SFA CTO Lesion Management
laser or directional atherectomy?

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Disclosure

Speaker name: Kevin, Chung-Ho Hsu

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
History

58 y/o male smoker
Hyperthyroidism
Hyperlipidemia
Left leg claudication for one year
L-ABI 0.55
Rx: aspirin 1# qd, cilostazol 100 mg bid
7Fr Cook Crossover sheath

CXI supporting catheter
Laser angioplasty with 2.5 mm Turbo Elite
5.0/150 mm Pacific extreme balloon at 10 atm
5.0/120 mm Impact DEB balloon at 8 atm x 5 min
Ultrasound (ABI 0.97)

LCFA: 100 cm/s
LSFA: 122 cm/s
LPOP: 135 cm/s
LPTA: 109 cm/s
L PDA: 98 cm/s
6 mo f/u Ultrasound (ABI 0.91)

LCFA: 124 cm/s
LSFA: 122 cm/s
LPOP: 200 cm/s
LPTA: 138 cm/s
L PDA: 105 cm/s
History

73 y/o female
Hypertension, Diabetes Mellitus, Uremia on regular hemodialysis, Insignificant CAD, VT
Rutherford 6 case, Long flush CTO of LSFA s/p PTA with stenting (Viabahn x 3)
Ostial SFA edge restenosis s/p cutting balloon angioplasty/DEB
Acute limb ischemia of left leg this time
20150921, ABI 0.37

LCFA: 128 cm/s  LSFA: 0 cm/s  LPOP: 10 cm/s

LPTA: 0 cm/s  L ped dorsalis: 0 cm/s
6Fr JR4 guiding catheter
Fountain catheter assisted thrombolysis
Overnight thrombolysis with urokinase, 60000 units/hour
Turbohawk LS/M Atherectomy
6.0/20 mm Cutting balloon at 10 atm, 6.0/80 mm Medtronics InPACT DCB at 10 atm x 5 min
20150923, ABI 0.82

LCFA: 162 cm/s

LSFA: 95 cm/s

LPOP: 148 cm/s

LPTA: 74 cm/s

L ped dorsalis: 243 cm/s
Directional Atherectomy: Key Trial

DEFINITIVE LE

- Study Design and Oversight
  - Prospective, non-randomized, global study
  - 800 patients, 47 centers
  - CEC + Steering Committee oversight/CEC adjudication
  - Angio + Duplex Core lab

Key Inclusion

- RCC 1-6
- ≥ 50% stenosis
- LL up to 20 cm
- RVD ≥ 1.5 mm to ≤ 7.0 mm

Key Exclusion

- Severe Ca++
- ISR
- Aneurysmal target vessel

Study Design & Primary Endpoints

- 800 patients
- 47 centers

Claudicants (RCC 1-3)
- 598 patients*
  - Primary patency by Duplex US at 12 mos

CLI (RCC 4-6)
- 201 patients
  - Freedom from major unplanned amputation at 12 mos

*1 censored due to informed consent violation
# Primary Patency in Subgroups

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Claudicants (n=743)</th>
<th>CLI (n=279)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patency (PSVR ≤ 2.4)</td>
<td>Lesion Length (cm)</td>
</tr>
<tr>
<td>SFA Only By Lesion Length</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 4 cm (n=184)</td>
<td>78%</td>
<td>2.3</td>
</tr>
<tr>
<td>4-9.9 cm (n=253)</td>
<td>83%</td>
<td>6.5</td>
</tr>
<tr>
<td>≥ 10 cm (n=232)</td>
<td>65%</td>
<td>14.6</td>
</tr>
</tbody>
</table>

## Lesion Type

<table>
<thead>
<tr>
<th>Type</th>
<th>Claudicants</th>
<th>CLI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL</td>
<td>78%</td>
<td>71%</td>
</tr>
<tr>
<td>Stenoses</td>
<td>81%</td>
<td>73%</td>
</tr>
<tr>
<td>Occlusions</td>
<td>64%</td>
<td>66%</td>
</tr>
</tbody>
</table>

## Lesion Location

<table>
<thead>
<tr>
<th>Location</th>
<th>Claudicants</th>
<th>CLI</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFA</td>
<td>75%</td>
<td>68%</td>
</tr>
<tr>
<td>Popliteal</td>
<td>77%</td>
<td>68%</td>
</tr>
<tr>
<td>Infrapop</td>
<td>90%</td>
<td>78%</td>
</tr>
</tbody>
</table>
Laser Atherectomy

Ultraviolet 308 nm excimer laser
Debulking thrombus, atheroma, emboli
Poor effect for heavy calcified vessel
The step by step technique can be used to cross SFA CTO, lead with laser not wire
Perforation 2%
Embolization 4%
Laser Atherectomy: Key Trial

EXCITE ISR

**Study Design and Oversight**
- Prospective, RCT, US study
- 250 patients, 40 centers
- Angio + Duplex Core lab

**Key Inclusion**
- RCC 1-4
- ISR lesion ≥ 4 cm, no lesion limit
- ≥ 1 patent tibial artery
- RVD ≥ 5.0mm to ≤ 7.0mm

**Key Exclusion**
- Target lesion extends >3 cm beyond stent margin
- Untreated inflow lesion
- Grade 4 or 5 stent fx

Dippel TCT LBCT 2014
EXCITE ISR

Primary Efficacy Endpoint

Freedom from TLR thru 6 months

- ITT: 73.5% (P<0.005)
- ITT w/o Bailout Stenting as TLR: 51.8%
- Per protocol: 46.7% (P<0.001)

- ELA + PTA: 78.1%
- PTA: 61.7% (P<0.05)
Rationale for Combination Treatment Atherectomy and DCB

Theoretical benefit for atherectomy

• DCB may inhibit the inflammatory response caused by mechanical trauma
• DCB may improve patency in longer lesions and occlusions
Rationale for Combination Treatment

Atherectomy and DCB

Theoretical benefit for DCB therapy

- Plaque removal could facilitate local drug delivery into vessel wall
- Atherectomy in SFA lesions improve clinical success by
  - Residual restenosis
  - Flow limiting dissections
  - Bailout stent rate
DAART = Directional Atherectomy + Anti-Restenotic Therapy

DEFINITIVE AR Pilot Study
Study Design

General and Angiographic Criteria Assessment

Lesion severely calcified?*

NO

Randomization

DAART (n=48)

DCB (n=54)

YES

DAART Severe Ca++ (n=19)

*Defined as: dense circumferential calcification extending > 5 cm
Inclusion Criteria

- Rutherford Clinical Category Score of 2, 3 or 4
- $\geq 70\%$ stenosis, restenosis or occlusion in the SFA and/or popliteal artery
- **Target lesion(s) length is 7-15 cm**
- Target vessel diameter is $\geq 4$ mm and $\leq 7$ mm

Exclusion Criteria

- In-stent restenosis
- Aneurysmal target vessel
- 2 or more lesions that require treatment in the target limb
DEFINITIVE AR 1-yr Result (Angio)

Kaplan-Meier curve of 12-month primary patency

## TABLE 3
Outcome Measures in Patients Treated With Laser Debulking (LD) + Drug-Eluting Balloon (DEB) Angioplasty vs. DEB Alone

<table>
<thead>
<tr>
<th></th>
<th>LD+DEB (n=24)</th>
<th>DEB Only (n=24)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 6 months</td>
<td>V 91.7%</td>
<td>58.3%</td>
<td>0.01</td>
</tr>
<tr>
<td>At 12 months</td>
<td>V 66.7%</td>
<td>37.5%</td>
<td>0.01</td>
</tr>
<tr>
<td>TLR at 12 months</td>
<td>V 16.7%</td>
<td>50%</td>
<td>0.01</td>
</tr>
<tr>
<td>Limb salvage at 12 months</td>
<td>V 91.7%</td>
<td>54.2%</td>
<td>0.003</td>
</tr>
<tr>
<td>Healing at 12 months</td>
<td>87.5%</td>
<td>62.5%</td>
<td>0.04</td>
</tr>
<tr>
<td>Major amputation</td>
<td>2 (8%)</td>
<td>11 (46%)</td>
<td>0.003</td>
</tr>
<tr>
<td>Death</td>
<td>3 (12%)</td>
<td>9 (37%)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Categorical data are given as the counts (percentage).

TLR: target lesion revascularization.
<table>
<thead>
<tr>
<th></th>
<th><img src="image1" alt="MLD" /></th>
<th><img src="image2" alt="Heavily calcified vessel" /></th>
<th><img src="image3" alt="Thrombus" /></th>
<th><img src="image4" alt="Long CTO" /></th>
<th><img src="image5" alt="Time" /></th>
<th><img src="image6" alt="Cost" /></th>
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<td><img src="image3" alt="Thrombus" /></td>
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<td><img src="image6" alt="Cost" /></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long CTO</td>
<td><img src="image4" alt="Long CTO" /></td>
<td><img src="image5" alt="Time" /></td>
<td><img src="image6" alt="Cost" /></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td><img src="image5" alt="Time" /></td>
<td><img src="image6" alt="Cost" /></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td><img src="image6" alt="Cost" /></td>
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<td></td>
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</tr>
</tbody>
</table>
Laser Debulking and DCB +/- Stent in de novo SFA/pop in CMUH, Taiwan, 2013~

<table>
<thead>
<tr>
<th></th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>19 patients</strong></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>75 (75-91)</td>
</tr>
<tr>
<td>Male</td>
<td>7 (37)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>11 (58)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>12 (63)</td>
</tr>
<tr>
<td>Renal Failure (GFR &lt; 60 or dialysis)</td>
<td><strong>14 (74)</strong></td>
</tr>
<tr>
<td>CAD</td>
<td><strong>16 (84)</strong></td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>3 (16)</td>
</tr>
</tbody>
</table>
Laser Debulking and DCB +/- Stent in de novo SFA/pop in CMUH, Taiwan, 2013~

Rutherford Class (RC)

- RC3: 5%
- RC4: 11%
- RC5: 63%
- RC6: 21%
<table>
<thead>
<tr>
<th></th>
<th>6 m</th>
<th>12 m</th>
<th>24 m</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Patency</strong></td>
<td>95%</td>
<td>95%</td>
<td>84%</td>
</tr>
<tr>
<td>(PSVR &lt; 2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assisted Patency</strong></td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>ABI</strong></td>
<td>0.56</td>
<td>0.85</td>
<td>0.80</td>
</tr>
<tr>
<td><strong>TLR</strong></td>
<td>5%</td>
<td>11%</td>
<td>16%</td>
</tr>
<tr>
<td><strong>Major amputation</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td>0</td>
<td>16%</td>
<td>16%</td>
</tr>
</tbody>
</table>
Take Home Message

For SFA CTO lesion, it is still challenging to maintain long term patency.
Combined atherectomy and drug eluting technology might achieve higher patency than DCB alone.
Choice of atherectomy device depends on lesion character and familiarity of the operator.
SFA CTO Lesion Management
laser or directional atherectomy?
Thanks For Your Attentions
What is the Impact of Lumen Gain with DAART?

DAART resulted in a significantly larger minimum lumen diameter (MLD) following the protocol-defined treatment in DEFINITIVE AR.

**MLD = 4.27**

DAART Arm

- **0.92** (DCB)
- **2.16** (DA)
- **0.23** (Pre-Dilatation)
- **0.96** (Baseline)

\[ \sim 15.1 \text{ mm}^2 \text{ lumen area} \]

**MLD = 3.78**

DCB Arm

- **1.61** (DCB)
- **1.39** (DA)
- **0.78** (Baseline)

\[ \sim 11.8 \text{ mm}^2 \text{ lumen area} \]

\[ p = 0.045 \]
A Difference in Residual Stenosis

Residual diameter stenosis was significantly lower in DAART arm

Post-Protocol-Defined...

Post-Adjunctive...

P = 0.0002

DAART

DCB

P = 0.0256

Percent
12-Month Patency: DAART RCT Patients

Increased lumen gain with DA before DCB may result in improved 12-month patency

<table>
<thead>
<tr>
<th></th>
<th>Percent</th>
<th>DUS Patency</th>
<th>Angiographic Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤30% Residual Stenosis Post-DA</td>
<td>77.8</td>
<td>N = 20</td>
<td>N = 17</td>
</tr>
<tr>
<td>&gt;30% Residual Stenosis Post-DA</td>
<td>68.8</td>
<td>N = 18</td>
<td>N = 16</td>
</tr>
<tr>
<td>90</td>
<td></td>
<td></td>
<td>94.1</td>
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