Final Results for the Chocolate Touch Drug Coated PTA Balloon Catheter for the Treatment of Femoropopliteal Lesions: The ENDURE Study

Prof. Dr. med. Gunnar Tepe
Chief Doctor
Institute of Diagnostic and Interventional Radiology
RoMed Clinic Rosenheim

Disclosures

* Study support by QTVascular

Angioplasty with POBA

Key Unmet Challenge:
Acute Arterial Trauma produced by Conventional Balloons

Torsional Stress
Impacted on vessel wall through twisting motion by conventional balloons

Radial Stress
Outwardly expands vessel wall during unfolding

Longitudinal Stress
Stretches vessel wall during unfolding

Constrained expansion to reduce Acute Arterial Trauma

Attributes
Nominal dose density of paclitaxel on Chocolate Touch is 3µg/mm², similar to other drug coated balloons
Unique excipient
20% more drug-coated surface compared to conventional balloons.
One step device, does not require pre-dilatation.

Chocolate Touch

Unique Platform: Chocolate
Proven Drug: Paclitaxel

2nd generation drug-coated peripheral balloon

Mid to Long Term Biological Effect of Paclitaxel for Reduced Tissue Growth in Vessel

Nominal dose density of paclitaxel on Chocolate Touch is 3µg/mm², similar to other drug coated balloons
Unique excipient
20% more drug-coated surface compared to conventional balloons.
One step device, does not require pre-dilatation.

Note: 1. Das et al, LINC 2013, Mustapha AMP 2015.
ENDURE Study Design

• Single or Tandem de novo lesion
• Total lesion length ≤ 150 mm
• RVD 4.5 – 6.0 mm
• Rutherford Grade 3-5

Clinical

ATK
30D 6MO 12MO

BTK
30D 3MO 6MO 12MO

ENDURE Study Design (Cont’d)

4 Sites in Germany and New Zealand (Single-arm study)

67 Total Patients Enrolled

70 Target Lesions

Principal Investigators:
- Dr. Thomas Zeller, Universitäts-Herzzentrum Freiburg-Bad Krozingen GmbH, Bad Krozingen, Germany
- Dr. Andrew Holden, Auckland City Hospital, Auckland, New Zealand
- Prof. Gunar Tepe, Rosenheim Medical Center, Germany
- Dr. Sebastian Sixt Hamburg University Cardiovascular Center, Germany

Treatment Strategy:
- No pre-dilation required
- Single or tandem de novo lesion
- Additional PTA balloon required if >30% residual stenosis / Type C or worse dissection
- Bail-out Stent permitted if >50% residual stenosis or flow-limiting dissection
- BTK Cohort cases upcoming

Chocolate Touch Clinical Data

ENDURE Study: Clinical Presentation

More complex Rutherford population than any other DCB studies

100% Classified Rutherford 3 and Above

IDE studies for Lutonix and IN.PACT excluded Rutherford 5 patients and included Rutherford 2 (29.5% and 37.7% in their DCB arms, respectively)

Chocolate Touch Clinical Data

ENDURE Study: Patient Characteristics

Highly relevant patient population, with wide-ranging medical history

Demographics

<table>
<thead>
<tr>
<th>Patients Enrolled</th>
<th>Male Patients</th>
<th>Age Range</th>
<th>Average Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>67</td>
<td>61%</td>
<td>53-92</td>
<td>69</td>
</tr>
</tbody>
</table>

Medical History

<table>
<thead>
<tr>
<th>Calculated EMD (range)</th>
<th>24.1 (7.7 – 42.2)</th>
</tr>
</thead>
</table>

Chocolate Touch Clinical Data

ENDURE Study: Lesion Characteristics

Core Lab Adjudicated Data (N=70)

Pre-Dilation Conducted: 26.9% (18/67)
Pre-treatment Fluoroscopy Time: 22.3±19.5 (1-135)
Targeted Artery: 7.1% (5/70)

Calcification

None to Mild: 45.7% (32/70)
Moderate: 11.4% (22/70)
Severe: 22.8% (16/70)

RVD

Proximal: 1.4±0.67 (0.5 – 2.7 mm)
Mid: 1.4±0.67 (0.5 – 2.7 mm)
Distal: 1.4±0.67 (0.5 – 2.7 mm)

Lesion Length (N=69)

7.3cm (1.5 – 16.5cm)

100% Total Occlusions (N=69)

Chocolate Touch Clinical Data

ENDURE Study: Core Lab Adjudicated Data

Pre-Dilation Conducted: 26.9% (18/67)
Pre-treatment Fluoroscopy Time: 22.3±19.5 (1-135)
Targeted Artery: 7.1% (5/70)

Calcification

None to Mild: 45.7% (32/70)
Moderate: 11.4% (22/70)
Severe: 22.8% (16/70)

RVD

Proximal: 1.4±0.67 (0.5 – 2.7 mm)
Mid: 1.4±0.67 (0.5 – 2.7 mm)
Distal: 1.4±0.67 (0.5 – 2.7 mm)

Lesion Length (N=69)

7.3cm (1.5 – 16.5cm)

100% Total Occlusions (N=69)
ENDURE Study: Procedural Results

Confirm high rates of procedural and device success with low rates of dissection (1.4%) and bail-out stenting (1.4%).

Acute Outcomes (% of Patients)

- Technical Success
- Device Success
- Procedural Success

ENDURE Study: Assessment of Clinical Improvement

Patients treated with Chocolate Touch demonstrated material improvement in ABI and Rutherford Category.

<table>
<thead>
<tr>
<th>Compared to Pre-Treatment</th>
<th>Average Change in ABI</th>
<th>Average Change in Rutherford</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days (N=56)</td>
<td>0.28</td>
<td>-2.7</td>
</tr>
<tr>
<td>6 months (N=46)</td>
<td>0.26</td>
<td>-2.5</td>
</tr>
<tr>
<td>12 months</td>
<td>0.29</td>
<td>-2.6</td>
</tr>
</tbody>
</table>

ENDURE Study: Major Adverse Events

6 Months (Cumulative) 12 Months (Cumulative)

<table>
<thead>
<tr>
<th>Per Protocol</th>
<th>Per Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically driven TLR</td>
<td>4</td>
</tr>
<tr>
<td>Amputation</td>
<td>D</td>
</tr>
<tr>
<td>All-cause Death</td>
<td>0</td>
</tr>
<tr>
<td>Total MAE</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reported Rate</th>
<th>Kaplan Meier*</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Months</td>
<td>88.5% (44/50)</td>
</tr>
<tr>
<td>12 Months</td>
<td>83.6% (43/53)</td>
</tr>
</tbody>
</table>

ENDURE Study Conclusions

- Combination of Chocolate platform and paclitaxel-coating offers potential to avoid stents almost entirely.
- Achieved low residual diameter stenosis (similar to stents) and no flow limiting dissections, resulting in extremely low rate of per protocol bail-out stenting.
- Shows promising evidence of drug effect by way of low late lumen loss and high patency at 12 months.
- The constraining structure may have protective effect on the paclitaxel (to be evaluated in upcoming IDE Study).
## Pivotal Study Design

**Study has received IDE approval from FDA**

<table>
<thead>
<tr>
<th>Design</th>
<th>Randomized, Multi-center, Prospective, Adaptive Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Population</td>
<td>Subjects with claudication or ischemic rest pain and an angiographically significant lesion in the superficial femoral or popliteal arteries</td>
</tr>
<tr>
<td>Enrollment</td>
<td>510 randomized subjects at up to 50 investigational sites. More than 50% of enrollment will occur in the U.S.</td>
</tr>
<tr>
<td>Randomization</td>
<td>Subjects will be randomized 1:1 to Chocolate Touch or Lutonix</td>
</tr>
<tr>
<td>Duration</td>
<td>6 years: 1 year enrollment and 5 years of follow-up</td>
</tr>
</tbody>
</table>
| Follow-up | • 1, 6, 12, 24 and 36 Months: Clinical Assessment  
• 1, 6, 12, 24 and 36 Months: Duplex Ultrasound (DUS)  
• 48 and 60 months: Telephone Contact |
| Adaptive Design | Study success is defined as Non-Inferiority. Company can test and continue to enroll to show superiority  
Non Inferiority interim analysis: 162 evaluable patients in each arm  
• If non-inferiority is achieved at interim analysis, data review by FDA can start  
• Superiority to Lutonix will be tested at interim analysis and final analysis |

---

**IDE Study Overview**

---

Copyright QT Vascular