Critical limb ischemia: 1-year results of the Critisch registry

Arne Stachmann
Department of Vascular and Endovascular Surgery
University of Münster and St. Franziskus Hospital Münster
Email: arne.stachmann@ukmuenster.de
Disclosure

Speaker name: Arne Stachmann

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
Key issues of the study

- First-line treatment strategies in CLI patients
- Prospective, monitored registry
- ‘Real-world’ data and consecutive patients
- All current endovascular technologies included
Overview

27 Vascular centers of excellence

Sponsors
DGG, DIGG

Recruitment time
20 months
01/2013-09/2014

1200 consecutive CLI patients (Rutherford 4-6)

First-line treatments
- Endovascular
- Bypass surgery
- CFA patchplasty
- No vascular intervention
  - Conservative
  - Major amputation

Multicentre prospective interdisciplinary registry
Study design

Critical limb ischemia lasting > 2 weeks
Rutherford stages 4 to 6

Excluded patients (n=59)

- Admission through ICU
- Inability to provide informed consent or dementia
- Denial of inclusion in the registry
- Admission to another ward

Exclusion criteria:
1. Acute limb threatening ischemia
2. Isolated interventions at the aorto-iliac segment
3. Bone fractures in relevant areas
4. Non-atherosclerotic disease

Informed consent
Eligibility for inclusion

n=1200 patients

CRITISCH Registry

Decision for type of treatment by the responsible physician (best treatment option)

Group I
Endovascular therapy
n=642 patients

Group II
Bypass surgery
n=284 patients

Group III
Patchplasty
n=126 patients

Group IV
No vascular intervention
n=126 patients

Group IVa
Conservative treatment
n=118 patients

Group IV
Primary amputation
n=30 patients
### characteristics and demographics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group I endovascular</th>
<th>Group II bypass</th>
<th>Group III patchplasty</th>
<th>Group IV Conservative</th>
<th>Group V Primary amputation</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number</td>
<td>642 (53.5%)</td>
<td>284 (23.7%)</td>
<td>126 (10.5%)</td>
<td>118 (9.8%)</td>
<td>30 (2.5%)</td>
<td>&lt;0.001a</td>
</tr>
<tr>
<td>Median age (years)</td>
<td>75</td>
<td>73</td>
<td>72</td>
<td>76</td>
<td>72.5</td>
<td>&lt;0.001b</td>
</tr>
<tr>
<td>Males</td>
<td>405 (63%)</td>
<td>192 (68%)</td>
<td>78 (62%)</td>
<td>74 (63%)</td>
<td>19 (63%)</td>
<td>0.705a</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>298 (46%)</td>
<td>118 (42%)</td>
<td>60 (48%)</td>
<td>54 (46%)</td>
<td>15 (50%)</td>
<td>0.648a</td>
</tr>
<tr>
<td>Previous acute coronary syndrome &lt; 6 months</td>
<td>25 (4%)</td>
<td>17 (6%)</td>
<td>2 (2%)</td>
<td>5 (4%)</td>
<td>3 (10%)</td>
<td>0.148a</td>
</tr>
<tr>
<td>CKD (60&lt;eGFR&lt;15)</td>
<td>251 (39%)</td>
<td>86 (30%)</td>
<td>29 (23%)</td>
<td>46 (39%)</td>
<td>12 (40%)</td>
<td>0.002a</td>
</tr>
<tr>
<td>ESRD (eGFR&lt;15)</td>
<td>65 (10%)</td>
<td>13 (5%)</td>
<td>11 (9%)</td>
<td>10 (8%)</td>
<td>3 (10%)</td>
<td>0.096a</td>
</tr>
<tr>
<td>Diabetes</td>
<td>310 (48%)</td>
<td>136 (48%)</td>
<td>43 (34%)</td>
<td>54 (46%)</td>
<td>19 (63%)</td>
<td>0.016a</td>
</tr>
<tr>
<td>Obesity (BMI &gt; 30 kg/m²)</td>
<td>93 (14%)</td>
<td>40 (14%)</td>
<td>19 (15%)</td>
<td>15 (13%)</td>
<td>4 (13%)</td>
<td>0.986a</td>
</tr>
<tr>
<td>Previous vascular intervention</td>
<td>251 (39%)</td>
<td>139 (49%)</td>
<td>40 (32%)</td>
<td>57 (48%)</td>
<td>13 (43%)</td>
<td>0.004a</td>
</tr>
<tr>
<td>Previous stroke/TIA</td>
<td>73 (11%)</td>
<td>31 (11%)</td>
<td>17 (13%)</td>
<td>14 (12%)</td>
<td>9 (30%)</td>
<td>0.040a</td>
</tr>
<tr>
<td>Current smoking</td>
<td>94 (15%)</td>
<td>89 (31%)</td>
<td>31 (25%)</td>
<td>16 (14%)</td>
<td>6 (20%)</td>
<td>&lt;0.001a</td>
</tr>
</tbody>
</table>
In Hospital Outcomes

Risk factors for death and/or amputation

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery disease</td>
<td>2.96</td>
</tr>
<tr>
<td>Acute coronary syndrome &lt; 6 months</td>
<td>3.67</td>
</tr>
<tr>
<td>ESRD (Dialysis or GFR&lt;15)</td>
<td>3.31</td>
</tr>
<tr>
<td>Chronic kidney disease (Stage 3-4)</td>
<td>6.34</td>
</tr>
<tr>
<td>Bypass surgery</td>
<td>3.34</td>
</tr>
</tbody>
</table>

One-year results

Questions

• Effectiveness of each strategy *(Criterion: OPG)*
• Role of statins and BMT
• Risk factors for amputation/death
**Table Vb.** Summary of efficacy outcomes (one year) for overall CLI cohort and suggested OPG for each endpoint

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Point (95% CI)</th>
<th>Efficacy OPG</th>
</tr>
</thead>
<tbody>
<tr>
<td>MALE + POD</td>
<td>76.9% (74.0-79.9)</td>
<td>71%</td>
</tr>
<tr>
<td>AFS</td>
<td>76.5% (73.7-79.5)</td>
<td>71%</td>
</tr>
<tr>
<td>RAS</td>
<td>46.5% (42.3-51.2)</td>
<td>39%</td>
</tr>
<tr>
<td>RAO</td>
<td>61.3% (58.0-64.9)</td>
<td>55%</td>
</tr>
<tr>
<td>Limb salvage</td>
<td>88.9% (86.7-91.1)</td>
<td>84%</td>
</tr>
<tr>
<td>Survival</td>
<td>85.7% (83.3-88.1)</td>
<td>80%</td>
</tr>
</tbody>
</table>

Endovascular therapy

Amputation-free survival

Rutherford

75% @ 1y

*P< .0001

> 71%

OPG
Bypass surgery

Amputation-free survival

Rutherford

> 71% OPG

72% @ 1y

*P< .0001
CFA-patchplasty

Amputation-free survival

Rutherford

> 71%

OPG

73% @ 1y

*P< .0001

PREOP

FU

1/2

66%

4 5 6

4 5 6

37% 42% 21%

13% 4% 10% 7%
No vascular Intervention

Amputation-free survival

Rutherford

> 71% OPG

72% @ 1y

*P < .0001
Primary major amputation

Survival probability (%)

Time (in months)

Number at risk

57% @ 1y

> 71%

OPG
Best medical treatment

Statins

Statins at discharge

58%
# Risk factors for amputation/death

Hazard Ratios and 95% confidence intervals, estimated by multivariate Cox regression models

<table>
<thead>
<tr>
<th>Group I: Endovascular revascularization</th>
<th>Hazard Ratio of AFS</th>
<th>95% confidence interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CKD</td>
<td>1.54</td>
<td>1.16 - 2.06</td>
<td>0.003</td>
</tr>
<tr>
<td>Rutherford 6</td>
<td>1.93</td>
<td>1.39 - 2.69</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AROV</td>
<td>1.28</td>
<td>0.94 - 1.73</td>
<td>0.117</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group II: Bypass surgery</th>
<th>Hazard Ratio of AFS</th>
<th>95% confidence interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CKD</td>
<td>2.17</td>
<td>1.39 - 3.40</td>
<td>0.001</td>
</tr>
<tr>
<td>Dacron/PTFE/other graft</td>
<td>1.86</td>
<td>1.17 - 2.94</td>
<td>0.008</td>
</tr>
<tr>
<td>Bypass above knee</td>
<td>0.29</td>
<td>0.14 - 0.60</td>
<td>0.001</td>
</tr>
<tr>
<td>PVI</td>
<td>1.50</td>
<td>0.95 - 2.39</td>
<td>0.083</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group III: FAP</th>
<th>Hazard Ratio of AFS</th>
<th>95% confidence interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CKD</td>
<td>1.93</td>
<td>0.94 - 3.93</td>
<td>0.072</td>
</tr>
<tr>
<td>TASC II C/D</td>
<td>2.70</td>
<td>1.02 - 7.19</td>
<td>0.046</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.40</td>
<td>0.18 - 0.88</td>
<td>0.023</td>
</tr>
<tr>
<td>AROV</td>
<td>1.86</td>
<td>0.89 - 3.88</td>
<td>0.098</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group IV: Conservative treatment</th>
<th>Hazard Ratio of AFS</th>
<th>95% confidence interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CKD</td>
<td>3.13</td>
<td>1.48 - 6.60</td>
<td>0.003</td>
</tr>
<tr>
<td>Rutherford 6</td>
<td>2.02</td>
<td>0.95 - 4.27</td>
<td>0.067</td>
</tr>
</tbody>
</table>

**CKD** – chronic kidney disease  
(< 60 mL/min/1.73 m² or dialysis)  
**AROV** – absence of run-off vessels  
**PVI** – previous vascular intervention
Conclusions

- When physicians are free to individualize CLI therapy, all first-line treatment options reached the OPG for AFS.

- **CKD** risk factor for amputation/death in all groups.

- **Statins** led to higher survival rate in all patients, however, only 58% with statins at discharge.
Thank you

CRITISCH Collaborators:

T. Schmitz-Rixen, MD, (Frankfurt), M. Steinbauer, MD, (Regensburg), H.H. Eckstein, MD (München), W. Lang, MD (Erlangen), H. Schelzig, MD, (Düsseldorf), H.J. Florek, MD, (Freital), M. Storck, MD, (Karlsruhe), B. Weis-Müller, MD, (Mönchengladbach), D. Böckler, MD, (Heidelberg), A. Billing, MD, (Offenbach), T. Hupp, MD, (Stuttgart), S. E. Debus, MD, (Hamburg), M. Spohn, MD, (Bamberg), H. Reinecke, MD, (Muenster), C. Schlensack, MD, (Tübingen), W, Klonek, MD, (Cloppenburg), H. Wenk (Bremen), R.G. Ritter, MD, (Bielefeld), K.L. Schulte, MD, (Berlin), T. Keck, MD (Lübeck), K. Balzer, MD, (Bonn), B. Mühling, MD, (Biberach), F. Adili, MD (Darmstadt), T. Zeller, MD (Bad Krozingen)
Critical limb ischemia: 1-year results of the Critisch registry

Arne Stachmann
Department of Vascular and Endovascular Surgery
University of Münster and St. Franziskus Hospital Münster
Email: arne.stachmann@ukmuenster.de