Is There a Role for Primary Amputation in Patients with Lower Extremity Occlusive Disease?: Primary Amputation is Ok

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Is There a Role for Primary Amputation in Patients with Lower Extremity Occlusive Disease?:

Disclosures: None

Not an amputationalist

Practice pattern: limb salvage

Primary Amputation

- Not a PC statement

- 53 Major Limb Salvage/ Amputation Prevention Centers in the US
- Only 7 Amputation centers (excluding REHAB)

AMPUTATION IS VIEWED AS A MEDICAL FAILURE

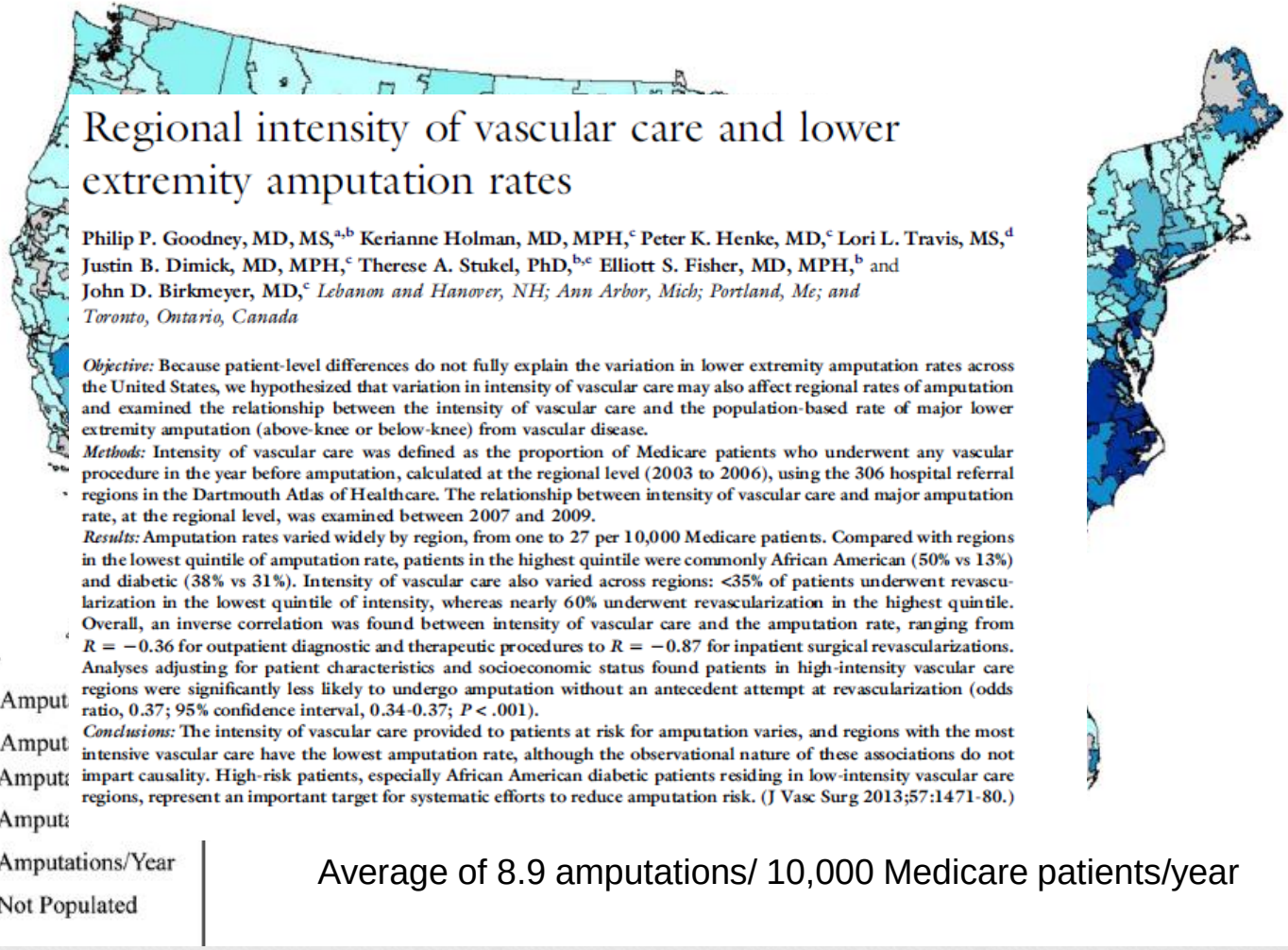
Clinical Practice

- Henry Ford Hospital : urban tertiary care hospital
- Amputations: 2 year experience

Is There a Role for Primary Amputation in Patients with Lower Extremity Occlusive Disease?: Background Information

1. Amputation is commonly performed
2. Bypass or revascularization procedures fail (many within the first year)
3. These failures can often be predicted preoperatively
4. Appropriate application of primary amputation improves costs, patient quality, and your outcome

Population-base Amputation rates for PAD by hospital referral regain in the United States



Regional intensity of vascular care and lower extremity amputation rates

Philip P. Goodney, MD, MS,[a,b] Kerianne Holman, MD, MPH,[c] Peter K. Henke, MD,[c] Lori L. Travis, MS,[d] Justin B. Dimick, MD, MPH,[c] Therese A. Stukel, PhD,[b,e] Elliott S. Fisher, MD, MPH,[b] and John D. Birkmeyer, MD,[c] *Lebanon and Hanover, NH; Ann Arbor, Mich; Portland, Me; and Toronto, Ontario, Canada*

Objective: Because patient-level differences do not fully explain the variation in lower extremity amputation rates across the United States, we hypothesized that variation in intensity of vascular care may also affect regional rates of amputation and examined the relationship between the intensity of vascular care and the population-based rate of major lower extremity amputation (above-knee or below-knee) from vascular disease.

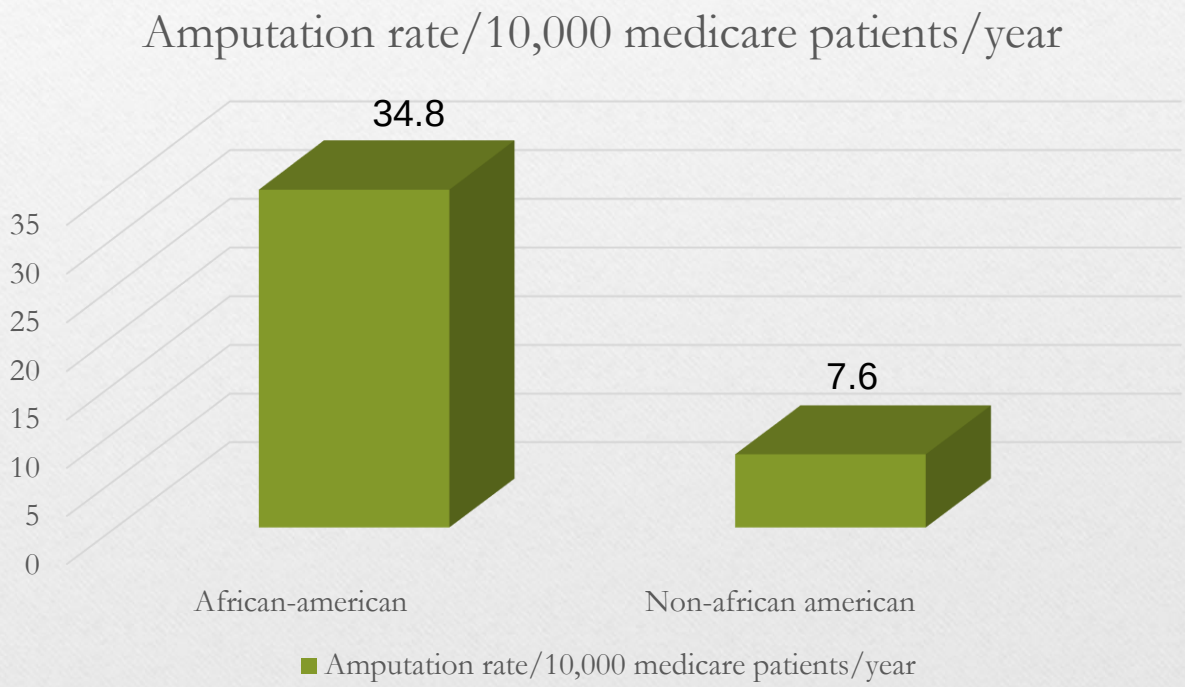
Methods: Intensity of vascular care was defined as the proportion of Medicare patients who underwent any vascular procedure in the year before amputation, calculated at the regional level (2003 to 2006), using the 306 hospital referral regions in the Dartmouth Atlas of Healthcare. The relationship between intensity of vascular care and major amputation rate, at the regional level, was examined between 2007 and 2009.

Results: Amputation rates varied widely by region, from one to 27 per 10,000 Medicare patients. Compared with regions in the lowest quintile of amputation rate, patients in the highest quintile were commonly African American (50% vs 13%) and diabetic (38% vs 31%). Intensity of vascular care also varied across regions: <35% of patients underwent revascularization in the lowest quintile of intensity, whereas nearly 60% underwent revascularization in the highest quintile. Overall, an inverse correlation was found between intensity of vascular care and the amputation rate, ranging from $R = -0.36$ for outpatient diagnostic and therapeutic procedures to $R = -0.87$ for inpatient surgical revascularizations. Analyses adjusting for patient characteristics and socioeconomic status found patients in high-intensity vascular care regions were significantly less likely to undergo amputation without an antecedent attempt at revascularization (odds ratio, 0.37; 95% confidence interval, 0.34-0.37; $P < .001$).

Conclusions: The intensity of vascular care provided to patients at risk for amputation varies, and regions with the most intensive vascular care have the lowest amputation rate, although the observational nature of these associations do not impart causality. High-risk patients, especially African American diabetic patients residing in low-intensity vascular care regions, represent an important target for systematic efforts to reduce amputation risk. (J Vasc Surg 2013;57:1471-80.)

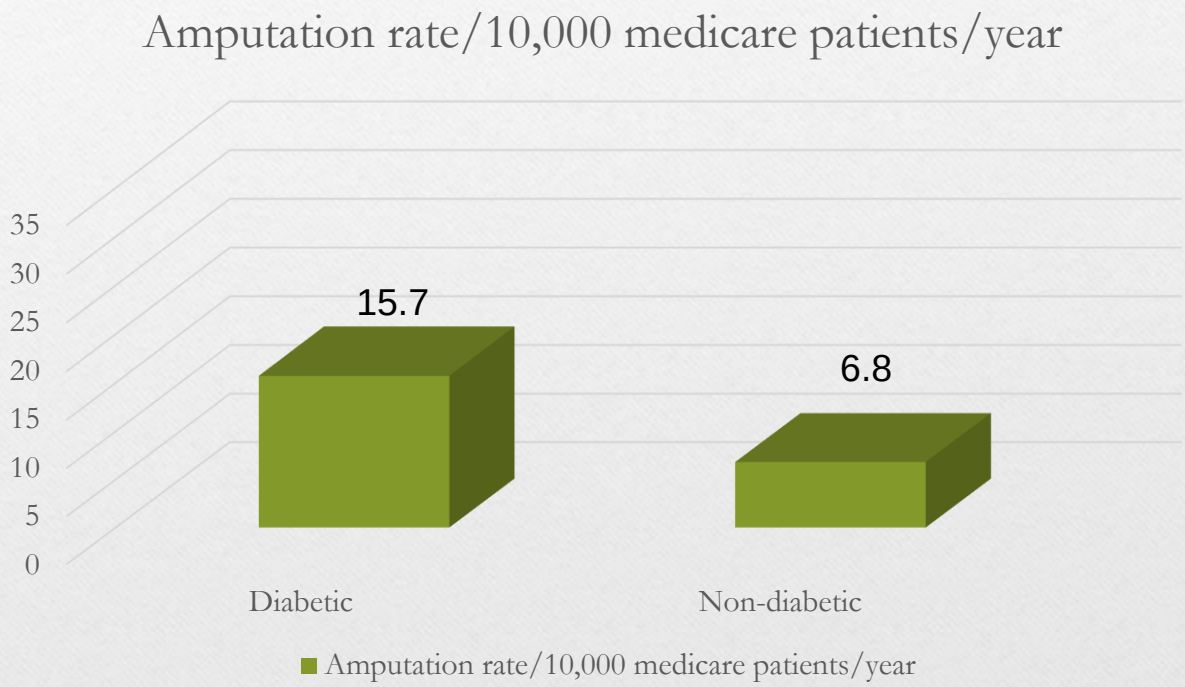
Average of 8.9 amputations/ 10,000 Medicare patients/year

Regional intensity of vascular car and lower extremity amputation rate



Goodney et al J Vasc Surg 2013;57:1471-80

Regional intensity of vascular car and lower extremity amputation rate



Goodney et al J Vasc Surg 2013;57:1471-80

Primary Amputation vs Revascularization

224 CLI Patients (5-year period)	
Primary Amputation	97 (43%)
Revascularization	127 (57%)

In our aging population, primary major amputations (AMP, below-knee or above-knee) continue

primary major AMP in 97 cases (43%) and revascularization in 127 cases (57%). On univariate analysis, nonwhite race/ethnicity, DM, ESRD, major tissue loss, dependent living situation, and nonambulatory status were all significant predictors of AMP versus LER (all $P < 0.01$). On multivariate analysis, major tissue loss, ESRD, DM, and nonambulatory status remained independent predictors of AMP versus LER (all $P < 0.05$). The system-related factors of time to

influence of patient-specific and system-related factors on the primary treatment modality (AMP versus LER) was determined with univariate and multivariate analyses. A total of 224 patients presented with CLI between March 1, 2001, and March 1, 2005. Patients were treated with primary major AMP in 97 cases (43%) and revascularization in 127 cases (57%). On univariate analysis, nonwhite race/ethnicity, DM, ESRD, major tissue loss, dependent living situation, and nonambulatory status were all significant predictors of AMP versus LER (all $P < 0.01$). On multivariate analysis, major tissue loss, ESRD, DM, and nonambulatory status remained independent predictors of AMP versus LER (all $P < 0.05$). The system-related factors of time to vascular surgery evaluation (mean 8.6 weeks, 7.1 vs. 9.3 weeks AMP versus LER, $P = 0.60$) and type of insurance (managed care, 17% vs. 24% AMP vs. LER, $P = 0.15$) had no influence on treatment. Fifty-four percent of all primary major AMPs were performed due to extensive gangrene or infection present at initial vascular evaluation which precluded limb salvage. Major tissue loss, ESRD, DM, and nonambulatory status are all independent predictors of treatment with primary AMP as opposed to revascularization. Treatment of CLI is determined by patient-specific factors and does not appear to be adversely influenced by system-related factors. Efforts toward improving limb salvage may be best directed at aggressive treatment of medical comorbidities to prevent the late complications of CLI. Earlier recognition of tissue loss and referral to the vascular specialist may lead to improved limb salvage.

Factors leading to major primary amputation versus revascularization

	p value	Odds ratio
Major tissue loss (54%)	0.002	5.5
ESRD	0.005	5.3
Diabetes mellitus	0.03	3.0
Non-ambulatory status	0.05	2.5

Abou-Zamzam et al Ann Vasc Surg 2007;21

Factors leading to major primary amputation versus revascularization

Major tissue loss	NON-DISPUTABLE
ESRD	?
Diabetes mellitus	?
Non-ambulatory status	Impaired ambulation?

PRIMARY AMPUTATION

- MAJOR TISSUE LOSS
  - Extensive tissue loss precluding successful foot salvage (proximal to mid-foot)
  - Extensive wound or infection not expected to heal despite revascularization

Illustrative Case

- Patient 57 y/o AA male with ESRD, DM, S/P Cadaveric Renal Transplant on immunosuppression with wet gangrene of right foot (2nd,3rd & 4th toes)
- ABI: Incompressible; toe pressure: 30 (non-involved toe) Monophasic waveform

O C S

- Debridement /
- Angiogram w T l 7/6/2015
- Further debri o
- Repeat PTA ar 2015
- Washout and R
- RT BKA 8/2

TPT: Tibio-peroneal trunk AT: Anterior tibial

O ures

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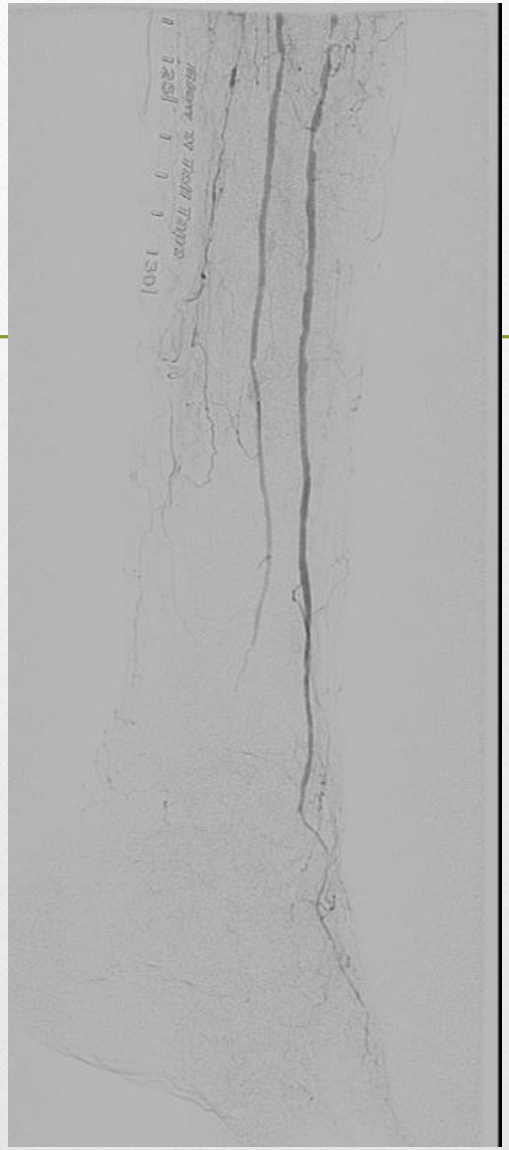
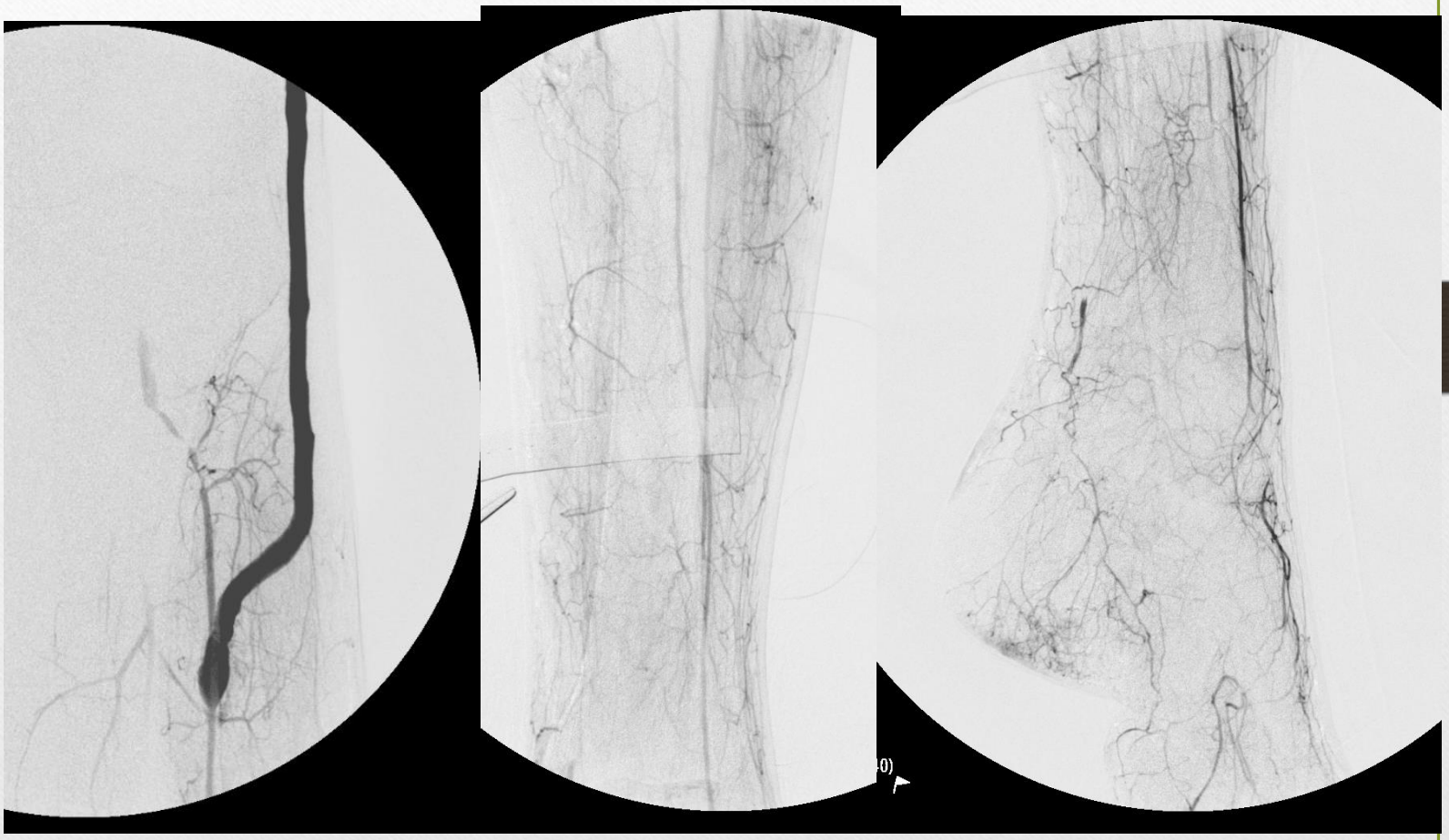
Trell Tape


Glow 'N Tell Tape
125
120
115
110
105
100
95
90


Glow 'N Tell Tape
125
120

Illustrative Case: Bypass



Management Options for
Critical Limb Ischemia
With a potentially salvageable limb

Confirmatory Testing
Optimize Modifiable Risk Factors

Observation

Amputation

Endovascular

Bypass revascularization

Is observation feasible in some situations?
What are the results of revascularization (endo/bypass)
Can we predict failure of revascularization?

When should primary amputation be performed?

Long-Term Outcome of Patients with Peripheral Arterial Disease and Tissue Loss Stratified to a Nonrevascularization Approach

Isabella Possagnoli, Christian Bianchi, Jason Chiriano, Theodore Teruya, Vicki Bishop, and Ahmed Abou-Zamzam, Loma Linda, California

Background: To evaluate the long-term outcome of patients presenting with peripheral artery disease (PAD) and tissue loss that were stratified in our limb preservation program to receive aggressive wound care without revascularization.

Methods: Veterans presenting with PAD and nonhealing wounds were prospectively enrolled into our Prevention of Amputation in Veterans Everywhere (PAVE) program. Patients were stratified according to management strategies, which include: revascularization, primary amputation, palliative limb care, and aggressive local wound care without revascularization (conservative group). This study focuses on the conservative cohort. Wound presentation, type of wound care provided, wound care-associated procedures, healing rates, revascularization, major amputation, wound recurrences, management of recurrent wounds, and patient survival were analyzed.

Results: Between January 2006 and November 2014, 601 patients were prospectively enrolled in our PAVE program. A total of 203 limbs in 183 patients with 231 wounds were allocated to the conservative group based on a validated pathway of care. Mean follow-up for this cohort was 33.6 months (range, 1.5–104). Complete wound healing was achieved in 148 limbs (73%). The mean time to healing was 4.1 months. Twenty-four limbs (11.8%) received "late revascularization" (beyond 6 months from enrollment). Overall limb preservation was 90% at 4 years, with 57% freedom from wound recurrence. In patients with recurrence over 80% were successfully managed without revascularization. Limb loss was attributed to infection in most cases.

Conclusions: In this selected group, an initial approach with aggressive wound care without revascularization appears justified with good limb salvage. Long-term analysis demonstrated a notable incidence of wound recurrence (43%) albeit most recurrences can be successfully managed without the need for late revascularization and no increased inci-

Observatio
Wound Car

Long-term Outcome of Patients with Peripheral Arterial Disease and Tissue Loss Stratified by a Non-Revascularization Approach

TcpO2 had to be greater than 30 mmHg (mean 48mmHg)
Average ABI was 0.77

Observation
Wound Care

203 Limbs with wounds	**f/u 33.6 mos**
Complete wound healing	148 (73%)
Recurrence rate	**64 (43%)**
Late Revascularization	**24 (12%)**
Ulceration did better than Gangrene	**80% vs 59%**

PAVE: Prevention of Amputation in Veterans Everywhere

Critical Limb Ischemia
With a potentially salvageable limb

Confirmatory Testing
Optimize Modifiable Risk Factors

Endovascular

Bypass revascularization

REVACULARIZATION

Endovascular vs Open Revascularization for CLI

BASIL (Bypass vs Angioplasty in Severe Ischemia of the Leg) (1999)

- First treatment strategies
- No difference in amputation free survival at 2 year
- No difference in quality of life measures at 2 years
- Surgery 1/3 great costs
- Trend of improved AFS > 2yrs

Best CLI (NIH)

- Multicenter NIH sponsored trial
- Randomization to open versus endovascular revascularization

Sponsored by the United Kingdom National Institute of Health Research

Critical Limb Ischemia

- What are the results of revascularization?
- What are the factors which adversely affect outcome with revascularization

Results of Bypass Revascularization in Management of CLI

- Why do we do bypass operations?
  - Limb salvage? Relief of ischemic rest pain? Wound healing?
- **Quality of Life and Functional Outcome** ?
  - Limb salvage
  - Graft patency
  - Amputation-free survival
  - Freedom from amputation
  - Major adverse limb event (MALE)

Results of Bypass Revascularization in Management of CLI

- Why do we do bypass operations?

Quality of Life and Functional Outcome

Factors adversely affecting quality of life and functional outcome
DM
Impaired ambulatory ability at the time of presentation (only 21% who did not ambulate pre-operatively went on to ambulate post operatively)
Dementia
Dependent living status: (only 4% went on to live independently at 6 months)

Results of Bypass for Critical Limb Ischemia: PREVENT III data: Multicenter study

Mortality	2.7%
Early bypass graft occlusion	5.2%
One-year secondary patency	80%
One-year limb salvage	88%
One-year survival	84%

CLI: inclusive of any vein conduit, redo-operations

Conte et al Results of PREVENT III…J Vasc Surg 2006;43

Infrapopliteal Angioplasty for Limb Salvage in the Setting of Renal Failure: Do Results Justify Its Use?

Bernadette Aulivola, MD,[1] Mauro Gargiulo, MD,[2] Marco Bessoni, MD,[2] Antonio Rumolo, MD,[2] and Andrea Stella, MD[3] Maywood, Illinois, USA, and Modena and Bologna, Italy

Multiple reports advocate the use of infrapopliteal angioplasty for limb salvage; however, its utility in the setting of renal failure is unclear. We performed angioplasty, rather than bypass, for tibial stenoses or occlusions <3 cm on 90 limbs of 79 patients (64.4% male, mean age 67.2 years), all with ischemic ulcer. Seventy (77.8%) had diabetes mellitus and 16 (17.8%) had end-stage renal disease (ESRD). Mean follow-up was 14.3 months (range 0.3-45). Associated femoropopliteal revascularization was required in 28 (31.0%) limbs. Primary angiographic success was achieved in 83 (92.2%) limbs. Residual stenosis or thrombosis occurred in two and five limbs, respectively. Dissection occurred in six limbs, all successfully treated with stent placement. Ulcer healing occurred after initial angioplasty in 41 (55.4%) non-ESRD and four (25%) ESRD limbs. Subsequent revascularization procedures were required in 21 (23.3%) limbs, including six bypasses and 15 repeat angioplasties, of which three underwent subsequent bypasses. Major amputation was required in 11 (14.9%) non-ESRD and seven (43.7%) ESRD limbs. Limb salvage was 84.4% and 80.2% in those without and 52.5% and 52.5% in those with ESRD at 1 and 3 years, respectively ($p = 0.01$). Thirty-day mortality was 2.2%. Overall actuarial survival was 82.2% and 62.1% at 1 and 3 years, respectively, and did not differ significantly between patients with and without ESRD ($p = 0.66$). Infrapopliteal angioplasty is a safe technique with low procedural morbidity and mortality. However, the inferior wound-healing and limb-salvage rates observed in patients with renal failure bring to question the utility of infrapopliteal angioplasty in this population.

Results of Bypass or Endovascular Revascularization for Critical Limb Ischemia: ESRD

Mortality	2-18% (10% NSQIP data)	(2.7%)
Early bypass graft occlusion	9-11%	(5.2%)
One-year secondary patency	49-80%	(80%)
One-year limb salvage	52-73%	(88%)
One-year survival	47-78%	(84%)

PREVENT III

10-18% of reconstructions end in amputation despite a patent bypass
Only 39% of limbs with extensive tissue loss were salvaged at 1 year

primary amputation may be the preferred approach.

More liberal use of primary amputation

Results of Bypass or Endovascular Revascularization for Critical Limb Ischemia: DM

	Effect of Diabetes
Bypass revascularization	+/-

	Effect of Diabetes
Endovascular revascularization	Reduced primary patency Decreased technical success* Decrease limb salvage**

Derubertis et al. Reduced primary patency rate …J Vasc Surg 47:2008

**Lazaris et al Clinical outcome of primary infrainguinal subintimal angioplasty in diabetic patients with critical lower limb ischemia J Endovasc Ther 2004*

***Bakken et al Impact of DM on outcomes of SFA endoluminal intervention J Vasc Surg 2007;46*

Can we predict failure of operative revascularization in patients with CLI?

	Pre-operative Factors Associated with Amputation or Graft Occlusion

Factors Associated with Amputation or Graft Occlusion One Year after Lower Extremity Bypass in Northern New England

Philip P. Goodney,[1] Brian W. Nolan,[1] Andres Schanzer,[2] Jens Eldrup-Jorgensen,[3] Daniel J. Bertges,[4] Andrew C. Stanley,[4] David H. Stone,[1] Daniel B. Walsh,[1] Richard J. Powell,[1] Donald S. Likosky,[1] and Jack L. Cronenwett,[1] for the Vascular Study Group of Northern New England Lebanon, New Hampshire; Worcester, Massachusetts; Portland, Maine; and Burlington, Vermont.

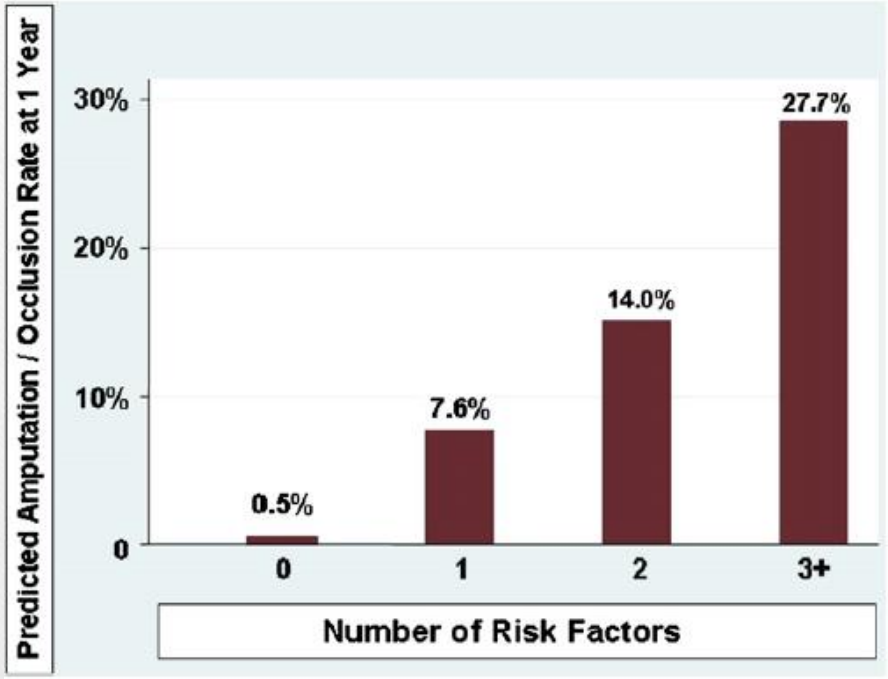


Fig. 4. Predicted risk of amputation or graft occlusion, by number of risk factors.

Age < 50 years
Non-ambulatory status preoperatively
ESRD
DM
CLI
Conduit requiting venovenostomy
Tarsal target
Nursing home residence

Prediction of amputation-free survival after lower extremity bypass

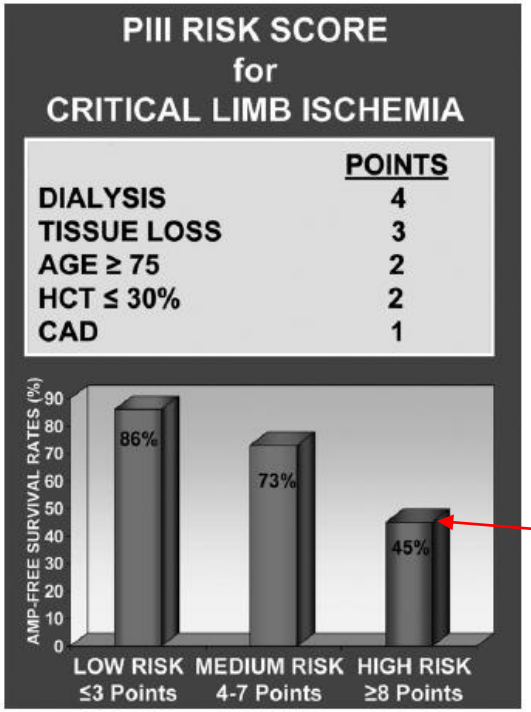


Fig 1. Score card. *PIII*, PREVENT III; *HCT*, hematocrit; *CAD*, coronary artery disease.

Amputation-free survival at one yr

Schanzer et al Validation of the PIII CLI risk score for the prediction of amputation-free survival in patients undergoing infrainguinal autogenous vein bypass for critical limb ischemia J Vasc Surg 2009;50

Tissue Loss: WIfI Classification: Wound, Ischemia, foot Infection

W (Wound) 0,1,2,3 I(Ischemia 0,1,2,3) fI (foot Infection 0,1,2,3)

a, Estimate risk of amputation at 1 year for each combination

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	L	M	VL	L	M	H	L	L	M	H	L	M	M	H
W-1	VL	VL	L	M	VL	L	M	H	L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H	M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

VL:Very Low L: Low M: Medium H: High

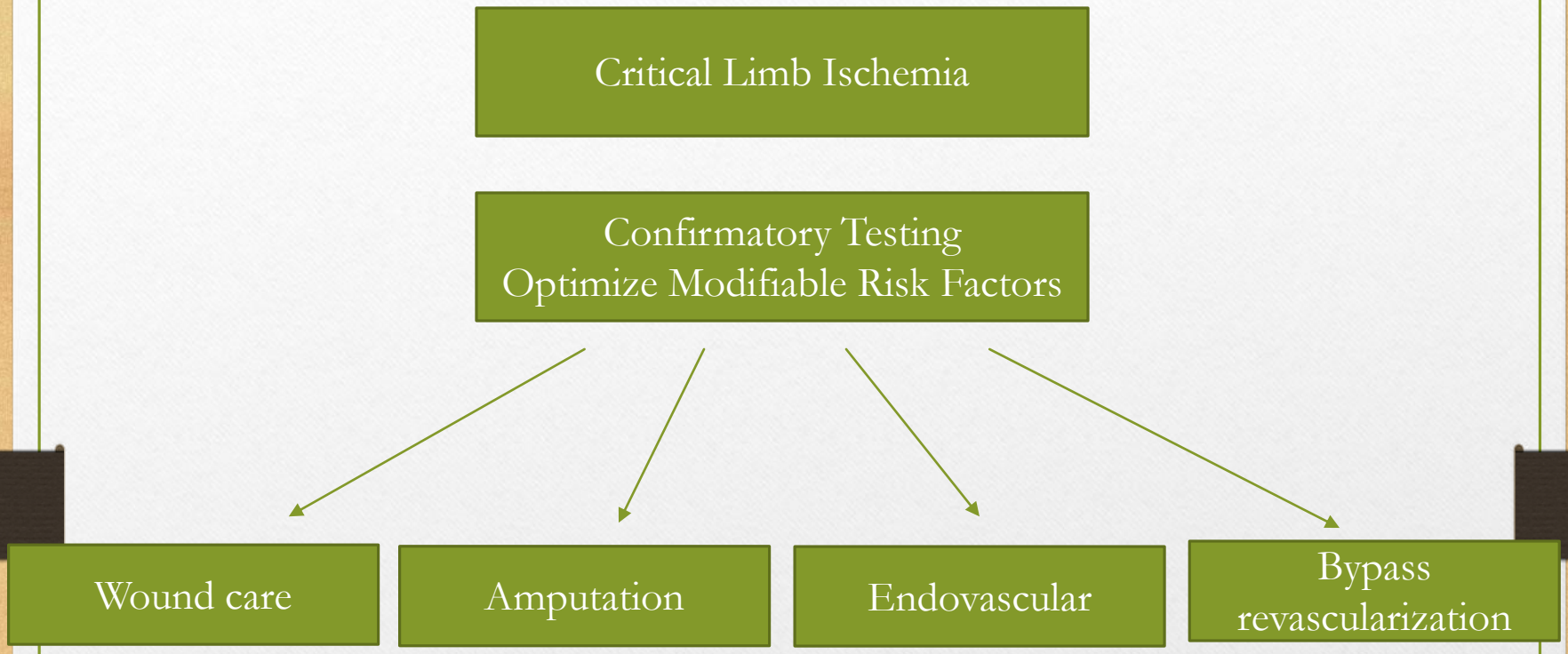
Tissue Loss: WIfI Classification: Wound, Ischemia, foot Infection

GRADE	WOUND		ISCHEMIA		INFECTION
	ULCER	GANGRENE	ABI	TP (mmHg)	
0	None	None	$\geq$0.8	$\geq$ 60	None
1	Shallow	none	0.6-0.79	40-59	Mild
2	Deep	Digits only	0.4-0.59	30-39	Moderate
3	Extensive	Extensive	< 0.39	$\leq$ 30	Severe

Tissue Loss: WIfI Classification: Wound, Ischemia, foot Infection

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 (2%)	222 (6%)	213 (28%)
Causey (2016) 160	21 (0%)	48 (25%)	42 (21%)	49 (31%)
Beropoulis (2016) 126	29 (13%)	42 (19%)	29 (19%)	26 (38%)
TOTAL 1189	**131 (4%)**	**314 (9%)**	**389 (11%)**	**355 (31%)**

Number of limbs at risk in each WIfI stage with % amputation at one yr in ()


Critical Limb Ischemia
Confirmatory Testing
Optimize Modifiable Risk Factors
Wound care
Amputation
Endovascular
Bypass revascularization

Critical Limb Ischemia

Confirmatory Testing
Optimize Modifiable Risk Factors

Wound care

Stable uncomplicated ulceration with criteria for possible healing

Critical Limb Ischemia

Confirmatory Testing
Optimize Modifiable Risk Factors

Endovascular

Living independently
Anatomical candidate

Bypass revascularization

Living independently
Surgical candidate

BASIL

BEST CLI

BEST-CLI

Critical Limb Ischemia

Confirmatory Testing
Optimize Modifiable Risk Factors

Amputation

Dementia
Non-ambulatory pre-op
Significantly impaired pre-op
Dependent living pre-op
Non-reconstructable anatomic disease
Major tissue loss
Tissue loss unlikely to heal with revascularization
Poor candidate for revascularization due to high risk of failure or limited life expectancy:
(ESRD, DM, CAD, Low Hct, Stage 4 WIfI, Limited ambulation)

Critical Limb Ischemia

Confirmatory Testing
Optimize Modifiable Risk Factors

Wound care

Stable uncomplicated tissue loss

Amputation

Dementia
Non-ambulatory pre-op
Dependent living pre-op
Non-reconstructable
Major tissue loss
Poor candidate for revascularization due to high risk of failure or limited life expectancy:
(ESRD, DM, CAD, Low Hct, Stage 4 WIfI, Limited ambulation)

Endovascular

Living independently
Anatomical candidate

Bypass revascularization

Living independently
Surgical candidate

BASIL

BEST CLI

BEST-CLI

Primary Amputation is a viable option in selected patient with critical limb ischemia

Cost and Quality of Life Issues in Critical Limb Ischemia

COSTS	In 2014, CMS paid approximately $3.6 billion for claims submitted by hospitals for inpatient and outpatient care delivered to patients with CLI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1915