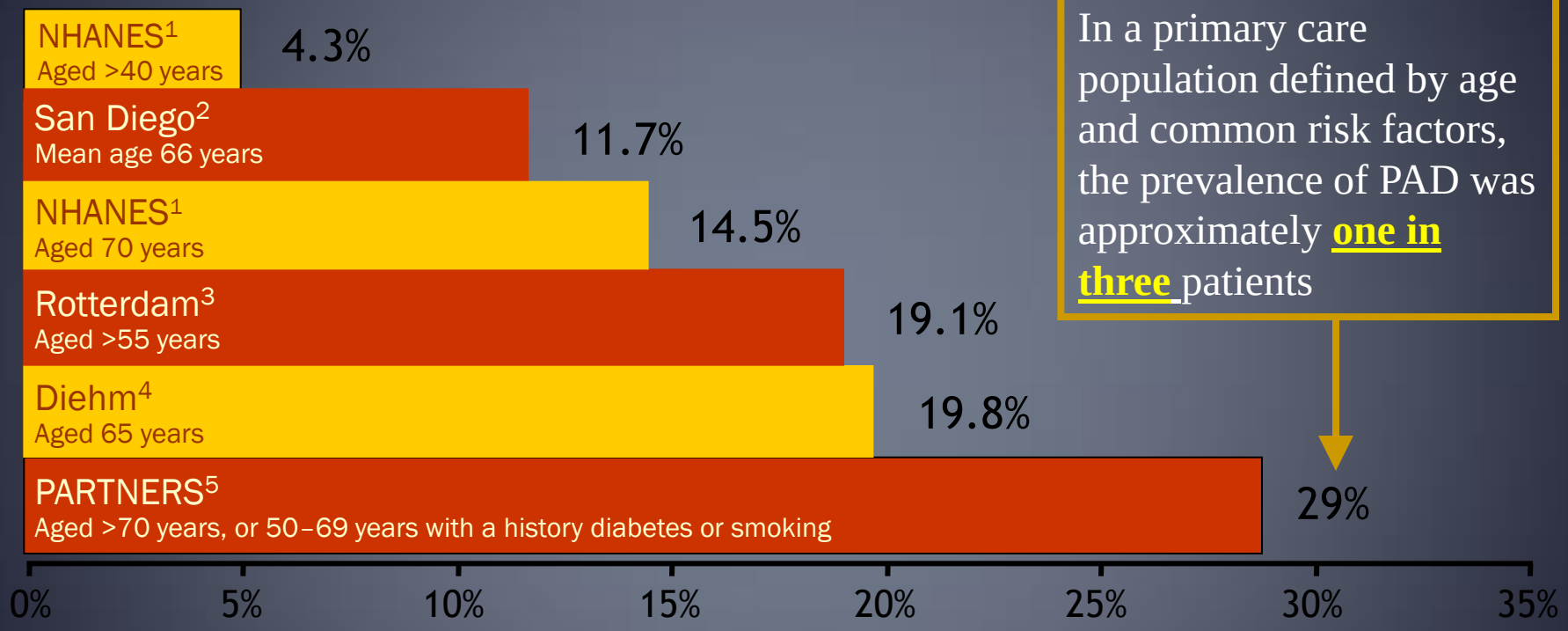
Critical Limb Ischemia – CLI

Advances in Limb Salvage

Ammar Safar, MD, FSCAI, FACC, FACP, RPVI

Interventional Cardiology & Endovascular Medicine

Prevalence of PAD



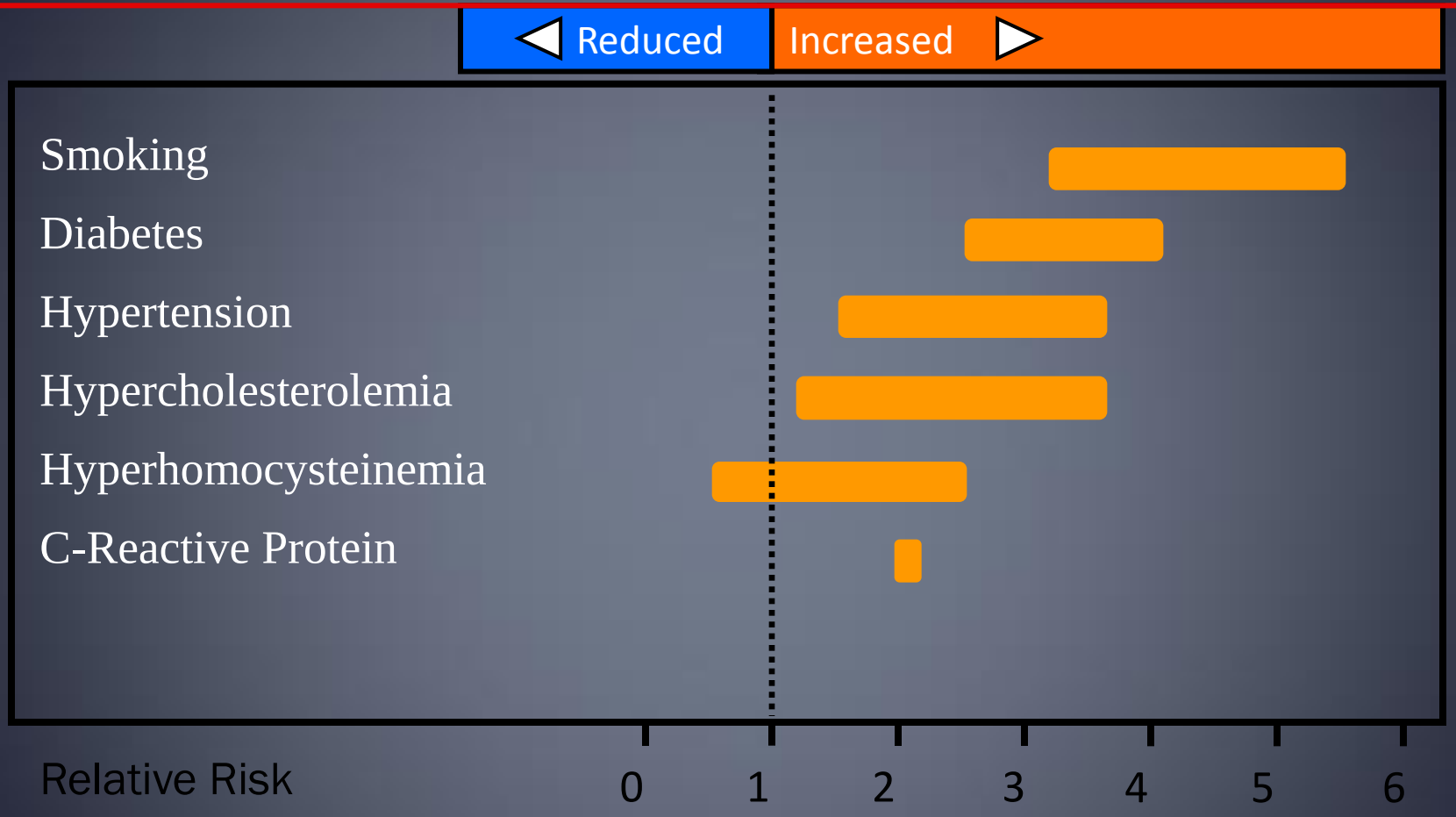
In a primary care population defined by age and common risk factors, the prevalence of PAD was approximately **one in three** patients

NHANES=National Health and Nutrition Examination Study

PARTNERS=PAD Awareness, Risk, and Treatment: New Resources for Survival [program].

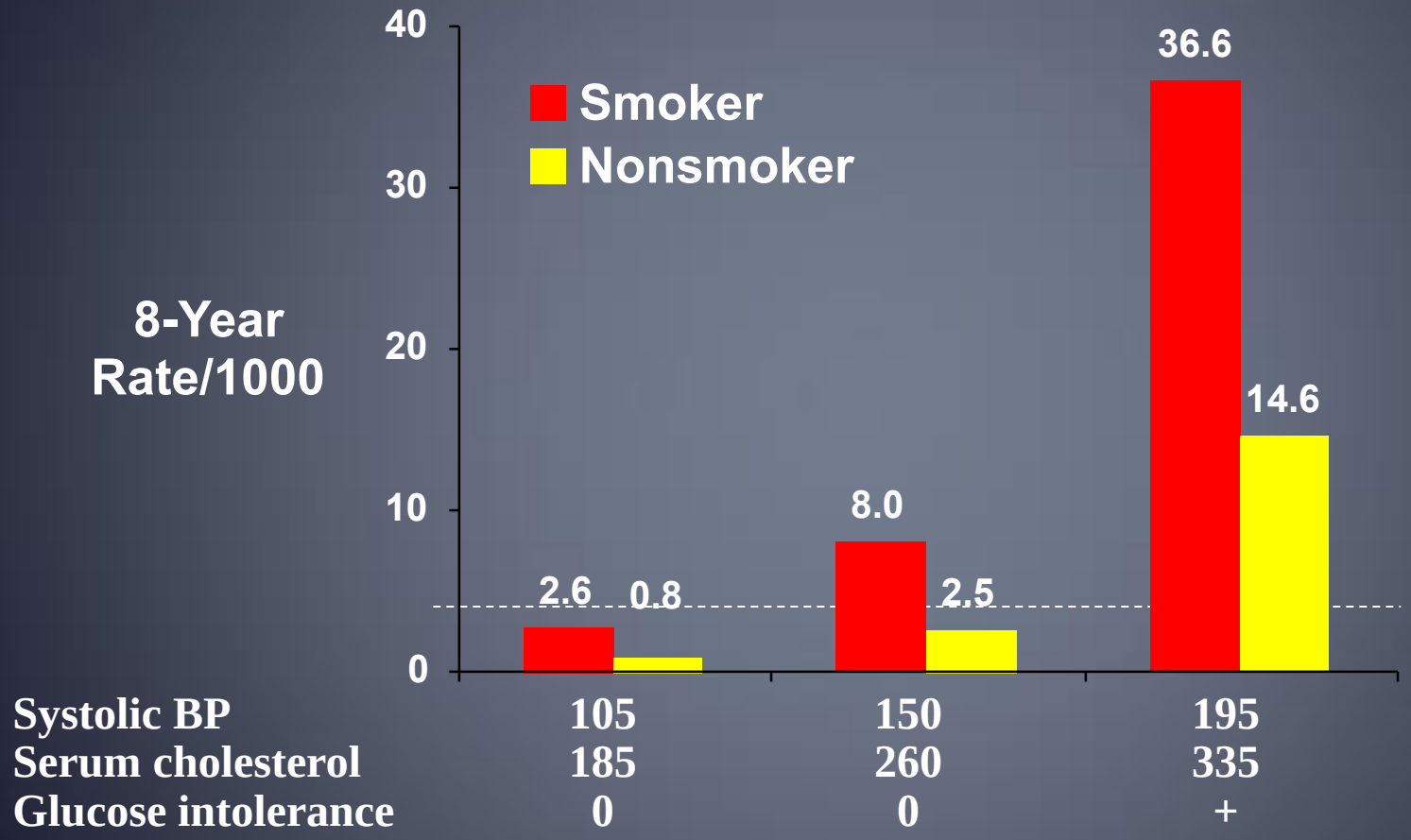
1. Selvin E, Erlinger TP. Circulation. 2004;110:738-743.
2. Criqui MH, et al. Circulation. 1985;71:510-515.
3. Diehm C, et al. Atherosclerosis. 2004;172:95-105.
4. Meijer WT, et al. Arterioscler Thromb Vasc Biol. 1998;18:185-192.
5. Hirsch AT, et al. JAMA. 2001;286:1317-1324.

Risk Factors for PAD



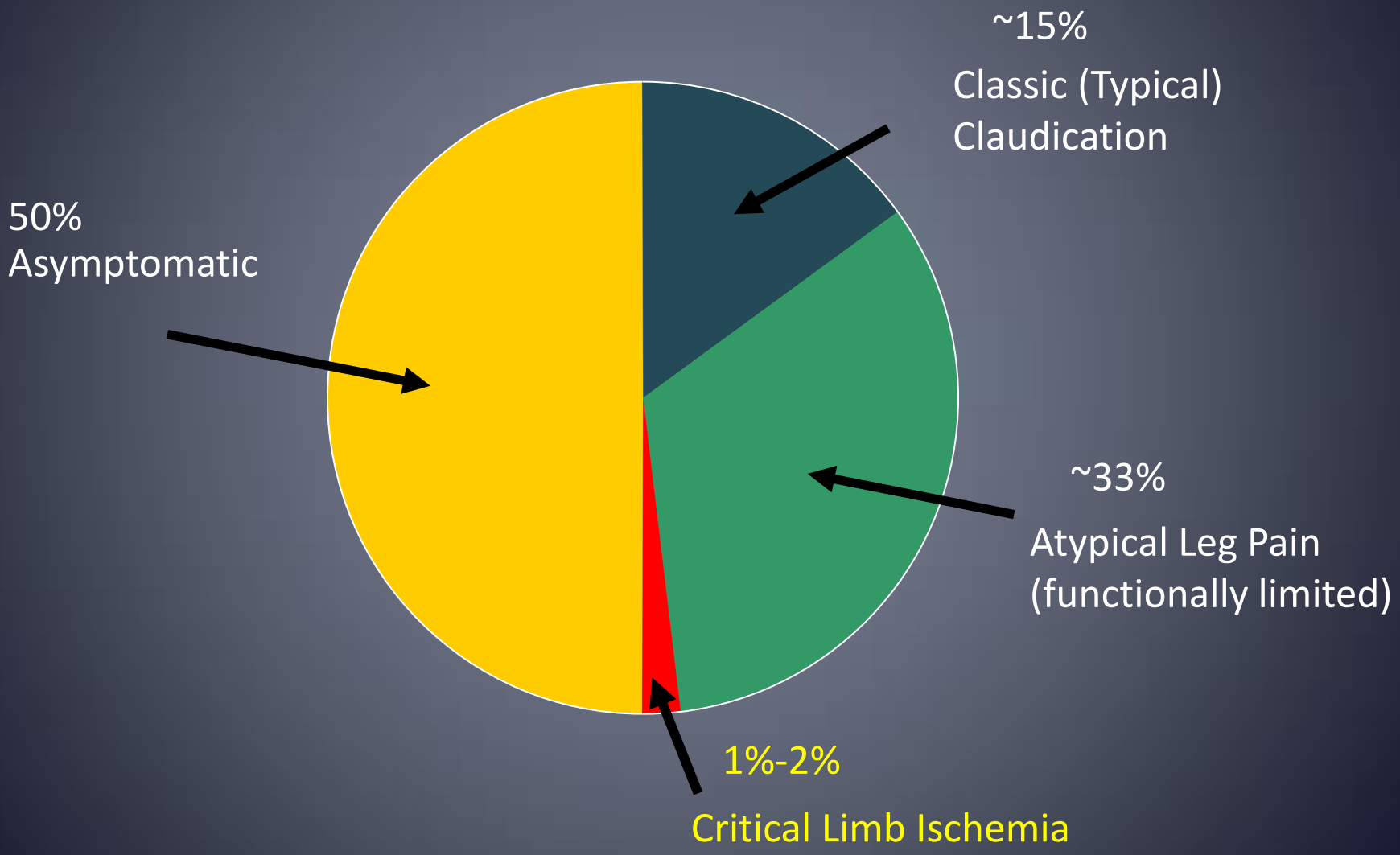
Hirsch AT, et al. J Am Coll Cardiol. 2006;47:e1-e192.

PAD Risk Factors are "Synergistic"

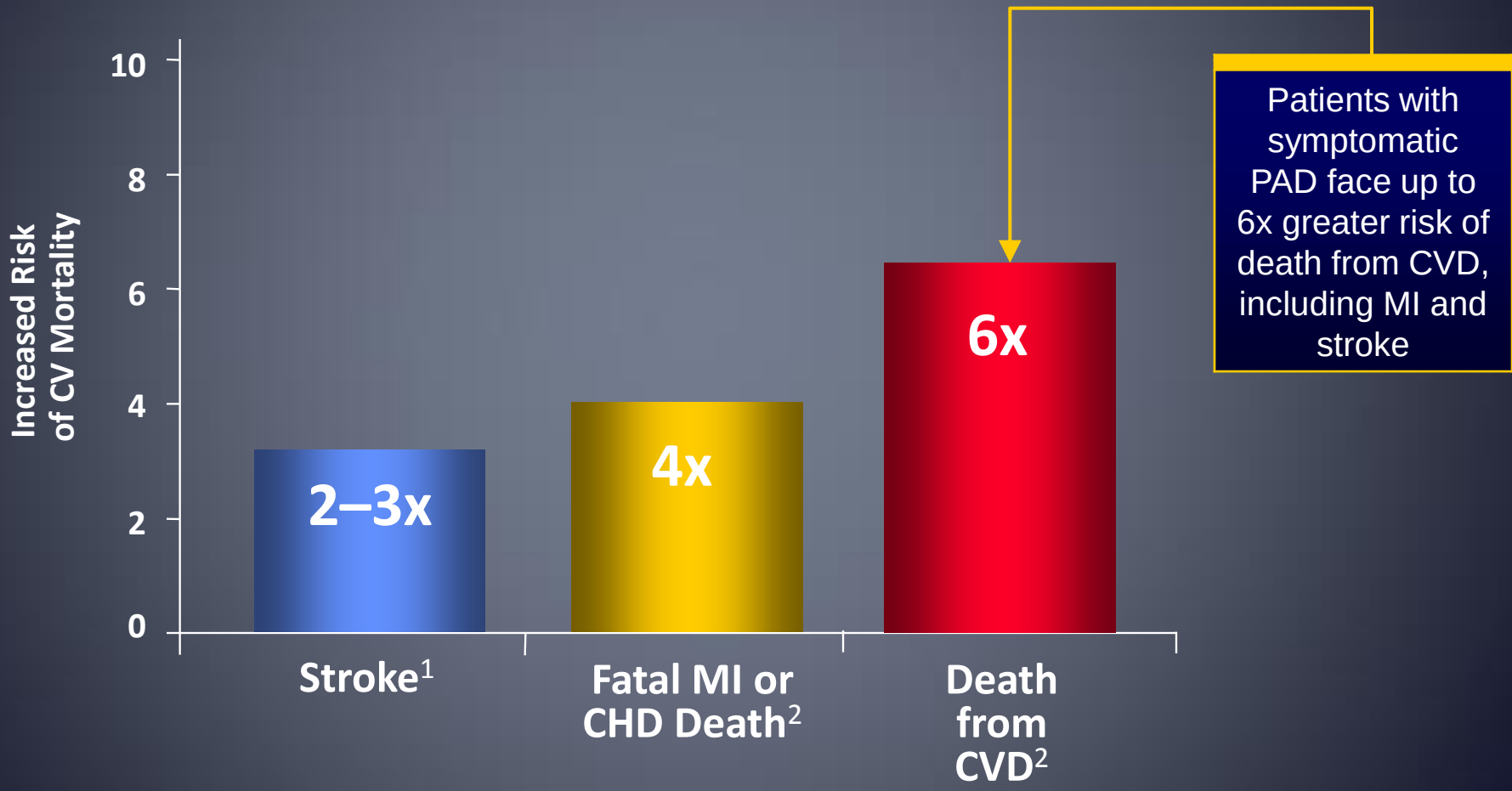


Adapted from TASC Working Group. *J Vasc Surg*. 2000;31(1 suppl):S1-S296.
Kannel WB et al. *J Am Geriatr Soc*. 1985;33:13-18.

PAD Presentation

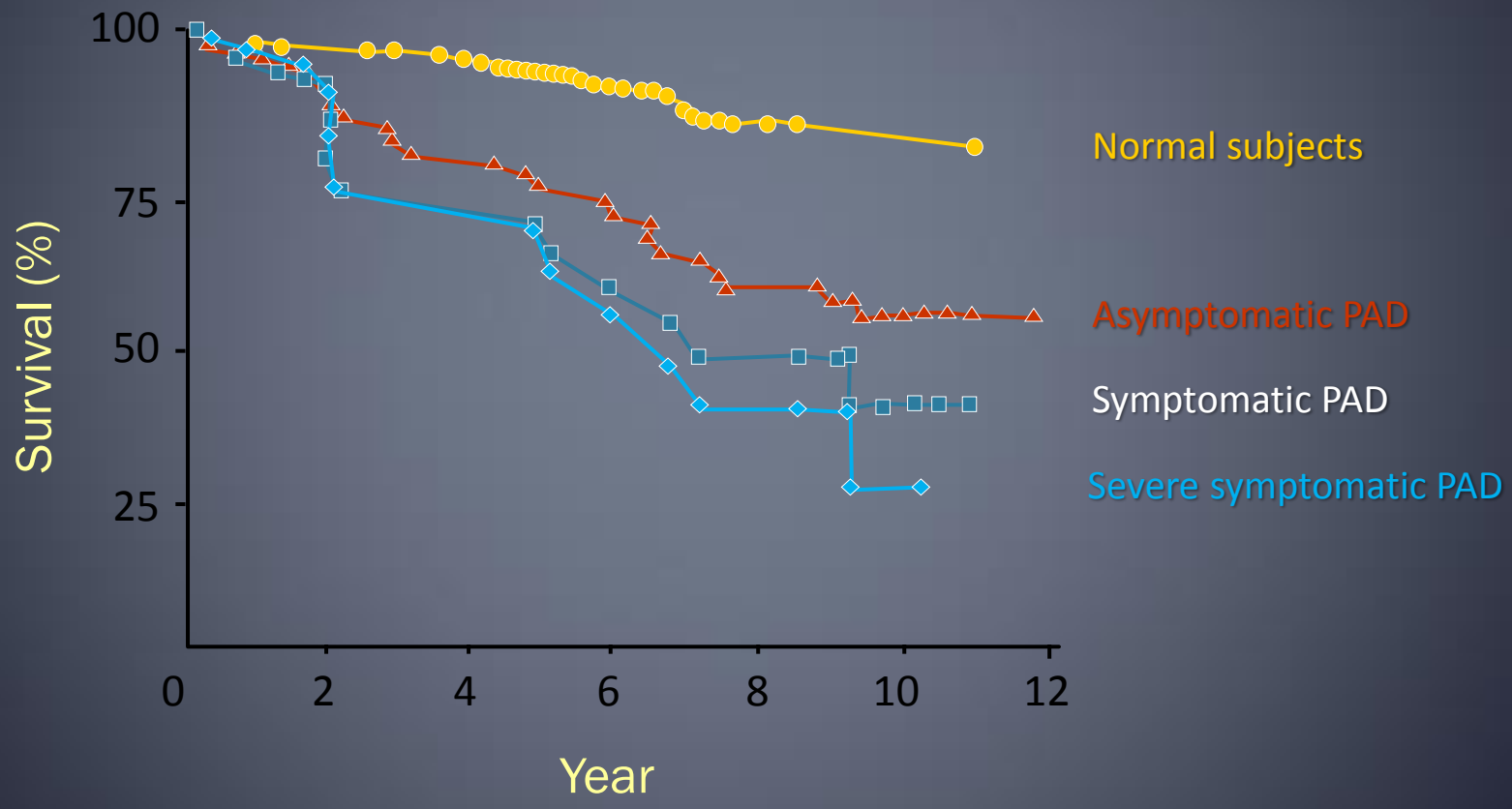


Cardiovascular Events with PAD



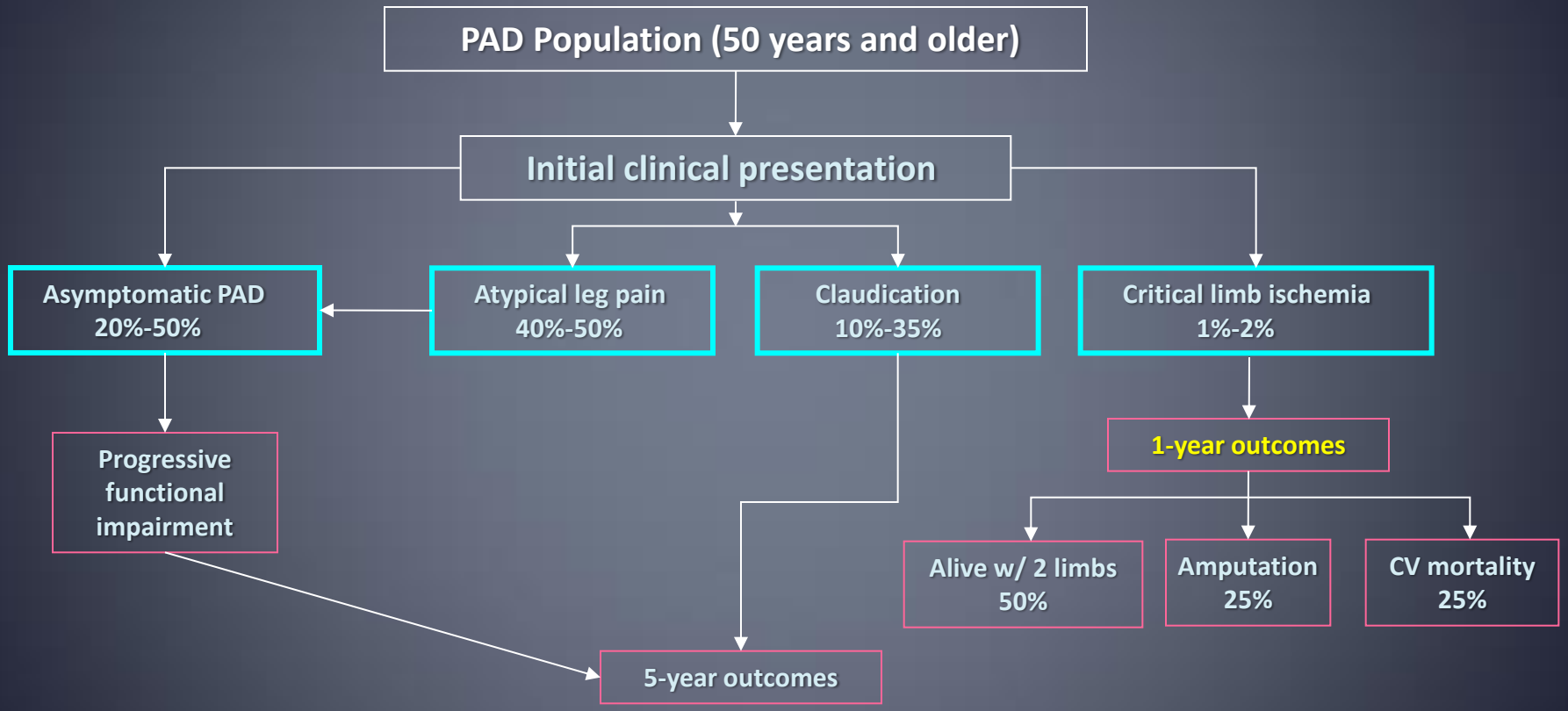
1. Kannel WB. *J Cardiovasc Risk*. 1994;1:333-339.
2. Criqui MH et al. *N Engl J Med*. 1992;326:381-386.

Prognosis: Survival in Patients With PAD



Criqui MH et al. N Engl J Med. 1992;326:381-386.

Natural History/Presentation of PAD



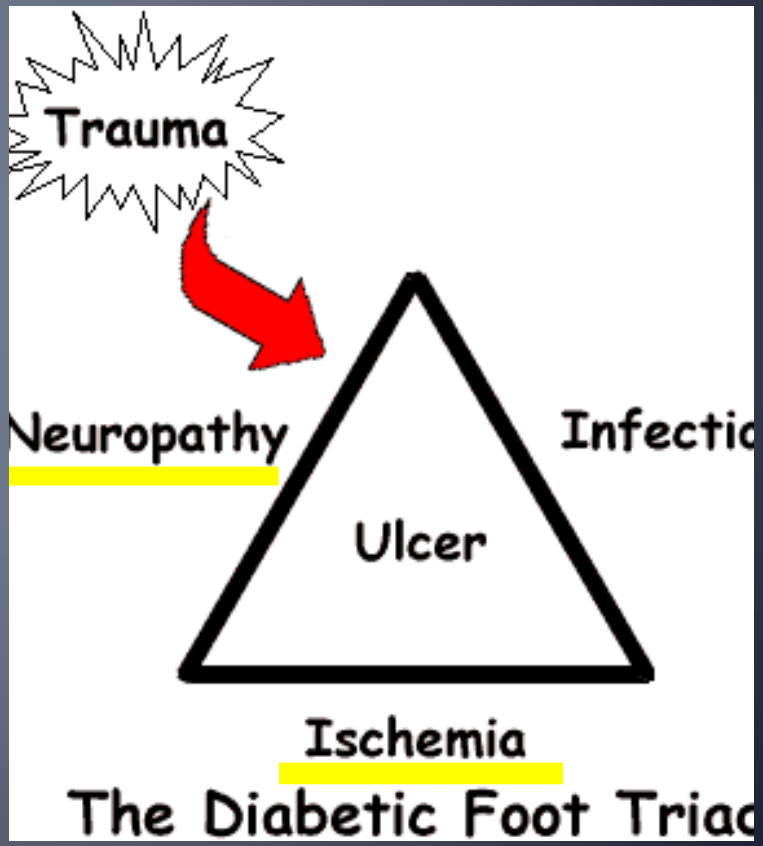
Hirsch AT, et al. Circulation. 2006;113:e463-654.

Clinical Classification of PAD

Fontaine		Rutherford		
Stage	**Clinical**	**Grade**	**Category**	**Clinical**
I	Asymptomatic	0	0	Asymptomatic
IIa	Mild claudication	I	1	Mild claudication
IIb	Moderate to severe claudication	I	2	Moderate claudication
		I	3	Severe claudication
III	Ischemic rest pain	II	4	Ischemic rest pain
IV	Ulceration or gangrene	III	5	Minor tissue loss
		III	6	Major tissue loss

Clinical Definition of CLI?

- Ischemic rest pain
- Ischemic ulcer
- Failure to heal wounds
- Gangrene



CLI

- Ischemic Rest Pain
  - Due to inadequate flow to match resting metabolism
  - Constant pain
  - Worsened by elevation (e.g. bedtime, sleep)
  - Improved with dependent position
    - e.g. Hanging foot over side of bed
  - *Limb threatening*

CLI

- Ischemic Ulceration
  - Inadequate flow to preserve cutaneous integrity
  - Most frequent sites
    - Over ‘contact’ areas on feet and toes
  - Can be quite painful
  - *Definitely limb threatening*

CLI

Gangrene

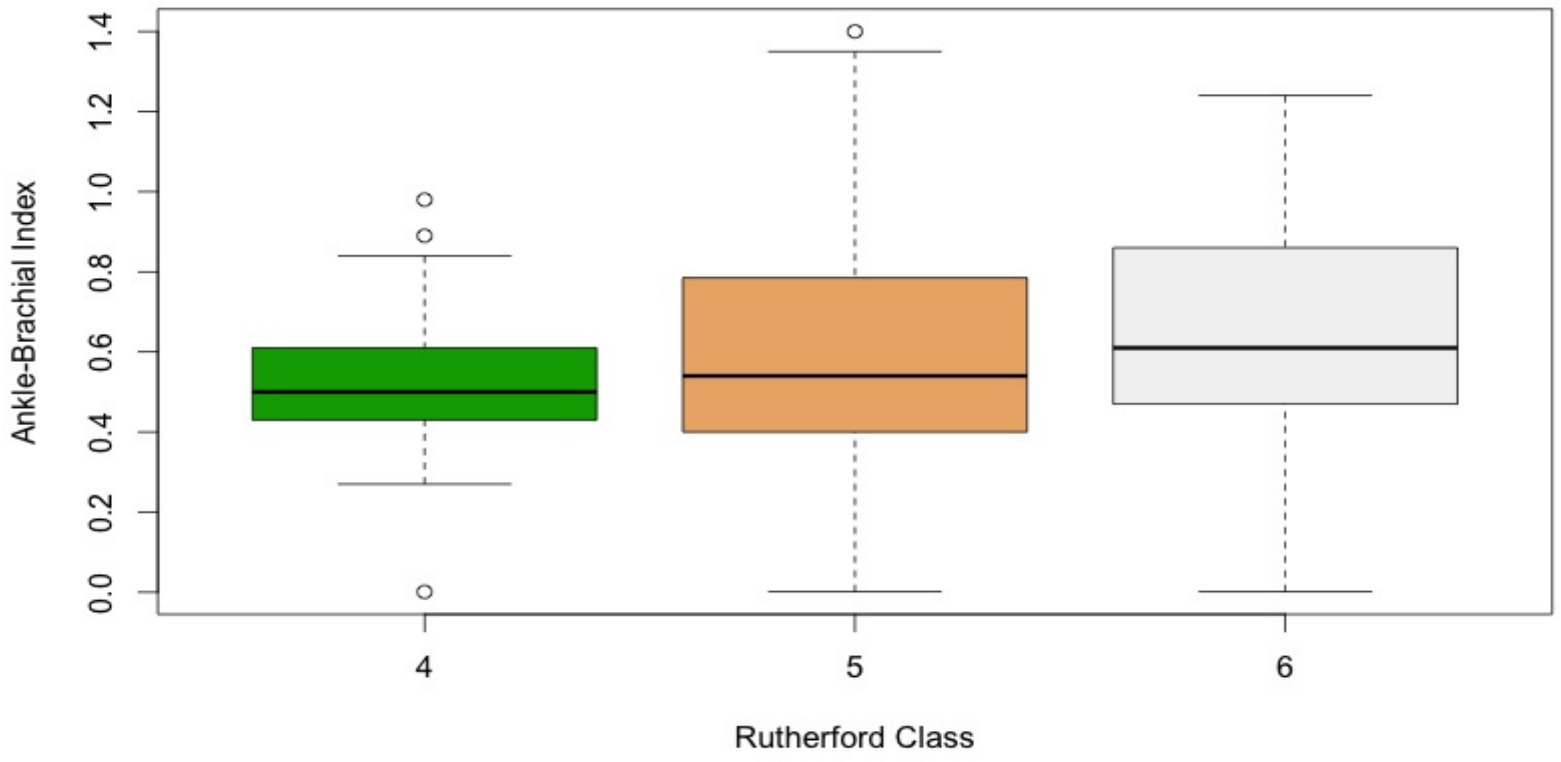
- Essentially dead tissue
  - Dry gangrene - mummified tissue (‘scab’)
    - Not threatening in and of itself
  - Wet gangrene - infected necrotic tissue
    - Acutely limb and life threatening
    - *Surgical emergency*

CLI - Hemodynamic Definition?

- Ankle Pressure < 50-70 mmHg
- Toe Pressure < 30-50 mmHg
- TcPO2 < 30-50 mmHg

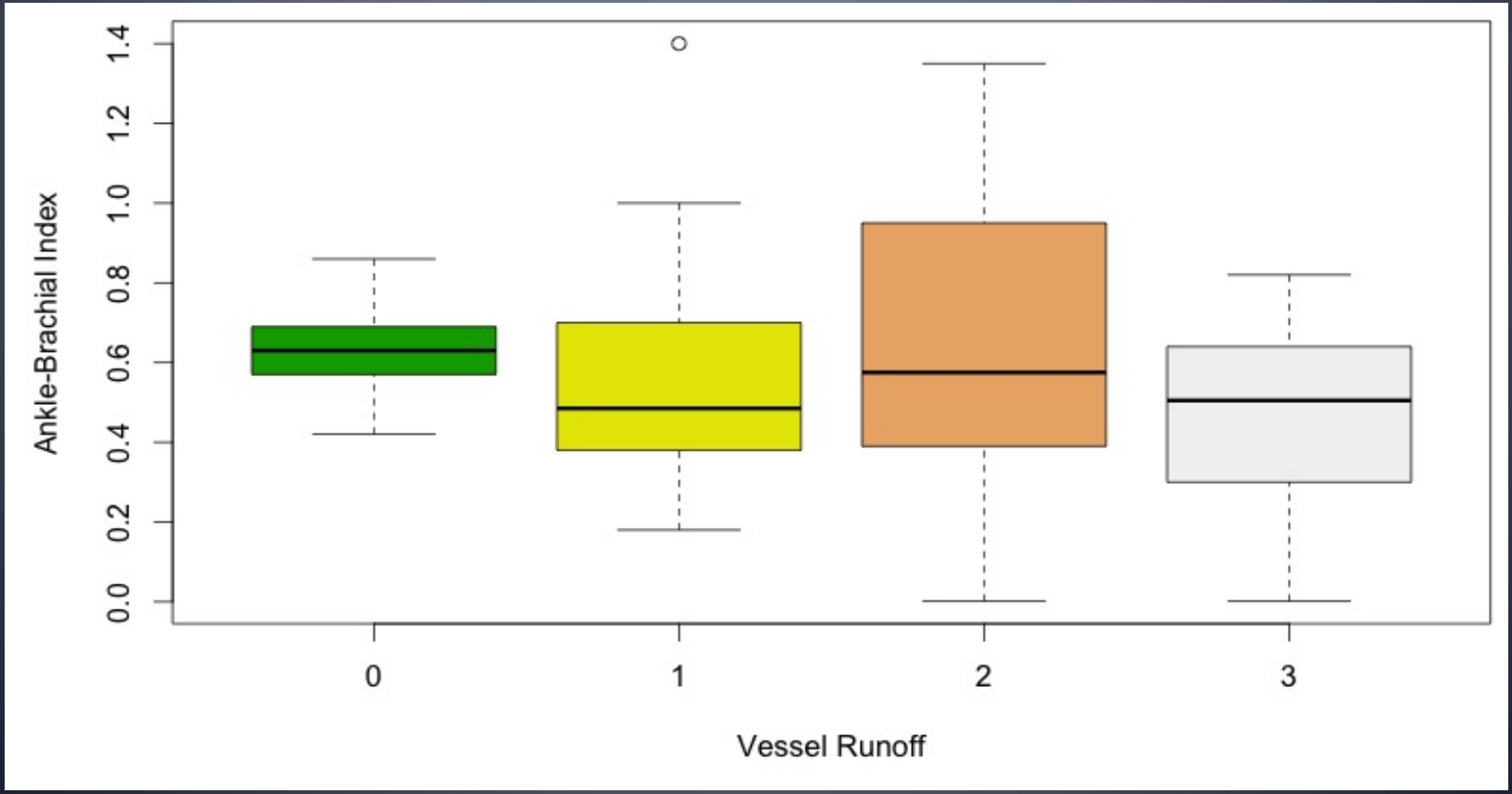
Validation of the relationship between ankle–brachial and toe–brachial indices and infragenicular arterial patency in critical limb ischemia

Matthew C Bunte[1], Jessen Jacob[2], Benjamin Nudelman[1] and Mehdi H Shishehbor[1]



Validation of the relationship between ankle–brachial and toe–brachial indices and infragenicular arterial patency in critical limb ischemia

Matthew C Bunte[1], Jessen Jacob[2], Benjamin Nudelman[1] and Mehdi H Shishehbor[1]

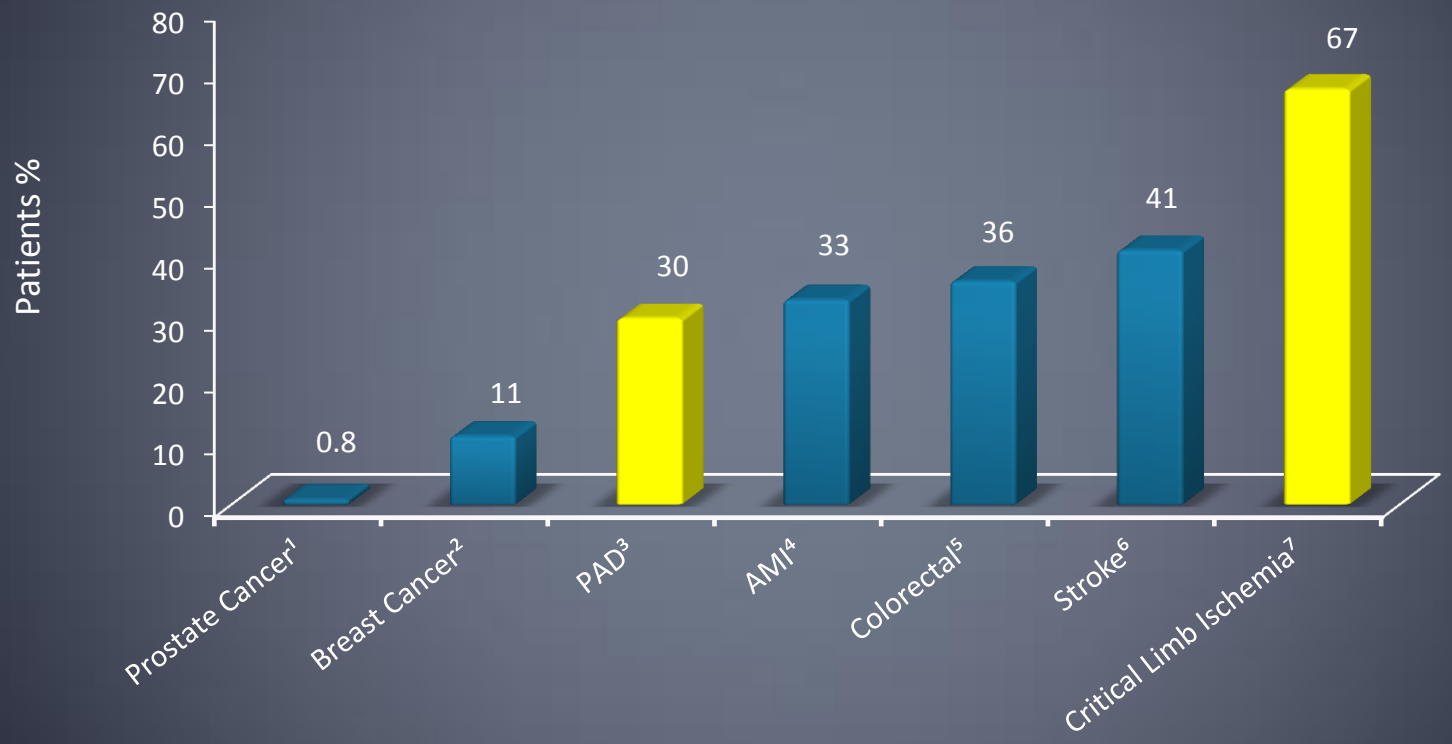


CLI
Prevalence

- **PAD affects 8-12 million people in the U.S.[1]**
- **Up to 2 Million with Critical Limb Ischemia (CLI)[2]**
  - **"The rule of Quarters"[3]**
    - **Within one year of CLI diagnosis:**
      - **25% will resolve**
      - **25% will have persistent CLI and ulceration**
      - **25% will undergo major amputation**
      - **25% will die**
  - **150,000 Amputations Yearly Due to CLI[2]**

1.US Department of Health & Human Services National Institute of Health August 2006.
2.Jaff, MR, Biamino G; "Conquering Critical Limb Ischemia" ;Endovascular Today, February 2004, Volume 3, No. 2
3. Rundback JH. Vascular Disease Management 2013; 10: 152-158

5-Year Mortality Rates for PAD and CLI



1. SEER Stat Fact Sheets: Prostate. National Cancer Institute Web site. http://seer.cancer.gov/statfacts/html/prost.html. Accessed April 24, 2013.
2. SEER Stat Fact Sheets: Breast. National Cancer Center Institute Web site. http://seer.cancer.gov/statfacts/html/breast.html. Accessed April 24, 2013.
3. Caro J., et al; The morbidity and mortality following a diagnosis of peripheral arterial disease: Long-term follow-up of large database. BMC Cardiovasc Disorders. 2005; 5: 14.
4. 4. Weitz JI, Byrne, J, Clagett GP, et al. Diagnosis and Treatment of Chronic Arterial Insufficiency of the Lower Extremities: A Critical Review *Circulation*.1996;94:3026-3049.
5. SEER Stat Fact Sheets: Colon and Rectum. National Cancer Institute Web site. http://seer.cancer.gov/statfacts/html/colorect.html. Accessed April 24, 2013.
6. Hartmann A, Rundek T, Mast H, et al. Mortality and causes of death after first ischemic stroke: the Northern Manhattan Stroke Study. *Neurology*. 2001;57:2000-2005.
7. Ljungman C, et al.*Eur J Vasc Endovasc Surg*. 1996;11:176-182.

If PAD/CLI Progresses, it may lead to AMPUTATION

- Average ***days in hospital*** – 71 days/year[1]
- ***Readmission*** rates – 74% at 1 year[2], 19.5 times/ year[1]
- ***Follow-up care*** in other institutions – 76% go to in-patient rehabilitation and skilled nursing facilities after discharge from the hospital[3]
- ***Depression*** – 32 to 34% suffer from depression symptoms[4]
- ***Ambulation*** – 60-80% can't walk[5]
- ***Contralateral amputation*** – 40%[2]
- ***2-year mortality*** rate – 40%[6]

1. 1. Henry AJ, et al. J Vasc Surg 2013;57:784-90.
2. Dillingham TR, et al. Arch Phys Med Rehabil. 2005;86:480-6.
3. Dillingham TR, et al. PM R 2011;3:336-344
4. Desmond DM and MacLachlan M. J Pain Symptom Manage 2006;31:362—368
5. Cruz CP, et al. AM J Surg. 2003;186:449-54.
6. Gardner SJ, et al. Endovasc Today 2011;10:38-44

CLI & Amputations

4M People with Critical Limb Ischemia

25% Die within 1 yr of CLI onset

30% will get amputation

Death within 1 year

Of those with an amputation… Nearly half will die within 1yr

Death Amputation

1. Nehler et al., Epidemiology of peripheral arterial disease and critical limb ischemia in and insured national population. *J Vasc Surg*, 2014; 60(3): 686-695
2. Misra et al., Proceedings from the Society of Interventional Radiology Research Consensus Panel on Critical Limb Ischemia. *J Vasc Interv Radiol*. 2013; 24(4): 451-458

CLI and Amputations

Amputations are prevalent for CLI treatment…

40%

of CLI patients will require a major amputation within 6 months of diagnosis[1]

150,000

Amputations per year due to CLI[2]

Amputations continue to be a primary treatment…

67%

of Medicare CLI patient amputations were the first procedure[2]

71%

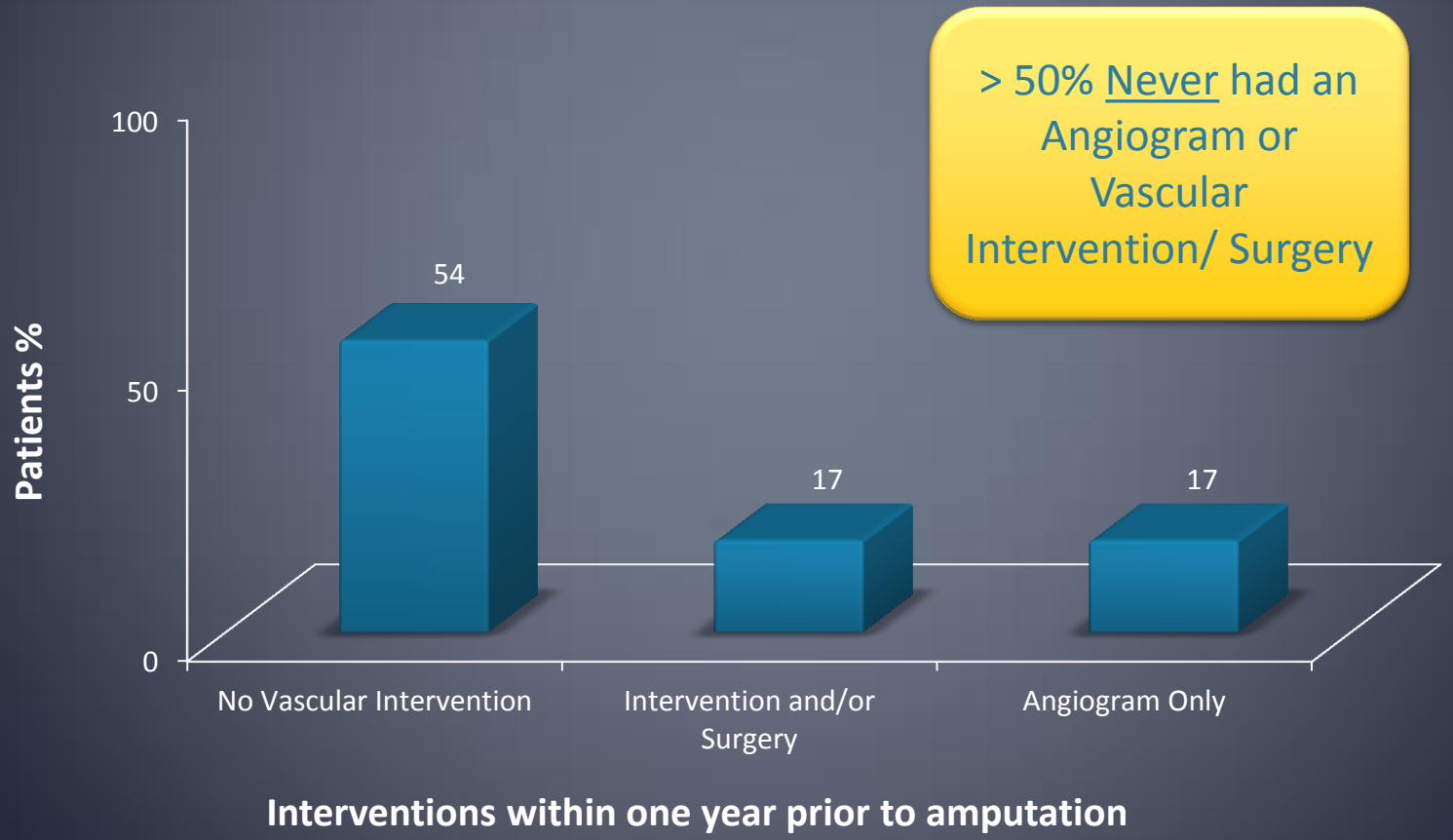
of major amputations* had no initial revascularization option offered[2]

**Major amputations as defined by amputation above the foot*

1. Hirsch AT, et al., ACC/AHA 205 Guidelines for PAD. Circulation. 2006; 113: 463-654
2. Jaff MR, Biamino G; Conquering Critical Limb Ischemia. Endovascular Today. 2004; 3:44-48.
3. Yost, ML. Cost-Benefit Analysis of Critical Limb Ischemia in the Era of the Affordable Care Act. Endovascular Today. May 2014; 29-36.

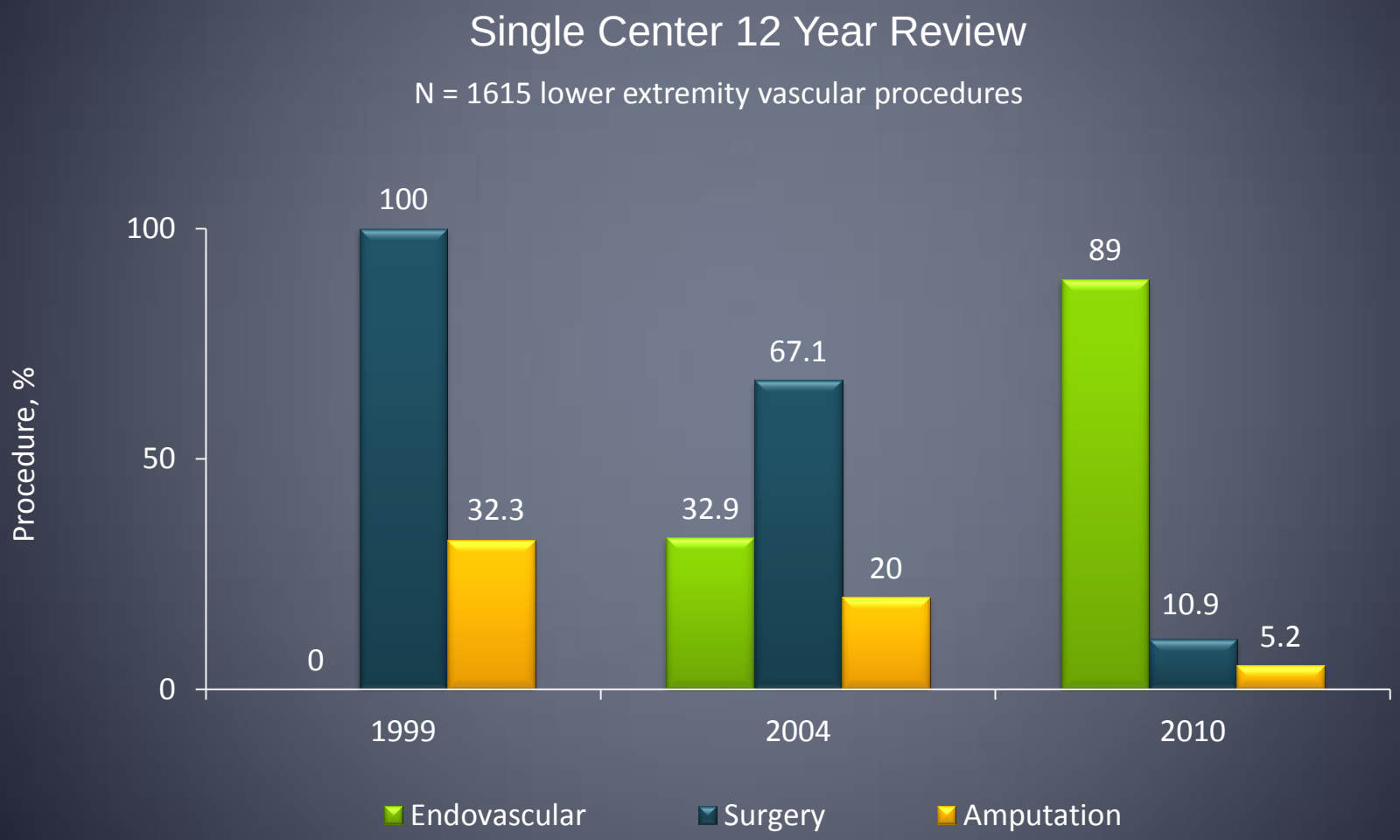
Angiograms and Revascularization are Underutilized Prior to Amputation[1]

20,464 MEDICARE Patients with PAD who underwent major leg amputations between 2003-2006.



Goodney PP, Travis LL, Nallamothu BK, et al. *Circ*: Cardiovasc Qual Outcomes. 2012;5:94-102.

Amputation Rates Decrease as Revascularization Rates Increase



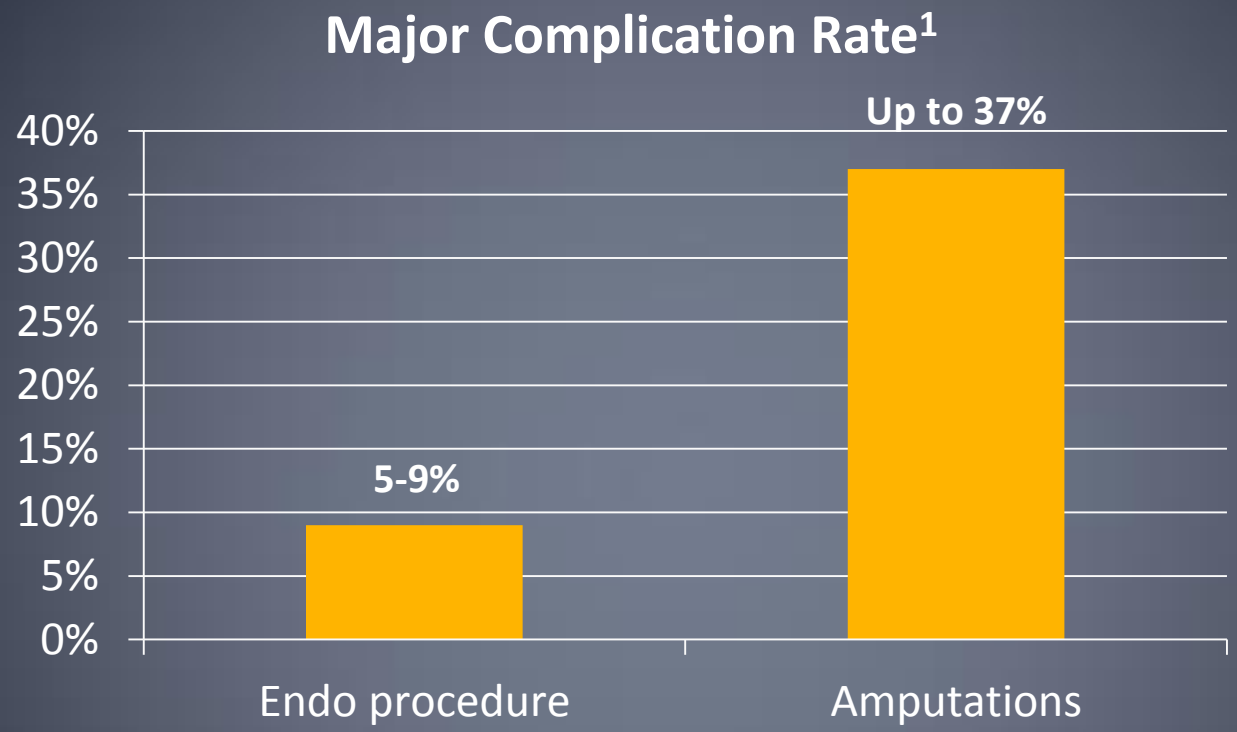
Balar NN, Dodla R, Oza P, et al. Endovascular Versus Open Revascularization for Peripheral Arterial Disease. *Endovascular Today.* 2011:61-64

Mortality & Morbidity of Amputations and Endovascular Interventions

Metric	Amputation[1,2]	Endovascular[1,3,4,5]
Perioperative mortality – ATK	5-10%	1-3%
Perioperative mortality – BTK	15-20%	
Major complications	20-37%	5-9%
Most frequent complications	DVT: 13-26% Infection: 10-30% Cardiac: 9-10%	Bleeding: 5-7% Infection: 1-4% Cardiac: 1%
In-hospital revision rate	ATK: 12% BTK: 20%	Revised with: Endo: 1% Bypass: 9% Amputation: 4%

1. Yost ML. Endovasc Today. 2014;May:29-36.
2. Isner JM, et al. Circulation. 1995; 91: 2687-2692
3. BASIL Trial participants. Lancet 2005; 366: 1925-34
4. Nowygrod R, et al. J Vasc Surg 2006; 43: 205-16.
5. Egorova N, et al. J Vasc Surg 2010; 51(4): 878-85.

What are the Economic consequences of amputations?



- Average hospital cost for wound infection = $19-$42K[1]
- Amputees are readmitted an average of 19.5 times/year, with over an average of 71 days spent in the hospital annually[2]

1. Yost, ML. Cost-Benefit Analysis of Critical Limb Ischemia in the Era of the Affordable Care Act. *Endovascular Today*. May 2014; 29-36.
2. Henry AJ, et al. J Vasc Surg 2013;57:784-90.

Health Care Economics

Day of Case

- Lab time to manage adverse event
- Bail-out stent rate: $1,070-$2,660/each[1]

Durability

- Re-intervention rate at $15,000 – 27,000 each[2]

Wound Healing

- Average cost to heal chronic wound = $17,096[3]

Amputation

- Amputation cost = $20,000 - $60,000[4]
- Annual cost of follow-up care = $49,000[5]
- Annual cost of nursing home: $70,000 – 100,000[5]

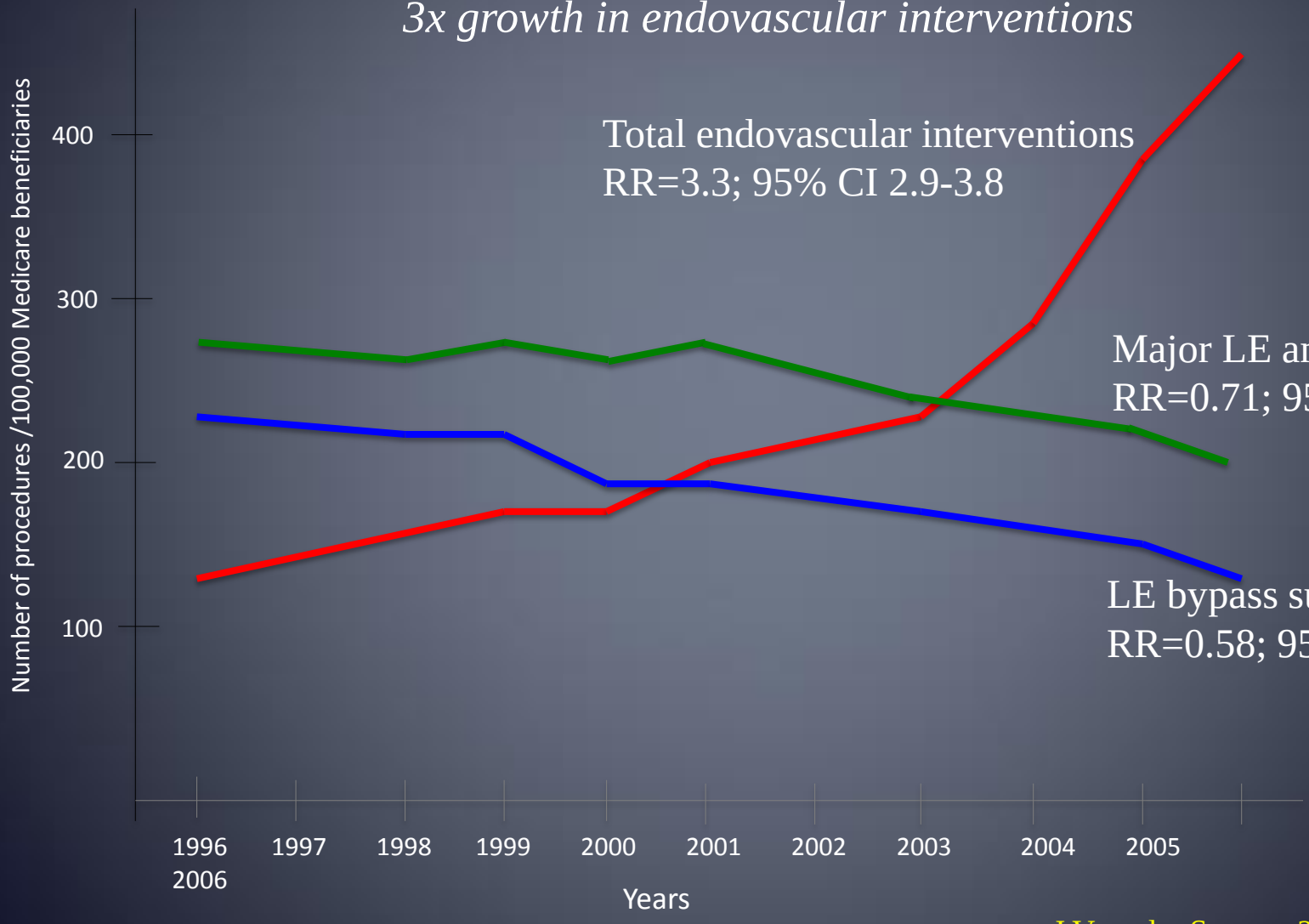
1. MRG Report; US Markets for Peripheral Vascular Devices 2011.
2. Jaff MR, Cahill KE, Yu AP, et al. Clinical outcomes and medical care costs among medicare beneficiaries receiving therapy for peripheral arterial disease. *Ann Vasc Surg.* 2010 Jul;24(5):577-87.
3. **Harrington C, Corea J, Zagari M, et al. A Cost Analysis of Diabetic Lower Extremity Ulcers Diabetes Care, 2000;23(9):1333-38.**
4. **Ollendorf DA, Kotsanos JG, Wishner WI, et al. Potential Economic Benefits of Lower Extremity Amputation Prevention in Diabetes. Diabetes Care, 1998: 21(8):1240-5.**
5. **Allie DE, Hebert CJ, Ingraldi A, et al. 24 Carat Gold, 14 Carat Gold or Platinum standards in the treatment of Critical Limb Ischemia: Bypass or Endovasc Intervention? J Endovasc Ther. 2009, 16.**

So, in Summary

- Annual cost of post amputation care is approximately $49,000, per patient
- Nursing home care after amputation is approximately $100,000 per patient
- *Annual cost of care and follow up, post limb salvage: $600*

Endovascular Intervention, Surgery & Amputation Trends: 1996-2006

3x growth in endovascular interventions



J Vascular Surgery 2009; 50:54-60

Endovascular Techniques

Subintimally dissect it

Stent

CLI

Sand

Laser

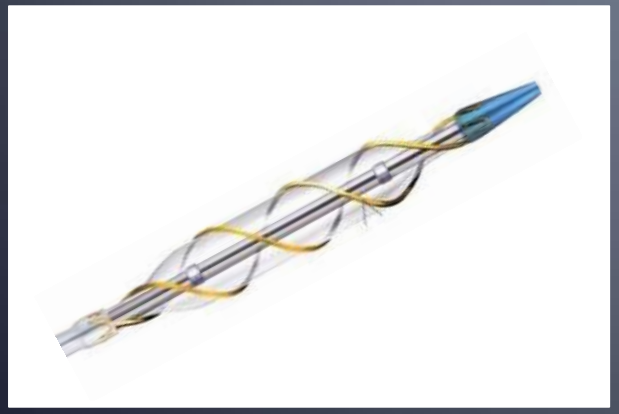
Freeze

Balloons

POBA

Cutting Balloon

Angiosculpt



PolarCath Balloon

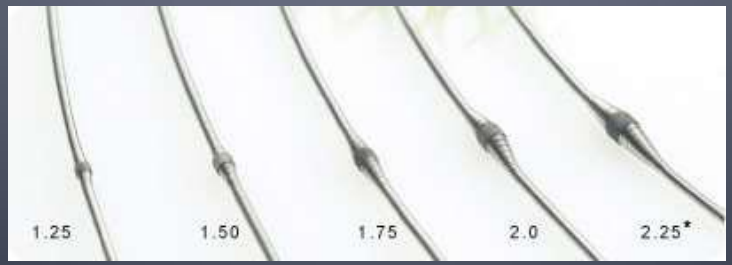
Atheterctomy

Turbo-Laser

Rotablator

Silver Hawk

CSI 360 Orbital Atherectomy



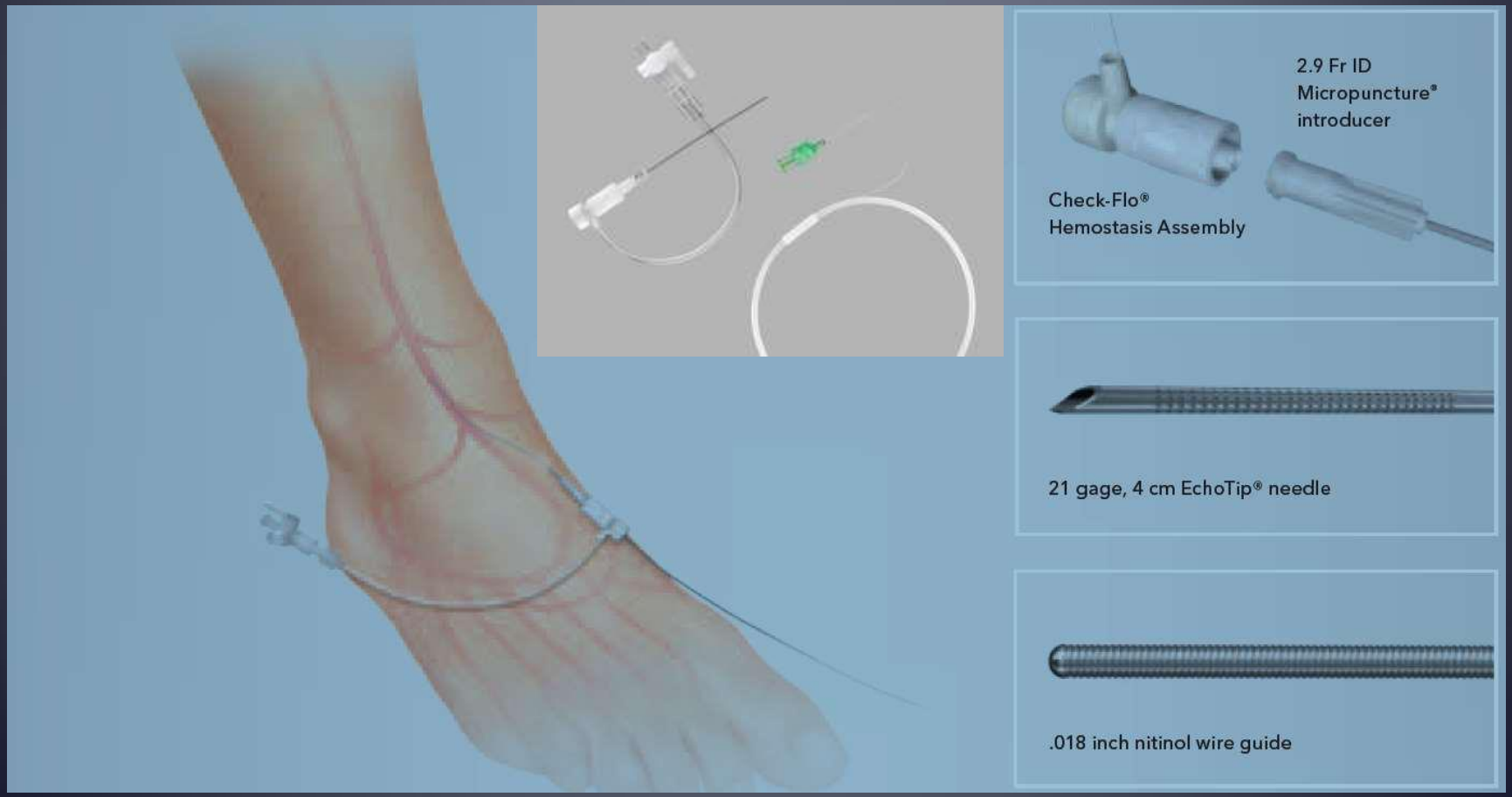
Drugs

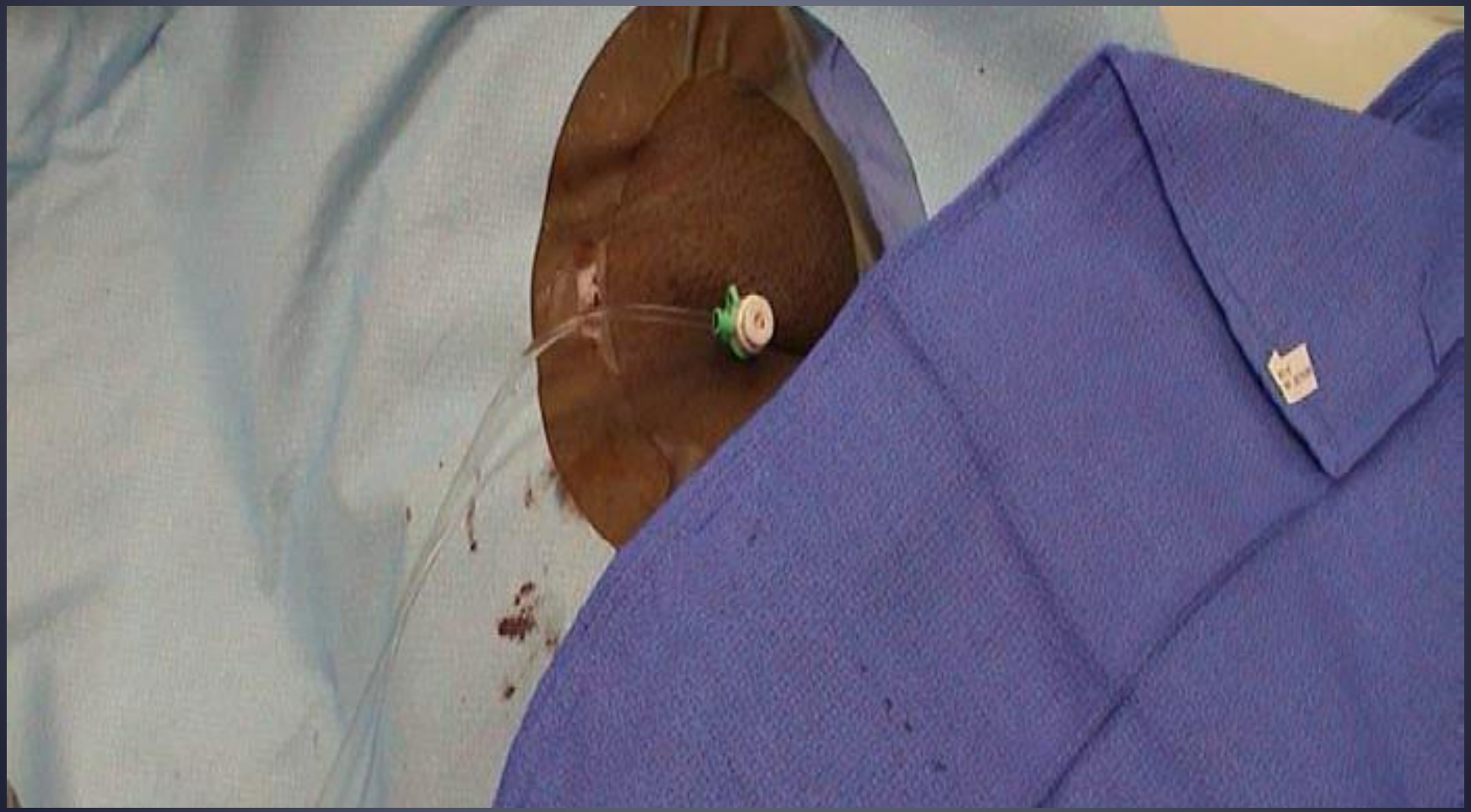
Drug Eluting Stents

Drug Eluting Balloon

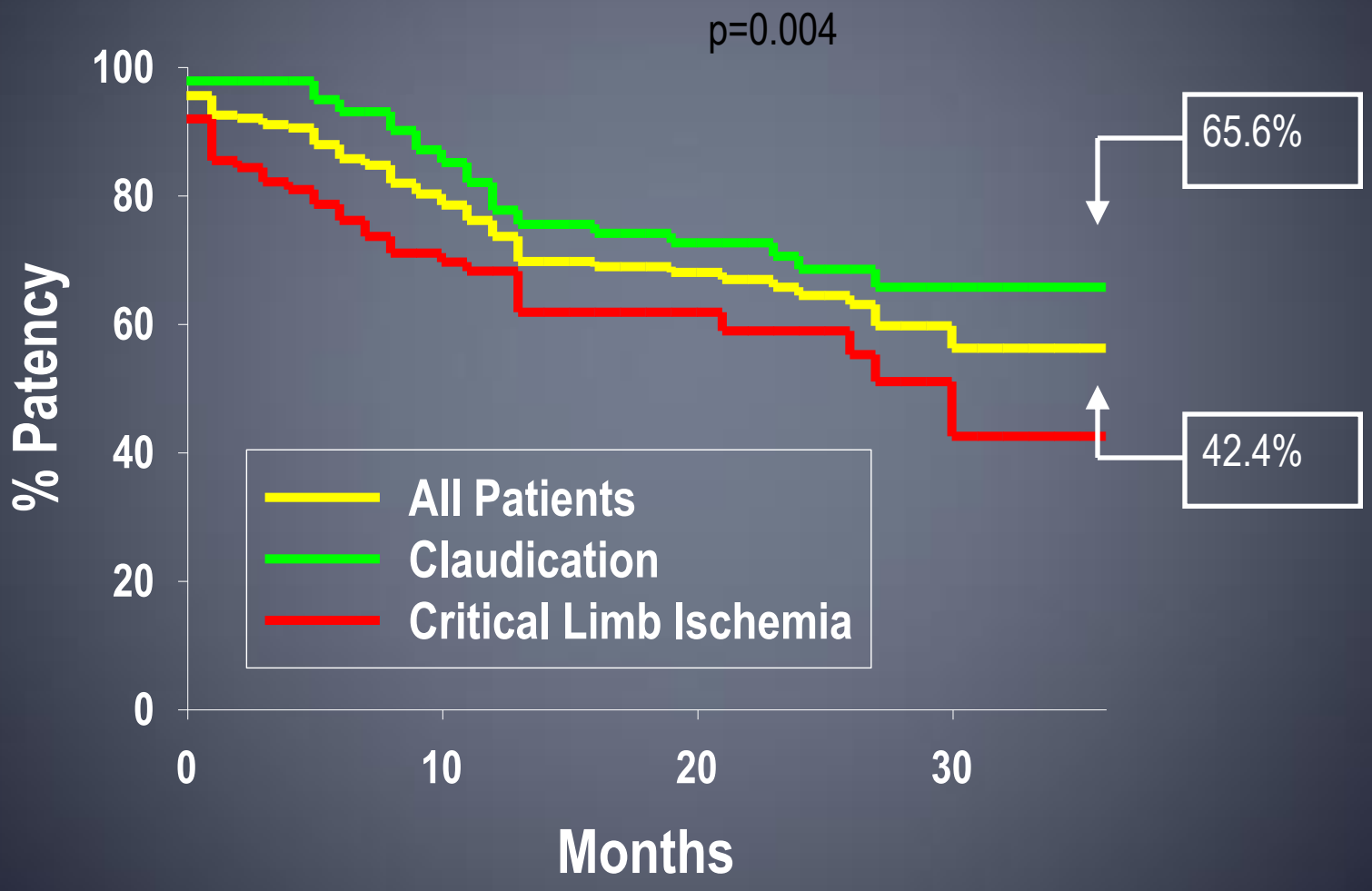
Retrograde Access

Pedal Access Tools

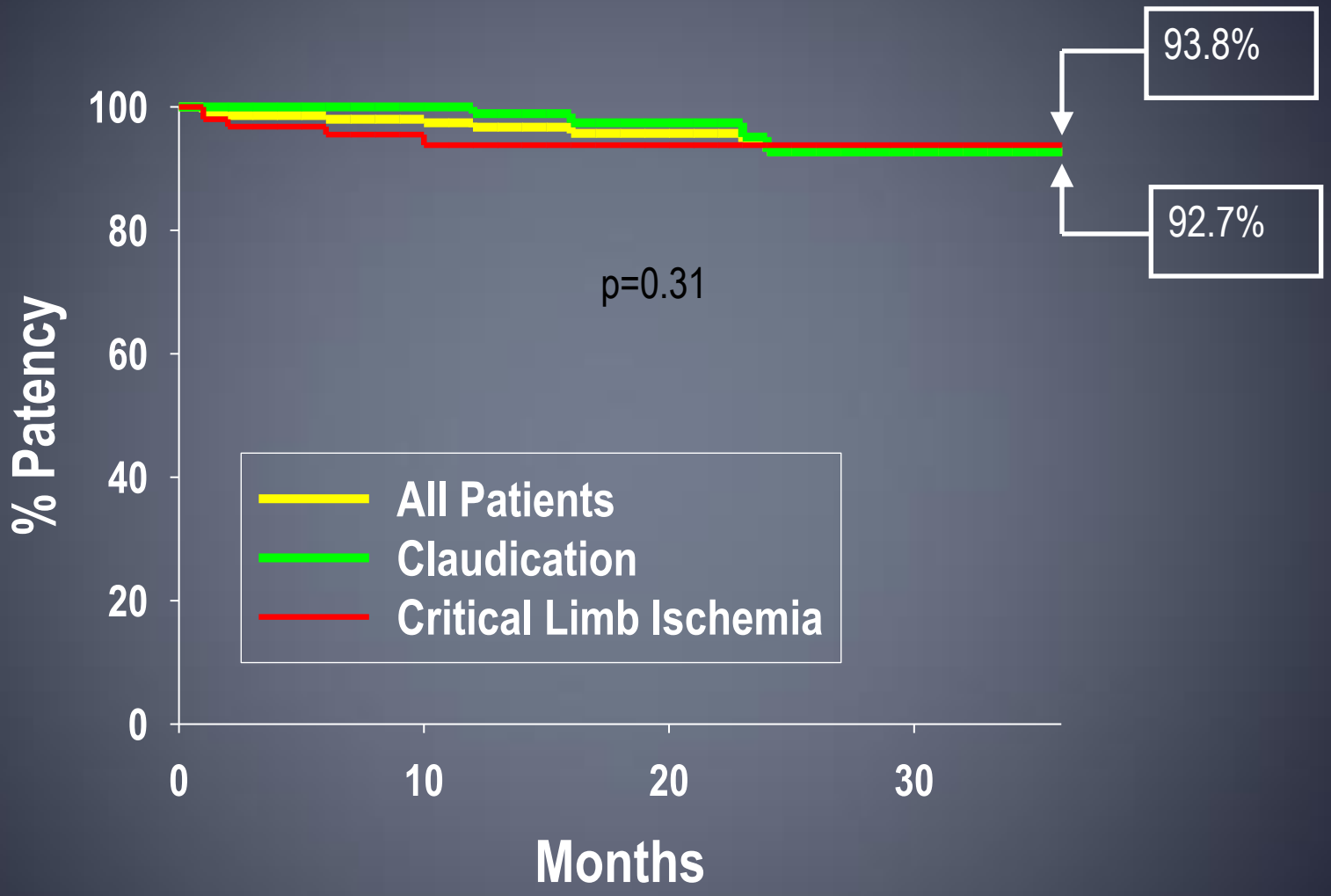


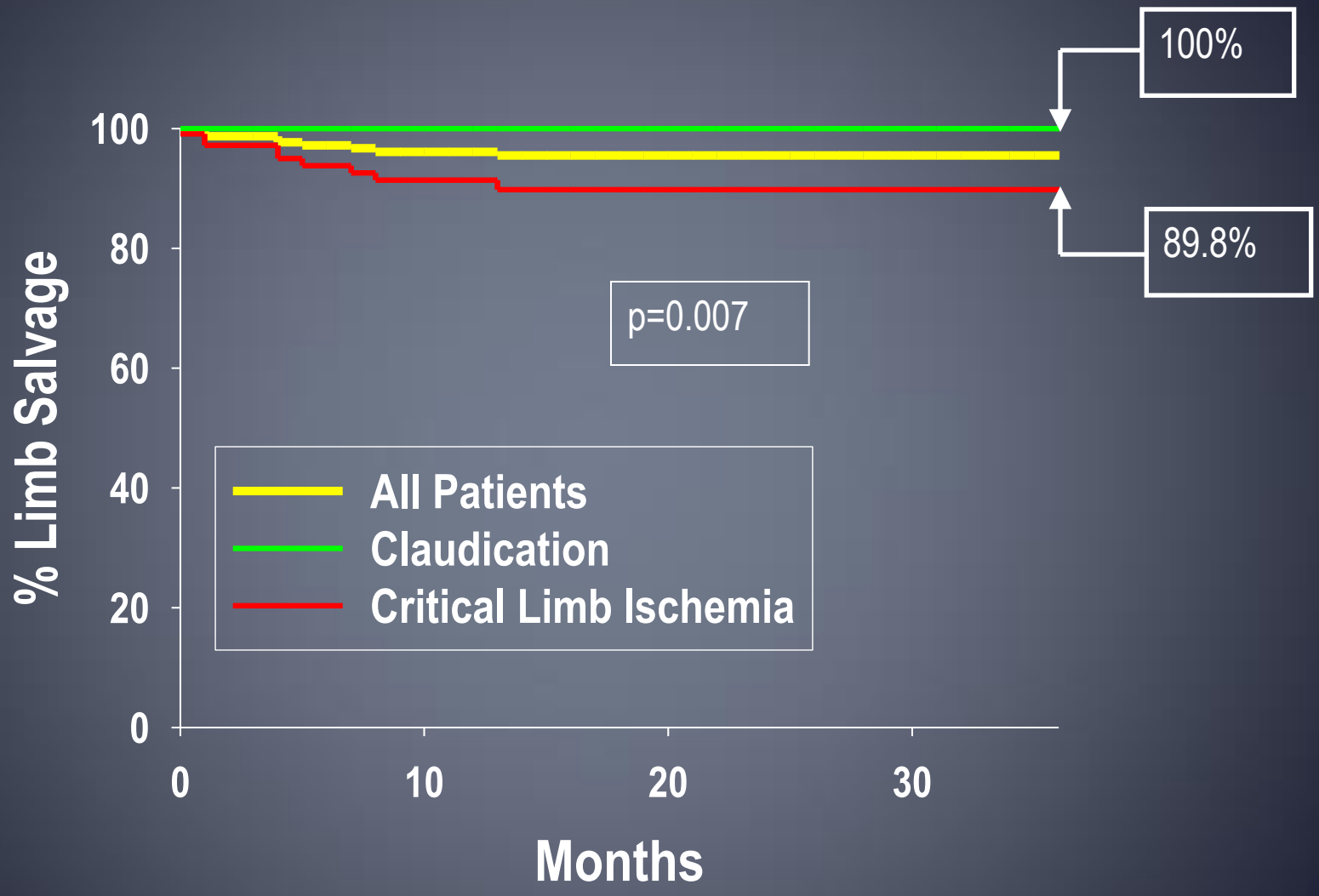
POBA-Primary Patency



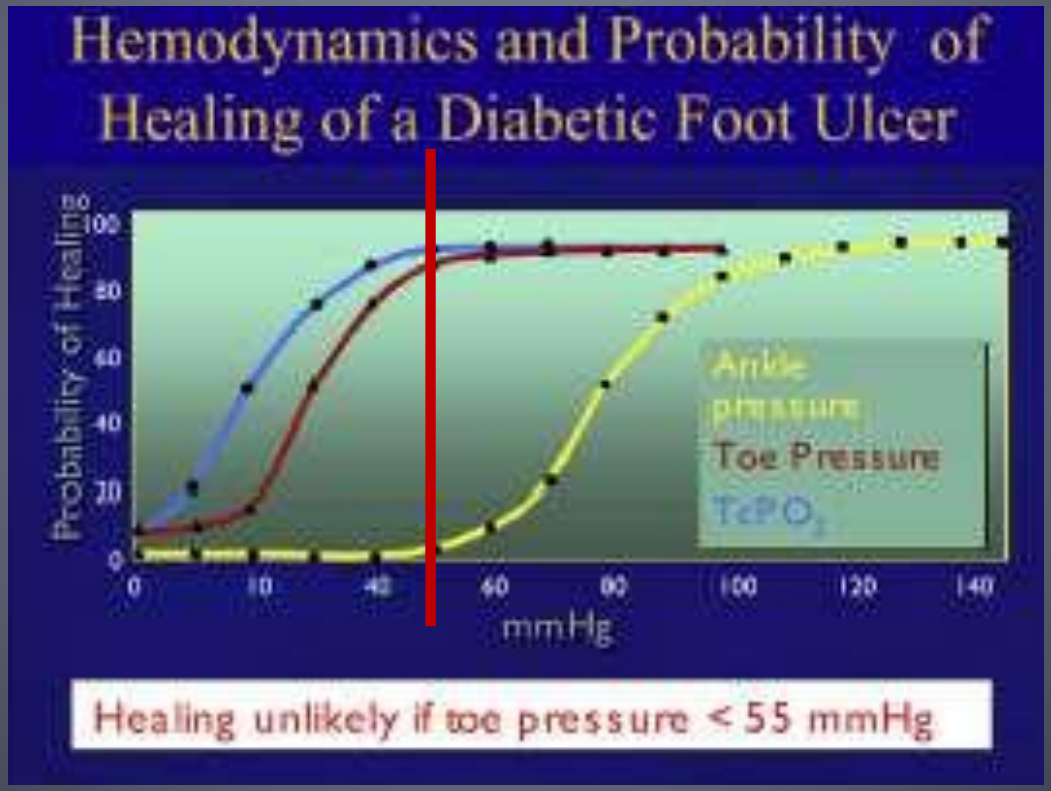
POBA-Assisted Patency



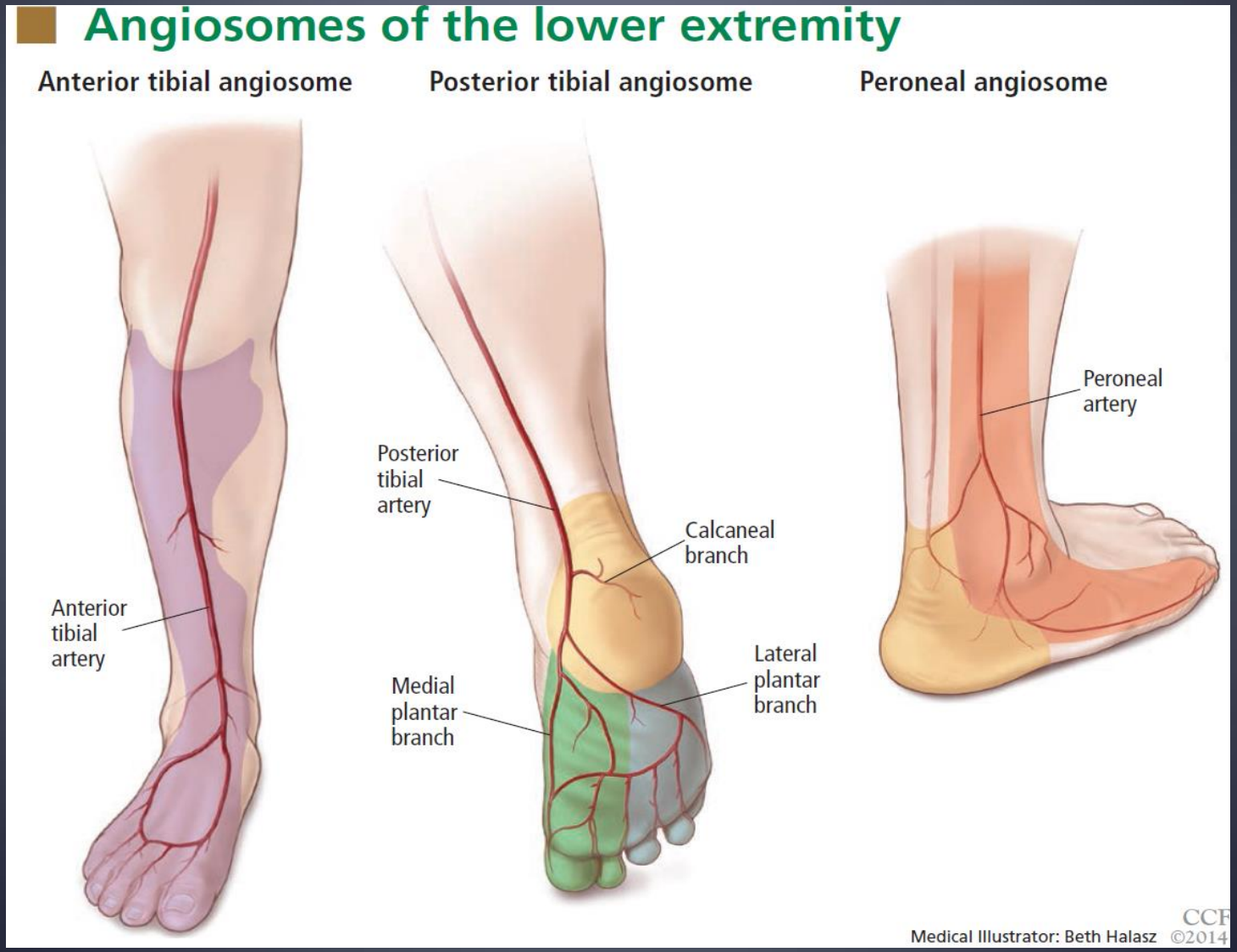
POBA-Limb Preservation



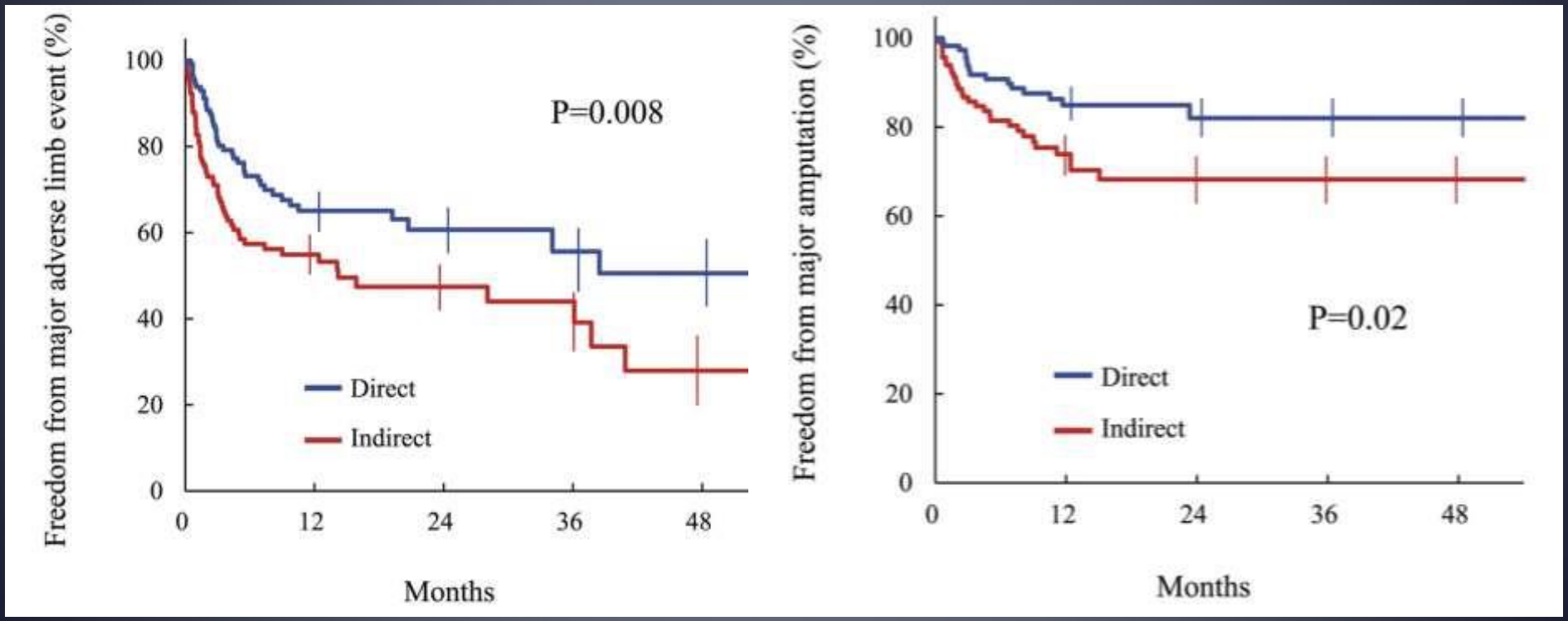
Importance of Restoring Perfusion



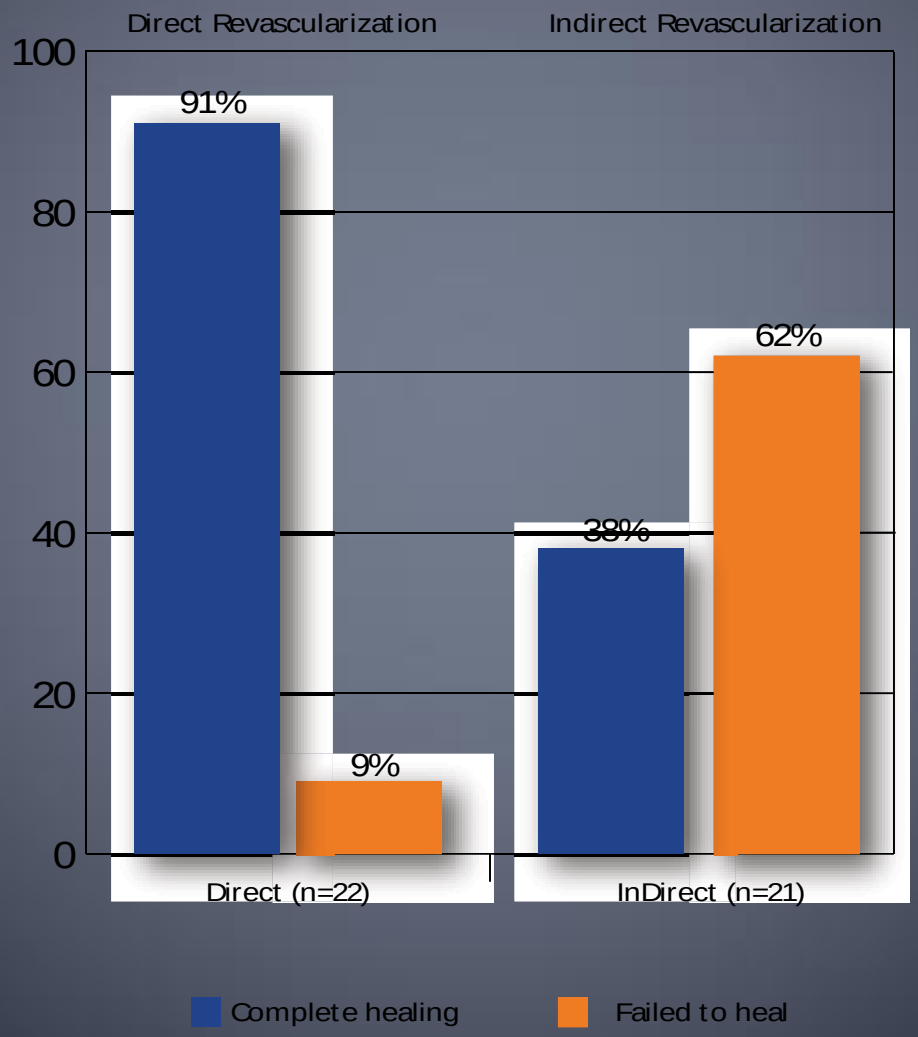
Angiosome Concept



Freedom from Amputation



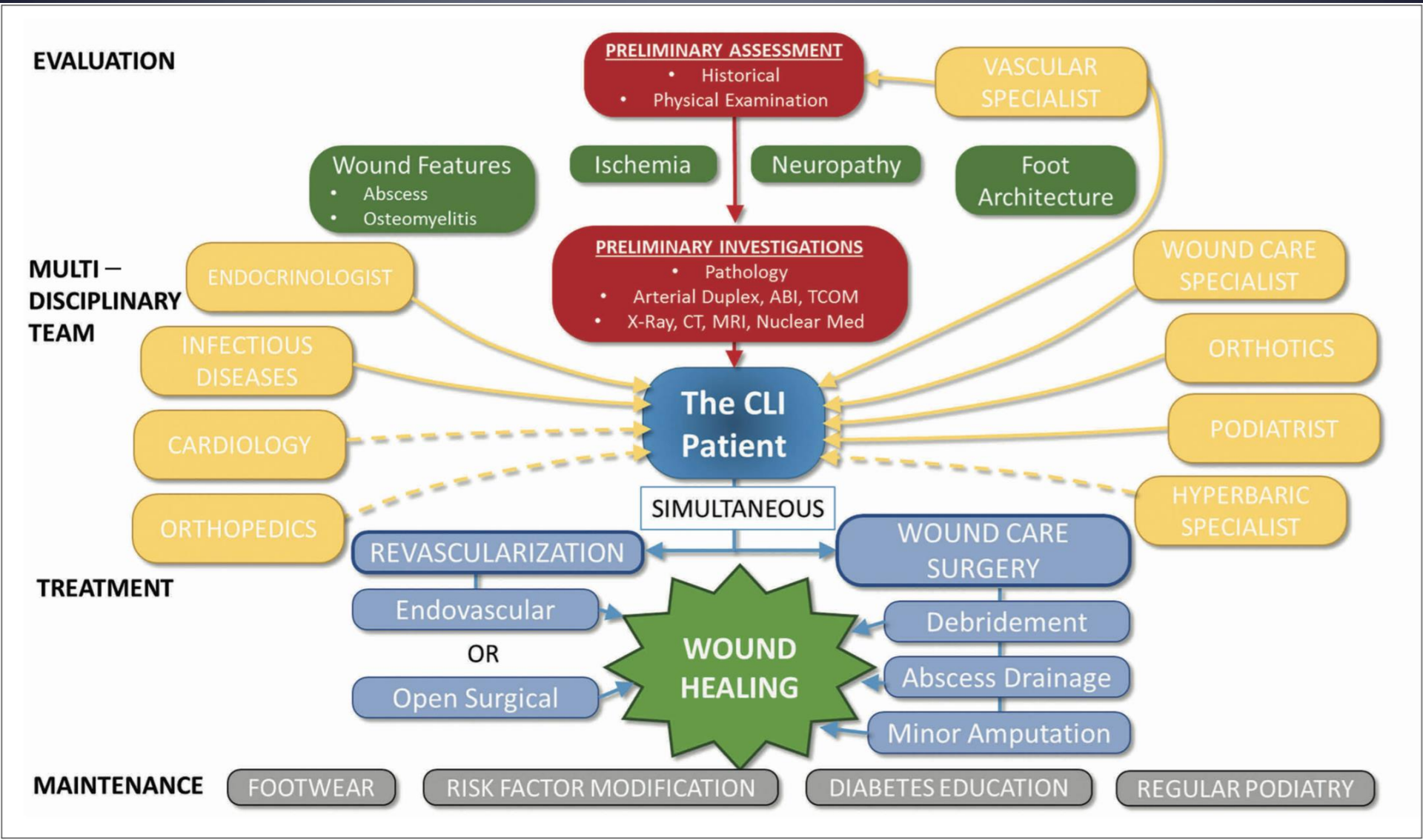
Complete Healing



Conclusion

- CLI patients are at the highest risk for adverse cardiovascular events
- Early detection and referral of CLI patients are keys in success to prevent major amputation and preserve limbs
- Functional studies (ABI, TBI) are helpful, however do not correlate with the clinical stage of CLI or vessels occluded
- Care for CLI patients should be team-based, with dedicated CLI team.
- Given the excessive morbidity and mortality associated with amputation, the treatment of critical limb ischemia should focus on *revascularization and limb salvage* rather than amputation.

Care Model for CLI
"CLI Team"



Thank You

Questions???