The relation of 2D perfusion angiography after BTK intervention and wound healing in patient with CLI
- Single center prospective study -

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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

Novel Methods for assessing endpoint in BK EVT

Wound Blush

Utsunomiya et al. JVS 2012: 55; 113-21

Visual assessment only

VFR


Additional device

Indigo carmine


Visual assessment only
Method of 2D perfusion angiography

2D Perfusion
Philips Volcano is tackling the PAD challenge head on

2D Perfusion imaging technology

Perfusion Imaging is a software product that provides functional information about tissues perfusion based on a digital subtraction angiography (DSA).

Provides interventionalists an objective understanding of the impact of their treatment to help determine the outcome of perfusion procedures.
Method of 2D perfusion angiography

1. Catheter position
   3-4.5Fr catheter placed in the P2.

2. Projection
   45 degree inner anterior oblique from long axis

3. Acquisition protocol
   - 50% diluted 370mg/mL iodine contrast
   - Injection of 3ml/sec over 2 sec.
   - ROI of hole foot area
Method of 2D perfusion angiography

Workflow and parameters

The time-density parameters are defined as follows:

1. **Arrival time**: Time from start of the measurement till the start of the contrast uptake. Provides a ratio of pre and post treatment velocity changes and a gross upper estimate of blood velocity from point of contrast injection to ROI if approximate distance between points are measured (e.g. external lead tape)

2. **Time to peak**: Reflects the flow rate of the bulk of the contrast (compared to fastest contrast in arrival time measure); shorter TTPs suggest higher flow rates

3. **Wash in rate**: Represents the steepness of the slope of the wash in curve

4. **Width**: Metric of duration of average contrast passage time. Larger widths (longer mean transit times) suggest slower passage of flow in and out of a region of interest

5. **Area under curve**: When the total amount of contrast is constant in a region of interest, it can be used to estimate volumetric blood flow

6. **Mean transit time**: Similar to width parameter, but taking asymmetry into account
Inclusion / Exclusion criteria

【Inclusion criteria】
✓ Ischemic and unhealed ulcer at the foot.
✓ Planned BTK intervention.

【Exclusion criteria】
✓ Intense inflammation (ex: Wifi FI-2or3).
✓ Major tissue loss (ex: Wifi W-3).
✓ Not available contrast media (ex: ESRD).
Definition

What “Successful Wound Heal” after BK EVT?

**Success**
- Complete heal within 3M.
- Without any additional intervention or surgery.

**Unsuccess**
- Delayed healing over 3M.
- Re-intervention within 3M.
- Wound dehiscence or infection after amputation.
- Need for adjunctive therapy.
Subjects

2D perfusion for BTK EVT with CLI
27 pts, 35 limbs

Institution: Saka General Hospital, Miyagi, Japan

Evaluable Limbs with Ulcer/ Gangrene
24 pts, 31 limbs

Exclusion:
- Unevaluable for the movement of foot: 3 limbs
- No ulcer (R4): 1 limbs

Success group
18 limbs

Unsuccess group
13 limbs

Criteria of “Unsuccess”
- Wound dehiscence or infection after minor amputation.
- Need for early re-intervention with operator’s decision.
- Not improved or delayed “Rest pain”.
- Need for additional therapy (ex: SCS)
### Results - Patient Characteristics -

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Success</th>
<th>Unsuccess</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of pts</td>
<td>24</td>
<td>14</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong> (years)</td>
<td>80.8 ± 5.2</td>
<td>81.1 ± 5.1</td>
<td>80.3 ± 5.6</td>
<td>0.73</td>
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<tr>
<td>Female (%)</td>
<td>4 (16.7)</td>
<td>3 (21.4)</td>
<td>1 (10.0)</td>
<td>0.59</td>
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<tr>
<td>Hypertension (%)</td>
<td>23 (95.8)</td>
<td>13 (92.9)</td>
<td>10 (100)</td>
<td>1.00</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>15 (62.5)</td>
<td>10 (71.4)</td>
<td>5 (50.0)</td>
<td>0.40</td>
</tr>
<tr>
<td>Dyslipidemia (%)</td>
<td>13 (54.2)</td>
<td>8 (57.1)</td>
<td>5 (50)</td>
<td>1.00</td>
</tr>
<tr>
<td>Renal insufficiency (%)</td>
<td>23 (95.8)</td>
<td>13 (92.9)</td>
<td>10 (100)</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Hemodialysis</strong> (%)</td>
<td>20 (83.3)</td>
<td>11 (78.6)</td>
<td>9 (90.0)</td>
<td>0.61</td>
</tr>
<tr>
<td>IHD (%)</td>
<td>13 (54.2)</td>
<td>6 (42.9)</td>
<td>7 (70.0)</td>
<td>0.24</td>
</tr>
<tr>
<td>CHF (%)</td>
<td>17 (70.8)</td>
<td>9 (64.3)</td>
<td>8 (80.0)</td>
<td>0.65</td>
</tr>
<tr>
<td>Low EF (&lt;40%, %)</td>
<td>2 (8.3)</td>
<td>0 (0)</td>
<td>2 (20.0)</td>
<td>0.16</td>
</tr>
<tr>
<td>CVD (%)</td>
<td>16 (66.7)</td>
<td>7 (50.0)</td>
<td>9 (90.0)</td>
<td><strong>0.04</strong></td>
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<tr>
<td>Non-ambulatory (%)</td>
<td>11 (45.8)</td>
<td>6 (42.9)</td>
<td>5 (50.0)</td>
<td>1.00</td>
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<tr>
<td>Cilostazol (%)</td>
<td>11 (45.8)</td>
<td>6 (42.9)</td>
<td>5 (50.0)</td>
<td>1.00</td>
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</table>
## Results - Limb and Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Success</th>
<th>Unsuccess</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of limbs</strong></td>
<td>31</td>
<td>18</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td><strong>Wound wite</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toe (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27 (87.1)</td>
<td>15 (83.3)</td>
<td>12 (93.3)</td>
<td>0.62</td>
<td></td>
</tr>
<tr>
<td><strong>Dorsal (%)</strong></td>
<td>4 (12.9)</td>
<td>2 (11.1)</td>
<td>2 (15.3)</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Heel (%)</strong></td>
<td>6 (19.4)</td>
<td>5 (27.8)</td>
<td>1 (7.7)</td>
<td>0.36</td>
</tr>
<tr>
<td><strong>Ankle (%)</strong></td>
<td>3 (9.7)</td>
<td>1 (5.6)</td>
<td>2 (15.4)</td>
<td>0.56</td>
</tr>
<tr>
<td><strong>Sole (%)</strong></td>
<td>3 (9.7)</td>
<td>1 (5.6)</td>
<td>2 (15.4)</td>
<td>0.56</td>
</tr>
<tr>
<td><strong>Rest pain (%)</strong></td>
<td>15 (48.4)</td>
<td>9 (50.0)</td>
<td>6 (46.2)</td>
<td>1.00</td>
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<tr>
<td><strong>Wound infection (%)</strong></td>
<td>6 (19.4)</td>
<td>5 (27.8)</td>
<td>1 (7.7)</td>
<td>0.36</td>
</tr>
<tr>
<td><strong>Gangrene (%)</strong></td>
<td>17 (54.8)</td>
<td>8 (44.4)</td>
<td>9 (69.2)</td>
<td>0.27</td>
</tr>
<tr>
<td><strong>Wifi class (1/2/3/4)</strong></td>
<td>10/5/8/8</td>
<td>7/3/3/5</td>
<td>3/2/5/3</td>
<td>0.56</td>
</tr>
<tr>
<td><strong>Inflow lesion (%)</strong></td>
<td>9 (29.0)</td>
<td>5 (27.8)</td>
<td>4 (30.8)</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Lesion location</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>POP (%)</strong></td>
<td>56 (19.4)</td>
<td>3 (16.7)</td>
<td>3 (23.1)</td>
<td>0.68</td>
</tr>
<tr>
<td><strong>ATA/ PA/ PTA (%)</strong></td>
<td>29 (94)/ 23 (74)/ 29 (94)</td>
<td>16 (89)/ 12 (67)/ 16 (89)</td>
<td>13 (100)/ 11 (85)/ 13 (100)</td>
<td>N.S.</td>
</tr>
<tr>
<td><strong>Below Ankle (%)</strong></td>
<td>27 (87.1)</td>
<td>14 (77.8)</td>
<td>13 (100)</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>BK run-off</strong></td>
<td>0.42 ± 0.62</td>
<td>0.56 ± 0.70</td>
<td>0.23 ± 0.44</td>
<td>0.15</td>
</tr>
<tr>
<td><strong>BK run-off 0 (%)</strong></td>
<td>20 (64.5)</td>
<td>10 (55.6)</td>
<td>10 (76.9)</td>
<td>0.28</td>
</tr>
<tr>
<td><strong>Pre-Procedural ABI</strong></td>
<td>0.75 ± 0.22</td>
<td>0.72 ± 0.25</td>
<td>0.79 ± 0.19</td>
<td>0.45</td>
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<tr>
<td><strong>PreSPP dorsal (mmHg)</strong></td>
<td>36.3 ± 22.7</td>
<td>38.8 ± 23.9</td>
<td>32.8 ± 21.2</td>
<td>0.48</td>
</tr>
<tr>
<td><strong>PreSPP plantar (mmHg)</strong></td>
<td>38.9 ± 21.7</td>
<td>42.9 ± 22.1</td>
<td>33.4 ± 20.6</td>
<td>0.23</td>
</tr>
</tbody>
</table>
## Results - Procedure and Wound Treatment -

<table>
<thead>
<tr>
<th>Procedure</th>
<th>All</th>
<th>Success</th>
<th>Unsuccess</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of limbs</td>
<td>31 (100)</td>
<td>31</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Balloon angioplasty</td>
<td>31 (100)</td>
<td>31</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td><strong>Treated vessel number</strong></td>
<td>1.48 ± 0.63</td>
<td>1.50 ± 0.62</td>
<td>1.46 ± 0.66</td>
<td>0.87</td>
</tr>
<tr>
<td>3 vessel run-off (%)</td>
<td>9 (29.0)</td>
<td>7 (38.9)</td>
<td>2 (15.4)</td>
<td>0.24</td>
</tr>
<tr>
<td>Angiosome direct (%)</td>
<td>22 (71.0)</td>
<td>13 (72.2)</td>
<td>9 (69.2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Pedal artery angioplasty (%)</td>
<td>18 (58.1)</td>
<td>9 (50.0)</td>
<td>9 (69.2)</td>
<td>0.46</td>
</tr>
<tr>
<td>Wound blush (%)</td>
<td>23 (74.2)</td>
<td>15 (83.3)</td>
<td>8 (61.5)</td>
<td>0.23</td>
</tr>
<tr>
<td>Debridement (%)</td>
<td>19 (61.3)</td>
<td>10 (55.6)</td>
<td>9 (69.2)</td>
<td>0.48</td>
</tr>
<tr>
<td>Minor amputation (%)</td>
<td>9 (29.0)</td>
<td>3 (16.7)</td>
<td>6 (46.2)</td>
<td>0.11</td>
</tr>
<tr>
<td>N.P.W.T. (%)</td>
<td>6 (19.4)</td>
<td>0 (0.0)</td>
<td>6 (46.2)</td>
<td>0.002</td>
</tr>
<tr>
<td>Skin grafting (%)</td>
<td>4 (12.9)</td>
<td>0 (0.0)</td>
<td>4 (30.8)</td>
<td>0.023</td>
</tr>
<tr>
<td>HBO (%)</td>
<td>4 (12.9)</td>
<td>3 (16.7)</td>
<td>1 (7.7)</td>
<td>0.62</td>
</tr>
<tr>
<td>Spinal Code Stimulation (%)</td>
<td>2 (6.5)</td>
<td>0 (0)</td>
<td>2 (15.4)</td>
<td>0.17</td>
</tr>
<tr>
<td>LDL apheresis (%)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>NA</td>
</tr>
</tbody>
</table>
Results – Clinical outcome Success vs. Unsuccess -

**Post SPP**

- **Success**: 57±17 mmHg  
  - p=0.0005

- **Unsuccess**: 35±14 mmHg

**Hospitalization term**

- **Success**: 43±32 days  
  - p=0.027

- **Unsuccess**: 75±41 days
Results - Clinical outcome Success vs. Unsuccess -

**Wound Healing Rate @ 3 months**

- **Success**: 100%  
- **Unsuccess**: 23.9%  

**Mean Wound Healing Term**

- **Success**: 42 ± 24 days  
- **Unsuccess**: 76 ± 23 days  

p < .0001  

p = 0.0005
Post-Procedural parameter - Success vs. Unsuccess -

“Wash-in rate”
(WIR, maximum slope of time-density curve)

41.1 ± 13.7
28.1 ± 9.8

\[ p = 0.007 \]

Cut-off: 31.2
Sensitivity: 89 %
Specificity: 77 %
AUC: 0.842
Limitation

- Single-center observational study.
- Small number.
- Short-term follow-up.
- Excluded major tissue loss and intense inflammation.

→ Need for multicenter study.
Conclusion

✓ Endpoint of BK EVT is still uncertain.
✓ Stability, visual impact, and digitization are important issue for identification.
✓ 2D perfusion satisfies ALL requirements.
✓ The cutoff "31.2" at Wash-in rate was useful for judgment of the end point of BK-EVT.
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- Single center prospective study -

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