Defining vessel prep: How can we set ourselves up for best results?

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Disclosure

Peter A. Schneider

Potential conflicts of interest to report:

Enter patients in studies sponsored by: Gore, Cordis, Medtronic, Silk Road, Bard, NIH, Limflow

Modest royalty: Cook

Scientific Advisory Board (non-compensated): Abbott, Medtronic, Boston Scientific

Chief Medical Officer: Intact Vascular, Cagent
Define Vessel Preparation

Technologies that Benefit
• Drug coated balloon
• Woven nitinol stent
• Bioabsorbable vasc scaffold
• Stent-graft/covered stent
• Self expanding nitinol stent
  – Including DES

Tools for Vessel Preparation
• PTA
• Modifications of angioplasty
• Atherectomy
• Lithoplasty

Sustained lumen gain that permits definitive treatment.
Define Vessel Preparation

• Lumen Gain
• Plaque modification
• Minimize arterial wall defects
• Prepare for drug delivery
• Change vessel compliance
• Prepare for definitive therapy
  – Results of vessel prep may help determine which definitive therapy is most appropriate
Drug Delivery Era

Vessel Prep = Drug Uptake

- Calcium limits drug uptake
- 5-20% of Paclitaxel taken up by artery wall.
- Uneven distribution of drug
- More drug into the artery wall is key, but must be done in a uniform manner, both longitudinally and circumferentially
- Better delivery = lower dose on the balloon?

Presentation Charing Cross Meeting 2016
“Drug needs to enter the medial layer within the first 3 days”, R. Virmani, MD
POBA is the most widely used form of vessel preparation at present.

Utility of vessel prep recognized in DCB trial design.
Can Vessel Prep Overcome the Challenges Posed By Calcification and Lesion Complexity?

**Calcium as a Barrier**

**Calcium Limits Vessel Expansion**

Significant difference in vessel compliance leads to overstretch in non-diseased tissue causing dissections, recoil, excessive injury, and poor outcomes.

**Calcium May Limit Drug Effect**

Increased lesion length is an independent predictor of decreased patency.

**Longer Lesion Length**

1. Freed MS, Manual of Interventional Cardiology,
2. Fanelli DEBELUM,
3. Laird, CCI, June 2010,
4. SMART Control IFU,
5. Matusumura, DURABILITY IJJS, July 2013,

Courtesy: L Garcia
Anterior tibial artery dissection after long segment recanalization

Above knee popliteal artery dissection at re-entry site

SFA dissections

Post-PTA Dissection

Balloons angioplasty causes too much acute injury

Why do we think that balloon angioplasty will be the best way to prepare the lesion, deliver the medication and treat the lesion, all at the same time?
Full balloon inflation: no waist

Inadequate stent expansion due to residual calcium.

Pre-dilatation  Stent Deployment  Final Result

SFA  Chronic Total Occlusion  220mm lesion length  POBA 6mm X 120mm balloon

Supera Stent 6.5mm

Courtesy M Razavi
Superb Trial

Deployment Technique and 12-Month Patency

L Garcia VIVA 2016
Shockwave Lithoplasty
DISRUPT PAD

<table>
<thead>
<tr>
<th>Severe Definition</th>
<th>Radiopacities noted prior to contrast injection involving both sides of the arterial wall</th>
<th>≥180° (both sides of the vessel at the same location) and &gt; half total lesion length</th>
<th>&gt;75% calcium length to lesion length</th>
<th>≥1 cm on both sides</th>
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<tbody>
<tr>
<td>None/mild</td>
<td>1.1%</td>
<td>1.1%</td>
<td>1.1%</td>
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<tr>
<td>Moderate</td>
<td>44.2%</td>
<td>1.0%</td>
<td>4.2%</td>
<td>0.0%</td>
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<tr>
<td>Severe</td>
<td>54.2%</td>
<td>97.9%</td>
<td>94.7%</td>
<td>98.9%</td>
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<tr>
<td>Total</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
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</table>

Balloon-based technique
Disrupts both deep & superficial calcium
Improves vessel wall compliance
Low pressure

Where Definition is used
1DISRUPT PAD Study, Resilient Study
3Confirm Ranges
4Definitive Ca++, Definitive AR, SUPERB

Pre and Post % Diameter Stenosis

![Bar chart showing pre and post diameter stenosis](chart.png)

N
<table>
<thead>
<tr>
<th>All Subjects</th>
<th>SFA</th>
<th>Popliteal</th>
<th>Moderate Ca</th>
<th>Severe Ca</th>
<th>Lesion &lt;5 cm</th>
<th>Lesion 5-10 cm</th>
<th>Lesion &gt;10 cm</th>
<th>Concentric Eccentric</th>
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<td>95</td>
<td>70</td>
<td>24</td>
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Angioscore
PANTHER Registry

Kanai et al: J Cardiol Cases 2012;5:e16

Blessing E. LINC 2016
Micro-Serration Scoring Technology: simple easy to use angioplasty balloon designed to provide controlled, predictable results in lumen gain.
Serration Pre-Clinical: SEM Porcine Model*

**Documented Linear Interrupted Scoring**

**Acute Animal Study: SEM**

**Chronic Animal Study**

PRELUDE Study
Presented by Andrew Holden at LINC 18

Disclosure: Co-Founder
Defining Vessel Preparation

Conclusion

• Vessel preparation is wide open as a field to be developed.
• Evidence of need for and results of vessel prep are mostly indirect but abundant.
• Vessel prep to optimize the use of DCBs
  – Deliver more medication and avoid more stents
• The result of vessel prep may ultimately influence selection of definitive therapy for a given patient.
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