Critical Limb Ischemia: Optimal care, an interdisciplinary challenge

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Disclosure

Speaker name: Markus Haumer, 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
## Peripheral Arterial Disease Grading of Severity

<table>
<thead>
<tr>
<th>Fontaine Stage</th>
<th>Rutherford Category</th>
<th>Ankle Pressure</th>
<th>Ankle Brachial Index</th>
<th>Asympt.</th>
<th>Claudication</th>
<th>Critical Limb Ischemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0</td>
<td>140</td>
<td>0.9</td>
<td>Asympt.</td>
<td>Claudication</td>
<td>Critical Limb Ischemia</td>
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<td>1</td>
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<td>IIb</td>
<td>2</td>
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<tr>
<td>III</td>
<td>4</td>
<td>50</td>
<td>(70)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>5</td>
<td></td>
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<tr>
<td></td>
<td>6</td>
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</table>
### Critical Limb Ischemia Definitions

#### Fontaine Stage

<table>
<thead>
<tr>
<th>III</th>
<th>IV</th>
</tr>
</thead>
</table>

#### Rutherford Clinical Category

<table>
<thead>
<tr>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ischemic Rest Pain</strong>&lt;br&gt; Ankle pressure &lt;70mmHg&lt;br&gt; Toe pressure &lt;50mmHg&lt;br&gt; $\text{TcPO}_2$ &lt;40mmHg&lt;br&gt; Skin perfusion pressure &lt;40mmHg</td>
<td><strong>Ischemic Ulceration</strong>&lt;br&gt; Ankle pressure &lt;50mmHg&lt;br&gt; Toe pressure &lt;30mmHg&lt;br&gt; $\text{TcPO}_2$ &lt;20mmHg&lt;br&gt; Skin perfusion pressure &lt;30mmHg</td>
<td><strong>Ischemic Gangrene</strong>&lt;br&gt; Ankle pressure &lt;50mmHg&lt;br&gt; Toe pressure &lt;30mmHg&lt;br&gt; $\text{TcPO}_2$ &lt;20mmHg&lt;br&gt; Skin perfusion pressure &lt;30mmHg</td>
</tr>
</tbody>
</table>

**Consensus Definitions from Peripheral Academic Research Consortium (PARC)**

Critical Limb Ischemia
Definition and Perspective

**Definition**

- Critical limb ischemia (CLI) is equated with a need for limb salvage.

**Perspective**

- Arterial reconstruction and / or major amputation are the therapies ultimately available to such patients.
Critical Limb Ischemia
Definition and Perspective

Definition
• Critical limb ischemia (CLI) is equated with a need for limb salvage.

Perspective
• Arterial reconstruction and/or major amputation are the therapies ultimately available to such patients.

The goal is clear: KEEP THE FOOT IN THE SHOE
Treatment of Critical Limb Ischemia
Network of Aims and Options

Survival
Death

Quality of Life

Limb Salvage

ABI
Treatment of Critical Limb Ischemia
Network of Aims and Options

- Revascularisation
- Wound Management
- Best Medical Treatment
- Survival
- Death
- Quality of Life
- Limb Salvage
- ABI
Treatment of Critical Limb Ischemia
Network of Aims and Options

- Survival vs Death
- Quality of Life
- ABI
- Revascularisation
- Wound Management
- Best Medical Treatment
- Limb Salvage
Treatment of Critical Limb Ischemia Guidelines

I

Lifestyle Modification

IIa

Best Medical Treatment

IIb

Exercise

III

Revascularisation

IV

Prostanoids

Local Therapy, Control of Infection, Amputation
Treatment of Critical Limb Ischemia Guidelines

- Pain Control
- Treatment of Infection
- Revascularisation
- Wound-Management
- Risk-Modification
- Prostanoids, Amputation

Management of critical limb ischaemia

- Rest pains
- Ischaemic lesion, gangrene

Urgent revascularisation

- Feasible
  - Endovascular revascularisation
- Unfeasible
  - Technical failure, endovascular revascularisation unsuitable
  - Surgical revascularisation

Clinical and non-invasive assessment of haemodynamic result (Table 1)

- Favourable
  - Control CVD risk factors, debridement, shoe adaptation (removal of weight-bearing stress to lesion), surveillance
- Unfavourable
  - Prostaglandins, consider spinal cord stimulation

Amputation, rehabilitation
Footulcers in Diabetic Patients

Delivery of Care in Daily Practice in Europe

Referral
6-55% late referral (i.e. >3 months) to a dedicated foot clinic

Pressure off-loading
0–68% casting in plantar fore- or midfoot ulcers

Vascular imaging
14-68% in patients with ABPI <0.5 or persistent ulcer (i.e. >1yr) or after major amputation; revascularization in 43%.
Critical Limb Ischemia
Still poor outcomes and lack of guideline adherence

Primary Amputation is still common!

Retrospective data (2009-2011) from largest German healthcare provider
41,882 hospitalisations due to PAD
49% Critical Limb Ischemia (n=20,685)
10% Amputations (n=4,298)

Revascularisation in 11% technically not feasible?
44% „Too late or too sick“?

Critical Limb Ischemia

Time Issues

Acute limb ischemia, dissection, hemorrhage, infarction and stroke are emergencies.

Chronic critical limb ischemia is an urgency.

„Time is tissue.“
„Helping fast is helping twice.“

Keep patients on a fast track for vascular imaging and (repeat-) revascularization.
Critical Limb Ischemia
Time Issues

Timeline

• Development of clinical disease: days / years
Critical Limb Ischemia
Time Issues

Timeline

- Development of clinical disease: days / years
- Patient care / Wound care: weeks / months
Critical Limb Ischemia

Time Issues

Timeline

- Development of clinical disease: \textit{days / years}
- Patient care / Wound care: \textit{weeks / months}
- Hemodynamic evaluation, vascular imaging and revascularisation: \textit{minutes / hours}

Consider repeat-imaging and -intervention!
Critical Limb Ischemia
An Interdisciplinary Approach

Interdisciplinary Core
- Vascular medicine physicians
- Interventional cardiologists
- Interventional radiologists
- Vascular surgeons

~80% of 120 (140) sites enrolling in BEST-CLI Trial have multidisciplinary CLI Teams [Endovascular Today 11/2015]

Complementary Disciplines
- Podiatrist, wound manager, diabetologist; microbiologist, plastic / orthopedic surgeon, prosthetist...

Attendees @ LINC 2016 (n ~ 5,000)
Critical Limb Ischemia
An Interdisciplinary Approach

Perfusion

Probability of Healing

„Flow-Team“

„Whole Patient-Team“

„Toe-Team“

NURSES AND TECHNICIANS

Teamwork matters

- Even an excellent revascularisation can be futile if it is not embedded in an optimal environment of patient care and follow-up.

Sisyphos at work
Critical Limb Ischemia
An Interdisciplinary Approach

A chain is only as strong as its weakest link!

• The patient is in a weak position!
• The patient needs a dedicated case-manager!
• The case-manager needs a dedicated team!
• Communicate!
• If needed, every good team-player can be a good team-leader!
• Enforce the team; if necessary, expand the team!
Critical Limb Ischemia
An Interdisciplinary Approach

Identification of CLI

- Suspicion of ischemia
- Hemodynamic evaluation
- Anatomical evaluation
Critical Limb Ischemia
An Interdisciplinary Approach

Identification of CLI
- Suspicion of ischemia
- Hemodynamic evaluation
- Anatomical evaluation

Identification of comorbidities
- Contributors to tissue loss
  - Diabetes, neuropathy, infection, vessel pathology, malnutrition...
- Contributors to strategy
  - CAD; CHD; HTN; HLP; CVD; CKD
Critical Limb Ischemia
Diagnostic Approach

- ABI
- Toe Pressure
- TcPO$_2$
- SPP
- DUS
- CTA
- MRA
- iaDSA
Critical Limb Ischemia Diagnostic Approach

Very often, vascular imaging is more readily available than adequate hemodynamic assessment. Field evidence, with the exception of the "desert foot," CLI is not defined by angiograms.

Critical Limb Ischemia
Critical Limb Ischemia
Diagnostic Approach

„CLI“, first defined in 1982, was intended to delineate a subgroup of patients with a threatened lower extremity primarily because of chronic ischemia.

Perfusion is only one determinant of outcome.

Risk stratification is based on three major factors that impact amputation risk and clinical management: Wound, Ischemia, and foot Infection (WIfI)

The Society for Vascular Surgery Lower Extremity Ischemia Diagnostic Approach


Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI)

Wound, Ischemia, and foot Infection (WIfI)

Wound, Ischemia, and foot Infection (WIfI)

Major factors that impact amputation risk and clinical management: Wound, Ischemia, and foot Infection (WIfI)

Risk stratification is based on three major factors that impact amputation risk: Wound, Ischemia, and foot Infection.
Critical Limb Ischemia
Non-angiographic Workup

**Rutherford 5**
Ischemic wound
Mild infection

**Rutherford 5 (6?)**
Ischemic toe

**Rutherford 6**
Ischemic limb

Ankle pressure 70mmHg

Ankle pressure >200mmHg
Toe pressure 0 (30) mmHg

Ankle pressure 30mmHg
Toe Pressure 0mmHg
## Critical Limb Ischemia

### Risk stratification according to WIfI

Estimate risk of amputation at 1 year for each combination

<table>
<thead>
<tr>
<th>Ischemia – 0</th>
<th>Ischemia – 1</th>
<th>Ischemia – 2</th>
<th>Ischemia – 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>W-0</td>
<td>L</td>
<td>M</td>
<td>H</td>
</tr>
<tr>
<td>W-1</td>
<td>L</td>
<td>M</td>
<td>H</td>
</tr>
<tr>
<td>W-2</td>
<td>M</td>
<td>H</td>
<td>H</td>
</tr>
<tr>
<td>W-3</td>
<td>H</td>
<td>H</td>
<td>H</td>
</tr>
</tbody>
</table>

Estimate likelihood of benefit of / requirement for revascularization (assuming infection can be controlled first)

<table>
<thead>
<tr>
<th>Ischemia – 0</th>
<th>Ischemia – 1</th>
<th>Ischemia – 2</th>
<th>Ischemia – 3</th>
</tr>
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<tbody>
<tr>
<td>f-0</td>
<td>f-1</td>
<td>f-2</td>
<td>f-3</td>
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<tr>
<td>f-0</td>
<td>f-1</td>
<td>f-2</td>
<td>f-3</td>
</tr>
</tbody>
</table>

W...Wound; I...Ischemia; f...foot Infection; VL...Very Low; L...Low; M...Moderate; H...High
Critical Limb Ischemia
Non-angiographic Workup

Rutherford 5
Ischemic wound
Mild infection

Rutherford 5 (6?)
Ischemic toe

Rutherford 6
Ischemic limb

Ischemic wound
Mild infection

Risk of Amp.: Moderate
Need of Revasc.: Moderate
Ankle pressure 70mmHg

Risk of Amp.: High
Need of Revasc.: High
Ankle pressure >200mmHg
Toe pressure 0 (30) mmHg

Risk of Amp.: High
Need of Revasc.: High
Ankle pressure 30mmHg
Toe Pressure 0mmHg

WIfI 121 / Stage 3

WIfI 320 / Stage 4

WIfI 330 / Stage 4
Critical Limb Ischemia
Validation of risk stratification according to WIFl

Distribution of WIFl clinical stages 1 to 4 among amputation and limb salvage cohorts

Incidence of major amputation and 1-yr amputation-free survival (AFS) among WIFl clinical stages 1 to 4

Critical Limb Ischemia
Cost Issues

Amputation

• There is no evidence for the cost-effectiveness of primary amputation.

• Total hospital cost of distal arterial revascularisation for limb salvage is significantly less than that of primary amputation.
### Chronic Limb Ischemia

**Modification of Risk – Medical Principles**

<table>
<thead>
<tr>
<th>I</th>
<th>IIa</th>
<th>IIb</th>
<th>III</th>
<th>IV</th>
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</thead>
<tbody>
<tr>
<td>Lifestyle Modification</td>
<td></td>
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</tr>
<tr>
<td>Best Medical Treatment</td>
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<tr>
<td><strong>Cumulative Relative Risk-Reduction</strong></td>
<td><strong>RRR</strong></td>
<td><strong>MACE/10a</strong></td>
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<tr>
<td><strong>Therapy</strong></td>
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</tr>
<tr>
<td>∅</td>
<td></td>
<td>40%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>∅ Smoking</td>
<td>50%</td>
<td>20%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antiplatelets</td>
<td>25%</td>
<td>15%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statins</td>
<td>30%</td>
<td>10%</td>
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</tr>
<tr>
<td>LDL-C 100 → 70</td>
<td>20%</td>
<td>8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE-I / ARB</td>
<td>25%</td>
<td>6%</td>
<td></td>
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</tr>
<tr>
<td>β-Blocker</td>
<td>25%</td>
<td>5%</td>
<td></td>
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</tr>
</tbody>
</table>

Fonarow GC et al. Am J Cardiol 2000;85:10A-17A.
Critical Limb Ischemia
Conclusions

Early recognition matters!
Early revascularisation matters!
Teamwork matters!
Keep the foot in the shoe!

- There is only one single case-report of a successful leg-transplantation in the literature!

[The Miracle of Cosmas and Damian]
Nurse and Technician Forum Part II

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