Maximally Invasive Vascular Surgery for the Treatment of Critical Limb Ischemia

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September 13, 2010
Overview

- Defining Critical Limb Ischemia
- Epidemiology and Natural History
- Rationale
- Evidence
- Cost analysis
- Conclusions
Definition [1]

- Critical Limb Ischemia (CLI)
  - Most advanced form of peripheral arterial disease (PAD)
  - Limb pain that occurs at rest and/or impending tissue loss (e.g. ulcers or gangrene) from lack of blood flow or a mismatch with tissue demand for oxygen

Definition [1]

History should be focused on distinguishing chronicity and global atherosclerotic disease burden

- Operative risk stratification
- Life expectancy determination
- Patient’s goals, quality of life and functional status.

Physical [2]:

- Ankle-brachial index (ABI); Toe-pressures (i.e. diabetics, noncompressible artery); <30mmHg (rest pain), <40mmHg (tissue loss)
- Segmental pressures; ankle <60mmHg (tissue loss), <40mmHg (rest pain)
- Pulse-volume Recordings (PVRs); flat or barely pulsative

Fontaine Stage and Rutherford Categories

- Universally accepted grading systems for PAD severity
- Provides patient stratification based on degree of ischemia and salvageability

# Rutherford Categories [1-2]

<table>
<thead>
<tr>
<th>Stage</th>
<th>Clinical</th>
<th>Grade</th>
<th>Category</th>
<th>Clinical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Asymptomatic</td>
<td>0</td>
<td>0</td>
<td>Asymptomatic</td>
</tr>
<tr>
<td>IIa</td>
<td>Mild claudication</td>
<td>I</td>
<td>1</td>
<td>Mild claudication</td>
</tr>
<tr>
<td>IIb</td>
<td>Moderate to severe claudication</td>
<td>I</td>
<td>2</td>
<td>Moderate claudication</td>
</tr>
<tr>
<td>III</td>
<td>Ischemic rest pain</td>
<td>II</td>
<td>4</td>
<td>Ischemic rest pain</td>
</tr>
<tr>
<td>IV</td>
<td>Ulceration or gangrene</td>
<td>III</td>
<td>5</td>
<td>Minor tissue loss</td>
</tr>
<tr>
<td></td>
<td></td>
<td>III</td>
<td>6</td>
<td>Major tissue loss</td>
</tr>
</tbody>
</table>

Epidemiology

- 500-1000 new cases of CLI per annum in a European or North American population of 1 million [1]

- Predictor variables leading to a diagnosis of CLI:
  - Diabetes 4X
  - Smoking 3X
  - Age >65 2X
  - ABPI <0.7 2X
  - ABPI < 0.5 2.5X
  - Dyslipidemia 2X

The Real Debate

- Define the Anatomy
  - Anatomic considerations [TASC class]

- Define the Clinical Endpoint:
  - Limb Specific?
    - Amputation free survival, wound healing, patency rates
  - Patient-specific?
    - Overall survival, freedom from Major Adverse Cardiac Events (MACE), functional outcomes

- Defining the Patient
TASC II Classification

BASIL Study [1]

- PRCT  Bypass vs. Angioplasty for CLI
  - UK Study, Aug 1999-July 2004
  - BSX arm= 228; BAP arm=224; infrainguinal dz.
  - Longitudinal 3 year follow-up; 5 year (~50% lost)
  - Intention to Treat Analysis all data
    - Amputation-free survival
    - Overall survival
  - Morbidity, re-interventions, HRQOL, cost-effectiveness as secondary end-points

# BASIL Study

**Table 1. Patient status at final follow-up**

<table>
<thead>
<tr>
<th>Variable</th>
<th>All (n = 452)</th>
<th>Angioplasty (n = 224)</th>
<th>Bypass (n = 228)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>4 (100)</td>
<td>1 (100)</td>
<td>3 (100)</td>
</tr>
<tr>
<td>In follow-up or dead Status</td>
<td>448 (100)</td>
<td>223 (100)</td>
<td>225 (100)</td>
</tr>
<tr>
<td>Dead</td>
<td>250 (56)</td>
<td>131 (59)</td>
<td>119 (53)</td>
</tr>
<tr>
<td>Alive with amputation</td>
<td>30 (7)</td>
<td>10 (4)</td>
<td>20 (9)</td>
</tr>
<tr>
<td>Alive no amputation</td>
<td>168 (38)</td>
<td>82 (37)</td>
<td>86 (38)</td>
</tr>
</tbody>
</table>

# BASIL Study

**Table II. Cox proportional hazards analysis, by time from randomization <2 years and >2 years**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Time from randomization</th>
<th>HR surgery vs angioplasty</th>
<th>Treatment by time period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Estimate</td>
<td>95% CI</td>
</tr>
<tr>
<td>Amputation free survival</td>
<td>&lt;2 years</td>
<td>1.06</td>
<td>(0.78-1.41)</td>
</tr>
<tr>
<td></td>
<td>&gt;2 years</td>
<td>0.80</td>
<td>(0.65-1.16)</td>
</tr>
<tr>
<td></td>
<td>Adjusted &lt;2 years</td>
<td>1.93</td>
<td>(0.75-1.20)</td>
</tr>
<tr>
<td></td>
<td>&gt;2 years</td>
<td>0.86</td>
<td>(0.60-1.07)</td>
</tr>
<tr>
<td>Overall survival</td>
<td>Unadjusted &lt;2 years</td>
<td>1.17</td>
<td>(0.83-1.66)</td>
</tr>
<tr>
<td></td>
<td>&gt;2 years</td>
<td>0.62</td>
<td>(0.43-0.90)</td>
</tr>
<tr>
<td></td>
<td>Adjusted &lt;2 years</td>
<td>1.19</td>
<td>(0.84-1.68)</td>
</tr>
<tr>
<td></td>
<td>&gt;2 years</td>
<td>0.61</td>
<td>(0.50-0.75)</td>
</tr>
</tbody>
</table>

CI, Confidence interval; HR, hazard ratio.

*Test of homogeneity of HR before and after 2 years from randomization.

*Adjusted for stratification, serum creatinine, body mass index, diabetes, age, smoking, statin at baseline, and below knee Bollinger score.

Other arguments

- Primary and secondary patency rates\textsuperscript{[1-2]}
  - Endo (3 yr data): 48.6\%, 62.9\%
  - Bypass (5 yr data): 63\%, 71\%

- Health-related Quality of Life \textsuperscript{[3]}
  - 3 years of data, VAscuQOL, SF-36, EuroQol
  - No significant difference

Economics

- **Retrospective review** [1]
  - 381 femoropopliteal revascularizations (open v. endo)
  - CLI subgroup analysis showed lost savings at 1 year in the endovascular arm due to re-interventions.
    - Amortized savings of $229 to $185 (p=0.71)

- **BASIL** [2]
  - Savings of $8469 initially with angioplasty, but after 1 year savings were $5521 and no longer significant

Economics

Medicare PAD population Report on costs [1]

- PAD-related Medicare Part A and B claims in 2001
- 6.8% of the Medicare population
- $4.37 billion spent on PAD treatment, 2.3% total expenditures
- One-third PAD patients accumulated healthcare costs.

Summary

- **Yes to Bypass:**
  - Younger patients, with appropriate operative risk and acceptable anatomy who will live long enough to realize the benefits of the procedure.

- **No to Bypass:**
  - Favorable anatomy in the Aorto-iliac/fem-pop segments.
  - Inappropriate operative risk, extensive tissue loss where, no identifiable targets.
Thanks!