In-Stent Restenosis: New Evidence From Laser + Drug Coated Balloons

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Disclosure

Speaker name: Ehrin J. Armstrong MD

I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Boston Scientific, Cardiovascular Systems, Medtronic, Philips
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
DCBs in Complex ISR

DCB better then PTA @ 1 year, however:

- Tosaka III indep. predictor of re-restenosis and re-occlusion
- Complete catch-up @ 3 years

Benefits of Laser Atherectomy in ISR

- Only FDA indicated atherectomy technology for ISR
- Treat multiple lesion morphologies
- Debulk lesion from the tip with no moving parts
- Gain 27% larger lumen with Turbo-Power vs. Turbo-Elite
- Directional debulking with Turbo-Power
Laser+DCB in ISR pre-Clinical Insights

Rabbit model of (carotid) CTO ISR by Fogarty Injury and BMS implant

Reduced % stenosis and intimal thickness with Laser+DCB vs. DCB alone at 28 days

<table>
<thead>
<tr>
<th>Sections</th>
<th>Lumen Area (mm²)</th>
<th>Neointimal Area (mm²)</th>
<th>Stenosis (%)</th>
<th>Neointimal Thickness (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA + DCB</td>
<td>6</td>
<td>2.91 ± 0.58</td>
<td>2.82 ± 0.3</td>
<td>49.59 ± 6.74</td>
</tr>
<tr>
<td>Laser + DCB</td>
<td>12</td>
<td>3.6 ± 0.94</td>
<td>2.36 ± 0.54</td>
<td>40.27 ± 11.50</td>
</tr>
</tbody>
</table>

P-value: 0.060

*Significant based on 1-tailed t-test (p < 0.05)


*Stellarex DCB is not currently approved for use in SFA ISR
Case Example

• 72M with non-healing ulcer of his right great toe.

• Prior SFA stent placement for claudication, known to have occluded stent for last 2 years.
Laser + DCB in ISR

Single center, randomized trial in complex ISR

- Compare safety and efficacy of laser debulking and DCB vs. DCB alone in CLI patients with complex SFA ISR
- N=48 (24 patients w/ Laser+DCB; 24 patients w/ DCB alone)
- Outcomes assessed at 12 months post-procedure

<table>
<thead>
<tr>
<th>Key Study Results</th>
<th>Laser + DCB (n=24)</th>
<th>DCB Alone (n=24)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ISR Length (cm)</td>
<td>20</td>
<td>23</td>
<td>n/a</td>
</tr>
<tr>
<td>Primary Patency (12 mon)</td>
<td>66.7%</td>
<td>37.5%</td>
<td>0.01</td>
</tr>
<tr>
<td>TLR (12 mon)</td>
<td>16.7%</td>
<td>50%</td>
<td>0.01</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>2 (8%)</td>
<td>11 (46%)</td>
<td>0.003</td>
</tr>
<tr>
<td>Limb Salvage (12 mon)</td>
<td>91.7%</td>
<td>54.2%</td>
<td>0.003</td>
</tr>
<tr>
<td>Wound Healing (12 mon)</td>
<td>87.5%</td>
<td>62.5%</td>
<td>0.03</td>
</tr>
</tbody>
</table>


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‘In this small initial experience, laser and DCB angioplasty is correlated with better outcomes in CLI patients with occluded SFA stent’


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“Real world” analysis of treatment of FP-ISR with laser + DCB (n=62) vs laser + PTA (n=50).

Retrospective analysis, two centers

N=112

33% CLI

74% Tosaka III

Average Lesion Length 247 ± 115 mm


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Laser Atherectomy Combined with Drug-Coated Balloon Angioplasty for Treatment of Femoropopliteal Restenosis


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*Stellarex DCB is not currently approved for use in SFA ISR*

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Conclusions

• ISR remains a difficult to treat clinical problem.

• DCB have benefit compared to angioplasty, but there is late catch-up.

• Laser atherectomy has efficacy for ISR compared to POBA alone.

• The combination of laser atherectomy and DCB may be the ideal treatment for FP-ISR.
Thank you