Status of The SPINACH Registry from Japan, Comparing Endo with Open Treatment for CLI

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Nothing to disclose

Background(1)  Demographic changes in Japan

Long-term exposure to diabetes is enhancing vascular disease including peripheral artery as well as renal artery.
Background(2) Demographic changes in Japan

Number of dialysis-dependent patents in Japan

The Japanese Society for Dialysis Therapy

Background(3) Features of Japanese CLI

Demographic differences of patents with CLI

<table>
<thead>
<tr>
<th>Study Name</th>
<th>BASH trial</th>
<th>PREVENT III</th>
<th>OLIVE registry</th>
<th>CRITSCH registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of study</td>
<td>multicenter</td>
<td>RCT</td>
<td>multicenter</td>
<td>multicenter</td>
</tr>
<tr>
<td>Revascularization</td>
<td>Bypass</td>
<td>Bypass</td>
<td>EVT</td>
<td>Bypass vs EVT</td>
</tr>
<tr>
<td>Subject</td>
<td>SLI</td>
<td>CLI</td>
<td>CLI</td>
<td>CLI</td>
</tr>
<tr>
<td>No. Pts</td>
<td>452</td>
<td>1404</td>
<td>314</td>
<td>1200</td>
</tr>
</tbody>
</table>

- Hypertension: 58% vs 82% vs 79%
- Diabetes: 42% vs 64% vs 71% vs 47%
- CAD: 36% vs 48% vs 46% vs 45%
- CVD: 21% vs 28% vs 21% vs 12%
- ESRD on dialys: 10% vs 12% vs 82% vs 9%

The reasons why so many dialysis-dependent patients undergo revascularization.

Data from The Dialysis Outcomes and Practice Patterns Study (DOPPS)


Table 3. Relative risk of mortality by continent

<table>
<thead>
<tr>
<th></th>
<th>Europe</th>
<th>Japan</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR</td>
<td>1.70</td>
<td>1.06</td>
<td>1.00</td>
</tr>
<tr>
<td>HR</td>
<td>3.21</td>
<td>0.84</td>
<td>0.78</td>
</tr>
</tbody>
</table>

Figure 2: Mortality in each DOPPS (Dialysis Outcomes and Practice Patterns Study) country versus the United States by sex


The tissue loss is easy to occur in Japanese CLI patients.

We need evidences how to select revascularization procedure for infrapopliteal arterial lesions with tissue loss.

“SPINACH Registry”

Surgical reconstruction versus peripheral intervention in patients with critical limb ischemia – a prospective multicenter registry in Japan: The SPINACH study design and rationale


Diabetes

Dialysis-dependent CKD

Infrapopliteal arterial lesion with microcirculation disorder.

The tissue loss is easy to occur in Japanese CLI patients.

We need evidences how to select revascularization procedure for infrapopliteal arterial lesions with tissue loss.
Factors affecting decision making process of CLI treatment

**Heterogeneity**

- Ulcer status
- Vascular factors
  - Focal or diffuse lesion
  - Heavy calcification
  - Etiology
  - Quality of vein conduit
- Systemic factors
  - Cardiac risk
  - Renal function
  - Walking ability
  - Life expectancy
  - Wound healing ability
- Social factors
  - Device differences
  - Knowledge and skill of the vascular team
- Rutherford 5 or 6
- Heel gangrene
- Infection

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**Because of such huge heterogeneity of CLI population including very sick patients, we selected prospective observational study rather than RCT.**

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**Distribution of the institutions participating the SPINACH Study**

**PI**: Azuma N. Vascular surgeon

**Co-PI**: Iida O. Interventional Cardiologist

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**Timeline for evaluation after registration**

- Enrollment/prior to revascularisation
- Immediately after revascularisation
- FU 1month
- FU 3month
- FU 6month
- FU 12month
- FU 24month
- FU 36month

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**Number of Registered Patients**

- Overall
- Endovascular treatment
- Bypass surgery*
- Non-revascularization

* Including hybrid revascularization and some endarterectomy

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**Data at registration**

**Patients Characteristics**

- **n = 559**
- Male sex: 575 (67%)
- Age (years): 73.4 ± 10
- Non-ambulatory status before CLI onset: 145 (26%)
- Smoking: 85 (16%)
- Diabetes mellitus: 407 (72.9%)
- Hypertension: 469 (87.9%)
- Dyslipidemia: 394 (70.7%)
- History of ischemic heart disease: 228 (41%)
- History of stroke: 132 (23.5%)
- Regular antidiabetic: 209 (37.9%)
- Bilateral CLI: 104 (19%)**

*Diabetic classification:*

- Category 4: 88 (16%)
- Category 5: 346 (65.9%)
- Category 6: 106 (19%)

Data are the mean ± SD or numbers (percentage).

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Patients Characteristics

![Graph showing percentages of patients treated surgically or endovascularly for Diabetes mellitus and ESRD on dialysis.]

Data at registration

- Patients with Diabetes mellitus: 65% surgical, 35% endovascular
- Patients on ESRD on dialysis: 91% surgical, 9% endovascular

Timeline for evaluation after registration:

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- FU 6 months
- FU 12 months
- FU 24 months
- FU 36 months

Main Outcome Measures

**Primary Endpoint**
Amputation-free survival at 36 months

**Secondary Endpoint**
- Freedom from MALE+POD
- Initial success rate
- Hemodynamic status of revascularized limb
- Time to ulcer healing
- Reintervention rate
- Patency rate at 36 months
- Survival at 36 months
- Freedom from MACE at 36 months
- Freedom from major amputation at 36 months
- Quality of life (Short form 36, VascuQOL)

Conclusions

The SPINACH registry will explore the current clinical outcomes of CLI treatment in real world setting in Japan, which will fill the gap of current evidences and guide vascular specialists to treat patients having infrapopliteal arterial lesions with tissue loss due to diabetes and renal failure.