Intravascular Lithotripsy: sound science reinforced by sound data

Focus session: Innovative solutions for calcified peripheral lesions

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Disclosure
Speaker name: Erwin Blessing

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☒ Other(s): Speakers honorarium: Shockwave

☐ I do not have any potential conflict of interest
Case example

Male patient
67 years
Rutherford 4 right leg
Previous stent implantation right SFA

**Duplex ultrasound right leg:**
Severely calcified stenosis CFA, occlusion deep femoral artery
Case example
Case example
DISRUPT PAD III RCT
Largest long-term Level 1 evidence in the treatment of heavily calcified femoropopliteal lesions

**Study Flow**

- **Calcified de novo femoropopliteal lesions**
  - IVL N = 153
  - IN.PACT DCB +/- stent
  - Procedural Success & 30-day F/U
  - Presented at VIVA 2020
- **PTA N = 153**
  - 1-Year Primary Patency + 2-Year F/U
  - New at SCAI 2022

**Endpoints**

- **Primary**: Procedural Success (residual stenosis ≤ 30% without flow-limiting dissection)
- **Powered Secondary**: Primary patency at 1-year (freedom from CD-TLR + freedom from restenosis determined by duplex US + freedom from provisional stenting)

**Design**

- Prospective Multicenter Single-Blind RCT
- 45 Global Sites
- 306 SFA/Popliteal Lesions
- 83% * Severe Calcification
- 129 mm* Avg. Calcified Length

*IVL Arm  †PARC Definition
Tepe et al. JSCAI, 2022.

* Angiographic core-lab adjudicated

SPL 66696 Rev. B - DISRUPT PAD III RCT: 1- & 2-Year Data In-Service. © 2022 Shockwave Medical Inc. All rights reserved.
Superior Prep

IVL's unique mechanism of action delivers significantly more luminal gain with lower dilation pressure and significantly lower dissections.

Superior Procedural Success

Atraumatic Treatment

Procedural Success = Residual stenosis ≤30% without flow-limiting dissections prior to DCB +/- stenting

Lower Max Pressure

(6.3atm vs. 11.3atm) p<0.0001

Reduction in Type ≥ C Dissections

(3.5% vs. 15.1%) p=0.03

12 Tepe et al. JSCAI, 2022.
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**Preserved Options**

IVL maintains control of the procedure by minimizing complications such as dissections, embolization, and perforations. IVL significantly reduces the need for bailout stents, preserving future treatment options.

### Reduced Dissections

<table>
<thead>
<tr>
<th>IVL</th>
<th>3.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ Type C Dissections</td>
<td></td>
</tr>
</tbody>
</table>

**77% Reduction in Type ≥ C Dissections**  
(77% (p=0.03))

**IVL**

<table>
<thead>
<tr>
<th>PTA</th>
<th>15.1%</th>
</tr>
</thead>
</table>

**PTA**

| 77% |

### Low Complications

0%

**Embolization**  
**Perforations**  
**Thrombus**  
**No Flow**

### Reduced Bailout Stenting

75% Reduction in Bailout Stenting  
(75% (p=0.0002))

<table>
<thead>
<tr>
<th>IVL</th>
<th>4.6%</th>
</tr>
</thead>
</table>

**IVL**

<table>
<thead>
<tr>
<th>PTA</th>
<th>18.3%</th>
</tr>
</thead>
</table>

**PTA**

| 75% |

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**Embolic protection:** Utilized in 1.3% of cases in IVL treatment arm.

**Provisional stent:** Utilized if residual stenosis ≥50% by visual estimate or unresolved ≥ Type D dissection, and trans-lesional gradient > 10 mmHg.

Tepe et al. JSCAI, 2022.

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Excellent Long-Term Results

IVL has demonstrated excellent patency out to two years in a severely calcified patient population.

Primary Patency*

<table>
<thead>
<tr>
<th></th>
<th>Months after index procedure</th>
<th>IVL + DCB</th>
<th>PTA + DCB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>90.1%</td>
<td>89.5%</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>80.8%</td>
<td>70.9%</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>74.4%</td>
<td>57.7%</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>65.7%</td>
<td>49.0%</td>
</tr>
<tr>
<td></td>
<td>30                          +30-day window for DUS evaluation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Log Rank P = 0.005

Primary Patency defined as freedom from provisional stenting at index procedure, freedom from clinically-driven target lesion revascularization, and freedom from restenosis determined by duplex ultrasound.

Tepe et al. JSCAI, 2022.

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**CONSISTENT OUTCOMES BETWEEN REAL-WORLD & RANDOMIZED TRIAL**

IVL Safely and Effectively Modifies Calcium Across Multiple Vessel Beds

### Exceptional SAFETY Profile

<table>
<thead>
<tr>
<th></th>
<th>DISRUPT PAD III RCT(^1)</th>
<th>DISRUPT PAD III OS(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>153</td>
<td>1367</td>
</tr>
<tr>
<td>Vessels</td>
<td>SFA/Pop</td>
<td>Iliac, CFA, SFA/Pop, Infrapop</td>
</tr>
<tr>
<td>Dissection (Type D-F)</td>
<td>0%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Perforation</td>
<td>0%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Embolization</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Slow Flow/No Reflow</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Abrupt Closure</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Thrombus</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Final Angiographic Complications (Core-Lab)**

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\(^1\)Tepe et al, J Am Coll Cardiol Intv 2021  
\(^2\)Armstrong E, VIVA Late Breaking Clinical Trial 2022
PREDICTABLE OUTCOMES IN CHALLENGING SITUATIONS
Predictably consistent results across vessel beds, challenging lesions, and complex patients

Majority of stenosis reduction from IVL treatment

Diameter stenosis, %

- Pre-procedure
- Post-IVL
- Final

Vessel Beds
- Iliac
- CFA
- SFA
- Popliteal
- BTK

Challenging Lesions
- ≥15cm
- Eccentric
- CTO
- Severe Ca

Complex Patients
- CLI
- Dialysis
- Female

Armstrong E, Late Breaking Clinical Trial and Shockwave-Sponsored Symposium, VIVA 2022

SPL-67519 Rev. B - DISRUPT PAD III Observational Study – 1373 In-Service. © 2022 Shockwave Medical Inc. All rights reserved.
Conclusions

IVL safely and effectively modifies superficial and deep calcium

Profound level 1 evidence of IVL plus DCB compared with POBA plus DCB in heavily calcified femoropopliteal lesions up to 2 years

Excellent acute technical success with low bail-out stent rates of IVL in heavily calcified lesions in various territories also in a real-world population
Welcome