My “Leave Nothing Behind” Algorithm

Xin Jia, MD
Vascular and Endovascular Surgery Department
Chinese PLA General Hospital, Beijing
Disclosure

Speaker name: Xin Jia, MD

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

✔ I do not have any potential conflict of interest
# IN.PACT Global Complex Lesion Analysis

## Angiographic Characteristics

<table>
<thead>
<tr>
<th>Lesion (N)</th>
<th>IN.PACT Admiral DCB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 227 subjects and lesions</td>
</tr>
<tr>
<td>De novo</td>
<td>67.0% (152/227)</td>
</tr>
<tr>
<td>Restenotic (non-stent)</td>
<td>12.8% (29/227)</td>
</tr>
<tr>
<td>In-stent restenotic</td>
<td>20.3% (46/227)</td>
</tr>
<tr>
<td>Lesion Length, ± SD</td>
<td>28.74 ± 7.11</td>
</tr>
<tr>
<td>Total Occlusions</td>
<td>70.1% (157/224)</td>
</tr>
<tr>
<td>RVD, ± SD</td>
<td>4.611 mm ± 0.896</td>
</tr>
<tr>
<td>Diameter Stenosis, ± SD</td>
<td>94.1% ± 10.7</td>
</tr>
<tr>
<td>Calcification (%)^1</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>26.9% (59/219)</td>
</tr>
<tr>
<td>Mild</td>
<td>37.4% (82/219)</td>
</tr>
<tr>
<td>Moderate</td>
<td>11.9% (26/219)</td>
</tr>
<tr>
<td>Moderately Severe</td>
<td>10.0% (22/219)</td>
</tr>
<tr>
<td>Severe</td>
<td>13.7% (30/219)</td>
</tr>
</tbody>
</table>

1. Dattilo R, et al. J Invasive Cardiol 2014:26:355-360. Severe calcium definition used by study sites and core laboratory as bilateral calcium at the same location (also measured in sections), ≥ half of the total lesion length, ≥180° (both sides of the vessel at the same location).
## IN.PACT Global Complex Lesion Analysis
### Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>IN.PACT Admiral DCB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 227 subjects</td>
</tr>
<tr>
<td><strong>Pre-dilatation (%)</strong></td>
<td>89.0% (202/227)</td>
</tr>
<tr>
<td><strong>Post-dilatation (%)</strong></td>
<td>44.7% (101/226)</td>
</tr>
<tr>
<td><strong>Dissections (%)</strong></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>36.1% (82/227)</td>
</tr>
<tr>
<td>A-C</td>
<td>35.6% (81/227)</td>
</tr>
<tr>
<td>D-F</td>
<td>19.3% (44/227)</td>
</tr>
<tr>
<td><strong>Provisional Stenting (%)</strong></td>
<td>42.5% (96/226)</td>
</tr>
<tr>
<td><strong>Device Success (%)</strong></td>
<td>99.2% (653/658)</td>
</tr>
<tr>
<td><strong>Procedural Success (%)</strong></td>
<td>99.1% (224/226)</td>
</tr>
<tr>
<td><strong>Clinical Success (%)</strong></td>
<td>99.1% (224/226)</td>
</tr>
</tbody>
</table>

1. All ITT subjects (stented and non-stented)
2. Device success defined as successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP.
3. Procedure success defined as residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site-reported estimate was used).
4. Clinical success defined as procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge.
IN.PACT Global Complex Lesion Analysis
Primary Patency through 420 Days

Number at risk: DCB 227, 213, 190, 157

Day 360: 89.1%
Day 420: 77.1%

1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularization through 36 months (adjudicated by a Clinical Events Committee blinded to the assigned treatment).
2. Number at risk represents the number of evaluable subjects at the beginning of each 60-day window.
## Reducing Stent-rate Through Vessel Preparation

<table>
<thead>
<tr>
<th>Study (* Core Lab)</th>
<th>Type</th>
<th>Patients</th>
<th>Lesions</th>
<th>Dissection (≥Grade D)</th>
<th>BO Stent</th>
<th>30-day MAE</th>
<th>Raney</th>
<th>1-year Raney</th>
</tr>
</thead>
<tbody>
<tr>
<td>*DEFINITIVE LE¹</td>
<td>DA</td>
<td>598 (RCC 1-3) 201 (RCC 4-6)</td>
<td>743 279</td>
<td>2.2% (13/598) 2.5% (5/201)</td>
<td>3.2% (33/1022)</td>
<td>1.0% (6/598) 3.5% (7/201)</td>
<td>78% 71%</td>
<td></td>
</tr>
<tr>
<td>*DEFINITIVE CA²</td>
<td>DA</td>
<td>133</td>
<td>168</td>
<td>0.8% (1/131)</td>
<td>4.1% (7/169)</td>
<td>6.9% (9/131)</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>VISION-IDE³</td>
<td>DA</td>
<td>130</td>
<td>130</td>
<td>NR</td>
<td>4.0%</td>
<td>17.6% (6-mo)</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>OASIS⁴</td>
<td>OA</td>
<td>124</td>
<td>201</td>
<td>NR</td>
<td>2.5%</td>
<td>3.2% (4/124)</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>CALCIUM 360⁶</td>
<td>OA</td>
<td>25</td>
<td>29</td>
<td>3.5% (1/29)</td>
<td>6.9% (2/29)</td>
<td>0%</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>*PATHWAY PVD⁷</td>
<td>RA</td>
<td>172</td>
<td>210</td>
<td>9% (15/172)</td>
<td>7% (14/210)</td>
<td>1.0% (2/172)</td>
<td>61.8%</td>
<td></td>
</tr>
<tr>
<td>*CELLO⁸</td>
<td>Las</td>
<td>65</td>
<td>65</td>
<td>NR</td>
<td>23.2% (15/65)</td>
<td>0%</td>
<td>54.3%</td>
<td></td>
</tr>
<tr>
<td>*EXCITE-ISR⁹</td>
<td>Las</td>
<td>169</td>
<td>169</td>
<td>2.4% (≥Grade C)</td>
<td>4.1% (7/169)</td>
<td>5.8% (9/155)</td>
<td>71.1% (6-mo)</td>
<td></td>
</tr>
</tbody>
</table>

It’s possible using Directional Atherectomy may complement DCB use in real-world lesions by reducing dissection rate and bail-out stenting¹,²

### Results
- **CALCIUM 360⁶**
  - OA: 25 patients, 29 lesions
  - Dissection: 3.5% (1/29)
  - BO Stent: 6.9% (2/29)
  - 30-day MAE: 0%
  - Raney: NR

- **PATHWAY PVD⁷**
  - RA: 172 patients, 210 lesions
  - Dissection: 9% (15/172)
  - BO Stent: 7% (14/210)
  - 30-day MAE: 1.0% (2/172)
  - 6-mo Raney: 61.8%

- **CELLO⁸**
  - Las: 65 patients, 65 lesions
  - Dissection: NR
  - BO Stent: 23.2% (15/65)
  - 30-day MAE: 0%
  - Raney: 54.3%

- **EXCITE-ISR⁹**
  - Las: 169 patients, 169 lesions
  - Dissection: 2.4% (≥Grade C)
  - BO Stent: 4.1% (7/169)
  - 30-day MAE: 5.8% (9/155)
  - 6-mo Raney: 71.1%

---


---

LINC 2021 | Connect China: Leave Nothing Behind | 500575 | 01/2021
My Algorithm for Femoro-popliteal Lesions

- Predilatation with plain balloon
- Binary DSA angiography
- Final treatment: DCB OR DCB + short stent OR All stent

- Heavily calcification sequential stenosis: Debulk
- Lesion located at NO Stent zone: Debulk or Surgery
- Heavily calcification long CTO: Primary stent

All patients undertake Duplex before discharge
<table>
<thead>
<tr>
<th>Patient Baseline Characteristics</th>
<th>Age</th>
<th>72.7±13.2 y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>73.5% (50/68)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>89.7% (61/68)</td>
<td></td>
</tr>
<tr>
<td>Smoking history</td>
<td>80.9% (55/68)</td>
<td></td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>66.2% (45/68)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>45.6% (31/68)</td>
<td></td>
</tr>
<tr>
<td>CAD</td>
<td>39.7% (27/68)</td>
<td></td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>11.8% (8/68)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>17.6% (12/68)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rutherford classification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1.5% (1/68)</td>
</tr>
<tr>
<td>3</td>
<td>76.5% (52/68)</td>
</tr>
<tr>
<td>4</td>
<td>11.8% (8/68)</td>
</tr>
<tr>
<td>5</td>
<td>10.3% (7/68)</td>
</tr>
</tbody>
</table>

### Basic Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion Location</th>
<th>SFA only</th>
<th>51.5% (39/76)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pop. artery only</td>
<td>10.5% (8/76)</td>
</tr>
<tr>
<td></td>
<td>Both SFA and PA</td>
<td>38% (29/76)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>Mean lesion</th>
<th>26.7cm ± 15.3cm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CTO lesion</td>
<td>73.6% (56/76)</td>
</tr>
<tr>
<td></td>
<td>Stenosis lesion</td>
<td>26.4% (20/76)</td>
</tr>
<tr>
<td></td>
<td>Severe calcification</td>
<td>61.8% (47/76)</td>
</tr>
</tbody>
</table>

| Vessel Preparation | Debulking TurboHawk | 31.8% (25/76) |

---

Clinical Results

Dissection A-C 67% (51/76)
Dissection D-F 33% (25/76)

Stent rate 37% (28/76)
Mean stented length 10.8 ± 9.2cm

Stent rate in:
Heavy calcification 47%(22/47)  (p =0.02)
Calcification 21%(6/29)
Safety Endpoints

30-day results:

All Cause Mortality 0% (0/68)
Complication rate 8.8% (6/68)
  • Hemotoma 2/68
  • Pseudoaneurysm 1/68
  • Distal embolization 3/68

Midterm results:

All Cause Mortality 2.9% (2/68) after 1 year, 4.4% (3/68) after 2 year.
**TASC C/D Lesions with DCB 2016-2018**

**Efficacy Outcomes**

- **Primary patency**
  - $74.2 \pm 7.6\%$ at 1 year,
  - $67.7 \pm 6.4\%$ at 2 year

- **Freedom from TLR**
  - $81.4 \pm 5.1\%$ at 1 year,
  - $73.6 \pm 5.4\%$ at 2 year

---

Case 1

- Male, 70+ y
- R3, PCI
- SFA + PA occlusion
PTA 5-200 + DCB 5-300

Images courtesy of Xin Jia, MD
FU after 12 months
Case 2

- Male, 75+ y
- R3, PCI x 2, Crea 230umol/L
- DUPLEX: SFA Proximal PSV 360cm/s
  - Middle 320cm/s
  - P2 380cm/s
  - BTK occlusion
- Debulk with TurboHawk™ peripheral plaque excision system
- Treat with DCB and PTA:
  - SFA: DCB 5.5-100
  - PFA 5-20 POBA
  - P2 DCB 5-40
  - BTK POBA 3-150

Images courtesy of Xin Jia, MD
FU @ 6 months

超声检查报告单
姓名： 性别：男 年龄： 科别：血管外科 部位：下肢
检查室：血管外科超声室

超声所见：
双侧股总动脉、股浅动脉、股深动脉近心端、腘动脉、胫前动脉及胫后动脉内中膜增厚、不光滑，可见多发强回声及混合回声斑块，大者位于右侧股总动脉分叉处，厚约3.9mm。
左侧腘动脉管腔内可见实质性中等回声充填，CDFI示上述动脉内未见血流信号。

超声印象：
1. 左侧腘动脉管腔内实质性中等回声充填
2. 下肢动脉粥样硬化

备注： 检查医生：薛立娟 签名： 检查日期：2016-6-10

FU @ 24 months

超声检查报告单
姓名： 性别：男 年龄： 科别：血管外科 部位：下肢
检查室：血管外科超声室

超声所见：
双侧股总动脉、股浅动脉、股深动脉近心端、腘动脉、胫前动脉及胫后动脉内中膜增厚、不光滑，可见多发强回声及混合回声斑块，大者位于右侧股总动脉分叉处，厚约3.9mm。
左侧腘动脉管腔内可见实质性中等回声充填，CDFI示上述动脉内未见血流信号。

超声印象：
1. 左侧腘动脉管腔内实质性中等回声充填
2. 下肢动脉粥样硬化

备注： 检查医生：薛立娟 签名： 检查日期：2019-6-10
Conclusions

- There is strong evidence supporting the efficacy of DCB in complex SFA lesions
- Stent usage could be remarkably reduced, mostly by using vessel preparation
- Large volume data and longer follow-up still needed
My “Leave Nothing Behind” Algorithm

Xin Jia, MD
Vascular and Endovascular Surgery Department
Chinese PLA General Hospital, Beijing