The Use of Intravascular Lithotripsy in Aorto-iliac Disease

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Disclosures: Dr. Andrew Holden

• Dr. Holden is a Medical Advisory Board Member for Medtronic, Boston Scientific, and Gore

• Dr. Holden is a Clinical Investigator for Medtronic, Boston Scientific, Gore, Abbott, Cagent, Endologix, Intact Vascular, Shockwave, Bard, Cook, Endospan, Intervene, Spectranetics, TriReme, Merit, Reflow, Terumo, Surmodics

• No other relevant disclosures
Aorto-Iliac Occlusive Disease (AIOD)

- Multiple consensus and practice guidelines now generally endorse an endovascular-first strategy for TASC II C and D AIOD lesions in experienced endovascular centers\(^1,2,3\)
- Calcification is common in TASC C/D AIOD with a significant risk of sub-optimal results and rupture during endovascular revascularization
- Society for Vascular Surgery guidelines recommend stent grafts in instances of severe calcification at risk of vessel rupture\(^4\)

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Shockwave IVL System Components
Shockwave Intravascular Lithotripsy
Shockwave Intravascular Lithotripsy

Emitters produce expanding and collapsing vapor bubbles resulting in a short burst of sonic pressure waves.

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

With multiple emitters in the catheter, a field effect is created.
# DISRUPT PAD Clinical Programs

<table>
<thead>
<tr>
<th></th>
<th>Disrupt PAD I</th>
<th>Disrupt PAD II</th>
<th>Disrupt BTK</th>
<th>PAD III RCT</th>
<th>PAD III OS</th>
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<tbody>
<tr>
<td><strong>Status</strong></td>
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<tr>
<td><strong>Target Lesions</strong></td>
<td>Severely calcified, SFA/pop lesions</td>
<td>Severely calcified, SFA/pop lesions</td>
<td>Severely calcified, SFA/pop lesions</td>
<td>Severely calcified, SFA/pop lesions</td>
<td>Severely calcified peripheral artery lesions</td>
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<td><strong>Study Design</strong></td>
<td>• Single-arm • Safety and effectiveness</td>
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<td>• Single-arm • Safety and effectiveness</td>
<td>• RCT • IVL+DCB vs PTA+DCB</td>
<td>• Single-arm • All-comers</td>
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<td><strong># Patients</strong></td>
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**Ongoing Trials**
Observational Study Status

- Angiography Core Laboratory adjudicated
- Total enrollment extended to 1500 patients
- Latest enrollment update 1153/1500 (77%)
- First 200 hundred patients initially analyzed...
Consistently low (<30%) residual stenosis achieved across all sub groups

Observational Study Effectiveness
Pre and Final % Diameter Stenosis

Core Lab Adjudicated, BTK lesions not reported due to N < 5
Adjunctive Therapy Use by Vessel Bed

High prevalence of adjunctive therapy across all arterial beds (91.8%)

- DCB was used across all vessel beds
- Iliac arteries mainly treated with IVL and stents
- CFA mainly treated with IVL and DCB
- Majority of atherectomy was used in SFA
Shockwave IVL in AIOD

• Experience outside of Observational Registry again limited to case presentations and small single centre series
• Shammas et al\(^1\) – single centre experience in 7 cases with 100% procedural success, no perforation or residual stenosis
• Adjuvant stenting in all cases

Safety and Efficacy of Lithoplasty in Treating Severely Calcified Iliac Arterial Disease: A Single Center Experience

Qais Radaideh, MD; Nicolas W Shammas, MD, MS; Gail A Shammas, BSN, RN; John Shammas BS
The Midwest Cardiovascular Research Foundation, Davenport, Iowa

Shockwave IVL in AIOD: Auckland Experience

- Shockwave IVL to facilitate TEVAR/EVAR – 4 cases
- Shockwave IVL to facilitate AIOD revascularization – 12 cases

Acute Procedural Outcomes in AIOD Cases at Auckland Hospital

- 7 males, 5 females
- Age mean 68 years (58 - 82)
- TASC D 75% (9 cases); TASC C 25% (3 cases)
- Acute procedural success 100%
- No residual stenosis > 20%
- Post-IVL dissection in 25% (3 cases)
- No embolic complications
- All cases managed with balloon-expandable covered stents (VBX 75%, Begraft 25%)
- CERAB reconstruction 83% (10 cases)
Shockwave IVL in AIOD: Case Example

58 year old female, smoker, claudicant  Rutherford 5 (blue toes)
Shockwave IVL in AIOD: Case Example

58 year old female, smoker, claudicant Rutherford 5 (blue toes)
Shockwave IVL in AIOD: Case Example

74 year old, Rutherford 3 right leg claudicant – Live case for VERVE 12/19!
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Shockwave IVL in AIOD: Case Example

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Conclusions

• Calcified aorto-iliac disease is a significant impediment to EVAR, TEVAR and TAVI with serious adverse events
• Calcification is common in severe AIOD and limits endovascular reconstruction
• Shockwave IVL is an important adjunct in both clinical settings and can facilitate optimum results
• At Auckland Hospital, we consider Shockwave IVL in TEVAR/EVAR cases with severe/concentric aorto-iliac calcific stenotic disease and heavily calcified TASC C/D AIOD
• Although the largest IVL catheter is currently only 7mm diameter, this does seem to facilitate subsequent device dilatation to nominal
• Larger devices are eagerly awaited!
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