Laser and DCB for SFA ISR: follow-up of a single center cohort up to 5 years

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Major histological findings in ISR

- In-stent restenotic lesions are complex and differ significantly from de-novo atherosclerotic lesions.
- In-stent restenotic lesions are heterogeneous and consist primarily of collagen and smooth muscle cells, with a high water content.
- Innermost intimal layer of dense smooth muscle cell tissue.
- Outermost intimal layer cell-poor scaffold or “sponge” comprised of collagen (largest volume constituent).
- Calcium is rarely present in in-stent restenotic lesions.
The problem of ISR

Cellular reaction
Extra-cellular matrix (ECM) > 50% of total volume (Thrombus)

Inoue S et al, JVS 2002;35:672-678
The problem of ISR

- Mechanism of luminal gain (PTA coronary ISR)
  - Tissue compression
  - Extrusion of tissue out of stent
  - Additional stent expansion (upto 56% of total luminal gain)

- NB additional stent expansion not possible in SE stents

Mehran R et al, Am J Cardiol 1996;78:618-622
The problem of ISR

- **Volumetric IVUS analysis (coronary)**
  - PTA provides good acute luminal gain (intra-stent volume decrease 50%)
  - After short delay (ca. $\frac{1}{2}$ hour) increase in intra-stent volume (32%)

- **Underscores need for tissue ablation**

Albertal M et al, Am J Cardiol 2005;95:751-754
The problem of ISR

- Balloon angioplasty will not be efficacious
- Treatment of in-stent restenosis requires a completely different approach
Multiple studies showed benefit of DCB vs. PTA in the short term

**DCB in SFA-ISR**
- N = 39
- ISR length = 8.3 cm

**DEBATE ISR**
- N = 44
- 100% DM, 75% CLI
- ISR length = 13.2 cm

**FAIR**
- RCT DCB vs. PTA
- N = 119
- ISR length = 8.2 cm

Virga V et al. JACC Cardiovasc Int 2014;7:411-415
Liistro F et al. JET 2014;21:1-8
Krankenberg H et al, Circulation 2015;132:2230-2236
ISR and DEB

- PACUBA trial
  - 74 patients (DCB n=35, PTA n=39)
  - Mean lesion length 17.3 ± 11.3 cm vs. 18.4 ± 8.8 cm
  - At 12 months
    - Primary patency 40.7% vs. 13.4% (p=0.02)
    - Freedom from TLR 49.0% vs. 22.1% (p=0.11)
    - Clinical improvement 68.8% vs. 54.5% (p=0.87)

Kinstner CM et al. JACC Intv 2016;9:1386–1392
ISR and ELA

- 250 Patients (169 ELA+PTA vs. 81 PTA)
- Mean ISR length: 19.6±12.0 vs. 19.3±11.9 cm
- Occlusive ISR: 30.5% vs. 36.8%

ELA+PTA: less complications, lower TLR rates, higher Primary Patency rates vs. PTA

Dippel E et al JACC Cardiovasc Int 2015;8:92-101
Combination therapy ELA-DCB

100% Occlusive (Tosaka III) ISR with mean ISR treated length: 22.4±9.4 cm vs. 25.9±8.7 cm

12-month Primary Patency: 66.7% vs. 37.5% (p= 0.01)

Gandini R et al, JET 2013;20:805-813
Combination therapy ELA-DCB

- 14 patients; mean age 78 ± 6.5 years
- Mean lesion length treated 133.2 mm ± 107.2 mm (range 10 mm – 380 mm)
- Tosaka class I n=2, Tosaka class III n=12 (85.7%)
- Mean Duplex follow-up 19.4 ± 9.4 months (range, 9-38 months)
- TLR n=1 (at 3 years after the ISR treatment)
- Primary patency 91.7%

van den Berg JC et al, JIC 2014;26:333-337
ISR and DCB

- Lesion length 132±86 mm (DEB)
- At 3 year follow-up complete catch-up
- No difference between DEB and POBA

<table>
<thead>
<tr>
<th></th>
<th>DEB (n=44)</th>
<th>BA (n=42)</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>All-cause death</td>
<td>9 (20)</td>
<td>9 (21)</td>
<td>1</td>
</tr>
<tr>
<td>Major amputation</td>
<td>1 (2)</td>
<td>1 (2)</td>
<td>1</td>
</tr>
<tr>
<td>Target lesion revascularization</td>
<td>18 (40)</td>
<td>18 (43)</td>
<td>0.8</td>
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<tr>
<td>Non-target lesion revascularization</td>
<td>10 (22)</td>
<td>8 (19)</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Liistro F et al. JET 2014;21:1-8
Grotti S et al. JET 2015;23:52-57
Long-term results ELA and DCB

Duplex FU @ 3 years
Patient demographics

- N=25 in-stent restenosis or occlusion (not extending beyond the stent) of the superficial femoral artery and popliteal artery
- In 4 patients occluded stent extended into the below-the-knee segment
- Mean age 71.8 years
Clinical presentation

<table>
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<tr>
<th>Rutherford classification</th>
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<tbody>
<tr>
<td>Class 1</td>
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<tr>
<td>Class 2</td>
<td>0</td>
</tr>
<tr>
<td>Class 3</td>
<td>10</td>
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<td>Class 4</td>
<td>6</td>
</tr>
<tr>
<td>Class 5</td>
<td>7</td>
</tr>
<tr>
<td>Class 6</td>
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</tbody>
</table>
Lesion characteristics

- Average lesion length 105.6 mm (range 10-380 mm)
- 1 patient with 2 short lesions
- Tosaka classification
  - Tosaka I n=6
  - Tosaka II n=0
  - Tosaka III n=20
Procedural details

- 100 % technical success
- Distal embolisation $n=2$ (successfully treated by endovascular means)
Follow-up

• Mean Duplex follow-up 35.1 months (range 4-77 months)
• Mean clinical follow-up 37.3 months (range 10-78 months)
• No amputations during follow-up in patients with CLI
## PP and fTLR (K-M estimates)

<table>
<thead>
<tr>
<th></th>
<th>Primary Patency</th>
<th>Freedom from TLR</th>
</tr>
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<tbody>
<tr>
<td>1 year</td>
<td>88.0%</td>
<td>89.7%</td>
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<tr>
<td>2 years</td>
<td>78.2%</td>
<td>85.9%</td>
</tr>
<tr>
<td>3 years</td>
<td>71.7%</td>
<td>76.4%</td>
</tr>
<tr>
<td>4 years</td>
<td>71.7%</td>
<td>76.4%</td>
</tr>
<tr>
<td>5 years</td>
<td>62.7%</td>
<td>70%</td>
</tr>
</tbody>
</table>
Perspective (cf. DCB alone @ 3 years)

Δ = 16.4%

Log Rank (Mantel-Cox) p = 0.59

Freedom from TLR

Grotti S et al. JET 2015;23:52-57
Conclusions

• The treatment of in-stent restenosis with conventional balloon angioplasty yields poor short-term results that can be improved by using drug coated balloon technology

• DCB treatment shows a catch-up phenomenon after 3 years

• Treatment of long femoral in-stent restenosis with a combination of laser debulking and drug coated balloons shows excellent short-term results and good long-term results
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