2024 MID-ATLANTIC CONFERENCE

12th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2024

Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 18-20

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Classifying PAD: Who Needs an Intervention and When?

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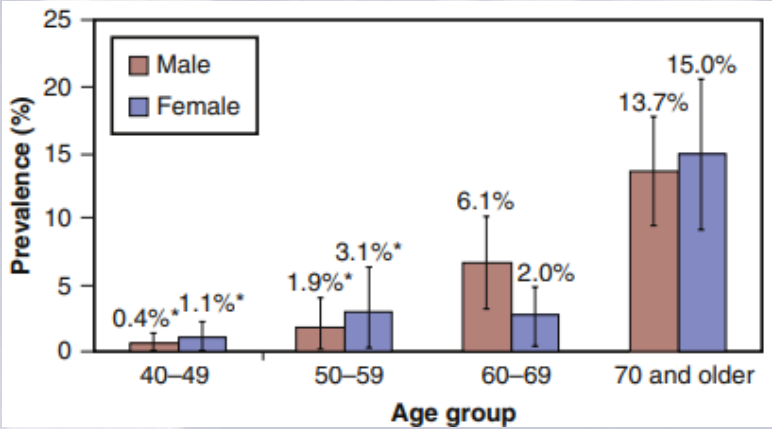
Peripheral Arterial Disease (PAD)

- Estimated 8.5 million Americans living with PAD
  - 20% of patients > 80 yrs old
    - Medicare annual incidence of 2.35%
    - Medicare overall prevalence of 10.69%



Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999–2000. Circulation. 2004;110(6):738–743

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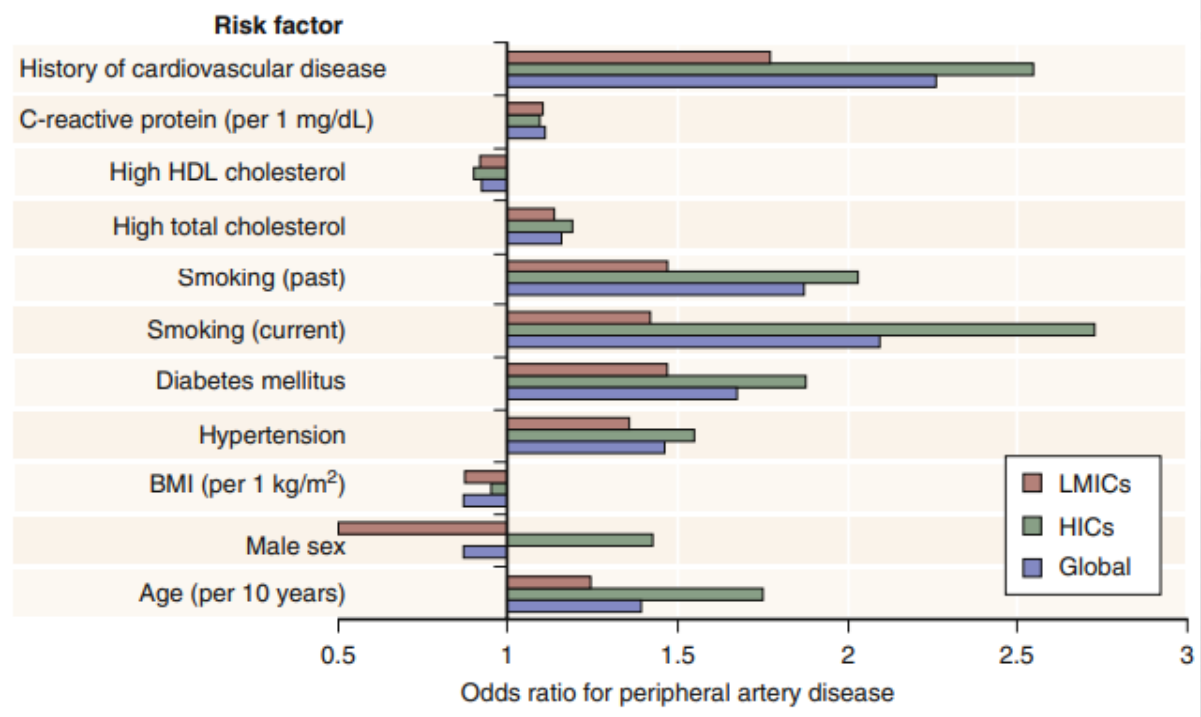
Who is at Risk?



Fowkes FG, Aboyans V, Fowkes FJ, McDermott MM, Sampson UK, Criqui MH. Peripheral artery disease: epidemiology and global perspectives. Nat Rev Cardiol. 2017;14(3):156–170

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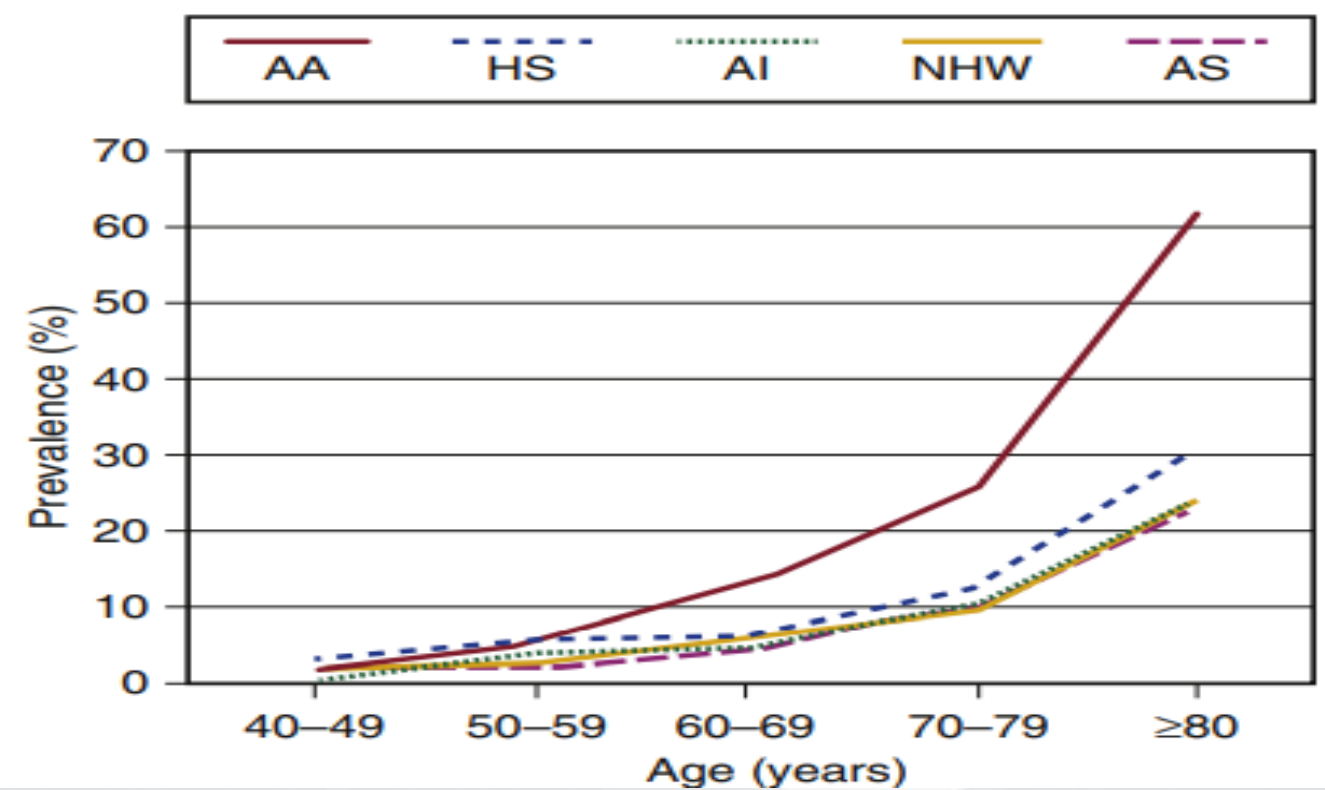
Who is at Risk?



Allison MA, Ho E, Denenberg JO, et al.
Ethnic-specific prevalence of peripheral arterial disease in the United States. Am J Prev Med. 2007;32(4):328–333

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Classification

TABLE 107.1 Stages of Chronic Limb Ischemia

Fontaine Grade	Rutherford Category	Clinical Description	Objective Criteria
I	0	Asymptomatic	Normal treadmill or reactive hyperemia test
IIa[a]	1	Mild claudication	Completes treadmill exercise[b]; AP after exercise >50 mm Hg but at least 20 mm Hg lower than resting value
IIb[a]	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise[b]; AP after exercise <50 mm Hg
III[a]	4	Ischemic rest pain	Resting AP <30–50 mm Hg; ankle or metatarsal PVR flat or barely pulsatile; TP <30 mm Hg
IV	5	Minor tissue loss[c]	Resting AP <50–70 mm Hg; ankle or metatarsal PVR flat or barely pulsatile; TP <40 mm Hg in nondiabetics, <50 mm Hg in diabetics; $tcPO_2$ <30 mm Hg
	6	Major tissue loss[d]	Same as Rutherford 5 (Fontaine IV)

CLTI: **C**hronic **L**imb **T**hreatening **I**schemia

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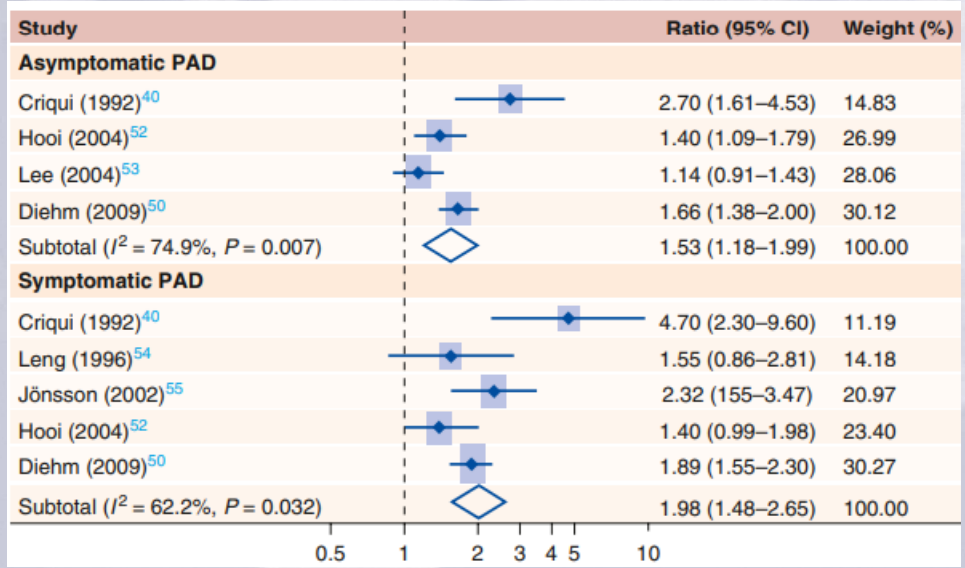
RC 0: Asymptomatic PAD

- The majority of individuals with PAD detected via non-invasive testing are asymptomatic:
  - Lower disease burden, adequate collateralization, limited activity levels
- Still have cardiovascular **mortality** risk and significant functional decline
  - Strongly associated w/ reduced ABI and ABI >1.4



Fowkes FG, Aboyans V, Fowkes FJ, McDermott MM, Sampson UK, Criqui MH. Peripheral artery disease: epidemiology and global perspectives. Nat Rev Cardiol. 2017;14(3):156– 170

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Rutherford 0: Asymptomatic PAD

- Though “asymptomatic” these patients have lower:
  - Physical activity levels
  - Walking velocity
  - 6 minute walk distance
  - Muscle mass
- Estimated 7% (4-11%) will progress to intermittent claudication over 5 years

RC 1-3: Intermittent Claudication (IC)

- IC: clinical syndrome characterized by reproducible leg pain brought on my exercise and relieved by rest
  - Distinguish from neurogenic, venous, joint, other MSK disorders
  - Symptoms can vary and be atypical

- Can affect proximal (hip/buttock/thigh) or distal (calf) muscles

RC 1-3: Intermittent Claudication (IC)

- Severity is generally described in terms of claudication distance/time
  - Grading claudication severity is subjective and can vary among different patients
  - Examples:
    - RC 1: “My legs ache when I do a 5-mile walk on the beach every other Saturday
    - RC 2: “I’ve been having to take a break after about 30 minutes when I walk my dog because my calves hurt”
    - RC 3: “I can’t get to the mailbox without taking a rest” or “I keep having to take breaks at my landscaping job and I might get fired”

RC 4: Ischemic Rest Pain

- Rest pain is classically described as burning pain in the ball of the foot and toes, typically worsened when the patient is in bed
  - Recumbent positioning exacerbates symptoms due to the loss of gravity-assisted flow to the foot.
  - Patients will often describe a need to dangle their legs over the side of the bed as a result
    - Often present with considerable edema as a result

RC 5-6: Tissue Loss

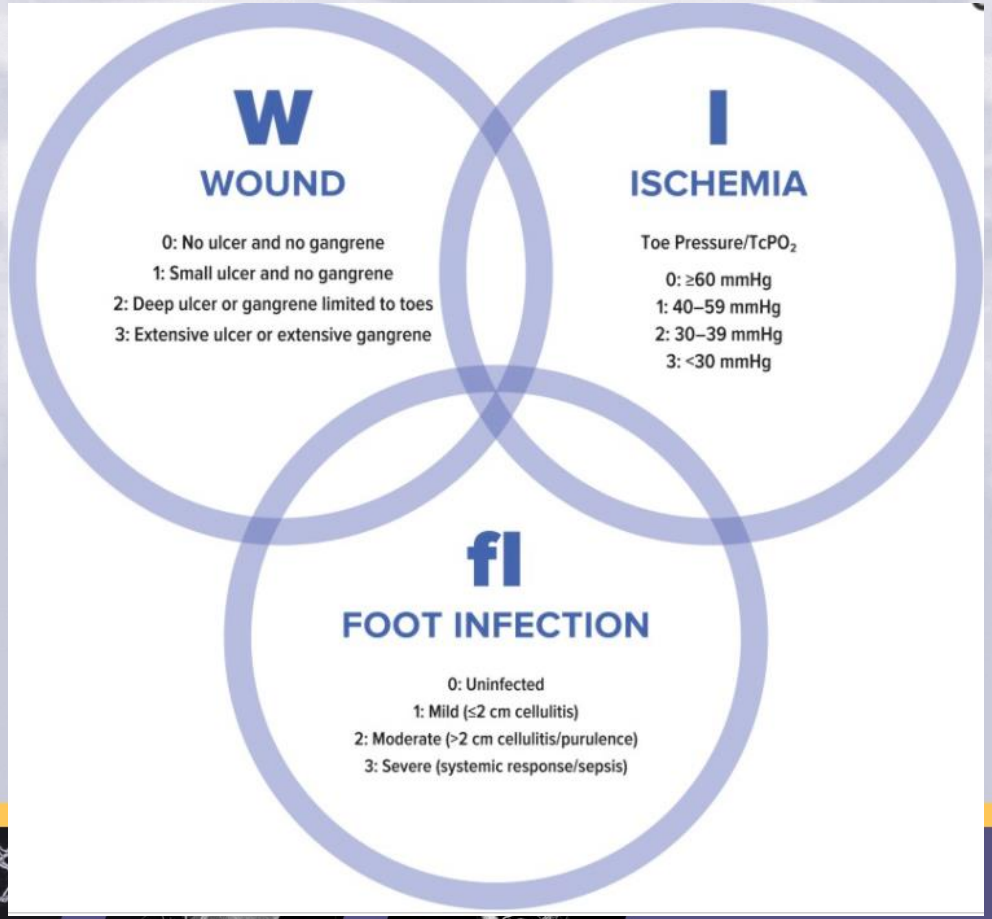
RC 5-6: Tissue Loss

- Minority of patients with PAD – estimated 1-10%
  - Risk factors – same as PAD but higher preponderance of diabetes and renal disease.
- Often first presentation of PAD – many do not have preceding claudication
  - Due to: distribution of disease (infrapopliteal), coexistant neuropathy, reduced mobility.

CLTI: Chronic Limb-Threatening Ischemia

- RC 4-6: Rest pain and Gangrene
- 1-year mortality: 22%
- 1 year major amputation rate without revasc: 22%

WIFI Score


W
WOUND
0: No ulcer and no gangrene
1: Small ulcer and no gangrene
2: Deep ulcer or gangrene limited to toes
3: Extensive ulcer or extensive gangrene
I
ISCHEMIA
Toe Pressure/TcPO2
0: ≥60 mmHg
1: 40–59 mmHg
2: 30–39 mmHg
3: <30 mmHg
fI
FOOT INFECTION
0: Uninfected
1: Mild (≤2 cm cellulitis)
2: Moderate (>2 cm cellulitis/purulence)
3: Severe (systemic response/sepsis)

WIFI Score

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

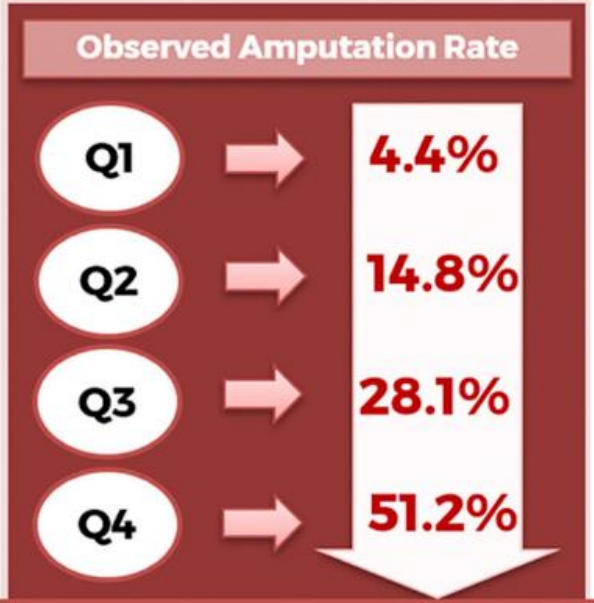
WIFI Score

Society for Vascular Surgery (SVS) WIfI Classification Identifies Patients Most Likely To Benefit From

Multicenter study of chronic limb-threatening ischemia (CLTI) of 1654 limbs and 169 amputations

Scores based on WIfI (Wound, Ischemia and foot Infection) clustered into quartiles

Risk difference quartiles
Q1 – Highest benefit
Q2 – Moderate benefit
Q3- Low benefit
Q4 – Questionable benefit



The SVS WIfI score identifies which CLTI patients will have the greatest and the least benefit from revascularization.

JVS Journal of Vascular Surgery
Official Publication of the Society for Vascular Surgery

Mayor et al. *J Vasc Surg September 2019*

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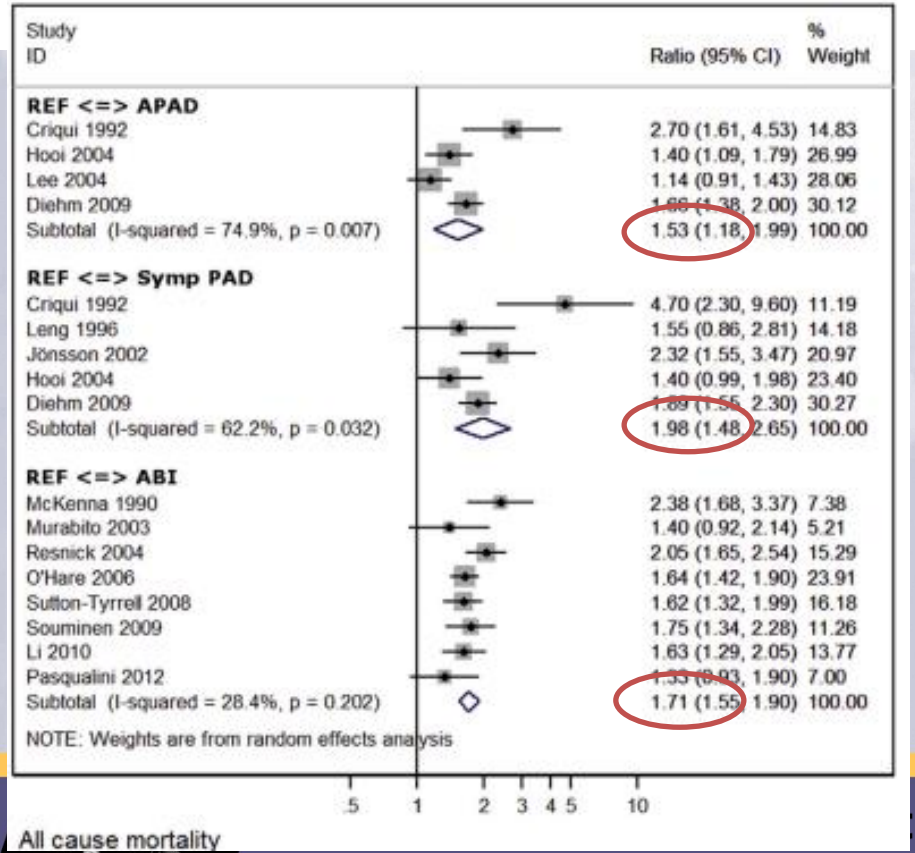
The Risk of Disease Progression in Peripheral Arterial Disease is Higher than Expected: A Meta-Analysis of Mortality and Disease Progression in Peripheral Arterial Disease

- Predictors of worsening: Age, male sex, smokers, DM, and CV disease
  - Asymptomatic -> Claudication: 7% over 5 years
  - Claudication -> Deterioration in IC or CLTI: 21% over 5 years
  - Amputation rate varied between 4 – 27%

The Risk of Disease Progression in Peripheral Arterial Disease is Higher than Expected: A Meta-Analysis of Mortality and Disease Progression in Peripheral Arterial Disease

- Mortality:
  - Asymptomatic – 19% at 5 years
  - Symptomatic – 27% at 5 years
  - Reference 13%



Who needs an intervention?

TABLE 107.1 Stages of Chronic Limb Ischemia

Fontaine Grade	Rutherford Category	Clinical Description	Objective Criteria
I	0	Asymptomatic	Norm[illegible]treadm[illegible] or [illegible]h[illegible]ere[illegible]a test
IIa[a]	1	Mild claudication	Com[illegible]letes tread[illegible]ill [illegible]ercise[b], [illegible]after exercise >50 mm Hg but at least 20[illegible]m Hg lowe[illegible]thar[illegible]esting value
IIb[a]	2	Mo[illegible]erate cla[illegible]dication	Betwee[illegible]ories 1 and 3
	3	Seve[illegible]ation	Cannot complete standard treadmill exercise[b]; AP after exercise <50 mm Hg
III[a]	4	Ischem[illegible]rest pain	Resting AP <30–50 mm Hg; ankle or metatarsal PVR flat or barely pulsatile; TP <30 mm Hg
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	6	Major tissue loss[d]	Same as Rutherford 5 (Fontaine IV)

EVERYONE

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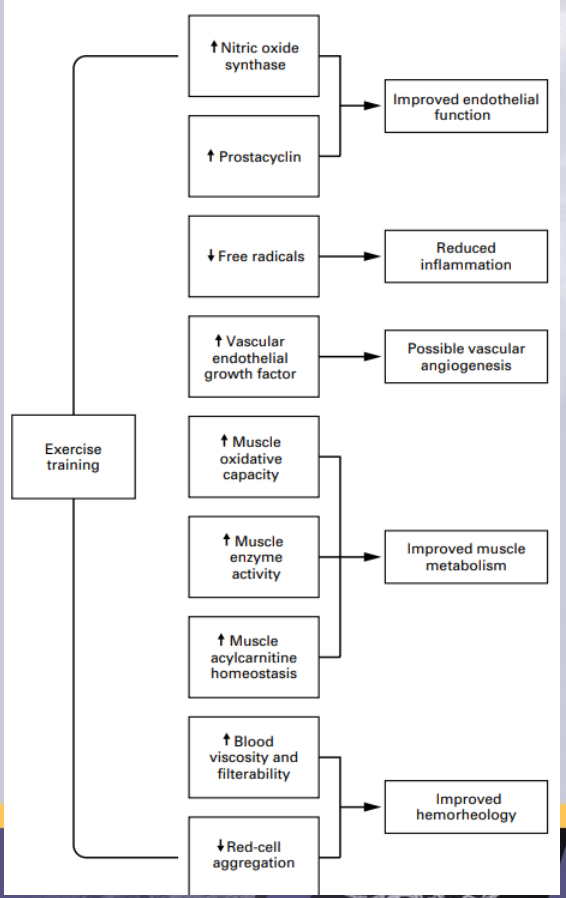
Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication

- Treatment of PAD is aimed at reducing risk of mortality from cardiovascular causes through medical therapy and risk factor modification:

TABLE 3. RISK-FACTOR MODIFICATION FOR PATIENTS WITH PERIPHERAL ARTERIAL DISEASE.*

Smoking cessation
Low-density lipoprotein cholesterol <100 mg/dl (2.6 mmol/liter)
Glycosylated hemoglobin <7.0 percent
Blood pressure <130/85 mm Hg
Angiotensin-converting–enzyme inhibition
Antiplatelet therapy
Aspirin or clopidogrel

IC Treatment: Exercise



Intensity

The initial workload of the treadmill is set to a speed and grade that elicits claudication symptoms within 3 to 5 min

Patients walk at this workload until claudication of moderate severity occurs, then rest standing or sitting for a brief period to permit symptoms to subside

Duration

The exercise–rest–exercise pattern should be repeated throughout the exercise session

The initial session will usually include 35 min of intermittent walking; walking is increased by 5 min each session until 50 min of intermittent walking can be accomplished

Frequency

Treadmill or track walking 3 to 5 times per week

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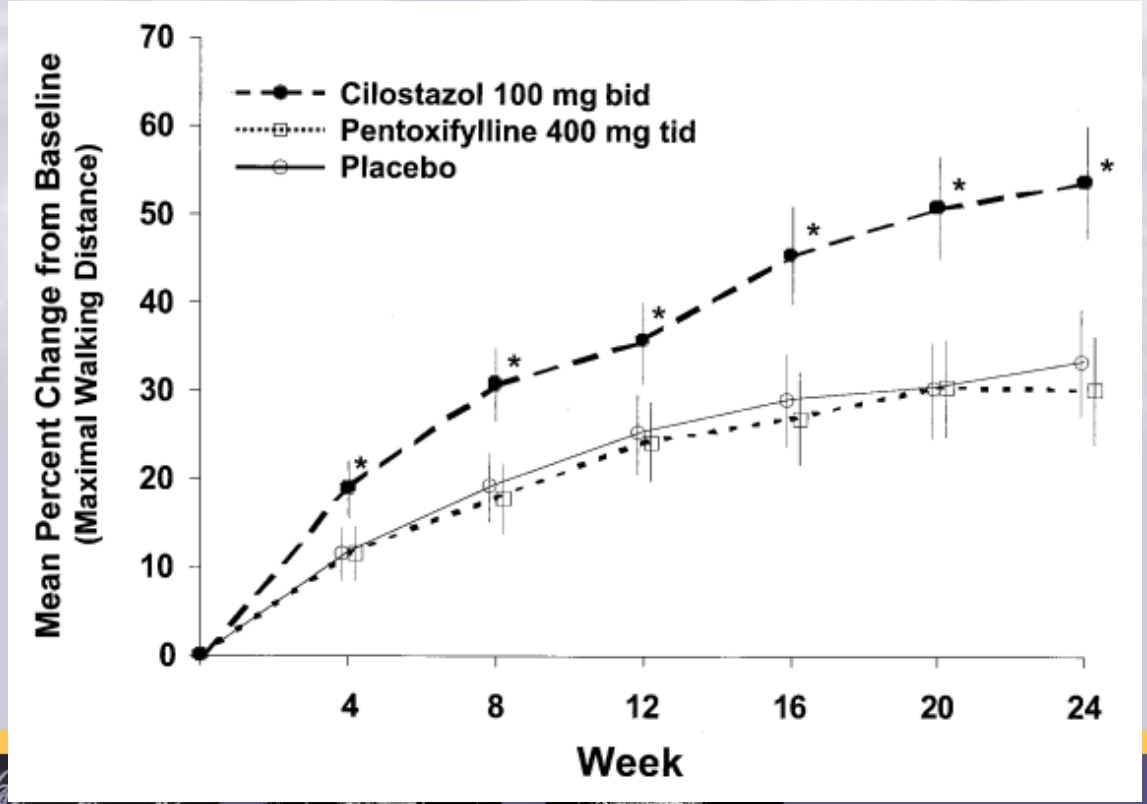
IC Treatment: Pharmacologic

- Cilostazol: Phosphodiesterase III inhibitor - increases cAMP –
  - Inhibits smooth muscle contraction and platelet aggregation
  - Actual mechanism in IC is unknown
  - **Contraindicated** in heart failure

- Pentoxifylline: nonselective PD inhibitor

A Comparison of Cilostazol and Pentoxifylline for Treating Intermittent Claudication



IC Treatment: Interventional

- Justification for interventions for IC is not based on anatomic or physiologic findings, rather severity of functional impairment

- Is it better than exercise?

Supervised Exercise Versus Primary Stenting for Claudication Resulting From Aortoiliac Peripheral Artery Disease

Six-Month Outcomes From the Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) Study

At 6 months, walking distance was exercise > revasc > medical therapy

Is intermittent claudication improved by percutaneous transluminal angioplasty? A randomized controlled trial

No difference at 2 years

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IC Treatment: Interventional

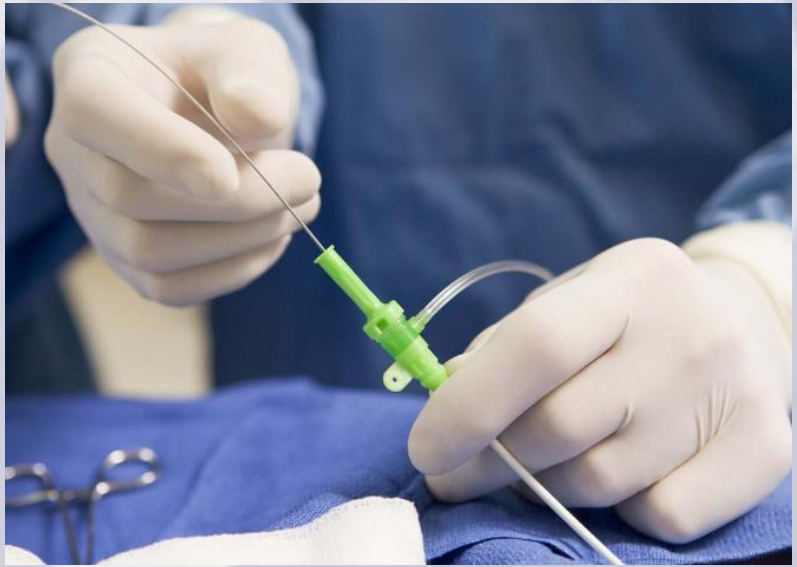
- Risk/ benefit ratio almost always favors initial medical therapy, though this is not always successful

- Reduced procedural risks of endovascular therapy have increased intervention rates for claudicants in recent years

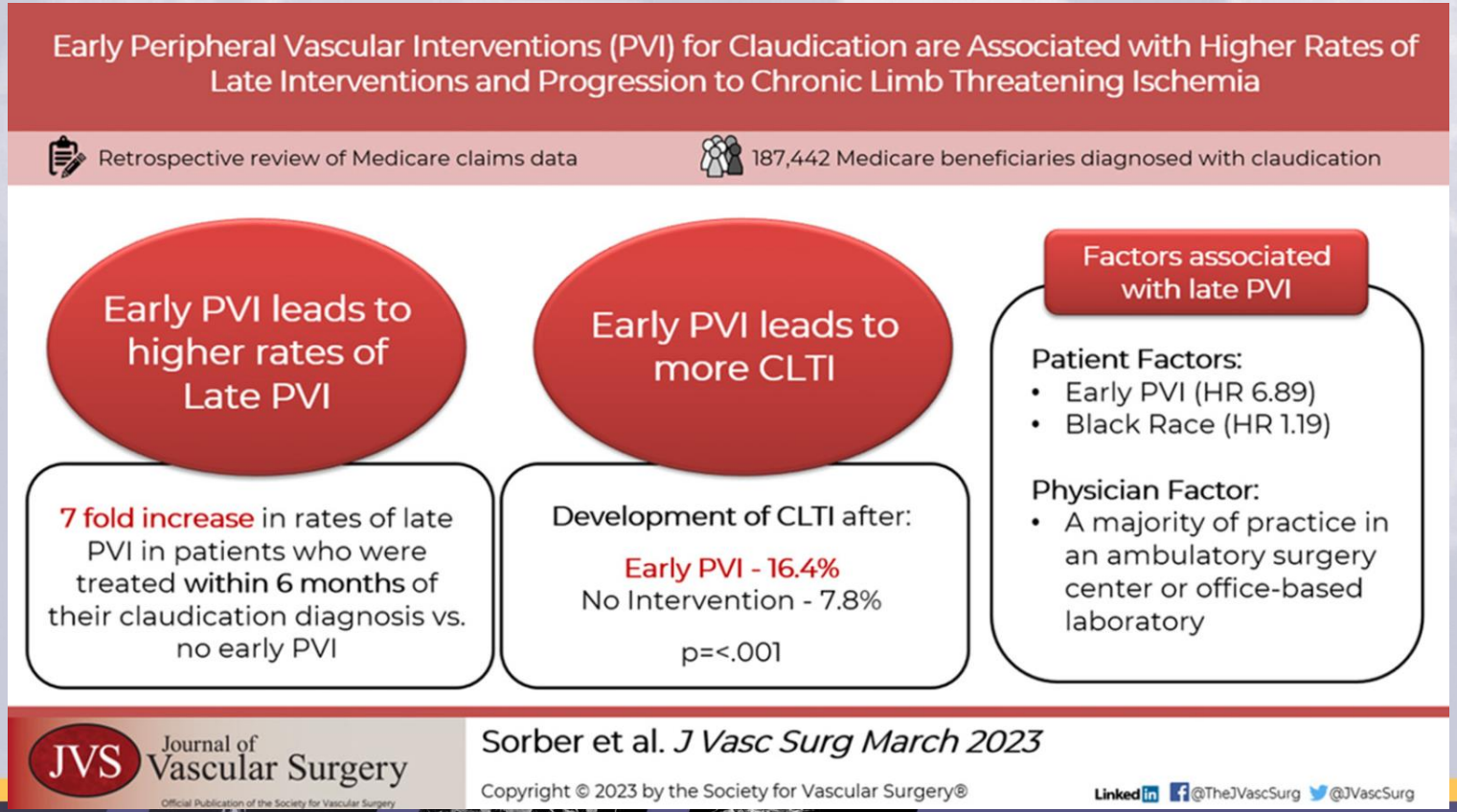
Outcomes and practice patterns in patients undergoing lower extremity bypass

  - lower extremity bypass procedures being performed for claudication rose from 19% - 31% from 2003 – 2009
    - 1-year major amputation rate of 1.6% for IC bypasses

IC Treatment: Open vs Endo?



IC Treatment: Interventional



CLTI Treatment

- Unlike IC, risk benefit ratio most often favors revascularization
  - Up to 25% of patients will undergo major amputation within 1 year
  - **BUT** up to 25% of patients will die of cardiovascular complications within 1 year as well.
  - In some cases, advances in wound care and optimization of medical therapy can lead to treatment success without revascularization

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CLTI: Amputation vs Revascularization

- Revascularization is the treatment of choice in the overwhelming majority
  - 10 – 40% undergo primary amputation due to overwhelming infection or unreconstructable disease.
- In select patients, amputation and prosthetic rehabilitation can offer an expedient return to a reasonable quality of life.
  - Ambulation rates up to 70% and as high as 90% in young, good risk patients after BKA
- Patients with major tissue loss who are too sick/bedbound/infirm are unlikely to realize benefits of revascularization and palliative AKA should be considered.

CLTI: Revascularization

Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 22, 2022 VOL. 387 NO. 25

Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia

A. Farber, M.T. Menard, M.S. Conte, J.A. Kaufman, R.J. Powell, N.K. Choudhry, T.H. Hamza, S.F. Assmann,* M.A. Creager, M.J. Cziraky, M.D. Dake, M.R. Jaff, D. Reid, F.S. Siami, G. Sopko, C.J. White, M. van Over, . Strong, M.F. Villarreal, M. McKean, E. Azene, A. Azarbal, A. Barleben, D.K. Chew, L.C. Clavijo, Y. Douville, L. Findeiss, N. Garg, W. Gasper, K.A. Giles, P.P. Goodney, B.M. Hawkins, C.R. Herman, J.A. Kalish, . Koopmann, I.A. Laskowski, C. Mena-Hurtado, R. Motaganahalli, V.L. Rowe, A. Schanzer, P.A. Schneider, J.J. Siracuse, M. Venermo, and K. Rosenfield, for the BEST-CLI Investigators†

A vein bypass first versus a best endovascular treatment first revascularisation strategy for patients with chronic limb threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal revascularisation procedure to restore limb perfusion (BASIL-2): an open-label, randomised, multicentre, phase 3 trial

Andrew W Bradbury, Catherine A Moakes, Matthew
Arul Ganeshan, Jack Hall, Simon Hobbs, Kim Houlihan
Athanasios Saratzis, Gemma Slinn, D Julian A Scott, Hany Zayed, Jonathan J Deeks, on behalf of the BASIL-2 Investigators

BEST-CLI versus BASIL-2 Trial: Conflicting Results?

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CLTI: Revascularization

Table 2. Independent and Combined Measures of Success for 331 Patients Receiving Lower-Extremity Bypass

	Successful		Failed	
Outcomes parameter	**n**	**%**	**n**	**%**
Graft patency to the point of healing	250	75.5	81	24.5
Limb salvage for 1 y	267	80.6	64	19.3
Maintenance of ambulatory status for 1 y	287	86.7	44	13.3
Survival for 6 mo	297	89.7	34	10.3
Clinical outcomes combining all parameters	147	44.4	184	55.6

- Ambulatory for 1 year
- Survival of 6 months

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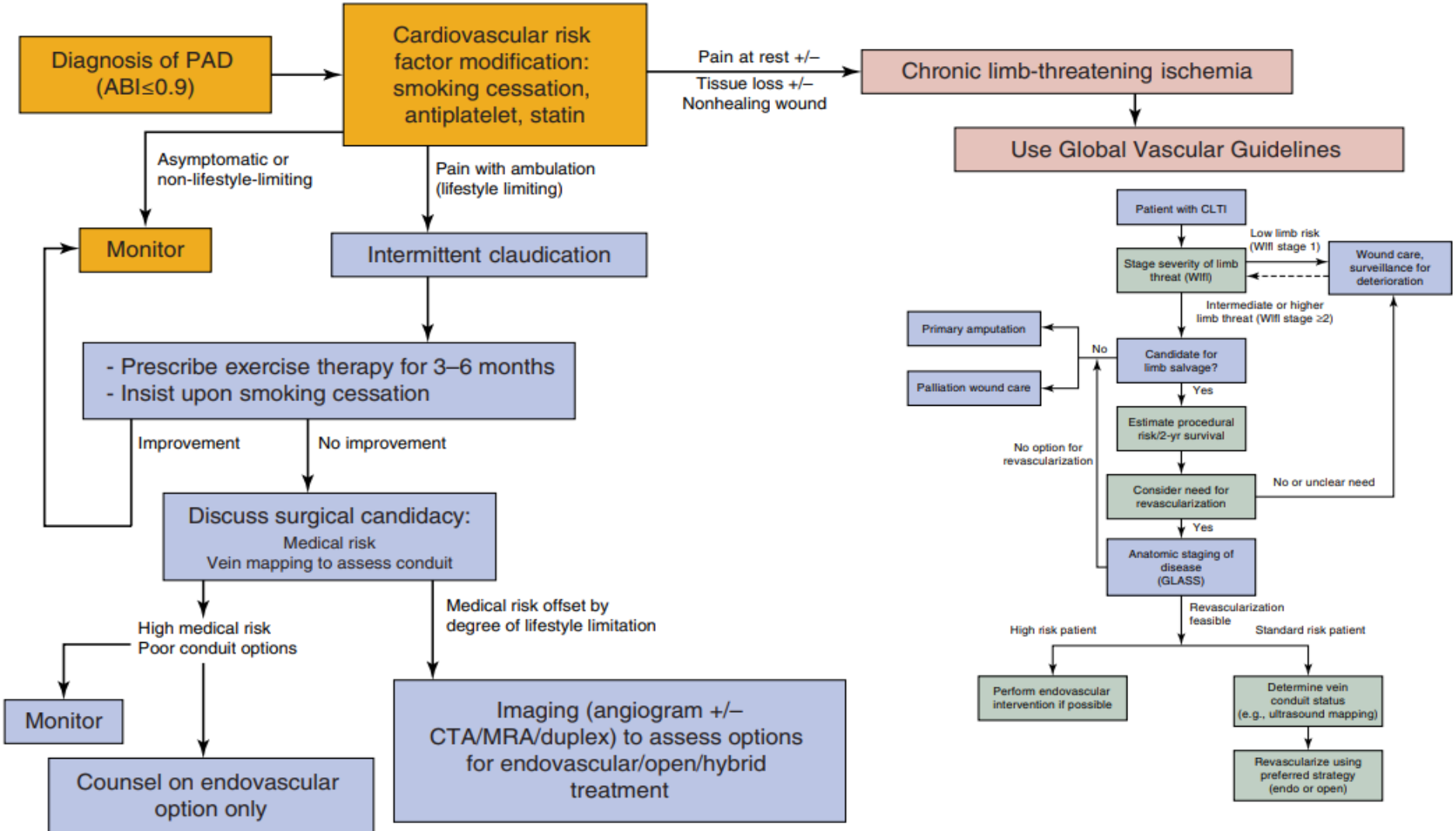
Diagnosis of PAD (ABI≤0.9)
Cardiovascular risk factor modification: smoking cessation, antiplatelet, statin
Pain at rest +/–
Tissue loss +/–
Nonhealing wound
Chronic limb-threatening ischemia
Use Global Vascular Guidelines
Asymptomatic or non-lifestyle-limiting
Pain with ambulation (lifestyle limiting)
Monitor
Intermittent claudication
- Prescribe exercise therapy for 3–6 months
- Insist upon smoking cessation
Improvement
No improvement
Discuss surgical candidacy:
Medical risk
Vein mapping to assess conduit
High medical risk
Poor conduit options
Medical risk offset by degree of lifestyle limitation
Monitor
Counsel on endovascular option only
Imaging (angiogram +/– CTA/MRA/duplex) to assess options for endovascular/open/hybrid treatment
Patient with CLTI
Stage severity of limb threat (WIfI)
Low limb risk (WIfI stage 1)
Wound care, surveillance for deterioration
Intermediate or higher limb threat (WIfI stage ≥2)
Primary amputation
Palliation wound care
No
Candidate for limb salvage?
Yes
Estimate procedural risk/2-yr survival
No option for revascularization
Consider need for revascularization
No or unclear need
Yes
Anatomic staging of disease (GLASS)
Revascularization feasible
High risk patient
Standard risk patient
Perform endovascular intervention if possible
Determine vein conduit status (e.g., ultrasound mapping)
Revascularize using preferred strategy (endo or open)

Thank You!

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