Disclosure

- I have no relationships to disclose.

- The use of some endoluminal stents still do not have FDA approval for specific anatomic location.

Natural history of lower extremity peripheral arterial disease

Clinical Presentation of Chronic Limb Ischemia

<table>
<thead>
<tr>
<th>Stage</th>
<th>Criteria / Clinical Features</th>
<th>Objective criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal ankle-brachial index (ABI) &gt; 1.0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Mild abnormality or ABI &lt; 0.95</td>
<td>Abnormal ABI &lt; 0.95</td>
</tr>
<tr>
<td>2</td>
<td>Moderate claudication or ABI &lt; 0.90</td>
<td>ABI &lt; 0.90</td>
</tr>
<tr>
<td>3</td>
<td>Severe claudication or ABI &lt; 0.80</td>
<td>ABI &lt; 0.80</td>
</tr>
<tr>
<td>4</td>
<td>Symptomatic rest pain or ABI &lt; 0.80</td>
<td>ABI &lt; 0.80</td>
</tr>
<tr>
<td>5</td>
<td>Ulcer or gangrene or ABI &lt; 0.80</td>
<td>ABI &lt; 0.80</td>
</tr>
</tbody>
</table>

ABI, ankle-brachial index; PTT, platelet time; TCD, transcranial Doppler; TEE, transesophageal echocardiography.

*Stage 1 and 2, categories 1, 2, and 3, are described by the core chronic arterial ischemia. Stage 1 or 2 may be assigned to a limb with a history of atherosclerotic disease.
Observed Effects of Stenosis in Limbs

- Single Stenosis
  - Resting flow preserved in Profunda (df) and Tibial (tib) despite ΔP across Stenosis
  - Calf flow with exercise cannot increase to normal levels and takes longer to recover due to reactive hyperemia.

Effects of Stenosis in Limbs

- Stenoses in Series
  - Autoregulation maintains resting flow, but absolute Tibial (tib) resting pressure limited due to additive lesions
  - With decrease in resistance in outflow bed, intervening artery, df, may "steal" from calf and lead to decrease in flow with exercise.

Concept of Critical Stenosis

- How do stenoses affect perfusion distally?
  - ΔP affected by length and especially radius (to 4th power from Poiseuille’s)
  - Inertial losses at entrance and especially exit of lesion from turbulence (ΔP inertia = velocity^2), velocity increased in stenosis.

- Resistance affects as well and thus low resistance circuits (i.e. carotid/renal) have more exaggerated ΔP per % stenosis
- Conversely, exercise cause hyperemia and decrease resistance in extremity unmasking critical stenosis, i.e. “Claudication”
Effects of Stenoses in Limbs

- Single lesions in non-“end” arteries seldom cause ischemic rest pain
  - Exception: occlusion of inflow vessel results in occlusion of collaterals
  - E.g. embolism to popliteal

- Multi-level occlusion causes rest pain
  - Blood must go through two, or more, collateral circulations before reaching distal limb
  - “Steal” occurs when inflow to 2 distinct beds is obstructed and distal bed perfusion is compromised by compensatory dilation in intervening segment

Evaluation/Diagnosis

- History
  - Risk factors
  - Walking distance
  - History of ulceration
  - Pain
  - Sexual Function

- Exam
  - Pulses
  - 0-3
  - Hair distribution
  - Skin
  - Ulcers/tissue loss
  - Bedside ABI

Non-Invasive Laboratory

Non-Invasive Imaging

- MRA
  - Pros
    - No radiation
    - No iodinated contrast
    - Excellent Imaging
  - Cons
    - Loss of signal in stents
    - Limited Evaluation of calcification
    - Pacemakers, hips, etc
    - Nephrogenic Dermato-fibrosis

- CTA
  - Pros
    - Excellent imaging even in stents
    - More detail of calcium burden
  - Cons
    - Iodine contrast
    - Radiation exposure
    - Renal Impairment

Traditional Angiography

- Allows for both diagnosis and therapy in same setting
- Can provide anatomic and hemodynamic detail
  - Measure gradient across lesion
    - >5-10 mmHg significant iliac lesion
  - Hyperemia test >15 mmHg drop in pressure
  - 1-5% risk of access site complication
- Requires radiation
- Iodinated contrast
- Although can control dose better than CTA

Anatomic Considerations
TASC Recommendations

- Goals of therapy
- Relief of pain
- Relief from infection
- Limb Salvage

Outcome

- Aorto-Femoral Bypass
- Iliac PTA & PTA/Stent

Comparison of ABF v PTA/S

- Single institution, retrospective
- TASC B-D
  - 86 Open
  - 83 Endo
  - GA
  - 96% open
  - 15% endo
  - Ancillary procedures
    - Open
    - 50% endart
    - 11% bypass
    - Endo 21%

Comparison of AFB v PTA/S

- Single Institution
  - 118 AFB v 174 PTA/S
  - Equivalent mortality
  - Sign increase in complications in AFB
  - Significantly greater improvement in ABI with AFB

Successful Treatment of Occlusion

- 89 Patients with 176 stents placed
  - All had occlusions of iliac of varying length
  - 24% required femoral endarterectomy and patch closure for extension to CFA
  - 3 yr 1st, 2nd patency, Limb Salvage
    - 76%, 90%, 97% respectively

Extra Anatomic Bypass

- Careful Evaluation of Donor Iliac can greatly improve outcome of Fem-Fem
- Hyperemic testing increase patency by 20%
- ThoracoFem demonstrate up to 79% patency at 5 years
Autogenous Reconstruction

- NAIS
- 5 yr primary patency 82%
- 5 yr assisted primary patency 94%
- All comers
- Native graft size > 7mm predicted success

Aortic Endarterectomy
- Reasonable patency in focal segments
- Dismal patency when extended to external iliac
- Significantly increased morbidity over AFB

Follow up

- AFB
  - 1, 3, 6, 12 month ABI and exam
  - Annual Anastomotic duplex
  - Class C recommendation
  - Some report f/u CT scan but no definitive recommendation

- Stent
  - 1, 3, 6, 12 month ABI and exam
  - Stent duplex
  - Multiple reported criteria
  - Velocity Ratio > 2 most sensitive, > 3 most specific

Suggested Reading

- TASC II

Chronic Limb Ischemia Part 2: Femoro-Popliteal Disease

Benjamin J Pearce, MD

Disclosure

- I have no relationships to disclose.

- The use of some endoluminal stents still do not have FDA approval for specific anatomic location.

TASC II Lesions

SVS Comprehensive Vascular Review Course
September 9-10, 2011
Intercontinental Chicago O’Hare
Outcome Measures

- ABI
- Duplex Surveillance
- Angiographic Restenosis
- Target Lesion Revascularization
- Patency
  - Primary, primary assisted, secondary
- Limb Salvage

Bypass Grafts

Patency by Indication

5-year patency following femoral popliteal bypass

<table>
<thead>
<tr>
<th>Claudiation</th>
<th>CLI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vein</td>
<td>80</td>
</tr>
<tr>
<td>Above-knee PTFE</td>
<td>75</td>
</tr>
<tr>
<td>Below-knee PTFE</td>
<td>65</td>
</tr>
</tbody>
</table>

CLSI – critical limb ischemia; PTFE – polytetrafluoroethylene graft.

Contemporary Results of Vein Bypass Grafts

- 44.4% Bad Ro vs. 7.4% Good Ro
- Amputation c Patent Graft: 41.7% v 4.3%
- Overall >60% death, amputation, graft failure in poor Ro cohort

5-year patency following femoral popliteal bypass

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<td>75</td>
</tr>
<tr>
<td>Below-knee PTFE</td>
<td>65</td>
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</tbody>
</table>

Contemporary Results Perc PTA for SFA lesions

- 100 limbs in 93 consecutive patients
- 55% claudication
- only 1 stent implanted

PTA + Selective Stenting in SFA

- 380 limbs in 329 Patients:
  - 67% male
  - 66% claudication
  - TASC lesions:
    - A: 48%
    - B: 18%
    - C: 22%
    - D: 12%

- Stents used in 37% of procedures
  - Utilized for suboptimal PTA
  - Recell
  - Dissection
  - Residual stenosis
Nitinol Stent Primary Patency: All Data

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<td>85%</td>
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<td>85%</td>
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</tr>
</tbody>
</table>

Weighted Average


PTA v PTA+Stent

- Improved patency for nitinol stents by both CTA(a) and Duplex(b)
- Consistent with functional outcome
- Distance walked
- Improved ABI

Role of Covered Stents

- Perceived Advantages
  - Less neointimal growth along stent struts
  - Exclusion of aneurysm/psa
  - "Trap" debris in artery
- Disadvantages
  - Larger sheath sizes to treat
  - Loss of collaterals

Viabahn v Surgical PTFE Bypass

- 100 Limbs Viabahn v. AK Pop PTFE
- 24 mos F/U
  - Viabahn
    - 17 Graft failures
    - 18 Re-interventions
  - AK Pop PTFE
    - 18 Surgeries
    - 1 Amputation
    - Open PTFE
    - 14 Graft failures
    - 17Re-interventions
    - 5 Total Amps
  - All Amps in pt c tissue loss pre-tx

BASIL Trial

- Randomized to Bypass v. PTA alone
- Mixed subintimal/true PTA
- Stent only for suboptimal PTA
- "ST/LI Patients"
- TASC/Ro score not reported
- No ABI cutoff
- Short term benefits—PTA
- Long term benefits—surgery
- Failed PTA group worse AFS than vein bypass

Overall Intervention v. Surgery

PTA of SFA

Recommendations

Adjunct Techniques—Open

- Distal Vein cuff
  - Miller cuff evaluated in Randomized Trial
  - 52% v 29% 2yr patency for BK PTFE
- AV Fistula
  - No data demonstrating improved patency
- Intraoperative Assessment
  - Angiography & 27% detection of significant lesion
  - IO Duplex > 250cm/sec detected 12% significant lesion
- Profundaplasty
  - Recommend as adjunct to bypass in SFA occlusion
  - Good results for rest pain with >50%neointimal stenosis and normal inflow
  - Limb salvage up to 70% for rest pain

Adjunct Techniques—Endo

- Cutting Balloon
- Atherectomy
- Drug Eluting Stents
- Crossing Devices
- Cryoplasty
  - All demonstrate equivalent Limb salvage in short term follow up in non-multi center trials

Adjunct Techniques—Endo

- Drug Elution
  - SIROCCO I/II
    - Sirolimus stents v Bare metal, failed to meet endpoints
- Drug Eluting Balloon Angioplasty
  - TLR 4% 6 months, 15% 24 mos in Taxol balloon v 37%/52% in control

Outcome of Failed Intervention

- 276 Limbs
  - 23 Failed < 200d
  - 6(2.1%) altered bypass sites
  - 3 Lost Ro Vessel
  - TASC: 14 no Δ, 3 worse, 4 better
- Re-interventions
  - 14 Repeat PTA/Stent
  - 5 Surgery
  - 1 Amputation
- Limb Salvage
  - 86% v 40% if no change in target
Failed Viabahn Stents

- 74 Limbs
- Mean F/u 16 mos
- 78% 1st Patency 12 mos
- Mean 1.5 Stents/limb
- No surgical interventions required
- No major amputation
- 9 Graft Occlusions
  - 8 Returned to same Rutherford score
  - 1 acute limb ischemia

Surveillance

- Open
  - 1, 3, 6, 9, 12 mos
  - ABI +/- 0.15
  - TBI +/- 0.1
  - Absolute velocity
    - > 280 cm/s
    - < 45 cm/s
  - Ratio > 3
- Endo
  - No consensus
  - Generally accepted to use similar criteria to open

Conclusion

- The change in TASC II categorization is a testament to improvement in endovascular technology and technique
  - Allows for consistent recommendation for therapy TASC A/B – Endo, TASC C/D – Open
  - Patient fitness remains paramount
- Major factors affecting outcome
  - Inflow, outflow, conduit
  - Diabetes, Renal Failure, Statin Administration

Conclusion

- No randomized data exists comparing novel techniques such as atherectomy or crossing devices v. Surgery
- Only one large multi-center trial has directly compared Infrainguinal bypass to angioplasty (BASIL)
- Registry data/Industry data/Single institution data show acceptable limb salvage rates with less morbidity when comparing endo to open therapy

Suggested Reading

- TASC II
  - J Endovasc Ther. 2009; 16(Suppl II): II5–II18
  - J Vasc Surg 2010; 51: 69S–75S