Treatment Strategies for Long Lesions of greater than 20 cm

Donald L. Jacobs, MD
C. Rollins Hanlon Professor and Chair
Chair of the Department of Surgery
Saint Louis University
Disclosure

Speaker name: Donald Jacobs, MD

I have the following potential conflicts of interest to report:

- [x] Consulting: **Abbott**
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] I do not have any potential conflict of interest
The challenge of long lesions

- Significant progress had been made in the endovascular treatment of long lesions
- Acute technical success
  - Very high and fairly well defined
- Long term success
  - Not as well known
  - Multiple variables impacting on results
    - Variable patient populations
    - Variable anatomic location, mechanics
    - Calcification
    - Evolving technique/tools
    - Limited follow up
Long stent data

• Durability 200
  – Bare nitinol stent (protégé)
  – 100 patients
  – mean lesion 24.2 cm (range 16–45)
  – 1 yr freedom from TLR 68.2%
  – 1 yr primary patency 64.8%

• Viastar
  – Viablan vs bare nitinol stent
  – 141 patients randomized
  – Mean lesion length 19.0 and 17.3 respectively
  – 1 yr freedom from TLR 85% and 77% respectively
  – 1 yr primary patency 78% and 54% respectively


**DES in long lesions**

- Zilver PTX single arm registry
  - 135 patients
  - Mean lesion length **22.6** cm
  - 1 yr primary patency **77.6%**
  - 1 yr freedom from TLR **85.4%**

- Supera 500 registry
  - 492 limbs
  - Mean lesion length 12.6 cm
  - 1 yr primary patency 83.3%
  - 2 yr primary patency 72.8%

- SUPERB trial long lesion subset
  - 87 pts in top tercile length
  - Mean lesion length 12.6 cm
  - 1 yr primary patency 88%
  - 1 yr freedom from TLR

---

**Interwoven nitinol in long lesions**

Atherectomy for long lesions

• Limited data
  – Relatively low patency
  – Significant procedural time/radiation
  – Significant risk of embolization

• Atherectomy and DCB
  – Not yet defined but good data on mid range lesions in some reports
  – But above risks persist with added cost concerns
# DCB vs DES in long lesions

Propensity based analysis to define similar cohorts in a real world experience

<table>
<thead>
<tr>
<th></th>
<th>DCB (N=131)</th>
<th>DES (N=97)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion length</strong></td>
<td>19.4 +/- 8.6 cm</td>
<td>19.5 +/- 6.5 cm</td>
</tr>
<tr>
<td><strong>Restenotic lesions</strong></td>
<td>52%</td>
<td>44%</td>
</tr>
<tr>
<td><strong>Total occlusion</strong></td>
<td>53%</td>
<td>63%</td>
</tr>
</tbody>
</table>

DCB and DES in long lesions

12 month follow up

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>DES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=131</td>
<td>N=97</td>
</tr>
<tr>
<td>Restenosis PSV &gt;2.4</td>
<td>24%</td>
<td>30%</td>
</tr>
<tr>
<td>TLR</td>
<td>16%</td>
<td>19%</td>
</tr>
</tbody>
</table>

Saint Louis University Experience with Interwoven Nitinol Stenting in Femoral-Popliteal Lesions

- Retrospective review
  - April 2010 and December 2011
- 54 limbs in 48 patients
- Mean follow up of 27.5 + 12.3 months
- Median follow up of 30 months
- Clinical follow up: clinical interview, ABIs, and duplex US

Brescia, et al, Stenting of femoropopliteal lesions using interwoven nitinol stents
Journal of Vascular Surgery
Volume 61, Issue 6, Pages 1472–1478
Selected sub-set of data on lesions > 10 cm length from Brescia et al data on interwoven nitinol stents

<table>
<thead>
<tr>
<th></th>
<th>DES N=97</th>
<th>DCB N=131</th>
<th>Woven nitinol N=43</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length</td>
<td>19.5 +/- 6.5 cm</td>
<td>19.4 +/- 8.6 cm</td>
<td>26.7 +/- 9.8 cm</td>
</tr>
<tr>
<td>Re-stenotic lesions</td>
<td>44%</td>
<td>52%</td>
<td>44%</td>
</tr>
<tr>
<td>Total occlusions</td>
<td>63%</td>
<td>53%</td>
<td>81%</td>
</tr>
<tr>
<td>TLR</td>
<td>16%</td>
<td>19%</td>
<td>16%</td>
</tr>
</tbody>
</table>

Mean FU of 27 months

Superb Trial impact of lesion length

Percent of Lesions without Restenosis by Lesion Length
(12 months SUPERB IDE Trial)

- Shortest Lesions (35.4±12.3cm): 88%
- Middle Lesions (73.5±10.8cm): 85%
- Longest Lesions (126.1±33.4cm): 88%
Saint Louis University experience with interwoven nitinol stents:

Outcomes by lesion length

<table>
<thead>
<tr>
<th></th>
<th>&lt; 15 cm (n=18)</th>
<th>15 - 30 cm (n=18)</th>
<th>&gt; 30 cm (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary patency</td>
<td>72.3% (13)</td>
<td>83.3% (15)</td>
<td>83.3% (15)</td>
</tr>
<tr>
<td>Primary assisted patency</td>
<td>88.9% (16)</td>
<td>88.9% (16)</td>
<td>88.9% (16)</td>
</tr>
<tr>
<td>Secondary patency</td>
<td>94.4% (17)</td>
<td>88.9% (16)</td>
<td>94.4% (17)</td>
</tr>
</tbody>
</table>

27 month mean and 30 month median follow up

Summary

• Long lesions can be treated endovascularly with good results using DES, DCB and interwoven nitinol showing similar 1 year results

• Interwoven nitinol stents show less impact of lesion length on patency

• With correct vessel preparation and technique, interwoven nitinol stents can provide a unique fracture free, calcium resistant, non drug dependent device for long term patency in long lesions
Treatment Strategies for Long Lesions of greater than 20 cm

Donald L. Jacobs, MD
C. Rollins Hanlon Professor and Chair
Chair of the Department of Surgery
Saint Louis University