The reconsideration of evaluation for complex SFA disease by the multidisciplinary modalities

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COI Disclosure

Speaker name:

Masahiko Fujihara, MD

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
Guidelines expand the indication of SFA intervention

3) Eur Heart J. 2011;32:2851-906
4) Eur Heart J. 2017 00, 1–60
Why didn’t use Imaging modality for peripheral intervention?

- **Angiography evaluation**
- **Angiography+IVUS evaluation**
# Imaging modality for peripheral intervention field

<table>
<thead>
<tr>
<th>Modality</th>
<th>Angiography</th>
<th>CTA</th>
<th>IVUS</th>
<th>OCT/OFDI</th>
<th>Angioscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMAGE</td>
<td><img src="image1" alt="Angiography Image" /></td>
<td><img src="image2" alt="CTA Image" /></td>
<td><img src="image3" alt="IVUS Image" /></td>
<td><img src="image4" alt="OCT/OFDI Image" /></td>
<td><img src="image5" alt="Angioscopy Image" /></td>
</tr>
<tr>
<td>resolution(μm)</td>
<td>200</td>
<td>300</td>
<td>80-150</td>
<td>10-20</td>
<td>200</td>
</tr>
<tr>
<td>Radiation Exposure</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Contrast Media</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>+/-</td>
<td>+/-</td>
</tr>
<tr>
<td>Technique</td>
<td>-</td>
<td>-</td>
<td>Easy</td>
<td>So So</td>
<td>Complex</td>
</tr>
<tr>
<td>Calcification</td>
<td>Yes</td>
<td>Yes</td>
<td>Just superficial</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Vessel size</td>
<td>Underestimation</td>
<td>Difficult</td>
<td>Overestimation</td>
<td>Accurate</td>
<td>Difficult</td>
</tr>
<tr>
<td>Long Axis</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (AltaView)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Clinical Question
Could we improve the clinical outcomes depend by years?
Technical and Clinical Success with IVUS

I would like to see a study on the impact of intravascular ultrasound (IVUS) on clinical outcomes after endovascular treatment for symptomatic peripheral artery disease presenting as femoropopliteal lesions. Femoropopliteal revascularization using endovascular treatment is not yet standardized. Despite today's widespread use of stents in clinical practice, some practice guidelines still advise against primary stenting in patients with intermittent claudication due to femoropopliteal lesions. The patency rate after stenting has varied from report to report, and this variation is also seen with other treatment approaches, such as drug treatment and debating. Variation in procedural quality is believed to be a major cause of these interreport discrepancies. It is characteristic of the type of variability that exists in practice.

Now that aggressive femoropopliteal stenting is the most common form of therapy used for TASC II A–C lesions, it is important to understand the clinical impact of IVUS use in FP stenting for TASC II A–C lesions associated with higher primary patency rate.
How to use IVUS for peripheral effectively?

1. Guidewire Passage
   - Wire Passage Route (sub/true)
   - Distal Lumen Area
   - External Elastic Membrane (EEM)

2. Baseline
   - Proximal Lumen Area
   - Minimum Lumen Area (MLA)

3. Decision Making
   - Lesion Characteristics
   - Calcification

4. Confirm result
   - Device Size
   - Post MLA (MSA)
   - Dissection

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Results from ZEPHYR (Zilver PTX) registry

1) Angio: Lesion length ≥ 16 cm
2) IVUS: EEM area ≤ 27 mm²
3) IVUS: MSA ≤ 12 mm²

Risk factors for restenosis

1-year restenosis rate was as low as 15% in cases with none of these risk factors, whereas it reached 51% in those with ≥ 2 risk factors

Masahiko Fujihara MD, Kishiwada Tokushukai Hospital, Osaka, Japan
1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularization through 12 months (adjudicated by a Clinical Events Committee blinded to the assigned treatment)

2. Number at risk represents the number of evaluable subjects at the beginning of the 30-day window prior to each follow-up interval

1. Number at risk represents the number of evaluable subjects at the beginning of the 30-day window prior to each follow-up interval

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Importantly, there was a trend towards improved outcomes in patients whose vessels were evaluated with IVUS pre-procedure.

Iida O, et al. JEVT 2017
Masahiko Fujihara MD, Kishiwada Tokushukai Hospital, Osaka, Japan
DCB procedure need the IVUS guided?

For DCB use, QVA analysis is recommended (Vessel size? Balloon Selection?)

Prox Lumen
EEM $6.2 \times 6.4$ mm
Area 32.1 mm²

Distal Lumen
EEM $5.7 \times 6.0$ mm
Area 27.1
QVA analysis is so vague in clinical setting??

Radiological technician A

B

C

D

Prox RVD
5.28 mm
Distal RVD
3.73 mm

Prox RVD
4.12 mm
Distal RVD
4.57 mm

Prox RVD
5.88 mm
Distal RVD
4.73 mm

Prox RVD
4.53 mm
Distal RVD
5.76 mm
How to evaluate the vessel calcification?
Intra-vascular evaluation

IVUS

OCT

OFDI

Angioscopy

By Special courtesy of Yusuke Tomoi
Kokura Memorial Hospital

Masahiko Fujihara MD, Kishiwada Tokushukai Hospital, Osaka, Japan
Calcification Validation based on PACSS

- **Grade 0**: no visible calcium
- **Grade 1**: Calcification < 5cm Unilateral
- **Grade 2**: Calcification ≥ 5cm Unilateral
- **Grade 3**: Calcification < 5cm Bilateral
- **Grade 4**: Calcification ≥ 5cm Bilateral

Rocha-Singh, Catheterization and Cardiovascular Interventions 2014
Masahiko Fujihara MD, Kishiwada Tokushukai Hospital, Osaka, Japan
Calcium arc assessment based on Calcium Burden Assessment Circumferential grade

0 - None
1 - 0-90°
2 - 91-180°
3 - 181-270°
4 - 271-360°

Fanelli F. Cardiovasc Interventional Radiology 2014
# CODE-study Material and Method

## Study Design

**A multicenter, Cross Sectional investigation (UMIN000023703)**

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Age &gt;20 years old</td>
<td>• CFA, POPA lesions</td>
</tr>
<tr>
<td>• Rutherford category 2-6</td>
<td>• In stent restenosis</td>
</tr>
<tr>
<td>• Successfully EVT for SFA lesions</td>
<td></td>
</tr>
<tr>
<td>• De novo lesions</td>
<td></td>
</tr>
</tbody>
</table>

### Endpoint

Lesion dilatation depend on calcification severity

### Imaging Modality

1. **Fluoroscopy**
2. **Angiography (QVA)**
3. **Intra vascular ultrasound (IVUS)**

<table>
<thead>
<tr>
<th>Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kishiwada Tokushukai Hospital</td>
</tr>
<tr>
<td>Saiseikai Nakatsu Hospital</td>
</tr>
<tr>
<td>Japanese Red Cross Kyoto Daini Hospital</td>
</tr>
<tr>
<td>Shin-Koga Hospital</td>
</tr>
<tr>
<td>Morinomiya Hospital</td>
</tr>
<tr>
<td>Osaka General Medical Center</td>
</tr>
<tr>
<td>Miyazaki Medical Association Hospital</td>
</tr>
</tbody>
</table>
Calcification Validation based on PACSS

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No visible calcium</td>
<td>22%</td>
</tr>
<tr>
<td>1</td>
<td>Grade 1 calcification</td>
<td>20%</td>
</tr>
<tr>
<td>2</td>
<td>Grade 2 calcification</td>
<td>5%</td>
</tr>
<tr>
<td>3</td>
<td>Grade 3 calcification</td>
<td>15%</td>
</tr>
<tr>
<td>4</td>
<td>Grade 4 calcification</td>
<td>39%</td>
</tr>
</tbody>
</table>

Rocha-Singh, Catheterization and Cardiovascular Interventions 2014
M. Fujihara, JEVT accepted
Masahiko Fujihara MD, Kishiwada Tokushukai Hospital, Osaka, Japan
Calcium arc assessment based on Calcium Burden Assessment Circumferential grade

0 - None
1 - 0-90°
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3 - 181-270°
4 - 271-360°

Fanelli F. Cardiovasc Interventional Radiology 2014
M. Fujihara, JEVTA accepted
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22%  16%  23%  18%  23%
Relation between post-procedural MLA and calcification arc more than 180°

<table>
<thead>
<tr>
<th>Calcification Arc</th>
</tr>
</thead>
<tbody>
<tr>
<td>No calcification (n=20)</td>
</tr>
<tr>
<td>&lt;180° calcification (n=46)</td>
</tr>
<tr>
<td>≥ 180° calcification (n=45)</td>
</tr>
</tbody>
</table>

Post-procedural MLA (mm²)

- No calcification: 17.7 [16.4, 19.0]
- <180° calcification: 15.4 [14.6, 16.3]
- ≥ 180° calcification: 12.8 [11.9, 13.7]

P value (vs. non calcification)

- P = 0.006
- P < 0.001

P value (vs. <180° calcification)

- P < 0.001

Adjusted by (Distal vessel area with or without stent implanted)

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The difference between Angio and IVUS evaluation of calcification

- Unilateral Calcification by angio:
  - <180°: 82
  - ≥180°: 18

- Bilateral Calcification by angio:
  - <180°: 62
  - ≥180°: 38

- Calcification by IVUS:
  - <180°: 38
  - ≥180°: 62

M. Fujihara, JEVT accepted
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Clinical Outcomes by vessel calcification severity

Based on circumferential grade

**P=0.018 log-rank**

<table>
<thead>
<tr>
<th>Days</th>
<th>0</th>
<th>180</th>
<th>360</th>
<th>540</th>
<th>720</th>
</tr>
</thead>
<tbody>
<tr>
<td>at risks (None Calc)</td>
<td>28</td>
<td>26</td>
<td>20</td>
<td>18</td>
<td>17</td>
</tr>
<tr>
<td>%</td>
<td>0</td>
<td>8.0</td>
<td>24.0</td>
<td>24.0</td>
<td>26.0</td>
</tr>
<tr>
<td>at risks (Calc&lt;180°)</td>
<td>52</td>
<td>42</td>
<td>35</td>
<td>20</td>
<td>13</td>
</tr>
<tr>
<td>%</td>
<td>0</td>
<td>12.5</td>
<td>27.8</td>
<td>33.3</td>
<td>41.8</td>
</tr>
<tr>
<td>at risks (Calc≥180°)</td>
<td>50</td>
<td>37</td>
<td>25</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>%</td>
<td>0</td>
<td>23.1</td>
<td>39.3</td>
<td>48.9</td>
<td>53.1</td>
</tr>
</tbody>
</table>

Based on PACSS grade

**P=0.138 log-rank**

<table>
<thead>
<tr>
<th>Days</th>
<th>0</th>
<th>180</th>
<th>360</th>
<th>540</th>
<th>720</th>
</tr>
</thead>
<tbody>
<tr>
<td>at risks (PACSS 0)</td>
<td>28</td>
<td>26</td>
<td>20</td>
<td>18</td>
<td>17</td>
</tr>
<tr>
<td>%</td>
<td>0</td>
<td>8.0</td>
<td>24.0</td>
<td>24.0</td>
<td>26.0</td>
</tr>
<tr>
<td>at risks (PACSS 1-2)</td>
<td>32</td>
<td>19.3</td>
<td>20</td>
<td>13</td>
<td>8</td>
</tr>
<tr>
<td>%</td>
<td>0</td>
<td>19.3</td>
<td>33.0</td>
<td>36.7</td>
<td>43.1</td>
</tr>
<tr>
<td>at risks (PACSS 3-4)</td>
<td>70</td>
<td>52</td>
<td>39</td>
<td>23</td>
<td>16</td>
</tr>
<tr>
<td>%</td>
<td>0</td>
<td>18.6</td>
<td>33.9</td>
<td>42.9</td>
<td>49.3</td>
</tr>
</tbody>
</table>

M.Fujihara, JEVT accepted

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• The calcification pattern of symptomatic SFA disease were analyzed
• In our study, 80% of cases showed calcifications
• On either previous reported criteria, 40-55% of patients were classified in severe calcification.
• Calcified lesion showed smaller MLA compared to non-calcified group
• Calcified arc more than 180° by IVUS were related to incomplete expansion and predict the poor clinical outcomes
The limitation of IVUS analysis and need further investigation focus on vessel calcification.

Could we measure the dose of vessel calcification?
In Summary

• IVUS imaging during EVT adds important information by providing controlled measurements of the cross-sectional area of the vessel lumen and wall.

• IVUS is useful in determining the mechanism and efficacy of balloon angioplasty, in guiding atherectomy devices, and in assuring appropriate placement of intravascular stents.

• The incorporation of an IVUS may improve the immediate and long-term results of endovascular interventions by decreasing complications from dissection and perforation.

• Further clinical trials are required to determine which setting deserve routine clinical use.
Why didn’t use imaging modality for SFA intervention?

Angiography evaluation

Angiography+IVUS evaluation
Thank you for your attention

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