Peripheral Vascular Disease Current Diagnosis and Management

Ed Wehling D.O.

Discussion Outline

- Definition of PVD and Critical Limb Ischemia
- Risk Factors for PVD and CLI
- Signs & Symptoms
- Diagnostic Tests
- Medical Management
- Surgical Options
- Endovascular Options
- Summary

Disease State – Natural History

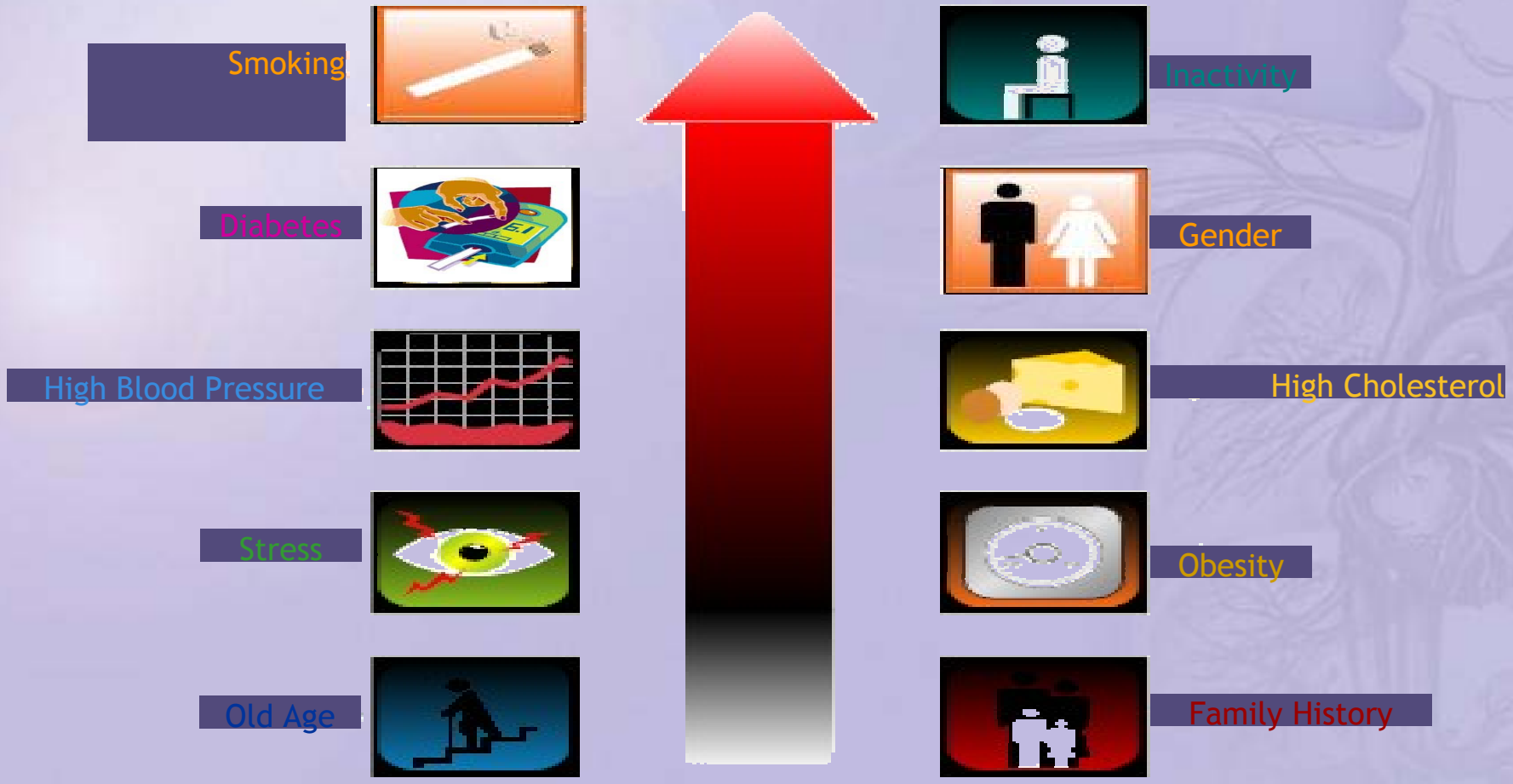
- Chronic Limb Ischemia is characterized by:
  - Persistent rest pain in the lower leg or foot
  - Tissue loss
  - May be preceded by worsening claudication symptoms
- Primary Cause
  - Chronic atherosclerotic stenosis and/or occlusion
  - 15% – 30% of patients with lower extremity PAD will progress from intermittent claudication to CLI over the course of their disease.[1,2]

1. Dormandy J, Mahir M, Ascady G., Balsano F, De Leeuw P, Blomberg P, Bousser MG, Clement D, Coffman J, Deutschinoff A, et al. Fate of the patient with chronic leg ischemia: a review article. J Cardiovasc Surg (Torino). 1989;30:50-57.
2. McDaniel MD, Cronenwett JL. Basic data related to the natural history of intermittent claudication. Ann Vasc Surg. 1989;3:273-277.
Image courtesy of Dr. Lanfroi Grazziani, Servizio di Emodinamica, Istituto Clinico "Città di Brescia" Brescia (Italy), www.extrem-es-angioplasty.it

Disease State – Natural History

- Risk Factors
  - Smoking
  - Smoking
  - Smoking
  - Diabetes
  - Elevated lipid levels (relationship)
  - Increasing Age
  - Male gender
  - Elevated homocysteine levels

Disease State – Natural History

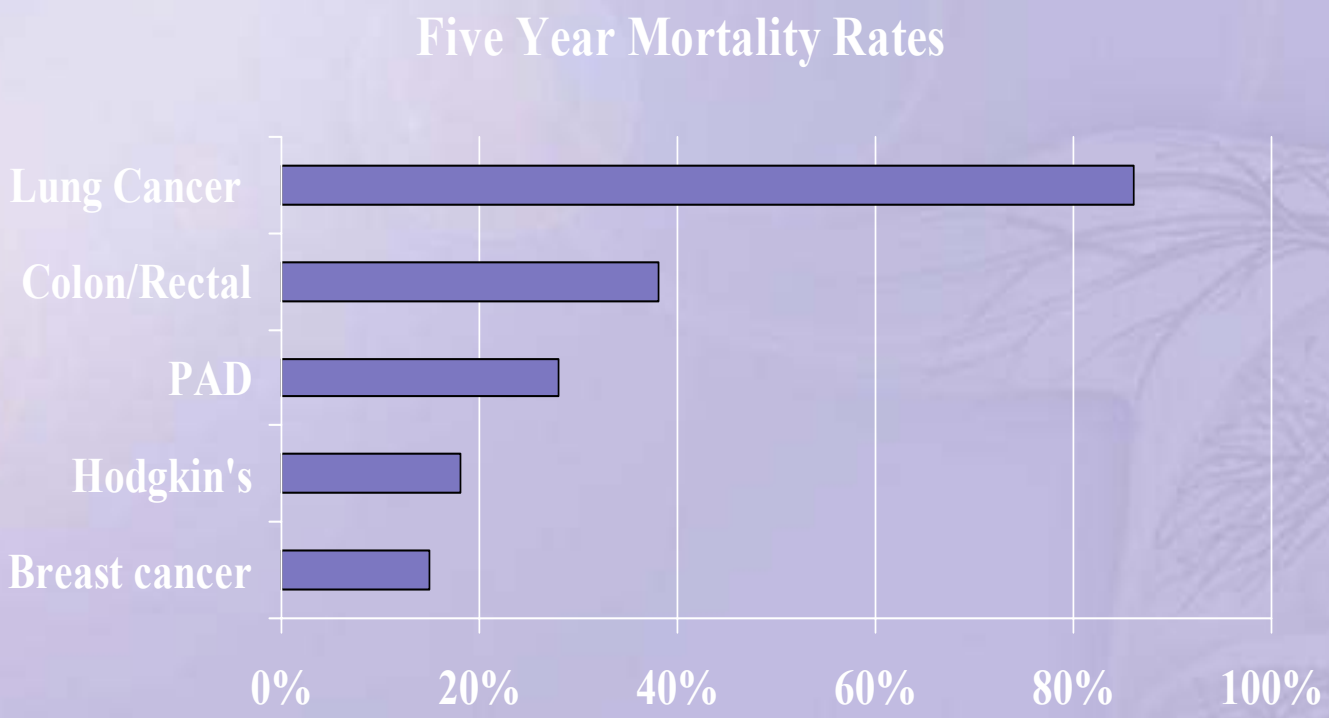


Disease State – Natural History

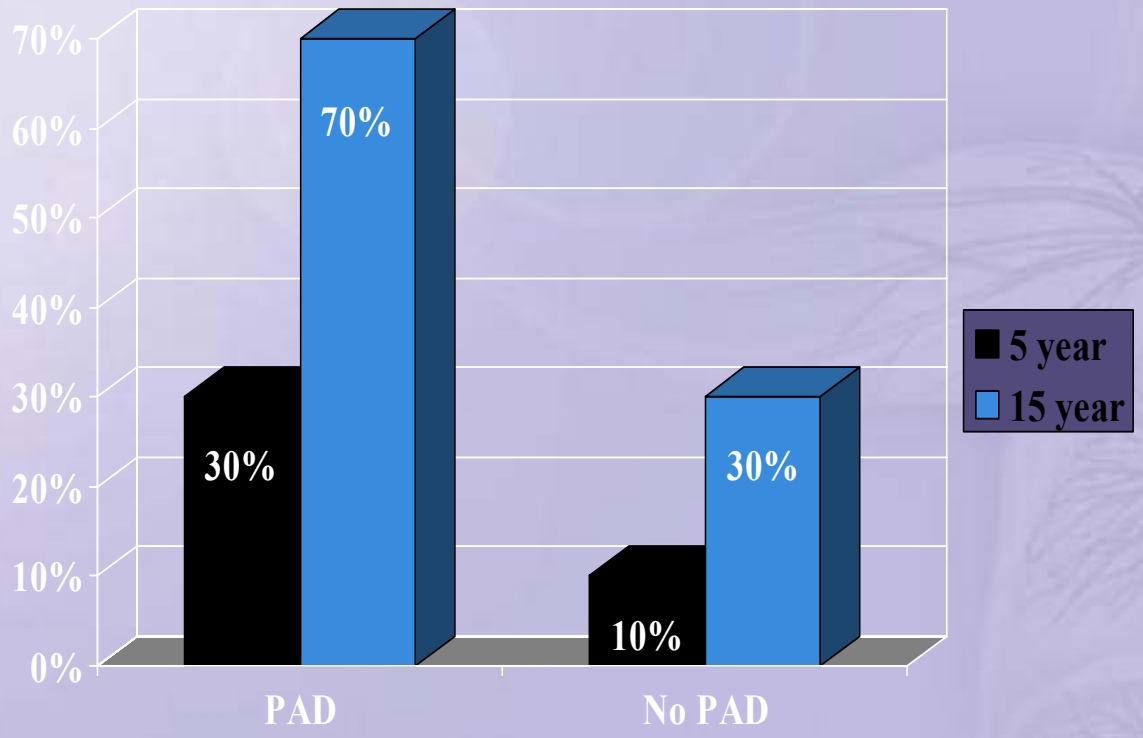
- Prognosis of Chronic Limb Ishemia is poor
  - Diffuse nature of the arterial obstructions
  - Concurrent cardiac, cerebrovascular, renal & pulmonary co-morbidities
  - 25% mortality rate in first year [4,5,6]
  - 25% amputation rate in first year
  - 50% of all below the knee amputation patients do not survive beyond 5 years

4. Weitz JI, Byrne J, Clagett P, et al. Diagnosis and treatment of chronic arterial insufficiency of the lower extremities: a critical review. *Circulation.* 1996;94:3026-3049.
5. TransAtlantic Inter-Society Consensus (TASC) on Management of Peripheral Arterial Disease (PAD). *J Vasc Surg.* 2000;31:1-296.
6. Pentacost MJ, Criqui MH, Dorros G, et al. Guidelines for peripheral percutaneous transluminal angioplasty of the abdominal aorta and lower extremity vessels. *Circulation.* 1994;89:511-531.

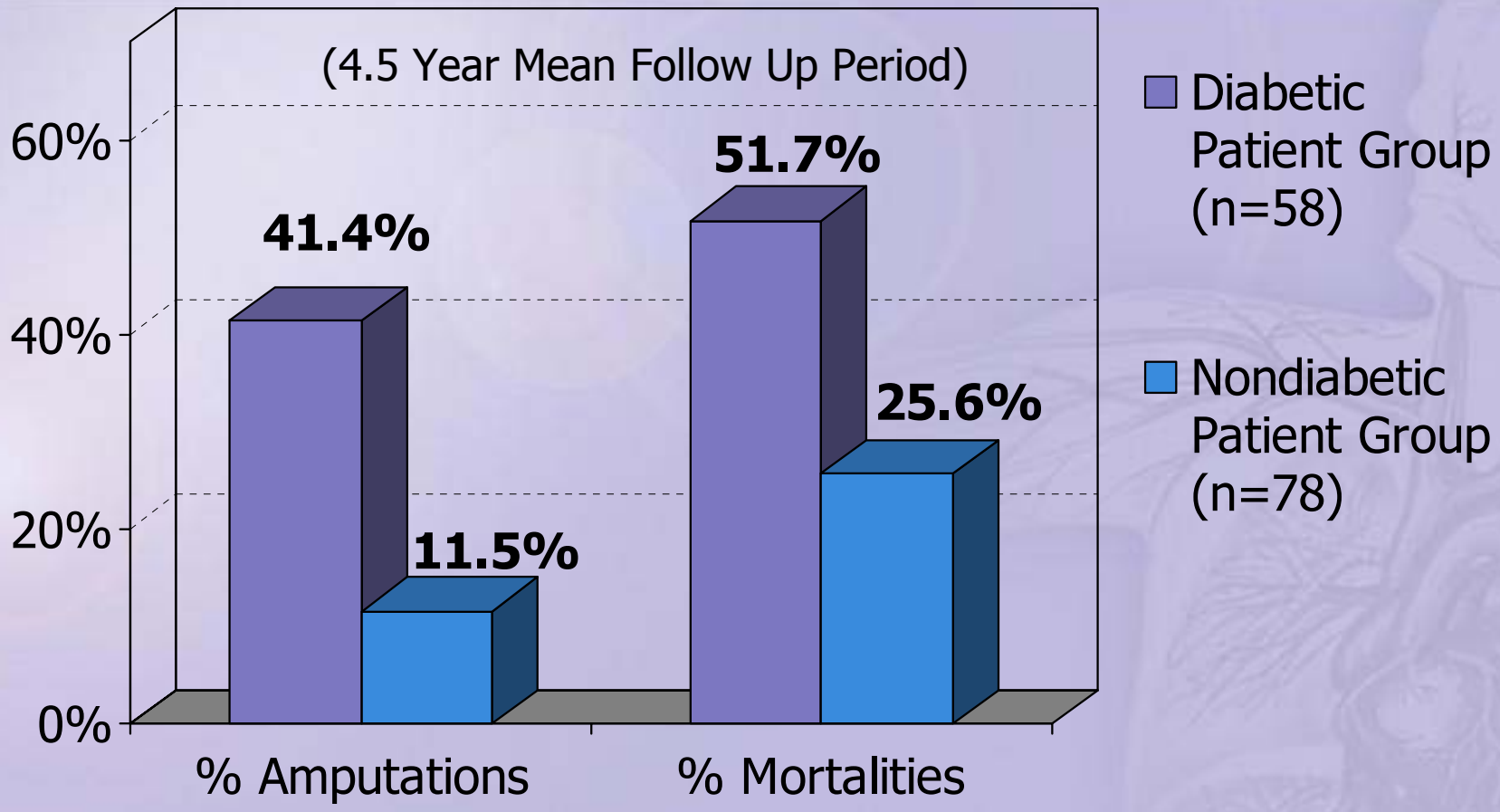
Disease State – Natural History



Mortality Rates- PVD v. No PVD



Disease State – Diabetic Patients



- Diabetic patients have a greater risk of lower extremity amputation and mortality than non-diabetic patients[3]

3. Jude EB et al. *Diabetes Care.* 2001;24:1433-1437.

Critical Limb Ischemia - Symptoms

1. Rest pain
   - Burning pain, usually worse in the distal foot & toes; typically most severe at night
   - Patients will dangle their feet over the edge of the bed for relief – promotes perfusion in feet & lower legs
   - May be accompanied by worsening claudication symptoms
   - "Pain out of proportion"

Critical Limb Ischemia - Symptoms

2. Ulcerations
   - Primarily ischemic, but may be a combination of ischemic and neuropathic
   - Ischemic ulcers:
     - Usually located on the feet (heels, tips of toes, between the toes)
     - Pressure points
     - Generally yellow, brown, gray, or blackened color
     - Borders and surrounding skin may appear as though they have been "punched out"

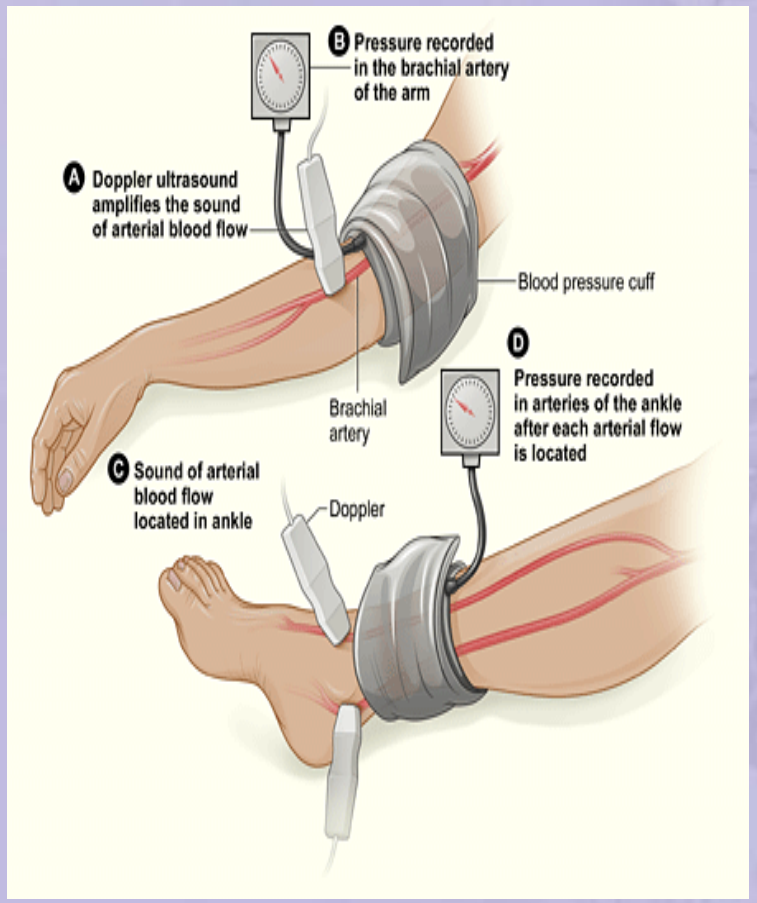
Image: woundcare.org

Critical Limb Ischemia - Symptoms

3. Gangrene
   - Arterial perfusion is inadequate – tissue necrosis occurs
   - Dry or Wet

Critical Limb Ischemia - Diagnostics

- Non-invasive tests
  - Elevation/dependency test
  - ABI (Ankle / Brachial Index)
  - CT-Angiography (CTA)
- Minimally-invasive tests
  - Peripheral Angiography (DSA- Digital Subtraction angiography)



Critical Limb Ischemia - Diagnostics

Elevation/dependency test

- Elevate limb to 45° to 60° for 30 to 60 seconds
- Elevated ischemic limbs will have pronounced white or yellow pallor
- A reddish/purple rubor when limb is dependent is strongly suggestive of CLI[6]

6. Pentacost MJ, Criqui MH, Dorros G, et al. Guidelines for peripheral percutaneous transluminal angioplasty of the abdominal aorta and lower extremity vessels. *Circulation.* 1994;89:511-531.

Critical Limb Ischemia - Diagnostics

Ankle-Brachial Index (ABI)

- Very sensitive, very easy

A ratio:

$$\frac{\text{Systolic ankle pressure (on the side of interest)}}{\text{Higher of either systolic brachial pressures}}$$

- Normal = 1.0
- PAD < 0.9
- <.7 severe disease
- <.5 ischemia

Critical Limb Ischemia - Diagnostics

- Angiography
  - Gold standard
  - Enables both diagnostic and intervention
  - NOT indicated in simple claudication
  - Indicated in rest pain, tissue loss, or failure of medical therapy

Critical Limb Ischemia - Diagnostics

Type	Advantages	Disadvantages
Digital Subtraction Angiography (DSA)	• Gold Standard – allows physician to determine the anatomic nature of lower leg arterial system and characterize type and severity of disease • Allows intervention	• Invasive • Exposure to nephrotoxic iodinated contrast • More costly than non-invasive
Spiral Computed Tomographic Angiography	• Allows 3-D reconstruction of carotid, abdominal aorta and branches (including lower extremities)	• Exposure to nephrotoxic iodinated contrast • Availability of 64 slice technology and software is limited, but expanding rapidly • Limited evaluation of distal main renal artery and segmental branches • No intervention capability
Nuclear Magnetic Resonance Angiography	• Non-invasive • Does not require iodinated radiocontrast agents • Allows direction detection of a stenosis and evaluation of renal function and perfusion • Theoretically suited for evaluation of tibial vessels	• Limited availability due to lack of MRA machines (and diagnostic software) • High cost of gadolinium • Limited evaluation of distal main, segmental and accessory renal arteries • No intervention capabiltity

Management of Limb Ischemia

Goals of Revascularization

- Restore adequate perfusion
- Reduce or eliminate ischemic pain
- Achieve wound healing salvage limb
- Limb Salvage is a commitment!

Images courtesy of Dr. Lanfroi Grazziani, Servizio di Emodinamica, Istituto Clinico “Città di Brescia” Brescia (Italy), www.extrem-es-angioplasty.it

Management of Limb Ischemia

Medical Management

- Antiplatelet (ASA®, Clopidogrel®, Dipyridamole®)
- Statins
- Control Pain
- Exercise
- Tobacco cessation
- Antibiotics for osteomylitis
- Prostaglandin infusions – vasodilatation
- Angiogenic growth factors – clinical trials

Management of Limb Ischemia

Surgery – "Gold Standard"

- Revascularization – Bypass surgery
  - Saphenous Vein – *in situ* grafting- reverse vein, cryovein
  - Synthetic Grafts – Dacron, PTFE

Management of Limb Ischemia

Amputation

- Trans-metatarsal Amputation (TMA) – remove gangrenous toes
- Below the Knee (BKA) or Above the Knee (AKA) Amputation – removal of the leg either below or above the knee
- Note: amputation still requires blood flow for tissue healing
- Many limb salvage procedures performed to spare more extensive amputation

Management of Limb Ischemia

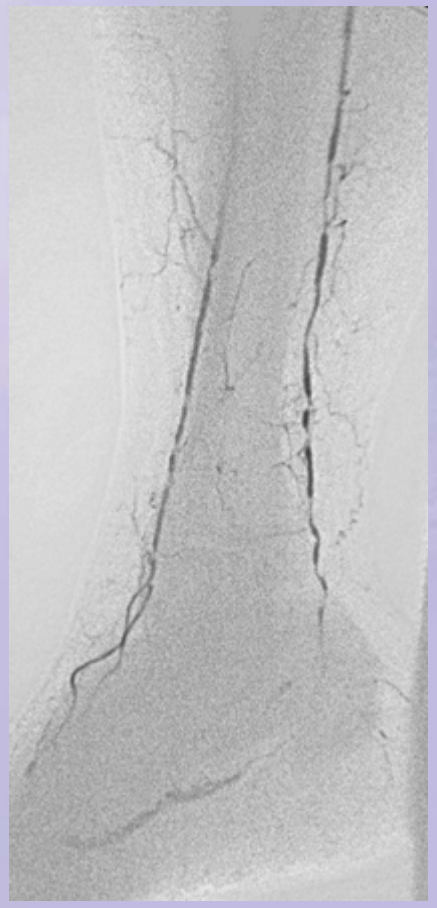
Why do Endovascular Procedures work?

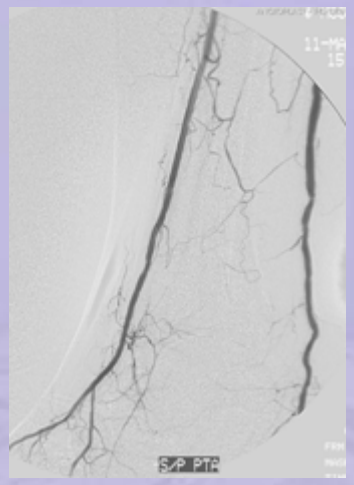
- The lower leg vessels usually connect in the foot so it is only necessary to open one of the three vessels for limb salvage
- Healing of ulcers or gangrene can be achieved by foot perfusion for 2 or 3 months
- Loss of patency after intervention may not result in recurrence- “collaterals”

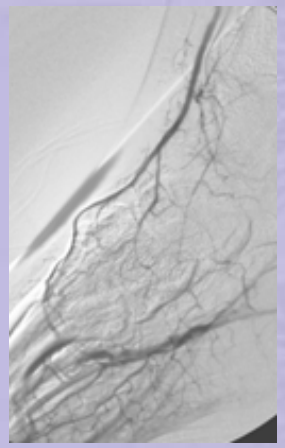
Management of Limb Ischemia

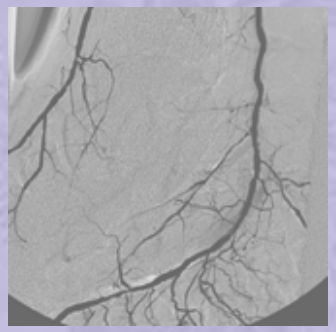
Approach to Lower Limb Salvage

- Illio-femoral limb revascularization to improve inflow
- Targeted treatment of infra-popliteal arteries to improve outflow or run-off
- Restoration of inflow without outflow is a recipe for failure









Management of Limb Ischemia

- Advantages of Endovascular Management
  - Avoids complications of general anesthesia
    - Procedures done with sedation/local
  - Avoids wound healing complications
    - Percutaneous, no incision
  - Less systemic stress
  - Early recovery and ambulation
  - Procedure may be repeated more readily than surgery
  - Preserves future surgical intervention options if no stent placed in future "landing zone"
- Disadvantages
  - Long term patency
  - Treatment dependant on interventional specialty (Cardiology v. Radiology v. Vascular Surgery)

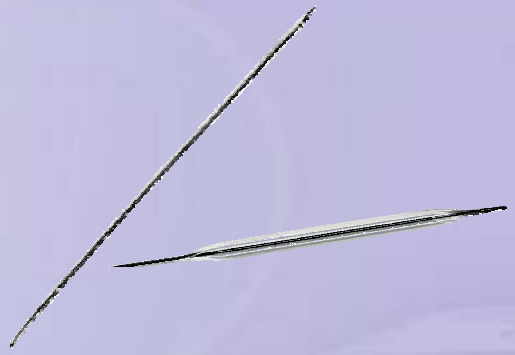
Endovascular Versus Surgery

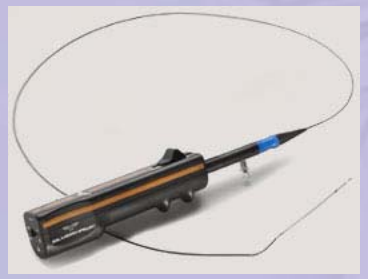
- BASIL (Bypass versus Angioplasty in Severe Ischemia of the Leg)
  - Landmark Study
  - Higher failure rates for angioplasty (20%) versus surgery(3%)
  - Amputation free survival was similar at one year
  - At 2 years, total survival and amputaion free survival rates higher in surgery
  - Angioplasty was cheaper than surgery

Management of Limb Ischemia

Endovascular Procedures

- Percutaneous Transluminal Angioplasty (PTA)
- Stenting
- Atherectomy
  - Directional
  - Laser
- "Specialized" Angioplasty Devices
  - Cutting Balloon
  - Cryoplasty





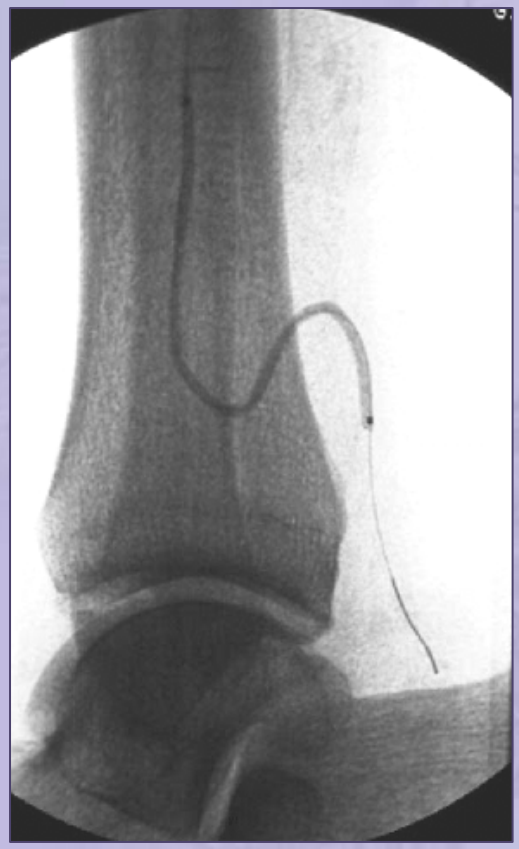
Percutaneous Transluminal Angioplasty (PTA)

Treatment

- Localized stretching of vessel wall with pressurized polymer-based balloon to break apart plaque and restore flow
- Low-profile, small diameter balloons of varying lengths

Best Use

- Balloon length should match lesion length to reduce number of inflations
- Considered the "gold standard" of endovascular options in SFA, Popliteal, and Tibial disease



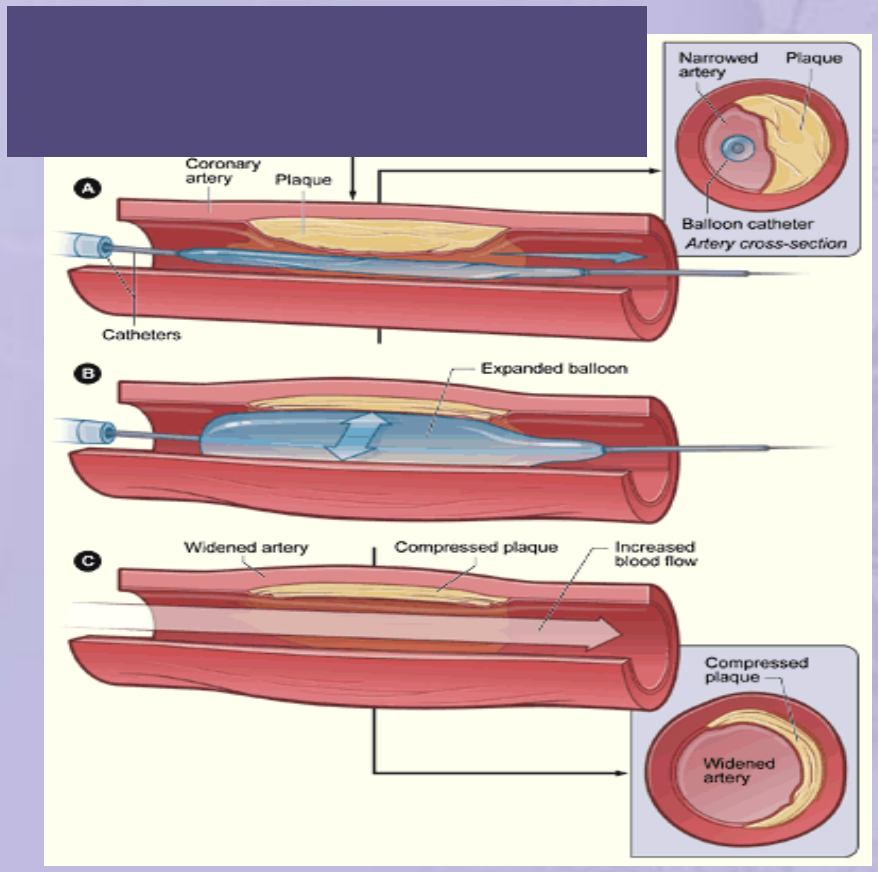
Percutaneous Transluminal Angioplasty (PTA)

Main Advantages (relative to other endovascular procedures)

- High technical and clinical success rates (>90%)
- Low major complication rate (<10%)
- May be repeated as necessary while preserving future surgical options

Main Disadvantages (relative to other endovascular procedures)

- Requires frequent follow-up/surveillance
  - Arterial surveillance every 3-6 months
- Technical success and patency vary by lesion location and morphology
  - In longer (>7 cm) and distal lesions efficacy greatly reduced
  - Better results in TASC A
  - Not indicated in TASC C and D lesions

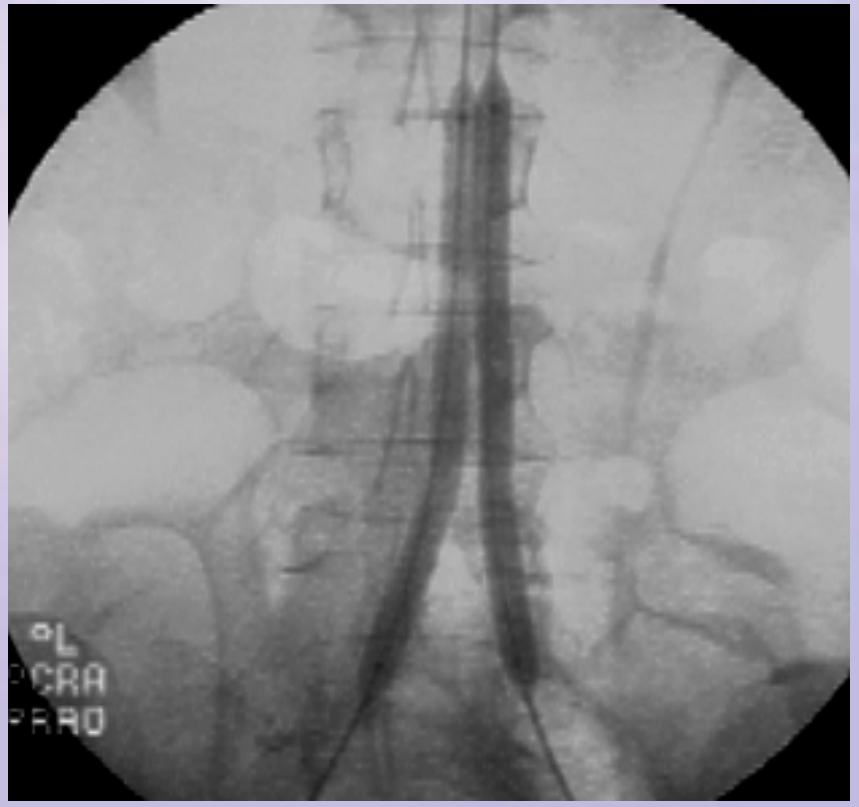


PTA Peripheral- Iliac

- Bilateral Iliac stenosis
- Distal aortic dissection
- Severe PVD with rest pain
- Tissue loss right foot

PTA Peripheral- Iliac

“Kissing Balloons”



Post PTA/Stent

Stenting

Treatment

- Placement of metallic tube in damaged artery to support and maintain lumen
- May be bare metallic, PTFE, or drug-eluting
- Covered or "bare"

Best Use

- Primary therapy for focal Iliac lesions
- Poor results in SFA, Popliteal, Tibial
- "Bail-out" for infrapopliteal PTA interventions if no improvement with PTA

Efficacy

- 95% technical success rate[12]
- Poor long term patency in SFA, Popliteal, Tibial

12. Wolosker, Nakano. Primary Utilization of Stents in Angioplasty of SFA. Vasc Endovasc Surg Jul-Aug; 37(4): 271-7. 2003

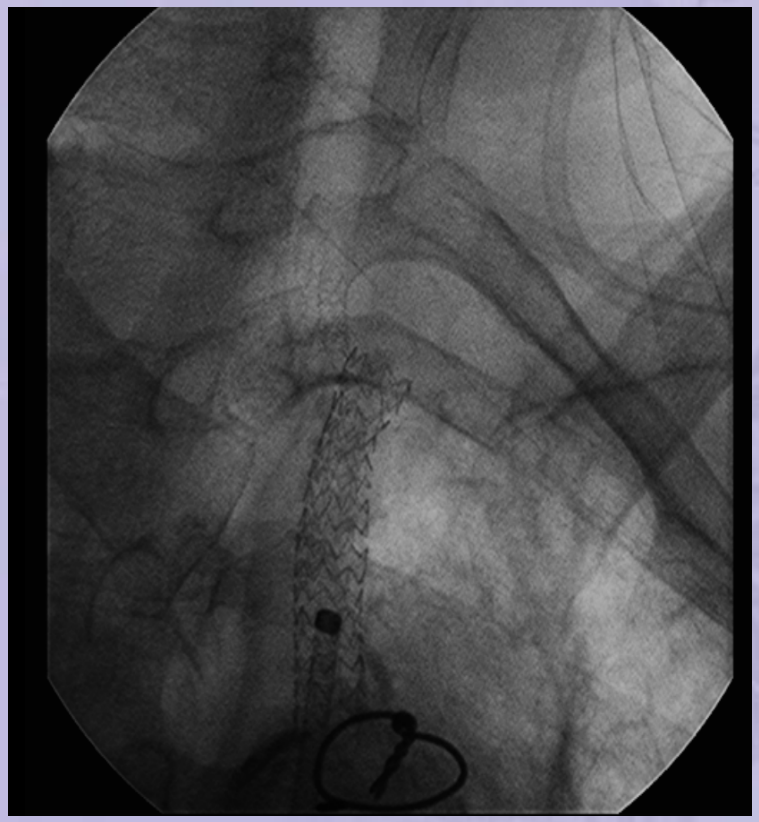
Stenting

Main Advantages (relative to other endovascular procedures)

- Studies suggest improved long term patency in appropriate lesions
- Rapidly evolving technology

Main Disadvantages (relative to other endovascular procedures)

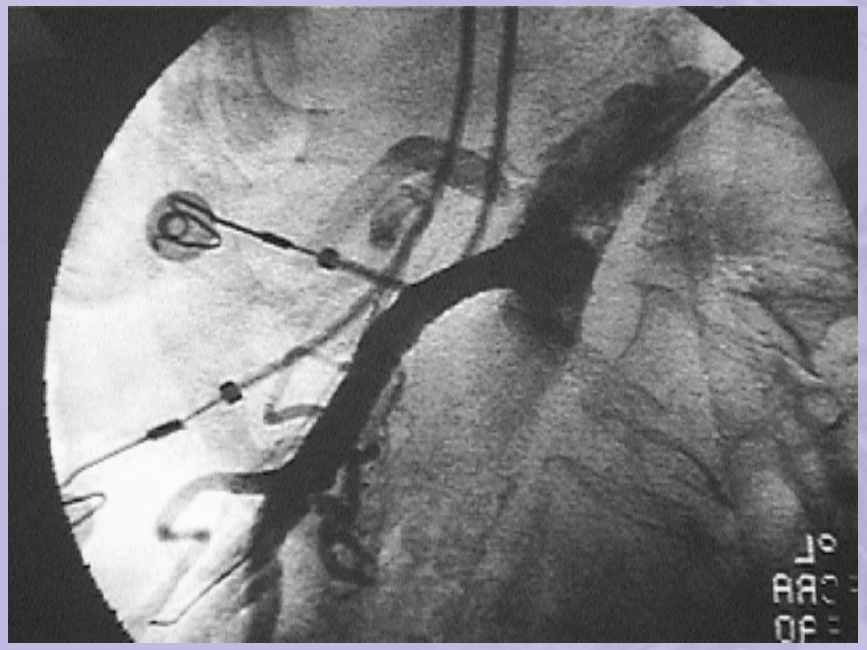
- Stent fracture may contribute to restenosis/thrombosis
- Like PTA, requires frequent clinical and angiographic surveillance
- Poor long term data on efficacy of SFA, Popliteal and Tibial stenting



Stenting- Mesenteric Applications

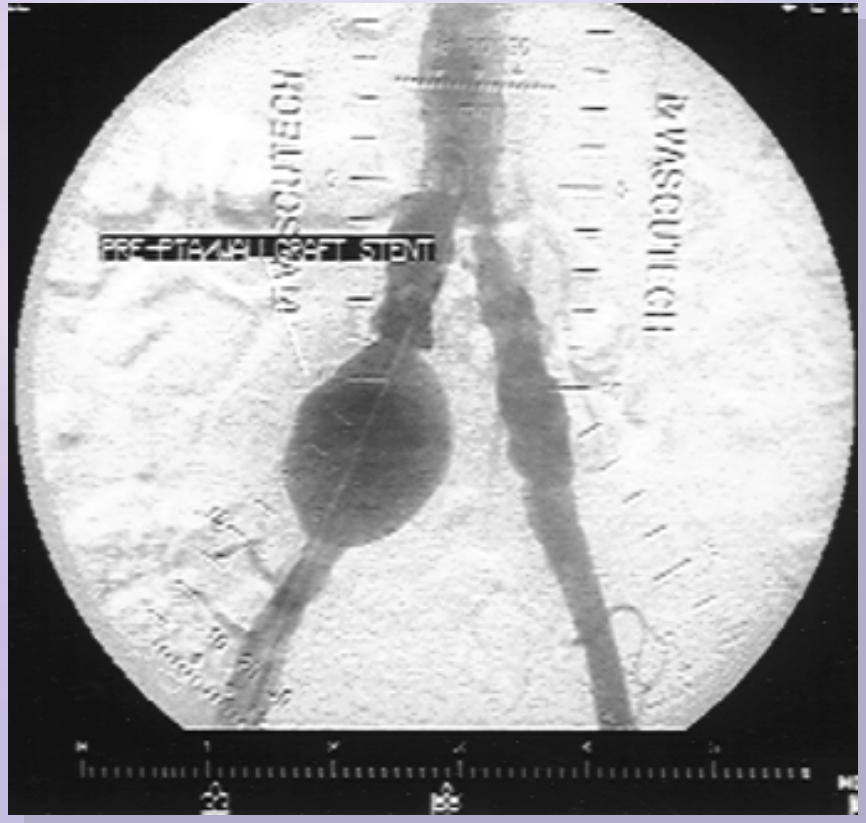
SMA Stenosis

Post Angiplasty/Stent



Stent Grafts- Covered Stents

Right Iliac Anuerysm



Post Stent graft Placement

Directional Atherectomy- "RotoRooter"

Treatment

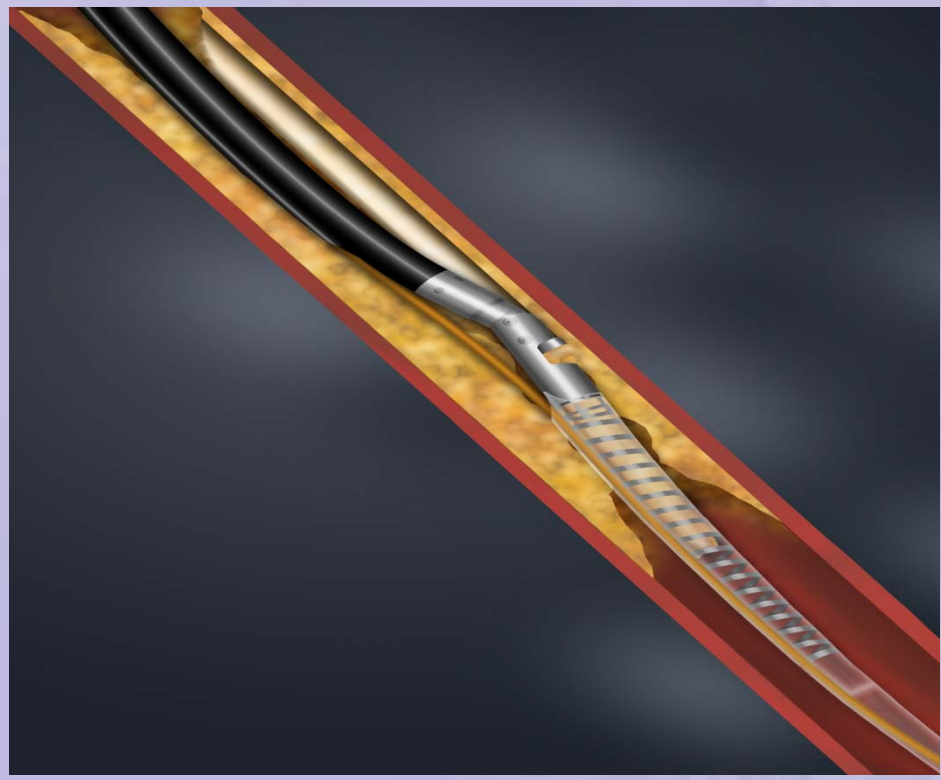
- Disposable monorail catheter connected to a battery-driven control unit
- Motor-driven carbide cutting blade
- Excised tissue stored in distal nosecone

Best Use

- "Debulking" of non-calcified lesions in SFA, CFA, popliteal and infrapopliteal arteries
- Often adjunctive to PTA balloon and/or stenting

Efficacy

- 80% 1-year patency[13]



13. Supplement to Endovascular Today (September, 2004)

Directional Atherectomy- "RotoRooter"

Main Advantages (relative to other endovascular procedures)

- Low major complication rate
- Reduced vessel barotrauma- PTA

Main Disadvantages (relative to other endovascular procedures)

- Tools and techniques require significant learning curve
- Risk of distal embolization
- Lack of long-term clinical data
- Like PTA, requires frequent clinical and angiographic surveillance
- Cost

Laser Atherectomy

- Treatment
  - Optical fibers arranged around a guidewire lumen
  - Catheter tip makes direct contact with diseased tissue and pulsed excimer laser light penetrates about 50 micrometers into the tissue
  - Vaporizes obstructive material
- Best Use
  - Adjunctive to PTA for in-stent restenosis, diffuse SFA occlusions and chronic total occlusions
- Efficacy
  - 85% procedural success rate (<50% residual stenosis)[14]
  - 6-month limb-salvage rates 90%[14]
  - 12-month patency rates 49% [15]

14. Laser Angioplasty for Critical Limb Ischemia (LACI) Phase 2 Study, Spectranetics Corporation, Colorado Springs, CO
15. Pulsed Excimer Laser Angioplasty (PELA) Trial, Spectranetics Corporation, Colorado Springs, CO

Laser Atherectomy

- Main Advantages (relative to other endovascular procedures)
  - Effective with complex, diffuse lesions and Chronic Total Occlusions
- Main Disadvantages (relative to other endovascular procedures)
  - Clinical results not demonstrated to be higher than stand-alone PTA
  - Requires capital equipment purchase and high learning curve
  - Potential lumen limited to the diameter of available catheters
  - 96% of cases require adjunctive use of PTA balloons[14]
  - Cost

14. Laser Angioplasty for Critical Limb Ischemia (LACI) Phase 2 Study, Spectranetics Corporation, Colorado Springs, CO

Cutting Balloon

- Treatment
  - Cutting blades (athertomes) placed longitudinally along surface of angioplasty balloon
  - Scores lesion with incisions to facilitate dilation of vessel
- Best Use
  - Bypass graft anastomosis
  - Bifurcation stenosis
- Efficacy
  - 95% technical success rate[16]

16. Engelke C, Sandhu C, Morgan RA, Belli AM. Using 6-mm Cutting Balloon angioplasty in patients with resistant peripheral artery stenosis: preliminary results. AJR Am J Roentgenol. 2002 Sep;179(3):619-23.

Cutting Balloon

- Main Advantages (relative to other endovascular procedures)
  - Controlled injury is localized to atherotome incision planes for predictable dilation of calcified lesions
- Main Disadvantages (relative to other endovascular procedures)
  - Restricted range of balloon diameters and lengths (1 & 2 cm lengths only) limits potential applications
  - Efficacy not proven to be superior to high-pressure PTA

Cryoplasty (Cooling Balloon)

- Treatment
  - Angioplasty balloon system consists of a disposable catheter, a reusable power module, a reusable inflation unit and disposable nitrous oxide cartridge
  - Liquid nitrous oxide fills angioplasty balloon and exposes ~500 microns of diseased vessel wall to -10° centigrade cold
  - Cold therapy intended to induce cell apoptosis and slow restenosis response
- Best Use
  - In-stent restenosis
- Efficacy
  - 9-month re-intervention rate <15% in patients with lesions <10 cm[17]

17. John Laird, MD, Michael R. Jaff, DO, Giancarlo Biamino, MD, Thomas McNamara, MD, Dierk Scheinert, MD, Patrick Zetterlund, MD, Elaine Moen, MD and James D. Joye, DO. Cryoplasty for the Treatment of Femoropopliteal Arterial Disease: Results of a Prospective, Multicenter Registry. Journal of Vascular and Interventional Radiology 16:1067-1073 (2005)

Cryoplasty (Cooling Balloon)

- Main Advantages (relative to other endovascular procedures)
  - May reduce neotintimal hyperplasia response
  - Suggested to be less-traumatic to vessel

- Main Disadvantages (relative to other endovascular procedures)
  - Not demonstrated to be safer or more effective than other forms of PTA
  - -10° C only induces apoptosis in approximately 50% of contacted cells; may not be enough to significantly reduce restenosis
  - Additional system set up time
  - Cost (multiple catheters, cartridges, etc.)
  - Restricted range of balloon diameters and lengths (4cm length only) limits potential applications

Outcomes with Endovascular Interventions

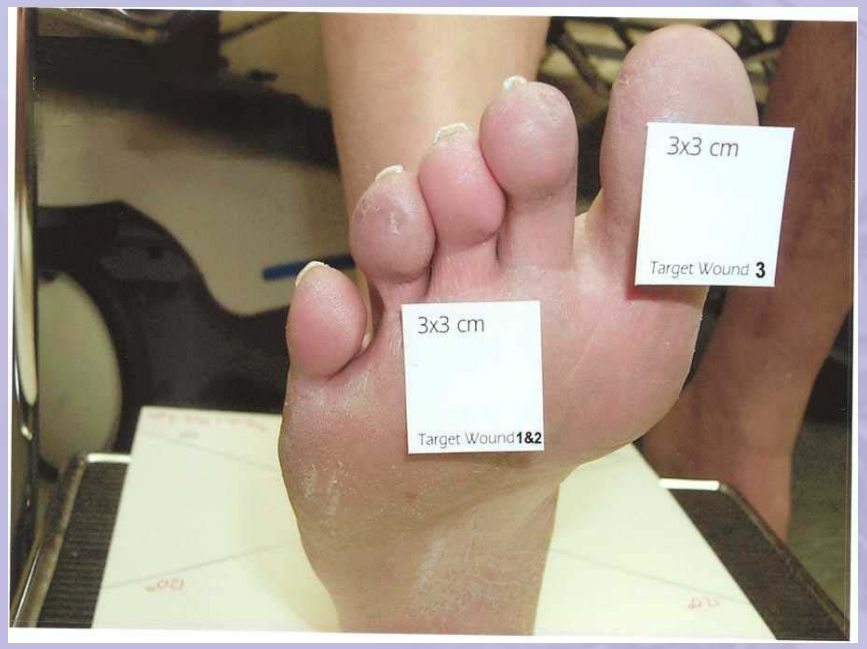
Arterial Ulcer

Post intervention

Outcomes with Endovascular Interventions

Severe PVD with Ischemia

Post intervention- 2 mo.



Outcomes with Endovascular Interventions

Arterial ulcer

Post intervention

Summary

- Chronic Limb Ischemia emerges as PAD progresses in severity
- Surgery is the "Gold Standard"
- Advantages of using interventional procedures to treat PAD
  - Avoids complications of general anesthesia
  - Avoids wound healing complications
  - Less systemic stress
  - Early recovery and ambulation
  - Procedure may be repeated more readily than surgery
  - Preserves future surgical intervention options
- Generally, all a patient needs is a few months of good flow – for foot survival or salvage

Thank You

Reference Summary

1. Dormandy J, Mahir M, Ascady G., Balsano F, De Leeuw P, Blomberg P, Bousser MG, Clement D, Coffman J, Deutschinoff A, et al. Fate of the patient with chronic leg ischemia: a review article. J Cardiovasc Surg (Torino). 1989;30:50-57.
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9. Faglia, Paolo, Clerci, Cleressi, Graziani, et al. Peripheral Angioplasty as the First-choice Revascularization Procedure in Diabetic Patients with Critical Limb Ischemia: Prospective Study of 993 Consecutive Patients Hospitalized and Followed Between 1999 and 2003. *Eur J Vasc Endovasc Surg.* 2005;29:620-627.
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13. Supplement to Endovascular Today (September, 2004)
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