AMPUTATION AS A LAST RESORT
– A Multidisciplinary Approach to Limb Salvage

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Conflicts/Disclosures

Consultant/Advisory Board/Research Support/ Educational Services

Daiichi Sankyo
Cook Medical
Cardiovascular Systems Inc.
Lake Region Medical
Spectranetics
Abbott Vascular
Terumo
Closys
Background

- Approximately **8 million Americans** over the age of 40 have PAD.
- PAD causes morbidity in the form of claudication (a painful cramp in the muscles of the leg with exercise)
- At its worst, PAD results in failing to heal wounds and ultimately amputation.

Clinical Presentations of PAD

- 50% Asymptomatic
- ~15% Classic (Typical) Claudication
- ~33% Atypical Leg Pain (functionally limited)
- 1%-2% Critical Limb Ischemia
CLI has Devastating Consequences to Patients
Within 1 Year of the Onset of CLI

Patient Prognosis\(^1\)

Of patients who get an amputation, 40% will die within 2 years\(^2\)

25%

25%

40%

60%

Death

Amputation

\(^2\) Jaff, M. EVT. 2004;3:2
Complications of Amputation

- **Phantom Pain**
  - 5-80%

- **Stump Infection**
  - 10-30%

- **Non-healing**
  - 10-30%
  - Poor circulation

- **DVT & PE**
  - Up to 40%
  - Increases with higher levels

- **Pneumonia**

- **Flexion contracture**

- **Renal insufficiency**
Complications of Amputation

- **Death**
  - Mortality increases with the level of amputation
    - BKA: 3-10%
    - AKA: 20%
    - Dramatic increase above 70 years of age

- **2/3rds of deaths are cardiovascular complications**
  - Stroke and heart attack
Cardiovascular Risk Increases With Decreases in Ankle-Brachial Index

Framingham “High Risk” = 20% at 10 years
Every patient with PAD is at “very high risk”

Peripheral Arterial Disease: All-Cause Mortality*

*Majority of deaths due to cardiovascular causes

Geographic Variation in Lower-Extremity Amputation Compared with National Average
So how do we address these staggering statistics?

by.... WORKING TOGETHER
The Importance of the Front Line
Patient and Physician Identification

• Many people *mistake the symptoms of PAD* for something else.
• *PAD often goes undiagnosed* by healthcare professionals.

Diagnosis of Peripheral Arterial Disease in High-Risk Patients

- PARTNERS evaluated 6979 patients in physicians’ offices
- Possibility of PAD evaluated in
  - All patients ≥70 yr; mean (±SD) age: 70 (±10 yr)
  - Patients 50 -69 yr with history of diabetes and/or smoking (at least 10 pack/yr)

Only 49% of PAD patients physicians knew they had PAD

Hirsch AT et al. JAMA. 2001;286:1317
Advance Age

- 40.3 Million Americans (13%) are age 65 and above. This number will be more than double by 2050

Type I & Type II Diabetes

- 10.9 Million Americans over the age of 65 (26.9%) have diabetes
- Diabetes is America’s fastest growing health problem

Kidney Disease

- 26 Million Americans have Kidney Disease
- Diabetes is the leading cause of Kidney Disease

12-14% of Americans w/PAD
Prevalence of PAD Increases With Age

### Table 2

Complications After Lower Limb Percutaneous Procedures in Patients Aged 80 or Above Compared to Patients Below the Age of 80

<table>
<thead>
<tr>
<th>Complication</th>
<th>&lt;80 Years (n=547, 88%)</th>
<th>≥80 Years (n=72, 12%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall complications</strong></td>
<td>47 (8.5%)</td>
<td>13 (18.1%)</td>
<td>0.010</td>
</tr>
<tr>
<td>Periprocedural complications</td>
<td>1 (0.2%)</td>
<td>2 (2.8%)</td>
<td>0.037</td>
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<tr>
<td>Arterial rupture</td>
<td>0</td>
<td>2 (2.8%)</td>
<td>0.013</td>
</tr>
<tr>
<td>Access site bleeding</td>
<td>1 (0.2%)</td>
<td>0</td>
<td>0.99</td>
</tr>
<tr>
<td>Critical embolization</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td><strong>Major complications</strong></td>
<td>10 (1.8%)</td>
<td>8 (11.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1 (0.2%)</td>
<td>4 (5.6%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stroke</td>
<td>7 (1.3%)</td>
<td>2 (2.8%)</td>
<td>0.32</td>
</tr>
<tr>
<td>Renal failure</td>
<td>1 (0.2%)</td>
<td>1 (1.4%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>1 (0.2%)</td>
<td>1 (1.4%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Any bleeding complication</td>
<td>12 (2.2%)</td>
<td>9 (12.5%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Groin hematoma</td>
<td>10 (1.8%)</td>
<td>8 (11.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Retroperitoneal hematoma</td>
<td>1 (0.2%)</td>
<td>0</td>
<td>0.99</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>1 (0.2%)</td>
<td>1 (1.4%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Other access-site complications</td>
<td>27 (4.9%)</td>
<td>9 (12.5%)</td>
<td>0.009</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>16 (2.9%)</td>
<td>4 (5.5%)</td>
<td>0.27</td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>4 (0.8%)</td>
<td>0</td>
<td>0.99</td>
</tr>
<tr>
<td>Groin infection</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Access vessel dissection/occlusion</td>
<td>5 (0.9%)</td>
<td>1 (1.4%)</td>
<td>0.52</td>
</tr>
<tr>
<td>Late bleeding (&gt;24 hours)</td>
<td>3 (0.6%)</td>
<td>4 (5.5%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Target segment acute/subacute occlusion</td>
<td>10 (2.2%)</td>
<td>0</td>
<td>0.82</td>
</tr>
</tbody>
</table>

Treatment Hampered in the Elderly

**Focus:**
Reducing symptoms and preventing further progression of disease.

*Regular physical activity:*
Start slow – simple walking regimens, leg exercises and treadmill exercise programs three times a week.

*Diet:*
Low in saturated fat, trans fat and cholesterol.
Diabetes
Diabetes Increases the 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.

Diagnosed Diabetes in the US: 2008

CDC BRFSS: Self-Reported Diabetes: 8.2% Nationwide

http://apps.nccd.cdc.gov/brfss/list.asp?cat=DB&yr=2008&qkey=1363&state=All

4 – 6% 6 – 8% 8 – 10% 10 – 12%
Global Projections For The Diabetes Epidemic: 2003-2025 (millions)

- World 2003 = 189 million
- World 2025 = 324 million
- Increase 72%
Diagnosed Cardiovascular Disease (CVD) and Total Mortality: U.S. Men and Women Ages 30-74

(Risk-factor adjusted Cox regression) NHANES II Follow-Up (n=6255)

* p<.05, ** p<.01, **** p<.0001 compared to none

<table>
<thead>
<tr>
<th>Patients' characteristics</th>
<th>Overall series</th>
<th>Propensity matched pairs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CKD classes 1-4 1330 pts</td>
<td>CKD class 5 95 pts</td>
</tr>
<tr>
<td>Age (years)</td>
<td>74.2 ± 10.8</td>
<td>61.9 ± 12.3</td>
</tr>
<tr>
<td>Age &gt;75 years</td>
<td>732 (55.0)</td>
<td>18 (18.9)</td>
</tr>
<tr>
<td>Female gender</td>
<td>668 (50.2)</td>
<td>40 (42.1)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>742 (58.6)</td>
<td>77 (81.1)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>530 (42.8)</td>
<td>54 (61.4)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1002 (75.7)</td>
<td>75 (78.9)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>843 (63.4)</td>
<td>66 (69.5)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>258 (19.4)</td>
<td>19 (20.0)</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>211 (15.9)</td>
<td>4 (4.2)</td>
</tr>
<tr>
<td>Indication for revascularization:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rest pain</td>
<td>291 (21.9)</td>
<td>11 (11.6)</td>
</tr>
<tr>
<td>Ulcer</td>
<td>847 (63.7)</td>
<td>58 (61.1)</td>
</tr>
<tr>
<td>Gangrene</td>
<td>152 (14.4)</td>
<td>28 (27.4)</td>
</tr>
<tr>
<td>Urgent/emergent procedure</td>
<td>936 (70.4)</td>
<td>80 (84.2)</td>
</tr>
<tr>
<td>Level of revascularization:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Femoropopliteal</td>
<td>649 (48.8)</td>
<td>50 (52.6)</td>
</tr>
<tr>
<td>Crural</td>
<td>586 (44.1)</td>
<td>37 (38.9)</td>
</tr>
<tr>
<td>Pedal</td>
<td>95 (7.1)</td>
<td>8 (8.4)</td>
</tr>
<tr>
<td>Type of revascularization:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endovascular revascularization</td>
<td>681 (51.2)</td>
<td>66 (69.5)</td>
</tr>
<tr>
<td>Surgical revascularization</td>
<td>649 (48.8)</td>
<td>29 (30.5)</td>
</tr>
<tr>
<td>Target vessel patent downward to the pedal arteries</td>
<td>803 (61.8)</td>
<td>64 (68.8)</td>
</tr>
<tr>
<td>FIMvasc score</td>
<td>2.0 ± 1.0</td>
<td>2.6 ± 0.9</td>
</tr>
<tr>
<td>Survival:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-day</td>
<td>95.5%</td>
<td>90.5%</td>
</tr>
<tr>
<td>1-year</td>
<td>75.9%</td>
<td>59.7%</td>
</tr>
<tr>
<td>2-year</td>
<td>68.3%</td>
<td>41.8%</td>
</tr>
<tr>
<td>3-year</td>
<td>59.7%</td>
<td>27.1%</td>
</tr>
<tr>
<td>4-year</td>
<td>52.5%</td>
<td>22.9%</td>
</tr>
<tr>
<td>Lower limb salvage:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-day</td>
<td>95.8%</td>
<td>88.9%</td>
</tr>
<tr>
<td>1-year</td>
<td>86.7%</td>
<td>64.3%</td>
</tr>
<tr>
<td>2-year</td>
<td>84.1%</td>
<td>57.7%</td>
</tr>
<tr>
<td>3-year</td>
<td>83.0%</td>
<td>57.7%</td>
</tr>
<tr>
<td>4-year</td>
<td>81.7%</td>
<td>57.7%</td>
</tr>
<tr>
<td>Amputation-free survival:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-day</td>
<td>91.8%</td>
<td>81.0%</td>
</tr>
<tr>
<td>1-year</td>
<td>68.8%</td>
<td>44.6%</td>
</tr>
<tr>
<td>2-year</td>
<td>61.0%</td>
<td>28.0%</td>
</tr>
<tr>
<td>3-year</td>
<td>52.9%</td>
<td>16.2%</td>
</tr>
<tr>
<td>4-year</td>
<td>46.0%</td>
<td>14.4%</td>
</tr>
</tbody>
</table>

Overall Survival in Patients with Renal Disease s/p Infrainguinal Endovascular Intervention

Fig. 1. Overall survival according to Cox regression analysis in patients with end-stage renal disease (CKD class 5) and patients with no or less severe renal failure (CKD class 1–4).

Who are the Vascular Specialists and Why are They Important?
For Healing to Happen, the Pipes Must be Open!
Angiosome Concept: Introduced by Taylor and Palmer in 1987 which divides the body into 3-dimensional vascular territories supplied by specific source arteries and drained by specific veins.
Angiosomes of Source Arteries (Lower leg)

- Anterior Tibial Artery (anterior/lateral)
- Posterior Tibial Artery (medial)
- Peroneal Artery (posterior)
Angiosomes of Source Arteries (Foot)

Iida O, et al. EVT. Sept 2010; 96-100.
Outflow Impacts Patency and Limb Salvage

Limb Salvage is Better with Good Outflow
5 Years Post-Endovascular Intervention
(N=361 limbs)

(SVS Modification Runoff Score)

Gallino, Circulation, 70; 619-624, 1984
Davies, JVS, 48:3; 619-626, 2008
Angiographic Considerations

- Vessel Size and disease length
- Calcification and location in respect to ostium
- Ability to tolerate antiplatelet therapy
- Important Collaterals
- Renal function
- Runoff status
- Access sites possible
- Patency duration requirement
Arterial Vasculature of the Lower Leg
“Think Outside the Box”
Options in Limb Revascularization

- **Endovascular reconstruction options**
  - Percutaneous transluminal angioplasty (PTA)
  - Atherectomy
  - Stents

- **Surgical reconstruction options**
  - Aortoiliac/aortofemoral reconstruction
  - Femoropopliteal bypass (above knee and below knee)
  - Femorotibial bypass
  - Endarterectomy
Endovascular Treatment

Balloon

Silverhawk

Diamondback 360

Laser

Stent
Two Major Goals in Treating Patients with PAD

Limb outcomes
- Improved ability to walk
- Prevention of progression to CLI and amputation
  • Increase in peak walking distance
  • Improvement in quality of life

Cardiovascular Morbidity and Mortality Outcomes
Decrease in morbidity from non-fatal MI and stroke
Decrease in cardiovascular mortality from fatal MI and stroke
PAD Treatment

• Focus: Reducing symptoms and preventing further progression of disease.
  • *Regular physical activity*: Start slow – simple walking regimens, leg exercises and treadmill exercise programs three times a week.
  • *Diet*: Low in saturated fat, trans fat and cholesterol.
  • *Smoking Cessation*: 4x risk of PAD than nonsmokers.
Medical Treatment

• Medications:
  • High blood pressure medications (ACE-Inhibitors)
  • High cholesterol medications (statins)
  • Cilostazol and pentoxifylline
  • Antiplatelet medications (aspirin & clopidogrel)
Pharmacotherapy for Critical Limb Ischemia

There are currently no Class I or IIa recommended medical treatments for CLI to improve limb outcomes (e.g., improve wound healing or amputation prevention)
Trends in Endovascular and Bypass Surgery

Fig. 1. Trends in endovascular interventions, major amputation, and lower extremity bypass surgery, 1996-2006. RR, Risk ratio; CI, confidence interval.
What is the Role of the Wound Care Clinic?

To Help Heal the Wound
How Diabetes Affects Wound Healing

• Blood Circulation
  • Microvascular disease: decreased blood flow and oxygen to the wound

• Neuropathy
  • Loss of sensation: inability to feel a blister, infection or surgical wound problem

• Immune System Deficiency
  • Ineffective immune cells
  • Higher Risk of Infection
Debride = Getting to the ‘Good Stuff’

Debride = (Fr). ‘To release or set free’

Cut Here!

Hyperkeratotic Tissue

ASWC 2008
Dressings: What Do We Know?

One Size DOESN’T Fit All…

• Selection is based on-
  – Wound requirements (i.e. moisture content)
  – Patient requirements (usage frequency/ cost)

• Think *Property*-- not *Product*
  *(or Brand Name!)*
Question: What is Our Goal?

Answer: A Clean, Moist Wound Bed
Foot Infection

• What do we KNOW?
  – Recognition is Critical, but challenging…

  • Pain
  • Pus
  • Erythema
  • Systemic Illness

Critical Colonization?
  ✓ Pain
  ✓ Pus
  ✓ Erythema
  ✓ Systemic Illness
Diabetic Foot Infections

What We Don’t Know

• Diagnosis: **NO definitive consensus**
  – Only 3 studies suitable for review
  – Deep tissue cultures most likely of benefit

• Antibiotic selection: **NO definitive consensus**
  – Only 23 studies identified (5 with oral agents)
  – Evidence too weak for specific drug recommendations or duration of therapy

O’Meara et al. Diabetic Med 2006;23:341
Hyperbaric Oxygen Therapy (HBO)
HBO

- Accelerate the rate of healing
- Reduce amputation rates
- Increase the number of wounds that are completely healed at long term follow-up

- HBO therapy is an adjuvant treatment and can be used at any stage of the wound care process.

Thank You!