Clinical Outcomes of Pedal Artery Angioplasty for Patients with Ischemic Wounds

Result from the Multicenter RENDEZVOUS Registry

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on behalf of the RENDEZVOUS registry investigators

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Disclosure

Speaker name: Tatsuya Nakama MD.

I have the following potential conflicts of interest to report:

- Consulting: Abbot Vascular, Boston Scientific
- Employment in industry: None
- Stockholder of a healthcare company: None
- Owner of a healthcare company: None
- Other(s): Honoraria received from Abbot Vascular, Boston Scientific, COOK, Medtronic
Experience of Pedal revascularization

An Extreme Recanalization: Transcollateral Retrograde Wiring for Below-the-ankle Occlusive Lesion

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Nakama T, et al. EJEVS Extra, 2014; 27: e7-e9
Pioneer of pedal intervention

Table II. Amputation-Free Survival Rate Estimated by Kaplan-Meier Analysis

What are the clinical implications of pedal artery intervention?
Clinical Implications of Additional Pedal Artery Angioplasty in Critical Limb Ischemia Patients With Infrapopliteal and Pedal Artery Disease

Tatsuya Nakama, MD¹, Nozomi Watanabe, MD, PhD¹, Toshiyuki Kimura, MD¹, Kenji Ogata, MD¹, Shun Nishino, MD¹, Makoto Furugen, MD, PhD¹, Hiroshi Koiwaya, MD, PhD¹, Koji Furukawa, MD², Eisaku Nakamura, MD, PhD², Mitsuhiro Yano, MD, PhD², Takehiro Daian, MD, PhD³, Nehiro Kuriyama, MD, PhD¹, and Yoshisato Shibata, MD¹

Hypothesis development

Adjunctive pedal intervention

Improve the rate of wound healing
Result from single center study

Time to wound-healing

- **PAA(+)**: 86.0 ± 18.7 days (IQR: 63 - 155)
- **PAA(-)**: 152.0 ± 60.2 days (IQR: 80 - 365)

**p value** = 0.05

<table>
<thead>
<tr>
<th>Months</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>9</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAA(+)</td>
<td>at risk</td>
<td>14</td>
<td>7</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>0</td>
<td>50</td>
<td>79</td>
<td>93</td>
</tr>
<tr>
<td>PAA(-)</td>
<td>at risk</td>
<td>18</td>
<td>12</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>0</td>
<td>29</td>
<td>53</td>
<td>60</td>
</tr>
</tbody>
</table>

Retrospective analysis for the clinical impact of pedal artery revascularization versus non-revascularization strategy for patients with critical limb ischemia.
Study synopsis

- **Study type**
  - Retrospective, multi-center

- **Number of patients**
  - 257 patients (257 limbs, R5 and 6)

- **Comparison group study**
  - PAA group vs Non-PAA group

Outcomes

○ Primary outcome
  · Rate of wound healing@1y (& time to wound healing)

○ Specify the indication of PAA
  · Delayed wound healing score (DH-Score)

## Backgrounds of patients

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>PAA group</th>
<th>Non-PAA group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>73.2 ± 11.0</td>
<td>72.2 ± 11.5</td>
<td>74.3 ± 10.4</td>
<td>0.121</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>175 (68.1)</td>
<td>96 (68.6)</td>
<td>79 (67.5)</td>
<td>0.857</td>
</tr>
<tr>
<td>Non-ambulatory status, n (%)</td>
<td>132 (51.4)</td>
<td>64 (45.7)</td>
<td>68 (58.1)</td>
<td>0.048</td>
</tr>
<tr>
<td>BMI&lt;18, n (%)</td>
<td>40 (15.6)</td>
<td>18 (12.9)</td>
<td>22 (18.8)</td>
<td>0.190</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>186 (72.4)</td>
<td>96 (68.6)</td>
<td>90 (76.9)</td>
<td>0.136</td>
</tr>
<tr>
<td>Dyslipidemia, n (%)</td>
<td>76 (29.6)</td>
<td>44 (31.4)</td>
<td>32 (27.4)</td>
<td>0.476</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>172 (72.8)</td>
<td>124 (76.1)</td>
<td>48 (73.5)</td>
<td>0.807</td>
</tr>
<tr>
<td>Smoking history, n (%)</td>
<td>111 (43.2)</td>
<td>67 (47.9)</td>
<td>44 (37.6)</td>
<td>0.099</td>
</tr>
<tr>
<td>Regular hemodialysis, n (%)</td>
<td>160 (62.3)</td>
<td>89 (63.6)</td>
<td>71 (60.7)</td>
<td>0.634</td>
</tr>
<tr>
<td>History of IHD, n (%)</td>
<td>148 (57.6)</td>
<td>88 (62.9)</td>
<td>60 (51.3)</td>
<td>0.062</td>
</tr>
<tr>
<td>Previous stroke, n (%)</td>
<td>69 (26.8)</td>
<td>34 (23.2)</td>
<td>35 (29.9)</td>
<td>0.311</td>
</tr>
<tr>
<td>Albumin&lt;3g/dL, n (%)</td>
<td>51 (19.8)</td>
<td>24 (47.1)</td>
<td>27 (23.1)</td>
<td>0.235</td>
</tr>
</tbody>
</table>

## Target limbs status

<table>
<thead>
<tr>
<th>Wound Classification</th>
<th>Overall</th>
<th>PAA group</th>
<th>Non-PAA group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutherford 6, n (%)</td>
<td>57 (22.2)</td>
<td>34 (24.3)</td>
<td>23 (19.7)</td>
<td>0.374</td>
</tr>
<tr>
<td>University of Texas grade ≥2, n (%)</td>
<td>119 (46.3)</td>
<td>71 (50.7)</td>
<td>48 (41.0)</td>
<td>0.121</td>
</tr>
<tr>
<td>SVS WIfI Classification</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WIfI Clinical Stage (high risk), n (%)</td>
<td>163 (63.4)</td>
<td>96 (68.6)</td>
<td>67 (57.3)</td>
<td>0.101</td>
</tr>
<tr>
<td>WIfI composite score</td>
<td>5.5 ± 1.7</td>
<td>5.7 ± 1.7</td>
<td>5.3 ± 1.7</td>
<td>0.157</td>
</tr>
<tr>
<td>WIfI composite score ≥5, n (%)</td>
<td>173 (67.3)</td>
<td>98 (70.0)</td>
<td>75 (64.1)</td>
<td>0.316</td>
</tr>
<tr>
<td>Wound location</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forefoot wounds, n (%)</td>
<td>190 (73.0)</td>
<td>104 (74.3)</td>
<td>86 (73.5)</td>
<td>0.887</td>
</tr>
<tr>
<td>Pressure area wounds, n (%)</td>
<td>40 (15.6)</td>
<td>21 (15.0)</td>
<td>19 (16.2)</td>
<td>0.785</td>
</tr>
</tbody>
</table>

Rate of wound healing

$P = 0.003$

59.3%  

Time after treatment (months)

<table>
<thead>
<tr>
<th>Interval (months)</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>9</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAA group (n= 140) at risk</td>
<td>140</td>
<td>99</td>
<td>75</td>
<td>65</td>
<td>52</td>
</tr>
<tr>
<td>%</td>
<td>0.0</td>
<td>28.3</td>
<td>43.8</td>
<td>49.9</td>
<td>59.3</td>
</tr>
<tr>
<td>Non-PAA group (n= 117) at risk</td>
<td>117</td>
<td>88</td>
<td>79</td>
<td>72</td>
<td>68</td>
</tr>
<tr>
<td>%</td>
<td>0.0</td>
<td>24.1</td>
<td>31.0</td>
<td>36.3</td>
<td>38.1</td>
</tr>
</tbody>
</table>

$P = 0.003$

365 days

211 days
Factors of Wound healing

Nonambulatory
HR: 2.02 (1.12-3.61)

Depth of wounds
HR: 3.24 (1.74-6.04)

Daily hemodialysis
HR: 2.89 (1.60-5.22)

Pedal angioplasty
HR: 0.43 (0.23-0.78)

Risk-stratification: DH-score

Delayed wound healing score (DH-score) was evaluated

DH-score 0
Low-risk population (n=28)

DH-score 1 - 2
Moderate-risk population (n=196)

DH-score 3
High-risk population (n=33)

WHR in low-risk population

WHR in moderate-risk population


P = 0.001

59.3%

33.9%
WHR in high-risk population

Summary of RENDEZVOUS registry

• PAA showed its positive effect on wound-healing

• PAA is recommended in the moderate-risk population

• However, in the high-risk population, PAA could not show its efficacy.

Take home message
Let us remember the past...
Let us continue the challenges
experiences will become evidences
Let us imagine the future
Trailblazing effort will open the Door of the future of CLI treatment
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