Learning from the producers: The LEGDEB experiences and 2-year outcomes

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Disclosure

Speaker name: Eugenio Stabile

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
LEGFLOW — Drug-Coated Balloon

**Excipient**

-- lipophilic and polymeric ammonium-salt-based

**Paclitaxel**

-- 3.0 μg/mm²

**Optical Imaging (100x)**

LEGFLOW DCB
Homogeneous, smooth amorphous coating

Hydrophilic Coating DCB
White powder of brittle crystalline coating

The ‘SAFEPAX’ drug coating technology should provide proper protection from low mass-related risk for distal embolization and prothrombotic effects.
LegDeb Registry Design

- Prospective
- Multicenter
- Femoropopliteal lesions
- PTA according to local standard practices

FOLLOW-UP
- Clinical examinations
- Duplex US
- Repeated angio in presence of intermediate or severe restenosis

ASSESSMENTS
- **Primary end point:** freedom from restenosis at 12 and 24 months
- **Secondary end point:** freedom from CD-TLR
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Drago Zhelev - UMBAL Sv. Georgi EAD, Plovdiv, Bulgaria
Vassil Chervenkoff - Tokuda Hospital Sofia, Bulgaria
Kim Taeymans, Peter Goverde - ZNA Hospital Stuivenberg, Antwerp, Belgium
Baseline characteristics

<table>
<thead>
<tr>
<th>Male</th>
<th>78%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>67 ± 10.8</td>
</tr>
<tr>
<td>Diabetes</td>
<td>50%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>79%</td>
</tr>
<tr>
<td>Hypercholesterolaemia</td>
<td>49%</td>
</tr>
<tr>
<td>Smoking history</td>
<td>51%</td>
</tr>
<tr>
<td>CLI (Rutherford Class ≥4)</td>
<td>43%</td>
</tr>
<tr>
<td>Rutherford Class</td>
<td>3.5 ± 0.9</td>
</tr>
<tr>
<td>Claudicant</td>
<td>57%</td>
</tr>
<tr>
<td>de novo lesions</td>
<td>58%</td>
</tr>
<tr>
<td>Restenosis</td>
<td>21%</td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td>22%</td>
</tr>
<tr>
<td>de novo lesion length</td>
<td>83.2 ± 42.1</td>
</tr>
<tr>
<td>In-stent restenosis lesion length</td>
<td>117.0 ± 39.5</td>
</tr>
<tr>
<td>Non in-stent restenosis lesion length</td>
<td>88.2 ± 30.9</td>
</tr>
</tbody>
</table>
Peculiarities of the LegDeb Registry

**Percent CLI**

- LEVANT 2: 6%
- IT SFA Registry: 7.6%*
- ILLUMENATE: 2%*
- LegDeb: 43.2%

*No patients enrolled in Rutherford class >4

**Lesion length mm (SEM)**

- LEVANT 1: 80.8
- IT SFA Registry: 76.3
- ILLUMENATE: 72.0
- LegDeb: 90.0

One-Year Clinical Outcomes of the Legflow Drug-Coated Balloon for the Treatment of Femoropopliteal Occlusions Registry

Eugenio Stabile, MD, PhD, Donato Gerardi, MD, Fabio Magliulo, MD, Drago Zhelev, MD, Vassil Chervenkov, MD, Kim Taeymans, MD, Doncho Kotsasov, MD, Peter Goverde, MD, Giuseppe Giugliano, MD, Bruno Trimarco, MD, and Giovanni Esposito, MD, PhD

Stabile E et al. JEVT 2018
LegDeb in context: High rates of freedom from TLR at 1 year in a population with 43% CLI.

1–year results:

- LEVANT 1: CLI 6%, 71%
- IT SFA Registry: CLI 8%, 92.4%
- ILLUMENATE: CLI 2%, 90%
- LegDeb: CLI 43%, 83.3%

Sources:
LEGDEB 24-months analysis

70 patients initially enrolled

77.1% available for 24-months analysis (n:54)

University of Napoli "Federico II" (26)

Vascular Clinica ZNA Hospital Stuivenberg, Antwerp (44)
### Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>70</td>
</tr>
<tr>
<td>Male</td>
<td>78%</td>
</tr>
<tr>
<td>Age</td>
<td>66 ± 11</td>
</tr>
<tr>
<td>Diabetes</td>
<td>50%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>77%</td>
</tr>
<tr>
<td>Hypercholesterolaemia</td>
<td>57%</td>
</tr>
<tr>
<td>Smoking history</td>
<td>56%</td>
</tr>
<tr>
<td>CLI (Rutherford Class ≥4)</td>
<td>31%</td>
</tr>
<tr>
<td>Rutherford Class</td>
<td>3.2 ± 0.8</td>
</tr>
<tr>
<td>de novo lesions</td>
<td>49%</td>
</tr>
<tr>
<td>Restenosis</td>
<td>18%</td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td>33%</td>
</tr>
<tr>
<td>Lesion length (overall)</td>
<td>99 ± 37</td>
</tr>
<tr>
<td>de novo lesion length</td>
<td>90 ± 41</td>
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<tr>
<td>In-stent restenosis lesion length</td>
<td>120 ± 17</td>
</tr>
<tr>
<td>Restenosis lesion length</td>
<td>86 ± 36</td>
</tr>
</tbody>
</table>
LegDeb Registry Results at 24-months

FREEDOM FROM TLR: 83.3%
FREEDOM FROM RESTENOSIS: 72.2%
LegDeb Registry Results at 24-months

- Freedom from Restenosis:
  - 1 year: 81% (N = 139)
  - 2 years: 72% (N = 70)

- Freedom from CD-TLR:
  - 1 year: 83% (N = 139)
  - 2 years: 83% (N = 70)
LegDeb Registry Results at 24-months

Freedom from TLR

- OVERALL: 83%
- IC: 84%
- CLI: 82%
- RESTENOSIS: 88%
- ISR: 94%
- DE NOVO: 76%
LegDeb Registry Peculiarities

CLI %*

* No patients enrolled in Rutherford class ≥4

LESION CHARACTERISTICS

* No patients enrolled in Rutherford class ≥4
DCB 24-months outcome

FREEDOM FROM RESTENOSIS
- LegDeb: 72% (CLI: 31%)
- IN.PACT SFA: 79% (CLI: 5%)
- ILLUMINATE: 76% (CLI: 2%)

FREEDOM FROM CD-TLR
- LegDeb: 83% (CLI: 31%)
- IN.PACT SFA: 91% (CLI: 5%)
- ILLUMINATE: 89% (CLI: 2%)
Summary and conclusions

• In a real-world population with SFA, Legflow achieved favourable outcomes:
  – 100 procedural and technical success rates
  – 83.3% freedom from TLR at 24 months

• This was achieved in a population with worse clinical status than in most clinical trials:
  – 43% had CLI
  – Average lesion 90.0 mm

• Legflow is an appealing, safe and effective treatment option in this challenging population
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