IS INFRAINGUINAL BYPASS A DYING PROCEDURE?

WHAT DO CONTEMPORARY OUTCOMES TELL US?

William P. Robinson, III MD
Division of Vascular and Endovascular Surgery
University of Virginia School of Medicine
Charlottesville, VA

DISCLOSURE

William Robinson, MD

- **No relevant financial relationship reported**

“Does anybody do lower extremity bypass anymore?”

and D femoro-popliteal disease: Mid-term outcomes from a single tertiary referral center

Jeffrey Lorne Grenville[1], Kong Teng Tan[2], Hadas Moshonov[2] and Dheeraj Kumar Rajan[2]

J Cardiovasc Surg (Torino). 2013 Dec;54(6):679-84.
Endovascular first as "preliminary approach" for critical limb ischemia and diabetic foot.
Setacicci C, Sirignano P, Galzerano G, Mazzitelli G, Benevento D, Cappelli A, Setacci F

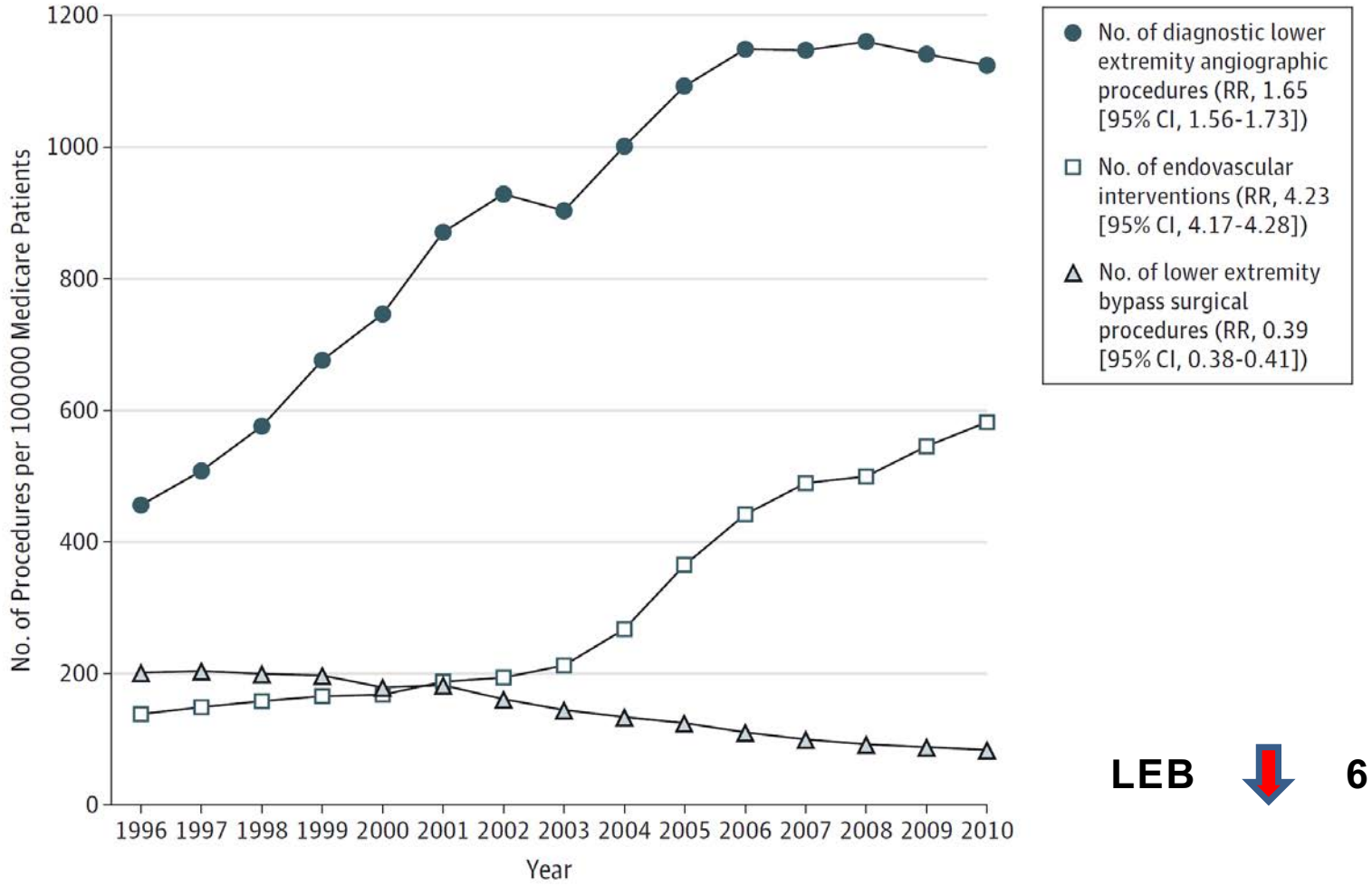
Limb Salvage in Patients With Peripheral Arterial Disease Managed by Endovascular First Approach

Kyin Kyin May, MBBS[1,2], Peter Ashley Robless, F[illegible] Harvinder Raj Singh Sidhu, FRCS[3], Ben Soo Yen[illegible] and Pei Ho, FRCS[1,2]

Long-term limb salvage and survival after endovascular and open revascularization for critical limb ischemia after adoption of endovascular-first approach by vascular surgeons

Hasan H. Dosluoglu, MD,[a,b] Purandath Lall, MBBS,[a,b] Linda M. Harris, MD,[b] and Maciej L. Dryjski, MD,[b] *Buffalo, NY*

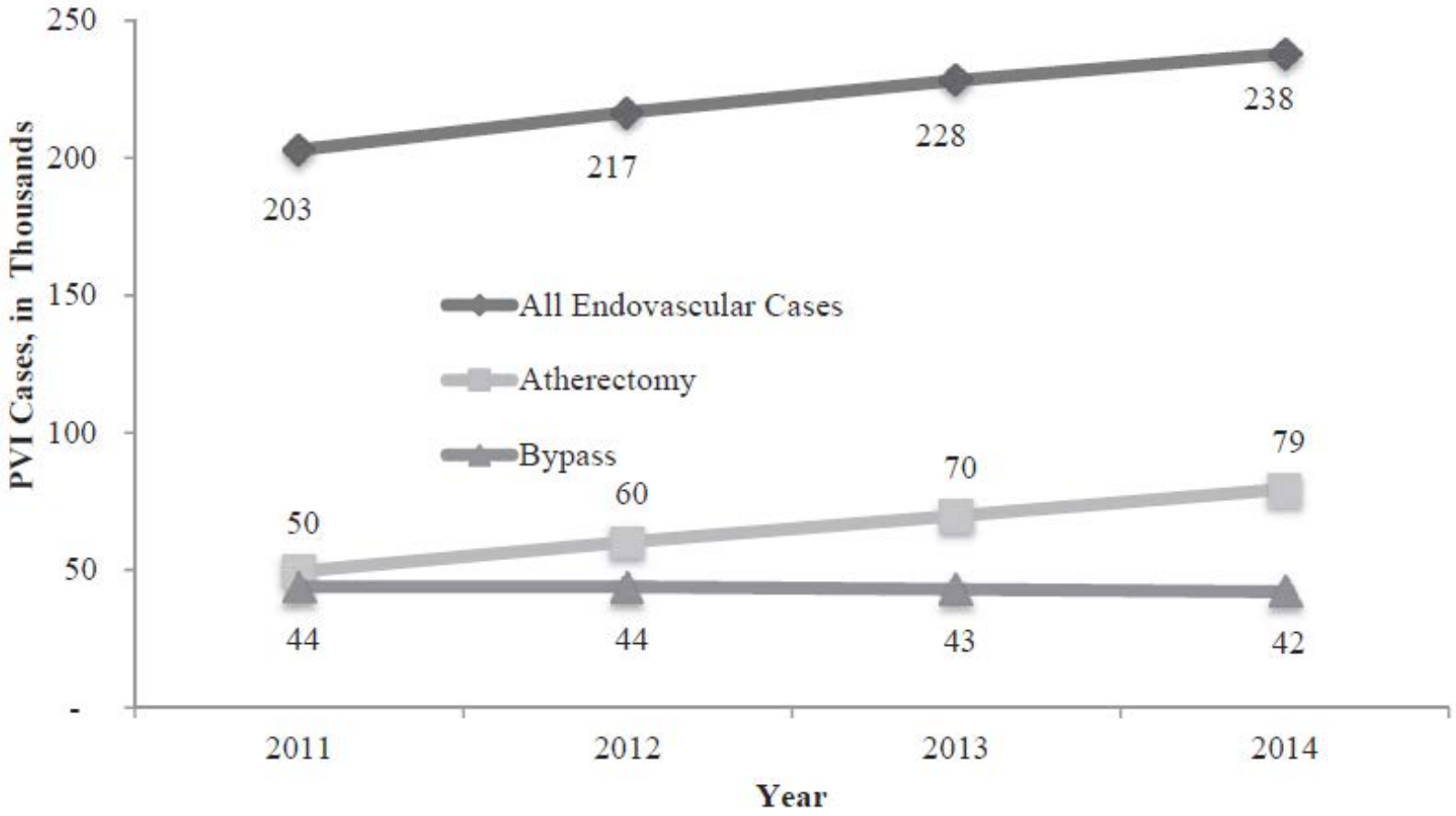
Paradigm Shift in PAD Therapy



LEB ↓ **61%**

The Increase in Endovascular Interventions has outpaced the Decline in Bypass Surgery by More Than **3:1** in Medicare Patients

Trends in PAD Therapy 2011-2014



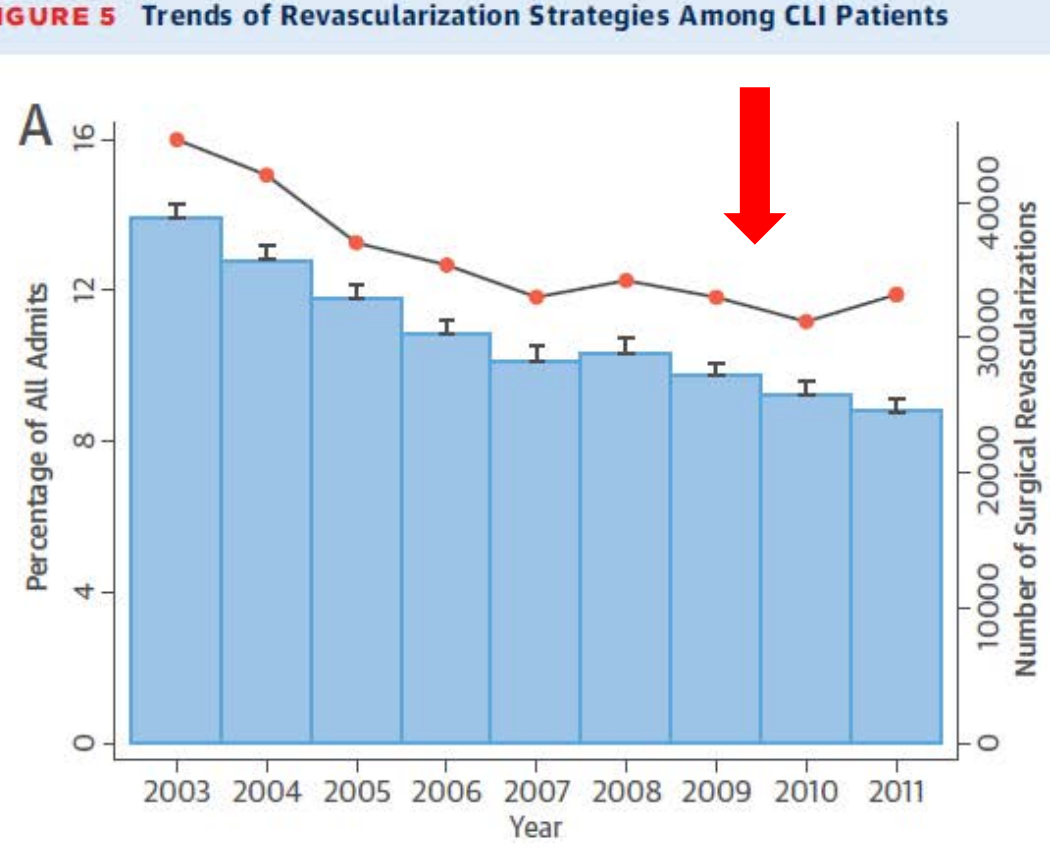
- Stabilization of Bypass Utilization (18% of revascularizations to 15%) in Medicare benficiaries ?
- Continued rapid growth in PVI due to growth of atherectomy

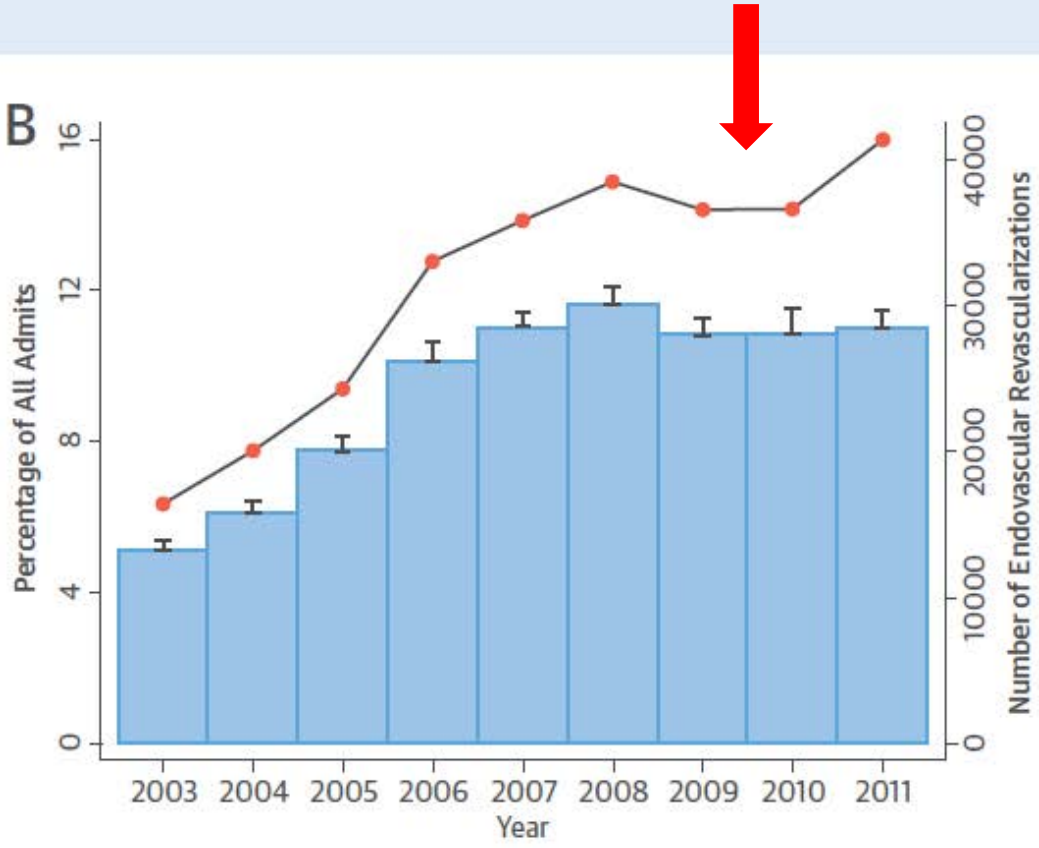
Mukherjee et al Journal of Vascular Surgery
February 2017

Trends in CLI Therapy in Entire U.S. Population

National Inpatient Sample: Estimated 3 million admissions for CLI in U.S., 2003-2011

FIGURE 5 Trends of Revascularization Strategies Among CLI Patients





Surgery

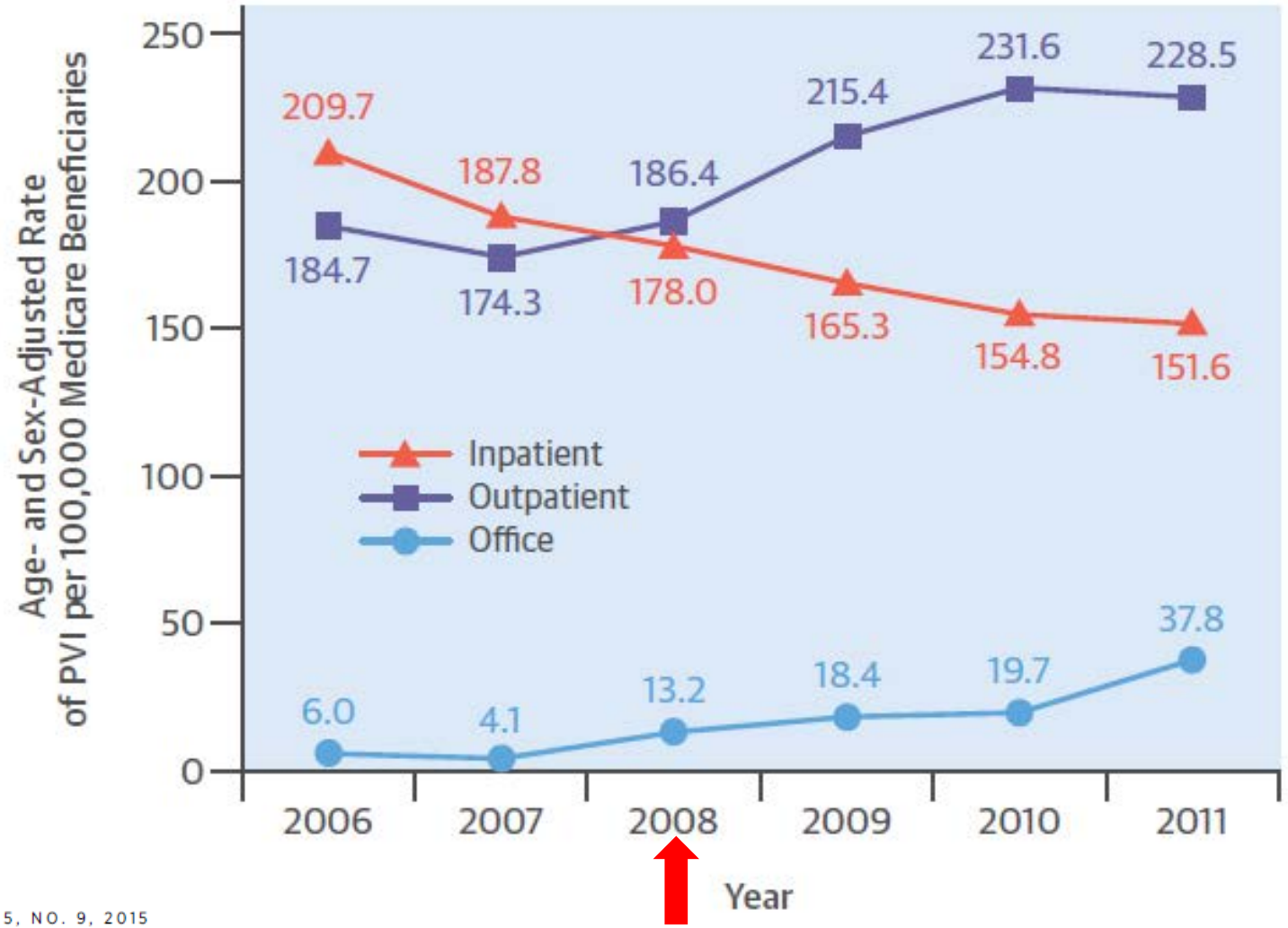
PVI

Agarwal *et al.*
Critical Limb Ischemia-Related Admissions in the United States

JACC VOL. 67, NO. 16, 2016
APRIL 26, 2016:1901-13

Shift in PAD Therapy to Outpatient Endovascular

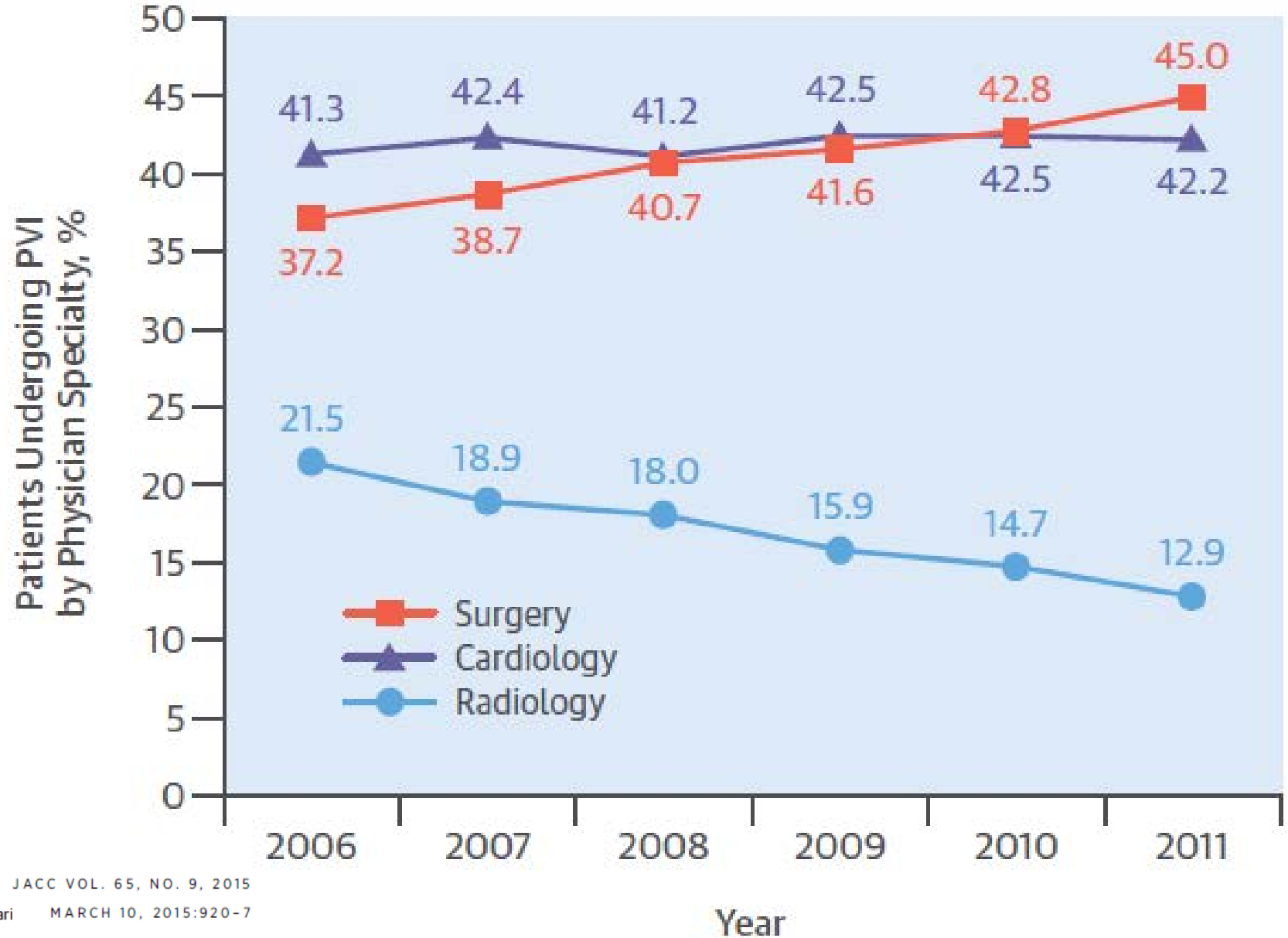
CENTRAL ILLUSTRATION Trends in PVI Among Medicare Beneficiaries



Establishment of Medicare "ambulatory payment classifications"

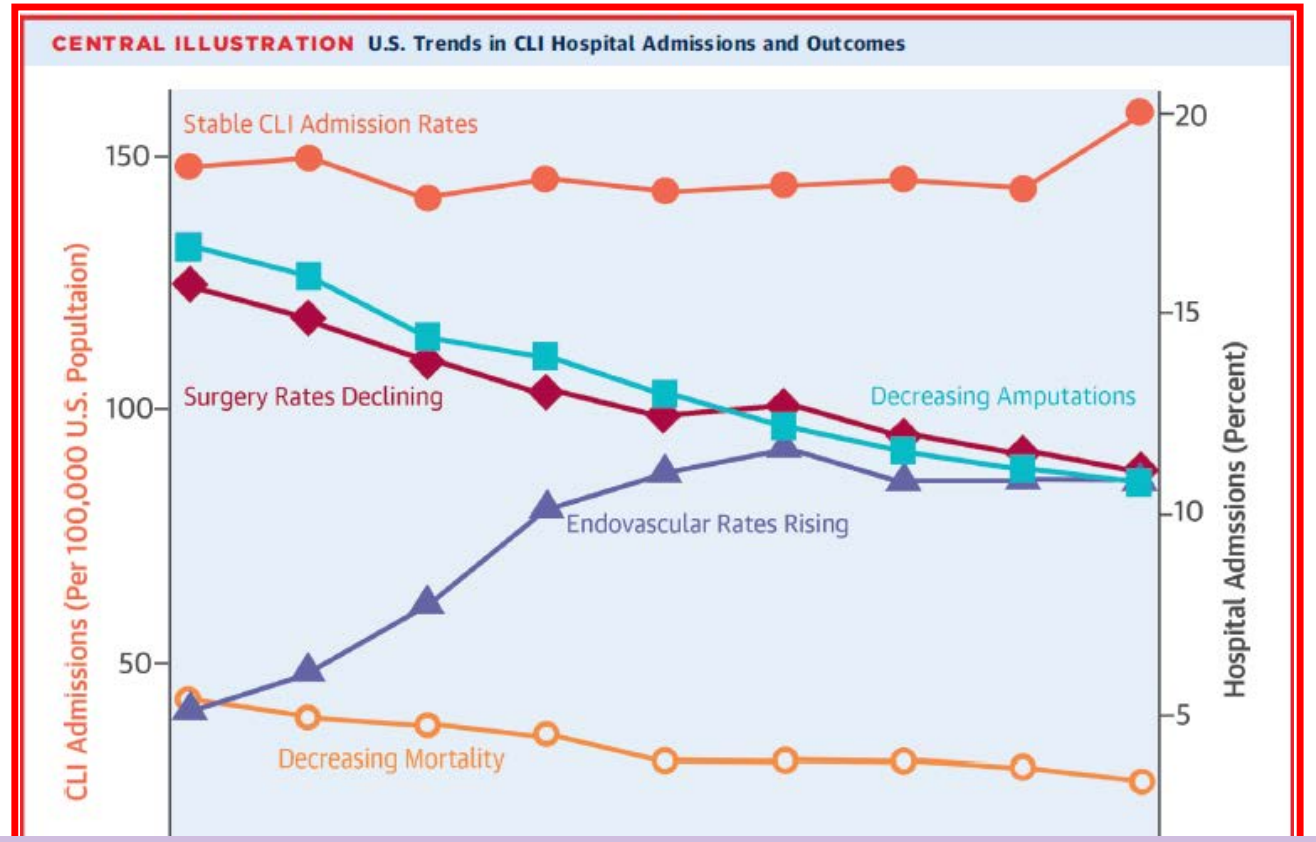
Jones *et al.*
Trends in PVI Among Medicare Beneficiari
JACC VOL. 65, NO. 9, 2015
MARCH 10, 2015:920-7

Trends in PVI and Physician Specialty



Jones *et al.*
Trends in PVI Among Medicare Beneficiari
JACC VOL. 65, NO. 9, 2015
MARCH 10, 2015:920-7

Implications of Increasing PVI



"There has been a significant increase in utilization of endovascular revascularization with a corresponding decrease in surgical revascularization, accompanied by a decrease in in-hospital death and major amputation rates in the United States during 2003 - 2011".

Agarwal

Critical Limb Ischemia-Related Admissions in the United States

APRIL 26, 2016:1901-13

Infrainguinal Bypass in the Endovascular Era

Bypass has declined 60% over 20 years

Exponential Growth of PVI

Bypass utilized in 15-18% revascularizations for PAD

- Vascular Surgeons as well as interventionalists driving this trend
- PAD treatment moving to the outpatient setting
- The decline in utilization of bypass appears to be stabilizing

- *Is this justified?*

- What are the contemporary results of bypass vs. endovascular therapy?

Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia

Michael S. Conte, MD,[a] Patrick J. Geraghty, MD,[b] Andrew W. Bradbury, MD,[c] Nathanael D. Hevelone, MPH,[d] Stuart R. Lipsitz, ScD,[e] Gregory L. Moneta, MD,[f] Mark R. Nehler, MD,[g] Richard J. Powell, MD,[h] and Anton N. Sidawy, MD,[i] *San Francisco; Calif; St. Louis, Mo; Birmingham, United Kingdom; Boston, Mass; Portland, Ore; Aurora, Colo; Hanover, NH; and Washington, DC*

- **Objective Performance Goals (OPGs) derived from historical controls against which new devices are compared**
- **Derived from results of lower extremity bypass with GSV (N=838) performed in three major randomized trials (1990-2007)**
- **Novel patient-centered efficacy endpoints**
  - ***Major Adverse Limb Events (MALE)***
  - ***Major Adverse Cardiovascular Events (MACE)***
- **Define key high risk groups with different expected outcomes**
  - **"Anatomic High Risk": Infrapopliteal Disease**

SVS OPGs for Revascularization for CLI

- Expected 30-day outcomes for CLI patients

Outcome	*30 day events (%; 95% CI)*	*Maximum allowable events (trial N = 392)*	*Safety OPG*
MACE	6.2% (4.7-8.1)	20 (5.1%, 3.1-7.8%)	8%
• Death	2.7%		
• MI	3.1%		
• CVA	1.0%		
MALE	6.1% (4.6-7.9)	18 (4.6%, 2.7-7.2)	8%
Amputation	1.9% (1.1-3.1)	5 (1.3%, 0.4-3.0)	3%

CONTEMPORARY OUTCOMES OF BYPASS AND ENDOVASCULAR THERAPY FOR CLI?

Lower Extremity Bypass and Endovascular Intervention for Critical Limb Ischemia Fail to Meet Society for Vascular Surgery's Objective Performance Goals for Limb-Related Outcomes in a Contemporary National Cohort

William P. Robinson, MD[a], J. Hunter Mehaffey, MD[b], Robert B. Hawkins, MD[b], Megan Tracci, MD[a], Mohammad Eslami, MD[c], and Gilbert R. Upchurch, Jr. MD[a]

- Objective: To determine if contemporary real world treatment of CLI meets SVS OPG benchmarks
- Utilized NSQIP Vascular-Targeted Modules for LEB and Infrainguinal Endovascular Intervention, 2011-2015
  - >100 clinical variables

Results: NSQIP cohort 2011-2015

17,986 total Lower Extremity Revascularizations
10,738 LEB (60%)
7,248 IEI (40%)

Exclude procedures for claudication and emergency procedures

11,043 Revascularizations Performed for CLI
6,909 LEB (63%)
4,134 IEI (37%)

Apply SVS OPG criteria:
Exclude ESRD (1,164)
Exclude bypass with prosthetic/ composite / spliced conduit (2,520)

Study Population: 7,359 OPG-Eligible Revascularizations
3,833 LEB (52%)
3,526 IEI (48%)

Revascularizations in OPG-Eligible Patients

Revascularizations for CLI in NSQIP in OPG-Eligible Patients	n =7359
Lower Extremity Bypass	n=3,833
Femoropopliteal bypass w/ single segment saphenous vein	1,865 (49%)
Femoral-tibial/pedal bypass w/ single segment saphenous vein	1,411 (37%)
Popliteal-tibial/pedal bypass w/ single segment saphenous vein	557 (15%)
Infrainguinal Endovascular Intervention	n=3,526
Femoropopliteal angioplasty/stenting/atherectomy	2,573 (73%)
Tibial angioplasty/stenting/atherectomy	953 (27%)

Outcomes in OPG-eligible CLI cohort

Endpoint (%)	SVS OPG Safety Threshold	OPG (n=838)	LEB (n=3,833)	p-value[a]	IEI (n=3,526)	p-value[b]
MACE	<8%	6.2 [4.7, 8.1]	4.2 [4.1-4.3]	0.013	3.1 [3.0-3.2]	<0.0001
MALE	<8%	6.1 [4.6, 7.9]	9.0 [8.7-9.2]	0.007	9.7 [9.4-10.0]	0.001
Amputation	<3%	1.9 [1.1, 3.1]	3.7 [3.6-3.8]	0.009	4.3 [4.2-4.5]	<0.0001

[a] LEB vs OPG

[b] IEI vs. OPG

Outcomes in Infrapopliteal CLI Revascularizations

Endpoint	SVS OPG Safety Threshold	OPG (n=505)	LEB (n=1,968)	p-value[a]	IEI (n=953)	p-value[b]
MACE	<10%	7.3 [5.2-10.0]	4.4 [4.3-4.6]	0.009	2.1 [2.0-2.2]	<0.0001
MALE	<9%	6.1 [4.2-8.6]	9.5 [9.1-9.8]	0.019	11.1 [10.4-11.8]	0.002
Amputation	<4%	2.2 [1.1-3.9]	4.1 [4.0-4.3]	0.040	6.4 [6.0-6.8]	0.0004

† defined as LEB to tibia/pedal target or IEI to tibial vessel

[a] LEB vs OPG

[b] IEI vs. OPG

Lower extremity bypass for critical limb ischemia decreases major adverse limb events with equivalent cardiac risk compared with endovascular intervention

J. Hunter Mehaffey, MD, Robert B. Hawkins, MD, Anna Fashandi, MD, Kenneth J. Cherry, MD, John A. Kern, MD, Irving L. Kron, MD, Gilbert R. Upchurch Jr, MD, *and* William P. Robinson, MD, *Charlottesville, Va*

Objective: Compare outcomes of Lower Extremity Bypass and Infrainguinal Endovascular Intervention for critical limb ischemia in a propensity-matched cohort

– NSQIP Vascular Targeted Modules 2011-2014

Revascularizations in Matched Cohort

Lower Extremity Bypass	1924 (50%)
Supragenicular Revascularization	1384 (71.9%)
Femoropopliteal bypass w/ single segment saphenous vein	730 (52.7%)
Femoropopliteal bypass w/prosthetic/spliced vein/composite	654 (47.3%)
Infragenicular Revascularization	540 (28.1%)
Femoral distal bypass w/ single segment saphenous vein	244 (45.2%)
Femoral distal bypass w/ prosthetic/spliced vein/composite	147 (27.2%)
Popliteal distal w/ single segment saphenous vein	116 (21.5%)
Popliteal distal bypass w/ prosthetic/spliced vein/composite	33 (6.1%)
Infrainguinal Endovascular Intervention	1924 (50%)
Supragenicular Revascularization	1352 (70.3%)
Femoropopliteal angioplasty/stenting/atherectomy	1352
Infragenicular Revascularization	572 (29.7%)
Tibial angioplasty/stenting	572

Outcomes: Bypass vs. Endovascular Intervention

Parameter	Endovascular	Open	p-value
MALE	**235 (12.2%)**	**177 (9.2%)**	**0.003**
Untreated Loss of Patency	32 (1.7%)	52 (2.7%)	0.03
Re-intervention	105 (5.5%)	93 (4.8%)	0.38
Amputation	131 (6.8%)	80 (4.2%)	0.0003

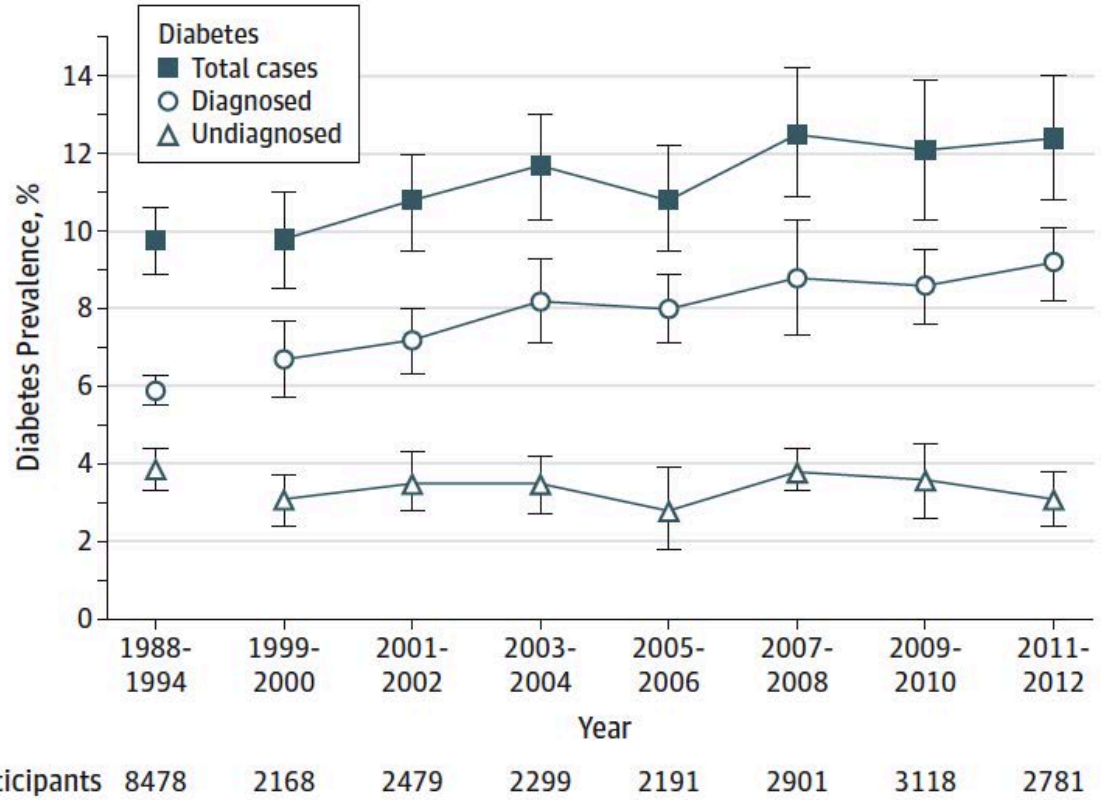
Parameter	Endovascular	Open	p-value
MACE	**72 (3.7%)**	**95 (4.9%)**	**0.07**
Stroke or MI	40 (2.1%)	54 (2.8%)	0.14
Mortality	41 (2.1%)	55 (2.9%)	0.15

Conclusions

- Revascularization for CLI not meeting SVS OPGs and the outcomes achieved between 1990 and 2007 with bypass
- Bypass associated with superior limb outcomes at 30 days compared to endovascular intervention
- Cardiovascular morbidity/mortality surpassed the cardiovascular safety thresholds established by SVS OPGs
  - 30-day MACE similar between bypass and endovascular intervention
  - CV morbidity associated with revascularization for CLI continues to improve

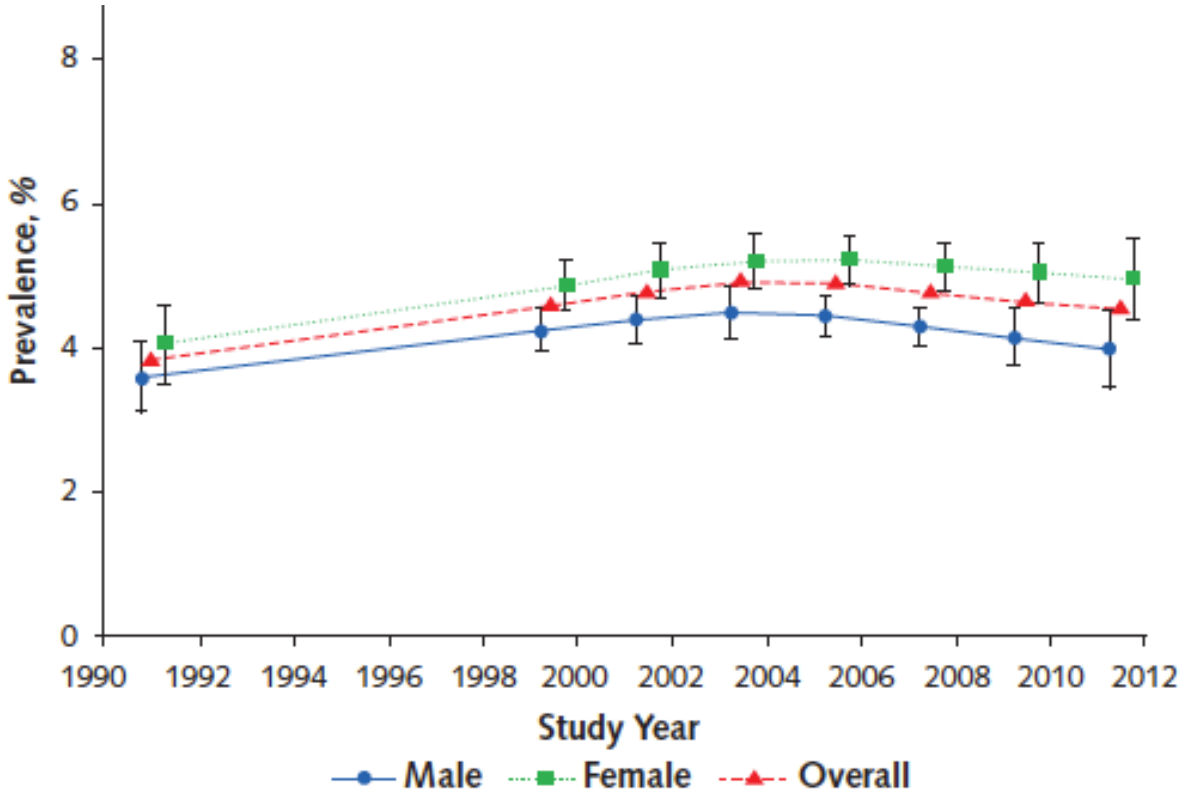
Epidemiologic shifts leading to more distal pattern of disease

Increasing diabetes



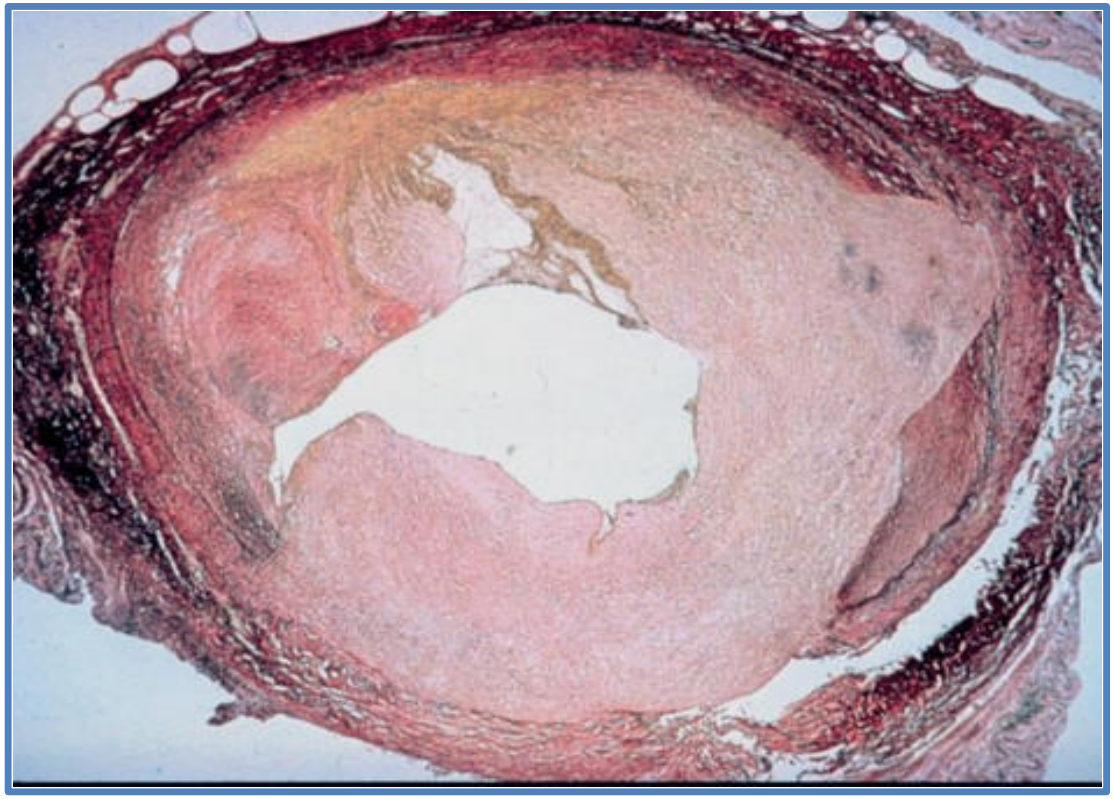
Menke A, Casagrande S, Geiss L, et al. *JAMA*. 2015;314(10):1021-9.

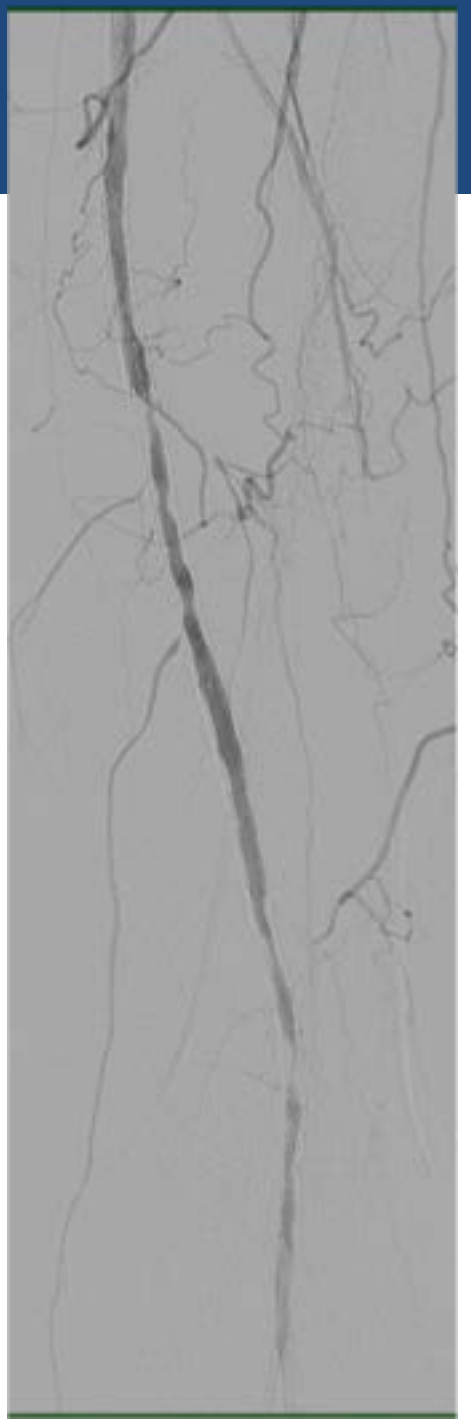
Decreasing Smoking



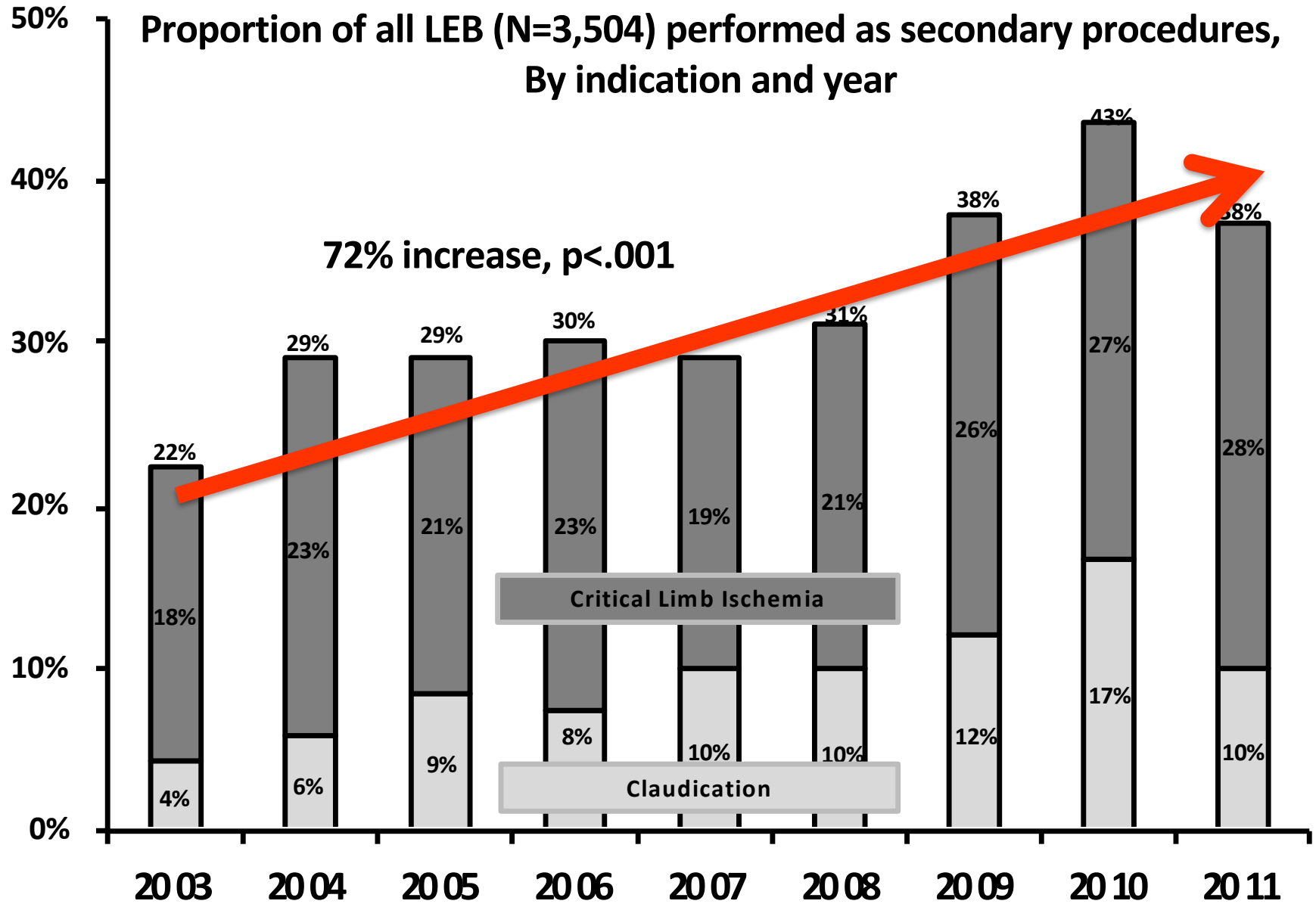
Murphy D, McCulloch CE, Lin F, et al. *Annals of Internal Medicine*. 2016.

The Real Problem: *Restenosis*

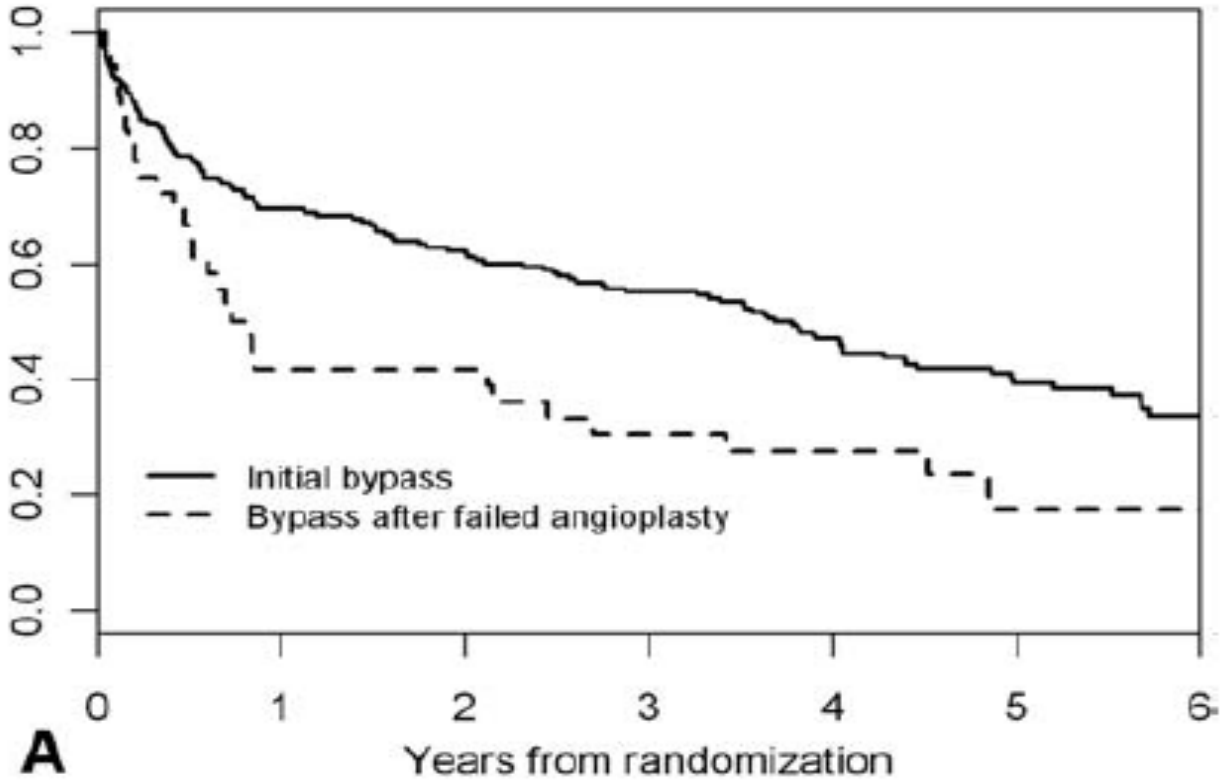




Growing impact of restenosis on the surgical treatment of peripheral arterial disease. Jones D et al; JAHA 2013



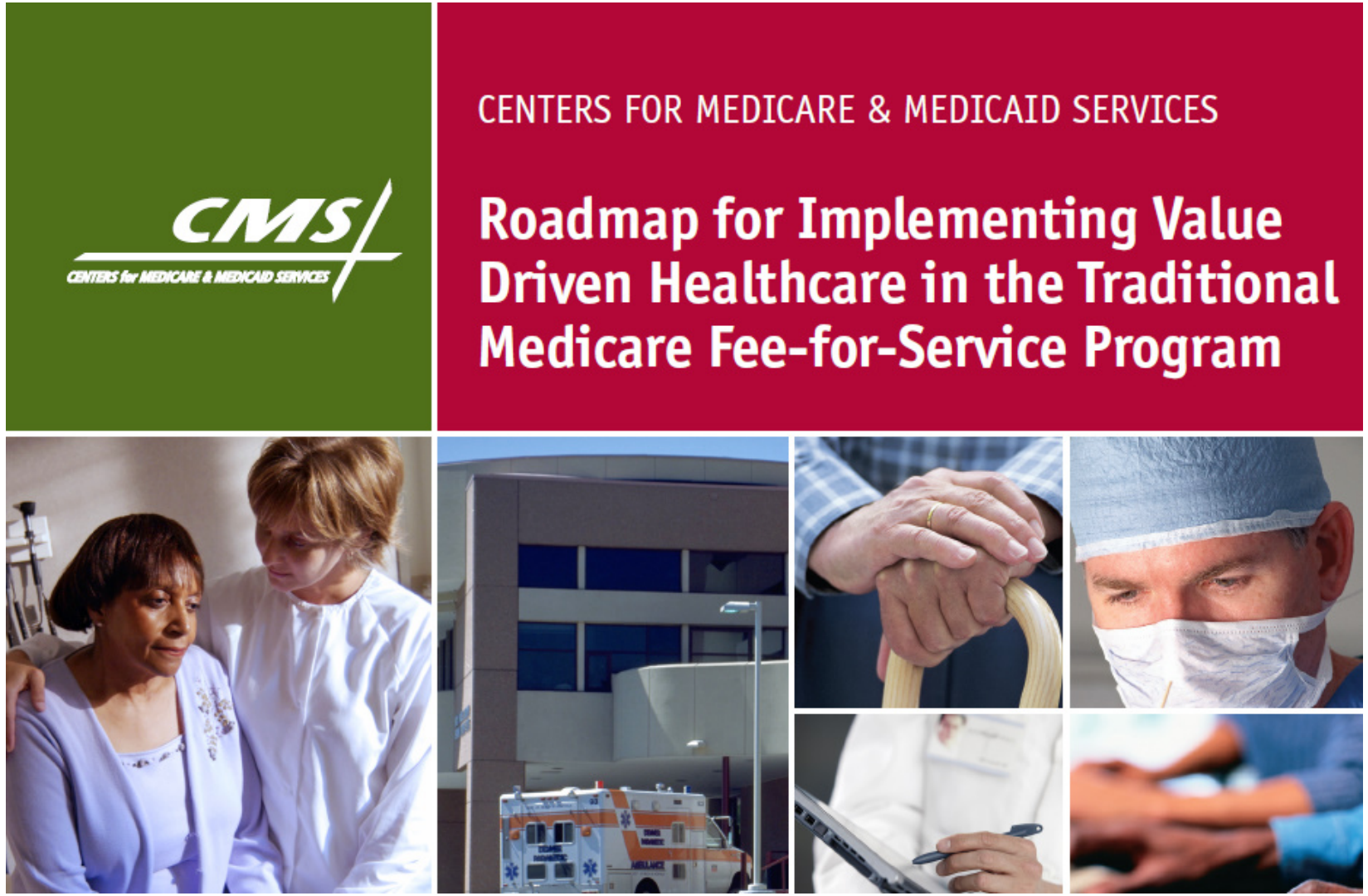
BASIL: Impact *of Treatment Received on Amputation-Free Survival*



"BAP was associated with a significantly higher failure rate than BSX. Most BAP patients ultimately required surgery. BSX outcomes after failed BAP are significantly worse than for BSX performed as a first revascularization attempt. BSX with vein offers the best long term AFS and OS.

Bradbury AW et al. J Vasc Surg 2010;51:18S-31S

Medicare & Medicaid, Payers, Employers Are Talking About "Value"



The value of infrainguinal bypass

- It is effective and durable.
- Performed with lower cardiovascular morbidity and mortality than thought
- Adaptable and effective in anatomically complex PAD
  - endovascular therapy more dependent on favorable lesion and anatomic characteristics
  - Epidemiologic trends (↑ elderly/DM/ ESRD) → Difficult anatomy likely to increase
- Necessary to treat the restenosis epidemic
- Cost –effective in tight financial times

- *No clear justification for widespread abandonment of bypass in favor of endovascular intervention*

Thoughts on the Role of Lower Extremity Bypass

- Maintain and improve our skills/ techniques in infrainguinal bypass
- Maintain and improve our judgement in lower extremity arterial occlusive disease
  - open and endovascular treatment as complementary rather than competitive techniques
- Transmit bypass skills/judgement to next generation of vascular surgeons and trainees across disciplines

Thank you

Surgeon, not institution, case volume is associated with limb outcomes after lower extremity bypass for critical limb ischemia in the Vascular Quality Initiative

Lily E. Johnston, MD, MPH,[a] Margaret C. Tracci, MD, JD,[a] John A. Kern, MD,[a,b] Kenneth J. Cherry, MD,[a]
Irving

Institutional volume: 1-137 LEB per year (median 27)

Surgeon Volume: 1-52 LEB per year (median 5.7)

Annual Surgeon Volume independently associated with improved primary bypass patency and reduced MALE

Institutional LEB volume was not associated with MACEs or MALEs ... However, average annual surgeon volume was independently associated with reduced MALEs ... patency. Institutional and surgeon volume did not predict MACEs.

Conclusions: In contradistinction to previous studies, there was no ... this study between institutional LEB volume and outcomes after LEB. However, greater average annua... volume was associated with improved primary patency and decreased risk of MALEs. Open LEB remain... and effective procedure for limb salvage. Limb-related outcomes in critical limb ischemia and claudication will be optimized if surgeons maintain adequate volume of LEB. (J Vasc Surg 2017;66:1457-63.)