Safety and Feasibility of Intravascular Lithotripsy for Treatment of Common Femoral Artery Stenoses

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Disclosure

Speaker name: Marianne Brodmann, MD

I have the following potential conflicts of interest to report:

☑ Consulting

Medtronic, BD BARD, Spectranetics, Intact Vascular, Soundbite Medical, Biotronik, Bayer, Daiichi Sankyo, Böhringer Ingelheim, Astra Zeneca
Calcification in CFA Disease

- Calcification is a key underlying factor in CFA disease.
- Common Femoral Endarterectomy (CFE) is the standard of care for common femoral artery stenosis.
- CFE is associated with good long-term patency, but:
  - It is not a benign procedure.
  - Not all patients are candidate.
  - It is associated with extended LOS.
- Endovascular interventions are growing in acceptance and have:
  - High technical success rates.
  - Lower reintervention rates.
Common Femoral Endarterectomy (CFE): Is Not A Benign Procedure

- A review of almost **2000 cases from the National Surgical Quality Improvement Program** database revealed:
  - Post operative complications are not rare
    - 15% composite rate of morbidity and mortality
  - Not all patients are ideal candidates for CFE

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**Predictors of wound complications**

<table>
<thead>
<tr>
<th>Predictor</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation Time</td>
<td>.0002</td>
</tr>
<tr>
<td>Weight</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Female</td>
<td>.0009</td>
</tr>
<tr>
<td>Diabetes</td>
<td>.03</td>
</tr>
<tr>
<td>Dialysis</td>
<td>.0016</td>
</tr>
<tr>
<td>Chronic Steroid Use</td>
<td>.0074</td>
</tr>
</tbody>
</table>

Common Femoral Endarterectomy (CFE): Patient Selection and Considerations

- Not all patients are good candidates for CFE:
  - History of healing wound problems
  - Obesity
  - Focal, calcified stenosis
  - Elderly
  - Concomitant external iliac or sfa disease
  - Physiologic high risk (for surgery)
- CFE can have an average length of stay of 4 + 5.8 days

Challenges with Current Endovascular Options

Despite the improving endovascular outcomes in complex CFA lesions, the challenge remains for a solution that is safe, achieving luminal gain while preserving the access point for future interventions.

**PTA**
- Risk of dissection and plaque shift
- Inability to address calcium results in high acute failure rate requiring a stent
- Traditionally - No Stent Zone!
- Can move and fracture due to hip mobility
- Stents can be crushed by large eccentric plaques
- May eliminate access point for future procedures
- Can jail the profunda, vital for distal collateralization
- Newer stent designs show promise, but limited data

**Stenting**
- Risk of embolization
- Multiple filters needed to protect both SFA and Profunda
- Operator Dependent
- Limited evidence to date; Atherectomy + DCB studies are ongoing

**Atherectomy**
- Jaff, M Cardiac Interventions, 2007
Intravascular Lithotripsy (IVL): Localized Lithotripsy to Treat Cardiovascular Calcium

Inspired by urological applications, but designed for cardiovascular system

**Lithotripsy**

30 years of safety data in kidney stone treatment

*Sonic Pressure Waves* preferentially impact hard tissue, disrupt calcium, leave soft tissue undisturbed

**Cardiovascular Lithotripsy**

Miniaturized and arrayed Lithotripsy Emitters for localized lithotripsy at the site of the vascular calcium

*Optimized for the Treatment of Cardiovascular Calcium*

Peripheral IVL System
How IVL Cracks Calcium In Situ

Expanding and collapsing vapor bubble creates a short burst of sonic pressure waves.

Sonic pressure waves travel through the vessel tissue with an effective pressure of ~50 atm.

A localized field effect within the vessel fractures both intimal and medial calcium.

The Shockwave IVL System consists of an IV pole-mountable generator, a connector cable, and a catheter that houses an array of lithotripsy emitters enclosed in an integrated balloon.
Peripheral IVL System: Clinical Programs

**DISRUPT PAD I**
- Pre Market
- Single Arm
- N = 35
- 2014

**DISRUPT PAD II**
- Post Market
- Single Arm
- N = 60
- 2015

**DISRUPT BTK**
- Post Market
- Single Arm
- N = 20
- 2017

**DISRUPT PAD III**
- Post Market
- Randomized
- N = 400
- 2017

**Observational Registry**
- Post Market
- Single Arm
- N = 1000
- 2017

**Study Completed**

**Enrolling**

Objective: To study the safety and effectiveness of the IVL System in the treatment of *calcified*, stenotic femoropopliteal or infrapopliteal peripheral arteries.
Common Femoral Case Series

**Objective**: Evaluate the safety and effectiveness of peripheral IVL to deliver localized lithotripsy to calcified, stenotic common femoral arteries

**Design:**
- Initiated in 2015 with Prospective Data collection, additional 2 sites added with retrospective data collection 2017-2018
- Core lab adjudicated

**Sites & Subjects**: 21 patients, 3 sites
- Medical University of Graz, Graz Austria
- St. Franziskus Hospital, Muenster Germany
- Heart Hospital of Austin, Austin Texas
## Baseline Characteristics N = 21

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean ± SD</td>
<td>71.9±10.1</td>
</tr>
<tr>
<td>Male Gender, % (n)</td>
<td>76.14% (16)</td>
</tr>
<tr>
<td>Rutherford Class, %</td>
<td></td>
</tr>
<tr>
<td>RC 1</td>
<td>4.7% (1)</td>
</tr>
<tr>
<td>RC 2</td>
<td>9.5% (2)</td>
</tr>
<tr>
<td>RC 3</td>
<td>52.3% (11)</td>
</tr>
<tr>
<td>RC 4</td>
<td>23.8% (5)</td>
</tr>
<tr>
<td>RC 5</td>
<td>9.5% (2)</td>
</tr>
<tr>
<td>RC 6</td>
<td>0.0% (0)</td>
</tr>
</tbody>
</table>

## Pre-procedure N = 21

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference vessel diameter, mm, mean ± SD (range)</td>
<td>6.1± 0.8 (4.5-7.5)</td>
</tr>
<tr>
<td>Mean luminal diameter, mm, mean ± SD (range)</td>
<td>1.7 ± 0.7 (0.0-2.8)</td>
</tr>
<tr>
<td>Diameter stenosis, % mean ± SD (range)</td>
<td>72.3% ± 12.8 (50.2-100.0)</td>
</tr>
<tr>
<td>Lesion length, mm, mean ± SD (range)</td>
<td>37.8 ± 16.7 (12.0-72.7)</td>
</tr>
<tr>
<td>Calcified length, mm, mean ± SD (range)</td>
<td>61.6 ± 30.7 (25.4-143.0)</td>
</tr>
<tr>
<td>Calcification†, % (n)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>28.6% (6)</td>
</tr>
<tr>
<td>Severe</td>
<td>71.4% (15)</td>
</tr>
</tbody>
</table>

*Core lab adjudicated*
### Procedural Details

- 100% Successful IVL delivery with no pre-dilatation
- 86% Procedures were combined IVL + DCB

#### Procedural Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Study Subjects N = 21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-dilatation, %</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>Successful IVL delivery</td>
<td>100.0% (21)</td>
</tr>
<tr>
<td>IVL Pulses, mean ± SD (range)</td>
<td>140 ± 58 (60-300)</td>
</tr>
<tr>
<td>Mean pressure, atm, mean ± SD</td>
<td>6.3 ± 1.4 (4.0-7.0)</td>
</tr>
<tr>
<td>Adjunctive Technology, %</td>
<td></td>
</tr>
<tr>
<td>Drug-Coated Balloon</td>
<td>85.7% (18)</td>
</tr>
<tr>
<td>Atherectomy</td>
<td>4.7% (1)</td>
</tr>
<tr>
<td>Stand-alone IVL</td>
<td>9.5% (2)</td>
</tr>
<tr>
<td>Length of Stay (days)</td>
<td>2</td>
</tr>
</tbody>
</table>

Core lab adjudicated
### Outcomes

No vascular complications including flow-limiting dissections, perforation, distal embolization or stenting

<table>
<thead>
<tr>
<th>Final Procedure</th>
<th>N=21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean luminal diameter, mm, mean ± SD (range)</td>
<td>4.8±1.1 (2.8-6.5)</td>
</tr>
<tr>
<td>Diameter stenosis, % mean ± SD (range)</td>
<td>21.3% ± 10.7 (5.1-40.0)</td>
</tr>
<tr>
<td>Acute gain, mm, mean ± SD (range)</td>
<td>3.1± 1.3 (0.7-5.5)</td>
</tr>
<tr>
<td>Dissection</td>
<td></td>
</tr>
<tr>
<td>Flow-limiting (Grade D-F)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Stents</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Perforation</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Thrombus</td>
<td>0% (0)</td>
</tr>
<tr>
<td>No reflow</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Abrupt closure</td>
<td>0% (0)</td>
</tr>
</tbody>
</table>

Core lab adjudicated
Case Example: CFA Lesion

Pre-procedure: 90% Stenosis 11.98 mm length

IVL Catheter: 6.5mm IVL balloon

Final: 10% Stenosis Acute Gain 5.5mm
Case Example: CFA Lesion

Pre-procedure

72% Stenosis
29.01 mm length

IVL Catheter

7.0mm IVL balloon

Final

11% Stenosis
Acute gain 4.5 mm
Summary: IVL Provides an Endovascular Option for CFA Disease

- Early experience shows promising results of IVL in highly calcified CFA arteries
  - Low residual stenoses and high acute gain
  - No vascular or angiographical complications such as flow-limiting dissections, provisional stenting, perforation, slow or no reflow
- Results from early CFA experience have similar results in both acute performance and safety as seen in Disrupt PAD I/II and BTK studies

IVL:
- May be a viable option for patients that are not good surgical candidates
- Won’t prohibit future surgical interventions if required
- May improve hospital efficiency and cost effectiveness with a reduced LOS compared to surgical intervention
- Early experience shows promising results of IVL in highly calcified CFA arteries
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