



SVS

SOCIETY *for* VASCULAR SURGERY

Ron Fairman, MD

***Vice-President* of the Society for Vascular Surgery**

MedCAC 2015



SVS

SOCIETY *for* VASCULAR SURGERY

Ron Fairman, MD
No Disclosures



- The **SVS** represents more than 5,000 practicing vascular surgeons across the US.
- The nation's oldest (1946) medical professional society with a **core mission dedicated to the comprehensive management and total care of patients with non-cardiac vascular diseases.**

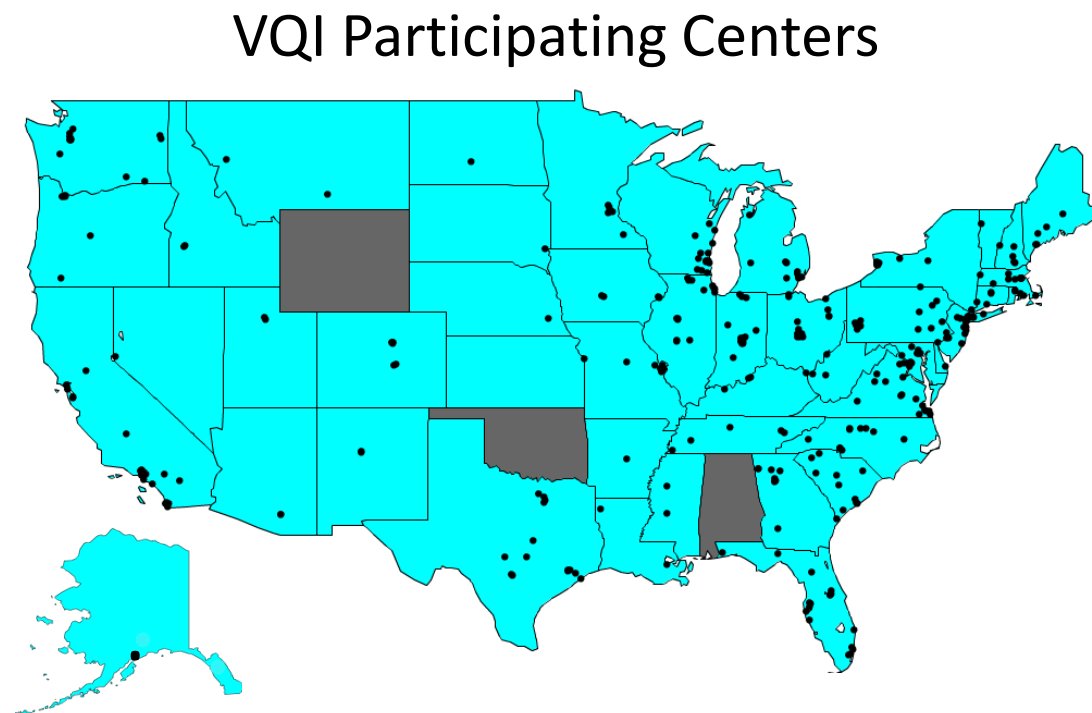
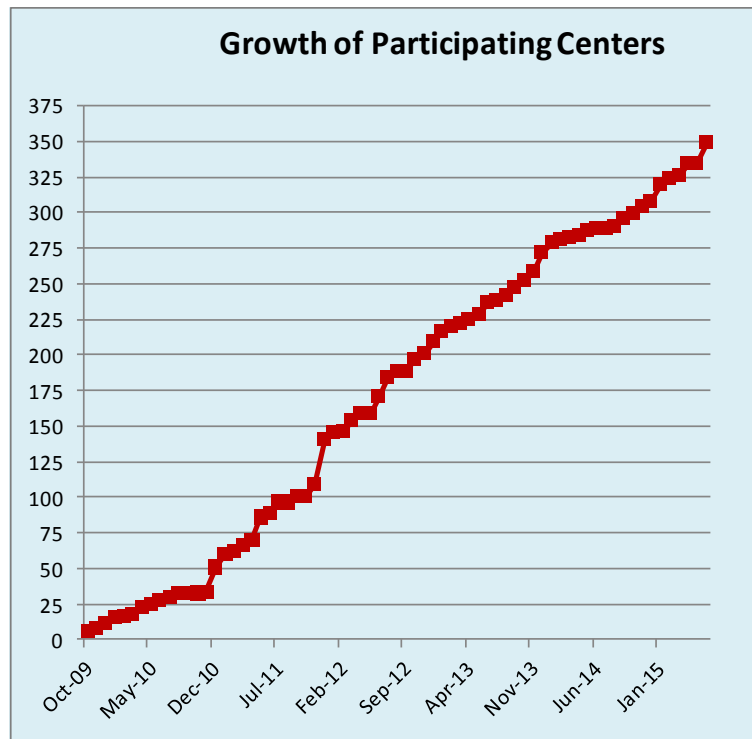


- By virtue of our **ACGME training** requirements and the comprehensive nature of our practice, we are uniquely qualified to comment on the scientific evidence of existing interventions that aim to improve health outcomes in the Medicare population, and address areas where evidence gaps exist related to lower extremity peripheral artery disease (PAD).
- Specifically, vascular surgeons utilize **all available modalities** (medical, exercise training, and interventional, both endovascular, and open surgical), and provide longitudinal follow-up of our patients with **LE PAD**.



- SVS founded the **Vascular Quality Initiative (VQI)** in 2011 as a registry to collect data about the quality, safety, efficacy and cost of vascular care.
- VQI data is analyzed and shared among regional groups to improve vascular health care
- **Patient Safety Organization (PSO):** established with the federal Agency for Healthcare Research and Quality.
- Participation requires 100% capture of all procedures and one year of follow-up reporting, in addition to perioperative reporting
- Outcome data is used for benchmarking that will lead to **cost reduction, quality improvement, new practice guidelines, and device performance.**

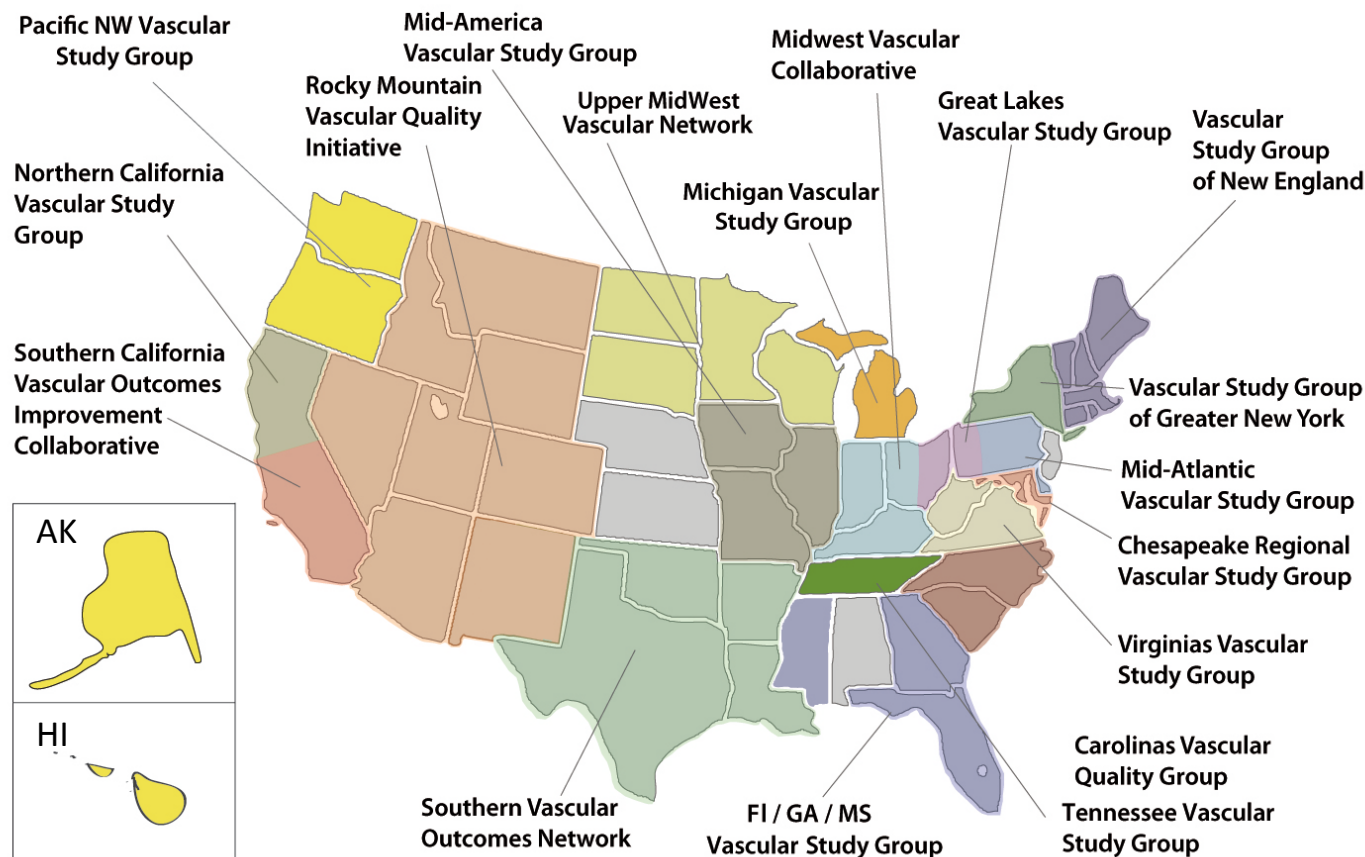
Vascular Quality Initiative®



350 Centers, 46 States + Ontario

Vascular Quality Initiative®

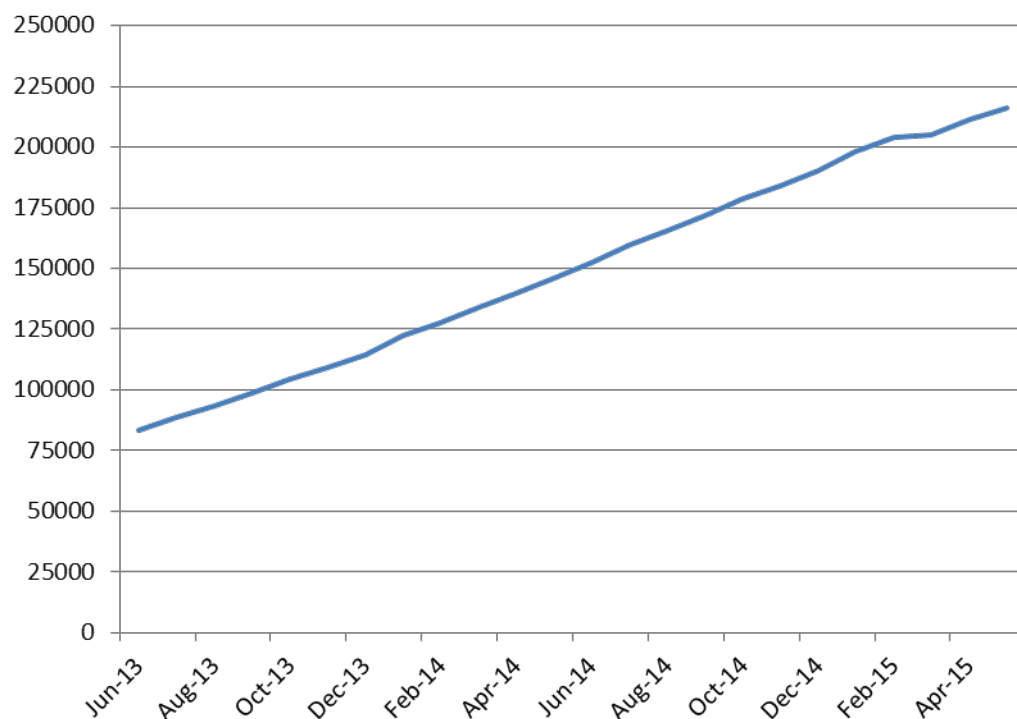
18 Regional Quality Groups



Vascular Quality Initiative®

Total Procedures Captured (as of 6/1/2015)	216,105
Carotid Endarterectomy	51,569
Carotid Artery Stent	8,016
Endovascular AAA Repair	20,486
Open AAA Repair	6,871
Peripheral Vascular Intervention	67,514
Infra-Inguinal Bypass	24,169
Supra-Inguinal Bypass	7,954
Thoracic and Complex EVAR	4,267
Hemodialysis Access	18,170
Lower Extremity Amputations	3,072
IVC Filter	3,096
Varicose Vein	921

VQI Total Procedure Volume





Practice Guidelines:
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. (*J Vasc Surg* 2014;59:220-34)



***Society for Vascular Surgery practice guidelines for
atherosclerotic occlusive disease of the lower
extremities: Management of asymptomatic disease
and claudication***

Society for Vascular Surgery Lower Extremity Guidelines Writing Group:

Michael S. Conte, MD, (Co-Chair), Frank B. Pomposelli, MD, (Co-Chair),
Daniel G. Clair, MD, Patrick J. Geraghty, MD, James F. McKinsey, MD, **Joseph L. Mills, MD**,
Gregory L. Moneta, MD, M. Hassan Murad, MD, Richard J. Powell, MD, Amy B. Reed, MD,
Andres Schanzer, MD, and Anton N. Sidawy, MD, MPH.

(J Vasc Surg 2015;61:2S-41S.)



Michael S. Conte, MD, FACS, FAHA
Co-Chair SVS Lower Extremity Practice Guidelines
Chair, Peripheral Vascular Disease Council of the
American Heart Association
Chair, Research Council, SVS

MedCAC 2015

Disclosures

- **Minor (<10K)**
 - Scientific Consultant- Medtronic, Cook
 - Speaker (one time event)- WL Gore

2015 SVS Clinical Practice Guideline in PAD

- Addresses evaluation and management of asymptomatic PAD and intermittent claudication
- Evidence-based reviews and consensus guideline development process
- J Vasc Surg 2015; 61:2S-41S

Asymptomatic PAD

- High prevalence; 20% or higher age >70
- Major risk factors: smoking, diabetes, HTN, dyslipidemia
- Portends increased risk for mortality and major adverse cardiovascular events
- Evidence does not support health benefit for population screening
- Smoking cessation programs, patient education about disease progression, lifestyle modifications (Grade 1)
- Evidence supporting medical interventions specific to the asymptomatic PAD population is presently weak.
 - Current AHA/ACC guideline for statin use does not incorporate ABI in the risk calculation
 - More research needed to support interventions targeting this population

Asymptomatic PAD

- We recommend against invasive treatments for PAD in the absence of symptoms, regardless of hemodynamic measures or imaging findings demonstrating PAD (Grade 1; LOE B)
- Exceptions:
 - Treatment of asymptomatic popliteal aneurysm (not considered within PAD)
 - Repeat interventions to maintain patency of prior lower extremity bypass grafts (Grade 1; LOE C)
 - Benefit of prophylactic interventions to maintain patency of prior endovascular treatments (e.g. PTA, stenting, atherectomy) is unknown, and more evidence is needed

Intermittent Claudication (IC)

- Common manifestation of PAD. Low risk of limb loss (<1%/year), but increased risk of CV events.
- May produce significant disability and impaired QoL
- Smoking cessation, risk factor modification, medical therapies targeting atherosclerosis, diabetes are considered SOC.
- Pharmacotherapy (cilostazol, pentoxifylline) may improve walking function and a therapeutic trial is appropriate in the absence of contraindications (Grade 2; LOE A)
- Exercise therapy and Revascularization yield greater improvements in walking ability and QoL compared to medical therapy alone

Recommendations: Medical treatment for intermittent claudication (IC)

		Grade	Level of evidence
4.1.	We recommend multidisciplinary comprehensive smoking cessation interventions for patients with IC (repeatedly until tobacco use has stopped).	1	A
4.2.	We recommend statin therapy in patients with symptomatic PAD.	1	A
4.3.	We recommend optimizing diabetes control (hemoglobin A _{1c} goal of <7.0%) in patients with IC if this goal can be achieved without hypoglycemia.	1	B
4.4.	We recommend the use of indicated β -blockers (eg, for hypertension, cardiac indications) in patients with IC. There is no evidence supporting concerns about worsening claudication symptoms.	1	B
4.5.	In patients with IC due to atherosclerosis, we recommend antiplatelet therapy with aspirin (75-325 mg daily).	1	A
4.6.	We recommend clopidogrel in doses of 75 mg daily as an effective alternative to aspirin for antiplatelet therapy in patients with IC.	1	B
4.7.	In patients with IC due to atherosclerosis, we suggest against using warfarin for the sole indication of reducing the risk of adverse cardiovascular events or vascular occlusions.	1	C
4.8.	We suggest against using folic acid and vitamin B ₁₂ supplements as a treatment of IC.	2	C
4.9.	In patients with IC who do not have congestive heart failure, we suggest a 3-month trial of cilostazol (100 mg twice daily) to improve pain-free walking.	2	A
4.10.	In patients with IC who cannot tolerate or have contraindications for cilostazol, we suggest a trial of pentoxifylline (400 mg thrice daily) to improve pain-free walking.	2	B
4.11.	We suggest the ACEI ramipril (10 mg/d) to improve pain-free and maximal walking times in patients with IC. (ACEIs are contraindicated in individuals with known renal artery stenosis).	2	B

ACEI, Angiotensin-converting enzyme inhibitor; PAD, peripheral arterial disease.

Intermittent Claudication

Recommendations: Exercise therapy

		<i>Grade</i>	<i>Level of evidence</i>
4.12.	We recommend as first-line therapy a supervised exercise program consisting of walking a minimum of three times per week (30-60 min/session) for at least 12 weeks to all suitable patients with IC.	1	A
4.13.	We recommend home-based exercise, with a goal of at least 30 minutes of walking three to five times per week when a supervised exercise program is unavailable or for long-term benefit after a supervised exercise program is completed.	1	B
4.14.	In patients who have undergone revascularization therapy for IC, we recommend exercise (either supervised or home based) for adjunctive functional benefits.	1	B
4.15.	We recommend that patients with IC be followed up annually to assess compliance with lifestyle measures (smoking cessation, exercise) and medical therapies as well as to determine if there is evidence of progression in symptoms or signs of PAD. Yearly ABI testing may be of value to provide objective evidence of disease progression.	1	C

ABI, Ankle-brachial index; *IC*, intermittent claudication; *PAD*, peripheral arterial disease.

Revascularization for IC

- Individualized decision based on severity of disability, anticipated risk versus benefit. Must consider comorbid factors, anatomic pattern and bilaterality.
- Treatment offered should be low risk, and offer a reasonable likelihood of sustained benefit
 - >50% likelihood of sustained efficacy (patency) for at least 2 yrs is a suggested threshold; Grade 1; LOE C)

*Level of
Grade evidence*

- | | | | |
|------|---|---|---|
| 5.1. | We recommend EVT or surgical treatment of IC for patients with significant functional or lifestyle-limiting disability when there is a reasonable likelihood of symptomatic improvement with treatment, when pharmacologic or exercise therapy, or both, have failed, and when the benefits of treatment outweigh the potential risks. | 1 | B |
| 5.2. | We recommend an individualized approach to select an invasive treatment for IC. The modality offered should provide a reasonable likelihood of sustained benefit to the patient (>50% likelihood of clinical efficacy for at least 2 years). For revascularization, anatomic patency (freedom from hemodynamically significant restenosis) is considered a prerequisite for sustained efficacy. | 1 | C |

EVT, Endovascular therapy.



Joseph L. Mills, Sr., MD, FACS

SVS Lower Extremity Practice Guidelines Committee

SVS Diabetic Foot Practice Guidelines Committee

Executive Council, SVS

**PAD Committee, International Working Group on the
Diabetic Foot (IWGDF) – USA representative**

MedCAC 2015

Disclosures

- **Minor (<10K)**
 - Speaker (one time event) - WL Gore Surgical Bypass Summit



CLI (Critical Limb Ischemia) is misunderstood condition and the term is somewhat of a misnomer. Foot ulcers with diabetes and PAD are a SPECTRUM with gradations of ischemia. Revascularization need depend on multiple factors including wound complexity and infection. Better concept of the threatened limb, limb-threatening ischemia.



The Perfect Storm: NCD

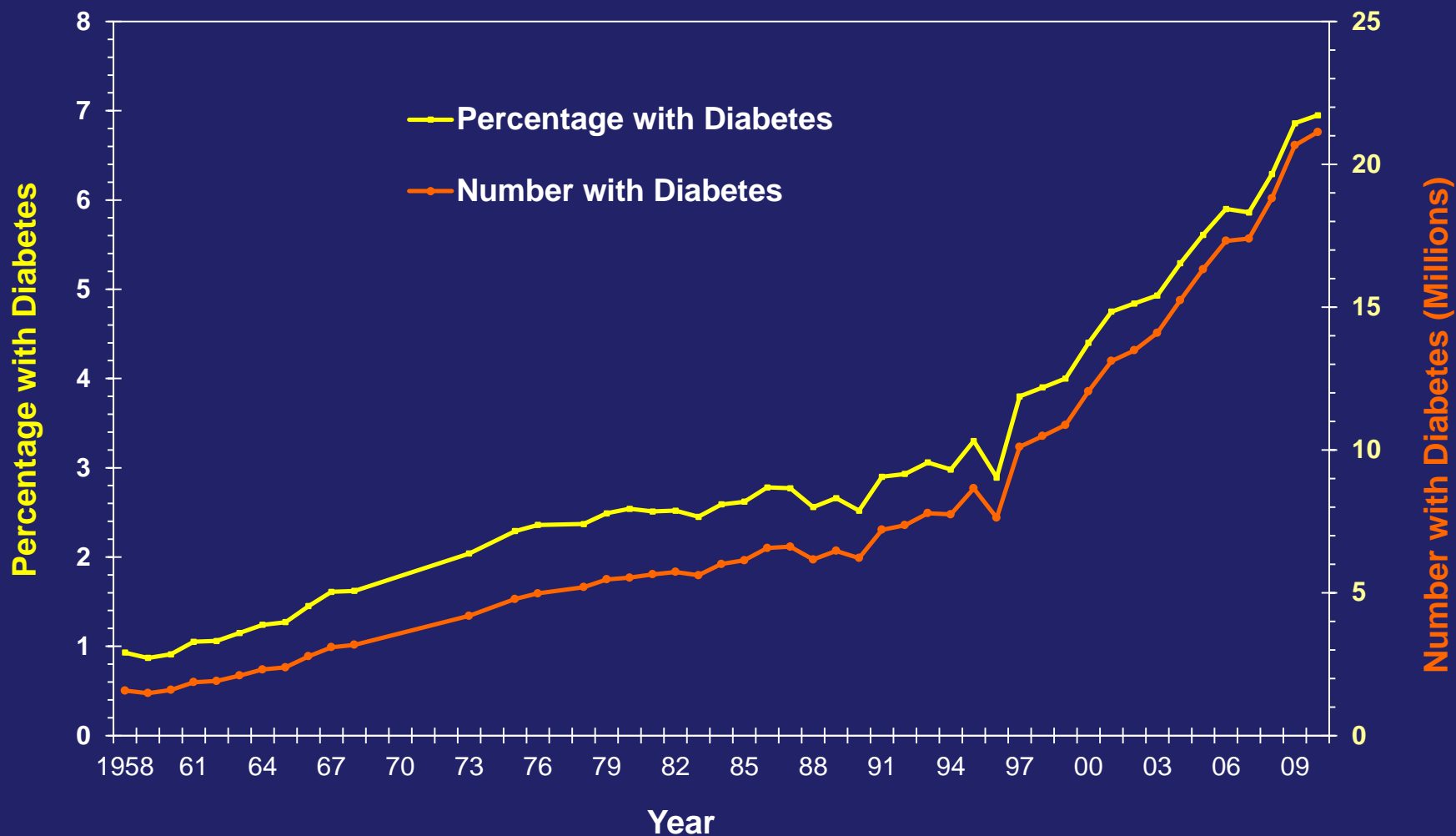
- We have transitioned gradually from the Age of Disaster to the Age of Disease, and now rapidly to the Age of Decay
- The Age of Decay = Non-Communicable Diseases
 - Aging population
 - **Diabetes**
 - Obesity
 - **PAD**

For the first time in the history of humankind:

Non-communicable diseases (NCDs) have become the leading cause of global mortality (60%)

BMJ 2009;339:b2857

Number and Percentage of U.S. Population with Diagnosed Diabetes, 1958–2010



CDC's Division of Diabetes Translation. National Diabetes Surveillance System
available at <http://www.cdc.gov/diabetes/statistics>



Diabetic Foot Complications

- Diabetes is diagnosed once every 17 seconds!
- Up to *70% of the lower extremity amputations* in the world are associated with diabetes
- *Every 20 seconds*, somewhere in the world, a lower extremity is amputated in a patient with diabetes

Costs of care

- The economic impact of DFUs (diabetic foot ulcers) is high and not well appreciated.
- In 2007, an estimated 20% of the total annual \$116 billion health care expenditures for diabetes care in the United States were directed to treatment of diabetic foot problems.
 - Kalish,Pomposelli 2009
 - Rogers et al. 2008
 - <http://www.diabetes.org/diabetes-basics/diabetes-statistics>).

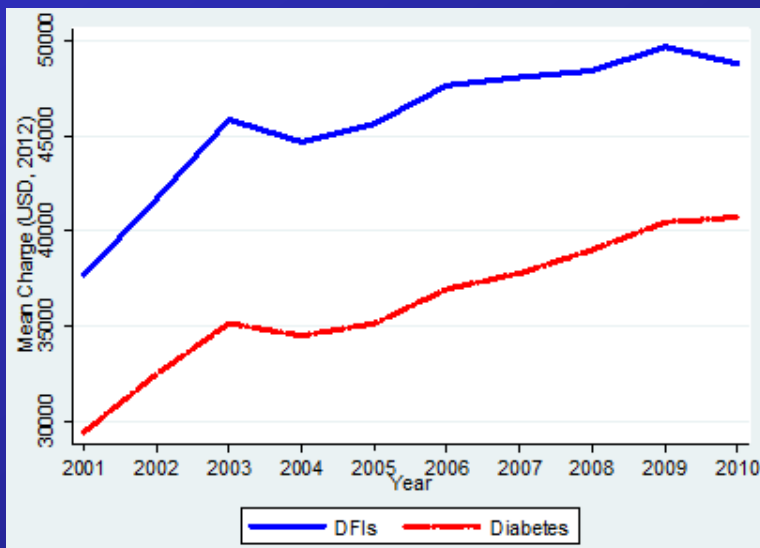
DFUs in Inpatient Settings

Skrepnek, Armstrong, Mills J Vasc Surg November 2014; 60(5):1255-65.

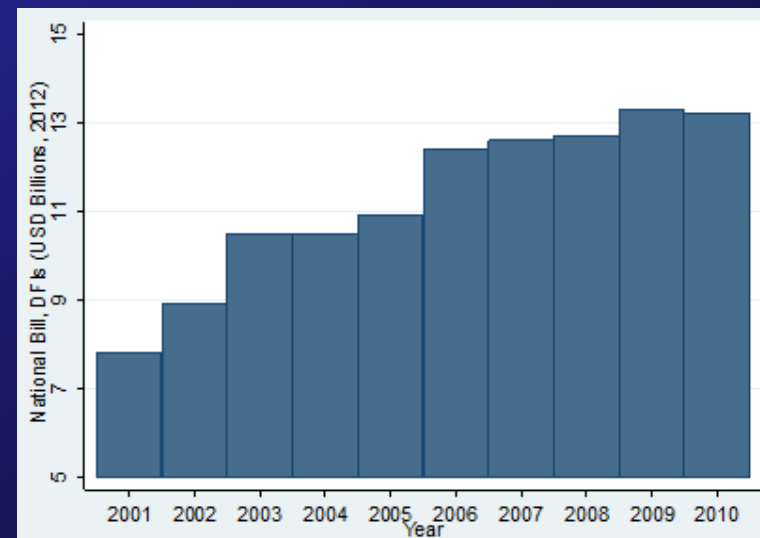
Economic Burden of Illness

- All-listed diagnoses, annual diabetes inpatient national bill = \$ 250.0 billion
 - Per case = \$37,603 (± 52086)
- All-listed diagnoses, DFU inpatient national bill = \$ 11.6 billion
 - Per case = \$47,538 (± 61975)
- Revascularizations, DFU inpatient national bill = \$ 4.0 billion
 - Per case = \$94,235 (± 90072) (Open = \$93,356 & EVT = \$90,691)

Mean Inpatient Charges, DFIs and Diabetes



National Inpatient Bill, DFIs alone



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,^c 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.)

Why do we need WIfI?

- CLI - ill-defined term with unclear natural history
- CLI was never intended to be applied to patients with diabetes
- Rutherford and Fontaine classifications inadequately address wounds and ignore infection altogether
- Our patients have changed but our classification system has not
- Impossible to determine outcomes without correct initial classification of patients and degree of limb threat

Editorial

The definition of critical ischaemia of a limb

Working Party of the
International Vascular Symposium

P. R. F. Bell, D. Charlesworth, R. G. DePalma,
H. H. G. Eastcott, B. Eklöf, J. D. Gruss, C. W. Jamieson,
P. J. Morris, A. N. Nicolaides and R. B. Rutherford

“Critical Limb Ischemia”

- Ischemic rest pain and absolute systolic ankle pressure of less than 40 mm Hg
- Ankle pressure < 60 mm Hg systolic in the presence of superficial necrosis of the foot or digital gangrene involving the base of the phalanx
- **“It was generally agreed that diabetic patients who have a varied clinical picture of neuropathy, ischaemia and sepsis make a definition even more difficult . . . and these patients should be excluded.”**
- **“Diabetic patients should not be included, or should be clearly defined as a separate category to allow analysis of the results in non-diabetic . . .”**

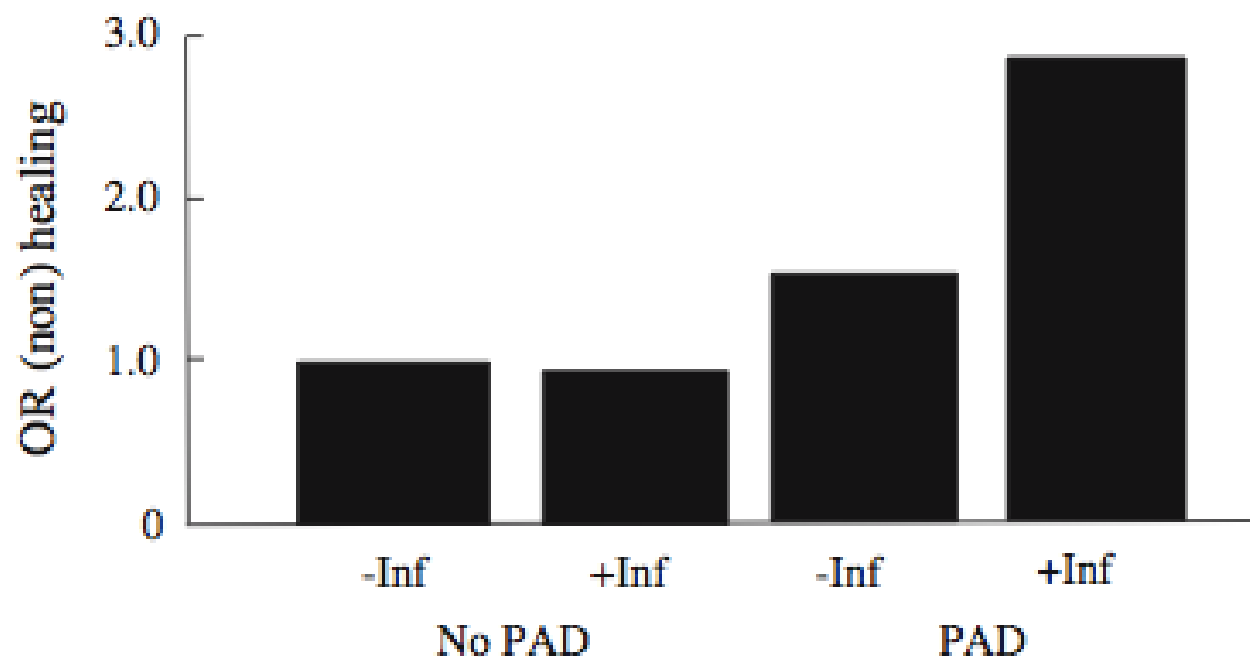
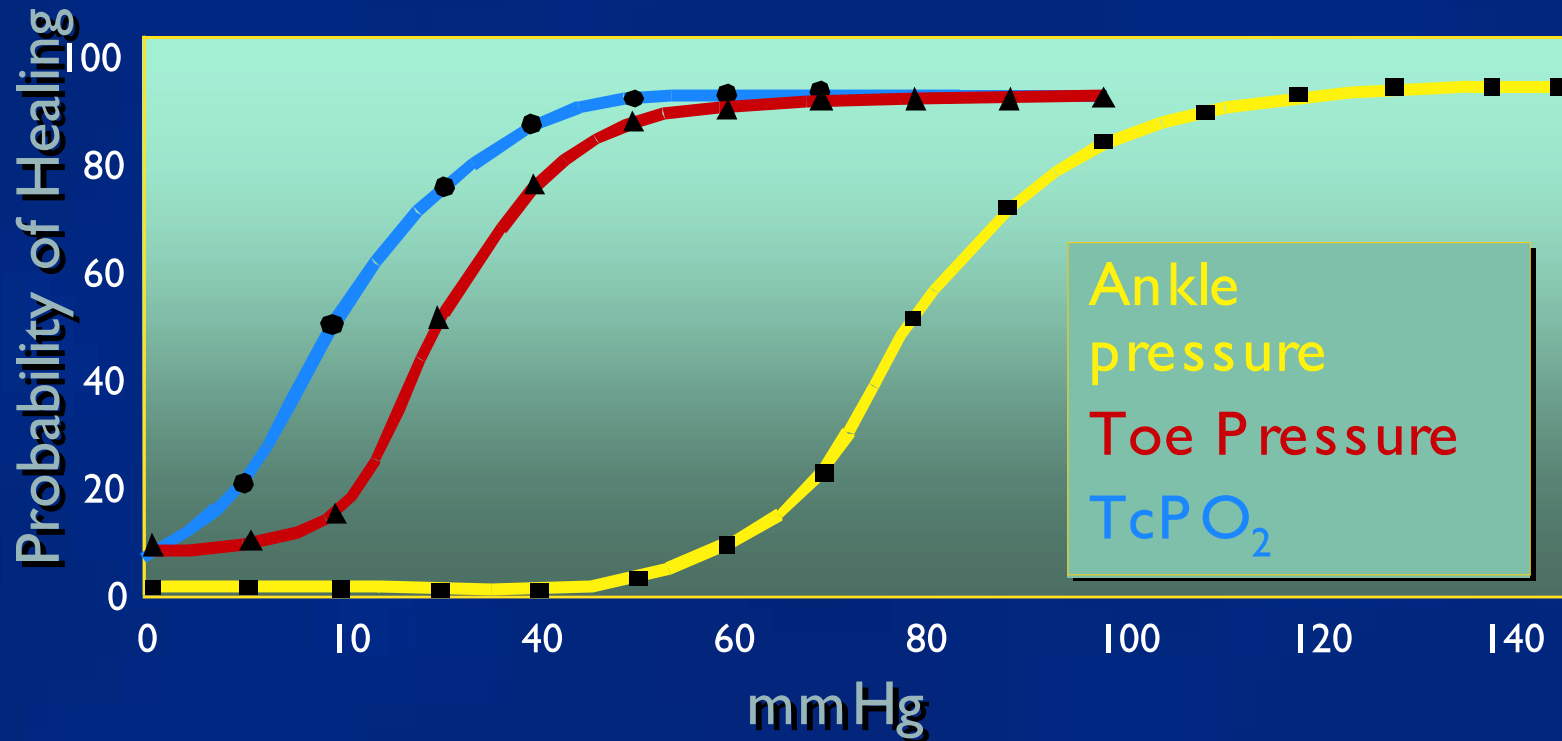


Fig. 1 ORs of healing per PAD and infection (Inf) status

Hemodynamics and Probability of Healing of a Diabetic Foot Ulcer



Healing unlikely if toe pressure < 55 mmHg

The Society for Vascular Surgery

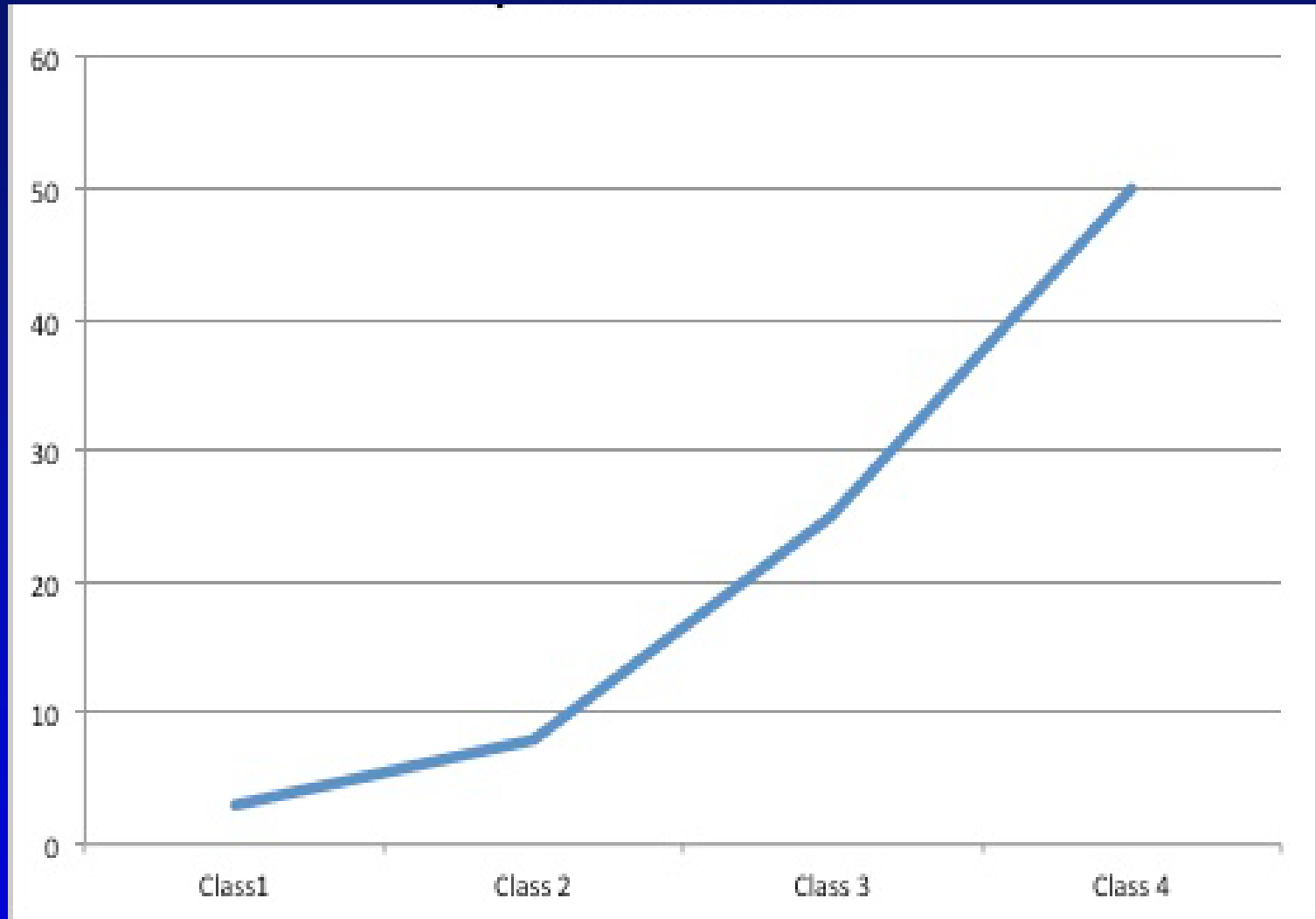
Lower Extremity Threatened Limb Classification

The **WIFI** Index

- **Wound**: extent and depth
- **Ischemia**: perfusion/flow
- **Foot Infection**: presence and extent
- Based upon existing validated systems or best available data with 4 point scales where
 - 0 = none
 - 1 = mild-moderate
 - 2 = moderate-severe
 - 3 = severe

WIFI was recently incorporated into the SVS VQI Registry

ONE-YEAR AMPUTATION RISK (%) BY SVS Wifi Class



VQI and similar registry tracking should be fostered & supported to evaluate real world outcomes of specific interventions with some stratification like Wifi

Is revascularization for limb salvage effective in "CLI" patients? YES

Table III. Meta-analysis of 1-month to 3-year patency, limb salvage, and patient survival in patients with critical limb ischemia comparing percutaneous transluminal angioplasty vs bypass grafting^a

Result	1 month	6 months	1 year	2 years	3 years
Primary patency					
PTA	77.4 ± 4.1	65.0 ± 7.0	58.1 ± 4.6	51.3 ± 6.6	48.6 ± 8.0
Bypass	93.3 ± 1.1	85.8 ± 2.1	81.5 ± 2.0	76.8 ± 2.3	72.3 ± 2.7
P	<.05	<.05	<.05	<.05	<.05
Secondary patency					
PTA	83.3 ± 1.4	73.8 ± 7.1	68.2 ± 5.9	63.5 ± 8.1	62.9 ± 11.0
Bypass	94.9 ± 1.0	89.3 ± 1.6	85.9 ± 1.9	81.6 ± 2.3	76.7 ± 2.9
P	<.05	<.05	<.05		
Limb salvage					
PTA	93.4 ± 2.3	88.2 ± 4.4	86.0 ± 2.7	83.8 ± 3.3	82.4 ± 3.4
Bypass	95.1 ± 1.2	90.9 ± 1.9	88.5 ± 2.2	85.2 ± 2.5	82.3 ± 3.0
Patient survival					
PTA	98.3 ± 0.7	92.3 ± 5.5	87.0 ± 2.1	74.3 ± 3.7	68.4 ± 5.5
Bypass	NA	NA	NA	NA	NA

NA, Not applicable; PTA, percutaneous transluminal angioplasty.

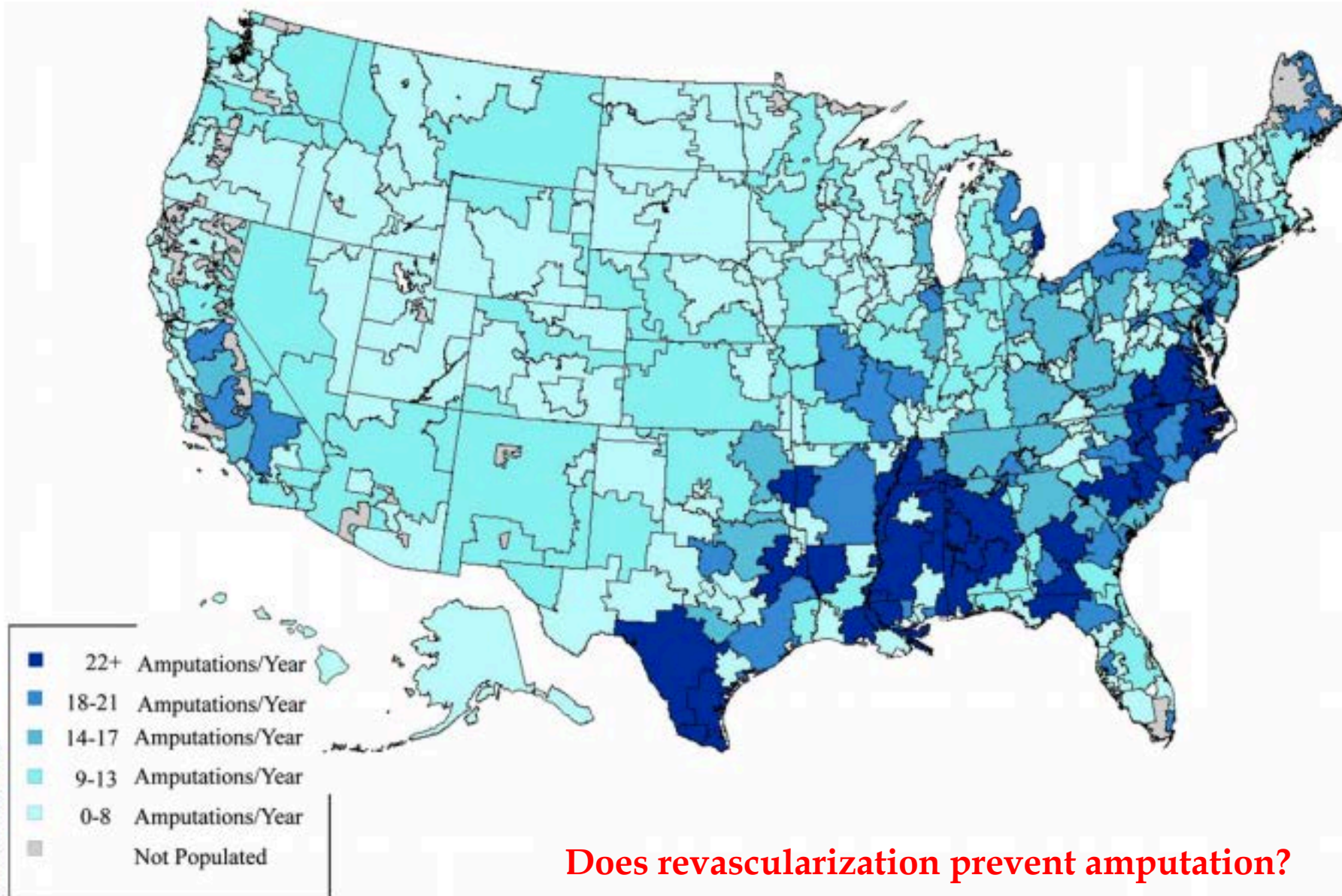
^aReprinted from *Journal of Vascular Surgery*, Romiti M, Albers M, Brochado-Neto FC, Durazzo AE, Pereira CA. Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia. 47(5) 975-981, 2008, with permission from Elsevier.⁴⁰

Historical controls: 15-34% amputation rates in non-revascularized patients

Brass et al (Circulase prospective trial) J Vasc Surgery 2011 Apr **2006;43:752-9.**

Apelqvist et al. J Vasc Surgery 2011 Jun;53(6):1582-88

Faglia et al. Eur Journal Vasc Endo Vasc Surgery 2005 Jun;29(6):620-7.



Does revascularization prevent amputation?

Fig 1. Population-based amputation rates for peripheral arterial disease (PAD) by hospital referral regions are shown on the map.

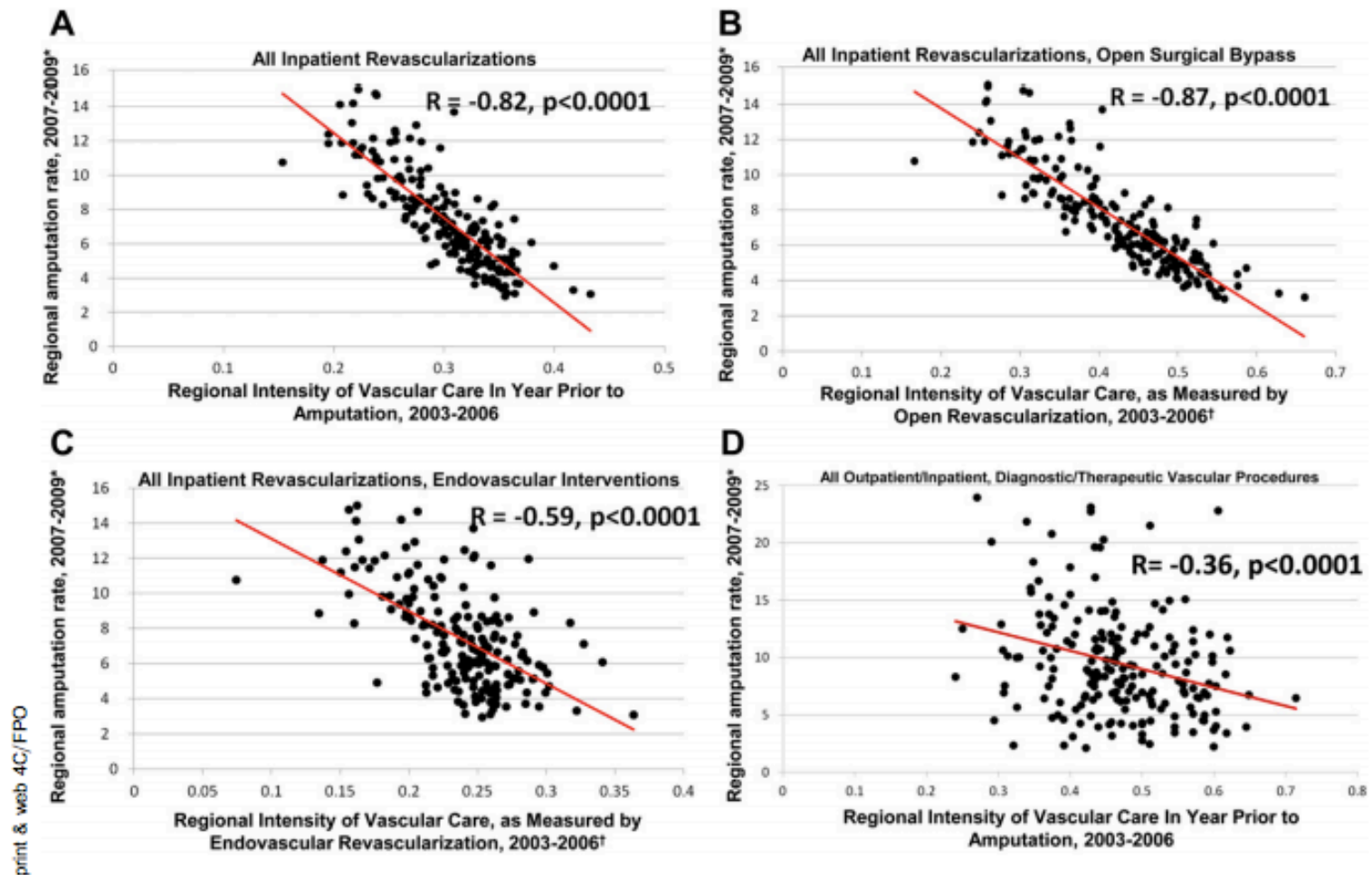


Fig 2. Correlation at the regional level is shown between intensity of vascular care and amputation rate. Intensity of vascular care is measured as a function of (A) all inpatient revascularizations, (B) all inpatient open surgical revascularizations, (C) inpatient therapeutic endovascular procedures, and (D) inpatient and outpatient diagnostic and therapeutic, open and endovascular revascularization procedures. *Amputation rates specifies major (above or below) knee amputation rate per 10,000 Medicare beneficiaries. †Intensity of care measured as a function of the number of procedures performed in the year prior to amputation.

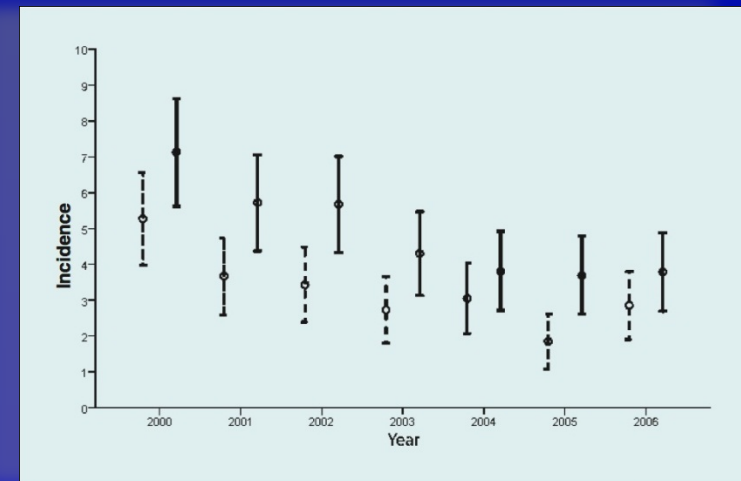
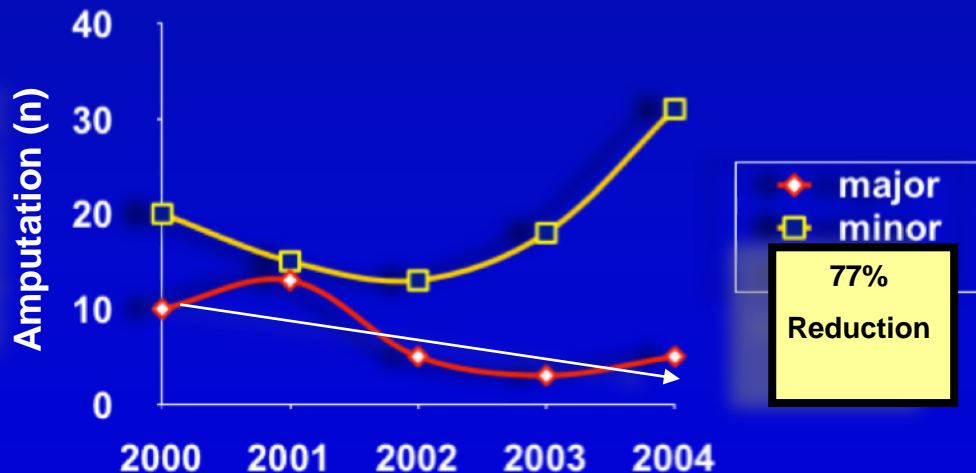
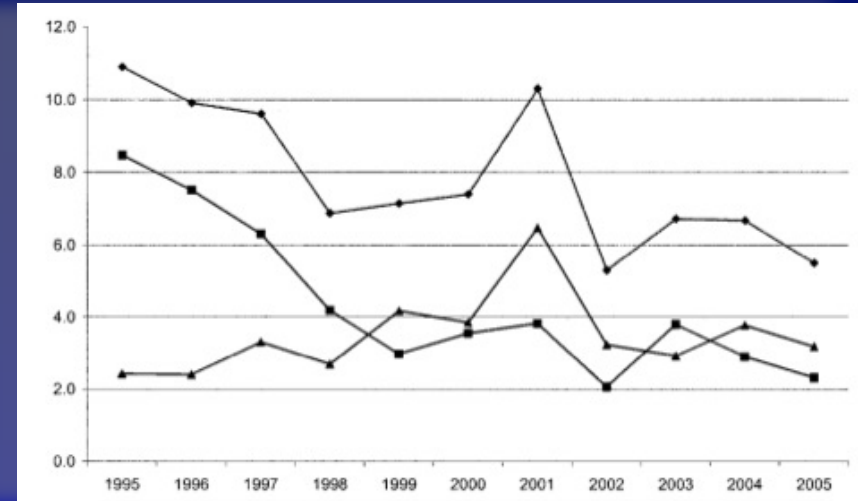
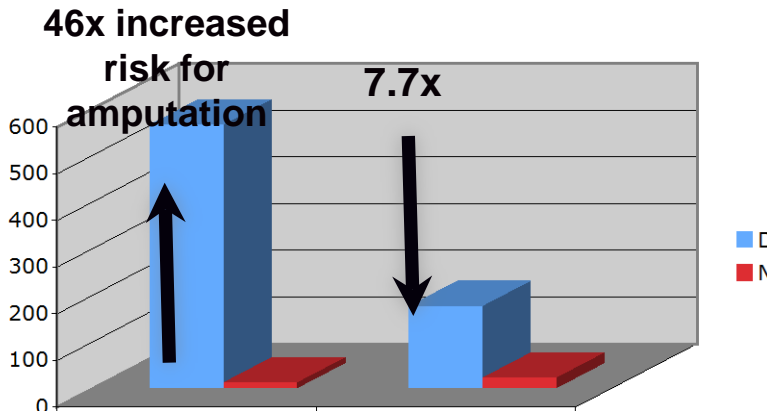
Recommendation 1: We recommend that referral to vascular surgeons for evaluation and care of such patients be encouraged

Regional variations in patterns of care and outcomes

- In practice, failure to heal and major limb amputation most often result from: (1) delayed presentation (patient inability or reluctance to seek care); and (2) delayed diagnosis and treatment, including failure to provide offloading; delayed diagnosis or inadequate drainage of infection; and **failure to recognize and treat ischemia.**
- **Recommendation 2:** All patients with non-traumatic foot wounds should receive routine noninvasive physiologic testing to assess blood flow before therapy (whether wound care alone, HBO, angioplasty, bypass or amputation)

Teams Reduce Amputations

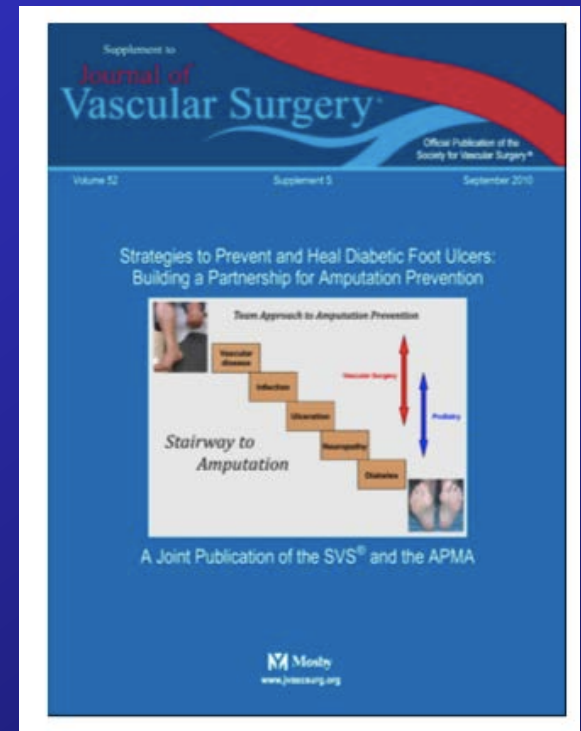
A Comparison Of First Year and Fifth Year LEA Rates Between DM and Non-DM Per 100,000 Persons



Diabetic Foot Teams

- Build a Team: “Toe and Flow” Model
 - Podiatry
 - Vascular Surgery
 - Seamless integration of care
- Management algorithm
 - Team management, algorithmic
 - Patient flow
 - Consistent application of principles

Recommendation 3: We recommend that the development of multidisciplinary limb limb salvage centers be encouraged (Key components of which are vascular surgery and podiatry)



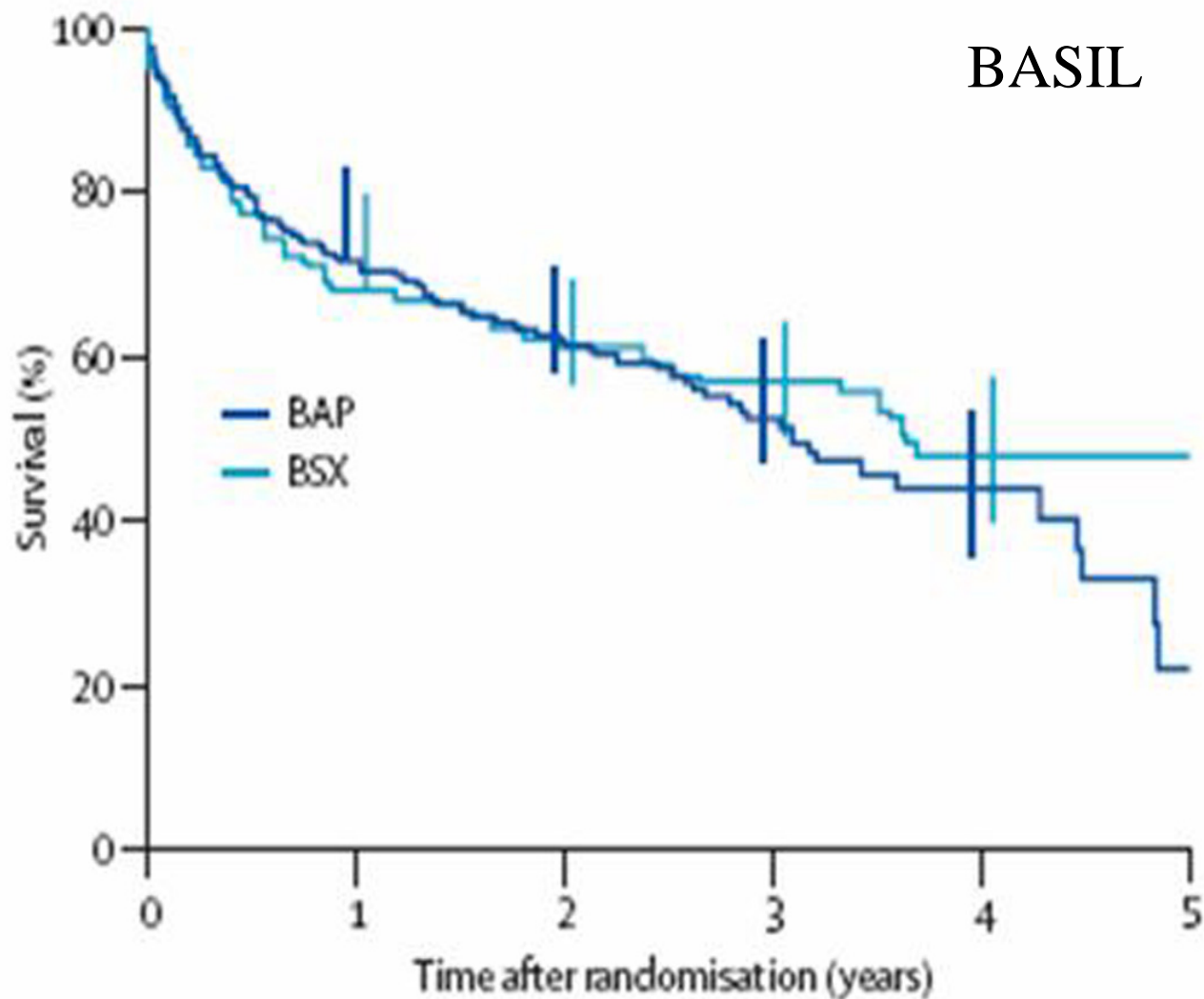
Journal of Vascular Surgery
Volume 52; Supplement; 2010
Joint SVS/APMA collaboration

BASIL Trial: long-term results

Still the only prospective open versus endovascular trial for severe limb ischemia

- Bypass first group had better amputation free survival than angioplasty first group (RR .85)
- Bypass first arm had lower all cause mortality than angioplasty first (RR 0.65, $p < 0.009$)
- Decreased survival associated with BMI, diabetes, age, serum creatinine level, and cigarette smoking

BASIL



Number at risk

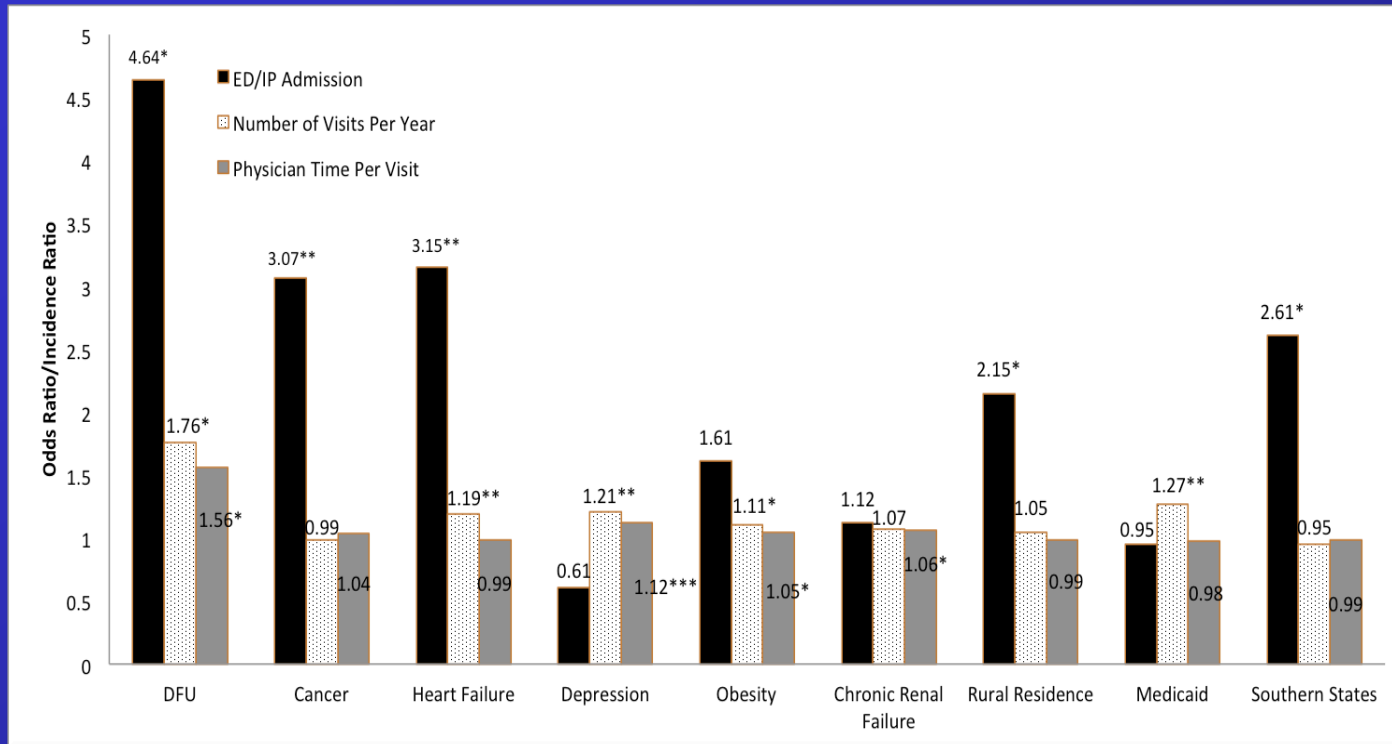
Angioplasty	224	149	100	51	19	2
Surgery	228	148	108	64	23	7

Evidence GAPS:

Data are critically lacking

- BASIL
- BEST (US) – in progress
- BASIL 2 and 3 (UK) – in progress
- **Recommendation 4:** We recommend that research support into the area of the limb threatening ischemia be expanded

DISPARITIES: NACMS Data (unpublished, in progress). Skrepnek, Mills, Armstrong
Among 539.9 million adult diabetic outpatient clinic cases in the U.S. from 2006-2010:



*** $p < 0.001$

** $p < 0.01$

* $p < 0.05$

Diabetes patients with foot ulcers are at greater risk for hospital admission and require more visits and physician time per year than outpatients with diagnoses of cancer, heart failure or chronic renal failure.

Racial and gender disparities

- Inferior outcomes of lower extremity bypass have been reported in blacks, Hispanics and women
 - Robinson et al JVS 2009; 49(6):1416–1425
 - Jain et al JVS 2014;60,(5):1275–1281

Such disparities are worthy of further assessment

Challenges of Chronic NCDs

- Physicians, especially surgeons, hospitals and health care systems have evolved primarily over the ages to deal with Disaster and Acute Diseases
- No system is currently well adapted to effectively prevent, manage and treat chronic NCDs
- The simple, seemingly pedestrian and mundane Diabetic Foot Ulcer provides an excellent window into the inadequacies of current models of care to manage such problems