Critical Limb Ischemia
A Collaborative Approach to Patient Care

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Vascular Institute of Chattanooga
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Saving Limbs
Renewing Lives
Critical Limb Ischemia represents the final stage of peripheral vascular disease progression.
Estimated that 1% of Americans over age 50 will face CLI
Amputation occurs in about 10% of CLI patients
"How do we as a medical community get ahead of and manage this disease for patients."
Community Network for CLI
Foot Path to Amputation in US
**Foot Path to Amputation in US**

- Major Amputation most often is the only treatment option offered for CLI patients
- No Attempt at Revascularization in 60% - 73% of CLI patients
- No Angiograms Performed in 51% - 73% of CLI patients
  - Despite a 90% odds reduction for amputation

### 2011-2014Q2

<table>
<thead>
<tr>
<th>Procedure</th>
<th>R4</th>
<th>R5</th>
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</thead>
<tbody>
<tr>
<td>PATIENTS</td>
<td>84</td>
<td>71</td>
</tr>
<tr>
<td>N=155</td>
<td></td>
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<tr>
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* 60 day limb salvage rate 100%
* Total limb salvage rate (any follow-up) 96%
Surgical Mind-Set
## Treatment for CLI

<table>
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<tr>
<th></th>
<th>Fem-Pop Intervention</th>
<th>Tibial Intervention</th>
<th>Pedal Intervention</th>
<th>BKA AKA AMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Surgeon</td>
<td>+</td>
<td>×</td>
<td>×</td>
<td>=</td>
</tr>
<tr>
<td>Vascular Surgeon</td>
<td>+</td>
<td>+</td>
<td>×</td>
<td>=</td>
</tr>
<tr>
<td>Interventionalist</td>
<td>+</td>
<td>+</td>
<td>×</td>
<td>=</td>
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<tr>
<td>Critical Limb Specialist</td>
<td>+</td>
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No amputations for the diagnosis of PAD ALONE
Fig 1. Population-based amputation rates for peripheral arterial disease (PAD) by hospital referral regions are shown on the map.
Access to Care, the right care...
Fig 1. Population-based amputation rates for peripheral arterial disease (PAD) by hospital referral regions are shown on the map.
Living in a medically underserved county is an independent risk factor for major limb amputation

Katharine L. McGinigle, MD, MPH, Corey A. Kalbaugh, MS, MA, and William A. Marston, MD, Chapel Hill, NC

Fig 2. Map showing the counties in North Carolina with persistent health professionals shortage, 2005-2009.
Living in a medically underserved county is an independent risk factor for major limb amputation

Katharine L. McGinigle, MD, MPH, Corey A. Kalbaugh, MS, MA, and William A. Marston, MD, Chapel Hill, NC

29% increased odds for Amputation

Fig 2. Map showing the counties in North Carolina with persistent health professionals shortage, 2005-2009.
Patient Associated Factors
Percent of Adults Who Smoke by Racial/Ethnic Group

- American Indian/Alaska Native (Non-Hispanic): 31.4%
- Multiple race (Non-Hispanic): 25.9%
- White (Non-Hispanic): 21.0%
- African American (Non-Hispanic): 20.6%
- Hispanic: 12.5%
- Asian (Non-Hispanic): 9.2%

SOURCE: CDC Vital Signs September 2011, Adult Smoking in the US
Body Mass Index

1985

CDC

No Data <10% 10%-14% 15%-19% 20%-24% 25%-29% ≥30%
Body Mass Index

1986

CDC

No Data <10% 10%-14% 15%-19% 20%-24% 25%-29% ≥30%
Body Mass Index
Body Mass Index

[Map showing Body Mass Index by state in 1988 with color coding for different percentage ranges]
Body Mass Index

[Map of the United States showing Body Mass Index levels in 1989. The map uses color-coding to indicate different BMI ranges across states.]
Body Mass Index
Body Mass Index
Body Mass Index

[Image of a map showing the Body Mass Index distribution in the United States in 1993]
Body Mass Index
Body Mass Index

1995

CDC

No Data <10% 10%-14% 15%-19% 20%-24% 25%-29% ≥30%
Body Mass Index

[Image of a map showing Body Mass Index distribution across the United States in 1998.]
Body Mass Index
Body Mass Index
Body Mass Index
Body Mass Index

2002 CDC

Maps of Body Mass Index in the United States.
Body Mass Index
Body Mass Index

Map showing Body Mass Index distribution across the United States in 2004.
Body Mass Index

[Map showing BMI distribution across the United States in 2005 by CDC, with color codes indicating percentage ranges: No Data, <10%, 10%-14%, 15%-19%, 20%-24%, 25%-29%, and ≥30%.]
Body Mass Index
Body Mass Index
Body Mass Index

[Map showing body mass index distribution across the United States for 2009]
Body Mass Index

[Map showing prevalence of Body Mass Index categories across the United States in 2010, with states colored according to their BMI percentages.]
Impact of Diabetes Worldwide

- Incidence of diabetes predicted to double WW by 2030\(^1,2\)
- Type II diabetes accounts for 90% of cases\(^3\)
- > 60% non-traumatic amputation cases are in diabetics\(^4\)
- Leading cause of blindness and renal failure\(^4\)
- 50-80% deaths in diabetics related to CV disease/stroke\(^4\)
- > 465B USD spent WW on diabetes-related health care\(^1\)

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\(^1\) International Diabetes Foundation, IDF Diabetes Atlas, Fifth Edition
\(^2\) World Health Organization
\(^3\) WebMD, Diabetes Health Center, Diabetes Statistical Information
\(^4\) American Diabetes Association
The “Diabetic Epidemic” is Worldwide
Diabetes affected 371M (8.3%) people in 2012

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<thead>
<tr>
<th>Region</th>
<th>Number in Millions</th>
<th>Prevalence</th>
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<tbody>
<tr>
<td>Europe</td>
<td>53</td>
<td>8.1%</td>
</tr>
<tr>
<td>US</td>
<td>25</td>
<td>8.3%</td>
</tr>
<tr>
<td>China</td>
<td>92</td>
<td>8.0%</td>
</tr>
<tr>
<td>India</td>
<td>63</td>
<td>8.7%</td>
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Atherosclerosis timeline

From first decade
- Growth mainly by lipid accumulation

From third decade
- Smooth muscle and collagen

From fourth decade
- Thrombosis, hematoma

Endothelial dysfunction

Adapted from Pepine CJ. Am J Cardiol. 1998;82(suppl 10A):23S-27S.
WHICH PATIENTS ARE MORE LIKELY TO HAVE CALCIUM?

PAD Patients with Metabolic Disorders Leading to Calcified Plaque and Media

**Advanced Age**
- 40.3M 65+yrs old in U.S.(1)
- 85+ age group is fastest growing in U.S.

**Diabetics**
- Up to 26M in U.S.(2)
- Diabetes is fastest growing health problem in U.S.

**Kidney Disease**
- Up to 31M in U.S. (3)
- Diabetes is leading cause of kidney disease

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1. U.S. Census Bureau, 2010
2. 2011 National Diabetes Fact Sheet Found on American Diabetes Association Website Searched on Dec. 26, 2011
WHICH PATIENTS ARE MORE LIKELY TO HAVE CALCIUM?

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Advanced Age

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40.3M 65+ yrs old in U.S.\(^{(1)}\)

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85+ age group is fastest growing in U.S.

Diabetes is fastest growing health problem in U.S.\(^{(2)}\)

Diabetes is leading cause of kidney disease

19.8% of Americans with PAD

Yost CLI Suppl 2016 and Yost CVD 2016.
In a primary care population defined by age and common risk factors, the prevalence of PAD was approximately one in three patients.
PARTNERS: Prevalence of PAD and Other CVD in Primary Care Practices

29% of Patients in a Target Population Were Diagnosed With PAD Using An Office-Based ABI

Patients diagnosed with PAD
- 44%
- 56%

PAD only

PAD and CVD

ABI=ankle-brachial index; CVD=cardiovascular disease.

US Economic Costs 2015
(Billions)

*Direct costs in the United States: PAD & CAD costs inflated to 2014$.

Who Pays the PAD Bill?

2013 PAD Patient Discharges by Payer

- Medicare: 75%
- Medicaid: 7%
- Private: 13%
- Other: 5%

Source: HCUP Query. Diagnosis codes for PAD.
Amputation Costs More than Revascularization

Per Patient Total Cost* of Major Amputation, Endovascular & Bypass

Source: THE SAGE GROUP estimates.

*Including Morbidity, Mortality & Revisions
CLI Prevelence and Cost 2015

2-3.4 Million

400,000-700,000 Treated w/
Revascularization or Amputation-Major & Minor

Cost $134-$248 Billion


CLI COSTS ACCOUNT FOR THE MAJORITY OF TOTAL PAD COSTS—55%-65%
Limb threat status is determined by the degree of ischemia. Limb salvage is dependent upon foot damage and angiosomal perfusion.

**Presentation**
CLI

Primary Care

Wound Care

Podiatric Specialists

Infectious Disease

Interventionalists

Endocrine

Vascular Medicine

Cardiology

Emergency Medicine
Primary Care
Podiatric Specialists
Infectious Disease
Interventionalists
Endocrine
Vascular Medicine
Cardiology
Emergency Medicine
Wound Care
10-Year Natural History in Patients With Intermittent Claudication

- Survival
- MI
- Intervention
- Amputation

Time (years)

Patients (%)
Figure A8 Survival of patients with peripheral arterial disease

Overview drawn from several studies.

Legend to A8: IC – intermittent claudication; CLI – critical limb ischemia
There are approximately 150,000 amputations per year in the U.S.

Amputation First?

- 417 patients in a Medicare population with lower leg CLI evaluated for amputation
- Primary Amputation 67%
- Infrainguinal Bypass 23%
- Angioplasty 10%
- Complications: 80% wound, 78% MI, and 81% Stroke: Primary Amputation

Only 16% had an Angiogram prior to Primary Amputation

Amputation First Approach Must Be Abolished!
Long Term Prognosis DM and CLI

- 564 Consecutive Diabetic patients admitted with CLI
- From 1999-2003
- 554 followed 12/2007

Amputation suggests a significant decrease in survival!

Non-Ambulatory Mortality Rate

Flu et al, J Vasc Surg, 2010;51:360
Intervention
National Trends in Lower-Extremity Interventions

Number of lower-extremity vascular procedures ≈ doubled from 357 to 581

Endovascular Interventions
RR = 3.3
(95% CI, 2.9-3.8)

Major Lower-Extremity Amputation
RR = 0.71
(95% CI, 0.7-0.8)

Lower-Extremity Bypass Surgery
RR = 0.58
(95% CI, 0.5-0.7)

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12 HOURS LATER

DRY GANGRENE

12 HOURS LATER
• 65 y/o WF with Rapid progression of Gangrene Right Foot

• PMH: DM, HTN, CAD

• Rutherford 6 Wet Gangrene
• No Surgical Bypass Options
• Classic Answer: BKA (Life Saving)
• Subintimal Dissection PTA
• Surgical Debridement of Infection
MICRO PUNCTURE ACCESS OCCLUDED POSTERIOR TIBIAL
RECONSTRUCTION OF BOTH ANTERIOR AND POSTERIOR CIRCULATIONS OF THE FOOT
RECONSTRUCTION OF BOTH ANTERIOR AND POSTERIOR CIRCULATIONS OF THE FOOT

ANGIOSOME CONCEPT
Figure A8 Survival of patients with peripheral arterial disease

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PREVENTING AMPUTATION AND IMPROVING SURVIVAL
Community Network for CLI