Intravascular Lithotripsy for Complex (calcified) Iliofemoral Disease

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Disclosures

I have the following potential conflicts of interest to report:

Proctor-Abbott Vascular, Cardiovascular Systems, Inc
Consultant-Cardiovascular Systems, Inc, Shockwave Medical
Advisory Board-Shockwave Medical
Challenges with Calcium in Lower Limb Revascularization

Calcification restricts vessel expansion resulting in higher residual stenosis and lower procedural effectiveness

Calcified lesions often require high balloon inflation pressure or adjunctive devices

Complications following treatment with endovascular procedures more frequent in calcified lesions

Images Courtesy of: 1) Dr Hector Dourron, Wellstar Cobb Hospital, 2) Case Presented at LINC 2016

*Baumann et al, Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia, J Endovasc Ther 2014
Calcification in CFA Disease

Calcification is common 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
  - Higher reintervention rates
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 fully dilate results in high acute failure rate requiring a stent

**Stenting**
- 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

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

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**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 Catheters
Expanding and collapsing vapor bubble creates a short burst of **sonic pressure waves within the balloon**, which is inflated from 2-6 atm. Sonic pressure waves travel through the vessel with an effective pressure of \(~50\) atm per pulse.

A **localized field effect** within the vessel fractures both **intimal** and **medial** calcium.
Optimal Technique Optimizes Therapeutic Energy

**Oversize Device 10% vs RVD**

Wall apposition facilitates efficient energy transfer. Optimized balloon sizing leads to improved patency

**Overlap Segments by 1 cm**

The sonic pressure waves create a spherical field effect that drops as the longitudinal distance from the emitters increases
OCT demonstrated calcium disruption leading to **acute luminal gain and alteration in vessel compliance** in both **peripheral and coronary arteries**

**Coronary Arteries**

**Peripheral Arteries**
Advantages of IVL

- Simple device over 0.014 wire, minimal learning curve
- Therapy allows vessel expansion at low pressure, usually 2-6 ATM, reducing risk of barotrauma and need for bail-out stenting
- No embolic protection needed
Challenges of IVL

- Currently one length (60mm) is available
- Codes /bills as PTA
- Not low profile
CFA Case Series With IVL

Results from the early common femoral experience have similar results in both acute performance and safety as was seen in Disrupt PAD I/II and Disrupt BTK

<table>
<thead>
<tr>
<th>Procedural Characteristics</th>
<th>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>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>Stents, %</td>
<td>0.0 % (0)</td>
</tr>
</tbody>
</table>

• 100% of patients had moderate or severe calcifications
• No vascular complications including flow-limiting dissections, perforation, distal embolization

Core lab adjudicated

Brodmann, et al, manuscript submitted
90 yo males
Presents w/ shin wound

IVL therapy delivery

Post 6.5 standalone IVL 300 pulses

6.5x60m m IVL
80y/o male with limiting claudication

6.5 x 60mm IVL standalone
Case performed by Bill Dixon M.D.
Tallahassee Memorial Healthcare
10/16/17

CFA PRE on patient w/ foot and toe ulcers

Post 6.5 Shockwave Lithoplasty
180 pulses and 6.0 DCB
Inflated to 6.4 diameter
IVL in Iliac Arteries

- Used as standalone or predilation for stenting
- Low pressure decreases risk of dissection/rupture
- No jailing of internal iliac artery
- May reduce the need for stent placement in external iliac
- Facilitates large bore access
IVL in Iliac Arteries

• **IVL Enables**
  - Transfemoral access, demonstrated improved safety over alternative access strategies for TAVR
  - Endovascular treatment without stent or additional surgical intervention
  - Full/unrestricted stent or stent-graft expansion
  - Difficult EVAR, TEVAR, and TAVR
IVL in Iliac Arteries

Heavily Calcified EIA

Shockwave Lithoplasty W/ 6x60mm

Post 6.0x60mm, standalone Shockwave Lithoplasty 180 pulses

Case performed by William Dixon M.D. Tallahassee Memorial Health Care on 7/10/17
Case Highlight:
- 85 year old with critical aortic stenosis & severe claudication with rest pain
- Not a surgical candidate due to lung disease
- No transcaval or subclavian access option available
- Pre-procedure angiogram demonstrating significant narrowing of bilateral iliac arteries
- Near occlusion of distal aorta

Why IVL?
- IVL has been shown to safely and effectively treat calcified iliacs in advanced of TAVI delivery, allowing safe transfemoral delivery
- Complication rate with IVL in Pre-TAVI use is very low with no perforations and no stents placed

Outcome
- Post-IVL iliac arteries allowing safe passage of a Medtronic Evolut R 26mm TAVR device (minimum vessel diameter required >5.5mm)
- Patient discharged following day
Large Bore Access – Pre-EVAR
Calcified Iliac Treatment prior to AAA Graft delivery

Case Highlight:
• Patient was to receive an 18Fr AAA graft
• Highly Calcified Iliac limited the options for a safe delivery of the AAA Graft
• IVL chosen to prep and modify the calcified vessels in order to enable passage of the graft

Why IVL?
• IVL has been shown to safely and effectively treat calcified Iliacs in advanced of EVAR & TEVAR delivery, allowing safe delivery\(^1\)
• Complication rate with IVL in Pre-EVAR/TEVAR use is very low with no perforations and no stents placed\(^1\)

Outcome
• Post-IVL iliac arteries allowing safe passage of the 18Fr AAA graft
• No complications (dissections, perforations, emboli)

1. Foteh M. The use of intravascular lithotripsy to facilitate the delivery of aortic endovascular grafts in calcified iliac arteries, Charing Cross 2019
Conclusions

- IVL is a unique therapy which allows safe, effective treatment of heavily calcified peripheral vessels, possibly reducing risk of complications
- Minimal learning curve, embolic protection not necessary
- Allows treatment of lesions which have historically required surgical revascularization (no-stent areas)
- May be used to facilitate large bore access (TAVR, EVAR, TEVAR) through diseased iliac arteries
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