

Outcomes of Patients with CLI in a Large Urban Safety Net Hospital: What Are the Results in This Setting?

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DISCLOSURE

Vincent Rowe, MD

- No relevant financial relationship reported

Questions?

- Should outcomes be the same in private and non-private hospitals?
- What results should we expect with CLI?
- Are these results feasible in the “real world”?

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Results - Demographics

	Af-Am (n=43)	Hispanic (n=148)	Other (n=17)	White (n=28)	p-value
Age	68±1.4	65±0.9	61±2.6	53±2.3	NS
Female	23 (53)	84 (57)	6 (35)	9 (32)	NS
DM	31 (72)	139 (94)	15 (88)	18 (64)	NS
HTN	34 (79)	108 (73)	7 (41)	15 (54)	0.06
Smoking	24 (56)	44 (30)	9 (53)	20 (71)	0.03
CAD	14 (33)	39 (26)	2 (12)	8 (29)	NS
Dyslipidemia	3 (7)	14 (10)	1 (6)	3 (11)	NS
Renal dysfn	4 (9)	14 (10)	2 (12)	2 (7)	NS

***Renal Dysfn: 9.3%**

Results - Presenting symptoms

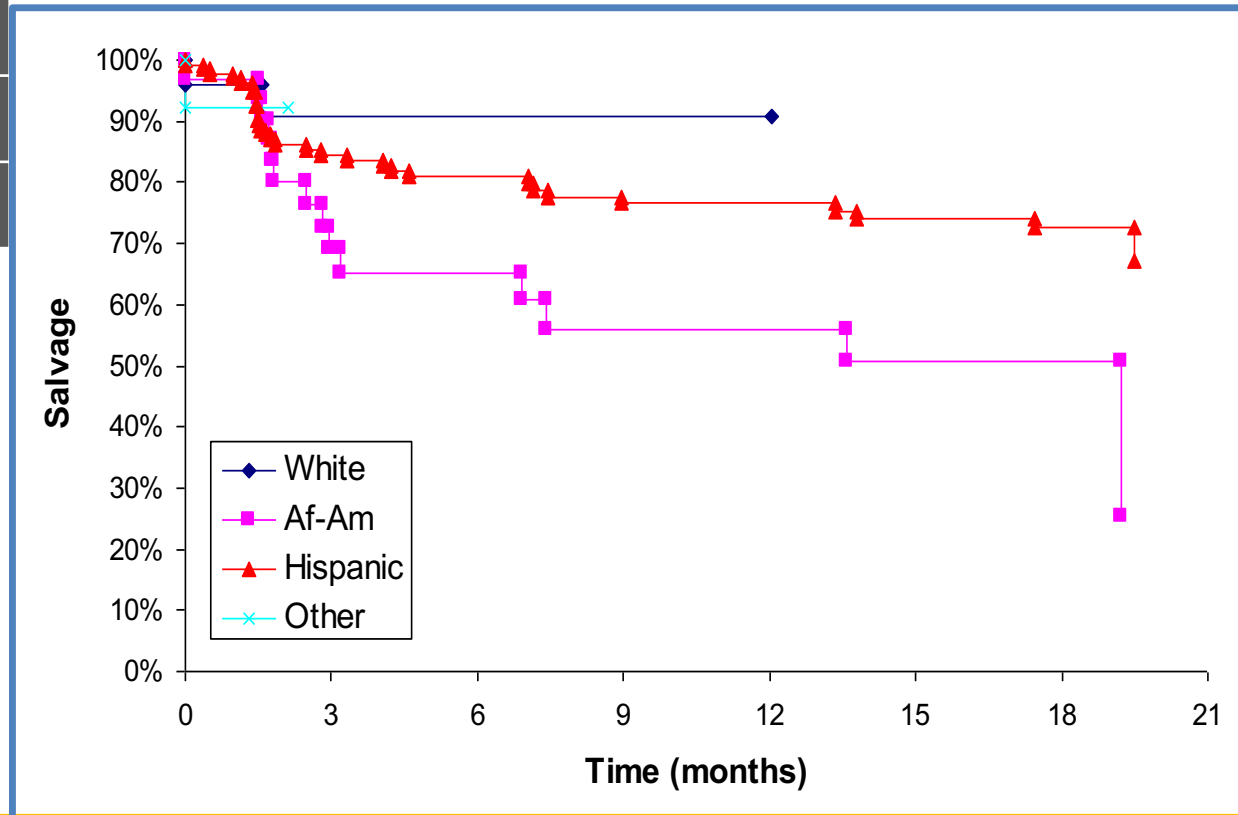
	Af-Am (n=43)	Hispanic (n=148)	Other (n=17)	White (n=28)	p-value
Claudication	4 (9)	7 (5)	3 (18)	5 (18)	NS
Rest pain	8 (19)	14 (10)	4 (24)	6 (21)	NS
Tissue loss	31 (72)	127 (86)	10 (59)	17 (61)	NS

***Tissue Loss: 78.3%**

Results - Limb salvage

Race	Salvage (18-mo %)
Af-Am	50.8
Hispanic	72.6
Other	92.3
White	90.8

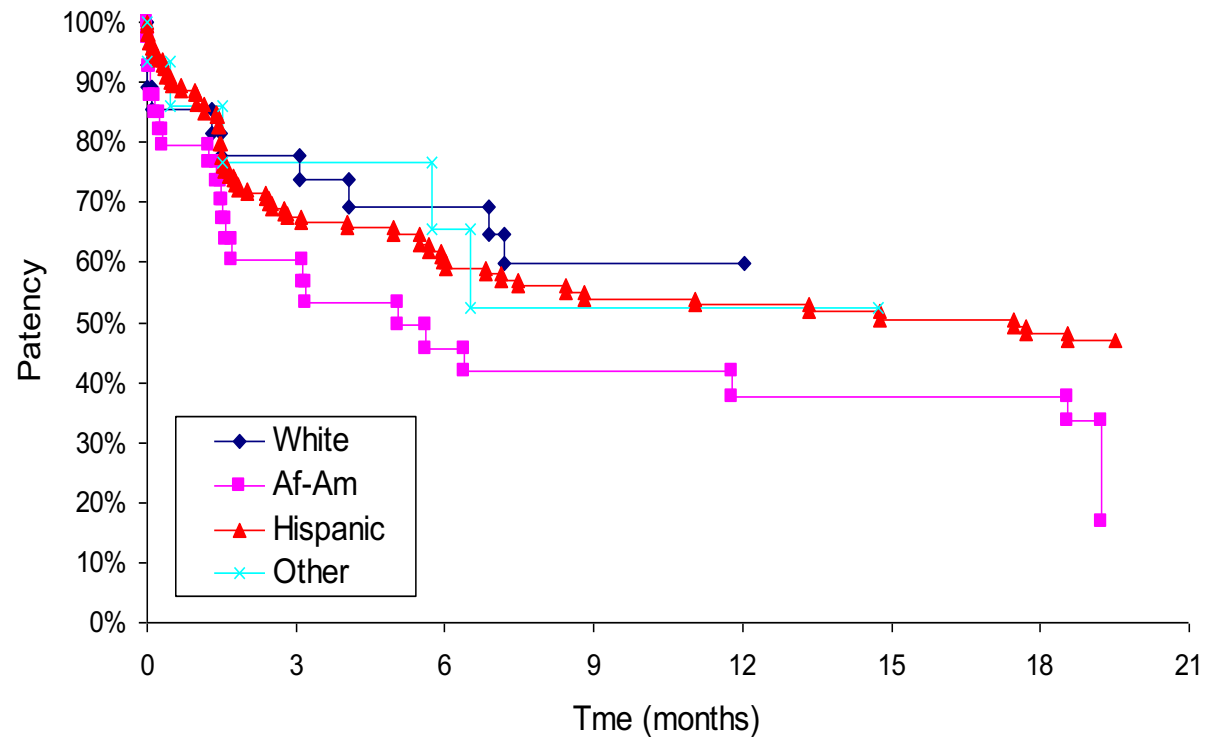
Hazard ratio = 8
p = 0.006



Results - Primary patency

Race	Patency (18-mo %)
Af-Am	33.5
Hispanic	46.9
Other	52.5
White	59.9

Hazard ratio = 1.95
p = 0.08



Results of PREVENT III: A multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery

Michael S. Conte, MD,^a Dennis F. Bandyk, MD,^b Alexander W. Clowes, MD,^c Gregory L. Moneta, MD,^d Lynn Seely, MD,^e Todd J. Lorenz, MD,^c Hamid Namini, PhD,^c Allen D. Hamdan, MD,^f Sean P. Roddy, MD,^g Michael Belkin, MD,^a Scott A. Berceci, MD,^h Richard J. DeMasi, MD,ⁱ Russell H. Samson, MD,^j and Scott S. Berman, MD,^k for the PREVENT III Investigators, *Boston, Mass;*

- Randomized, Double Blinded
- Multicenter – 83 centers (US and Canada)
- Efficacy of edifoligide (EF2 decoy)
 - Competitive inhibitor of EF2
 - Inhibit SMC proliferation and reduce intimal hyperplasia

Ethnic origin

White	526 (74.4%)	491 (70.4%)
Black	116 (16.4%)	133 (19.1%)
Asian	3 (0.4%)	7 (1.0%)
Hispanic	53 (7.5%)	54 (7.7%)
Other	9 (1.3%)	12 (1.7%)

CLI criterion (worst)

Rest pain	184 (26.0%)	169 (24.2%)
Nonhealing ulcer	273 (38.6%)	280 (40.2%)
Gangrene	247 (34.9%)	246 (35.3%)

Comorbidities

Hypertension	577 (81.6%)	569 (81.6%)
Diabetes	461 (65.2%)	439 (63.0%)
CAD	353 (49.9%)	324 (46.5%)
CVD	144 (20.4%)	140 (20.1%)
Smoking*	520 (73.5%)	513 (73.6%)
Dyslipidemia	393 (55.6%)	373 (53.5%)
Dialysis	84 (11.9%)	86 (12.3%)

Inflow	146 (20.7%)	147 (21.1%)
Infrainguinal (either limb)	190 (26.9%)	193 (27.7%)



<i>Variable</i>	<i>Edifoligide</i>	<i>Placebo</i>	<i>P value</i>
Protocol-specified end points			
Primary trial end point (nontechnical failure)	25.2	25.5	.69
All clinical failures	34.8	36	.51
Freedom from clinically significant stenosis	44.3	46.1	.62
Amputation/ reintervention-free survival	50.1	48.6	.47
Conventional end points			
Primary patency	61.5	59.5	.38
Primary assisted patency	78.6	74.7	.10
Secondary patency	82.6	77.5	.02
Limb salvage	87.7	89.2	.37
Survival	83.2	84.4	.55

JAMA Cardiology Comparisons of Coronary and Com

Paul G. Barnett, PhD, J
Karen Joynt Maddox, M

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Comparison of Surgical Outcomes Between Teaching and Nonteaching Hospitals in the Department of Veterans Affairs

Shukri F. Khuri, MD,* Samer F. Najjar, MD,* Jennifer Daley, MD,† Barbara Krasnicka, PhD,‡ Monir Hossain, MS,‡ William G. Henderson, PhD,§ J. Bradley Aust, MD,|| Barbara Bass, MD,¶ Michael J. Bishop, MD,‡ John Demakis, MD,** Ralph DePalma, MD,** Peter J. Fabri, MD,†† Aaron Fink, MD, James Gibbs, PhD,§ Frederick Grover, MD,§§ Karl Hammermeister, MD,§§ Gerald McDonald, MD,** Leigh Neumayer, MD,||| Robert H. Roswell, MD,¶¶ Jeannette Spencer, MS, RN,† Richard H. Turnage, MD,## and the participants in the VA National Surgical Quality Improvement Program

From the *VA Boston Healthcare System, West Roxbury, Massachusetts, Harvard Medical School, Boston, Massachusetts, Brigham and Women's Hospital, Boston, Massachusetts; †VA Boston Healthcare System, West Roxbury, Massachusetts; ‡VA Boston Healthcare System, West Roxbury, Massachusetts, Institute for Health Policy, Massachusetts General Hospital/Partners HealthCare System, Harvard Medical School, Boston, Massachusetts; §Hines VA Cooperative Studies Program Coordinating Center, Hines, Illinois; ||Department of Surgery, University of Texas Health Science Center, San Antonio, Texas; ¶VA Maryland Health Care System, University of Maryland, Baltimore, Maryland; #National Anesthesia Services, VA Puget Health Care System, Seattle, University of Washington, Seattle, Washington; **Health Services Research and Development Service, Department of Veterans Affairs Headquarters, Washington DC; ††Tampa VA Medical Center, University of South Florida College of Medicine, Tampa, Florida; ‡‡Atlanta VA Medical Center, Decatur, Georgia, Emory University School of Medicine, Atlanta, Georgia; §§Denver VA Medical Center, University of Colorado Health Sciences Center, Denver, Colorado; |||VA Salt Lake City Health Care System, University of Utah Medical Center, Salt Lake City, Utah; ¶¶Veterans Integrated Service Network 8, Bay Pines, Florida; ##VA North Texas Health Care System, University of Texas Southwestern Medical School, Dallas, Texas

Objective

To determine whether the investment in postgraduate education and training places patients at risk for worse outcomes and higher costs than if medical and surgical care was delivered in nonteaching settings.

Summary Background Data

The Veterans Health Administration (VA) plays a major role in the training of medical students, residents, and fellows.

Methods

The database of the VA National Surgical Quality Improvement Program was analyzed for all major noncardiac operations performed during fiscal years 1997, 1998, and 1999. Teaching status of a hospital was determined on the basis of a background and structure questionnaire that was independently verified by a research fellow. Stepwise logistic regression was used to construct separate models predictive of 30-day mortality and morbidity for each of seven surgical specialties and eight operations. Based on these models, a severity index for each patient was calculated. Hierarchical logistic regression models were then created to examine the relationship between teaching versus nonteaching hospitals

and 30-day postoperative mortality and morbidity, after adjusting for patient severity.

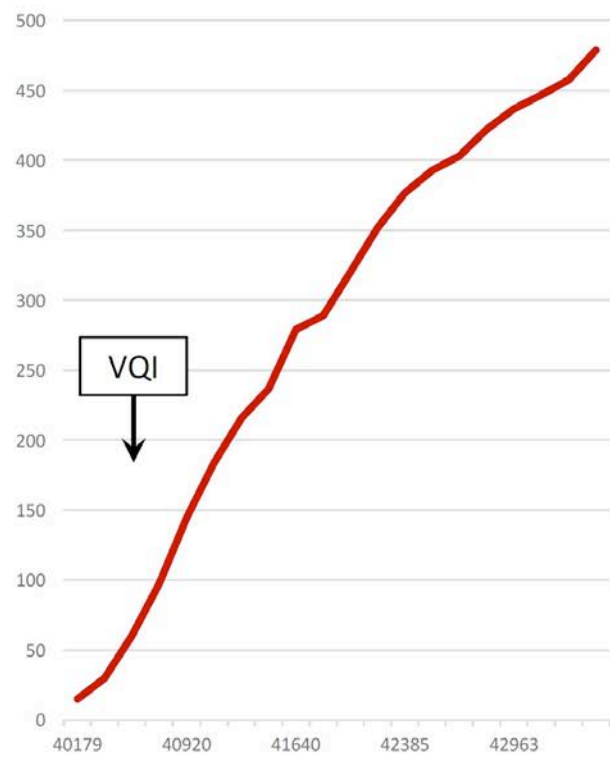
Results

Teaching hospitals performed 81% of the total surgical workload and 90% of the major surgery workload. In most specialties in teaching hospitals, the residents were the primary surgeons in more than 90% of the operations. Compared with nonteaching hospitals, the patient populations in teaching hospitals had a higher prevalence of risk factors, underwent more complex operations, and had longer operation times. Risk-adjusted mortality rates were not different between the teaching and nonteaching hospitals in the specialties and operations studied. The unadjusted complication rate was higher in teaching hospitals in six of seven specialties and four of eight operations. Risk adjustment did not eliminate completely these differences, probably reflecting the relatively poor predictive validity of some of the risk adjustment models for morbidity. Length of stay after major operations was not consistently different between teaching and nonteaching hospitals.

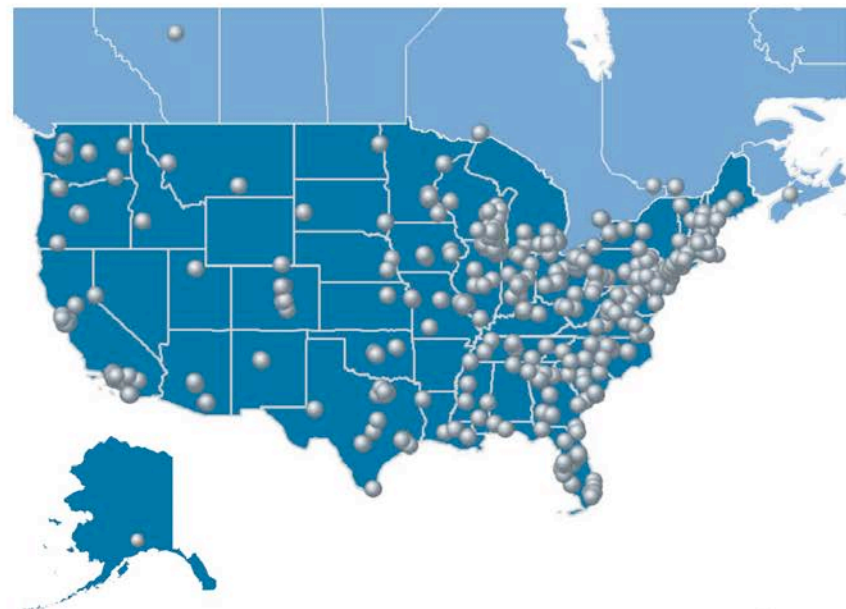
Conclusion

Compared with nonteaching hospitals, teaching hospitals in the VA perform the majority of complex and high-risk major procedures, with comparable risk-adjusted 30-day mortality

Number of Participating Centers



Location of VQI Participating Centers



479 Centers, 46 States + Canada



Questions?

- Should outcomes be the same in private and non-private hospitals?
- **What results should we expect with CLI?**
- Are these results feasible in the “real world”?

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*

- SVS LEB objective performance goals (OPG)
- Prevent III, BASIL, Circulase II Trials
- Benchmark for future CLI therapies (**including endovascular**)
- Excluded prosthetic grafts and ESRD patients

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Table Va. Summary of safety outcomes for overall CLI cohort

<i>Outcome</i>	<i>30 day events (%; 95% CI)</i>	<i>Maximum allowable events (trial N = 392)</i>	<i>Safety OPG</i>
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%

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

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Table Vb. Summary of efficacy outcomes (one year) for overall CLI cohort and suggested OPG for each endpoint

<i>Outcome</i>	<i>Point (95% CI)</i>	<i>Efficacy OPG</i>
MALE + POD	76.9% (74.0-79.9)	71%
AFS	76.5% (73.7-79.5)	71%
RAS	46.5% (42.3-51.2)	39%
RAO	61.3% (58.0-64.9)	55%
Limb salvage	88.9% (86.7-91.1)	84%
Survival	85.7% (83.3-88.1)	80%

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- Negative factors:
 - Age > 80 years old with tissue loss
 - Poor quality saphenous vein
 - Prosthetic conduit
 - Infrapopliteal level

Questions?

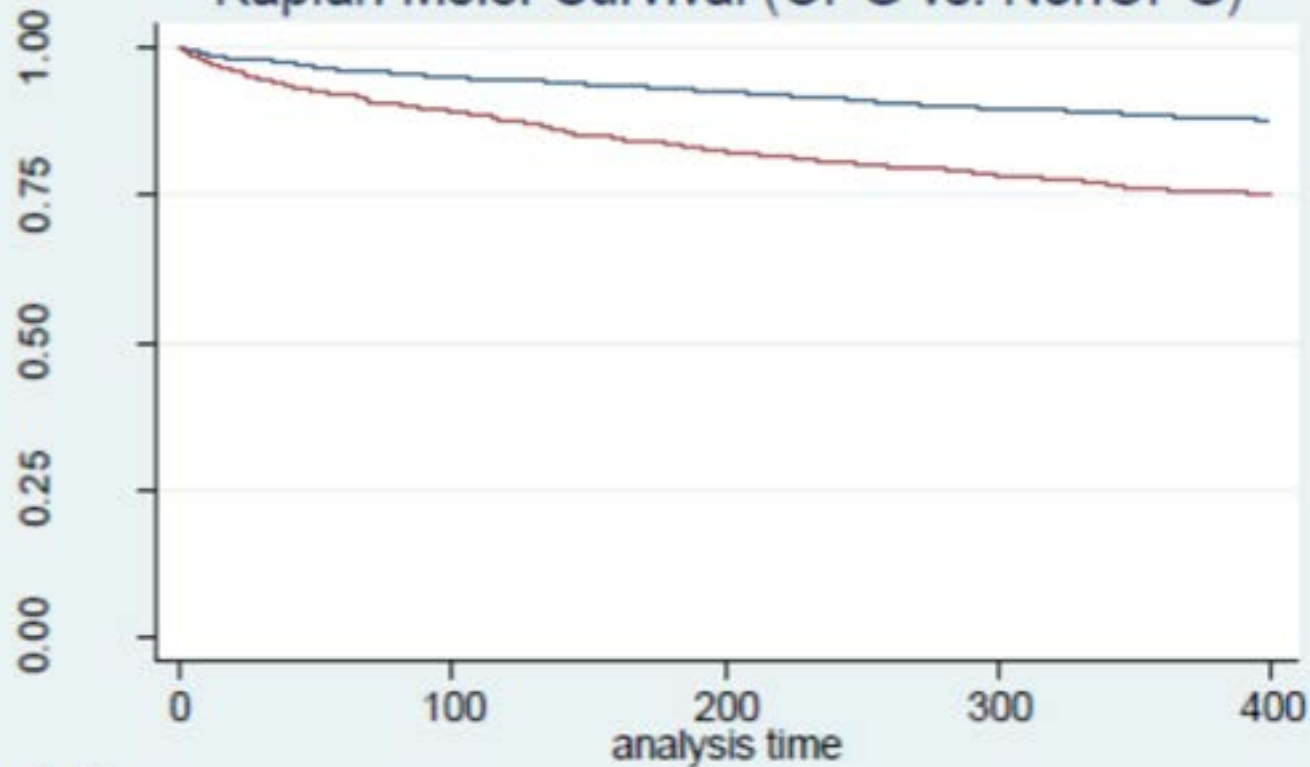
- Should outcomes be the same in private and non-private hospitals?
- What results should we expect with CLI?
- **Are these results feasible in the “real world”?**

The Society for Vascular Surgery's objective performance goals for lower extremity revascularization are not generalizable to many open surgical bypass patients encountered in contemporary surgical practice

Julia T. Saraidaridis, MD,^a Emel Ergul, MS,^a Virendra I. Patel, MD, MPH,^a David H. Stone, MD,^b Richard P. Cambria, MD,^a and Mark F. Conrad, MD, MMSc,^a *Boston, Mass; and Lebanon, NH*

- All LEB in VSGNE for CLI
- 2003 -2013
- SVS Objective Performance Goals (OPG)

Kaplan Meier Survival (OPG vs. NonOPG)



Number at risk

nonOPG = 0 2360

2032

1888

1750

1619

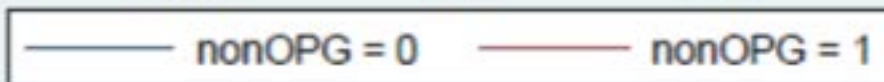
nonOPG = 1 1249

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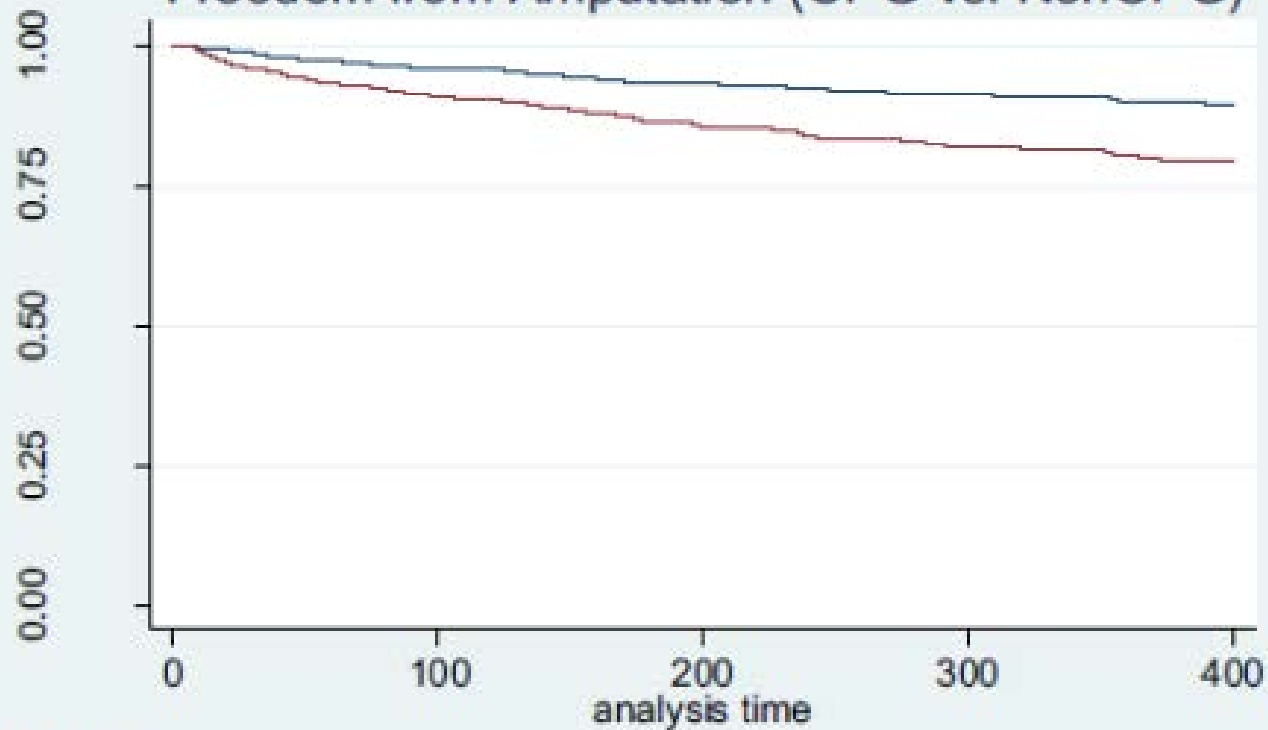
902

819

740



Freedom from Amputation (OPG vs. NonOPG)



Number at risk

nonOPG = 0 2190

1431

1296

1008

436

nonOPG = 1 1120

610

526

410

171

— nonOPG = 0 — nonOPG = 1

<i>Demographic</i>	<i>Non-OPG (n = 1249), No. (%)</i>	<i>OPG (n = 2360), No. (%)</i>	<i>P value</i>
Age, years	69.2	68.8	.34
Female sex	502 (40.2)	788 (33.4)	<.001
Nonwhite	99 (7.9)	159 (6.4)	.19
Any smoking	1030 (82.5)	1915 (81.0)	.33
Current smoking	423 (33.9)	887 (37.6)	.03
Hypertension	1142 (91.4)	2054 (87.0)	<.001
Diabetes	771 (61.7)	1328 (56.3)	.002
Diabetes requiring insulin	483 (38.7)	691 (29.3)	<.001
CAD	560 (44.8)	783 (33.2)	<.001
History of coronary artery bypass grafting	73 (5.8)	68 (2.9)	<.001
Congestive heart failure	323 (25.9)	414 (17.5)	<.001
Chronic obstructive pulmonary disease	372 (29.8)	593 (25.1)	.003
History of previous			
Ipsilateral bypass	220 (17.6)	240 (10.2)	<.001
Ipsilateral PVI	171 (13.7)	358 (15.2)	.23
Carotid endarterectomy/carotid artery stenting	147 (11.8)	209 (8.9)	.005
Major amputation	86 (6.9)	104 (4.4)	.002
Preoperative aspirin	930 (74.5)	1779 (75.4)	.54
Preoperative statin	865 (69.3)	1601 (67.8)	.38
Popliteal distal target			
Above the knee	441 (35.3)	233 (9.9)	<.001
Below the knee	323 (25.9)	768 (32.5)	<.001
Tibial distal target	328 (26.3)	991 (42.0)	<.001
Pedal distal target	117 (9.4)	349 (14.8)	<.001
Prosthetic conduit	1001 (80.1)	—	—
ESRD	343 (27.5)	—	—

CAD, Coronary artery disease; *ESRD*, end-stage renal disease; *PVI*, peripheral vascular intervention.

Results

<i>Outcome measures</i>	<i>Non-OPG group (n = 1249)</i>	<i>OPG group (n = 2360)</i>	<i>P value</i>	<i>SVS OPG, %</i>
Safety outcomes at 30 days, No. (%)				
MALE	69 (5.5)	113 (4.8)	.34	<8
MACE	115 (9.2)	147 (6.2)	.001	<8
Myocardial infarction	67 (5.4)	110 (4.7)	.35	
Death	65 (5.2)	46 (2.0)	<.001	
Amputation	32 (2.6)	21 (0.9)	<.001	<3
Efficacy outcomes at 1 year, % (SE)				
Survival	75.9 (1.3)	88.3 (.7)	<.001	>80
Freedom from amputation	80.9 (1.6)	90.1 (.8)	<.001	>84

MACE, Major adverse cardiovascular event; *MALE*, major adverse limb event; *SE*, standard error; *SVS*, Society for Vascular Surgery.

<i>MALE 30:</i>			<i>MACE 30:</i>		
<i>Risk factor</i>	<i>OR</i>	<i>P value</i>	<i>Risk factor</i>	<i>OR</i>	<i>P value</i>
Age	0.98	.01	Age	1.03	<.001
Female	1.46	.02	Female	1.21	.17
Nonwhite	0.96	.87	Nonwhite	1.57	.13
ESRD	0.98	.94	ESRD	1.70	.004

<i>Survival:</i>			<i>Amputation:</i>		
<i>risk factor</i>	<i>HR</i>	<i>P value</i>	<i>Risk factor</i>	<i>HR</i>	<i>P value</i>
Age	1.05	<.001	Age	0.99	.10
Female	0.87	.02	Female	1.08	.54
Non-white	1.72	.002	Nonwhite	1.13	.57
ESRD	3.41	<.001	ESRD	2.94	<.001
Diabetes	1.26	<.001	Diabetes	1.16	0.28
Prosthetic	1.26	<.001	Prosthetic	2.15	<.001
Smoking	1.20	.01	Infrapopliteal target	2.17	<.001
CAD	1.40	<.001	Previous ipsilateral bypass	1.54	.004
			Previous PVI	1.69	<.001

CAD, Coronary artery disease; *ESRD*, end-stage renal disease; *HR*, hazard ratio; *PVI*, peripheral vascular intervention.

Smoking	0.64	.01
Diabetes	1.42	.02
Prosthetic	1.28	.10
Infrapopliteal target	1.35	.03
CAD	2.17	<.001

ESRD, end-stage renal disease; *MACE*, major adverse limb event; *OR*,

Recommended Changes

<i>End point</i>	<i>SVS OPG, %</i>	<i>Non-OPG, %</i>	<i>ESRD, %</i>	<i>Prosthetic, %</i>
Safety outcomes at 30 days				
MALE	<8	<8	<8	<8
MACE	<8	<11	<16	<11
Amputation	<3	<4	<6	<4
Efficacy outcomes at 1 year				
Survival	>80	>70	>52	>73
Limb salvage	>84	>73	>56	>75

ESRD, End-stage renal disease; *MACE*, major adverse cardiovascular event; *MALE*, major adverse limb event; *SVS*, Society for Vascular Surgery.

Changing Era

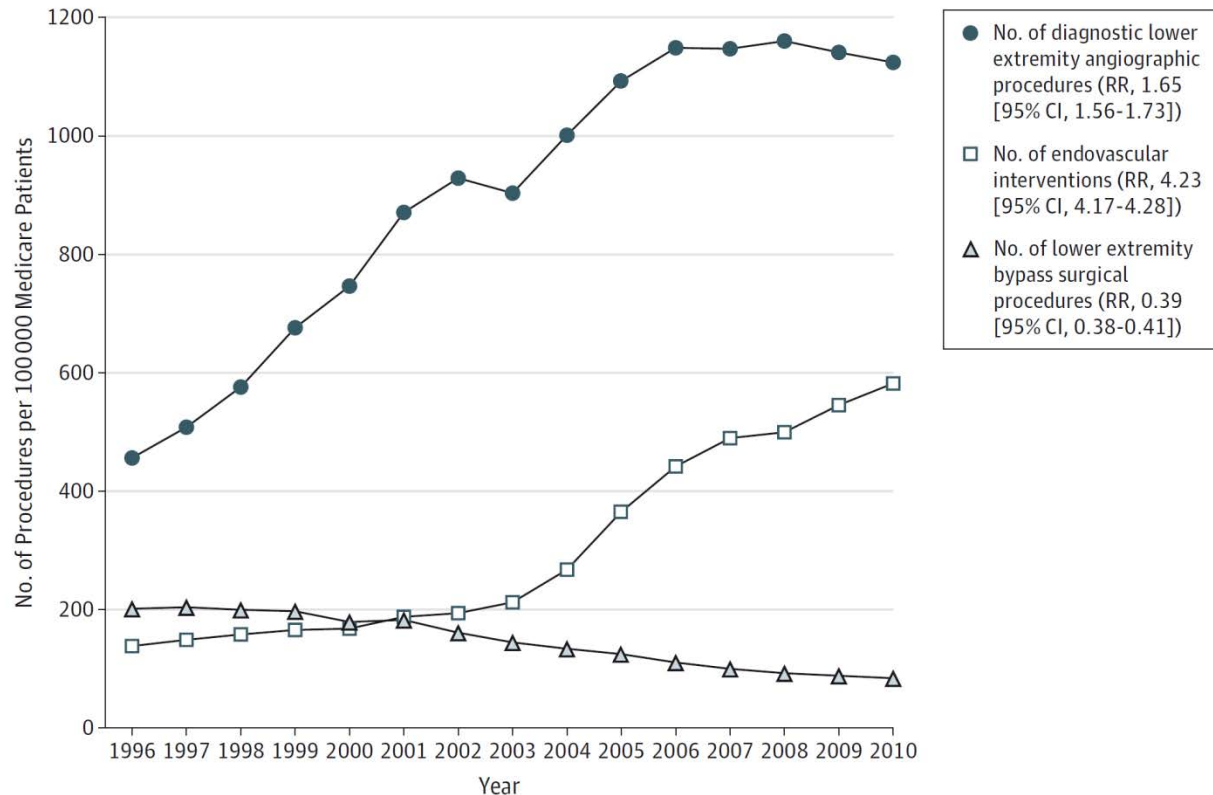
- Medications
 - Statins
 - Oral anticoagulants
 - Antiplatelet agents
- Endovascular
 - Lower profile systems
 - Drug delivery interventions
 - Retrograde access
 - Atherectomy

Changing Era

- Surgery
 - Are we as good as we used to be?

Trends in PAD Therapy

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



Resident Experience

	2010		2017	
	<u>Mean</u>	<u>Std Dev</u>	<u>Mean</u>	<u>Std Dev</u>
Femoral, Profunda Endarterectomy	10.8	6	15.2	9
Femoral-Popliteal Bypass, Vein	10.3	6	10.5	6
Femoral-Popliteal Bypass, Prosth	8.6	6	7.0	6
Translum balloon angio femoral-popl	18.8	13	40.5	22
Translum atherectomy femoral-popliteal	4.7	7	4.6	6
Endarterectomy, superf femoral, popl	2.1	2	2.6	3
Infrapopliteal Bypass, Vein	15.5	9	15.9	10
Infrapopliteal Bypass, Prosthetic	4.2	4	4.2	4
Translum ballon angio, tibioperoneal	11.2	9	17.8	12
Translum atherectomy, tibioperoneal	2.2	4	3.0	5

Resident Experience

	2010		2017	
	<u>Mean</u>	<u>Std Dev</u>	<u>Mean</u>	<u>Std Dev</u>
Femoral, Profunda Endarterectomy	10.8	6	15.2	9
Femoral-Popliteal Bypass, Vein	10.3	6	10.5	6
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Translum atherectomy, tibioperoneal	2.2	4	3.0	5

Changing Era

- Surgery
 - Are we as good as we used to be?
- Patients
 - Distal disease
 - Diabetes/Obesity
 - ESRD

Recent Public Hospital Experience

	2006 (Avg. %)	Last 100 (Avg. %)
Age > 80	6.7	13
Race - Hispanic	62.7	76
Race – Af. American	18.2	7
Diabetes	86.0	81
ESRD/Renal Insuff.	9.3	25

Recent Public Hospital Experience

	2006 (Avg. %)	Last 100 (Avg. %)
Age > 80	6.7	13
Race - Hispanic	62.7	76
Race – Af. American	18.2	7
Diabetes	86.0	81
ESRD/Renal Insuff.	9.3	25

Recent Public Hospital Experience

	2006 (Avg. %)	Last 100 (Avg. %)
Age > 80	6.7	13
Race - Hispanic	62.7	76
Race – Af. American	18.2	7
Diabetes	86.0	81
ESRD/Renal Insuff.	9.3	25

Recent Public Hospital Experience

	2006 (Avg. %)	Last 100 (Avg. %)
Age > 80	6.7	13
Race - Hispanic	62.7	76
Race – Af. American	18.2	7
Diabetes	86.0	81
ESRD/Renal Insuff.	9.3	25

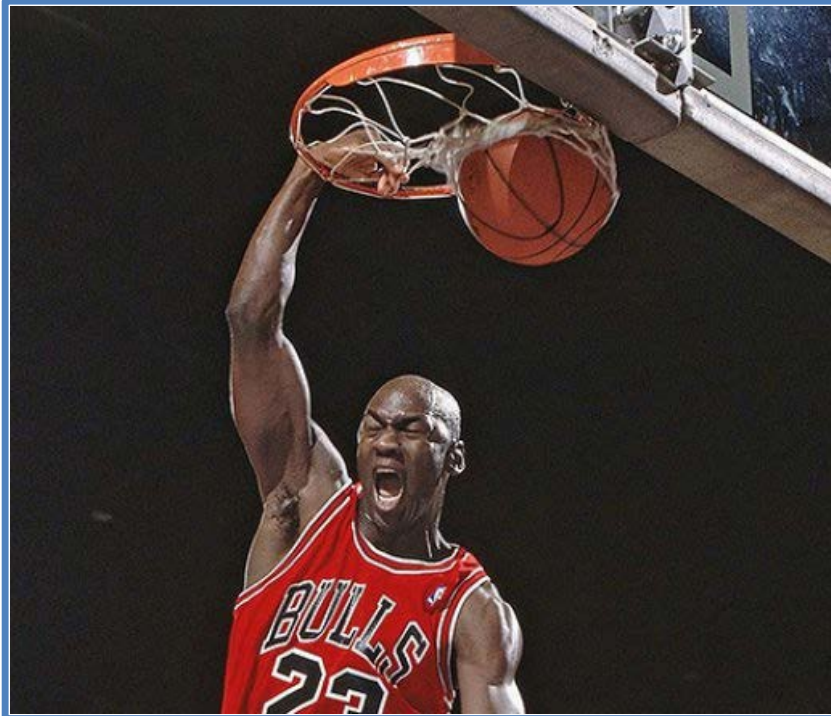
Recent Public Hospital Experience

	2006 (Avg. %)	Last 100 (Avg. %)
Age > 80	6.7	13
Race - Hispanic	62.7	76
Race – Af. American	18.2	7
Diabetes	86.0	81
ESRD/Renal Insuff.	9.3	25





Hard to compare!!!





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



Conclusion

- Should outcomes be the same in private and non-private hospitals?
 - For the most part, Yes
- What results should we expect with CLI?
 - SVS Guidelines provide great starting point
- Are these results feasible in the “real world”?
 - Yes, but with risk adjustments
 - Revisions of guidelines every 5 years

THANK YOU