Disclosures:
- Cardiovascular Systems Inc.
- Bard Peripheral Vascular
- Endologix, Inc.

Objectives

1. Appreciate the scope of PAD and Amputation.
2. Define the goals of therapy.
3. Recognize the available options for endovascular treatment.
Peripheral arterial disease (PAD), atherosclerosis, is present in up to 29% of the US population and estimated 202 Million people worldwide.

Critical Limb Ischemia (CLI) was diagnosed in more than 3.4 million Americans in 2015 and predicted to increase to more than 4 million by 2030.

Patients with critical limb ischemia have an overall poor prognosis:
- 1 year mortality = 25%
- 5 year mortality = 50%

Patients presenting with CLI:
- Initial Treatment
  - 50% revascularized
  - 25% medical management only
  - 25% receive a primary amputation

CLI patient 1 year later:
- 25% CLI resolved
- 30% alive with amputation
- 20% continue to have CLI
- 25% have died

Introduction and demographics of amputation

- Approximately 120,000 LE amputations are performed annually in the US.
- The lifetime direct healthcare cost for an amputee patient is $794,027.
- When aggregated for the total number of LE amputations, the expected lifetime cost is roughly $95.2 billion.


Introduction and demographics of amputation

- Following an initial LE amputation,
  - 27% will have 1 or more re-amputations within 1 year.
  - 40% progressed to a higher level of limb loss within a year.
  - 62% if patient has DM.
  - 55% of those with PAD will have the other limb amputated within 2-3 years.

How endovascular surgeons are trained

- Endovascular approach first, open surgery second.
- Requirements for a successful revascularization:
  - Inflow, Conduit, Outflow
  - "Faucet, hose, sprinkler"
- Role of outflow in wound healing:
  - More flow to the wound should result in better wound healing.
  - Endovascular technique allows attempts at three vessel treatments and may reach vessels too small for open surgery.
- Role of stents in endovascular surgery:
  - Primarily "bail-out" with exceptions.
  - DO NOT cover your surgical zones, aka "no stent territories."
Endpoints

- Patency
- Amputation free survival
- Wound healing
- Functional status
- Quality of Life

Rutherford classification

- Stage 0 – Asymptomatic
- Stage 1 – Mild claudication
- Stage 2 – Moderate claudication
- Stage 3 – Severe claudication
- Stage 4 – Rest pain
- Stage 5 – Ischemic ulceration not exceeding ulcer of the digits of the foot
- Stage 6 – Severe ischemic ulcers or frank gangrene

General List of Therapeutic Options

- conservative management
  - risk factor management
  - walking
  - Cilostazol
  - endovascular interventions
  - angioplasty
  - atherectomy
  - stent
- open surgical procedures
  - endarterectomy
  - bypass with vein graft
  - bypass with synthetic graft
  - bypass with biograft
  - gene therapy
  - angiogenesis
General List of Therapeutic Options

- endovascular interventions
  - angioplasty
  - atherectomy
  - stent

Plain Old Balloon Angioplasty (POBA)

- Angioplasty was first described by the US interventional radiologist Charles Dotter in 1964.
- On January 16, 1964, Dotter percutaneously dilated a tight, localized stenosis of the superficial femoral artery (SFA) in an 82-year-old woman with painful leg ischemia and gangrene who refused leg amputation.
- The first percutaneous coronary angioplasty on an awake patient was performed in Zurich by the German radiologist Andreas Gruentzig on September 16, 1977.

Results:

- 5 year patency, 36% for class A and B lesions, 12% for class C and D lesions
- 4 year limb salvage, 70-80%
- 37% require “bail-out” stent

“Late outcomes of balloon angioplasty and angioplasty with selective stenting for superficial femoral-popliteal disease are equivalent” Journal of Vascular Surgery Volume 54, Issue 4, October 2011, Pages 1051-1057.e1
Cryo-Balloon

• Cryoplasty uses nitrous oxide as the dilation medium at -10°C
• Apoptosis of the smooth muscle cells in the vessel wall,
• plaque modification,
• reduces elastic recoil of the vessels by altering elastin fibers in the wall.

• Outcomes were initially good with up to 75% 3 year patency.
• Reduced amount of “Bail-out” stenting but did not change 1 year patency from POBA
• Meta-analysis in 2013 was inconclusive for benefit of Cryoplasty
• Cryotherapy is now being marketed as an alternative to RF ablation in chronic Afib.


Cutting Balloons

• Atherotomes deliver a controlled fault line by scoring the plaque longitudinally rather than an uncontrolled dissection.
• micro-surgical blades extend 0.005”
• Allows for decreased risk of barotrauma and neointimal hyperplasia
• Typically used in 2-4 mm vessels


Chocolate Balloon

• Standard balloons are wrapped with pleated folds. This can create rotational torque on a plaque when they open.
• Nitinol constraining structure of the Chocolate balloon creates “pillows” and “grooves” with uniform expansion to improve plaque modification and reduce dissection.
• Maintains a cylindrical shape to allow for more controlled expansion and rapid deflation; reduces need for cutting balloons.

Drug Coated Balloon Angioplasty (DCB)

- Drug eluting devices inhibit neointimal growth of vascular smooth muscle cells and therefore potentially prevent restenosis
- Paclitaxel bound to different agents and dripped onto standard balloons in different strengths.
  - anti proliferative
  - rapid cellular uptake
  - Downstream losses can inhibit wound healing and rare cases of vasculitis reported.

General Results fem-pop lesions:
- 1 year patency 65% to 82% DCB vs 52% POBA
- Freedom from TLR 87% DCB vs 83% POBA
- no significant difference in amputation or mortality
- Similar conclusions from the below knee trials

References:
Atherectomy

- Ather-
  ather-
  athero-
  meaning gruellike, soft, paste-matters, atheroma, atheromatous (Gr. athēr, gruel, porridge)
- -ectomy
  word element (Gr.), excision, surgical removal

List of Options for Atherectomy

- directional (Turbohawk)
- rotational (Rotoblader)
- orbital (Diamondback)

List of Options for Atherectomy

- photoablative (Laser)
- aspirational (Pathway)
- hybrid (Phoenix)
- contact (Crosser)
The Physics of the MOA: Centrifugal Force

Centrifugal Force = Mass x Rotational Speed²

Radius of the Orbit

Crown Mass

Solid Crown

Solid Micro Crown

Orbit Radius

Offset Center of Mass Creates Orbital Motion

DRIVESHAFT Rotation Axis

Offset Distance = Orbit Radius

ORBIT Rotation Axis

Center of Mass

Plaque

• Orbital motion produces 360° of contact
• As Orbit Radius increases, Centrifugal Force decreases for inherent safety
Atherectomy Results

- Orbital
  - Freedom from TLR or restenosis 80% (patency)
  - "bail out" stenting 5% (vs. 78% with PTA alone)
  - MAE
    - perforation 0%
    - dissection 16%
    - embolization 2.6%

Dattilo R, Himmelstein SI, Cuff RF. The COMPLIANCE 360° Trial: a randomized, prospective, multicenter, pilot study comparing acute and long-term results of...

Atherectomy Results

- Directional
  - 12 month patency 78%
  - Freedom from major amputation 95%
  - "bail out" stenting 3.2%
  - MAE
    - perforation 5%
    - dissection 2.3%
    - embolization 3.8%

McKinsey JF, Zeller T, Rocha-Singh KJ, Jaff MR, Garcia LA. Lower extremity revascularization using directional atherectomy: 12-month prospective results of the...

Atherectomy Results

- Photobalative, study of In-Stent Restenosis
  - 6 month freedom from TLR 73% (patency)
  - Freedom from major amputation 95%
  - "bail out" stenting 4.1%
  - MAE
    - perforation 5%
    - dissection 7.7%
    - embolization 8.3%

**Atherectomy Choices**

<table>
<thead>
<tr>
<th>Atherectomy Type</th>
<th>Directional</th>
<th>Rotational</th>
<th>Photothermolysis</th>
<th>Distal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atherectomy</td>
<td>SilverHawk</td>
<td>Turbo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below the knee</td>
<td></td>
<td>Jetstream</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcified plaque</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombotic lesion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BTK lesion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Highly calcified</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent restenosis with thrombus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic total occlusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 1: Atherectomy Devices and Where Each Device is Most Advantageous**

*Bare Metal Endovascular Stents*

- Bare Metal: balloon expandable, self-expanding
- Covered: balloon expandable, self-expanding
- Drug Eluting
- What's new

**Endovascular Stents**

*The first intraluminal stent was developed by Julio Palmaz, in 1985.*

- Bare Metal: balloon expandable, self-expanding
- Covered: balloon expandable, self-expanding
- Drug Eluting
- What's new

**Bare Metal Endovascular Stents**

- Bare Metal: balloon expandable, self-expanding
Endovascular Stents: Results

- Iliac stents, covered vs uncovered
  - Patency 18 months 95% vs. 73%
  - Biggest difference in TASC C and D
  - However no difference in rate of amputation


Endovascular Stents: Results

- Femoral-Popliteal lesion >100mm
  - Self-expanding stent vs. plain PTA
    - 1 year patency 87% vs 45%
  - Covered self-expanding vs. bare metal SE
    - 1 year patency 78% vs. 53%


Endovascular Stents

- Drug Eluting above the knee
  - Initial enthusiasm dampened by 31% stent fractures and no advantage
  - Paclitaxel coated, self expanding vs. POBA
    - 2 year patency 74% vs. 26%
    - Provisional DES 83% vs provisional BMS 64%

Endovascular Stents

- Drug eluting vs. POBA below the knee
- 1 year patency 75% vs. 57%
- However no difference in amputation or TLR
- DES vs. BMS
  - Significantly better patency 85% vs. 54%
  - fewer amputations 2% vs 12%

Follow up:
Generally all endovascular interventions

- Aspirin
- Clopidogrel
- Statin
- CV risk factor modification
- Ultrasound and ABI at 1 month, 6 months

Cases
Case TL

74 year old gentleman with a long standing history of diabetes, who presented with a gangrenous left 2nd toe.

HTN
Chol
Non smoker
Hgb A1c of 7
Previously healed left 3rd toe amputation

Pedal Pules non palpable
ABI non compressible
left digital pressure 23 mm Hg
Arterial Duplex demonstrated diffuse calcification and monophasic distal waveforms

Case SB

70 year old lady with a history of right SFA stents, coronary stents, ongoing tobacco use, hypertension and hypercholesterolemia is referred by her podiatrist for foot pain.

She has known spine disease s/p multiple injections without relief. She has no palpable pulses below the groin, no ulcers, worsened with exercise which she says is mostly limited by her back.

She has worsening bilateral LE rest pain especially on the left. ABI 0.45 right and 0.2 left, no ulcers.

CTA showing diffusally small vessels with iliac disease on the left and flush occlusion on the right SFA. Right tibial vessels are patent.

Conclusions:

• Amputation is still far too frequent and costly
• Advanced endovascular techniques continue to improve outcomes while reducing patient risk and discomfort.
• Drug coated balloon angioplasty promises to reduce recurrence of peripheral occlusive lesions.
• Orbital Atherectomy is designed to treat calcified vascular disease
• Endovascular Stents can be used in a wide variety of applications.