Aggressive revascularization strategy for patients with CLI

Current status of below-the-ankle, pedal intervention

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on behalf of the RENDEZVOUS registry investigators

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- Owner of a healthcare company: None
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Pedal revascularization

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

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Department of Cardiology, Miyazaki Medical Association Hospital, Miyazaki City, Japan

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

Key issue of “aggressive” strategy

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

Improve the rate of wound healing

Adjunctive pedal intervention

Improve the rate of wound healing
**Exceptional wound healing rate**

- **PAA(+) 92.9%**
- **PAA(-) 59.7%**

**Time to wound-healing**

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

\[ p \text{ value} = 0.05 \]

<table>
<thead>
<tr>
<th>Months</th>
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<th>6</th>
<th>9</th>
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<td><strong>PAA(+) at risk</strong></td>
<td>14</td>
<td>7</td>
<td>3</td>
<td>1</td>
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Discrepancy of rate of LS and WH

What does this “reality” mean?
Incomplete wound healing

Serious clinical problem
Freedom from major amputation

It’s only a **first step** of the management of CLI patients.
What should we do?

Evidences from trials

Experiences in daily practice
Accumulation of experiences

Severe pedal disease = poorer clinical outcomes
Result of latest clinical trials

Nonambulatory, Low Alb, Rutherford 6, Infection, Angiosome indirect EVT, Poor pedal artery run-off

Diabetes, Infection, Poor pedal artery run-off

Shiraki T, et al. EJEVS 2015; 49, 565-73
Kawarada O, et al, CCI 2012; 80: 861-71
Pedal artery revascularization...
Exceptional wound healing rate

**Time to wound-healing**

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

*P*=0.05

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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 study

- **Number of patients**
  - 257 patients (257 limbs)

- **Comparison group study**
  - Pedal artery angioplasty (PAA) demonstrated or not

PAA group vs Non-PAA group

Outcomes

- Primary outcome
  - Wound healing rate @ 1yr
    (& time to wound healing)

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

## Patients’ backgrounds

<table>
<thead>
<tr>
<th></th>
<th>Overall (n=257)</th>
<th>PAA group (n=140)</th>
<th>Non-PAA group (n=117)</th>
<th>P value</th>
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</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>
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<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></td>
<td></td>
<td></td>
<td>0.070</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>
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<td>Regular hemodialysis, n (%)</td>
<td>160 (62.3)</td>
<td>89 (63.6)</td>
<td>71 (60.7)</td>
<td>0.634</td>
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<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>
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<tr>
<td>Previous stroke, n (%)</td>
<td>69 (26.8)</td>
<td>34 (24.3)</td>
<td>35 (29.9)</td>
<td>0.311</td>
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<tr>
<td>Albumin&lt;3.0 g/dL, n (%)</td>
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<td>0.235</td>
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### Target limbs status

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<tr>
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<th>Overall (n=257)</th>
<th>PAA group (n=140)</th>
<th>Non-PAA group (n=117)</th>
<th>P value</th>
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<td><strong>Wound Classification</strong></td>
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<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>
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<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>
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<tr>
<td><strong>SVS WIfI classification</strong></td>
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<tr>
<td>WIfI Clinical Stage 4 (high risk), n (%)</td>
<td>163 (63.4)</td>
<td>96 (68.6)</td>
<td>67 (57.3)</td>
<td>0.101</td>
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<tr>
<td>WIfI composite score 5.5 ± 1.7</td>
<td>5.5 ± 1.7</td>
<td>5.7 ± 1.7</td>
<td>5.3 ± 1.7</td>
<td>0.157</td>
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<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>
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<tr>
<td><strong>Wound location</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Forefoot wounds, n (%)</td>
<td>190 (73.9)</td>
<td>104 (74.3)</td>
<td>86 (73.5)</td>
<td>0.887</td>
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<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>

Primary outcomes; Rate of wound healing

Factors of Wound healing

Nonambulatory
HR: 2.02 (1.12-3.61)

UT grade 2 or 3
HR: 3.24 (1.74-6.04)

Daily hemodialysis
HR: 2.89 (1.60-5.22)

Positive influence
HR: 0.43 (0.23-0.78)

Negative influence

Pedal angioplasty

Delayed wound healing score (DH-score) was evaluated.

- **DH-score 0**
  - Low-risked population (n=28)

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

- **DH-score 3**
  - High-risked population (n=33)

Wound healing in moderate-risk population


Rate of wound healing (%)

Time after treatment (months)

$P = 0.001$

59.3%

33.9%
Wound healing in high-risk population


P = 0.477

Rate of wound healing (%)

Time after treatment (months)

29.4%

35.7%
Utilities of DH-scoring system

Low-risk population
Acceptable but controversial

Moderate-risk population
Good indication

High-risk population
Too much treatment

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**.

Final message from my presentation

Let us remember the past
Let us continue the challenges
Let us imagine the future
Let us remember the past...
Let us continue the challenges
experiences will become evidences
Let us imagine the future
Trailblazing effort open the “Door”
Aggressive revascularization strategy for patients with CLI

Current status of below-the-ankle, pedal intervention

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