Role of Stenting in the DCB Era

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Faculty disclosure  Marianne Brodmann

I disclose the following financial relationships:

Consultant for BARD and Covidien Company
Receive grant/research support from Biotronik
Paid speaker for Medtronic
Background: SFA anatomy and dynamics

Longest, most stressed of body’s vessels

Cyclic forces and vessel deformations

- Torsion
- Flexion
- Compression
- Bending
- Shortening

Stents and Stent’s Related Challenges

Implants reduce vessel compliance and their ability to absorb deformations

Smouse HB Changes in major peripheral arteries during joint movement before and after stent placement in the cadaver model. TCT 2004
Stents and Stent’s Related Challenges

Implants are subject to fatigue stress and fractures

- Fractures may trigger restenosis
- Long term incidence and implications of stent fractures remain unknown
- Higher fracture rates associated with longer stents and higher physical exercise

Stents and Stent’s Related Challenges

In-Stent-restenosis 1-year incidence: 18 ~ 40%, ISR recurrence: higher than its first time incidence

Freedom From Recurrent ISR by ISR Class

ISR 2-year recurrence

- 49.9% in class I (focal)
- 53.3% in class II (diffuse)
- 84.8% in class III (occlusive)

2. J.Laird et al. The Treatment of Femoropopliteal In-Stent Restenosis. JACC 2012
in consideration of PAD chronic nature, preservation of future therapy options should be a general target of everyday clinical strategy, especially for patients with long life and quality of life expectancy
Role of Stents in the DCB era?

To manage vessel recoil, refractory plaque resistance, persistent flow limiting dissections after Optimal PTA

Endovascular Revascularization Mechanisms

<table>
<thead>
<tr>
<th></th>
<th>PTA</th>
<th>BMS</th>
<th>DES</th>
<th>Ather</th>
<th>DCB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilatation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Scaffolding</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Debulking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Drug Elution</td>
<td>X</td>
<td></td>
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<td>X</td>
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</tbody>
</table>
Role of Stents in the DCB era?

To manage severe Calcium and associated challenges

- Calcium not fully detected by Angiography
- Increases the occurrence of dissections post PTA
- Cause of stent malapposition, sub-optimal expansion
- Predictor of stent fractures
- Potential barrier for optimal drug absorption

Role of Stents in the DCB era?

To resolve failure after Optimal PTA

Prolonged inflations reduce dissection entity and rates and the need for stents

- Inflation times of 180 sec improve immediate infrainguinal PTA results vs. to a short dilation strategy
- Significantly fewer major dissections and a modest reduction of residual stenoses are observed

<table>
<thead>
<tr>
<th>Inflation Time (sec)</th>
<th>30</th>
<th>180</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major dissection (grades 3 and 4)</td>
<td>16</td>
<td>5</td>
<td>.010</td>
</tr>
<tr>
<td>Minor or no dissection (grades 1 and 2)</td>
<td>21</td>
<td>32</td>
<td>.010</td>
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<tr>
<td>Further interventions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent</td>
<td>20</td>
<td>9</td>
<td>.017</td>
</tr>
<tr>
<td>Further dilation (prolonged dilation, dilation with larger diameter)</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Residual stenosis (&gt;30%)</td>
<td>16</td>
<td>8</td>
<td>.097</td>
</tr>
<tr>
<td>Complication (embolization, thrombosis)</td>
<td>12</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Mean ankle-brachial index (before, after intervention)</td>
<td>0.66, 0.87</td>
<td>0.65, 0.84</td>
<td></td>
</tr>
</tbody>
</table>

1. Pre-dilatation (CTOs, sub-occl. lesions, Ca++)
   a. standard PTA Ø1 mm less than RVD
   b. Balloon length > lesion length or planned DCB length, whichever is longer
   c. inflation time ~ 2 minutes
   d. inflation pressure: < RBP as needed to reach full PTA balloon expansion

2. DCB
   a. DCB Ø: RVD = 1:1
   b. inflation time ≥ 3min
   c. inflation pressure: <RBP as required to reach full DCB expansion

3. Post-Dilatation if residual stenosis >50% or flow limiting dissection
   a. standard or high pressure PTA balloon Ø 1:1 to RVD
   b. short / focal length as necessary to treat the extent of residual stenosis or dissection
   c. inflation time ≥ 3 minutes

4. Provisional Spot Stenting for persistent residual stenosis >50% or flow limiting dissections
   1. Min. length as necessary to fully treat the residual stenosis or dissection
In spite of Optimal PTA, scaffolds are still needed, likely at rates proportional to lesion complexity

Provisional stent rates in DCB Trials as function of lesion length

DCB and Provisional Stenting

How DCBs have changed my Stent practice

University of Graz, Austria
Case Example: IN.PACT Italian Registry

105-Patient multicenter Registry

Key Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>48.6%</td>
</tr>
<tr>
<td>RC≥3</td>
<td>72.4%</td>
</tr>
<tr>
<td>Lesion length</td>
<td>76.3 mm</td>
</tr>
<tr>
<td>CTO</td>
<td>29.8%</td>
</tr>
<tr>
<td>Ca++</td>
<td>16.7%</td>
</tr>
</tbody>
</table>

- **Optimal PTA limit Stent use**
- **IN.PACT DCB + Optimal PTA results in high Primary Patency and sustained functional benefit**

Primary Patency

1-year Primary Patency = 83.7%
2-year Primary Patency = 72.4%

3.5-fold ↑ in walk capacity at 2-year

(Micari A et al. J Am Coll Cardiol Intv 2013)
Case Example: DEBATE SFA

104-Patient, single center Randomized Study

1-Year Restenosis and TLR

Key Characteristics

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<th>Value</th>
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<tbody>
<tr>
<td>Diabetes</td>
<td>77.4%</td>
</tr>
<tr>
<td>RC≥3</td>
<td>100.0%</td>
</tr>
<tr>
<td>Lesion length</td>
<td>94.0 mm</td>
</tr>
<tr>
<td>CTO</td>
<td>54.5%</td>
</tr>
<tr>
<td>Ca++</td>
<td>21.8%</td>
</tr>
</tbody>
</table>

IN.PACT DCB with systematic stent is superior to stent alone in complex lesions and highly diseased population (diabetes and CLI >70%)

1-Year Restenosis: subintimal vs. true lumen

(F.Liistro et al. J Am Coll Cardiol Intv 2013)
Key requisites of Stents in the DCB era

Stent mechanical characteristics may be even more important when needed provisionally after failed PTA

1. High fracture resistance to withstand fatigue stress and Ca++ related forces

2. Adequate radial force to react to Ca++ and highly resistant lesions

3. Precise deployment for correct positioning without geographic miss

4. Wide mix including short lengths for spot / focal stenting
Complete SE Stent

Clinically Proven

- 12-month TLR = 8.4%
- 12-month TVR = 11%
- 12-month MAE = 11%

Primary Patency

90.9% (360d)
78.3% (390d)

Accurate deployment and availability of short lengths

- Triaxial Shaft Design with Dual Deployment Handle
- Short lengths down to 20 mm

Optimized Radial Force and Fracture resistance

0% Fractures by FEA Corelab assessment
My fem-pop treatment algorithm

1. Clinically proven
2. Resistant
3. Strong
4. Precise
Conclusions

• DCB + Optimal PTA is backed by compelling evidence and gaining first-line treatment role in fem-pop practice

• DCB made stents just less necessary, still necessary at rates proportional to lesion complexity

• Stent mechanical features even more important when used after failed PTA as typical for old CTOs, highly resistant, highly calcified lesions

• Only best stents will survive in the DCB era