Revascularisation for Claudication: *When is it indicated, when not?*

Markus Haumer  
Landesklinikum Baden-Mödling  
Austria
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
What a claudicant faces

↑ Risk
Adverse Cardiovascular Events Premature Death Limb Loss

↓ Quality
Quality of Life Exertional Leg Pain Role Functioning
Too Much Sitting Increases Mortality Risk


• Evidence shows that sedentary behaviour contributes to
  • All-cause death
  • Cardiovascular death
  • Cancer death
  • Incidence of cardiovascular disease, cancer, and type 2 diabetes

René Magritte (1951) *Perspective I*
Too Much Sitting Increases Mortality Risk


- Minimize the amount of time spent in prolonged sitting
- Break up long periods of sitting as often as possible
- Accumulate 150 to 300 minutes of moderate intensity physical activity or...equal..., each week.
...but Johnny Walker is still alive!
Exertional Leg Symptoms
Comorbidities in Claudicants

→ Lumbar disc disease: 36%
→ Spinal stenosis: 11%
→ Hip arthritis: 4%
→ Knee arthritis: 12%


Is PAD the main driver of symptoms or just a comorbidity?
# Chronic Limb Ischemia Definitions

## Ankle Pressure
- **Stage I**: 140
- **Stage IIa**: 50
- **Stage IIb**: 70

## Chronic Limb Ischemia Definitions
- **Asympt.**: Ankle Brachial Index (ABI) 0.9
- **Claudication**: ABI 0.0
- **Critical Limb Ischemia**: ABI 0.0
### Claudication Definitions

#### Fontaine Stage

<table>
<thead>
<tr>
<th>IIa</th>
<th>IIb</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

#### Rutherford Category

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild Completes treadmill exercise</td>
<td>Moderate Between Categories 1 and 3</td>
<td>Severe Cannot complete treadmill exercise and AP* after exercise &lt;50mmHg</td>
</tr>
<tr>
<td>AP* after exercise &gt;50mmHg but ≥20mmHg lower than resting value</td>
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</tr>
</tbody>
</table>

## Claudication Definitions

<table>
<thead>
<tr>
<th>Fontaine Stage</th>
<th>Rutherford Category</th>
<th>Max. Walking Distance</th>
<th>Quality of Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ila</td>
<td>1</td>
<td>±500m</td>
<td>Happy smile</td>
</tr>
<tr>
<td>Iib</td>
<td>2</td>
<td>±100m</td>
<td>Sad smile</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Events in Claudicants
15 Year Study of 2.777 Veterans

- Mortality rate: 12% per year
  2/3 due to heart disease
- Revascularisation rate: 18% after 10 years
- Minor amputations: <10% after 10 years
- Major amputations: <10% after 10 years

Chronic Limb Ischemia Management – General principles

I   IIa   IIb
Lifestyle Modification

Best Medical Treatment

Exercise

III
Revascularisation

IV
Prostanoids

Local Therapy, Amputation
Treatment of Claudication
Network of Aims and Options

- Survival
- Death
- Quality of Life
- Walking Capacity
- ABI
Treatment of Claudication
Network of Aims and Options

- Supervised Exercise
- Best Medical Treatment
- Revascularisation
Treatment of Claudication
Network of Aims and Options

- Supervised Exercise
- Best Medical Treatment
- Revascularisation
- Survival Death
- Walking Capacity
- Quality of Life
- ABI
Treatment of Claudication
Network of Aims and Options
The relative benefits of these 3 strategies of care are not known because no multicenter clinical trials have directly compared these 3 strategies.

Study of the comparative effectiveness of claudication treatment strategies is in the top 50 of all American health challenges.

Murphy TP et al. *Circulation* 2012;125:130-9
## Modification of Risk

### Lifestyle Modification

<table>
<thead>
<tr>
<th>Therapy</th>
<th>RRR</th>
<th>MACE/10a</th>
<th>Risk Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>50%</td>
<td>20%</td>
<td>40%</td>
</tr>
<tr>
<td>ASS</td>
<td>25%</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>Statins</td>
<td>30%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>LDL-C 100 → 70</td>
<td>20%</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>ACE-I / ARB</td>
<td>25%</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>ß-Blocker</td>
<td>25%</td>
<td>5%</td>
<td></td>
</tr>
</tbody>
</table>

### Best Medical Treatment

Fonarow GC et al. Am J Cardiol 2000;85:10A-17A.
Best Medical Treatment

Improvement of Walking Distance

NO BENEFIT

Heparin / OAC
Ginkgo biloba
Vitamin E
Omega-3-FA
Padma 28
Garlic

POSSIBLE BENEFIT

Cilostazol
High dose statins
Naftidrofuryl
Pentoxifylline
Prostanoids
Ramipril

Treatment of Claudication
Network of Aims and Options

- Supervised Exercise
- Best Medical Treatment
- Revascularisation
- Walking Capacity
- ABI

Aims:
- Supervised Exercise
- Best Medical Treatment
- Revascularisation

Options:
- Survival
- Death
- Quality of Life
- Walking Capacity
- ABI

Neutral, Positive, Negative
## Exercise vs. Revascularisation

3 RCTs

<table>
<thead>
<tr>
<th>Trial</th>
<th>Interventions</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MIMIC Trial</strong></td>
<td>OMC + SE ± PTA</td>
<td>n=127 (93 fem-pop; 34 aorto-iliac); ABI 0.66 – 0.69</td>
<td>1°EP: ICD / AWD</td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>Mild to Moderate Intermittent Claudication</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CLEVER Study</strong></td>
<td>OMC + SE vs. OMC + PTA</td>
<td>n=111 (aorto-iliac); ABI 0.66 – 0.73</td>
<td>1°EP: PWT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2°EP: QoL</td>
</tr>
<tr>
<td></td>
<td>Claudication: Exercise Vs. Endoluminal Revascularization</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IRONIC Trial</strong></td>
<td>OMC + HBE vs. OMC + PTA</td>
<td>n=78 (mixed); ABI 0.73 – 0.74</td>
<td>1°EP: PWT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2°EP: QoL</td>
</tr>
<tr>
<td></td>
<td>Invasive Revascularization Or Not in IC</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Circulation 2014;130:939-47.</td>
<td></td>
<td></td>
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[OMC... Optimal Medical Care, SE...Supervised Exercise; HABE...Home Based Exercise, ICD...Initial Calication Distance; AWD...Absolute Walking Distance; PWT...Peak Walking Time]
Angioplasty
Intermittent Claudication @ LINC 2015

32 Cases
- ABI (median): 0.48
  Range: 0.00 - 0.67
  IQR: 0.40 - 0.60
- Intensity of Claudication: Severe (RB Category 3)
- Absolute (?) walking distance: 50 meters (IQR 20-100)
# Exercise vs. Revascularisation

## 3 RCTs

<table>
<thead>
<tr>
<th>Trial</th>
<th>Description</th>
<th>Findings</th>
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<tr>
<td><strong>MIMIC Trial</strong></td>
<td>Mild to Moderate Intermittent Claudication</td>
<td>PTA confers benefit ($p&lt;0.05$)</td>
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<tr>
<td></td>
<td><em>EJVES 2008;36:680-8.</em></td>
<td></td>
</tr>
<tr>
<td><strong>CLEVER Study</strong></td>
<td>Claudication: Exercise Vs. Endoluminal Revascularization</td>
<td>SE is superior in PWT ($p=0.04$)</td>
</tr>
<tr>
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<td><em>Circulation 2012;125:130-9.</em></td>
<td>Improvement in QoL is greater with PTA (n.s.)</td>
</tr>
<tr>
<td><strong>IRONIC Trial</strong></td>
<td>Invasive Revascularization Or Not in IC</td>
<td>PTA improves QoL ($p&lt;0.01$) and claudication distance ($p=0.003$)</td>
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**Notes:**

- OMC... Optimal Medical Care, SE...Supervised Exercise, HABE...Home Based Exercise, ICD...Initial Claudication Distance, AWD...Absolute Walking Distance, PWT...Peak Walking Time, QoL...Quality of Life
Effects of lower extremity PTA on CV outcome in Claudicants

**PTA vs. OMT** (non-randomized)

- **678 Claudicants**
  - ABI ≤0.9; ≥50% Stenosis

- **PTA-Group** (n=264)
  - ABI: 0.68 ± 0.19
  - RB-Category 3: 85%*
  - MWD: 124 ± 306 meters*

- **OMT-Group** (n=215)
  - ABI: 0.66 ± 0.17
  - RB-Category 3: 37%*
  - MWD: 403 ± 532 meters*  
  
  *p<0.001
Effects of lower extremity PTA on CV outcome in Claudicants

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→ OMT-Group (n=215)
  ABI: 0.66 ± 0.17
  RB-Category 3: 37%*
  MWD: 403 ± 532 meters*  *p<0.001

Survival in Intermittent Claudication

Pooled Data  Angioplasty Registry

Survival (n=2,930)
97.2% @ 1 yr
90.8% @ 3 yr
83.4% @ 5 yr

Treatment of Claudication
Network of Aims and Options

- Supervised Exercise
- Best Medical Treatment
- Revascularisation
- Survival
- Death
- Quality of Life
- Walking Capacity
- ABI

Arrow indications:
- Neutral
- Positive
- Negative
Treatment of Claudication
Network of Aims and Options

- Supervised Exercise
- Best Medical Treatment
- Revascularisation
- Survival
- Death
- Quality of Life
- ABI
- Walking Capacity

- neutral
- positive
- negative
Treatment of Claudication
Network of Aims and Options

Survival
Death

Quality of Life

Walking Capacity

ABI

Supervised Exercise

Best Medical Treatment

Revascularisation

Survival
Death

Quality of Life

Walking Capacity

ABI

Supervised Exercise

Best Medical Treatment

Revascularisation

neutral
positive
negative
Risks of Revascularisation

Patient-Specific Factors

TASC A  TASC B  TASC C  TASC D

FCR  FCR  FCR  FCR

- FAILURE (F)
- COMPLICATION (C)
- RECURRENCE (R)
Risks of Revascularisation

Risks of Revascularisation
Risk Reduction

Patient-Specific Factors

TASC A  TASC B  TASC C  TASC D

FCR  FCR  FCR  FCR

Careful Selection and Preparation

- Patients
- Treating Physicians
- Treatment Strategy
Revascularisation for Claudication?

**YES**
- PAD is cause of moderate / severe claudication or PAD is „subcritical“
- OMT is established
- SE is not available, feasible or successful
- Risk/Benefit-Ratio is adaequate

**NO**
- Severe comorbidities
- Intolerance or non-adherence to antithrombotic therapy

René Magritte (1934) *La Modèle Rouge*
Revascularisation for Claudication:  
When is it indicated, when not?

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