Extending Application of Intravascular Lithotripsy (IVL) to a High Risk Real World Population

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Background
• Coronary arterial calcification increases procedural complexity in percutaneous coronary intervention (PCI) with a higher risk of major adverse cardiac events1.
• Up until recently methods of calcium modification have included high pressure non-compliant and cutting balloons and artherectomy.
• The Disrupt-CAD I study suggested benefit with the use of intravascular lithotripsy (IVL) in selected cases2.
• We present outcomes for IVL-assisted PCI in a broader all comers population.

Methods
• We included all procedures utilizing IVL at our institution from May 2016 to May 2018.
• Demographic, procedural and post-procedural outcomes were recorded with comparison between those enrolled in Disrupt-CAD I to a clinical population, including OCT data on mean luminal area (MLA) and mean residual area stenosis (MRAS) post PCI.
• The indication for IVL use was based on presence of an undilatable lesion, severe calcification on angiography or on intravascular imaging.

Results
• 27 procedures (mean 77.4 years, 81% male) were included (14 study and 13 clinical procedures).
• The clinical group differed by including patients with acute coronary syndromes (31%), renal replacement therapy (15%), left main stem and multivessel intervention (15%).
• 15% in total had a previous undilatable lesion.
• Optical coherence tomography (OCT) was utilised in 63% of cases (see Figure 2).
• Total procedural success was 93% with 100% facilitation of stent delivery.
• On OCT post PCI, the MLA and MRAS were similar in both groups (See Table 1).

Discussion
• IVL has been shown to be a safe and feasible alternative for calcium modification
• A further 30 clinical cases have been performed at our institution following abstract submission including:
  • Rotational atherectomy unsuccessful IVL facilitated PCI
  • Rotational atherectomy assisted IVL facilitated PCI
  • Acute ST elevation acute coronary syndrome primary PCI
  • Peripheral use in the iliofemoral system to aid vascular access for transcatheter aortic valve implantation
• Advantages of IVL
  • Provides a more controlled means of calcium modification
  • Averts no-reflow as seen in rotational atherectomy
  • Allows continuous simultaneous coronary guidewire placement in bifurcation intervention particularly LMCA
  • Has the ability to modify calcification without further vessel injury with minimal trauma on soft tissue
• Disadvantages of IVL
  • Bulky balloon and may require guideliner supported delivery

Table 1. Comparison of MLA and MAS on OCT post PCI between the 2 cohorts

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<thead>
<tr>
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<th>Disrupt-CAD I cohort</th>
<th>Clinical cohort</th>
<th>p value</th>
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<tbody>
<tr>
<td>MLA post PCI</td>
<td>4.8+/−1.8mm²</td>
<td>4.2+/−1.4mm²</td>
<td>0.55</td>
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<tr>
<td>MRAS post PCI</td>
<td>24.3%</td>
<td>21.9%</td>
<td>0.22</td>
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References

Conclusion
• IVL is a novel technology enabling modification of severe coronary calcification and provides a safe and feasible alternative to currently available techniques with increasing clinical applicability.

Disclosure information
• Dr Todd Brinton is a co-founder of Shockwave Medical®