand-alone Directional Peripheral Plaque Excision Systems for endovascular treatment of peripheral arterial disease in the femoro-popliteal and tibial-peroneal arteries.

Details & Oversight:
- Pre-specified diabetic vs. non-diabetic patency analysis
- Prospective, non-randomized, global study
- 800 subjects enrolled at 47 centers
- CEC and Steering Committee oversight
- Angiographic and Duplex core laboratory analyses
Study Design and Primary Endpoints

800 patients
47 centers

Claudicants (RCC 1-3)
598 patients*

Primary patency by Duplex US at 12 mos

CLI (RCC 4-6)
201 patients

Freedom from major unplanned amputation at 12 mos

*1 censored due to informed consent violation

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## Pre-Dilation and Adjunctive Therapy
### Analysis by Lesion

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Directional Atherectomy PTA</td>
<td>9%</td>
</tr>
<tr>
<td>Post-Directional Atherectomy PTA (no stent)</td>
<td>33%</td>
</tr>
<tr>
<td>Mean pressure</td>
<td>6.6 atm</td>
</tr>
<tr>
<td>Bail-Out Stent</td>
<td>3%</td>
</tr>
<tr>
<td>Embolic Protection device used</td>
<td>21%</td>
</tr>
<tr>
<td>Subgroup (lesions analyzed)</td>
<td>Mean Lesion Length (cm)</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>All claudicants (743)</td>
<td>7.5</td>
</tr>
<tr>
<td>Diabetic (n= 345)</td>
<td>7.6</td>
</tr>
<tr>
<td>Non-diabetic (n = 398)</td>
<td>7.4</td>
</tr>
</tbody>
</table>
Definitive/LE Conclusions:
Comparative SFA 12-Month Primary Patency
PTA, BMS, DES and DEF LE Sub-analyses by Lesion Length

4. Tepe et al. NEJM 2009;360:669-90
5. Lanas, ISBT 2012
7. Ansell, WVA 2010
DEFINITIVE LE Conclusions

Largest independently-adjudicated study of peripheral atherectomy performed to date

Directional atherectomy is safe & effective at 12 months
- Effective for short, medium and long lesions in claudicants & CLI patients
  - 83% Patency in SFA (4-10cm) in claudicant patients
  - 78% Patency in Infra-popliteal (6.0cm) in CLI patients
  - 95% Limb Salvage in CLI patients
- Low distal embolization requiring intervention -1.6%
- Low complication rate needing treatment is 7.6%

Diabetics perform equally well when treated with directional atherectomy to non-diabetics for claudicants
PROSPECTIVE CSI-INITIATED STUDIES FOCUSED ON CALCIFIED LESIONS

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Max. Inflation Pressure (atm)</th>
<th>Bail-out Stent (%)</th>
<th>Perforation (%)</th>
<th>Embolization (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OASIS(^1) (n=201)</td>
<td>N/R</td>
<td>2.5</td>
<td>1.5</td>
<td>0.5</td>
</tr>
<tr>
<td>CONFIRM I(^2) (n=1,146)</td>
<td>5.7</td>
<td>3.8*</td>
<td>0.9</td>
<td>N/R</td>
</tr>
<tr>
<td>CONFIRM II(^2) (n=1,734)</td>
<td>5.4</td>
<td>5.8*</td>
<td>0.6</td>
<td>2.2</td>
</tr>
<tr>
<td>CONFIRM III(^2) (n=1,886)</td>
<td>5.9</td>
<td>5.2*</td>
<td>0.7</td>
<td>2.2</td>
</tr>
<tr>
<td>CALCIUM 360(^3) (n=29)</td>
<td>5.9</td>
<td>6.9</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>COMPLIANCE 360(^2) (n=38)</td>
<td>4.0</td>
<td>5.3</td>
<td>0.0</td>
<td>2.6</td>
</tr>
</tbody>
</table>

*Based on reported dissection treatment.

In real-world patient populations AND the most challenging lesions Orbital Atherectomy demonstrates successful lesion modification while maintaining low rates of procedural adverse events.

2. CSI Data on file
CONFIRM 360° Study Design

- Three consecutive prospective registries conducted under common protocol from 2009 to 2011
  - Over 200 US hospitals
  - Over 350 physicians
- Real-world patients
  - No inclusion/exclusion criteria
- Three generations of OAS
  - Diamondback 360°, Predator 360°, Stealth 360°

3,135 patients/4,766 lesions
The largest PAD real-world patient data set
COMPLIANCE 360° Study

OAS Outperforms Balloon Angioplasty in ATK Lesions

- Prospective
- Multi-center
- Randomized (1:1)
- Calcified ATK Lesions

Max. Balloon Pressure

<table>
<thead>
<tr>
<th></th>
<th>Max Pressure</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OAS</td>
<td>4.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Balloon</td>
<td>9.1</td>
<td></td>
</tr>
</tbody>
</table>

Adjunctive Stenting

<table>
<thead>
<tr>
<th></th>
<th>100.0%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OAS</td>
<td>5.3%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Balloon</td>
<td>77.8%</td>
<td></td>
</tr>
</tbody>
</table>

Patency* at 12 Months

<table>
<thead>
<tr>
<th></th>
<th>OAS n=32 lesions</th>
<th>PTA n=23 lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patency</td>
<td>81.2%</td>
<td>78.3%</td>
</tr>
</tbody>
</table>

Similar patency despite large difference in stents placed

\[ p = 0.998 \]


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CALCIUM 360° Study
OAS Outperforms Balloon Angioplasty in BTK Lesions

- Prospective, multi-center
- Randomized (1:1)
- Below the Knee lesions
- ≈95% moderate and severe calcium

<table>
<thead>
<tr>
<th>OAS + POBA n=29</th>
<th>POBA ARM n=35</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Avg Balloon Inflation, *p = 0.001</td>
<td>5.9 atms*</td>
</tr>
<tr>
<td>Flow Limiting Dissections</td>
<td>3.4%</td>
</tr>
<tr>
<td>Embolization</td>
<td>0</td>
</tr>
<tr>
<td>Perforation</td>
<td>0</td>
</tr>
<tr>
<td>Bail-out stenting</td>
<td>6.9%</td>
</tr>
<tr>
<td>12 months Restenosis</td>
<td>9%</td>
</tr>
<tr>
<td>12 months MAE, **p = 0.006</td>
<td>6.7%**</td>
</tr>
</tbody>
</table>

MAE (major adverse events: major amputation (above the ankle), all-cause mortality and TLR/TVR).

CALCIUM 360° Primary Endpoint Composite

Primary Endpoint Success
≤ 30% Residual Stenosis With No Dissections Type C - F

OAS + POBA Arm: 93.1%
POBA Arm: 82.4%
OASIS was a multi-center IDE study completed in 2007 to establish safety and acute procedural efficacy.

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Study Overview</th>
<th>Objectives</th>
<th>Key Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>OASIS</td>
<td>Prospective</td>
<td>- Primary endpoints:</td>
<td></td>
</tr>
<tr>
<td>124 Patients</td>
<td>Single-arm: OAS</td>
<td>- Efficacy: Acute reduction in % diameter stenosis of target lesions</td>
<td></td>
</tr>
<tr>
<td>201 Lesions</td>
<td>Multi-center</td>
<td>- Safety: Major Adverse Events (MAEs) at 30 days</td>
<td></td>
</tr>
</tbody>
</table>

*Major adverse events include death, myocardial infarction, amputation or target vessel revascularization.

Jetstream Clinical Studies

Pathway PVD study
- 172 patients at 9 European centers
  - 51% had lesions with moderate to high calcium, 31% total occlusions
  - 74% TLR-free at 12 months
- Patients with diabetes had MAE rates and clinical improvement similar to those without diabetes

Jetstream Calcium Study
- Multicenter study of patients with moderately to severely calcified peripheral artery disease (N=21)
- Results show that the JetStream Atherectomy System removes and remodels superficial calcium in moderately and severely calcified lesions, resulting in significant luminal gain

JET Post-market Registry
- Ongoing registry to observe effects of Jetstream on various lesion types/morphologies

Meahara et al. IBET 2013, Miami, FL.
ClinicalTrials.gov NCT01468435
PVD Study Results

- Jetstream™ device success was 99% (208/210 lesions were cleared)
- 85% of patients TLR-free at 6 months, 74% TLR-free at 12 months
- Stenting performed in 7% of lesions during the index procedure

### Major Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>30 Days (n=172)</th>
<th>6 Months (n=162)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAE</td>
<td>2 (1%)</td>
<td>31 (19%)</td>
</tr>
<tr>
<td>TVR</td>
<td>0 (0%)</td>
<td>4 (2%)</td>
</tr>
<tr>
<td>Death</td>
<td>0 (0%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Amputation</td>
<td>2 (1%)³</td>
<td>2 (1%)</td>
</tr>
<tr>
<td>TLR</td>
<td>0 (0%)</td>
<td>25 (15%)</td>
</tr>
<tr>
<td>MI (non-Q-wave)</td>
<td>0 (0%)</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

### Incidences of TLR or Restenosis by Lesion Location

<table>
<thead>
<tr>
<th>Lesion Location</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFA (n=134)</td>
<td>23 (17.2%)</td>
<td>41 (30.6%)</td>
</tr>
<tr>
<td>ATA (n=2)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>TPT (n=13)</td>
<td>1 (7.7%)</td>
<td>2 (15.4%)</td>
</tr>
<tr>
<td>PTA (n=1)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Popliteal artery (n=58)</td>
<td>9 (15.5%)</td>
<td>14 (24.1%)</td>
</tr>
<tr>
<td>Peroneal artery (n=2)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total (n=210)</td>
<td>33 (15.7%)</td>
<td>57 (27.1%)</td>
</tr>
</tbody>
</table>

ATA: anterior tibial artery; MAE: major adverse event; MI: myocardial infarction; PTA: posterior tibial artery; SFA: superficial femoral artery; TLR: target lesion revascularization; TPT: tibioperoneal trunk; TVR: target vessel revascularization.

PVD Study Results: Diabetes

- The 12-month MAE rate was 25% among diabetic patients (N=80) and 31.5% among non-diabetic patients (N=92).
- Rutherford category improvement and hemodynamic success rates at 12 months did not differ significantly between diabetic and non-diabetic patients.

12-Month Major Adverse Events

- Death
- MI
- TLR
- TVR
- Amputation

Jetstream Calcium Study

Design
- Prospective, single arm, multicenter study of the treatment effects of Jetstream in moderately to severely calcified peripheral artery disease

Primary Endpoint
- Calcium removal and luminal gain as measured by IVUS from pre to post-treatment
  - 2-3 matched slices from pre and post-atherectomy segment sites with maximum calcium reduction were analyzed
  - Minimum lumen area and proximal and distal reference sites (defined as least diseased sites) were also analyzed

Secondary Endpoints
- MAE (target lesion or vessel revascularization, death, unplanned amputation or MI) and use of adjunctive balloons or stents
Conclusions

- PAD encompasses diverse patient and lesion characteristics
- Atherectomy may reduce the negative influence of challenging scenarios (e.g., calcification) on the feasibility and efficacy of endovascular therapies
- Atherectomy may enhance efficacy of drug-coated therapies in select patients
Thank You!