Claudication and Critical Limb Ischemia

Endovascular Treatment of Peripheral Arterial Disease

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Peripheral Arterial Disease

- Affects ~20% of adults older than 55
- Estimated 27 million in the US and Europe
- 50% are asymptomatic
- Prevalence increases with age, smoking, diabetes
- Incidence of symptomatic PAD between 1 and 3.6 per 1000 population
- Incidence 2-fold higher in men
- In patients with asymptomatic disease, 5-10% will develop symptoms in 5 years

Peripheral Arterial Disease

- Critical leg ischemia most frequent in DM
- One fifth of people with PAD have typical symptoms
- One-third with atypical leg symptoms
- Despite relatively slow and low rate of local complications, patients with PAD have 5 year mortality rates of 25-30% (mainly from coronary or cerebral vascular disease)

Symptoms

- Intermittent claudication
  - Calf pain most common
  - Buttock/hip pain with proximal disease
  - Ankle/foot pain with distal disease
- Critical limb ischemia
  - Rest pain, ulceration, gangrene
  - Indicates severe, often multilevel arterial disease
- Acute arterial occlusion
  - Trauma, thrombosis, embolism

Differential Diagnosis

- PAD
- Neurogenic pseudoclaudication
- Venous claudication
- Skeletal muscle metabolic abnormalities
- Arterial entrapment syndromes
- Thromboangiitis obliterans
- Fibromuscular dysplasia
- Extravascular compression

Physical Findings

- Subcutaneous atrophy
- Hair loss
- Pallor
- Coolness
- Dependent rubor
- Brittle toenails
- Decreased/absent pulses
- Bruits
Diagnostic Modalities

- **Ankle-Brachial Index (ABI)** = Highest ankle pressure/Highest brachial pressure
  - Normal 0.9 to 1.3
  - 0.71 - 0.9 - mild obstruction
  - 0.41 - 0.7 - moderate obstruction
  - <0.4 - severe obstruction
- Should also be measured after exercise
  - If no drop in ABI after exercise likely not PAD
  - 20 mm Hg drop considered significant
- BP below 90 mm Hg - intermittent claudication, below 60 mm Hg c/w rest pain
- ABI may underestimate disease in calcified, noncompressible arteries (often ABI >1.5)

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Lesion Classification

- **TASC Classification**
  - A - Single stenosis < 3 cm
  - B - Single stenosis 3-10 cm, heavily calcified lesion <3 cm, multiple lesions <3 cm
  - C - Single stenosis or occlusion >5 cm, multiple stenosis or occlusion each 3 to 5 cm
  - D - Complete FA, SFA occlusions

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Medical Therapy

- **Smoking Cessation**
  - Doesn’t significantly improve walking capacity
  - May decrease severity of claudication and risk of developing rest pain
- **Exercise**
  - Significantly improves walking time in addition to surgery versus exercise or surgery alone
  - More effective than antiplatelet therapy
  - Patients should walk to near-maximal pain daily for over 6 months
  - Mechanism?

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CT Angiography

MR Angiography

Duplex ultrasonography
MR Angiography
CT Angiography
Invasive Angiography

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1. Arch Intern Med. 1999;159:337-345
2. J Vasc A. 1995;276:975-980
Technological advances leading to more PTA increasingly used in CLI

Historically, PTA used in patients with "

Improved outcomes with self-expanding and nitinol

Initially used to treat suboptimal PTA or related

Drug-eluting Stents

DES (SMART stent, Cordis, sirolimus-eluting) have shown mixed results

Stents

Initially used to treat suboptimal PTA or related complications

1st stents were balloon expandable with poor clinical outcomes (4 year patency rates 37-52%)

- Equivalent risk of long-term failure compared to PTFE bypass grafts and roughly twice the risk of venous bypass grafts

- Meta-analysis revealed patency rates of 59% at 1 year and 45% at 5 years

SIRROCCO 1 Trial (36 patients)¹

- 6-month data restenosis 0% versus 17%
- 18-month data restenosis 0% with slow-eluting stents, 25% with fast-eluting stents, and 29% with BMS
- 24-months, DES >40% with BMS 47%

SIRROCCO 2 Trial (57 patients)²

- 6-month data similar to SIRROCCO 1
- 18 month pooled data showed (mean stent diameter) early advantage was lost

²²

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7. TCT, 2003
Zilver PTX

- Paclitaxel eluding self-expanding stent
- Zilver PTX trial – pts randomized to Zilver PTX vs angioplasty with second randomization (Zilver PTX vs Zilver BMS) in pts with suboptimal PTA
  - Event-free survival (death, TLR, amputation, worsening claudication) - 86.6% vs. 77.6%
  - Vessel Patency at 2 years
    - PTA - 57.8%
    - Provisional stenting
    - Zilver BMS - 62.7%
    - Fracture rate 0.9%
- FDA approved 10/11
- Duration of antiplatelet therapy?

Stent-grafts

- Initial “home-made” from balloon expandable stents and vascular grafts
  - High complication rates, 20% early occlusion, high restenosis rates (<20% at 3 years)
- Current endovascular grafts more promising, now made with PTFE and nitinol
- Only Gore VIABAHN endoprosthesis with data in peer-reviewed literature
  - 3 year patency rates ~80% (1200 limbs, 9.5-13.9 cm), higher than synthetic graft bypass¹
  - Kedora, et al. 100 patients randomized to Viabahn stent vs. fem-pop bypass with synthetic graft. 1° patency rate (74%) and 2° patency (84%) same in both groups
  - Ideal lesions - >1 cm of healthy vessel proximal and distal to lesion, no popliteal lesions, at least 1 open lower leg vessel, no significant calcification
  - ?Thrombosis risk, collaterals

directional atherectomy

- Silverhawk Plaque Excision Device (Fox Hollow Technologies)
  - FDA approved in June 2003 for peripheral vasculature
  - Single center reports
    - Univ. Arizona - patency 2° 68%, 2° 73% at 10 months
    - Columbia - patency 1° 58%, 2° 83% at 12 months
    - Cleveland Clinic - patency 1° 43%, 2° 57% at 1 year
    - South Florida - patency 1° 62%, 2° 76% at 1 year
    - Iowa - patency 1° 19%, 2° 31% at 1 year
  - TALON Registry – 19 centers, 601 patients, 1258 lesions
    - Target lesion revascularization free - 90% at 6 months, 80% at 1 year
    - Limb salvage rates universally > 70%
    - No randomized-controlled trials currently

Silverhawk atherecotomy

- High frequency mechanical vibration @20,000 cycles/sec for crossing CTO’s
- PATRIOT trial – 84% success crossing wire resistant CTO’s, no perforations

Novel Therapies

Re-entry catheters

Distal protection devices
Antiplatelet Therapy after PTA

- ASA, dipyridamole, and ticlopidine have all been shown superior to placebo
- No comparative studies
- Patients with PAD in CAPRIE had a 24% relative risk reduction in CVA, MI or vascular death
- Most interventionalist treating with ASA indefinitely and plavix for one month

Case #1

- 62 yo male with RLE exertional claudication and stable angina
- Risk factors - FH CAD, HTN, tobacco abuse
- ABI at rest 0.54 on RLE, left leg normal
- Referred for LE angiogram, coronary angiogram
Case #2
- 69 yo with nonhealing wound on left big toe
- Exertional calf claudication
- CAD, ischemic cardiomyopathy, NYHA class 3 CHF, DM with peripheral neuropathy, Class 4 CKD
Case #3

- 79 year old female with limiting left lower extremity claudication and nighttime rest symptoms
- Previous right iliac artery stenting
- CAD, ongoing tobacco abuse
- Long right SFA occlusion known from previous cath
Case #4

- 80 year old with bilateral non-healing foot ulcers
- DM with severe neuropathy
- Evaluated by orthopedist who recommended amputation
- Palpable femoral and popliteal pulses bilaterally without pulses in feet
Case 5

- 72 yo with DM, HTN, hyperlipidemia, CRI, ongoing tobacco abuse
- Underwent aortobifemoral bypass for AAA and bilateral iliac stenosis in 1/2009
- Developed severe limiting claudication several months later
- LE ultrasound revealed markedly elevated peak velocities at anastomotic sites (>6 m/s on right, >3 m/s on left, rest ABI 0.61 on right, 0.89 on left)
Case # 6

- 82 year old Madras cowboy with left calf claudication
- CAD with multiple PCI’s, chronic stable angina, HTN, hyperlipidemia, ongoing tobacco use
- Absent left pedal pulses, 2+ on right
- ABI 0.67 on left
- MRA showed focal distal left SFA stenosis
Case #6

- 86 year old with left calf claudication
- Risk factors – DM, previous smoking history, hyperlipidemia, known CAD
- Abnormal ABI’s
- MRA showing diffuse distal SFA and popliteal disease