How Low Can You Go?

SELUTION SLR™ Tibial Artery Sirolimus-Coated Balloon Angioplasty in the Setting of CLTI

A/Prof Tjun Tang MD FRCS (Gen) FAMS
Senior Consultant
Department of Vascular Surgery
Singapore General Hospital

LINC 2020
Disclosures

Speaker name:

TJUN TANG MD FRCS(Gen)

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) – Investigator-initiated grant from Medalliance

☐ I do not have any potential conflict of interest
Goals of BTK Interventions in CLTI

- Restore straight-line pulsatile blood flow to the foot for wound healing
- Direct/Angiosome-directed endovascular revascularization if possible
  - Significantly improves wound healing and major amputation rates
- Access and traverse
Tibial Artery Angioplasty in CLTI: CHALLENGES

- Endovascular therapy for infra-popliteal arterial occlusion preferred option:
  - Minimally invasive and repeatable procedure
  - Setting of CLTI – patient with multiple co-morbidities
  - Lack of surgical venous conduits (Diabetics)
- Problem is prolonged wound healing (3-6 months!)
- POBA/BMS plagued by vessel restenosis
- Efficacy of paclitaxel–coated balloons in reducing restenosis and target lesion revascularization?

Wound
Healed!!

Wound
The DM Foot Challenge in Singapore
SGH Lower Limb Angioplasty Experience

- 1200 lower limb angioplasties for CLTI over last 18 months
- 95% CLTI vs 5% claudicants!
- Patients present late!
- > 90% diabetics
- Approx. 50% with renal impairment
- Multi-level disease
Pre-initiated, prospective, non-randomized single-center trial, investigating the safety and efficacy of the Treatment with the Solution Sirolimus Coated Balloon in TASC C and D Tibial occlusive disease in patients with critical limb ischemia from SigaPorE.

NCT04071782
Primary Objective

• To evaluate the **6-month** safety and performance outcome of the Selution™ Sirolimus DCB
• Treatment of **long tibial occlusive lesions (TASC C and D)** in patients with CLTI
PRESTIGE Endpoints

- Freedom from device- or procedure-related mortality through 30 days
- Freedom from Target Lesion Revascularization (TLR) at 6 months and 12 months post-study procedure
  - Defined as any re-intervention performed for ≥50% diameter stenosis of target lesion
- Freedom from major target limb amputation
- Primary Patency rate at 6 and 12 months post-study procedure
- Technical success (i.e. able to cross and dilate lesion to achieve <30% residual stenosis)
- Clinical success (i.e. improvement of Rutherford classification at follow-up)
- Wound healing (i.e. complete closure of wound / >70% healed)
Study Site and Recruitment Targets

• SGH, Department of Vascular Surgery
• 2 senior experienced endovascular surgeons
• Trial fully enrolled
  – Originally 20 patients planned but extended to 25
• 3 month enrollment (October - December 2019)
• As of 18 Jan 2020:
  – 71 patients screened
  – 27 eligible (2 did not meet angiographic inclusion)
  – 25 patients enrolled
Inclusion Criteria

1. De novo and post-PTA restenotic lesions located in tibial arteries
2. Target lesion is >100mm, TASC C or D lesion
3. Target lesion has angiographic evidence of stenosis >50% or occlusion
4. Lesion traversed with standard guidewire and predilated to <30% residual stenosis
5. Target vessel diameter visually estimated to be > 1.5 mm and <4.5mm below knee
6. Any tibial vessel intervened on must have distal reconstitution above ankle
7. Inflow iliac, SFA and popliteal lesions treated first prior to treating BTK lesions. (<30% residual stenosis and no evidence of embolization)
8. Angiographic evidence of at least one vessel runoff through ankle and into foot
Eligible patients identified & consented for study prior to procedure

Pre-op investigations performed 7 days before op
- Walking Impairment Questionnaire
- EQ5D
- Ankle Brachial Pressure Index (ABPI)
- Duplex Ultrasound

Day of Op
To assess angiographic inclusion criteria intra-operatively

If meet angiographic inclusion criteria, patient will be enrolled into study – For treatment with SCB
- ABI and ultrasound post-procedure and before discharge

If do not meet angiographic inclusion criteria, to either proceed any products, at individual discretion

Inclusion
1. Age > 21, able to give consent
2. Diagnosed with CLI
3. Rutherford 4 to 6

Exclusion
1. Wheelchair bound
2. Previous stenting done at lower limb
3. Intervention is performed to prepare for planned major amputation
4. Neurotropic ulcer / heel pressure ulcer / ulcer involving calcaneus
5. Uncorrected bleeding disorders
**Post-op Follow Up**

**1 month POST-SURGERY**
- Clinical follow-up (telephone or office visit)
- Data collected:
  - Walking impairment questionnaire
  - EQ-5D

**3 months POST-SURGERY**
- Clinical follow-up (telephone or office visit)

**6 months POST-SURGERY**
- Clinical follow-up (office visit)
- Data collected:
  - Walking impairment questionnaire
  - EQ-5D
  - Ankle Brachial Index Test
  - Duplex Ultrasound

**12 months POST-SURGERY**
- Clinical follow-up (office visit)
- Data collected:
  - Walking impairment questionnaire
  - EQ-5D
  - Ankle Brachial Index Test
  - Duplex Ultrasound
### Patient Demographics

<table>
<thead>
<tr>
<th></th>
<th>Number (n=25)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age, years (sd)</td>
<td>63.72 ± 9.73</td>
<td></td>
</tr>
<tr>
<td>Mean BMI (sd)</td>
<td>24.40 ± 4.88</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17</td>
<td>68.0</td>
</tr>
<tr>
<td>Female</td>
<td>8</td>
<td>32.0</td>
</tr>
<tr>
<td>Ethnic Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>18</td>
<td>72.0</td>
</tr>
<tr>
<td>Malay</td>
<td>4</td>
<td>16.0</td>
</tr>
<tr>
<td>Indian</td>
<td>3</td>
<td>12.0</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td>5</td>
<td>20.0</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>16</td>
<td>64.0</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>4</td>
<td>16.0</td>
</tr>
</tbody>
</table>

### Co-Morbidities (%)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>22</td>
<td>88.0</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>19</td>
<td>76.0</td>
</tr>
<tr>
<td>Hypertension</td>
<td>22</td>
<td>88.0</td>
</tr>
<tr>
<td>Family history of CAD</td>
<td>1</td>
<td>4.0</td>
</tr>
<tr>
<td>CVA in the past 12 months</td>
<td>1</td>
<td>4.0</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>3</td>
<td>12.0</td>
</tr>
<tr>
<td>Angina</td>
<td>2</td>
<td>8.0</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>4</td>
<td>16.0</td>
</tr>
<tr>
<td>End Stage Renal Failure (ESRF)</td>
<td>11</td>
<td>44.0</td>
</tr>
</tbody>
</table>

Diabetes – 88%

ESRF – 44%
## Procedural Information

<table>
<thead>
<tr>
<th>Reason for Intervention</th>
<th>Number (n=25)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutherford Classification</td>
<td></td>
<td>100</td>
</tr>
<tr>
<td>5 (Minor tissue loss — nonhealing ulcer, focal gangrene with diffuse pedal ischemia)</td>
<td>25</td>
<td>100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lesion details</th>
<th>Total lesions treated with DCB (n=33)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of Treated Vessel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior Tibial Artery (ATA)</td>
<td>17</td>
<td>51.5</td>
</tr>
<tr>
<td>Posterior Tibial Artery (PTA)</td>
<td>10</td>
<td>30.3</td>
</tr>
<tr>
<td>Common Plantar Artery</td>
<td>3</td>
<td>9.1</td>
</tr>
<tr>
<td>Dorsalis Pedis Artery (DPA)</td>
<td>3</td>
<td>9.1</td>
</tr>
<tr>
<td>De novo</td>
<td>21</td>
<td>63.6</td>
</tr>
<tr>
<td>Re-stenotic</td>
<td>12</td>
<td>36.4</td>
</tr>
<tr>
<td>TASC Classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C (multiple stenosis, &gt; 10cm lesion length)</td>
<td>18</td>
<td>54.5</td>
</tr>
<tr>
<td>D (multiple occlusion, &gt; 10cm lesion length)</td>
<td>15</td>
<td>45.5</td>
</tr>
<tr>
<td>Calcification Classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 (focal)</td>
<td>6</td>
<td>18.2</td>
</tr>
<tr>
<td>3 (mild)</td>
<td>6</td>
<td>18.2</td>
</tr>
<tr>
<td>4 (moderate)</td>
<td>11</td>
<td>33.3</td>
</tr>
<tr>
<td>5 (severe)</td>
<td>10</td>
<td>30.3</td>
</tr>
<tr>
<td>DCB details</td>
<td>Number of balloons (n=54)</td>
<td>Percentage (%)</td>
</tr>
<tr>
<td>Balloon Diameter (mm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.0</td>
<td>3</td>
<td>5.6</td>
</tr>
<tr>
<td>2.5</td>
<td>16</td>
<td>29.7</td>
</tr>
<tr>
<td>3.0</td>
<td>17</td>
<td>31.5</td>
</tr>
<tr>
<td>3.5</td>
<td>18</td>
<td>33.3</td>
</tr>
</tbody>
</table>
PRESTIGE Trial Case Examples

2 months post-op

1 month post-op

2 months post-op
CASE STUDY: SGH03

Procedure date: 31 Oct 2019

Clinical Indication: 3rd and 4th toes gangrene

Proposed procedure: Left LL Angioplasty, 3rd and 4th toe ray amputation

Target Vessel: ATA

Vessel details: TASC D, CTO, 300mm in length

Procedural details

(1) Antegrade crossing subintimal 0.018”wire; Cook CXI catheter support
   - Predilation: JADE (POBA) 2x180mm (dorsalis pedis distal ATA)
   - Treated: Selution SLR 2.5x150mm

(2)
   - Predilation: Jade (POBA) 3x150mm (distal to prox ATA)
   - Treated: Selution SLR 3x150mm

Final Outcome: < 30% Residual Stenosis

Post-Angioplasty Angiogram findings: 2 vessel run off via ATA and peroneal. DP2+
SGH03 – Wound Healing Progression

Post-Amputation (Oct 2019)

1 week post-op

1 month post-op

2 months post-op
CASE STUDY: SGH19

63-year-old Chinese male RIGHT lateral foot non healing wound for 4 weeks
PMHx: diabetes, hypertension, hypercholesterolemia, ESRF (DM nephropathy)
Op date: 26 Dec 2019

**Target Vessel 1 - ATA**
Vessel details: TASC D, long CTO and multifocal stenosis up to 95% (320mm)
Procedural details:
- Predilation: Armada 18 (POBA) 3x150mm
- Treated: 2x Selution 3.5x150mm
Final Outcome: < 30% Residual Stenosis

**Target Vessel 2 - DPA**
Vessel details: TASC C, Multifocal stenosis up to 90%, 60mm in length
Procedural details:
- Predilation: Coyote (POBA) 2x100mm
- Treated: Selution 2.5x150mm
Final Outcome: < 30% Residual Stenosis
CASE STUDY: SGH22

54 year old Chinese male; Diabetes, Hypercholesterolaemia, hypertension
Failed right lower limb angioplasty at another local hospital
Op date: 30 Dec 2019
Clinical Indication: RIGHT foot dorsal gangrene and 4th toe wet gangrene

**Target Vessel 1 - PTA**
Vessel details - TASC D, Proximal to mid PTA CTO, 150mm
Procedural details -
  - Predilation: JADE (POBA) 3x240mm
  - Treated: 2x Selution 3 x150mm
Final Outcome - < 30% Residual Stenosis

**Target Vessel 2 - Common Plantar and Lateral Plantar**
Vessel details - TASC C, Multifocal stenosis up to 99%, 150mm
Procedural details -
  - Predilation: JADE (POBA) 2x180mm
  - Treated: Selution 2.5x150mm
Final Outcome - > 30% Residual Stenosis mid CPA
SGH22 – Wound Healing Progression

Pre-procedure

Post-op Day 1

One Week

Day 10

2 Weeks

Day 17
Selution™ Balloon SGH Experience

- Positive Initial SCB Experience
- 2mm, 2.5mm, 3.0mm, 3.5mm and 4.0mm x150mm used
- Generally followed a 1:1 POBA-DCB sizing although using a DCB 0.5mm bigger no issue
- Good trackability over an 0.018” platform
- Short Deflation time
- Good visible markers to place the balloon accurately
- Minimal slow flow phenomenon even after treating infra-malleolar lesions
- No serious adverse events using the balloon catheter
- Six months data awaited – available July 2020
Jade – Solution – PTx Combo
Is Selution™ the Solution?

I was lucky to be in the right place at the right time. But many others were also in the same place. The difference was that I took action.

— Bill Gates

Right Place, Right Time, Prime Time?
Thank You!

tang.tjun.yip@singhealth.com.sg
How Low Can You Go?
SELUTION SLR™ Tibial Artery Sirolimus-Coated Balloon Angioplasty in the Setting of CLTI

A/Prof Tjun Tang MD FRCS (Gen) FAMS
Senior Consultant
Department of Vascular Surgery
Singapore General Hospital

LINC 2020