Endovascular Therapy in Peripheral Arterial and Venous Disease

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- PAD basics
- Intervention/Surgical indications
- Endovascular Tool Box
- Case examples
- Outcomes
- Venous Stasis Ulcer and Pathology
- Venous ulcer treatment strategies

Major Manifestations of Arterial Thrombotic Disease
- Ischemic stroke
- Transient ischemic attack
- Myocardial infarction
- Angina pectoris (stable, unstable)
- Peripheral arterial disease
- Critical limb ischemia, rest pain, gangrene, necrosis

Vascular Disease in the US

CHD = coronary heart disease. PAD = peripheral arterial disease.
Includes fatal and nonfatal events. American Heart Association Heart Disease and Stroke Statistics 2019. Estimated to reach 19 million.

Pathologic Progression of PAD
Atherosclerosis > Thrombus Formation > Ischemia > Limb Pain > Impairment

Atherosclerosis and platelet activation lead to the formation of a thrombus in arteries. Narrowed arteries and formation of a thrombus impedes blood flow to the periphery and results in ischemia. Ischemia may lead to painful symptoms, cell death, and physical impairment.

Ross R. N Engl J Med
Peripheral Vascular Disease

It’s more than meets the eye

Risk Profile of PAD

63% of PAD patients had polyvascular* disease

Key Finding

Polyvascular disease = 63%

PAD patients with polyvascular disease had concomitant symptomatic cerebrovascular or cardiovascular disease or both.


Risk Factors for PAD in the United States

Current Smoking 4.46
Diabetes 2.72
Hypertension 1.75
Hyperlipidemia 1.68

Odds ratios for risk factors

Diabetes Increases Risk of PAD

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

*P<0.05 vs. normal glucose tolerance.
Diabetes and Atherosclerosis

Diabetes mellitus:
• Accelerates atherosclerosis 200%–400%
• Risk of coronary artery ischemic events increases 2–4 times
• Results in 4 times risk of stroke
• PAD develops a decade earlier
• CV risk equivalent to 3 non-diabetic risk factors


Diabetic Patients with PAD are at Increased Risk for Poor Outcomes

Smoking is the single most important avoidable risk factor for the development of PAD and intermittent claudication

Progression of Intermittent Claudication

Relative 5-Year Mortality Rates

Decline in Survival Associated With Severity of PAD


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

ABI >0.85
ABI 0.4–0.85
ABI <0.4
**PAD Disease Management**

<table>
<thead>
<tr>
<th>Symptomatic Treatment</th>
<th>Prevention of Ischemic Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Exercise(^1)</td>
<td>• Control of risk factors(^4)</td>
</tr>
<tr>
<td>• Smoking cessation(^1,2)</td>
<td>• Smoking</td>
</tr>
<tr>
<td>• Pharmacologic therapy</td>
<td>• Hyperlipidemia</td>
</tr>
<tr>
<td>– Pentoxifylline(^3)</td>
<td>• Hypertension</td>
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<tr>
<td>– Cilostazol(^3)</td>
<td>• Diabetes</td>
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<tr>
<td>• Selective use of interventional therapy(^4)</td>
<td>• Antiplatelet therapy(^2)</td>
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</table>

3. Pletal (cilostazol) Prescribing Information.

**Indications for Surgical Intervention**

- Gangrene
- Non-healing ulcers
- Ischemic rest pain
- Claudication causing lifestyle deterioration refractory to pharmacologic intervention and behavioral modification

**Surgical Options**

- Percutaneous
  - Angioplasty
  - Atherectomy
  - Stenting
  - Laser
- Surgical
  - Endarterectomy
  - Bypass

**Options**

- Limb/wound should be evaluated for healing potential prior to deciding on intervention
- Comorbidities and overall health need to be evaluated prior to intervention
- Anatomic classification should guide treatment (TASC)

**Background**

- Operative series have consistently demonstrated 5 year limb salvage rates of 80% or greater
  - Complications may occur in up to 25% patients after peripheral arterial bypass surgery
- Morbidity may compromise functional outcomes as less than 50% patients report a return to “normal” by 6 months postoperatively

**Background**

- Increasing application of endovascular therapy to all territories of the arterial tree
- Percutaneous endovascular infrainguinal interventions (PVI) have been proposed as first line therapy for PAOD
- PVI: primary patency rates vary, and secondary interventions are common
- Enthusiasm for broadening PVI indications has continued to increase!

Claudication? Limb Salvage?
Peripheral Angioplasty

5 year patency

Claudication 40%
Limb Salvage 28%

Stenosis 43%
Occlusion 32%

Good Runoff 47%
Poor Runoff 28%

Overview of new technologies for lower extremity revascularization.

Development of small diameter catheter systems (0.014/0.018)
Flexible, self-expanding Nitinol stents

Cannulation of Contralateral Iliac Artery

Technique

• Contralateral access
• Placement of a working sheath 6Fr Raabe or Balkan in the CFA or SFA
• Use of an .035” angled/straight glidewire with an angled or straight 4Fr/5FR catheter
• Try to stay intraluminal but frequently end up subintimal using the “loop” of the distal wire to advance
• REENTRY
• Retrograde popliteal/tibial approach
Frontrunner XP Peripheral CTO

- .039" distal tip size
- 2.3mm jaw opening
- 90 and 120cm lengths
- Responsive torque
- Shapeable distal tip
- Blunt micro-dissection technology

Outback and Pioneer Catheter

Enables rapid, safe, and reproducible re-entry of a guidewire from the subintimal space back into the true lumen of a peripheral vessel.

Outback® LTD Re-Entry Catheter

- Deploy cannula in either "T" or "L" view
- Advance wire
- Retract needle
- Remove device

Mechanism of Action

Stable Rotation
Front-Cutting

ROTATIONAL ATERECTOMY

Mechanism of Action

Porcine Model®

Angioplasty result with vessel injury
Rotablator® system result with minimal vessel injury

Rotational Atherectomy Intended Benefits
- Designed to:
  - Minimize vessel wall stretch and elastic recoil
  - Eliminate vessel barotrauma
  - Produce a smooth lumen/channel
  - Facilitate passage of adjunct devices
The Rotablator® System is designed to ablate plaque into micro particles. In the image at left, a 5 micron bead compares the size of the micro particles to red blood cells. The micro particles pass through the circulation and are then removed by the reticuloendothelial system.

Does not require an Embolic Protection Filter
EPFs are designed to capture 100+ micron particles.

Peripheral Case Examples

<table>
<thead>
<tr>
<th>Pre Treatment</th>
<th>Post Treatment</th>
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</thead>
<tbody>
<tr>
<td>AT Disease</td>
<td></td>
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<tr>
<td>SFA Disease</td>
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<tr>
<td>2.0mm RotaLink, followed by 3.0 x 120mm Laser</td>
<td>5x200mm PTA</td>
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Gangrene of the forefoot

83 yo female Smoker
Presented to wound care
Vascular evaluation performed in multidisciplinary clinic

Severe Tibial Disease

PTA Tibiae Vessels

Runoff into foot
Extensive Debridement

- 56 yo diabetic male
- Seen in wound care clinic
- Vascular and Podiatric evaluation obtained in joint consultation

Popliteal Occlusion
Silver Hawk Atherectomy

SFA and Tibial Disease

Peripheral Arterial Disease

- 80 y.o.
- Hypertension
- High Cholesterol
- 2 week history of progressive toe pain

Total Occlusion
The PAD Guideline is Intended to Guide Lifelong Primary to Specialty PAD Care

Population at risk:
Age and risk factors
Establish the PAD diagnosis

Population with symptoms:
Improve limb outcomes
Prevent CV ischemic events

Medical Therapy
Endovascular Therapy
Surgical Therapy

Integrated care requires a partnership of vascular specialists (vascular medicine, cardiology, interventional radiology, nursing, podiatry, and others)

- ABI
- TBI
- Duplex US
- MRA
- CTA
- Angiography

Symptoms

- Achy or heavy feeling, burning, throbbing, muscle cramping and swelling.
- Prolonged sitting or standing tends to intensify symptoms.
- Pruritis
- Painful skin ulcers

Symptoms

- Varicosity
- Thrombophlebitis
- Hyperpigmentation
- Bleeding from clusters
- Ulceration
- Edema
- Itching
- Restless legs
- Cramps

Etiology

- Reflux 80%
- Venous obstruction 18-28%
  - Resultant edema and skin changes = Postthrombotic syndrome
- Muscle Pump Dysfunction
Risk Factors

- Genetic
- Female gender
  - Hormones
    - Progesterone, estrogen
- Pregnancy
- Age: >50
- Greater height
- Prolonged standing
- Obesity

Valvular Dysfunction

- Physical damage: splitting, tearing, thinning, adhesion to wall
- Reduction in number
  - Not age related
- Monocyte and macrophage infiltration
  - Overexpression of Intracellular adhesion molecules
  - Wall hypertrophy, disruption of collagen synthesis, and destruction of extracellular matrix proteins

Venous Hypertension

- Hydrostatic pressure vs Mechanical/muscular pressure
  - A. K. Tassiopoulos et al.
  - 1153 cases of ulcerated legs and venous disease
  - Reflux in superficial, deep, and perforating veins
  - Incompetent valves

Stasis Pathophysiology

- Usually associated with venous incompetence
- Primary and secondary reflux
- Edema
- Vein wall dilatation
- Inflammation/Pigmentation (Hemosiderin deposits)
- “Fibrin cuffing”
- Ulceration

Perforating veins

- Penetrate the deep fascia, tributaries of the saphenous veins, valves are located just distal to penetration of the deep fascia
- Veins cross the deep fascia obliquely
- Muscle contraction causes the valves to close prior to venous compression so blood is forced proximally (musculo-venous pump)

Anatomy

- Tunica intima: endothelium with BM and elastic lamina
  - Produces endothelium derived relaxing factor and prostacyclin
- Tunica media:
  - Circumferential SM
  - Maintains venous pressure gradient
- Tunica externa: Collagen
  - Stability
Valves
• Venous valves:
  – One way
  – Two cusps of CT skeleton covered by endothelium
  – Closure at > 30cm/s
  – Exception: IVC, common iliacs, portal, cranial sinus

Patient Assessment
• History
  – History of symptoms and onset
  – History of venous complications
  – Desire for treatment
  – Comorbidities
  – Rule out secondary cause including failure
• Examination
  – Patient in general
  – Pedal pulses
  – Grunts
  – Veins
    Trendelenburg test
    Venous claudication

Investigation
• All get a Duplex scan
• Examines
  – Deep veins
  – Superficial veins
  – Incompetence and patency

Duplex scan
• Vast majority have superficial incompetence only.
• Sensitivity 95% for identifying the competence of the saphenofemoral and saphenopopliteal junctions.
• Less sensitive for identifying incompetent perforators

Classification: CEAP

Clinical classification
• C0: no visible or palpable signs of venous disease
• C1: telangiectasia or reticular veins
• C2: varicose veins
• C3: edema
• C4a: pigmentation or eczema
• C4b: lipodermatosclerosis or atrophie blanche
• C5: healed venous ulcer
• C6: active venous ulcer
• S: symptoms, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other
• A: complaints attributable to venous dysfunction
• A: asymptomatic

CEAP

Etiologic classification
• E: increased
• E: primary
• E: secondary (post-thrombotic)
• E: no venous cause identified

Anatomic classification
• A: important veins
• A: perforator veins
• A: deep veins
• A: no venous location identified

Pathophysiologic classification
• P: basic CEAP
• P: reflux
• P: obstruction
• P: reflux and obstruction
• P: no venous pathophysiology identifiable

*Eklof et al. J of Vasc Surg 2004


Compression Stockings

- Worn during the day
- Elastic stockings with adjustments in pressure
- Lower pressure stockings (20-30 mmHg) for edema and DVT prophylaxis
- Higher pressure (30-40+ mmHg) for ulcers and significant venous disease
- Operator dependent
  - Difficult to put on
  - Physical impediments/Comorbidities
- 50% of patients were unable to get them on alone
- 30-65% noncompliance noted in clinical trials in venous centers

Efficacy of Compression Therapy

1. 22 trials comparing healing of venous ulcers using compression stockings
   - Compressive therapy more effective than non-compression
   - Higher pressure were more effective than lower
   - Multilayer compression was better than single layer bandaging
2. 466 patients with a healed ulcer
   - Continued use of compression stocking reduced reoccurrence within 3-5 year
3. ESCHAR study: 500 limb trial that compares surgery and compression vs. compression alone for ulcer treatment
   - Combination therapy had lower rates of recurrence of ulcer at year 4 (24% vs. 52%)

More invasive

- Endovenous laser ablation of saphenous vein (EVLT)
- Surgical excision of veins (“Stripping”)

Catheter-based Treatments

- Endovenous laser EVLA
- Radiofrequency ablation RFA
- Primarily to treat saphenous insufficiency (great or small)

Radiofrequency ablation

Heats the tissue surrounding the catheter electrode to a specified temperature. Radiofrequency works well on tissue composed primarily of collagen

Special probes have been designed for the radiofrequency device to manage non-saphenous and perforator veins.
All Is Not what it seems

Conclusions

- Understanding PAD pathology
- Understanding who benefits from medical, interventional vs surgical bypass
- Treating venous insufficiency with ablation therapy
- Treating mixed arterial and venous disease