Peripheral Arterial Disease: Early Detection and Interventional Treatment Options

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Disclosures

• No relevant financial disclosures to discuss
• I will discuss the off-label use of various stents
Peripheral Arterial Disease and Claudication

• **Peripheral Arterial Disease (PAD)**
  A disorder caused by atherosclerosis that limits blood flow to the limbs

• **Claudication**
  A symptom of PAD characterized by pain, aching, or fatigue in working skeletal muscles. Claudication arises when there is insufficient blood flow to meet the metabolic demands in leg muscles of ambulating patients
The problem: peripheral arterial disease

**PAD affects 8-12 million people in the U.S.**¹

150,000 Amputations Yearly Due to CLI²

Up to 2 Million with Critical Limb Ischemia (CLI)²

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¹ US Department of Health & Human Services National Institute of Health August 2006.
² Jaff, MR, Biamino G; “Conquering Critical Limb Ischemia”, Endovascular Today, February 2004; Volume 3, No. 2

Images provided by CSI.
Defining a Population “At Risk” for Lower Extremity PAD

• Age less than 50 years with diabetes, and one additional risk factor (e.g., smoking, dyslipidemia, hypertension)
• Age 50 to 69 years and history of smoking or diabetes
• Age 70 years and older
• Leg symptoms with exertion (suggestive of claudication) or ischemic rest pain
• Abnormal lower extremity pulse examination
• Known atherosclerotic coronary, carotid, or renal artery disease
Prevalence of PAD

In a primary care population defined by age and common risk factors, the prevalence of PAD was approximately one in three patients.

NHANES=National Health and Nutrition Examination Study;
PARTNERS=PAD Awareness, Risk, and Treatment: New Resources for Survival [program].

29\% of Patients Were Diagnosed With PAD Using ABI

PARTNERS: Prevalence of PAD and CVD in Primary Care Practices

ABI=ankle-brachial index; CAD=coronary artery disease; CVD=cardiovascular disease.

Gender Differences in the Prevalence of PAD

Diabetes Increases Risk of PAD

Impaired Glucose Tolerance was defined as oral glucose tolerance test value ≥140 mg/dL but <200 mg/dL.

*P ≤ .05 vs normal glucose tolerance.

Risk Factors for PAD

- Smoking: Reduced
- Diabetes: Increased
- Hypertension: Increased
- Hypercholesterolemia: Increased
- Hyperhomocysteinemia: Increased
- C-Reactive Protein: Increased

Association Between ABI and All-Cause Mortality*

Age range=mid- to late-50s; *Median duration of follow-up was 11.1 (0.1–12) years.
Adapted from O’Hare AM et al. Circulation. 2006;113:388-393.
A Risk Factor “Report Card” for all Individuals with Atherosclerosis

**Tobacco smoking**
- Complete, immediate cessation

**Hypertension**
- BP less than 130/85 mmHg

**Diabetes**
- Hb A1C < 7.0

**Dyslipidemia**
- LDL Cholesterol less than 100 mg/dl
- Raise HDL-c
- Lower Triglycerides

**Inactivity**
- Follow activity guidelines

**Antiplatelet therapy (like ASA or Clopidogrel) is:**

*Mandatory*
Pathway of Disability in Intermittent Claudication


- PAD Reduced muscle strength
- Poor walking ability and IC
- Disability

Denervation, muscle-fiber atrophy, decreased type II fibers, decreased oxidative metabolism

Cycle of deconditioning: decreased HDL, poorer glycemic control, poorer BP control
PAD in Women:

Often Unrecognized and Untreated According to AHA

American Heart Association scientific statement - February 15, 2012

Healthcare providers should proactively increase awareness of and test women at risk for PAD

- The AHA, Vascular Disease Foundation and Peripheral Artery Disease Coalition

“Women with peripheral artery disease, or PAD, are two to three times more likely to have a stroke or heart attack than those without it — yet it’s often unrecognized and untreated, especially in women”\(^1\)

5 Year Mortality rates for PAD and CLI

Ethnicity and PAD: The San Diego Population Study

PAD
Prognosis
The Natural History of PAD

- Individuals with PAD are at increased risk for cardiovascular ischemic events due to concomitant CAD (fatal and non-fatal MI) and cerebrovascular disease (fatal and non-fatal stroke).

- Cardiovascular events are more frequent than ischemic limb events in any lower extremity PAD cohort, regardless of the clinical presentation.
The Natural History of PAD

- Individuals with PAD are at increased risk for cardiovascular ischemic events due to concomitant CAD (fatal and non-fatal MI) and cerebrovascular disease (fatal and non-fatal stroke).

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Natural History of Atherosclerotic Lower Extremity PAD

**PAD Population (50 years and older)**

**Initial clinical presentation**

- **Asymptomatic PAD**
  - 20%-50%

- **Atypical leg pain**
  - 40%-50%

- **Claudication**
  - 10%-35%

- **Critical limb ischemia**
  - 1%-2%

**Progressive functional impairment**

**1-year outcomes**

- Alive w/ 2 limbs: 50%
- Amputation: 25%
- CV mortality: 25%

**5-year outcomes**

(to next slide)

Natural History of Atherosclerotic Lower Extremity PAD

For each of these PAD clinical syndromes

- Asymptomatic PAD 20%-50%
- Claudication 10%-35%
- Atypical leg pain 40%-50%

5-year outcomes

- Limb morbidity
  - Stable claudication 70%-80%
  - Worsening claudication 10%-20%
  - Critical limb ischemia 1%-2%
    - Amputation (see CLI data)

- CV morbidity & mortality
  - Nonfatal CV event (MI or stroke) 20%
  - Mortality 15%-30%
    - CV causes 75%
    - Non-CV causes 25%

10-Year Natural History in Patients With Intermittent Claudication

Survival
MI
Intervention
Amputation

Patients (%)

Time (years)

Critical Limb Ischemia (CLI)

Fate of Patients With CLI After Initial Treatment
Summary of 6-month outcomes from 19 studies

- Alive without amputation: 45%
- Alive with amputation: 35%
- Dead: 20%

Critical limb ischemia is defined as ischemic rest pain, non-healing wounds, or gangrene.

PAD
Clinical Presentations
Individuals with PAD Present in Clinical Practice with Distinct Syndromes

**Asymptomatic:** Without obvious symptomatic complaint (but usually with a functional impairment).

**Classic Claudication:** Lower extremity symptoms confined to the muscles with a consistent (reproducible) onset with exercise and relief with rest.

**“Atypical” leg pain:** Lower extremity discomfort that is exertional, but that does not consistently resolve with rest, consistently limit exercise at a reproducible distance, or meet all “Rose questionnaire” criteria.
Individuals with PAD Present in Clinical Practice with Distinct Syndromes

*Critical Limb Ischemia:* Ischemic rest pain, non-healing wound, or gangrene

*Acute limb ischemia:* The five “P’s, defined by the clinical symptoms and signs that suggest potential limb jeopardy:
  - Pain
  - Pulselessness
  - Pallor
  - Paresthesias
  - Paralysis (& polar, as a sixth “p”).
Clinical Presentations of PAD

- Classic (Typical) Claudication: ~15%
- Atypical Leg Pain (functionally limited): ~33%
- Critical Limb Ischemia: 1-2%
- Asymptomatic: 50%

50% Asymptomatic

~15% Classic (Typical) Claudication

~ 33% Atypical Leg Pain (functionally limited)

1-2% Critical Limb Ischemia
Early Screening of patients for PAD

- Over 50 years old
- Current or past smoker
- Kidney disease
- High blood pressure
- High cholesterol
- Leg fatigue, heaviness, or cramping
- Pain in the legs and/or feet that disturbs sleep
- Toes or feet look pale, discolored or bluish
- Sores / wounds on toes, feet, or legs that heal slowly or not at all
- One leg or foot feels colder than the other
- Poor nail growth and decreased hair growth over time on toes and legs
Clinical Assessment of Peripheral Arterial Disease
Components of Clinical Assessment

• Complete history
  • Risk factor assessment
  • Activity assessment
• Review of medications
• Physical examination
  • Inspection of lower extremities
  • Pulse exam
Questions for Patients

• Do you develop discomfort in your legs when you walk?
  • Cramping, aching, fatigue
• Do you get this pain when you are sitting standing, or lying?
• Do symptoms only start when you walk?
• Does the discomfort always occur at about the same distance?
• Do symptoms resolve once you stop walking?
The Ankle-Brachial Index (ABI)

• The first diagnostic assessment that should be done to evaluate a patient for PAD after a pulse exam in the presence of risk factors or if claudication is suspected.

• Inexpensive, accurate and can be done in the Ambulatory & Primary Care Setting

• The ABI is 95% sensitive and 99% specific for PAD

• Predicts limb survival, potential for wound healing, and mortality
The Ankle-Brachial Index (ABI)

- Indicated
  - In the absence of palpable pulses, or if pulses are diminished
  - In the presence or suspicion of claudication, foot pain at rest, or a non-healing foot ulcer
  - Age greater than 70 years of age, >50 years with risk factors (diabetes, smoking)
Concept of ABI

The systolic blood pressure in the leg should be approximately the same as the systolic blood pressure in the arm.

Therefore, the ratio of systolic blood pressure in the leg vs the arm should be approximately 1 or slightly higher.

ABI has been found to be 95% sensitive and 99% specific for angiographically diagnosed PAD.

Calculating the ABI

Right Leg ABI

Higher right-ankle pressure
(DP or PT pulse)

Higher arm pressure
(of either arm)

Left Leg ABI

Higher left-ankle pressure
(DP or PT pulse)

Higher arm pressure
(of either arm)

ABI Interpretation

≤ 0.90 is diagnostic of peripheral arterial disease

ABI Limitations

- Possible false negatives in patients with noncompressible arteries, such as some diabetics and elderly individuals
- Insensitive to very mild occlusive disease and iliac occlusive disease
- Not well correlated with functional ability and should be considered in conjunction with activity history or questionnaires
Referring to the Vascular Lab

Caveats for referral to vascular lab

- Assessment of the location and severity is desired
- Patients with poorly compressible vessels
- Normal ABI where there is high suspicion of PAD

Vascular Lab Evaluation

- Segmental pressures
- Pulse volume recordings
- Treadmill

PAD Diagnosis
Segmental Pressures (mm Hg)

<table>
<thead>
<tr>
<th>Segmental Pressures</th>
<th>150</th>
<th>110</th>
<th>108</th>
<th>62</th>
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<tbody>
<tr>
<td>Brachial</td>
<td>150</td>
<td>146</td>
<td>100</td>
<td>84</td>
</tr>
<tr>
<td>ABI</td>
<td>0.54</td>
<td>0.44</td>
<td></td>
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</tr>
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</table>
Pulse Volume Recordings
Exercise ABI

- Confirms the PAD diagnosis
- Assesses the functional severity of claudication
- May “unmask” PAD when resting the ABI is normal
- Aids differentiation of intermittent claudication vs. pseudoclaudication diagnoses
Exercise Testing

- Indicated when the ABI is normal or borderline, but symptoms are consistent with claudication;
- An ABI fall post-exercise supports a PAD diagnosis;
- Assesses functional capacity (patient symptoms may be discordant with objective exercise capacity).
The Plantar Flexion Exercise ABI

**Benefits:**

- Reproduces treadmill-derived fall in ABI
- Can be performed anywhere
- Inexpensive

Color Duplex Ultrasonography
Arterial Duplex Ultrasound Testing

- Duplex ultrasound of the extremities is useful to diagnose anatomic location and degree of stenosis of peripheral arterial disease.

- Duplex ultrasound is useful to provide surveillance following femoral-popliteal bypass using venous conduit (but not prosthetic grafts).

- Duplex ultrasound of the extremities can be used to select candidates for:
  (a) endovascular intervention;
  (b) surgical bypass, and
  (c) to select the sites of surgical anastomosis.

However, the data that might support use of duplex ultrasound to assess long-term patency of PTA is not robust.
Angiograms and Revascularization are Underutilized Prior to Amputation

According to Medicare Data

N = 20,464 Patients with PAD who underwent major leg amputation (2003 – 2006)

Amputation rates decrease as Revascularization rates increase

Single Center 12 Year Review

N = 1615 lower extremity vascular procedures

Goals of Therapy for PAD

- Identify CAD/CVD
- Prevent Progression of Disease/Amputation
- Modify Atherosclerotic Risk Factors To Reduce Risk of Mortality
- Improve Functional Capacity/QOL
Therapy for Intermittent Claudication

- **Symptom/Limb**
  - Tobacco Cessation
  - Foot Care
  - Control of DM
  - Reduction in Cholesterol
  - Antiplatelet Agents
  - Exercise
  - Cilostazol

- **Life**
  - Tobacco Cessation
  - Control of DM
  - Reduction in Cholesterol
  - Reduction in BP
  - Antiplatelet Agents
  - Exercise

Columbia University Medical Center
Cardiovascular Research Foundation
Effects of tobacco cessation

- Reduces progression of PAD
  - CLI and amputation
- Reduces IC symptoms
- Reduces CV morbidity and mortality
- Improves graft patency
CAPRIE Study

Outcome by Subgroup

Mean & 95% CI

Stroke

MI

PAD

All patients

Aspirin better

Clopidogrel better

The HOPE Study: PAD Subgroup Analysis

<table>
<thead>
<tr>
<th>No. of Patients</th>
<th>Incidence (%) of Composite Outcome in Placebo Group</th>
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<tbody>
<tr>
<td>PAD</td>
<td>4051 22.0</td>
</tr>
<tr>
<td>No PAD</td>
<td>5246 14.3</td>
</tr>
</tbody>
</table>

Relative Risk in Ramipril Group

The Effect of Atorvastatin on Pain-Free Walking Time

Intent-to-treat population

Mohler, E. Presented at AHA 2002,

Columbia University Medical Center
Pharmacologic Effects of Cilostazol

Cilostazol

- Antiplatelet activity
- Antithrombotic activity
- Produces vasodilation
- Mildly increases heart rate
- Increases blood flow
- In vitro inhibition of vascular smooth muscle cells
- Decreases triglycerides
- Increases HDL-C
Effect of Cilostazol on Walking Distance in Patients With Claudication

Maximal Walking Distance
- Cilostazol 100 mg bid
- Cilostazol 50 mg bid
- Placebo (n=140)

Pain-Free Walking Distance

* P<.05 vs placebo

Indications for Revascularization

- Lifestyle-disabling claudication (refractory to exercise or pharmacotherapy)
- Rest pain
- Tissue loss
Lower-extremity ischemia: therapeutics

Surgical
- Aorto-bifemoral, femoral-popliteal, etc., bypass
- Generally good symptom relief and durability, but is dependent on inflow, conduit used, outflow disease, etc.,
- Risks increase with abdominal operation, medical comorbidities
- Recovery period is significant
Anatomic Factors Used to Determine Risk–Benefit Ratio of Percutaneous Intervention

<table>
<thead>
<tr>
<th>Anatomy of Disease</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>Disease located across joint spaces (CFA and popliteal artery disease) warrants a more conservative approach</td>
</tr>
<tr>
<td></td>
<td>Disease localized to infra-popliteal segment is not generally a target for treatment in patients with claudication</td>
</tr>
<tr>
<td>Stenosis versus Occlusion</td>
<td>Stenoses are associated with higher procedural success and patency rates, and lower procedural complexity compared with occlusions</td>
</tr>
<tr>
<td>Pattern of Disease</td>
<td></td>
</tr>
<tr>
<td>Focal versus Diffuse</td>
<td>Focal pattern is associated with higher procedural success and patency rates, and lower procedural complexity compared with diffuse pattern.</td>
</tr>
<tr>
<td>Lesion and Vessel Calcification</td>
<td>Vessel calcification predicts increased procedural complexity</td>
</tr>
<tr>
<td>Tibial Run-off</td>
<td>Poor tibial run-off is felt to be associated with lower long-term patency of more proximal interventions, and increases the risks associated with complications such as distal embolization</td>
</tr>
</tbody>
</table>
TASC Classification of Aortoiliac Lesions

(Slide 1 of 2)

**Type A lesions:**
- Unilateral or bilateral stenoses of CIA
- Unilateral or bilateral single short (≤3 cm) stenosis of EIA

**Type B lesions:**
- Short (≤3 cm) stenosis of infrarenal aorta
- Unilateral CIA occlusion
- Single or multiple stenosis totaling 3–10 cm involving the EIA not extending into the CFA
- Unilateral EIA occlusion not involving the origins of internal iliac or CFA
TASC Classification of Aortoiliac Lesions
(Slide 2 of 2)

Type C lesions:
- Bilateral CIA occlusions
- Bilateral EIA stenoses 3–10 cm long not extending into the CFA
- Unilateral EIA stenosis extending into the CFA
- Unilateral EIA occlusion that involves the origins of internal iliac and/or CFA
- Heavily calcified unilateral EIA occlusion with or without involvement of origins of internal iliac and/or CFA

Type D lesions:
- Infra-renal aortoiliac occlusion
- Diffuse disease involving the aorta and both iliac arteries requiring treatment
- Diffuse multiple stenoses involving the unilateral CIA, EIA, and CFA
- Unilateral occlusions of both CIA and EIA
- Bilateral occlusions of EIA
- Iliac stenoses in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery
The ideal revascularization procedure for treating patients with lower limb ischemia varies depending on the lesion severity:

- **Type A**: endovascular procedures are recommended
- **Type B**: endovascular procedures are recommended unless an open revascularization procedure (surgery) is required for other lesions in the same anatomic area
- **Type C**: open revascularization procedures are recommended. Endovascular procedures are only recommended in patients who have a low healing potential following surgical revascularization
- **Type D**: endovascular procedures are not recommended as first-line treatment
Aortoiliac

• Improved outcomes with endovascular treatment
• TASC II revised classification of aortoiliac disease that may be approached with percutaneously
• Subset of patients better served by surgery (typically aortobifem bypass)
  • Significant aortoiliac anuerysmal disease
  • Diffuse aortoiliac disease involving the CFA
Technique

• Stent is considered required for:
  • Residual stenosis > 30%
  • Residual gradient > 5-10 mmHg
  • Flow limiting dissection
  • Treatment of restenosis and occlusion
Balloon Expandable Peripheral Stent

- Primarily used when precision needed in placement

- Aortoiliac bifurcation most commonly used site

- Higher risk of rupture compared to self expanding stents
Balloon Angioplasty – Armada Balloon

- Standard balloon used for stand alone angioplasty

- Also used to pre-dilate lesions and post dilate both balloon expandable and self expanding stents

- Balloon expandable stents are usually post dilated with a balloon that is equal to or larger than the stent size

- Self expanding stents are usually post dilated with a smaller balloon than the stent size
Technique

• Balloon-expandable stents
  • Aortoiliac bifurcation lesions
  • CIA
  • Proximal EIA

• Self-expanding stents
  • Distal EIA
Self Expanding Stent – ABSOLUTE Pro

- Nitonol scaffold

- Continues to expand as it reaches body temperature

- Lower risk of perforation compared to balloon expandable stents
Aortoiliac Occlusive Disease: 
*Angioplasty With or Without Stenting*

- High procedural success rates (90%)
- Excellent long-term patency (≥70% at 5 years)
- Factors associated with a poor outcome:
  - Long segment occlusion
  - Multifocal stenoses
  - Eccentric calcification
  - Poor runoff
Outcome

• Major complications: approx 4%
  • Vascular access
  • Iliac perforation
  • Distal embolization
Interventional Technique

• Retrograde ipsilateral access
• Predil with 5x30 ARMADA balloon
• Stent with 8x40 ABSOLUTE stent
• Postdil with 7x30 ARMADA balloon
Interventional Technique

- **Retrograde contralateral access**
- **Crossover sheath into RCIA**
- **Predil with 5x20 Armada balloon**
- **Stent with 8x30 SMART Flex stent**
- **Postdil with 7x30 Armada balloon**
Common Femoral

• Best treated with surgical endarterectomy
  • Typically combined with patch arterioplasty
• Avoid stenting due to proximity to hip joint
  • Possibility of flow limiting dissection
  • Possibility of plaque shift into PFA and SFA
Caveat on CFA

Recent availability of atherectomy devices has allowed percutaneous treatment of noncalcified CFA lesions

Silverhawk

ABBOTT Vascular has recently released the SUPERA stent which has remarkable flexibility and allows CFA stenting.

CORDIS SMART Flex stent has been recently released and may be used in the CFA if necessary
Self Expanding Stent – SMART-FLEX stent

- Nitinol stent with unique design allowing this stent to be used in the CFA and also in the popliteal

- Can also be used in the SFA and Iliac artery
Angiographic Appearance of Common Femoral Artery Lesion With Prominent Calcification (arrows)
Calcium is most prevalent in the lower leg and is often underestimated.

Angiography underestimates severe calcium by >50%.


Images courtesy of Dr. David Allie, MD, Cardiovascular Institute of the South, Lafayette, LA.
Calcium contributes to lower success rates\(^{1}\)

- 74% of flow limiting dissections occur in calcium\(^{1}\)
- Dissections significantly larger in calcified vs non-calcified plaque\(^{1}\)

- 51% Patency at 1 year\(^{2}\)
- 36% Patency at 2 years\(^{2}\)

- 28% fracture rate; presence of calcium is predictor\(^{3}\)
- 41% patency at 12 months with stent fracture\(^{4}\)

- Non-orbital atherectomy technologies not optimized for performance in calcium\(^{5}\)
- 22% bail out stent rate for some technologies\(^{6}\)

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3. TCT 2008, Abstract, D. Scheinert, MD. Department of Clinical and Interventional Angiology, Heart Center and Park Hospital, University of Leipzig Hospital.
5. Review of Atherectomy devices. Information on file at CSI.
• Increased lab time to manage adverse event
• Increased bail-out stent rate: $1,070-$2,660/each

• Increased re-intervention rate at $15,000 – 27,000 each

• Average cost to heal chronic wound = $17,096

• Amputation cost = $20,000 - $60,000
• Annual cost of follow-up care = $49,000
• Annual cost of nursing home: $70,000 – 100,000

Calcium Can Be Predicted

Independent Calcium Prediction Variables

• ABI > 1.31
  Patients with arterial calcification, such as chronic kidney disease
  patients, will present with falsely elevated ABI.6
• ABI ≤ 0.4 Critical Limb Ischemia2
• Diabetes: Especially if neuropathy present3,4
• Calcium found on forefoot X-Ray4
• History of tobacco use2
• Creatinine > 1.72
• Glomerular Filtration Rate (GFR) < 605

Diamondback’s Unique Mechanism of Action
Centrifugal Force & Differential Sanding

**Centrifugal Force:**
- Orbital Motion produces 360° of contact
- Create a smooth concentric lumen
- Increasing speed = Increases radius of orbit

**Benefits:**
- Ability to treat multiple vessel diameters with one crown
  - Treat large lumens through small sheath
- Allows for constant blood-flow
  - Constant flushing of particulate
- Fingertip control of rotational speed
  - Low, Medium & High speed settings
COMPLIANCE 360° Study
OAS Outperforms Balloon Angioplasty in ATK Lesions

- Prospective
- Multi-center
- Randomized (1:1)
- Calcified ATK Lesions

Max. Balloon Pressure

<table>
<thead>
<tr>
<th></th>
<th>OAS n=38</th>
<th>BALLOON n=27</th>
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<tr>
<td>10</td>
<td>4.0</td>
<td>9.1</td>
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Bail-Out Stenting

<table>
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<tr>
<th></th>
<th>OAS</th>
<th>BALLOON</th>
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<tr>
<td>80%</td>
<td>77.8%</td>
<td>5.3%</td>
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</table>

Revascularization at 12 Mos

- 18.8% OAS
- 21.7% PTA

Similar patency despite large difference in stent usage

1. COMPLIANCE 360° Clinical Study. Data on File.
CALCIUM 360° STUDY
OAS Outperforms Balloon Angioplasty in BTK Lesions


- Prospective, multi-center
- Randomized
- 95% severe and moderate calcium
- Below the Knee lesions

Max Balloon Pressure
Average Max Balloon Pressure (atm)

OAS  Balloon
5.9  9.4

p = 0.001

Freedom From Restenosis

OAS  Balloon
93.3%  80.0%

100%
50%
0%

POBA  OAS + POBA
n=25  n=25

93.3%  57.9%

100%
50%
0%

p = 0.006

Results at 12 Months

Freedom From Major Adverse Events*

OAS  Balloon
93.3%  57.9%

100%
50%
0%

* Major adverse events: major amputation (above-the-ankle), death and TLR/TVR
Case study:
PATIENT WITH TOE ULCER SCHEDULED FOR AMPUTATION TREATED WITH ORBITAL AHERECTOMY

A 65+ Year-Old Male
Diabetic
Current Smoker
Hypertension
Hyperlipidemia

Scheduled amputation
• left great toe

Prox SFA: 3 lesions, heavy Ca+
Distal SFA and Pop: 10cm CTO

Orbital Atherectomy
One 2.00 mm Solid Crown (all four lesions)
Low-Pressure PTA at 4 atms

Wound fully healed within a few weeks
Amputation avoided

PRE-TREATMENT
100% stenosis of distal SFA

POST-TREATMENT
20% residual stenosis

PRE-TREATMENT

POST-TREATMENT

Case courtesy of Ajit Naidu, MD Eliza Coffee Memorial Hospital (Florence, AL)
Results May Vary
Percutaneous Treatment of Noncalcified Common Femoral Artery Lesion
SFA/Popliteal

• High rates of immediate success

• High rates of restenosis and stent fracture

  • Main factors:

    • 1. nature of atherosclerosis (diffuse, occlusive, with severe intimal calcification)

    • 2. physical forces resulting from movement of the knee and hip joints
Atherosclerosis of the Femoropopliteal Artery
TASC Classification of Femoral Popliteal Lesions
(Slide 1 of 2)

Type A lesions:
- Single stenosis ≤10 cm in length
- Single occlusion ≤5 cm in length

Type B lesions:
- Multiple lesions (stenoses or occlusions), each ≤5 cm
- Single stenosis or occlusion ≤15 cm not involving the infrageniculate popliteal artery
- Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass
- Heavily calcified occlusion ≤5 cm in length
- Single popliteal stenosis
TASC Classification of Femoral Popliteal Lesions
(Slide 2 of 2)

**Type C lesions:**
- Multiple stenoses or occlusions totaling >15 cm with or without heavy calcification
- Recurrent stenoses or occlusions that need treatment after two endovascular interventions

**Type D lesions:**
- Chronic total occlusions of CFA or SFA (>20 cm, involving the popliteal artery)
- Chronic total occlusion of popliteal artery and proximal trifurcation vessels
Technique

- Contralateral CFA access
- Antegrade ipsilateral access is an option
- Retrograde popliteal access rarely required
  - Usually for SFA occlusion with absent proximal stump but attractive distal stump
- Stenting usually done with self-expanding nitinol stents
- PTFE covered (Viabahn stents) usually used as bailout for perforations
Technique

- Noncalcified lesions: angioplasty alone

- Ostial SFA to disease into popliteal: atherectomy with Silverhawk and adjunctive low pressure angioplasty

- Heavily calcified lesions: angioplasty with low threshold for stenting or Diamondback OAS then balloon angioplasty with standard balloon, DCB, Chocolate balloon +/- stenting based on result
Drug Coated Balloon

- Paclitaxel

- Residual dissections left untreated unless flow limiting

- Costly since only one inflation delivers drug
Balloon Angioplasty – Chocolate Balloon

- Specialty balloon for Iliac, SFA, and Popliteal angioplasty

- Wrapped in a wire which scores calcium and plaque causing a controlled plaque fracture reducing the need for bailout stenting
Excimer Laser

- Adjunct to angioplasty and stenting
- Effective in calcium
- Effective for restenotic lesions especially in stent restenosis
- Effective in treating thrombus
Chronic Total Occlusions

- Recanalization possible in 95% of cases
  - Dependent on willingness to perform subintimal angioplasty
- Multiple devices available
  - Frontrunner
  - Outback (re-entry device)
- No clear consensus on strategy
Frontrunner (Cordis)
FrontRunner Catheter

Intraluminal MicroDissection

- Blunt controlled passage through occlusion
- Uses elastic properties of adventitia vs inelastic fibrocalcific plaque
OutBack Re-entry Catheter
### Outcomes of Percutaneous Therapies for Femoropopliteal Disease

<table>
<thead>
<tr>
<th>Interventional Strategy</th>
<th>Study</th>
<th>n</th>
<th>Occlusions (Percent)</th>
<th>Lesion Length (cm)</th>
<th>Follow-up (Months)</th>
<th>Patency (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angioplasty</td>
<td>PMA FDA studies</td>
<td>86</td>
<td>49</td>
<td>8.7</td>
<td>12</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>RCT in Literature</td>
<td>191</td>
<td>N/R</td>
<td>8.9</td>
<td>12</td>
<td>28</td>
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<tr>
<td>Brachytherapy</td>
<td>PARIS(^2)</td>
<td>105</td>
<td>N/R</td>
<td>(\ast)</td>
<td>12</td>
<td>71.4</td>
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<tr>
<td></td>
<td>Minar et al.(^3)</td>
<td>57</td>
<td>29</td>
<td>8.6</td>
<td>6</td>
<td>71.6</td>
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<tr>
<td>Cryoplasty</td>
<td>Laird et al.(^4)</td>
<td>102</td>
<td>15</td>
<td>4.7</td>
<td>9</td>
<td>70.1</td>
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<tr>
<td>Excimer Laser</td>
<td>PELA(^5)</td>
<td>101</td>
<td>100</td>
<td>20</td>
<td>12</td>
<td>79</td>
</tr>
<tr>
<td>Nitinol Stent</td>
<td>SIROCCO II(^6)</td>
<td>28</td>
<td>57</td>
<td>7.6</td>
<td>18</td>
<td>82.1</td>
</tr>
<tr>
<td></td>
<td>Schillinger et al.(^7)</td>
<td>51</td>
<td>37</td>
<td>10.1</td>
<td>12</td>
<td>63</td>
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<tr>
<td>Sirolimus-Eluting Nitinol Stent</td>
<td>SIROCCO II(^6)</td>
<td>29</td>
<td>76</td>
<td>8.7</td>
<td>18</td>
<td>79.3</td>
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<tr>
<td>Nitinol Stent/Brachytherapy</td>
<td>VIENNA 5(^8)</td>
<td>~40</td>
<td>N/R</td>
<td>16.8</td>
<td>6</td>
<td>66.7</td>
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<tr>
<td>Stent Graft (Viabahn)</td>
<td>Kedora et al.(^9)</td>
<td>50</td>
<td>N/R</td>
<td>**</td>
<td>12</td>
<td>73.5</td>
</tr>
</tbody>
</table>

*Mean lesion length not reported. Study included patients with stenoses 5-15 cm and occlusions <5 cm
**Majority were TASC C lesions (74%)
Infrapopliteal

• Treatment of CLI: most commonly accepted indication
• Technique
  • Retrograde contralateral or antegrade ipsilateral
  • 0.014 guidewires
  • Angioplasty of tibial vessels usually produces stable angiographic result
  • If resistant to angioplasty, cutting balloon and rotational atherectomy are adjuctive modalities
Infrapopliteal Artery Angioplasty
for Treatment of Critical Limb Ischemia
(wound between fourth and fifth interspace of right foot)
Outcomes

• Literature confined mostly to observational studies
• Major reported outcome is freedom from major amputation
• Patency is secondary
• Procedural success rate > 90%
• Amputation free survival @ 6m: >85%
## Outcomes of Percutaneous Therapies for Infrapopliteal Disease

<table>
<thead>
<tr>
<th>Intervenional Strategy</th>
<th>Study</th>
<th>Number of Stenoses Treated</th>
<th>Procedural Success (Percent)</th>
<th>Follow-up (Months)</th>
<th>Amputation-Free Survival* (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary stent-supported angioplasty using bare metal coronary stents</td>
<td>Feiring et al⁴</td>
<td>82</td>
<td>94</td>
<td>12</td>
<td>87</td>
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<tr>
<td>Primary stent-supported angioplasty using drug-eluting coronary stents</td>
<td>Commeau et al⁵</td>
<td>30</td>
<td>100</td>
<td>7.7</td>
<td>100</td>
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<tr>
<td>Primary stent-supported angioplasty using nitinol self-expanding stents</td>
<td>Kickuth et al⁶</td>
<td>35</td>
<td>100</td>
<td>6</td>
<td>100</td>
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<tr>
<td>Cryoplasty</td>
<td>Below-the-knee CHILL⁴</td>
<td>111</td>
<td>94</td>
<td>6</td>
<td>94</td>
</tr>
</tbody>
</table>

*Freedom from major amputation in patients with CLI
Infrapopliteal

• Drug Eluting Stents?
  • PARADISE trial (DES vs historical cont)
  • Primary endpoint: major amputation, tissue healing, relief of rest pain
    • Technical success in delivery: 100%
    • Angiographic success: 96%
    • CYPHER 83%
    • Wound healing & relief of rest pain: 93%
• Results:
  • Amputation better that BASIL PTA arm at 1 and 3 years
  • Amputation better than BASIL surg arm at 1 but not 3 years
  • Survival similar with BASIL PTA and surg arm at 1 and 3 years
Complications

• Distal embolization: 2-5%
  • When occurs treatment is based upon site of distal embolization and clinical indication for procedure
  • Treatment options:
    • Angioplasty
    • Aspiration
    • Thrombectomy
    • Thrombolysis
    • Surgical bypass
ANGIOJET – Rheolytic Thrombectomy
EKOS
Ultrasound assisted – catheter directed thrombolysis
Complications

• Perforation
  • Uncommon but serious
  • More frequent when subintimal
  • Clinical consequence depends on site of perforation
    • Iliacs are life threatening
    • Infrainguinal less serious
• Management
  • Hemostasis w angioplasty balloon at site of perf
  • Proximal balloon inflation
  • Reversal of anticoagulation
  • If larger perforation ➔ covered stent
Iliac Artery Perforation During Percutaneous Treatment of Left External Iliac Artery Occlusion
Complications

• AV Fistula

  • Minor AVF common (artery & veins in common sheath

  • Treat with prolonged low-pressure balloon inflations

  • Rarely an uncovered nitinol stent will be needed to treat a significant and persistent AVF
Complications

• Access site complications
  • CFA-CFV fistula
  • PSA
  • RPB
    • Antegrade access is associated with increased risk of bleeding complications
Summary

• Procedural success rates for iliac intervention approach surgery
• Endarterectomy is “gold standard” for CFA disease
• Perc revasc of FP has procedural success >95%, but has high rate of restenosis
• Infrapop disease should only be attempted for CLI → limb salvage rates >85%