Latest treatment approaches for patients with PAD
Management of the condition with exercise

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Goals

• Identify patients with PAD using history, physical exam and appropriate noninvasive testing

• Treat PAD patients with:
  – risk factor modification including antiplatelet therapies, to decrease the risk of MI and stroke
  – Therapies to improve limb status
PAD

• Asymptomatic
• Claudication
• Rest Pain
• Tissue Loss - Gangrene or ulceration
Vascular Disease in the US

<table>
<thead>
<tr>
<th></th>
<th>Annual Incidence (Millions)</th>
<th>Prevalence (Millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>0.73&lt;sup&gt;1&lt;/sup&gt;</td>
<td>4.6&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>TIA</td>
<td>0.50&lt;sup&gt;3&lt;/sup&gt;</td>
<td>4.9&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>ACS</td>
<td>1.93&lt;sup&gt;5*&lt;/sup&gt;</td>
<td>12.6&lt;sup&gt;2†&lt;/sup&gt;</td>
</tr>
<tr>
<td>PAD</td>
<td>---</td>
<td>8–12&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

TIA = transient ischemic attack. ACS = acute coronary syndrome. PAD = peripheral arterial disease.

*Includes coronary insufficiency, nocturnal and variant angina, atrial/papillary and undetermined MI;
†includes history of MI or stable/unstable angina pectoris or both.

## PAD-Related Risk Factors

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Relative Risk</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes¹</td>
<td>4.05*</td>
<td>2.8-5.9</td>
</tr>
<tr>
<td>Smoking¹</td>
<td>2.55*</td>
<td>1.76-3.68</td>
</tr>
<tr>
<td>Hyperlipidemia¹</td>
<td>1.10*</td>
<td>1.06-1.14</td>
</tr>
<tr>
<td>(10 mg/dL increase in total cholesterol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension¹</td>
<td>1.51*</td>
<td>1.15-1.99</td>
</tr>
<tr>
<td>Hyperhomocysteinemia²</td>
<td>1.44†</td>
<td>1.10-1.87</td>
</tr>
</tbody>
</table>

* PAD diagnosis based on ABI <0.90.
† PAD diagnosis based on history of peripheral arterial reconstruction or limb amputation, or an ABI <0.50.

Identifying Patients at Risk for PAD

- Consider PAD in:
  - Any patients with exertional leg pain
  - Patients >50 years old with risk factors
  - All patients >70 years old
Diagnosis and Assessment of Disease Severity

- Vascular history
- Physical examination
- Ankle-brachial index (ABI) measurement
- Noninvasive vascular laboratory tests
Functional Description of Intermittent Claudication

- **Symptoms**
  - Exertional aching pain, cramping, tightness, fatigue
  - Occur in muscle groups, not joints (buttocks, hips, legs, calves)
  - Are reproducible from one day to the next on similar terrain
  - Resolve completely with 2-5 minutes of rest
Common Sites of Claudication

- **Obstruction in**
  - Aorta or iliac artery
  - Femoral artery or branches
  - Popliteal artery or distal

- **Ischemia in**
  - Buttock, hip, thigh
  - Thigh, calf
  - Calf, ankle, foot
## Relationship Between Comorbidities and Atypical Leg Symptoms

<table>
<thead>
<tr>
<th>Disease</th>
<th>Atypical/ Carry On (n=41)</th>
<th>Atypical/ Stop (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuropathy score, mean</td>
<td>4.3</td>
<td>3.1</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>24.4</td>
<td>26.7</td>
</tr>
<tr>
<td>Disk disease, %</td>
<td>29.3</td>
<td>31.1</td>
</tr>
<tr>
<td>Spinal stenosis, %</td>
<td>9.7</td>
<td>13.6</td>
</tr>
<tr>
<td>Depression, %</td>
<td>5.1</td>
<td>18.8</td>
</tr>
</tbody>
</table>

Does the Patient Have Intermittent Claudication?

<table>
<thead>
<tr>
<th>Characteristic of Discomfort</th>
<th>Claudication</th>
<th>Pseudoclaudication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discomfort</td>
<td>Cramping, tightness, aching, fatigue</td>
<td>Same, tingling, burning, numbness</td>
</tr>
<tr>
<td>Location of Discomfort</td>
<td>Buttock, hip, thigh, calf, foot</td>
<td>Same</td>
</tr>
<tr>
<td>Exercise-induced</td>
<td>Yes</td>
<td>Variable</td>
</tr>
<tr>
<td>Distance</td>
<td>Consistent</td>
<td>Variable</td>
</tr>
<tr>
<td>Occurs with Standing</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Action for Relief</td>
<td>Stand</td>
<td>Sit, change position</td>
</tr>
<tr>
<td>Time to Relief</td>
<td>Less than 5 minutes</td>
<td>Up to 30 minutes</td>
</tr>
</tbody>
</table>
Important Questions for Patients

- Do you develop any cramping or fatigue in the muscles of either leg that occurs when you walk?
- Do symptoms only start when you walk?
- Do symptoms resolve once you stop walking?
- Do the symptoms occur in one or both legs?
- Do you have any nonhealing foot wounds?
Physical Exam

**CLINICAL EXAMINATION OF THE PATIENT WITH PAD**

- Measure blood pressure in both arms
- Auscultate abdomen for presence of bruits
- Palpate for presence of abdominal aortic aneurysm
- Palpate and record pulses (femoral, popliteal, posterior tibial, dorsalis pedis)
- Evaluate for elevation pallor and dependent rubor
- Inspect feet for ulcers, fissures, calluses, tinea, tendonous xanthomas; evaluate overall skin care
- Measure ankle-brachial index
Office Measurement of the Ankle–Brachial Index (ABI)

Adapted from the PARTNERS Program.
Understanding the ABI

\[
\text{ABI} = \frac{\text{Ankle systolic pressure}}{\text{Brachial artery systolic pressure}}
\]

- Both ankle and brachial systolic pressures should be taken using a hand-held Doppler instrument
- For both arm and leg, use higher of 2 pressures
- The ABI is 95% sensitive and 99% specific for PAD

The Ankle-Brachial Index (ABI)

• ABI measurement is the optimal method to detect PAD
  – Inexpensive, accurate, and office-based
  – Provides an international standard, validated by angiographic detection, for defining PAD prevalence
  – Predicts limb survival, propensity for wound healing, and short- and long-term patient survival\(^1,2\)

• When is an ABI measurement indicated?
  – Presence or suspicion of claudication; pain at rest; or nonhealing foot ulcer
  – Age >70 years or >50 years with risk factors (diabetes, smoking)

PARTNERS

Diagnosis of PAD in High-Risk Patients

29% of patients were diagnosed with PAD using ankle-brachial index

Clinical Presentation of PAD Patients

- Chronic Limb Ischemia
- Acute Limb Ischemia
- Stable Claudication
- Asymptomatic PAD

Peripheral Arterial Disease (PAD) Mortality*

*Kaplan-Meier survival curves based on mortality from all causes.
†Large-vessel PAD.
Decline in Survival Associated With Severity of PAD

ABI = ankle-brachial index, PAD = peripheral arterial disease.

ABI = ankle-brachial index, PAD = peripheral arterial disease.
Correlation of ABI with Leg Function and Physical Activity

- As compared with higher ABI scores, lower ABI scores were consistently associated with:
  - shorter distance walked in 6 minutes
  - lower accelerometer-measured activity over 7 days
  - poorer standing balance
  - slower walking velocity at usual and fast pace
  - lower summary performance scores

- More than 60% of participants with ABI <0.40 had to stop during the 6-minute walk, while fewer than 5% with ABI ≥ 1.0 stopped

Other Noninvasive Diagnostic Tests

- Segmental blood pressure recording
- Segmental pulse volume recording
- Exercise stress testing
- Reactive hyperemia
- CW Doppler and duplex ultrasound

Pulse Volume recorder
Pulse volume recordings

- Require specific equipment and training
- Provide information on level and severity of disease
- Can be used in exercise testing as well
Duplex Ultrasonography

- Duplex Studies
- Provide too much information
- Time consuming
- Expensive
# Noninvasive Tests Summary

## Noninvasive Vascular Testing for PAD

<table>
<thead>
<tr>
<th>Test</th>
<th>Disease Localization</th>
<th>Quantitation of Disease Severity</th>
<th>Relative Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI</td>
<td>–</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Segmental pressure analysis</td>
<td>++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Pulse volume recordings</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Transcutaneous oximetry</td>
<td>+</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
<td>Doppler waveform analysis</td>
<td>+++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Arterial duplex</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
</tr>
<tr>
<td>Exercise Doppler</td>
<td>–</td>
<td>+++</td>
<td>+++</td>
</tr>
</tbody>
</table>
Arteriography

- Provides an anatomic but not a physiologic assessment
- Perform only when considering a revascularization intervention (eg, surgery, PTA, stents)
- Always assess inflow and outflow (ie, aortogram with runoffs)
Peripheral Arterial Disease: Disease Management
Progression of Intermittent Claudication

Population >55 yr

Intermittent Claudication 5%

Peripheral Vascular Outcomes

Worsening Claudication 16%

Lower Extremity Bypass Surgery 7%

Major Amputation 4%

Other Cardiovascular Morbidity/Total Mortality

Nonfatal Cardiovascular Event (MI/Stroke, 5-year Rate) 20%

5-yr Mortality 30%

Cardiovascular Cause 75%

Adapted from Weitz JI et al. Circulation. 1996;94:3026-3049.
PAD Management: Treatment Goals

- Reduce risk of MI and stroke
- Relieve symptoms of claudication by
  - Supervised exercise (regular, structured, cardiac rehabilitation model)
  - Pharmacotherapy
  - Revascularization (endovascular or surgical)
PAD Management: Prevention of Ischemic Events

Risk factor modification

- Smoking cessation
  - Goal: complete cessation
- Lipid management
  - Initiate therapy at LDL > 70 mg/dL
- Blood pressure control
  - Goal <120/70 mm Hg\(^1\)
  - 130/80 if diabetic
- Blood sugar control (diabetic patients)
  - Goal: HbA\(_{1c}\) <6.5\%\(^2\)

Physical Activity
- 30 min / day

Weight
- BMI 18-25

A-Fib
- NSR or INR 2-3

Antiplatelet therapies

Goal: reduction in risk of MI, stroke, and vascular death

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CAPRIE Study
Distribution of Symptomatic Atherosclerosis in CAPRIE

Cerebrovascular Disease
- 24.6%
- 7.3%
- 3.3%
- 3.8%

Coronary Artery Disease
- 29.9%
- 3.3%
- 11.9%

Peripheral Arterial Disease
- 19.2%

26% overlap of 2 vascular beds

Data on file, Sanofi-Synthelabo Inc.
CAPRIE Study
Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events
Rationale

• Patients who have atherosclerotic disease (recent MI, recent ischemic stroke, or established PAD) are at risk for subsequent ischemic events and will benefit from antiplatelet therapy

• Atherosclerosis is a generalized vascular disease

• Antiplatelet agents have been proven to be effective in diverse manifestations of atherosclerotic disease

### Methodology

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Prospective, randomized, blinded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>19,185 patients with atherosclerotic vascular disease</td>
</tr>
<tr>
<td>Patient Types Included</td>
<td>Recent ischemic stroke (≤ 6 mo)</td>
</tr>
<tr>
<td></td>
<td>Recent MI (≤ 35 d)</td>
</tr>
<tr>
<td></td>
<td>Established peripheral arterial disease</td>
</tr>
<tr>
<td>Study Drugs</td>
<td>Clopidogrel bisulfate: 75 mg qd</td>
</tr>
<tr>
<td></td>
<td>Aspirin: 325 mg qd</td>
</tr>
<tr>
<td>Treatment Duration</td>
<td>Up to 3 yrs (mean 1.6 yr)</td>
</tr>
<tr>
<td>Investigational Centers</td>
<td>304 in 16 countries, including the US</td>
</tr>
</tbody>
</table>
### Inclusion Criteria

<table>
<thead>
<tr>
<th>Recent Ischemic Stroke</th>
<th>Recent Myocardial Infarction</th>
<th>Established Peripheral Arterial Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Presumed ischemic origin</td>
<td>• Onset ≤35 days before randomization</td>
<td>• Current intermittent claudication AND</td>
</tr>
<tr>
<td>• Onset ≥1 wk and ≤ 6 mo before randomization</td>
<td><strong>Two of:</strong></td>
<td>Ankle-brachial index ≤0.85; 2 readings on separate days OR</td>
</tr>
<tr>
<td>• Persistent neurologic signs ≥1 wk from onset</td>
<td>– Ischemic pain ≥20 min</td>
<td>• Previous intervention (amputation, reconstructive surgery, or angioplasty)</td>
</tr>
<tr>
<td>• CT or MRI ruling out intracranial hemorrhage, nonrelevant intracranial disease</td>
<td>– CK, CK-MB, LDH, or AST 2x normal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– New ≥40 msec Q waves in ≥2 adjacent leads or new dominant R wave in V₁</td>
<td></td>
</tr>
</tbody>
</table>
Inverse Relationship Between ABI and Risk of Cardiovascular Events

10.2% Increase in Relative Risk per 0.1 decrease in ABI ($P = 0.039$)

Efficacy of Clopidogrel vs Aspirin in MI, Ischemic Stroke, or Vascular Death (N = 19,185)

**CAPRIE Study**

**Efficacy of Clopidogrel vs Aspirin in MI, Ischemic Stroke, or Vascular Death (N = 19,185)**

<table>
<thead>
<tr>
<th>Months of Follow-Up</th>
<th>Cumulative Event Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>12</td>
<td>9</td>
</tr>
<tr>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>20</td>
<td>15</td>
</tr>
<tr>
<td>24</td>
<td>18</td>
</tr>
<tr>
<td>28</td>
<td>21</td>
</tr>
<tr>
<td>32</td>
<td>24</td>
</tr>
<tr>
<td>36</td>
<td>27</td>
</tr>
</tbody>
</table>

**Overall Relative Risk Reduction²**

- **Aspirin:** 5.83%¹
- **Clopidogrel:** 5.32%¹

- **P = 0.045²**

*ITT analysis.
2. PLAVIX Prescribing Information.

*Median Follow-up = 1.91 years*

- **Aspirin:** 8.7%*²
- **Clopidogrel:**

PAD 23.7%

RR Reduction ²
Lipid Treatment

- Placebo
- Simvastatin

RR = 0.62
P < 0.008
PAD Management: Antiplatelet Therapies

• Lifetime antiplatelet therapy recommended for patients at risk for ischemic events \(^1,^2\)

• Clopidogrel is the only oral antiplatelet therapy indicated for reducing the risk of MI, stroke, and vascular death in patients with established PAD \(^3\)

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\(^2\) Clagett GP, Krupski WC. *Chest*. 1995;108(suppl 4):431S-443S.

\(^3\) Plavix\(^\circledR\) (clopidogrel bisulfate) Prescribing Information. March 2001.
## Symptomatic Therapies

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentoxifylline (Trental®)*</td>
<td>• ↓ Blood viscosity</td>
</tr>
<tr>
<td>Cilostazol (Pletal®)†</td>
<td>• ↓ Platelet aggregation</td>
</tr>
<tr>
<td></td>
<td>• Trigger vasodilation</td>
</tr>
<tr>
<td></td>
<td>• Improve lipid profile</td>
</tr>
</tbody>
</table>

*Trental is a registered trademark of Aventis Pharmaceuticals Inc.
†Pletal is a registered trademark of Otsuka America Pharmaceutical, Inc.

Maximal Walking Distance
Before and After Drug Withdrawal

Cilostazol 100 mg bid (n=16)
Pentoxifylline 400 mg tid (n=13)
Placebo (n=16)

Treatment of PAD
Effect of Drug Therapy on Walking Distance

Meta-analysis of 4 randomized, placebo-controlled trials

<table>
<thead>
<tr>
<th>Compound, dose</th>
<th>N</th>
<th>Placebo</th>
<th>Treatment Favored</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentoxifylline, 1200 mg/day</td>
<td>698</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cilostazol, 200 mg/day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>516</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cilostazol, 100 mg/day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>239</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cilostazol, 200 mg/day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>81</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Relative Increase in Maximum Walking Distance
(ratio of change in exercise performance versus placebo)

Most Common Adverse Event

- **Headache**
- **Diarrhea**
- **Abnormal Stools**
- **Palpitations**

Exercise for PAD?

• Your legs hurt when you walk so go out and walk?
Requirements of Exercise Programs

A successful program includes
5 sessions per week (3 supervised + 2 unsupervised)

PAD diagnosis
12-week supervised program
Lifetime maintenance

Effect of Exercise Training on Walking Ability in PAD

Controlled trials
Uncontrolled trials

Treatment of PAD
Effect of Exercise Training

Meta-analysis of 21 Studies

- Exercise Training
- Control

Onset of Claudication Pain
Maximal Claudication Pain

Treatment of PAD
Effect of Exercise Components on Walking Distance

<table>
<thead>
<tr>
<th>Exercise Component</th>
<th>Duration</th>
<th>Frequency</th>
<th>Length of Program</th>
<th>Training End Point</th>
<th>Mode of Exercise</th>
<th>Walking Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise Duration</td>
<td>&lt; 30 min/session</td>
<td>144 ± 419</td>
<td></td>
<td></td>
<td>Walking</td>
<td>287 ± 127</td>
</tr>
<tr>
<td></td>
<td>≥ 30 min/session</td>
<td>653 ± 364 *</td>
<td></td>
<td></td>
<td>Combination</td>
<td>512 ± 483 *</td>
</tr>
<tr>
<td>Exercise Frequency</td>
<td>&lt; 3 session/wk</td>
<td>249 ± 350</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 3 sessions/wk</td>
<td>541 ± 263 *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of Program</td>
<td>&lt; 26 weeks</td>
<td>275 ± 228</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 26 weeks</td>
<td>519 ± 409 *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training End Point</td>
<td>Onset of Pain</td>
<td>196 ± 78</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Near-Maximal Pain</td>
<td>607 ± 427 *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* $P < 0.05$

Exercise Program

![Bar graph showing walking time by protocol period (Entry, Mid, Exit) for Control and Exercise groups. The graph indicates a significant difference (*P < 0.05) between the groups at the exit stage.]
ACC/AHA 2005 Guidelines

Treatment of Claudication

Exercise

- Supervised exercise training should be the initial treatment
  - 30-45 minute sessions
  - 3 or more times per week
  - At least 12 weeks

- Value of unsupervised exercise programs is not well established

Drug therapy

- Cilostazol 100 mg twice daily
  - Can improve symptoms & increase walking distance
  - Indicated for lifestyle-limiting claudication
  - Contraindicated in patients with heart failure

- Pentoxifylline 400 mg three daily
  - Consider as an alternative to cilostazol
  - Effectiveness of pentoxifylline is marginal and not well established
Intermittent Claudication Exercise Programs

**Pros**
- Effective at improving exercise performance, walking distance, and physical functioning
- Safe, with no recorded morbidity or mortality
- Potential to improve other atherosclerosis risk factors
- Cost-effective

**Cons**
- Require motivated and compliant patient
- Limited availability of supervised programs
Follow-up and Counseling

• Set reasonable expectations for patient
  – Exercise program
  – Other lifestyle changes
• Refer patient for supervised walking program, if available
Follow-up Care for Patients in PAD Rehabilitation

- Reevaluate patient 90 days after initiation of therapeutic program
  - Assess symptomatic status of limb
  - Reassess atherosclerotic risk factor intervention and antiplatelet therapy
  - Review compliance with home exercise therapy
  - Consider pharmacologic therapy for nonresponders
- Continue monitoring every 90 days until patient improves
  - Thereafter, monitor every 6 months
Indications for Revascularization for Intermittent Claudication

- Lifestyle-limiting symptoms
- Continued disability despite appropriate nonsurgical management
- Technically feasible revascularization options exist
- Expectation of favorable risk/benefit ratio
Surgical and Endovascular Treatment Options

• Surgical
  – endarterectomy
  – bypass

• Endovascular
  – percutaneous transluminal angioplasty
  – percutaneous transluminal angioplasty with stent placement
Revascularization for Aorto-Iliac Arterial Disease

Aortofemoral Bypass

- Primary patency at 5 years of 81-85% \(^1\)
- Perioperative mortality 5-8% \(^1\)
- Reserved for severe diffuse disease cases \(^2\)
- Indicated for Rutherford class \(\geq 3\) \(^2\)

Percutaneous Intervention

- Patency at 5 years of 65-80% \(^1\)
- Perioperative mortality 0.1% \(^1\)
- Treatment of choice \(^3\)
- Indicated for Rutherford class \(\geq 2\) \(^2\)

Lesion-guided approach for treatment of aorto-iliac disease

A Endovascular is procedure of choice

B Endovascular is preferred therapy

C Surgery is preferred for good-risk

D Surgery is procedure of choice

Treatment of PAD
Revascularization for Femoro-Popliteal Disease

Femoro-Popliteal Bypass Surgery
- Primary patency at 5 years of 60-80%
- Autologous veins preferred to synthetic grafts
- Perioperative mortality 0-3%
- Indicated for Rutherford class $\geq$ 3

Femoro-Popliteal Angioplasty
- Patency at 2-5 years ranges between 40-70%
- Technical problems due to several anatomic issues:
  - Occlusions vs stenosis
  - Diffuse disease
  - Adductor canal
  - Disease in run off vessels
- Perioperative mortality is very low
- Indicated for Rutherford class $\geq$ 2
Lesion-guided approach for treatment of femoro-popliteal disease

A
Endovascular is procedure of choice

B
Endovascular is preferred therapy

C
Surgery is preferred for good-risk

D
Surgery is procedure of choice

**ACC/AHA 2005 Guidelines**

**Treatment of Claudication**

**Endovascular therapies**
- Only indicated for patients with
  - Vocational or lifestyle-limiting disability;
  - Reasonable likelihood of symptomatic improvement;
  - Prior failure of exercise or pharmacological therapy; and,
  - Favorable risk-benefit ratio
- Not indicated as a prophylactic treatment
- Preferred method for revascularization of TASC type A iliac and femoropopliteal arterial lesions

**Surgery**
- Indicated for patients
  - With significant functional disability from symptoms
  - Who are unresponsive to exercise or pharmacotherapy
  - Who have a reasonable likelihood of symptomatic improvement
- Surgical intervention is not indicated to prevent progression to limb-threatening ischemia
Exercise vs Stenting for Claudication

Change in WIQ

- Pain Severity: OMC - 16.3, Exercise - 26.3, Stenting - 40.4
- Walking Distance: OMC - 25.1, Exercise - 1.47, Stenting - 16.5
- Walking Speed: OMC - 30.8, Exercise - 24, Stenting - 29.3
- Stair Climbing: OMC - -0.5, Exercise - 10.2, Stenting - 24

CLEVER: Circulation. 2012;125:130-139
Exercise vs Stenting for Claudication

Change in Community Walking

Pair-wise comparisons

<table>
<thead>
<tr>
<th></th>
<th>Difference (steps)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise vs. OMC</td>
<td>78</td>
<td>0.06</td>
</tr>
<tr>
<td>Stent vs OMC</td>
<td>120</td>
<td>0.10</td>
</tr>
<tr>
<td>Exercise vs Stenting</td>
<td>42</td>
<td>0.47</td>
</tr>
</tbody>
</table>

CLEVER: Circulation. 2012;125:130-139
Albany Vascular Institute Experience

Intrainguinal Bypass for Claudication

1987-1997

- 4468 lower extremity bypass operations performed
- 409 (9%) indication=claudication
Case

- 41 year old white male
- CC: Right calf cramping at 1 block
- Sx: worsening over last 2 months
Case Study

- PMH: S/P PTCA at age 38 for angina
- Family History: Father expired from MI at age 51, Brother nonfatal MI age 45
- Smoke: 2 ppd
- Social History: UPS delivery
- Medications: none
Case Study

- Physical exam
  - BP 114/74 HR 75 5 feet 10in 165 lbs.
  - Lungs clear, Cor RRR no murmurs
  - Abdomen: negative
  - Carotids without bruits
  - Absent distal pulses decreased right femoral pulse
Case Study

- Hct 46%
- LFTS normal
- PT/PTT normal
Case Study

• Abnormal ABI Bilateral
• PVRS dampened at thigh bilateral
Case Study

- What's the next step?
  - Lipid management
  - Plavix
  - Smoking cessation
  - Cilostazol
  - Exercise
Case Study

• 3 month follow-up
• Walking distance decreased no longer can work
• Lipids at goal
• On Clopidogrel
Case Study

- Underwent aortoiliac endarterectomy
Case Study

- Postoperative PVR’S
- Continues in follow-up
Clinical Treatment Goals for Patients With PAD

- Improve functional status
  - Improve symptoms
  - Improve QOL
  - Improve exercise capacity
- Preserve the limb
  - Decrease the need for revascularization
- Prevent progression of atherosclerosis
- Reduce cardiac and cerebrovascular mortality
  - Reduce nonfatal events such as MI and stroke
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