First-line treatment strategies in patients with critical limb ischemia: 1-year outcomes from the CRITISCH registry

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Disclosures

Speaker name:

Theodosios Bisdas, 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
Overview

27 vascular centres of excellence

Sponsors
DGG, DIGG

Recruitment phase
20 months
01/2013-09/2014

First-line treatment strategies
• Endovascular
• Bypass surgery
• CFA patchplasty
• No vascular intervention
  • Conservative
  • Primary amputation

1200 consecutive CLI patients (Rutherford 4-6)
Selected endpoints

- Major amputation and/or death (composite endpoint)
- Major adverse limb event (MALE: major amputation and/or any reintervention)
- Clinical improvement (Rutherford)
- Risk factors (multivariate logistic regression analysis)

In-hospital outcomes

Current practice of first-line treatment strategies in patients with critical limb ischemia

Theodoreos Biedas, MD, 2 Matthias Burrows, PhD, 1 and Giorgio Torella, MD, 1 for the First-Line Treatments in Patients With Critical Limb Ischemia (CRITICS) Collaborative, Munich, Germany

Objective Critical limb ischemia (CLI) is growing in global prevalence and is associated with high rates of limb loss and mortality. However, a relevant gap of evidence about the most optimal treatment strategy still exists. The aim of this study was to assess the current practice of all first-line treatment strategies in CLI patients in German vascular centers (ER), bypass surgery (BS), femoropopliteal artery bypass grafting (FAP), conservative treatment, and primary amputation or death, or both, during the hospital stay. Secondary outcomes were hematoma formation, infections, and re-intervention. Unevacuated study centers were additionally built to receive. The study included 1200 consecutive patients. First-line treatment choice was ER in 641 patients (53.4%), BS composite and proximal was not in 24 patients (3.3% after ER, in 0.7% after BS, in 0% after FAP, and 9% after primary amputation. After treatment, the 6-month mortality rate was 3.5% after ER, 0.7% after BS, in 0.3% after FAP, and 5% after primary amputation. The 6-month survival rate was 99.4% after ER, 98.9% after BS, in 97.5% after FAP, and 94.7% after primary amputation, and 0% if death and BS combined for ER (OR 3.56, 95% CI 1.57-8.08) and for BS 3.56 for ER (OR 3.27, 95% CI 1.25-8.40) and for BS 3.56 for ER (OR 3.27, 95% CI 1.25-8.40) and for BS 3.56 for ER (OR 3.27, 95% CI 1.25-8.40) and for BS 3.56 for ER (OR 3.27, 95% CI 1.25-8.40) and for BS 3.56 for ER (OR 3.27, 95% CI 1.25-8.40). Conclusion: The CRITICS registry revealed ER as the most common first-line approach in CLI patients. Coronary artery disease and FAP are independent risk factors for the composite end point. Special attention should be paid to CLI patients with renal insufficiency without diabetes (OR 3.56, 95% CI 1.25-8.40)

Critical limb ischemia (CLI) is the most severe form of peripheral arterial vascular disease and remains a substantial cause of death and health care costs. The 6-month mortality rate was 20%, and the inpatient hospital treatment averaged €20,000 at 1 year. In the PAD Awareness, Risk, and Treatment: New Resources for Survival (PARTNERS) study, which included patients aged 50 to 70 years with history of smoking or diabetes, the overall proportion of CLI patients was 29%. Considering the time prevalence and the metabolic syndrome is growing in global prevalence, the clinical and socioeconomic effect of the disease will be magnified in the future.

Nevertheless, there is still a relevant lack of evidence for the most optimal treatment strategies in CLI. This can be explained due to the involvement of different disciplines, the lack of high-level evidence, and the rapid material evolution to the endovascular techniques. The first randomized endovascular angioplasty in severe ischemia of the legs (RASIL-2) and Femoropopliteal vs Endovascular surgery in Patients With Critical Limb Ischemia (BEST-CLI) trial are anticipated after 2015, and whether their results will cover all aspects of the disease remains unknown.

At present, the durability of the endovascular approach in CLI patients is a matter of debate, and a current meta-analysis review stressed that the endovascular approach is not inferior to bypass surgery (BS) for limb salvage in those patients. Hence, decision making depends on the patient's expertise, and little is known about which approach accounts for the first-line treatment strategies in CLI patients among the vascular centers.
Amputation-free survival @ 1 year
Overall cohort

OVERALL
74%

RUTHERFORD 4
78%

RUTHERFORD 5
72%

RUTHERFORD 6
70%
Endovascular-first

- Amputation-free survival: 75% @ 1y
- MALE-free probability: 54% @ 1y

<table>
<thead>
<tr>
<th>Rutherford stages</th>
<th>Preop</th>
<th>FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/2</td>
<td>22%</td>
<td>8%</td>
</tr>
<tr>
<td>3</td>
<td>20%</td>
<td>4%</td>
</tr>
<tr>
<td>4</td>
<td>21%</td>
<td>3%</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*P < .0001
Bypass surgery-first

Amputation-free survival

MALE-free probability

Rutherford stages

71% @ 1y

49% @ 1y

*P < .0001

Number at risk

284 191 133 48 23

1/2 3 4 5 6

PREOP

FU

25% 25%

4

5

6

10%

15%

4%
CFA patchplasty

Amputation-free survival

MALE-free probability

Clinical improvement

74% @ 1y

58% @ 1y

*P < .0001

PREOP:
- 37%
- 42%
- 5

FU:
- 21%
- 6
- 1/2
- 3
- 4
- 5
- 6

Amputation-free survival

Number at risk:
- 126
- 90
- 66
- 29
- 17

Clinical improvement

Number at risk (in months):
- 0
- 6
- 12
- 18
- 24

MALE-free probability (in months): 126, 74, 55, 23, 12

Clinical improvement (in months): 1, 2, 3, 4, 5, 6
No vascular intervention
Conservative treatment

Amputation-free survival

MALE-free probability

Clinical improvement
Primary amputation
Survival @ 1 year

Survival probability (%)

Time (in months)

Number at risk
30 15 13 11 7

57% @ 1y
Risk factors for amputation and/or death @ 1 year

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>HR</th>
<th>95%CI (lower)</th>
<th>95%CI (upper)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender</td>
<td>1.28</td>
<td>0.97</td>
<td>1.69</td>
<td>0.083</td>
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<tr>
<td>Diabetes</td>
<td>1.31</td>
<td>1.01</td>
<td>1.69</td>
<td>0.038</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>1.61</td>
<td>1.22</td>
<td>2.12</td>
<td>0.001</td>
</tr>
<tr>
<td>Dialysis</td>
<td>2.57</td>
<td>1.75</td>
<td>3.77</td>
<td>0</td>
</tr>
<tr>
<td>Acute coronary syndrome &lt; 6 months</td>
<td>1.5</td>
<td>0.9</td>
<td>2.5</td>
<td>0.08</td>
</tr>
</tbody>
</table>

No difference between endo and open repair
Statins and amputation-free survival

Only 58% of CLI-patients received statins at discharge
Conclusions

• The first-line treatment strategies, as they were selected, led to amputation-free survival > 70% @ 12 months

• Primary amputation showed the lowest survival rate (57%)
  – Future research should focus on improving selection criteria and risk-factor management for each CLI patient

• Statins increased AFS rate in CLI patients

• Cohorts at higher risk after 12 months:
  – Male gender / Diabetes / CKD / Dialysis /Previous ACS
Thank you!

CRITISCH Collaborators:

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