Anatomically Challenging Lesion Locations: What are My Treatment Options?

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Disclosure

Speaker name:

..................G. Torsello...................................................

I have the following potential conflicts of interest to report:

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

☐ I do not have any potential conflict of interest
What Does the Data say in challenging lesions?

• Long Lesions
• Total Occlusions
• Instent Restenosis
Femoro-popliteal ISR

Frequent (20-37% at 1 year)

Technically challenging

Recurrent (50-85% if occlusive)
ISR: No strong evidence or consensus

- POBA
- Cutting balloon
- Atherectomy
- Rotational thrombectomy
- Cryoplasty
- Stent-in-stent
- Laser
- DES
- Covered stent
- DCB
DCB for In-stent Restenosis (ISR)
Consistent Freedom from Reintervention

IN.PACT Global ISR\(^1\)

Mean age = 68 y
Diabetes = 35.1%
LL = 17.2±10.5 cm
CTO = 34.0%
Prov. Stent = 13.4%

SFA-ISR\(^2\)

Mean age = 66 y
Diabetes = 48.7%
LL = 8.3±7.9 cm
CTO = 20.5%
Prov. Stent = 10.3%

PLAISIR\(^3\)

Mean age = 69 y
Diabetes = 30%
LL = 8.6±3.2 cm
CTO = 2%

FAIR\(^4\)

Mean age = 69 y
Diabetes = 45%
LL = 8.2±7.1 cm
CTO = 28.6%
Prov. Stent = 1.0%

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### Imaging Sub-Cohorts

**Clinical Cohort**

- **1406 pts**
- **≥ 100 pts**
- **DCB 150 mm**

**de novo ISR**

- **N=131 pts**
- M. Brodmann et al. JACC CI. 2017;10:2113

**Long Lesion (≥ 15 cm)**

- **N=157 pts**
- D. Scheinert et al. CCI, 2019;11:e005654

**CTO (≥ 5 cm)**

- **N=126 pts**
- G. Tepe et al. JACC CI. 2019;12:248

### Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>DCB (N=131 Subjects)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Y)</td>
<td>67.8 ± 10.1</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>35.1% (46/131)</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>81.5% (106/130)</td>
</tr>
<tr>
<td>Hyperlipidemia (%)</td>
<td>72.1% (93/129)</td>
</tr>
<tr>
<td>Current Smoker (%)</td>
<td>35.9% (47/131)</td>
</tr>
<tr>
<td>Previous Peripheral Revasc. (%)</td>
<td>100.0% (131/131)</td>
</tr>
<tr>
<td>Concomitant BTK Disease (%)</td>
<td>43.3% (55/127)</td>
</tr>
</tbody>
</table>

### Lesion Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>DCB (N=149 Lesions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion type:</td>
<td></td>
</tr>
<tr>
<td>De Novo</td>
<td>0.0% (0/149)</td>
</tr>
<tr>
<td>Non-stented Restenotic</td>
<td>0.0% (0/149)</td>
</tr>
<tr>
<td>In-Stent Restenosis</td>
<td>100.0% (149/149)</td>
</tr>
<tr>
<td>Lesion Length (cm)</td>
<td>17.17 ± 10.47</td>
</tr>
<tr>
<td>Total Occlusions (%)</td>
<td>34.0% (48/141)</td>
</tr>
<tr>
<td>Calcification (%)</td>
<td>59.1% (78/132)</td>
</tr>
<tr>
<td>Severe Calcification (%)</td>
<td>8.3% (11/132)</td>
</tr>
</tbody>
</table>

IN.PACT Global ISR Imaging Cohort<sup>1</sup>
Effectiveness and Safety Outcomes

### 1-Year Primary Patency

**DCB 88.7%**

- **Clinically-Driven TLR**
  - 7.3% (9/124)

- **Primary Safety Endpoint**<sup>†</sup>
  - 92.7% (115/124)

- **Major Adverse Events**<sup>‡</sup>
  - 8.9% (11/124)

- **Death (all-cause)**
  - 0.0% (0/124)

- **Major Target Limb Amputation**
  - 0.0% (0/124)

- **Thrombosis**
  - 0.8% (1/124)

- **Any TLR**
  - 8.1% (10/124)

- **Any TVR**
  - 9.7% (12/124)

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<sup>*</sup> Six subjects did not complete the study through the follow-up period

<sup>**</sup> Clinically Driven TLR: Any re-intervention within the target lesion(s) due to symptoms or drop of ABI of ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI

<sup>†</sup> Primary Safety Endpoint: Composite of 30-day freedom from device- and procedure-related mortality and 12-month freedom from major target limb amputation and clinically-driven TVR

<sup>‡</sup> Major Adverse Events: Composite of death, major target limb amputation, clinically driven TVR, and thrombosis

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<sup>1</sup> Brodmann et al. JACC Cardiovasc Interv. 2017;10:2113-2123
DCB for Long Lesions (LL)
Primary Patency

All data from Core-Lab Adjudicated Studies

* ISR studies
  a. Iida O. et al., report proportion-based patency of the ZEPHYR study
  b. Subset analysis of previously-reported data. IN.PACT Global Complex Lesion cohort consists of 227 subjects enrolled in the three IN.PACT Global pre-specified imaging cohorts (long lesion, chronic total occlusion, and in-stent restenosis) exhibiting lesion lengths >18 cm.
  c. Bausback Y. et al., A mix of DCBs were used in the REAL PTX study
DCB for Long Lesions (LL)
Primary Patency

IN.PACT Global Complex Long Lesions

Mean age = 69 y
Diabetes = 38.7%
LL = 28.7 ± 7.1 cm
CTO = 70.1%
ISR = 20.3%
Severe calc = 13.7%

1-year PP DCB 89.1%

IN.PACT Global Long Lesions

Mean age = 70 y
Diabetes = 41.0%
LL = 26.4 ± 8.6 cm
CTO = 60.4%
ISR = 0.0%
Severe calc = 19.6%
Prov. Stent = 39.4%

1-year PP DCB 91.1%

SFA-Long

Mean age = 68 y
Diabetes = 57.2%
LL = 25.1 ± 7.9 cm
CTO = 49.5%
ISR = NA
Severe calc = 13.3%
Prov. Stent = 10.5%

1-year PP DCB 83.2%

1. IN.PACT Admiral paclitaxel-coated PTA balloon catheter Instructions for Use. M052624T001_Rev1G
3. A. Micari et al. JACC Cardiovasc Interv. 2016 May 9;9(9):950-6
IN.PACT Global CTO Imaging Cohort

Baseline Characteristics | DCB (N=126 Subjects)
--- | ---
Age, Y | 67.5 ± 10.4
Male, % | 69.0% (87/126)
Diabetes, % | 29.6% (37/125)
Hypertension, % | 82.3% (102/124)
Hyperlipidemia, % | 64.5% (78/121)
Current Smoker, % | 49.2% (62/126)
Previous Peripheral Revasc., % | 33.3% (42/126)
Concomitant BTK Disease, % | 41.0% (48/117)

Lesion Characteristics | N = 127 Lesions
--- | ---
Lesion Type: % (n/N) |
De novo | 92.1% (117/127)
Restenotic (non-stented) | 7.9% (10/127)
In-stent Restenosis | 0.0% (0/128)
Lesion Length, cm | 22.83 ± 9.76 cm
Total Occlusions, % | 100% (127/127)
Calcification, % | 71.0% (88/124)
Severe Calcification, % | 3.2% (4/124)

IN.PACT Global CTO Imaging Cohort\(^1\)

Effectiveness and Safety Outcomes

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<tr>
<th>1-Year Outcomes</th>
<th>DCB (N=126 subjects)</th>
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<tr>
<td>Clinically-Driven TLR(^*)</td>
<td>11.3% (13/115)</td>
</tr>
<tr>
<td>Clinically-Driven TVR(^†)</td>
<td>11.3% (13/115)</td>
</tr>
<tr>
<td>Primary Safety Endpoint(^‡)</td>
<td>88.7% (102/115)</td>
</tr>
<tr>
<td>Major Adverse Events(^§)</td>
<td>15.7% (18/115)</td>
</tr>
<tr>
<td>Death (all-cause)</td>
<td>4.3% (5/115)</td>
</tr>
<tr>
<td>Major Target Limb Amputation</td>
<td>0.0% (0/115)</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>4.3% (5/115)</td>
</tr>
</tbody>
</table>

\(^1\) Any re-intervention within the target lesion(s) due to symptoms or drop of ABI of ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI.

\(^†\) Any re-intervention within the target vessel due to symptoms or drop of ABI ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI.

\(^‡\) Composite of 30-day freedom from device- and procedure-related mortality and 12-month freedom from major target limb amputation and clinically-driven TVR.

\(^§\) Major Adverse Events: Composite of death, major target limb amputation, clinically-driven TVR, and thrombosis.

IN.PACT global – CTO- Subcohort

Three-year freedom from CD-TLR

G. Torsello et al. Three-year sustained clinical efficacy of drug-coated balloon angioplasty in a real-world femoropopliteal cohort
JEVT 2019 conditionally accepted for publication
What are my treatment options?

- **COMPLEX LESION or NO STENTING LOCATION**
  - VESSEL PREP + DCB

- **SHORT, NONCALCIFIED**
  - POBA + DCB

- **FLOW-LIMITING DISSECTION or RESIDUAL STENOSIS >50%**

**Stent**
Summary

- The IN.PACT Global Study remains the largest real-world drug-coated balloon (DCB) study with independent adjudication through 4 years.
- The results of subgroup analyses demonstrate durable effectiveness of the IN.PACT Admiral DCB also in patients with ISR, CTO and long fempop lesions.
- The results are consistent with those of other studies showing that DCB is a viable solution for the treatment of complex femoropopliteal disease.
Thank you!

homepage: www.gefaesschirurgie-muenster.de

St. Franziskushospital Münster
THANK YOU
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