Chronic Limb Threatening Ischemia and the BEST-CLI Trial

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Disclosures

- None
- BEST-CLI trial Site PI for JHUSOM
  - Trial supported by NHLBI: 1U01HL107407-01A1

Outline

- Chronic limb-threatening ischemia
  - Definitions
  - Epidemiology
  - Natural History
  - Treatment Algorithms
  - Impediments to Optimal Management
- BEST-CLI trial
- Multidisciplinary approach to limb preservation

Definitions

- Peripheral Arterial Disease (PAD)
  - a disorder causing lower extremity arterial obliteration that limits blood flow to the limbs and may lead to arterial insufficiency

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  - a disorder causing lower extremity arterial obliteration that limits blood flow to the limbs and may lead to arterial insufficiency
- Chronic Limb Threatening Ischemia (CLI)
  - a state of arterial insufficiency manifested by **chronic**, inadequate tissue perfusion at rest
  - characterized by ischemic rest pain, **ulcers or gangrene**
  - presence of **objective** hemodynamic evidence of arterial insufficiency

Etiology of PAD

- Atherosclerosis
- Embolization
- Thrombosis
- Buerger's Disease
- Vasculitis
- Arterial Trauma
- Popliteal Entrapment
- Popliteal Adventitial Cystic Disease

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Epidemiology of PAD and CLI

- Peripheral Arterial Disease
  - Prevalence: 25-30% patients > 80 years old in the US
    - > 200 million people worldwide

Hirsch AT. Circulation 2012;125 (110);1449-1472
Norgren L. Int Angiol 2007;6(2):81-157
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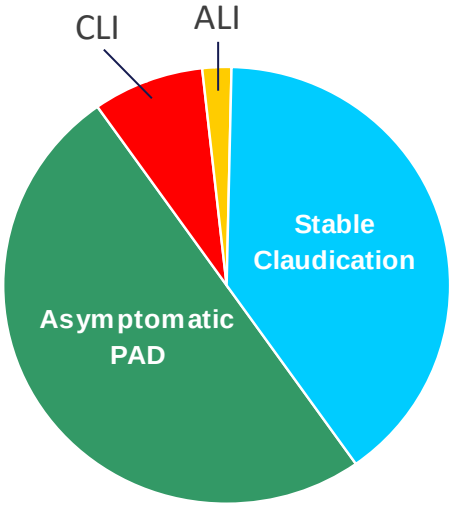
Fowkes FG et al. Lancet 2013;382:1329-40.
Nehler MR. J Vasc Surg 2014;60(3):686-695

Epidemiology of PAD and CLI

- Peripheral Arterial Disease
  - Prevalence: 25-30% patients > 80 years old in The US
    - > 200 million people worldwide
- Chronic Limb Threatening Ischemia (CLI)
  - Prevalence: ~11% of patients with PAD
  - Incidence: 500 – 3,500 cases/million/year



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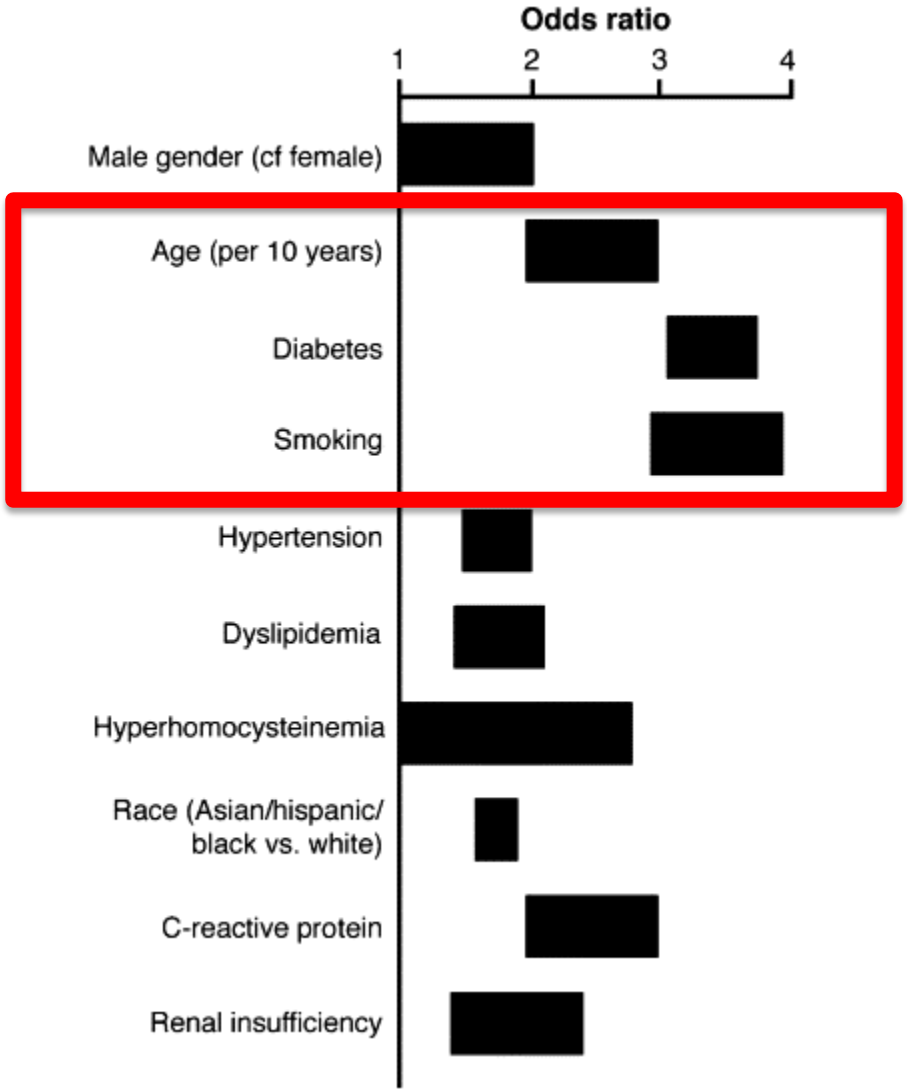
Demographic Factors



Norgren L et al. TASC II. J Vasc Surg 2007;45:S5-67.

THE LANCET

2013;382:1329-40

Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis

F Gerald R Fowkes, Diana Rudan*, Igor Rudan*, Victor Aboyans, Julie O Denenberg, Mary M McDermott, Paul E Norman, Uchechukwe K A Sampson, Linda J Williams, George A Mensah, Michael H Criqui*

	People living with peripheral artery disease in year 2000 (thousands)			People living with peripheral artery disease in 2010 (thousands)			Rate of change (2000–10)		
	High-income countries	Low-income and middle-income countries	Worldwide	High-income countries	Low-income and middle-income countries	Worldwide	High-income countries	Low-income and middle-income countries	Worldwide
25–29 years	2311	10756	13068	2381	12037	14419	3·02%	11·91%	10·34%
30–34 years	2803	11469	14272	2760					
35–39 years	3486	11247	14733	3343					
40–44 years	4071	11138	15209	3938					
45–49 years	4528	11408	15936	4851					
50–54 years	4907	9902	14808	5503					
55–59 years	4530	9111	13641	5948					
60–64 years	5342	9074	14416	6242	11787	18029	16·85%	29·90	
65–69 years	5287	8416	13704	5547	10124	15670	4·90%	20·29%	%
70–74 years	5594	6953	12547	6043	9020	15063	8·02%	29·73%	%
75–79 years	4808	4960	9768	5370	7012	12382	11·68%	41·36%	5%
80–84 years	3107	3015	6123	4723	4396	9118	51·98%	45·77%	92%
85–89 years	2246	1411	3658	3028	2087	5115	34·80%	47·86%	·84%
≥90 years	1174	544	1717	1611	864	2474	37·22%	58·82%	4·09%
Total	54195	109405	163600	61287	140775	202062	13·08%	28·67%	23·51%

From 2000 to 2010 worldwide prevalence of PAD increased by 23.5%

Additions in the table might deviate from the world total in the last digit due to rounding.

Table 2: **Estimated number of people living with peripheral artery disease in high-income countries, low-income and middle-income countries, and worldwide in the years 2000 and 2010, and the rate of change from 2000 to 2010**

Diagnosis

- CLI is suspected in patients with atherosclerotic risk factors who:
  - Burning, gnawing pain in distal foot at rest made worse by elevation and improved with dependency
  - Tissue loss usually affecting the distal extremity
- On Physical Exam
  - Ulceration or gangrene; dependent rubor; thin, shiny skin; absence of hair
  - No palpable pulses

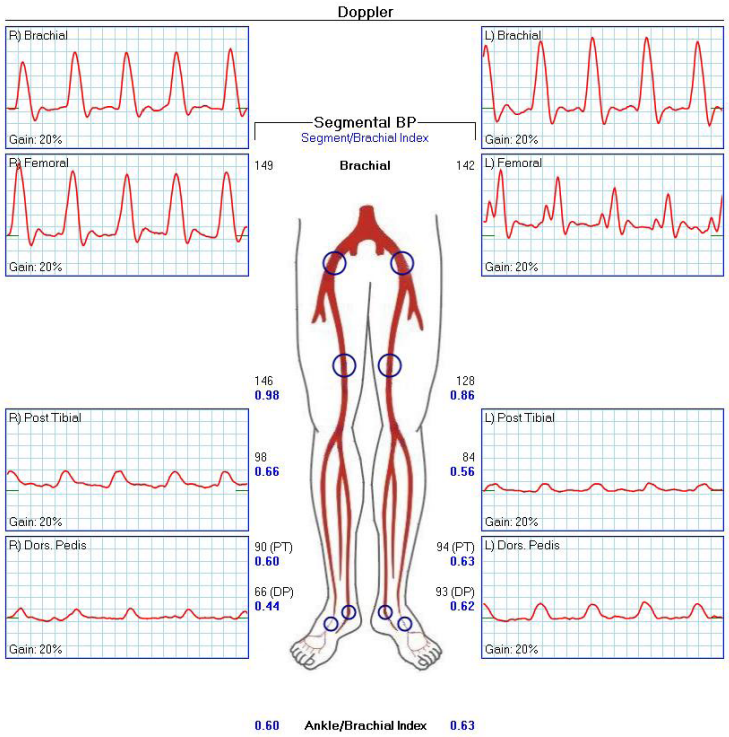
Confirmation of CLI

Vascular Laboratory

- **Physiological Studies**
  - Ankle Brachial Index (ABI)
  - Toe pressures
  - Doppler waveforms
  - Pulse Volume Recordings (PVR)
  - Transcutaneous oximetry ($TcPO_2$)

Hemodynamic Definitions of CLI

	Patients with Tissue Loss	Patients with Ischemic Rest Pain
Ankle pressure	<70 mm Hg	<50 mm Hg
Toe pressure	<50 mm Hg	<30 mm Hg
TcPO2	<40 mm Hg	<20 mm Hg



- ABIs ≤ 0.4
  - Anyone with ABI > 0.9 deserves further investigation

Patel MR et al. PARC. J Am Coll Cardiol. 2015;65:931-41

Natural History of CLI

REVIEW ARTICLES

Richard P. Cambria, MD, Section Editor

The natural history of untreated severe or critical limb ischemia

>1,500 patients in 13 studies at 1 year f/u

----22% major amputation rate

did not receive revascularization with a minimum follow-up of ≥1 year. Predefined outcomes of interest were mortality, major amputation, and wound healing. Random-effects meta-analysis was used to pool cumulative incidence across studies.

Results: We identified 13 studies enrolling 1527 patients. During a median follow-up of 12 months, all-cause mortality rate was 22% (confidence interval [CI], 12%-33%) and major amputation rate was 22% (CI, 2%-42%). Worsened wound or ulcer was found at 35% (CI, 10%-62%). There was a trend toward improvement in mortality and amputation rate in studies done after 1997. The quality of evidence was low because of increased risk of bias and inconsistency.

Conclusions: Mortality and major amputations are common in patients who have untreated CLI during a median follow-up of 1 year, although these outcomes have improved in recent times. (J Vasc Surg 2015;62:1642-51.)

Risk of Amputation is affected by

- Degree of ischemia

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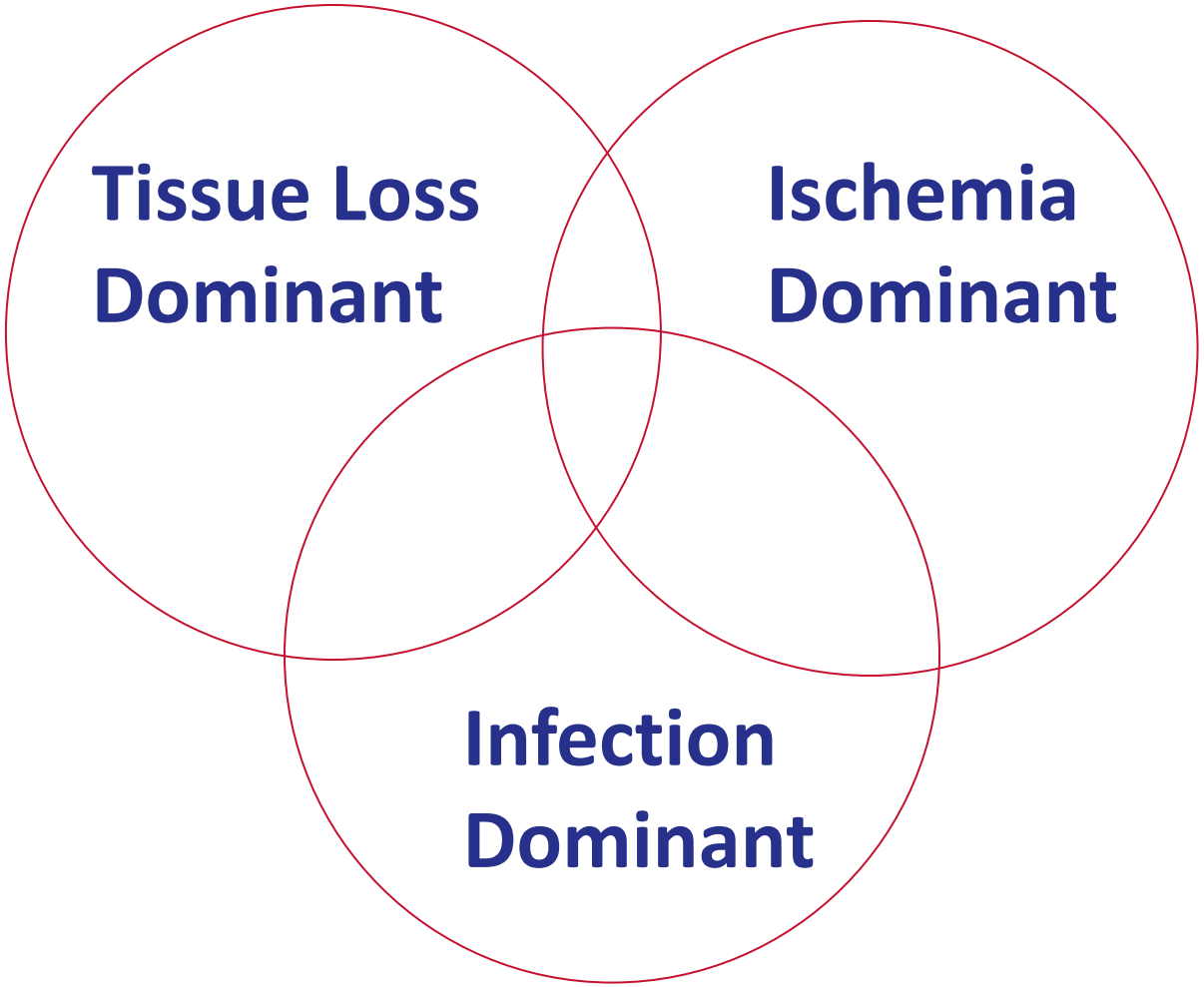
- Extent and depth of tissue loss

Risk of Amputation is affected by

- Degree of ischemia
- Extent and depth of tissue loss

- Presence and extent of infection

Limb Issues Often Overlap



D.G. Armstrong, J.L. Mills / Wound Medicine 1 (2013) 13–14

Society for Vascular Surgery

WIfI Index

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI)

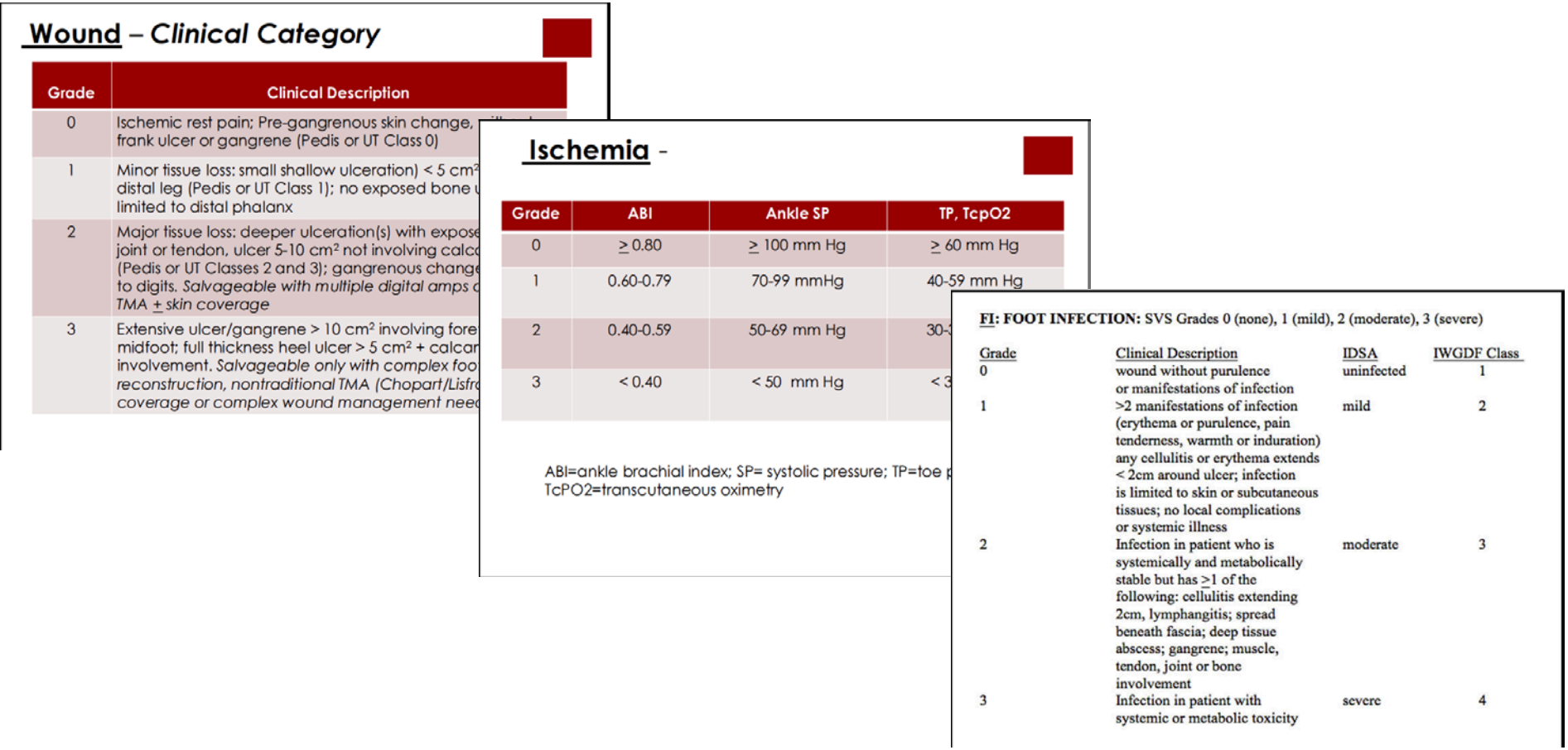
Joseph L. Mills, Sr, MD,[a] Michael S. Conte, MD,[b] David G. Armstrong, DPM, MD, PhD,[a] Frank B. Pomposelli, MD,[c] Andres Schanzer, MD,[d] Anton N. Sidawy, MD, MPH,[e] and George Andros, MD,[f] on behalf of the Society for Vascular Surgery Lower Extremity Guidelines Committee, *Tucson, Ariz; San Francisco and Van Nuys, Calif; Brighton and Worcester, Mass; and Washington, D.C.*

Critical limb ischemia, first defined in 1982, was intended to delineate a subgroup of patients with a threatened lower extremity primarily because of chronic ischemia. It was the intent of the original authors that patients with diabetes be excluded or analyzed separately. The Fontaine and Rutherford Systems have been used to classify risk of amputation and likelihood of benefit from revascularization by subcategorizing patients into two groups: ischemic rest pain and tissue loss. Due to demographic shifts over the last 40 years, especially a dramatic rise in the incidence of diabetes mellitus and rapidly expanding techniques of revascularization, it has become increasingly difficult to perform meaningful outcomes analysis for patients with threatened limbs using these existing classification systems. Particularly in patients with diabetes, limb threat is part of a broad disease spectrum. Perfusion is only one determinant of outcome; wound extent and the presence and severity of infection also greatly impact the threat to a limb. Therefore, the Society for Vascular Surgery Lower Extremity Guidelines Committee undertook the task of creating a new classification of the threatened lower extremity that reflects these important considerations. We term this new framework, the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System. Risk stratification is based on three major factors that impact amputation risk and clinical management: Wound, Ischemia, and foot Infection (WIfI). The implementation of this classification system is intended to permit more meaningful analysis of outcomes for various forms of therapy in this challenging, but heterogeneous population. (J Vasc Surg 2014;59:220-34.)

- Wound: extent and depth
- Ischemia: perfusion/flow
- Foot Infection: presence and extent

WIfI Classification

- Designed to be analogous to the TNM staging system for cancer
- Based upon existing validated systems or best available data with 4 point scales



Wound – *Clinical Category*

Grade	Clinical Description
0	Ischemic rest pain; Pre-gangrenous skin change, frank ulcer or gangrene (Pedis or UT Class 0)
1	Minor tissue loss: small shallow ulceration) < 5 cm² distal leg (Pedis or UT Class 1); no exposed bone limited to distal phalanx
2	Major tissue loss: deeper ulceration(s) with expose joint or tendon, ulcer 5-10 cm² not involving calc (Pedis or UT Classes 2 and 3); gangrenous change to digits. *Salvageable with multiple digital amps TMA ± skin coverage*
3	Extensive ulcer/gangrene > 10 cm² involving fore midfoot; full thickness heel ulcer > 5 cm² + calcar involvement. *Salvageable only with complex foo reconstruction, nontraditional TMA (Chopart/Lisfr coverage or complex wound management nee*

Ischemia -

Grade	ABI	Ankle SP	TP, TcpO2
0	≥ 0.80	≥ 100 mm Hg	≥ 60 mm Hg
1	0.60-0.79	70-99 mmHg	40-59 mm Hg
2	0.40-0.59	50-69 mm Hg	30-
3	< 0.40	< 50 mm Hg	< 3

ABI=ankle brachial index; SP= systolic pressure; TP=toe p
TcPO2=transcutaneous oximetry

FI: FOOT INFECTION: SVS Grades 0 (none), 1 (mild), 2 (moderate), 3 (severe)

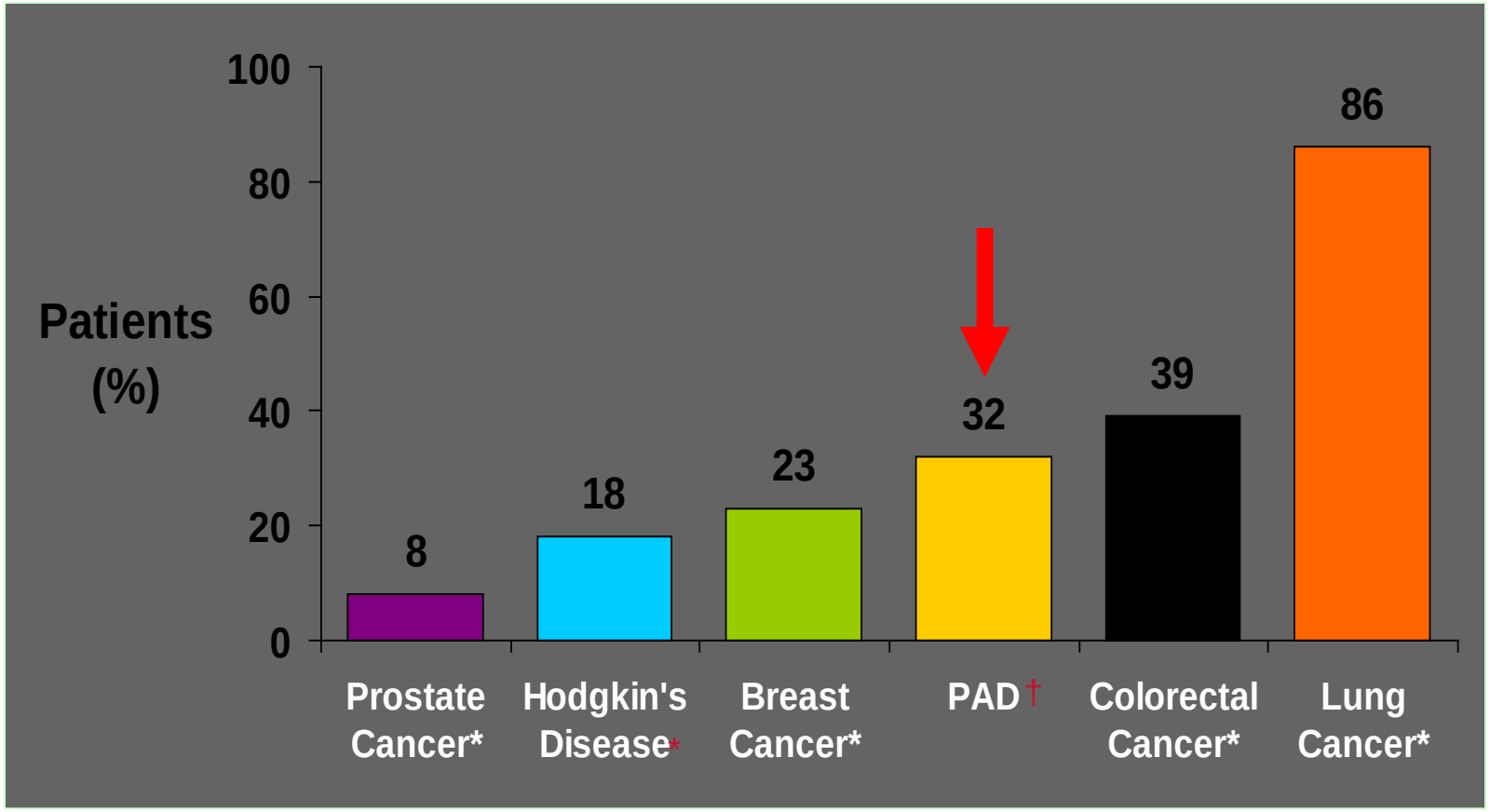
Grade	Clinical Description	IDSA	IWGDF Class
0	wound without purulence or manifestations of infection	uninfected	1
1	>2 manifestations of infection (erythema or purulence, pain tenderness, warmth or induration) any cellulitis or erythema extends < 2cm around ulcer; infection is limited to skin or subcutaneous tissues; no local complications or systemic illness	mild	2
2	Infection in patient who is systemically and metabolically stable but has ≥1 of the following: cellulitis extending 2cm, lymphangitis; spread beneath fascia; deep tissue abscess; gangrene; muscle, tendon, joint or bone involvement	moderate	3
3	Infection in patient with systemic or metabolic toxicity	severe	4

Risk of Amputation vs WIfI Stage

Study (year): # limbs at risk	Stage 1	Stage 2	Stage 3	Stage 4
Cull (2014): 151	37 (3%)	63 (10%)	43 (23%)	8 (40%)
Zhan (2015): 201	39 (0%)	50 (0%)	53 (8%)	59 (37%)
Darling (2015): 551	5 (0%)	111 (10%)	222 (11%)	213 (24%)
Causey (2016): 160	21 (0%)	48 (25%)	42 (21%)	49 (31%)
Beropoulis (2016): 126	29 (13%)	42 (19%)	29 (19%)	26 (38%)
Ward (2016): 98	5 (0%)	21 (14%)	14 (21%)	58 (34%)
Darling (2016): 992	12 (0%)	293 (4%)	249 (4%)	438 (21%)
N = 2279 (weighted mean)	148 (3.4%)	628 (8.3%)	652 (10.3%)	851 (25%)
Median (% 1 yr amputation)	0%	10%	19%	34%

Courtesy of J Mills

Relative 5-Year Mortality Rates



*American Cancer Society. Cancer Facts and Figures, 2000.

†Criqui MH et al. N Engl J Med. 1992;326:381-6.

Goals Of Treatment

- Medical therapy to optimize cardiovascular risk
- Wound management
- Revascularization (measures to improve limb perfusion)

Hirsch AT et al. J Am Coll Cardiol 2006;47:1239-131
Conte MS and Farber A. BJS 2015;102:1007-1009

Medical Therapy

- Antiplatelet agents (ASA or clopidogrel)
- Tobacco cessation
- Statins
- Diabetes control
- Blood Pressure Reduction
  - < 130/85 mm Hg
  - preferably with ACE-I

J Am Coll Cardiol. 2016 Mar 22;67(11):1338
Circ Res. 2015 Apr 24;116(9):1509

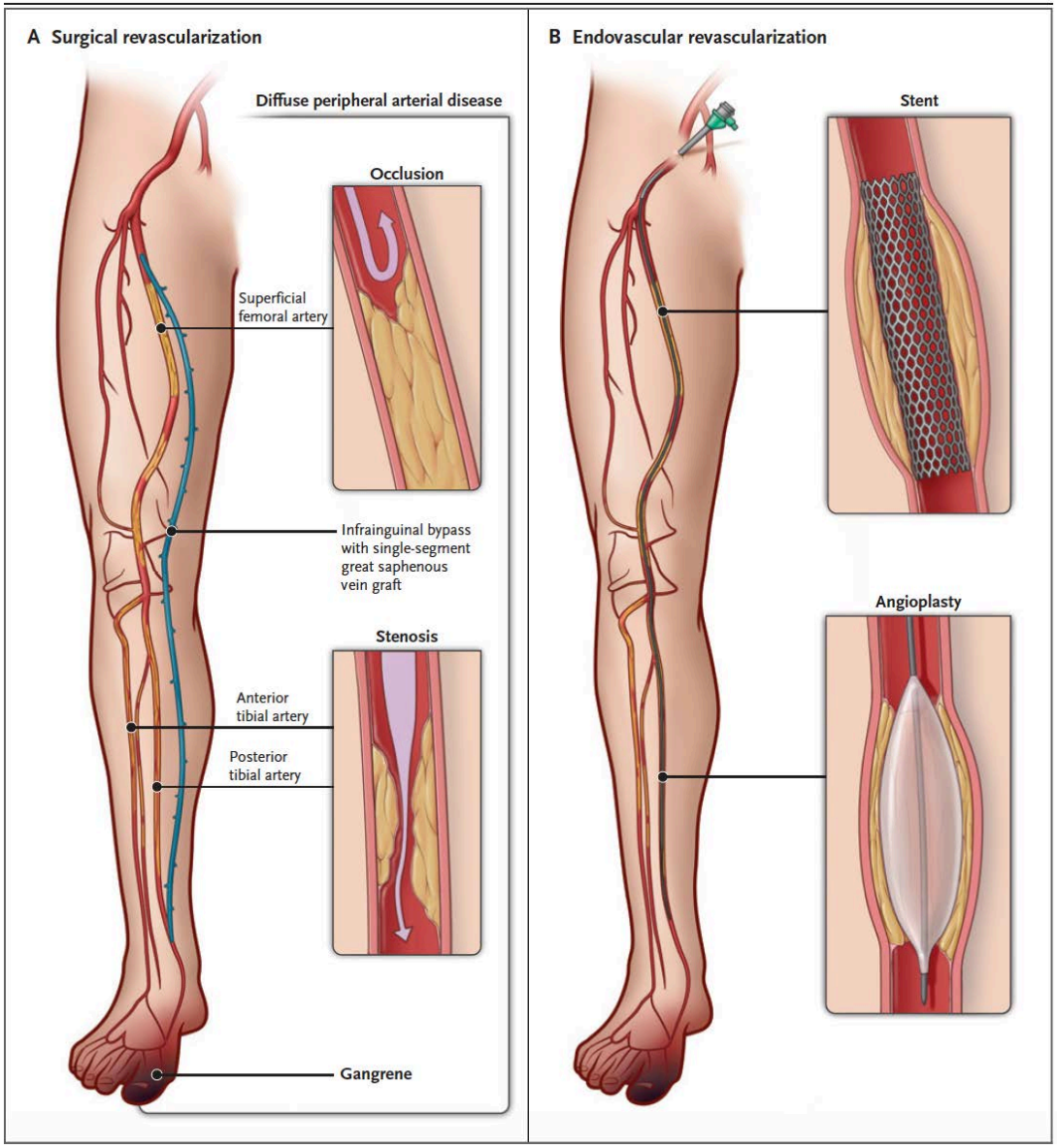
Wound Management

- Antibiotics
- Debridement / Minor amputation
- Wound management & offloading

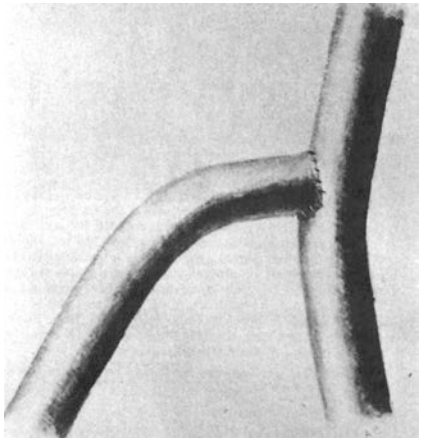
Revascularization

- Relieve pain
- Heal wounds
- Preserve a functional limb
- Avoid major amputation
- Maintain ambulatory status

Revascularization Options in CLI

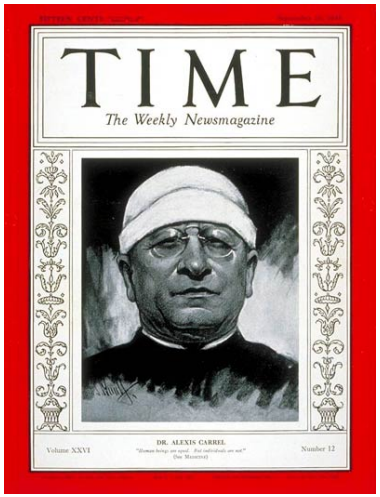


Surgical Bypass



1906- Technique of vascular anastomosis described

(Carrel A, Guthrie CC. Surg Gynecol Obstet 2:266,1906)



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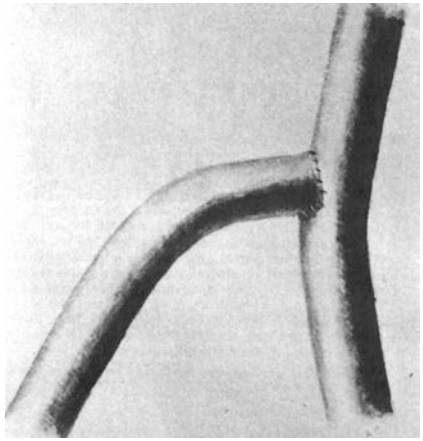

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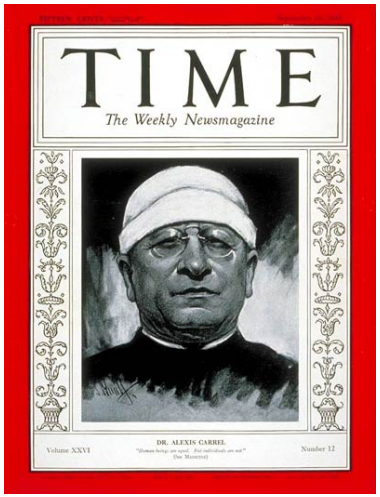
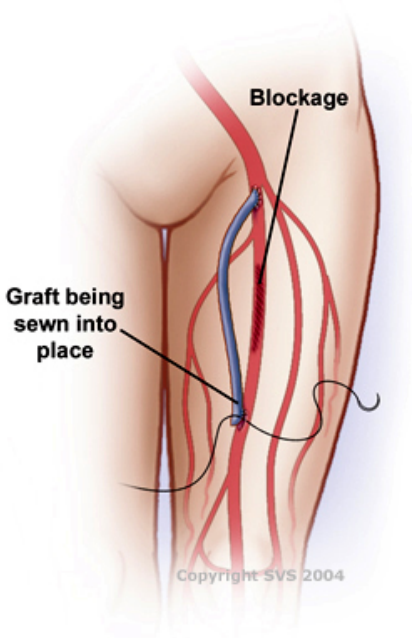




1948- 1st successful femoral popliteal bypass using rGSV in a patient with PAD

(Kunlin J. Rev Chir Paris 70:206-236, 1951)

Infrainguinal Bypass

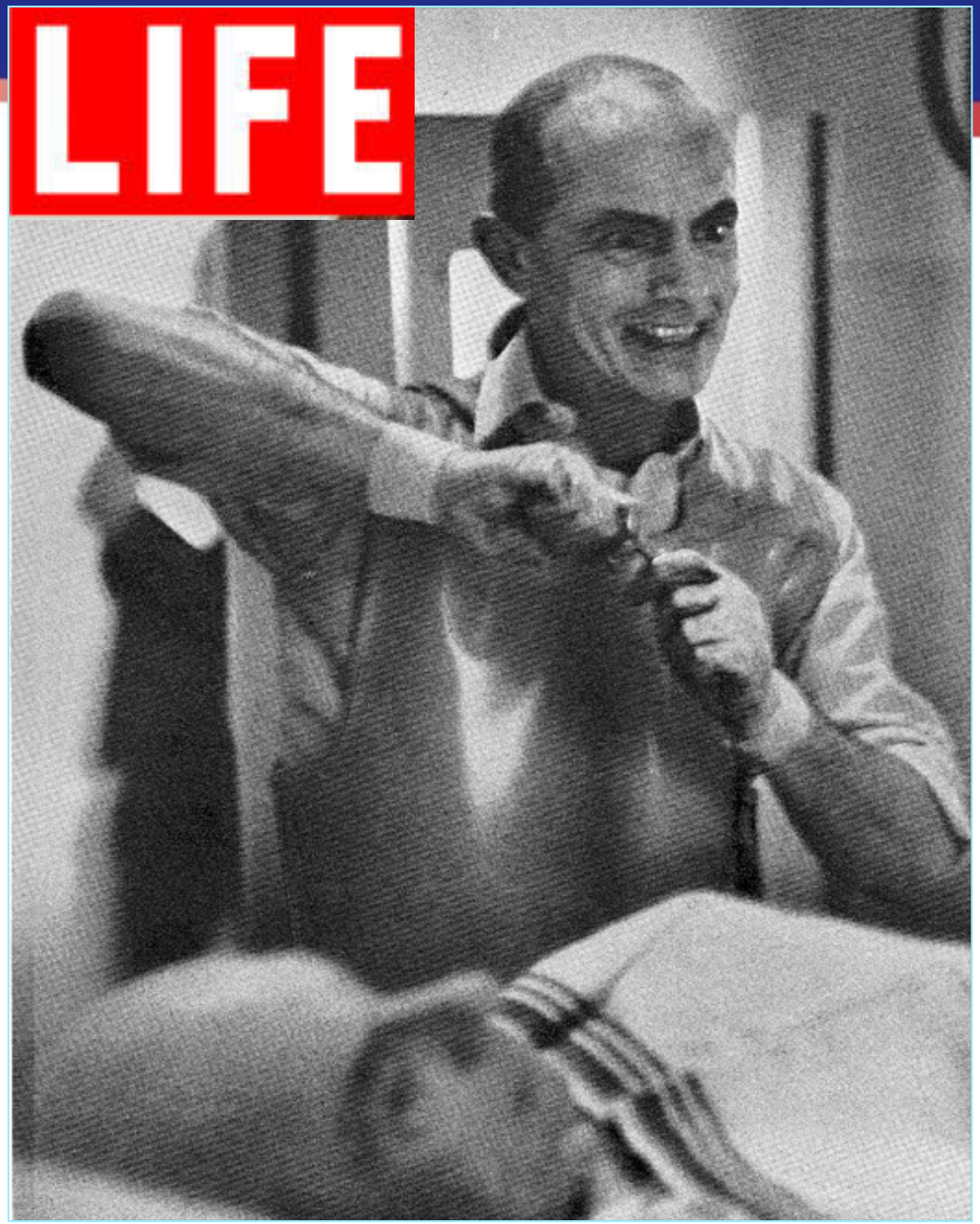
	Primary Graft Patency @ 5 years	Secondary Graft Patency @ 5 years	Limb Salvage @ 5 years
Taylor L. et al N=300	80%	84%	90%
Shah D. et al N=2,048	72%	81%	95%
Pomposelli FB. et al. N=1,032	57%	63%	78%

Perioperative mortality: 1-6%

Infrainguinal Bypass

- Traditional treatment
- Durable outcomes
- Long follow up periods available

- Invasive
- Is associated with
  - blood loss
  - morbidity
  - mortality
  - wound complications



1964

Charles Dotter

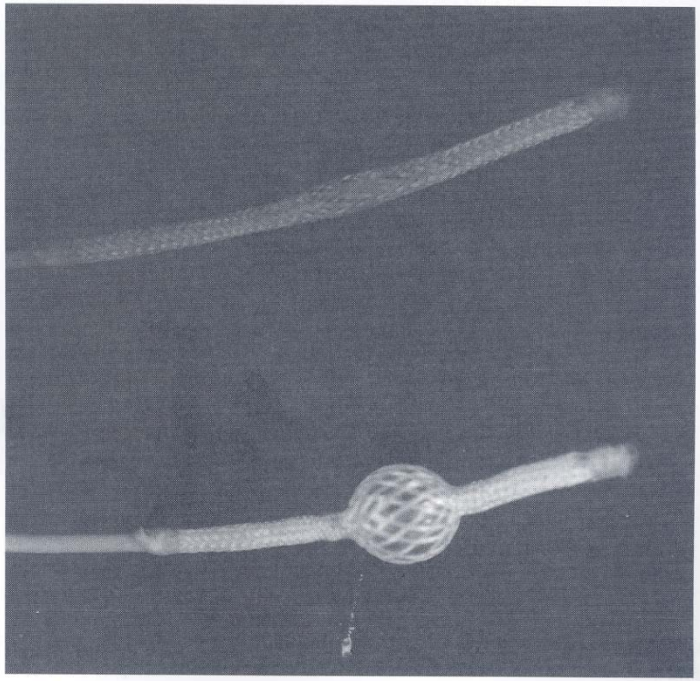
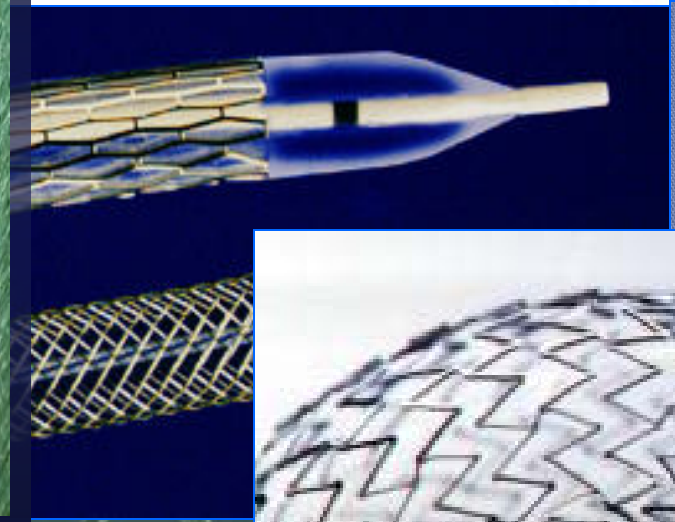
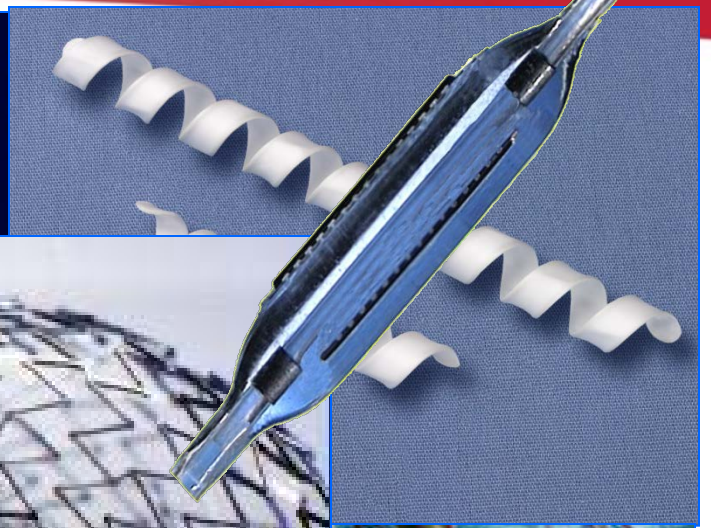
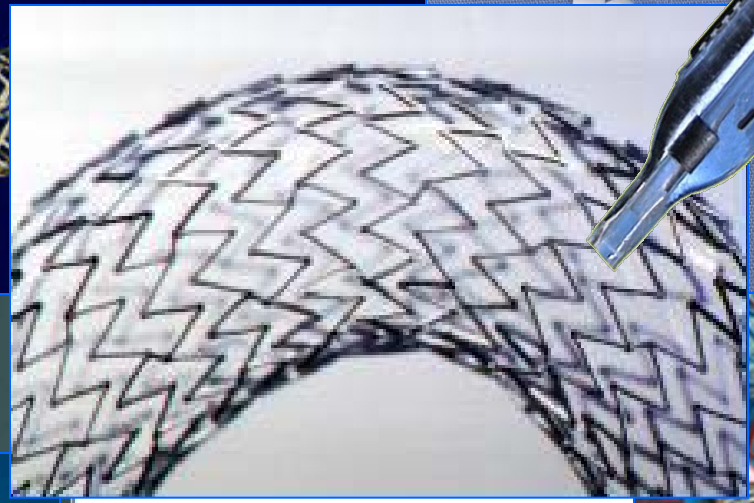


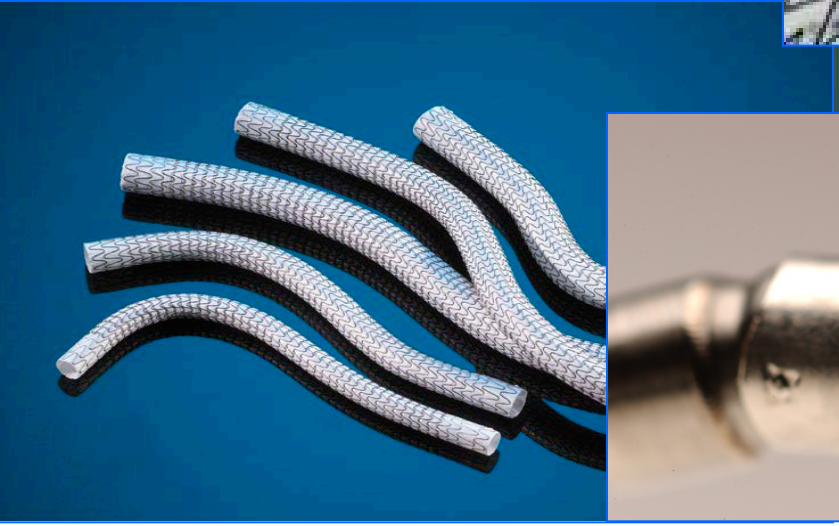
Figure 22.2 Original Dotter dilating catheter (courtesy of Mrs. Enid Ruble).

Novel Technology



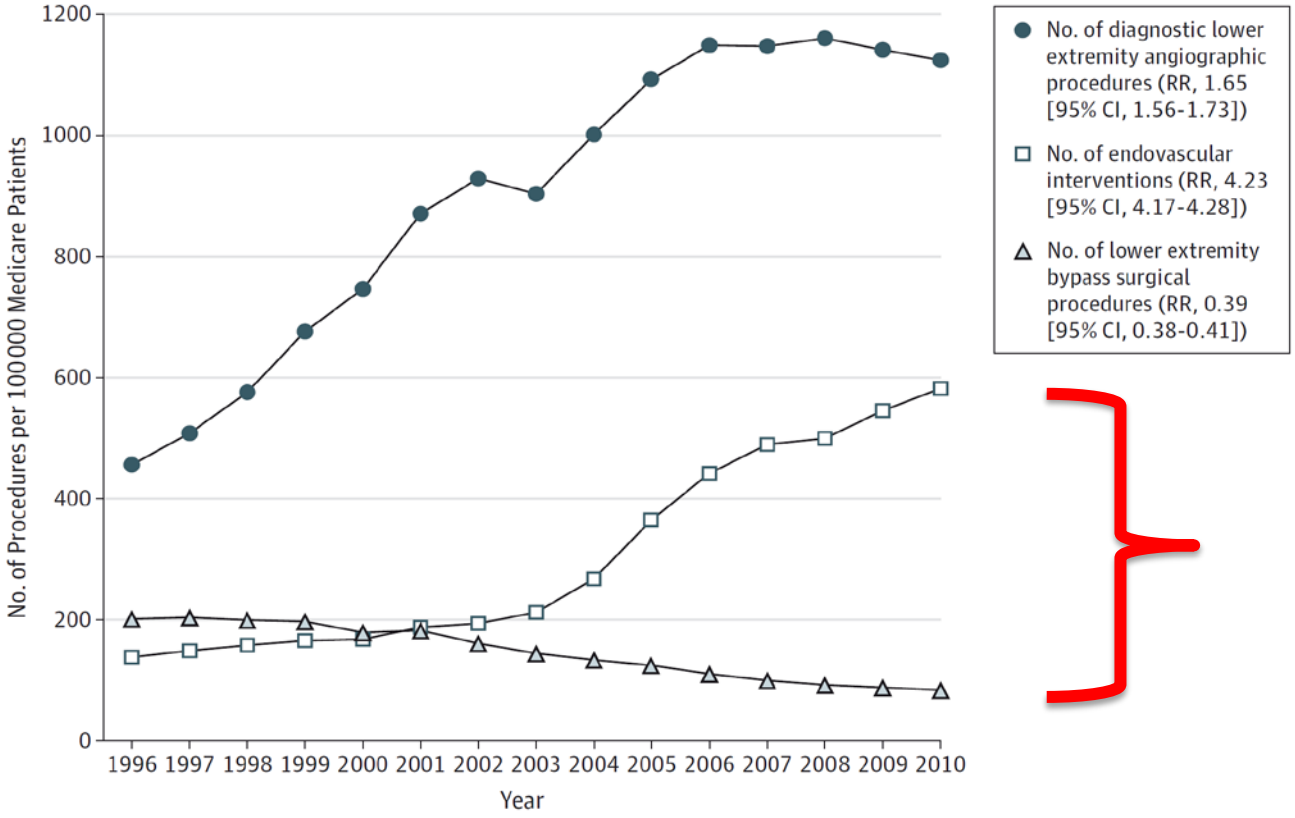






Trends in PAD Therapy

Figure 2. Trends in Diagnostic Angiography, Therapeutic Endovascular Interventions, and Lower Extremity Bypass Surgery, 1996-2010

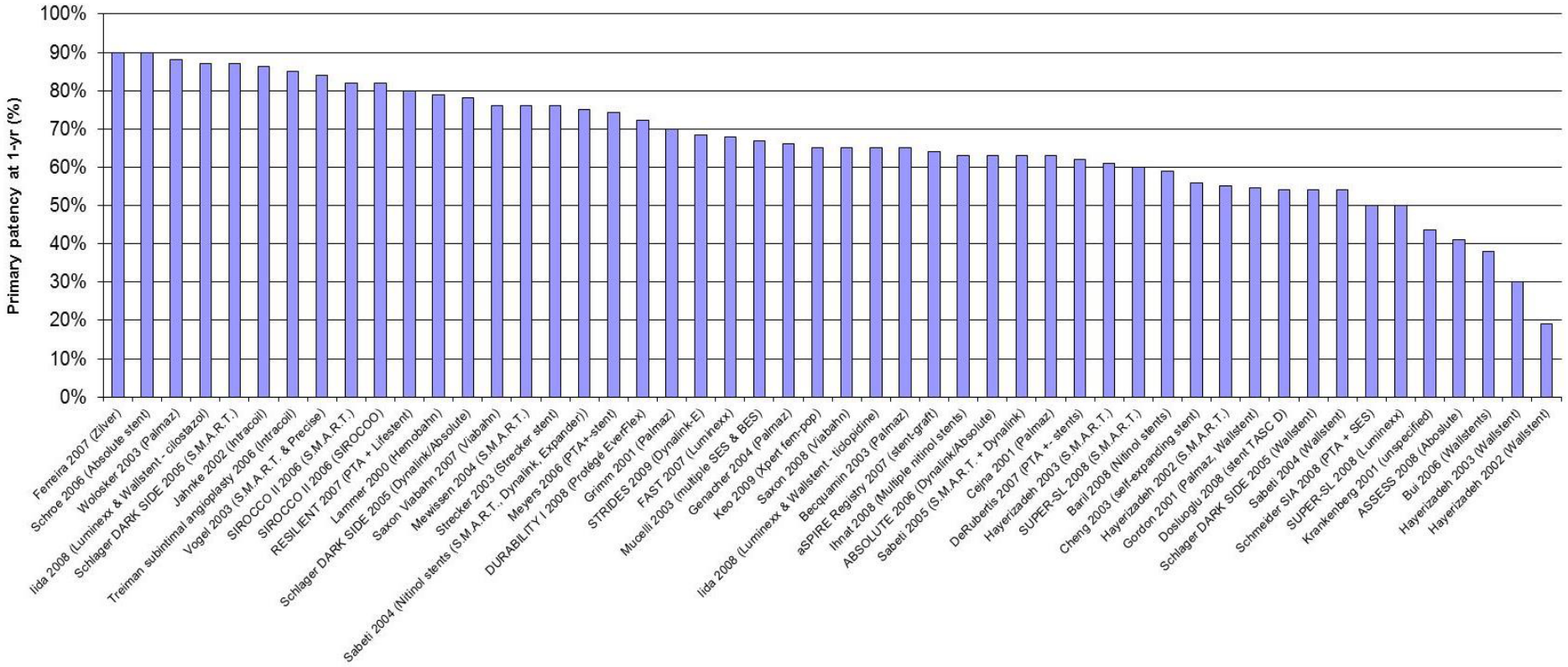


Goodney et al. JAMA Surg 2015;150(1):84-86

Endovascular Treatment Options

- Plain Balloon Angioplasty (PTA)
- Stenting
- Atherectomy
- Laser assisted PTA
- Brachytherapy
- Stent grafts
- Drug eluting stents
- Drug coated balloons
- Bioabsorbable stents
- ……

There is a lot of literature…



Publications reporting 1-yr patency following SFA stenting or stent-grafting from 2000-2009

courtesy L. Schwartz

Endovascular Therapy for CLI

- Minimally invasive
- No need for
  - general anesthesia
  - incisions
  - hospitalization
- Lower morbidity and mortality

- Decreased durability
  - Low patency rates in some vascular beds
- Expensive
- Driven by business interests

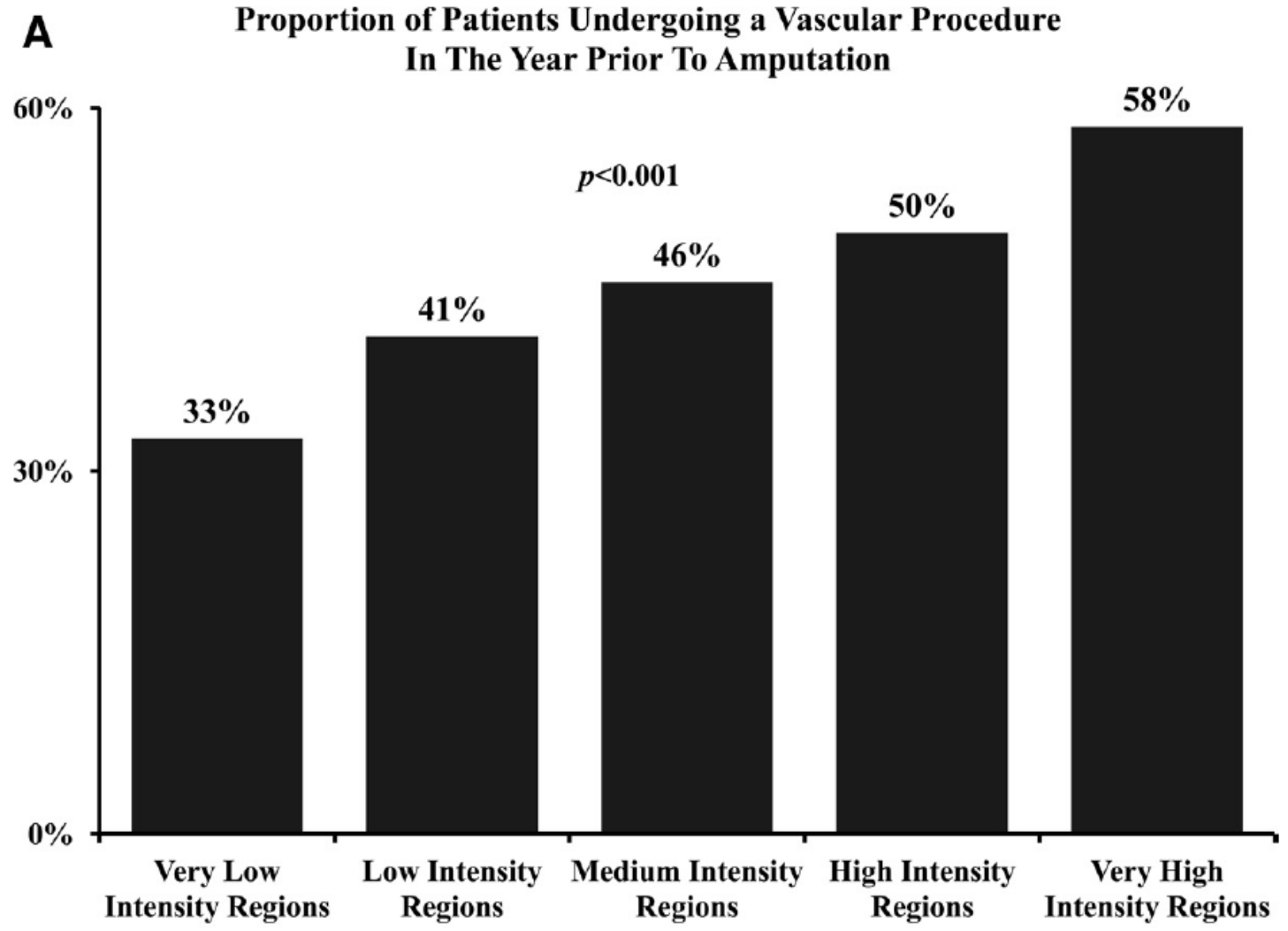
We have tools that work….

…but which tool works best for whom and when?

Current Status of Limb Revascularization?

1. Variability in Treatment
2. Absence of Value-driven Care
3. Insufficient Comparative Effectiveness Data

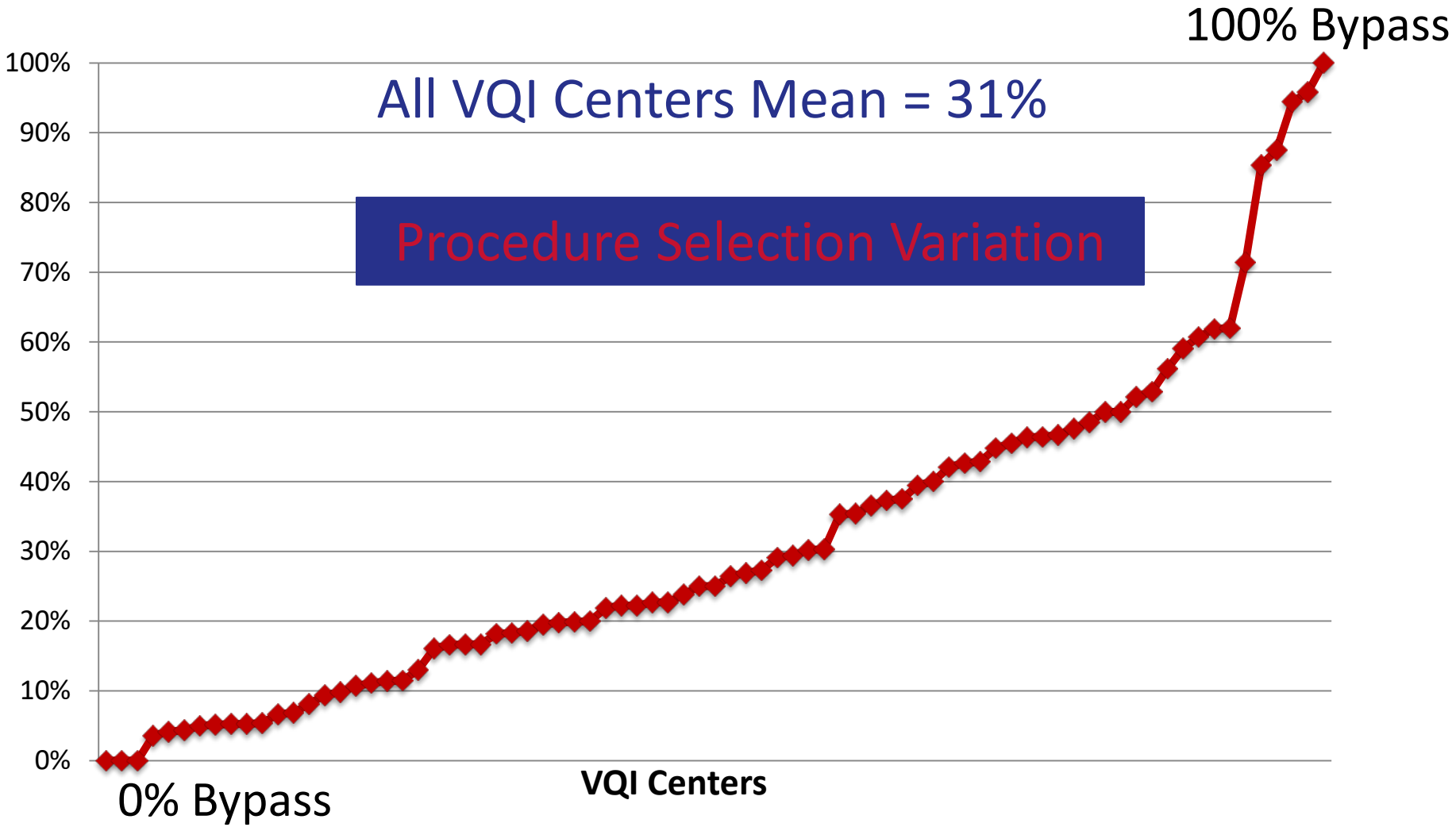
Variability of Intensity of Vascular Care Across Regions of the United States



Goodney et al, Circulation CV Q+O 2012 (5) 94-102

Vascular Quality Initiative

% of Patients with CLI and PAD treated with Surgical Bypass (vs. Endovascular Therapy)



CLI is

Very Expensive

Americans pay much higher prices for healthcare services

OECD Prices for Hospital and Physician Services, Pharmaceuticals, and Diagnostic Imaging

	Total hospital and physician costs, 2013[a]		Diagnostic imaging prices, 2013[a]		Price comparison for in-patent pharmaceuticals, 2010 (U.S. set to 100)[b]
	Bypass surgery	Appendectomy	MRI	CT scan (abdomen)	
Australia	$42,130	$5,177	$350	$500	49
Canada	—	—	—	$97	50
France	—	—	—	—	61
Germany	—	—	—	—	95
Netherlands	$15,742	$4,995	$461	$279	—
New Zealand	$40,368	$6,645	$1,005	$731	—
Switzerland	$36,509	$9,845	$138	$432	88
United Kingdom	—	—	—	—	46
United States	$75,345	$13,910	$1,145	$896	100

[a] Source: International Federation of Health Plans, 2013 Comparative Price Report.
[b] Numbers show price indices for a basket of in-patent pharmaceuticals in each country; lower numbers indicate lower prices. Source: P. Kanavos, A. Ferrario, S. Vandoros et al., "Higher U.S. Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs," *Health Affairs*, April 2013 32(4):753–61.

National health care costs of peripheral arterial disease in the Medicare population

Alan T Hirsch[1,2], Lacey Hartman[3], Robert J Town[3] and Beth A Virnig[3] *Vascular Medicine* 2008; 13: 209–215

BEST-CLI

- Medicare expenditure on CLI > $4 billion

  (CHF = $3.9B, Cerebrovascular disease = $3.7B)

  - 90% inpatient care
  - $1,700 per patient (>2X avg beneficiary)
  - 3% of total Medicare budget

At the end of the day we need to know how to manage this patient…

- 75 year old diabetic woman with right forefoot gangrene
- PE: normal femoral but no distal pulses
- Rt ABI: 0.3

Which FIRST *Revascularization Option* in CLI Has the BEST Value?

Bypass Surgery

VS

Endovascular Therapy

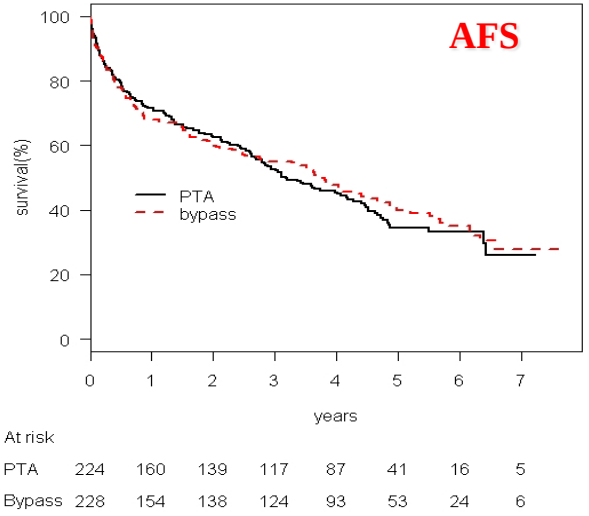
Limitations of Published Data

- Retrospective
- Poorly controlled
- Suboptimal endpoints
- Sponsor and Operator bias
- Patients with claudication and CLI are “lumped together”
- Short or incomplete follow up

Is There any Level I Evidence?

BASIL Trial

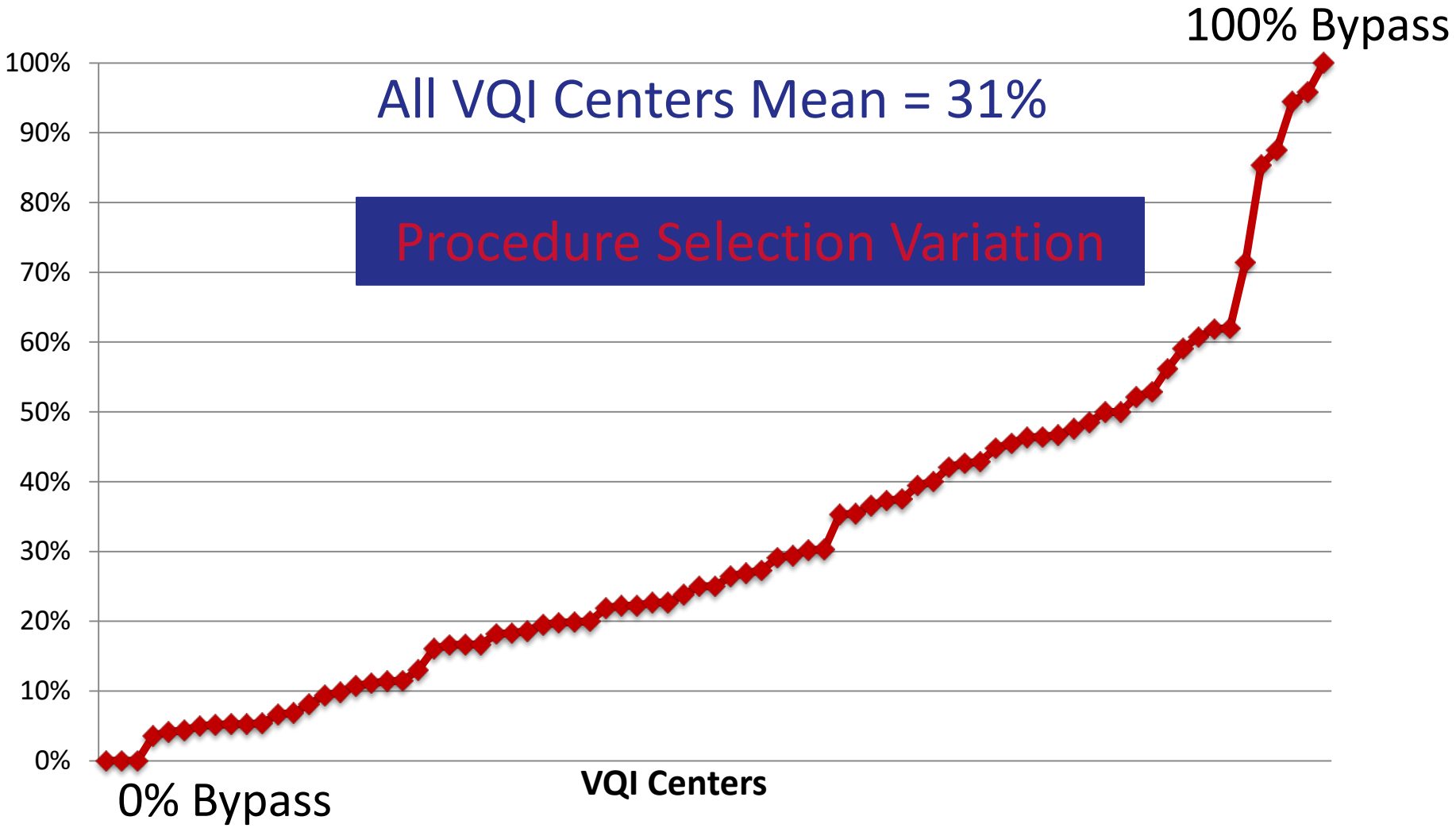
- **Aim**: To compare outcomes of surgery-first strategy with angioplasty first strategy in patients with CLI
- **Results**:
  - No significant difference in amputation-free survival at >5 year follow-up
  - Trend toward benefit for surgery noted in those patents who survived more than 2 years
- **Limitations:**
  - Underpowered
  - Endovascular therapy limited to angi
  - Lack of lesion standardization



Adam DJ. Lancet. Dec 3 2005;366(9501):1925-1934
Bradbury A. J Vasc Surg 2010; 51(5 Suppl)5S-17S

Vascular Quality Initiative

% of Patients with CLI and PAD treated with Surgical Bypass (vs. Endovascular Therapy)



BEST-CLI

Best **E**ndovascular vs. Best **S**urgical **T**herapy in Patients with **C**ritical **L**imb **I**schemia

Sponsored by the National Heart Lung and Blood Institute

BWH

BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

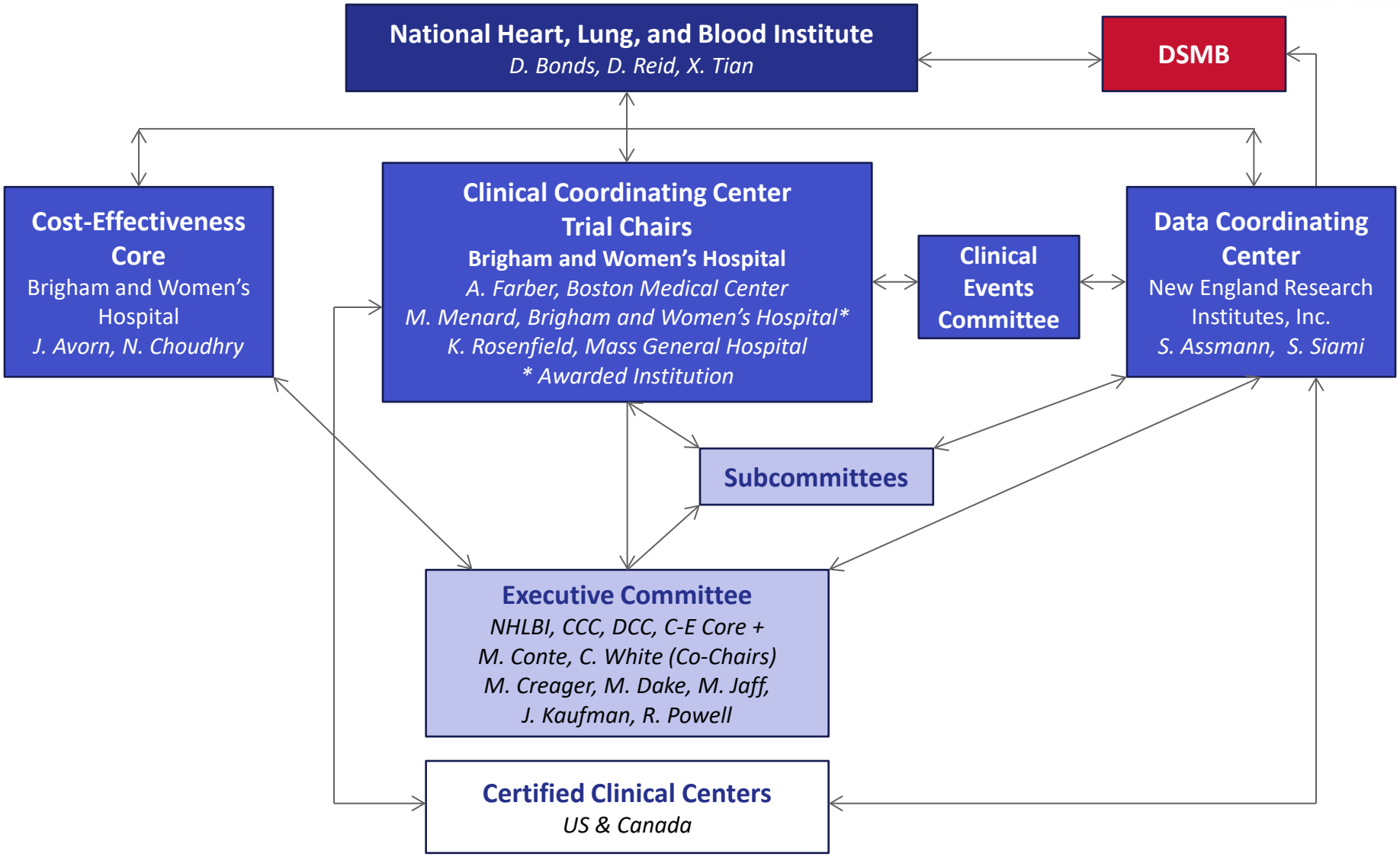
MGH 1811

neri
New England Research Institutes

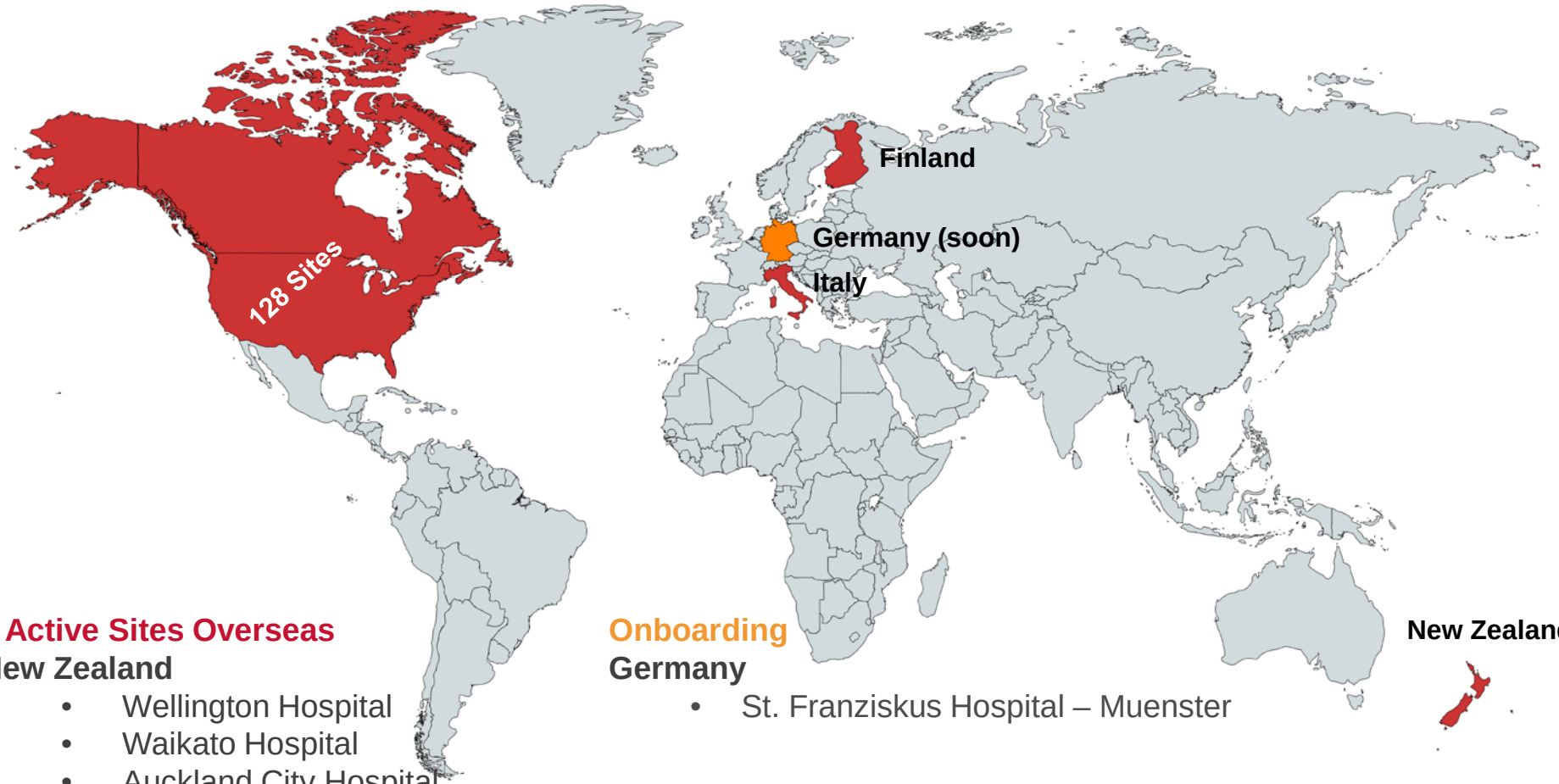
BEST-CLI Trial: Overview

- Prospective, randomized, multicenter, multispecialty, pragmatic, open-label superiority trial
- 2100 patients at 160 clinical sites
- Funded at level of $25 million
- ***Goal: to assess treatment efficacy, functional outcomes, cost and value in patients with CLI and infrainguinal PAD who are candidates for both open vascular and endovascular surgery***

BEST Trial Organization



BEST-CLI Global Footprint



5 Active Sites Overseas

New Zealand

- Wellington Hospital
- Waikato Hospital
- Auckland City Hospital

Finland

- Helsinki University Hospital

Italy

- San Giovanni di Dio Hospital

Onboarding

Germany

- St. Franziskus Hospital – Muenster

133 sites currently open for enrollment

BEST-CLI is a Pragmatic Trial

- Definition of “Best Treatment” is left to the investigator
- All commercially available endovascular therapies allowed as long as accepted as standard of care
- All surgical bypass techniques and conduits allowed
- Trial approximates “real world”

BEST-CLI Trial Design: Two Cohorts

- **Cohort #1 Patients with adequate single segment great saphenous vein (SSGSV) N=1620**

  Open surgery vs. Endovascular treatment

- **Cohort #2 Patients without adequate SSGSV** (if randomized to OPEN conduit may include arm vein, short saphenous vein, composite vein, cryopreserved vein, and prosthetic conduit) **N=480**

  Open surgery vs. Endovascular treatment

Novel Primary Endpoint

Major Adverse Limb Event (MALE) – free survival

MALE defined as:

- Above ankle amputation or
- **Major** re-intervention
  - new bypass graft
  - jump/interposition graft revision
  - thrombectomy/thrombolysis

Key Secondary Endpoints

- Re-intervention and Amputation-free Survival
- Amputation-free Survival
- MALE

Additional Secondary Endpoints

- Freedom from hemodynamic failure
- Freedom from clinical failure
- Freedom from critical limb ischemia
- Number of re-interventions per limb salvaged
- Freedom from re-interventions (major and minor) in index limb

Robust Cost-Effectiveness Analysis

- Functional status / quality of life measures
  - EQ5D as main measure; also SF-12
- All financial costs of care
  - Hospital care (index admission and all f/u)
  - Outpatient care
  - Rehabilitation

Collaboration within BEST-CLI

Inclusive of everyone who performs revascularization for CLI:

- Vascular Surgeons
- Interventional Cardiologists
- Interventional Radiologists

What about Podiatry???

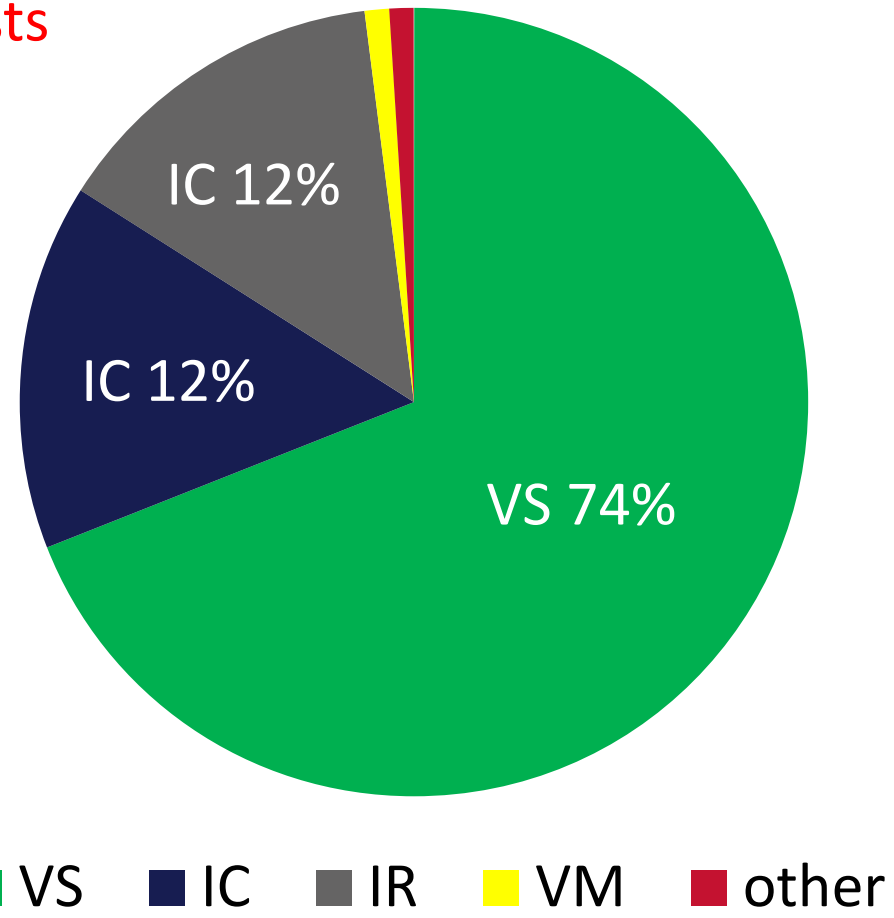
If our trial is going to define practice it has to involve everyone.

BEST-CLI Site Multidisciplinary Status

- **72 % sites are multidisciplinary**
  - VS alone 28%
  - VS + IR 23%
  - VS + IC 32%
  - VS + IR + IC 13%

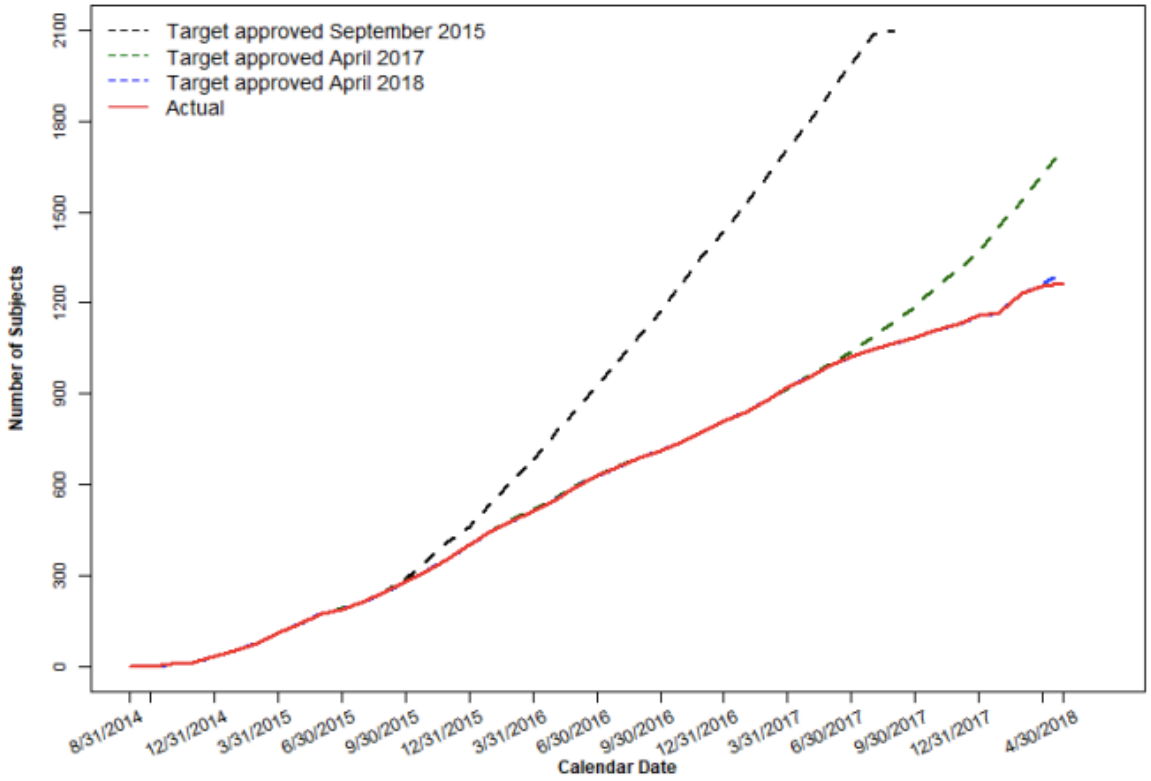
BEST Investigator Data

- Investigators by Specialty (n= 930)
  - 690 Vascular Surgeons
  - 114 Interventional Cardiologists
  - 111 Interventional Radiologists
  - 3 Vascular Medicine
  - 12 Other specialties



Enrollment Update

- As of March 26, 2019 -
  - 1657 subjects randomized (**79%** complete)



Patient Characteristics (as of 4/9/2018 data freeze)

- Strata
  - Rest pain, no tibial dz 8%
  - Rest pain and tibial dz 12%
  - Tissue loss, no tibial dz 24%
  - Tissue loss and tibial dz 56%

BEST-CLI is positioned

- Provide a treasure trove of relevant data about CLI and its management

What questions will BEST-CLI answer?

- How does **infrainguinal bypass with optimal conduit (SSGSV)** fare against **endovascular therapy?**
- How does **bypass with non-optimal conduit** fare against **endovascular therapy?**

Define an evidence-based standard of care for revascularization of CLI

dysfunction

- Will prospectively validate **the SVS WIfI** classification
- Will relate comparative **hemodynamic outcomes** of revascularization **to clinical outcomes**

What about the wounds???

Case Example

- 69 year old female
  - PMH: DM, HPL, CAD, obesity
- Underwent left partial ray amputation at OSH for wet gangrene
- Wound ischemia -> dry gangrene
- Recommended LLE AKA because foot not salvageable

Physical Exam

Randomized to Bypass

- Left common femoral endarterectomy with bovine pericardium patch angioplasty
- Left CFA to PTA bypass w Propaten and vein patch

TMA with rotational plantar flap (Podiatry)

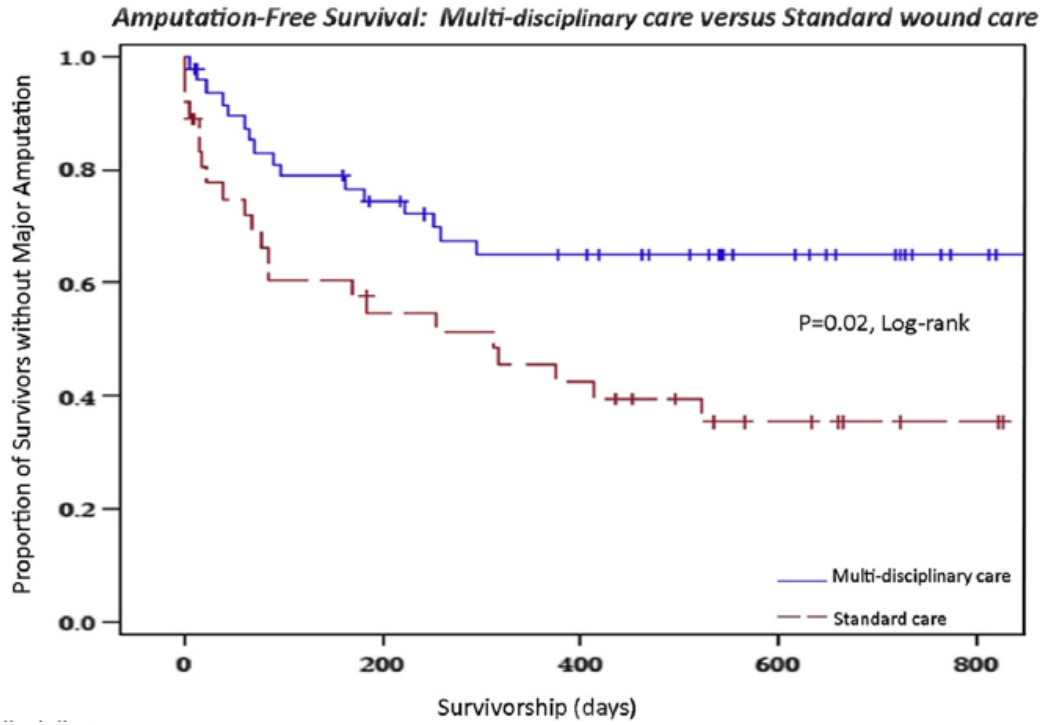
Post-Op

- Intra-op Cx: E. cloacae, Proteus, MSSA
- ID: Zosyn x6 weeks (PICC)
- Discharged to Rehab
- Fu in Multi-D clinic
  - Sutures out/healed by 14 d post-op

A Multifactorial Problem Needs a Multidisciplinary Approach

Multidisciplinary care improves amputation-free survival in patients with chronic critical limb ischemia

Jayer Chung, MD, J. Gregory Modrall, MD, Chul Ahn, PhD, Lawrence A. Lavery, DPM, and R. James Valentine, MD, *Dallas, Tex*



(J Vasc Surg 2015;61:162-9.)

The Johns Hopkins Experience

Multidisciplinary Diabetic Foot & Wound Service

- Multidisciplinary team
  - Vascular surgery, surgical podiatry, endocrinology
    - Single clinic visit
    - Robust home health nursing group
  - Consultants
    - Ortho foot & ankle, plastic surgery, ID, PMNR
- Inpatient/outpatient

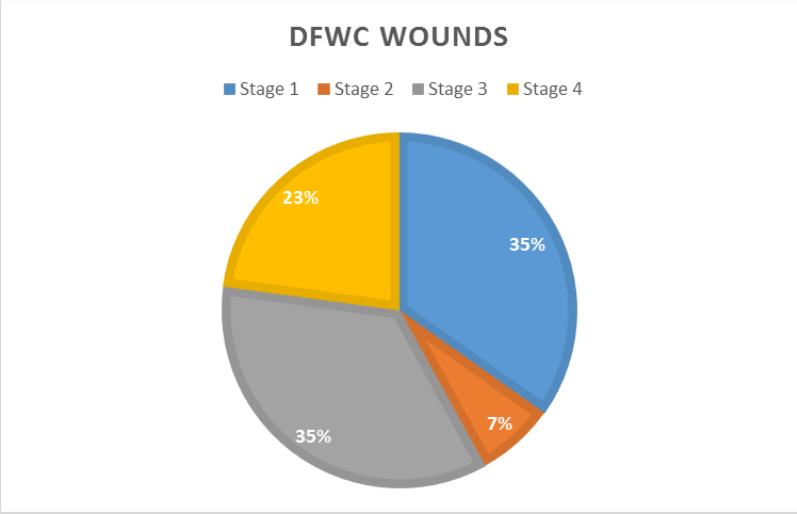
The Johns Hopkins Experience

Multidisciplinary Diabetic Foot & Wound Service

The Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIfI) classification system predicts wound healing but not major amputation in patients with diabetic foot ulcers treated in a multidisciplinary setting

Nestoras Mathioudakis, MD, MHS,[a,b] Caitlin W. Hicks, MD, MS,[a,c] Joseph K. Canner, MHS,[d] Ronald L. Sherman, DPM, MBA,[a] Kathryn F. Hines, PA-C,[a] Ying W. Lum, MD,[c] Bruce A. Perler, MD, MBA,[c] *and* Christopher J. Abularrage, MD,[a,c] *Baltimore, Md* (J Vasc Surg 2017;■:1-8.)

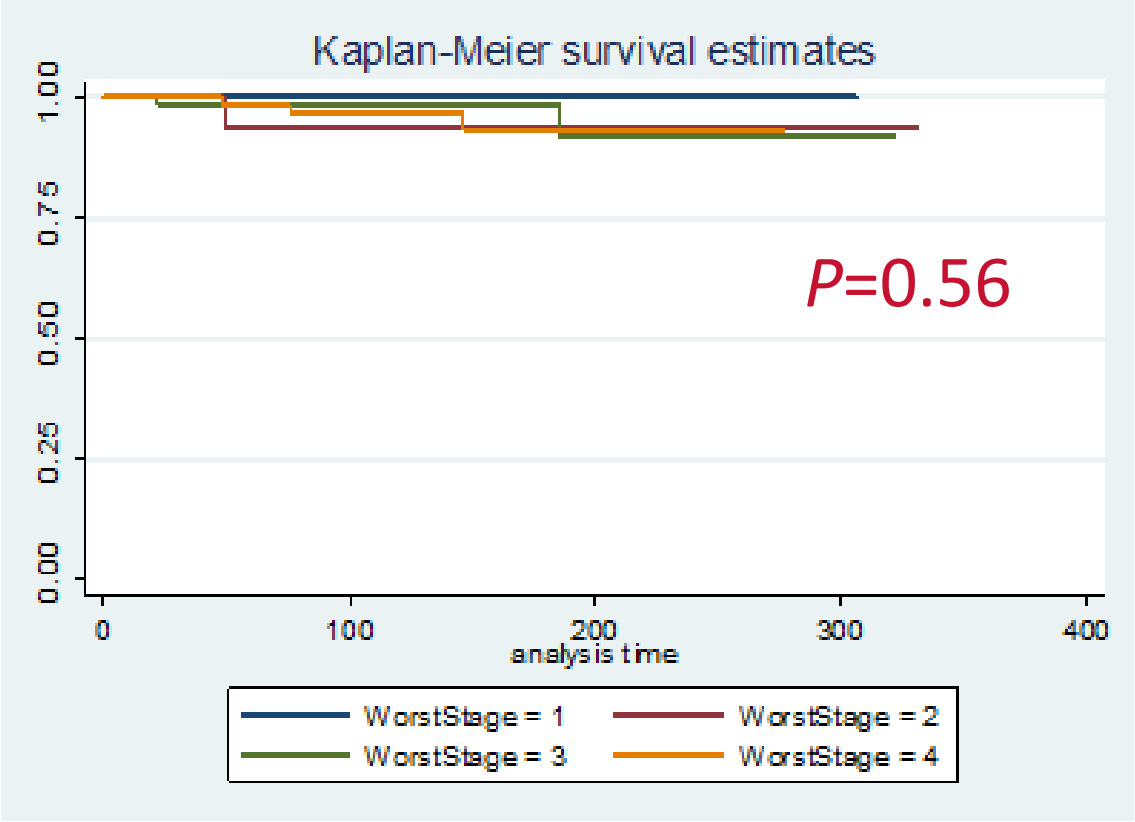
- July 2012 – Dec 2015
- 290 Diabetic patients
- 412 wounds
  - 58% WIfI Stage 3 or 4
- 352 Debridments & minor amputations
- 118 revascularizations



The Johns Hopkins Experience

Multidisciplinary Diabetic Foot & Wound Service

- Major amputation at 1 year



The Burden of Limb Salvage

Time spent

The Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIfI) classification independently predicts wound healing in diabetic foot ulcers

Caitlin W. Hicks, MD, MS,[a,b] Joseph K. Canner, MHS,[c] Nestoras Mathioudakis, MD, MHS,[a,d] Ronald Sherman, DPM,[a,b] Mahmoud B. Malas, MD, MHS,[c,d] James H. Black III, MD,[b] *and* Christopher J. Abularrage, MD,[a,b] *Baltimore, Md* (J Vasc Surg 2018;■:1-8.)

Table III. One-year outcomes for diabetic foot ulcer (DFU) patients overall and by Wound, Ischemia, and foot Infection (WIfI) stage

Variable	Overall (N = 709)	Stage 1 (n = 230)	Stage 2 (n = 141)	Stage 3 (n = 179)	Stage 4 (n = 159)	*P* value
WHT, days	127.9 ± 4.8	96.9 ± 8.3	78.5 ± 6.4	146.9 ± 9.6	195.1 ± 10.6	<.001
12-month wound healed, %	84.9 ± 1.7	94.1 ± 2.0	96.3 ± 2.3	83.1 ± 3.4	67.4 ± 4.4	<.001

WHT, Wound healing time.
Values are reported as mean ± standard error of the mean.

WIfI Stage Predicts Costs

Overall costs of multidisciplinary care

Inpt & Outpt $$$	Stage 1	Stage 2	Stage 3	Stage 4	*P*
Total Revenue	13,205	16,406	42,470	58,374	<.001
Total Cost	12,577	14,692	38,141	52,733	<.001
Variable Direct	5,698	6,534	16,849	24,564	<.001
Variable Indirect	1,556	1,814	4,204	5,726	<.001
Fixed Direct	1,572	1,752	4,699	6,083	<.001
Fixed Indirect	3,751	4,593	12,389	16,359	<.001
Variable Net Margin	6,122	9,176	22,623	26,635	<.001
Overall Net Margin	2,176	3,270	6,466	7,980	.008

Controlling Costs

Major vs. Minor amputations

Diabetic foot ulcers in a multidisciplinary setting
An economic analysis of primary healing and healing with amputation

J. APELQVIST, G. RAGNARSON-TENNVALL*, U. PERSSON* & I. LARSSON†
From the Department
† Department of Orth

Journal of Internal

Multi-D teams decrease major amps & save $$$

< 70	27	314 (27–805)
⩾ 70	50	360 (44–992)
Sex		
male	43	316 (27–968)
female	34	379 (44–992)
Toe pressure ⩽ 45 and/or ankle pressure < 80 mmHg†	60	371 (44–992)
Toe pressure > 45 and ankle pressure ⩾ 80 mmHg†	14	267 (27–531)
Healing time		
⩽ 2 months	8	356 (27–968)
3–4 months	30	312 (44–745)
> 5 months	39	366 (96–992)
Minor amputations	27	258 (27–501)*
Major amputations	50	390 (44–992)

Controlling Costs

Major vs. Minor amputations

A Diabetic Foot Service Established by

Single Center Study examining Outcomes Pre/Post DFS

Decreased Amputations

Decreased Surgeries

Conclusion

Early referral to DFS=

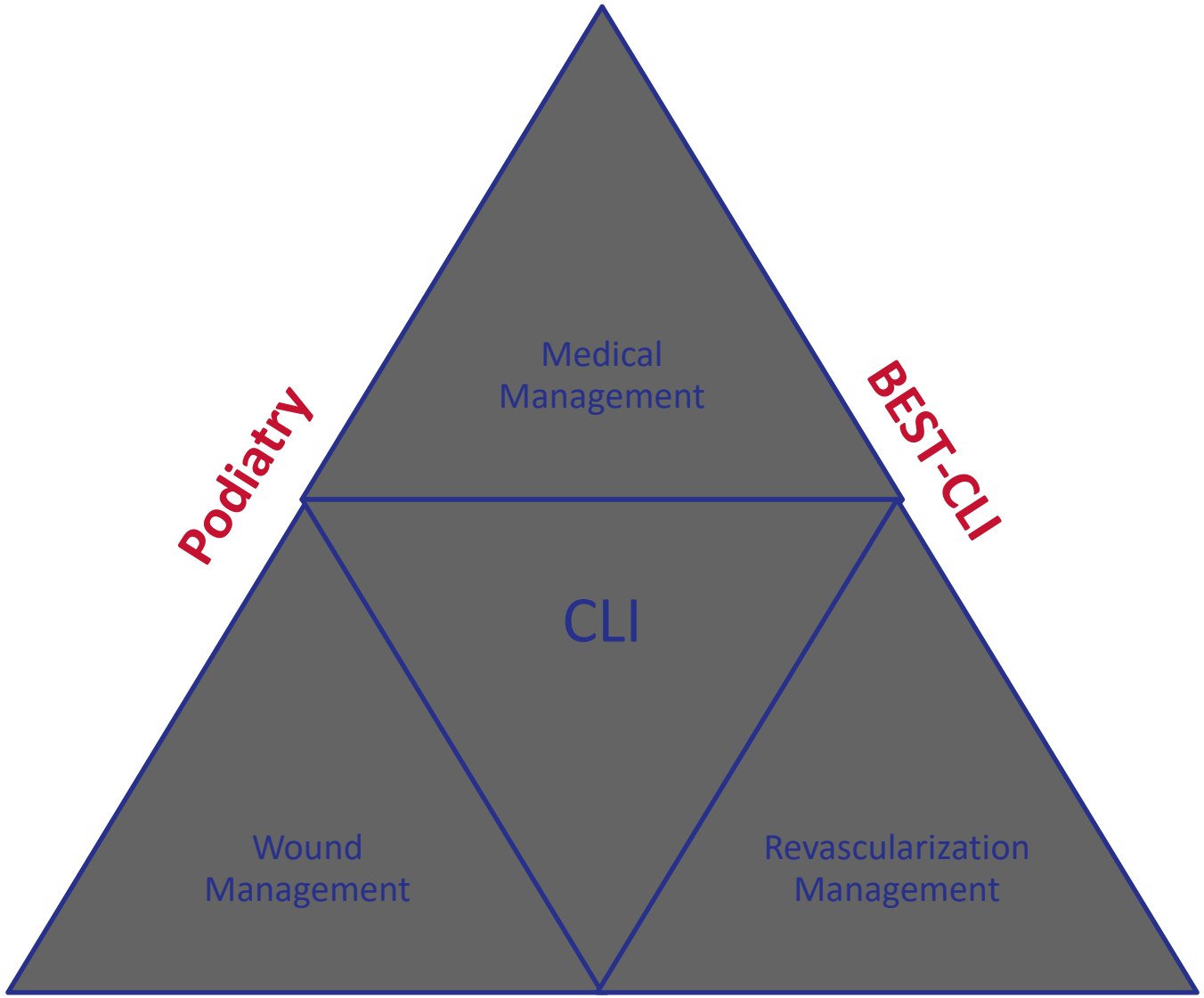
1. **Earlier presentation of disease**
2. Reduced delays to treatment
3. Decreased costs of care

tion of diabetic to nondiabetic amputations decreased; foot surgery rates also dropped (53.7/10,000 in 2006 vs. 7.5/10,000 in 2009). The number of open revascularization procedures decreased, but the rates of endovascular procedures remained generally constant. Hospital admission rates decreased after initially peaking, and the length of stay was unchanged (16 vs. 15.5 days in 2004 and 2009, respectively).

Conclusions: The integration of a vascular unit with community care has been associated with improved outcomes for patients with diabetic foot disease. Improvements were not related to the increased number of vascular procedures or hospitalizations, but did coincide with a greater proportion of patients attending the foot unit. The referral of patients to the unit facilitates the rapid management of severe disease, reducing delays deleterious to outcomes.

BEST-CLI, Podiatry, and CLI

An Important Relationship



BEST-CLI, Podiatry, and CLI

Our Plea to You

- Continue to take excellent care of patients
- Be cognizant of CLI in patients who present with foot wounds
- Liason with BEST-CLI investigators to optimize blood flow
- Aggressive and early debridement/minor amputation as needed
- Consider establishing/joining a multi-D limb preservation team
    - This is where CLI care is headed!

Thank You

Questions?

@CaitlinWHicks
@HopkinsSurgery
@BEST-CLI