Dissections: Prevent, Minimize or Repair?

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Disclosure

Speaker name:

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
Background

• PTA is associated with high incidence of restenosis when used for anything but focal, noncomplex lesions\(^1\)

• Dissections are reported in up to 84% of PTA procedures\(^2\), with distinct differences in rates reported by site vs core lab\(^3\)

• Effects of dissections on long term outcomes still poorly understood and thus the importance of preventing/minimizing their occurrence highly underestimated

Limitation of Balloon Angioplasty

1. Torsional (Twisting)
   - Unfolding expansion
   - Torsional (shear) stress

2. Radial (Expanding)
   - Uncontrolled expansion
   - Radial expansion

3. Longitudinal (Elongating)
   - Uncontrolled expansion
   - Longitudinal dilatation

Vessel trauma can manifest as severe dissection and elastic recoil
## Dissections Rates (≥ Grade D) in Recent DCB Studies

<table>
<thead>
<tr>
<th>Project</th>
<th>Study</th>
<th>Dissection Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lutonix™</strong></td>
<td>Global Registry</td>
<td>Grade D: 5.5% (7/127)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Grade E: 2.4% (3/127)</td>
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<tr>
<td></td>
<td></td>
<td>Grade F: 1.6% (2/127)</td>
</tr>
<tr>
<td></td>
<td>Global Registry Long Lesion</td>
<td>Grade D: 8.3% (4/48)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Grade E: 4.2% (2/48)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Grade F: 4.2% (2/48)</td>
</tr>
<tr>
<td></td>
<td><strong>Global Registry ISR</strong></td>
<td>Grade D: 16.7% (2/12)</td>
</tr>
<tr>
<td><strong>Stellarex™</strong></td>
<td><strong>ILLUMENATE EU</strong></td>
<td>Flow limiting: 0.4% (1/254)</td>
</tr>
<tr>
<td></td>
<td><strong>ILLUMENATE Global</strong></td>
<td>Grade D: 19.7% (81/416)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flow limiting: 0.3%</td>
</tr>
<tr>
<td></td>
<td><strong>ILLUMENATE Pivotal</strong></td>
<td>Flow limiting: 0.0%</td>
</tr>
<tr>
<td><strong>IN.PACT™ Admiral™</strong></td>
<td><strong>IN.PACT SFA</strong></td>
<td>Grade D-F: 0.0% (0/221)</td>
</tr>
<tr>
<td></td>
<td><strong>IN.PACT Global ISR</strong></td>
<td>Grade D-F: 4.7% (7/149)</td>
</tr>
<tr>
<td></td>
<td><strong>IN.PACT Global CTO</strong></td>
<td>Grade D-F: 23.6% (30/127)</td>
</tr>
<tr>
<td></td>
<td><strong>IN.PACT Global long Lesion</strong></td>
<td>Grade D-F: 14.9% (24/161)</td>
</tr>
</tbody>
</table>

Dissection Severity Negatively Affects Outcomes

- Significant increase in bailout stenting with dissection severity
- Severe dissection is a significant risk factor for restenosis

Primary Patency (PSVR < 2.5)

<table>
<thead>
<tr>
<th></th>
<th>12 Months</th>
<th>24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non Severe Dissection (≈ 40%)</td>
<td>65%</td>
<td>53%</td>
</tr>
<tr>
<td>Severe Dissection (≈ 60%)</td>
<td>11%</td>
<td>7%</td>
</tr>
</tbody>
</table>

P < 0.001 log-rank

Potential Solution to Minimize Vessel Dissection

The pillows and grooves formed by cage minimize pressure differentials that can cause dissections.

**Chocolate™* PTA with Controlled Dilatation**
Case presentation

• 89-year old male
• Medical history
  – High grade AV-block
  – Aortic valve stenosis and mitral valve insufficiency
  – Type 2 diabetes mellitus (NID)
  – Anemia
Case presentation

- Presents with ischemic rest pain of left foot and cyanosis of 3rd toe
- ABI 0.6
- Duplex: 6 cm occlusion of distal SFA
CO$_2$ angiography
Chocolate balloon 5 x 80 mm
Control angiography
Control angiography
Control angiography

No distal embolization
Chocolate Bar Study\textsuperscript{1,2}: Overview

Prospective, multicenter, real-world post market registry evaluating use of Chocolate\textsuperscript{TM*} balloon catheter in above and below the knee lesions

- 488 patients enrolled
- 33 sites
- Independent adjudication by core labs\textsuperscript{3,4}

**Inclusion Criteria**
- Any ATK or BTK lesion with at least 1 vessel runoff successfully crossed with a guidewire
- Use of atherectomy/re-entry devices accepted

**Exclusion Criteria**
- Presence of a flow-limiting dissection at the target lesion prior to use of the Chocolate\textsuperscript{TM*} PTA balloon (secondary to the use of another device)
- Patients with Rutherford 6
- Chocolate\textsuperscript{TM*} PTA balloon not used in accordance with study protocol (2 min inflation to at least nominal pressure)

1. Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC
3. Vascore DUS Core Lab, Boston, MA, US
4. Yale University Core, New Haven, CT
Dissection Rates Across Standard and Specialty PTA

<table>
<thead>
<tr>
<th></th>
<th>ABSOLUTE PTA Arm</th>
<th>RESILIENT PTA Arm</th>
<th>Chocolate BAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATK</td>
<td>16%</td>
<td>40%</td>
<td>0%</td>
</tr>
<tr>
<td>BTK</td>
<td>32%</td>
<td>15%</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>12%</td>
<td>12%</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>12%</td>
<td>12%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>8%</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>0%</td>
<td>2%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Results are from different studies and results may vary in head-to-head study; for illustration purposes only.

3. Data on file with Medtronic. CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC.
Summary

• Optimal balloon angioplasty can lead to good acute results without the need for stenting

• Complex lesions still pose a challenge even with DCB, with observed reliance on stenting

• Chocolate™ balloon catheter is an advanced angioplasty balloon that delivers controlled dilation of the vessel
  • Minimizes the formation of dissections
  • Results from the Chocolate Bar registry show freedom from flow limiting dissection of 100% and very low bailout stent rate
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