The role of arterial bypass in infrainguinal occlusive disease

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Presentation Outline:

- Review of Infrainguinal Occlusive Disease
  - Classifications/Terms
- Patentcy Rates (bypass vs endovascular)
  - Femoropopliteal
  - Infrapopliteal
  - Pedal bypass
  - Alternative bypass conduits
- Limb Salvage
- Quality of life
- Amputation Rates
- Conclusion
Infrainguinal Occlusive Disease

- Infrainguinal Occlusive disease
  - 5% of men and 2.5% of women over 60 have claudication symptoms. 20% have progressive symptoms and 10% require amputations (Current. 2004)

- 66% increase in patients with PAD of the lower extremities in the next 10 years (TASC. 2000)

- Mortality risk in intermittent claudication 30% at 5 yrs, 50% at 10 years and 70% at 15 years (TASC. 2000)

- Survival rates in trans-tibial amputees
  - 62% at 1 year, 49% at 2 years, 27% at 5 years and 15% at 10 years. (Pohjolainen T et at. 1998)
Rutherford Classifications and Terms

- **Claudication** - extremity pain +/- weakness brought on by activity and relieved by rest.
- **Ischemic Rest Pain** - severe pain not relieved by rest or analgesics - localized to the forefoot, toes or ischemic lesions.
- **Critical Limb Ischemia** - Rest pain, tissue loss, ulceration and gangrene.
- **Limb salvage/Foot preservation** (chronic critical ischemia) - Preservation of foot functionality without major amputation or the remediation of symptoms.
- **Patency**
  - Primary = uninterrupted patentcy without additional procedures
  - Assisted primary = no loss of patency, but prophylactic intervention to maintain patency
  - Secondary = restoration of patency after occlusion

# Categories of limb ischemia

<table>
<thead>
<tr>
<th>Grade</th>
<th>Category</th>
<th>Clinical description</th>
<th>Objective criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>Asymptomatic—no hemodynamically significant occlusive disease</td>
<td>Normal treadmill or reactive hyperemia test</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>Mild claudication</td>
<td>Completes treadmill exercise†; AP after exercise &gt;50 mm Hg but at least 20 mm Hg lower than resting value</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>Moderate claudication</td>
<td>Between categories 1 and 3</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>Severe claudication</td>
<td>Cannot complete standard treadmill exercise† and AP after exercise &lt;50 mm Hg</td>
</tr>
<tr>
<td>II*</td>
<td>4</td>
<td>Ischemic rest pain</td>
<td>Resting AP &lt;40 mm Hg, flat or barely pulsatile ankle or metatarsal PVR; TP &lt;30 mm Hg</td>
</tr>
<tr>
<td>III*</td>
<td>5</td>
<td>Minor tissue loss—nonhealing ulcer, focal gangrene with diffuse pedal ischemia</td>
<td>Resting AP &lt;60 mm Hg, ankle or metatarsal PVR flat or barely pulsatile; TP &lt;40 mm Hg</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Major tissue loss—extending above TM level, functional foot no longer salvageable</td>
<td>Same as category 5</td>
</tr>
</tbody>
</table>

*AP, Ankle pressure; PVR, pulse volume recording; TP, toe pressure; TM, transmetatarsal.

*Grades II and III, categories 4, 5, and 6, are embraced by the term chronic critical ischemia.

†Five minutes at 2 mph on a 12% incline.

### TASC classification of femoropopliteal/ infrapopliteal lesions

#### Femoropopliteal lesions
- **TASC A:** Single stenosis <3cm
- **TASC B:** Single stenosis 3-5cm long, heavily calcified stenosis
- **TASC C:** Single stenosis or occlusion >5cm long or multiple stenoses/occlusions each 3-5cm
- **TASC D:** Complete occlusion of common femoral artery/superficial femoral artery/popliteal artery

#### Infrapopliteal lesions
- **TASC A:** Single stenosis <1cm
- **TASC B:** Multiple focal stenoses each <1cm long in tibial vessels, one or two stenoses <1cm long at the tibial trifurcation
- **TASC C:** Stenoses 1-4 cm long, 1-2 cm occlusions of tibial arteries or extensive stenosis at trifurcation
- **TASC D:** Tibial occlusions >2cm long or diffusely diseased tibial arteries

Femoropopliteal lesions
Fem-pop Patency Rates: Claudication

   a. 304 procedures (1989-1992)
   b. Avg lesion length <10cm
   c. 21.1% cross over to surgery from PTA

<table>
<thead>
<tr>
<th></th>
<th>1 yr</th>
<th>5yr</th>
<th>8yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bypass</td>
<td>76%</td>
<td>44%</td>
<td>28%</td>
</tr>
<tr>
<td>PTA</td>
<td>48%</td>
<td>25%</td>
<td>17%</td>
</tr>
</tbody>
</table>

Jamsen et al. 2003.
Fem-pop Patency Rates: Claudication cont.

   a. Femoropopliteal bypass – 5 year patency 80% with GSV
   b. 75% patency with PTFE graft

Hunink M et al. 2003.

3. Radiology 2001

<table>
<thead>
<tr>
<th></th>
<th>3 year</th>
<th>5 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claudication + stenosis</td>
<td>61%/(63% with stent)</td>
<td>55%</td>
</tr>
<tr>
<td>Claudication + occlusion</td>
<td>48%/(64% with stent)</td>
<td>42%</td>
</tr>
</tbody>
</table>

Muradin et al. 2001.
# Fem-pop Patency Rates: Critical Limb Ischemia

   a. 257 limbs PTA (1992-1995) -
   b. 38% (29/75) Popliteal PTA required bypass
      - Bypass 1 year patency rate 72%
   c. 45% of SFA PTAs required bypass
      - Bypass 1 year patency rate of 74%

<table>
<thead>
<tr>
<th></th>
<th>1 year- primary</th>
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<tbody>
<tr>
<td><strong>SFA</strong></td>
<td>13%</td>
</tr>
<tr>
<td><strong>Popliteal</strong></td>
<td>11%</td>
</tr>
</tbody>
</table>

Parsons et al. 1998

   b. 923 PTA/473 stents

<table>
<thead>
<tr>
<th></th>
<th>3 year</th>
<th>5 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLI + stenosis</td>
<td>43%/(65% with stent)</td>
<td>38%</td>
</tr>
<tr>
<td>CLI + occlusion</td>
<td>30%/(63% with stent)</td>
<td>25%</td>
</tr>
</tbody>
</table>

(P < .001)

Muradin et al. 2001


<table>
<thead>
<tr>
<th></th>
<th>5 year primary patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA – CLI stenosis/occlusion</td>
<td>47% (+/- 10)/12% (+/- 12)</td>
</tr>
<tr>
<td>Bypass – CLI GSV/PTFE</td>
<td>66% (+/- 7)/47% (+/- 6)</td>
</tr>
</tbody>
</table>

Hunink M et al. 2003.
Infrapopliteal lesions
## Infrapopliteal patency rates - PTA for CLI

### 1. Ann of Vasc Surg 2001
   - **a.** PTA - 37 procedures (1992-1999)
   - **b.** 66% tissue loss; 33% rest pain

### 2. JVIR 2000
   - **a.** PTA on 72 limbs (1996-1997)
   - **b.** Avg lesion length 7.7cm (TASC D)
   - **c.** 17% major amputation
   - **d.** Restenosis rate 38%

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<thead>
<tr>
<th></th>
<th>1 year</th>
<th>2 year</th>
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<tbody>
<tr>
<td>PP</td>
<td>72%</td>
<td>56.3%</td>
</tr>
<tr>
<td>LS</td>
<td>82.3%</td>
<td>82.3%</td>
</tr>
<tr>
<td>Survival</td>
<td>85.4%</td>
<td>61%</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th></th>
<th>1.5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>PP</td>
<td>48%</td>
</tr>
<tr>
<td>SP</td>
<td>56%</td>
</tr>
<tr>
<td>Stenosis/occlusion</td>
<td>56%/32%</td>
</tr>
</tbody>
</table>

Soder et al. JVIR 2000.
Infrapopliteal patency rates: Bypass for CLI

1. **J Vasc Surg 2006**
   a. Meta-analysis - 2320 grafts
   b. Popdistal/pedal
   c. 2.3% 30 day mortality comparable to PTA with beter FP

<table>
<thead>
<tr>
<th></th>
<th>1 year</th>
<th>5 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>PP</td>
<td>81.5%</td>
<td>63.1%</td>
</tr>
<tr>
<td>SP</td>
<td>85.9%</td>
<td>70.7%</td>
</tr>
<tr>
<td>FP</td>
<td>88.5%</td>
<td>77.7%</td>
</tr>
</tbody>
</table>

2. **J Vasc Surg 1996**
   a. 299 patients - >80 yrs old with CLI
   b. Perioperative mortality rate of 2.3%

<table>
<thead>
<tr>
<th></th>
<th>5 years</th>
</tr>
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<tbody>
<tr>
<td>PP</td>
<td>72%</td>
</tr>
<tr>
<td>AP</td>
<td>80%</td>
</tr>
<tr>
<td>SP</td>
<td>87%</td>
</tr>
<tr>
<td>LS</td>
<td>92%</td>
</tr>
</tbody>
</table>

Hearn et al. 1995.
DP/ Plantar/ Tarsal artery bypass

J Vasc Surg 2003
- Retrospective review for CLI - 1032 bypasses to DPA (91% with DM)
- PP at 4 years - DM 65.9% vs non-DM 56.3% (p < 0.04)
- 5 year SP - Saphenous 67.6% vs other conduit 46% (p < 0.001)

<table>
<thead>
<tr>
<th></th>
<th>PP</th>
<th>SP</th>
<th>Limb Salvage</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 year</td>
<td>56.8</td>
<td>62.7</td>
<td>78.2</td>
<td>48.6</td>
</tr>
<tr>
<td>10 year</td>
<td>37.0</td>
<td>41.7</td>
<td>57.7</td>
<td>23.8</td>
</tr>
</tbody>
</table>

J Vasc Surg 2004
- Retrospective review 98 procedures, 95% tissue loss
- 30 day mortality 1.0%

<table>
<thead>
<tr>
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<th>PP</th>
<th>SP</th>
<th>LS</th>
<th>Survival</th>
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</thead>
<tbody>
<tr>
<td>1yr</td>
<td>67%</td>
<td>70%</td>
<td>75%</td>
<td>91%</td>
</tr>
<tr>
<td>5yr</td>
<td>41%</td>
<td>50%</td>
<td>69%</td>
<td>63%</td>
</tr>
</tbody>
</table>

PTFE/ Other conduits

1. Meta-analysis of autologous vein bypass
   - Arm vein, lesser saphenous, SFA
   - 2618 grafts
   - Absolute risk reduction of major amputation
     - 4.6% at 12 months;
     - 7.6% at 36 months;
     - 14.8% at 60 months

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<thead>
<tr>
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<th>5 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>PP</td>
<td>67.6 (62.2-73.0)</td>
<td>46.9 (35.5-58.3)</td>
</tr>
<tr>
<td>SP</td>
<td>82.2 (78.4-86.0)</td>
<td>66.5 (54.9-78.2)</td>
</tr>
<tr>
<td>FP</td>
<td>88.4 (84.9-91.8)</td>
<td>76.4 (68.0-84.8)</td>
</tr>
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</table>

Parentheses represent 95% CI

- **Meta-analysis**
  
  **1980-2001**

  - Analysis included PTFE grafts combined with distal vein patch, arteriovenous fistulas, PTFE-vein graft

<table>
<thead>
<tr>
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<th>1 year</th>
<th>5 year</th>
</tr>
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<tr>
<td>PP</td>
<td>59.0 (53.3-64.7)</td>
<td>30.5 (22.9-38.2)</td>
</tr>
<tr>
<td>SP</td>
<td>66.4 (60.1-72.7)</td>
<td>39.7 (28.9-50.5)</td>
</tr>
<tr>
<td>FP</td>
<td>77.7 (71.7-83.7)</td>
<td>55.7 (45.9-65.5)</td>
</tr>
</tbody>
</table>

Albers et al. 2003.
High Restenosis Rates with PTA/Stents

  - Prospective study analyzing restenosis or reocclusion
  - 50% claudication/50% CLI
  - TASC C and D

- Results:
  - 40/58 limbs failed by 12 months (70.2%) – Primary patency rate 22% 1 year and 12% 2 years.
  - 21/40 limbs had reintervention with PTA – Secondary patency rate of 46% 1 year and 11% at 2 years.
    - 14/21 limbs failed again despite PTA (67%)

Limb Salvage (LS)

Arterial Bypass

1. **J Vasc Surg**
   a. Retrospective review - 299 patients > 80 years old with CLI (Pomposelli et al. 1998)
   b. LS was 92% at 5 years

2. **J Vasc Surg**
   a. Dorsalis pedis artery bypass in CLI - 1032 procedures (Pomposelli et al. 2003)
   b. LS was 92% at 1 year, 78.2% at 5 years and 57.7% at 10 years

3. **J Vasc Surg**
   1. PTFE grafts for tibial bypass with a distal vein patch in CLI - 514 procedures (Neville et al. 2001)
      a. LS was 88.3% at 1 year and 79.2% at 4 years
Quality of Life/Independence

- **J Vasc Surg** (Chung et al. 2006)
  - 334 patients with CLI
    - Ambulatory function
      - 91% to 72% at 6 and 12 months (p<.01)
    - Residential Status
      - 96% preop to 91% independent post op at 6 months (p<.01)

- **J Vasc Surg** (Pomposelli et al. 1998)
  - 299 patients with CLI - >80 years old
    - Ambulatory function
      - 92% were ambulatory preop/29% with assistance device
      - 92% were ambulatory postop/40% required assistance device
      - 44% of non-ambulatory patients became ambulatory
    - Residential status
      - 96% independent living to 90% independent living after surgery
    - Survival - 44% at 5 years
      - vs. 27% survival at 5 years after amputation
BASIL - Bypass vs Angioplasty in Severe Ischaemia of the Leg

**Lancet 2005**
- Randomized control trial with CLI - 228 surgery-first and 224 angio-first
- Primary end point = amputation free survival
- Only 29% of the potential patients were eligible for the study = selection bias

**Results:**
1. Amputation free survival at 1 year - Surgery 68% vs PTA 71%
2. Adjusted hazard Ratio (95% CI) of Surgery relative to PTA
   a. All cause mortality
      1. 2 years - 0.34 (0.17-0.71) \( p<.004 \)
   b. Amputation-free survival -
      1. 2 years - 0.37 (0.17-0.77) \( p<.008 \)
3. Re-intervention Rates
   a. Surgery 18% vs. PTA 26% (CI 0.04-15%)

Wound healing - Bypass

1. *J Vasc Surg* (Chung et al. 2006)
   - 409 infrainguinal bypass procedures for CLI
   - 75% complete wound healing at 12 months
   - Lesion severity at presentation predicted poor wound healing $p < .01$

   - 91 patients – infrainguinal bypass procedures
   - 73% wound healing at 6 months
   - 85% palpable pulses vs 42% non-palpable pulses healed $p < .004$
Conclusions:

- Patentcy rates/durability in arterial bypass are superior to endovascular procedures
- Decrease in reintervention following bypass procedures
- Excellent limb salvage rates in bypass
- Maintenance of independence/QOL
- Wound healing
References:


Photography and images provided by Dr. Mark Nehler, Associate Professor, UCHSC. 2006.