Proposal of a new criteria for Calcified SFA disease with multi-modality evaluation - a prospective multi center analysis: CODE study-

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Disclosure

Speaker name:

Mashiko Fujihara

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

• Most of endovascular devices are unable to cope with vessel calcified lesions
• Optimal dilatation is the most important to keep a long term patency
• However, no ideal solutions were made for the treatment of calcified lesions

Balloon angioplasty does not work for calcified lesion
Is there a role for DCB in calcified arteries?

Grade 1
- Little Calcification
- Primary patency: 100%
- Late Lumen Loss: 0.45

Grade 2
- Grade 2a: 100%
- Grade 2b: 90%
- Primary patency: 0.52
- Late Lumen Loss: 0.59

Grade 3
- Grade 3a: 90%
- Grade 3b: 87.5%
- Primary patency: 0.68
- Late Lumen Loss: 0.66

Grade 4
- Grade 4a: 50%
- Grade 4b: 50%
- Primary patency: 0.72
- Late Lumen Loss: 0.75

Fanelli F. Cardiovasc Interventional Radiology 2014
## Current definition of Calcified Lesion

<table>
<thead>
<tr>
<th>Proposed Peripheral Arterial Calcium Scoring System (PACSS)</th>
<th>Calcium Burden Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Journal</strong></td>
<td></td>
</tr>
<tr>
<td>Catheterization and Cardiovascular Intervention 2014</td>
<td>Cardiovasc Interventional Radiology 2014</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td></td>
</tr>
<tr>
<td>Rocha-Singh KJ</td>
<td>Fanelli F</td>
</tr>
<tr>
<td><strong>Length cut off</strong></td>
<td></td>
</tr>
<tr>
<td>Calcium Length</td>
<td>Calcium Length</td>
</tr>
<tr>
<td>$&lt; 5\text{cm} \geq 5\text{cm}$</td>
<td>$&lt; 3\text{cm} \geq 3\text{cm}$</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>Uni/Bilateral</td>
<td>Circ $&gt;90^\circ$</td>
</tr>
<tr>
<td>Intimal</td>
<td>$&gt;180^\circ$</td>
</tr>
<tr>
<td>Medial</td>
<td>$&gt;270^\circ$</td>
</tr>
<tr>
<td>Mixed</td>
<td>$&gt;360^\circ$</td>
</tr>
</tbody>
</table>
Evaluation of Calcification
- Vessel or Lesion calcification-

Calcified vessel with mild stenosis

Mild Calcified vessel with occlusion

Calcified vessel with severe stenosis
Background

• Reported criteria does not fit to heavily calcified real world cases
• Mild calcification were seen in most of the cases
• In patients on hemodialysis, most of the lesion are densely calcified
• We investigated calcified pattern in SFA by using Fluoroscopy, Angiography and Intra vascular ultrasound (IVUS).
# Material and Method

## Study Design

A multicenter, Prospective, Cross Sectional investigation

### Inclusion Criteria

- Age >20 years old
- Rutherford category 2-6
- Successfully EVT for SFA lesions
- de novo lesions

### Exclusion Criteria

- CFA, POPA lesions
- In stent restenosis

### Endpoint

Evaluations of SFA lesion calcification in real world patients

### Imaging Modality

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

### Center

- Kishiwada Tokushukai Hospital
- Saiseikai Nakatsu Hospital
- Kyoto Daini Red Cross Hospital
- Shin-Koga Hospital
- Morinomiya Hospital
- Osaka General Medical Center
- Miyazaki Medical Association Hospital
Evaluation of Calcification by Fluoroscopy and Angiography

Calcification Length by 3 views

Lesion Length
Calcification based on PACSS Criteria

Uni/bilateral Type

Intima/Media/Mixed Type
Evaluation by IVUS

1) Circumferential grade evaluation by calcium arc

Grade 0
None

Grade 1
0-90°

Grade 2
91-180°

Grade 3
181-270°

Grade 4
271-360°

2) Presence of calcified nodule

Fanelli F. Cardiovasc Interventional Radiology 2014
## Patient and Lesion Characteristics

**N=143 cases**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years old)</td>
<td>73.1± 8.5</td>
</tr>
<tr>
<td>Lesion Length (mm)</td>
<td>144.8±86</td>
</tr>
<tr>
<td>Male (%)</td>
<td>66.7</td>
</tr>
<tr>
<td>Ref vessel size (mm)</td>
<td>5.2±1.0</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>93.3</td>
</tr>
<tr>
<td>TASC CD (%)</td>
<td>46.2</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>56.0</td>
</tr>
<tr>
<td>CTO (%)</td>
<td>30.3</td>
</tr>
<tr>
<td>Dyslipidemia (%)</td>
<td>57.3</td>
</tr>
<tr>
<td>BTK run-off</td>
<td>1.4±0.9</td>
</tr>
<tr>
<td>Obesity (%)</td>
<td>22.6</td>
</tr>
<tr>
<td>Current Smoking (%)</td>
<td>36.6</td>
</tr>
<tr>
<td>eGFR (ml/min)</td>
<td>44.8±29.1</td>
</tr>
<tr>
<td>Chronic Kidney Disease (%)</td>
<td>61.0</td>
</tr>
<tr>
<td>Serum Ca (mg/dl)</td>
<td>11.2±18.0</td>
</tr>
<tr>
<td>Hemodialysis (%)</td>
<td>26.7</td>
</tr>
<tr>
<td>Serum P (mg/dl)</td>
<td>4.5±6.1</td>
</tr>
<tr>
<td>Coronary Artery Disease (%)</td>
<td>56.0</td>
</tr>
<tr>
<td>Intact PTH (mg/dl)</td>
<td>90.4±91</td>
</tr>
<tr>
<td>Critical Limb Ischemia (%)</td>
<td>27.0</td>
</tr>
<tr>
<td>Alb (mg/dl)</td>
<td>3.9±0.5</td>
</tr>
<tr>
<td>Rutherford Classification</td>
<td>3.32±1.0</td>
</tr>
</tbody>
</table>
Primary Outcomes

Symptomatic PAOD patients with SFA lesions who succeeded in EVT: 143 patients

- No Calcification Lesion
  - N=27 19.9%

- Calcification Lesion
  - N=116 81.1%

Analysis of calcification
## Primary Outcomes based on PACCS

**Fluoroscopy /Angiography findings**

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcification Length, in SFA (cm)</td>
<td>133.5 ± 90</td>
</tr>
<tr>
<td>Calcification Length, in lesion (cm)</td>
<td>95.5 ± 72</td>
</tr>
<tr>
<td>Lesion length (cm)</td>
<td>159.2 ± 86</td>
</tr>
<tr>
<td>Lesion/Calc in lesion ratio</td>
<td>0.72 ± 0.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral (%)</td>
<td>20.0</td>
</tr>
<tr>
<td>-Intima type (%)</td>
<td>7.8</td>
</tr>
<tr>
<td>-Medial type (%)</td>
<td>22.2</td>
</tr>
<tr>
<td>-Mixed type (%)</td>
<td>70</td>
</tr>
<tr>
<td>Bilateral (%)</td>
<td>80.0</td>
</tr>
</tbody>
</table>
IVUS findings

1) Circumferential Grade Evaluation

2) Presence of calcified nodule

- Grade 0: 20.8%
- Grade 1: 30.7%
- Grade 2: 20.8%
- Grade 4: 27.7%

- 32.4% e.g. Calcified Nodule by Angio and Angioscopy
Calcium Grading by PACSS

- **Grade 1:** Uni, <5cm
- **Grade 2:** Uni, ≥5cm
- **Grade 3:** Bi, <5cm
- **Grade 4:** Bi, ≥5cm

- **Single:**
  - 22% (Mild)
  - 7% (Severe)

- **Bilateral and/or ≥5cm:**
  - 16% (Mild)
  - 52% (Severe)

- **≥50mm:** 59%
- **Bilateral and/or ≥5cm:** 68%

*Rocha-Singh, PACSS, CCI 2014*
Calcium Burden Grading by Fanelli’ Method

- >30mm (Type b) were 89%
- >270-360° were 54%
- Type 2a,3a,4a were not exist
Conclusions

• The calcification pattern of real Japanese patients with symptomatic SFA disease were analyzed
• Vessel calcification does not correlate to lesion
• A various pattern of calcification were seen in stenosis and outside of stenosis
• In our study, 80% of cases showed calcifications
• On either PACSS or Fanelli’ criteria, 55-69% of patients were classified in severe calcifications
• Further analysis will be needed to quantify calcified lesion for best treatment
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