MEDICAL TREATMENT OF PAD
+
ANTICOAGULATION THERAPY IN ARTERIAL DISEASE

The good physician treats the disease; the great physician treats the patient who has the disease.
William Oslller

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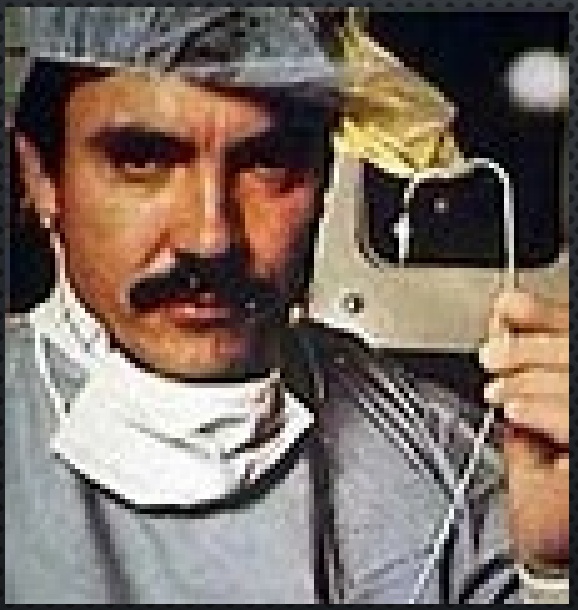
ACOI 2019

DISCLOSURES

- I AM FROM NJ

Liberty Enlightening the World ("La Liberté éclairant le monde"), **Frédéric Auguste Bartholdi**

ARE PHYSICIANS BAD PILOTS ?



Yes!!

DATA IS IMPORTANT

Honoré Daumier

" A man is only as old as his arteries"
Pierre.J.Cabanis

PARIS MARATHON

- THINGS ARE NOT ALWAYS AS THEY APPEAR

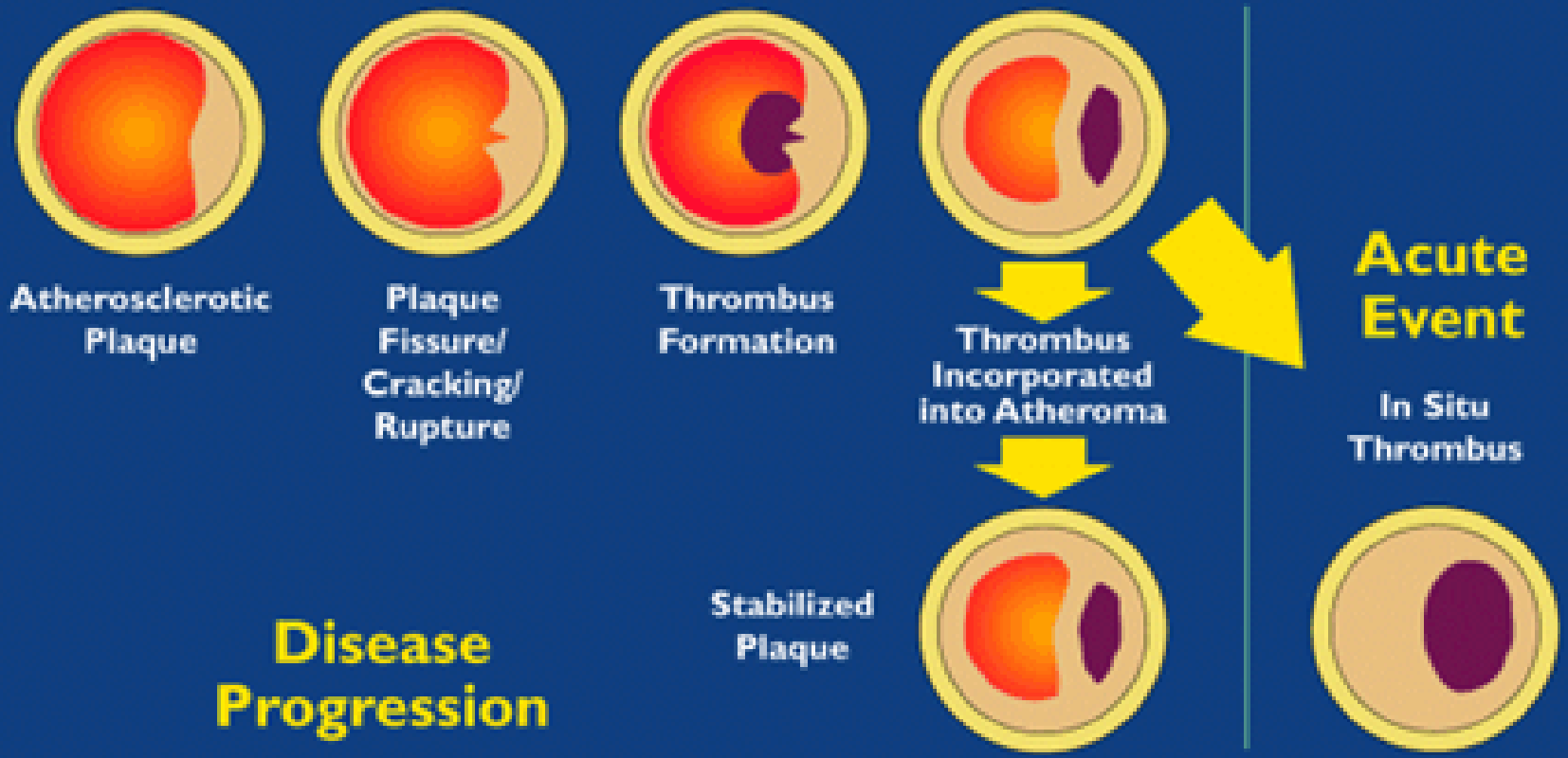
What are the most important questions

- Is there PAD?
- What is the Pathophysiology ?
- Who is at Risk?
- Are there co-morbidities ?
- Are these co-morbidities treatable? If so, what is an appropriate treatment strategy ??

EPIDEMIOLOGY

- Atherosclerosis the most common cause
- 30% patients with CVD have PAD as only clinical manifestation
- Asymptomatic and symptomatic disease are independent risk factor for CAD Morbidity and Mortality

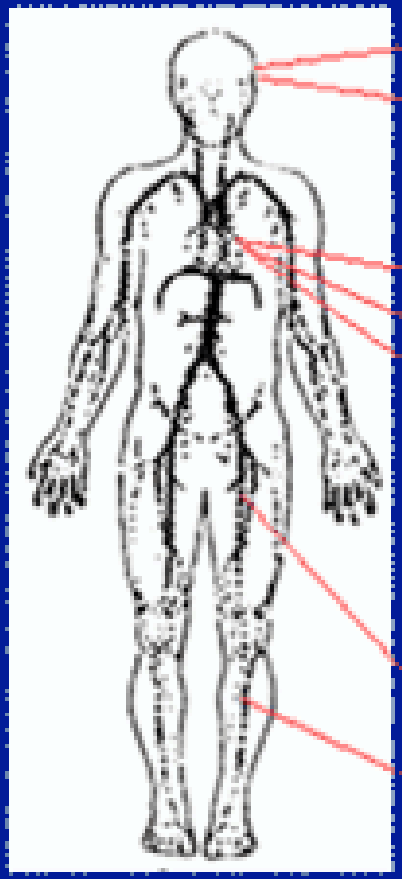
Atherosclerosis: The Pathogenesis of Acute Clinical Events



INCIDENCE

- 8-12 MILLION PEOPLE ARE PRESUMED TO HAVE PAD IN THE USA
- 16% OF POPULATION 55 OR OLDER

Manifestations of Atherosclerosis



- Transient ischemic attack
- Ischemic stroke
- Unstable angina pectoris
- Non-Q-wave myocardial infarction
- Q-wave myocardial infarction

Ischemic sudden death

- Claudication
- Critical limb ischemia, rest pain, gangrene, amputation

WHO IS AT RISK?

The Old Courtesan.
'Rodin'

Bare ruin'd choirs, where late the sweet birds sang.
In me thou seest the twilight of such day
As after sunset fadeth in the west.

Shakespeare

Risk Factors for PAD

Primary

-Older age -Diabetes-Smoking

Other Associated Factors

-HTN -Sedentary Lifestyle

-Low HDL -Elevated Cholesterol

-Elevated Fibrinogen

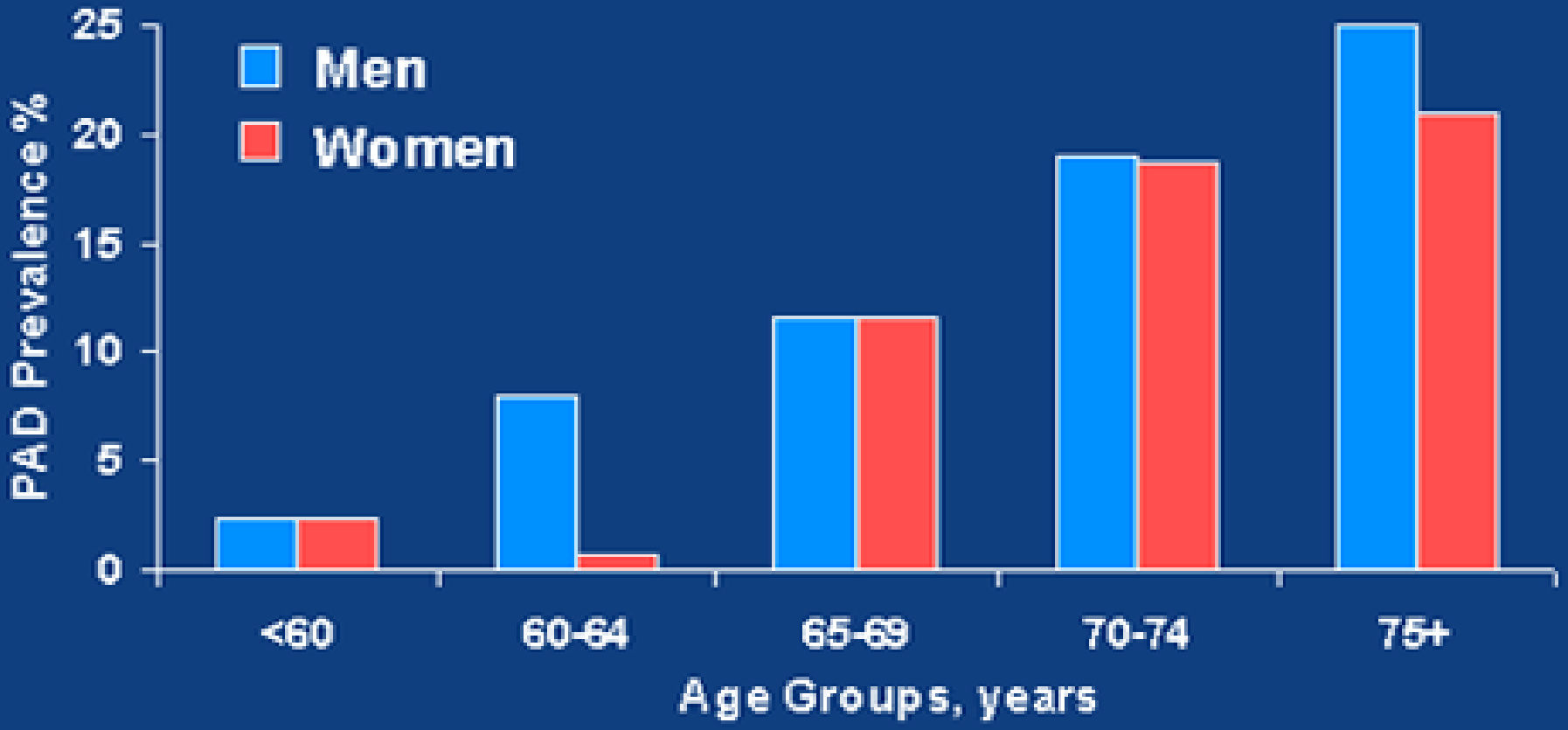
-High Lipoprotein a

-Elevated Homocysteine (Debunked)

SMOKING

- Most preventable risk factor.
- Primary PAD risk factor.
- Implicated in 1/3 of CAD death.
- Doubles risk of Stroke.

Age Dependent Prevalence of PAD



Adapted from Criqui. *Circulation*. 1985:510-515.

ARE THERE CO-MORBIDITIES?

Ten Year Relative Risk of Mortality for Patients with PAD

Cause of Death	Relative Risk
All causes	3.1
Cardiovascular disease	5.9
Coronary heart disease	6.6

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

Diabetes and the CV System

Diabetes mellitus:

- Accelerates atherosclerosis 200-400%
- Results in 2-4 times the risk of coronary artery ischemic events
- Results in 4 times the risk of stroke
- CV risk equivalent to 3 non-diabetic risk factors
- PAD 11 times more prevalent
- PAD develops a decade earlier

Peripheral Vascular Disease. 5th edition. W.B.Saunders & Co. 1980.
Cardiovascular Disease and Diabetes Mellitus. Symposium at 58th Annual Scientific Session, American Diabetes Association. June, 1998. Chicago.

Prevalence of PAD

- Asymptomatic

.9%-22%

- Symptomatic

2%-6% of population

Relative Prevalences of PAD and Intermittent Claudication (IC)

Age (yrs)	PAD	IC
40-59	2,100,000	901,000
60-69	1,600,000	803,000
≥70	4,700,000	2,530,000
	8,400,000	4,234,000

Criqui MH. *NEJM*. 1992;326:381-86.
Hiatt W. *Circulation*. 1995;91:1472-79.
Porter J. *Modern Medicine*. 1987;55:66-75.
U.S. Census Data,
www.census.gov/population/estimates/nation/intfile2-1.txt

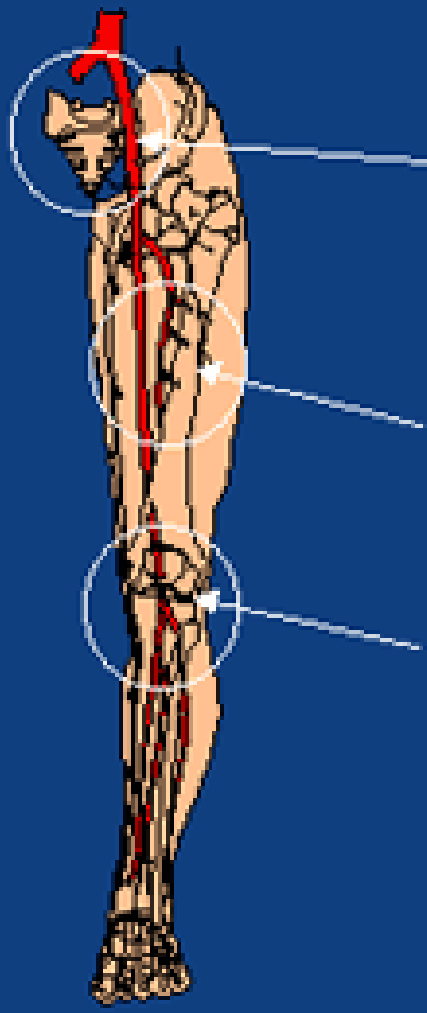
IS THERE PAD?

Claudication: The Functional Limitation of PAD

- Exertional aching pain, cramping, tightness, fatigue
- Occurs in muscle groups, not joints
- Reproducible from one day to the next (level of walking ability consistent)
- Resolves completely within 2-3 minutes
- Occurs again at same distance once activity has been resumed

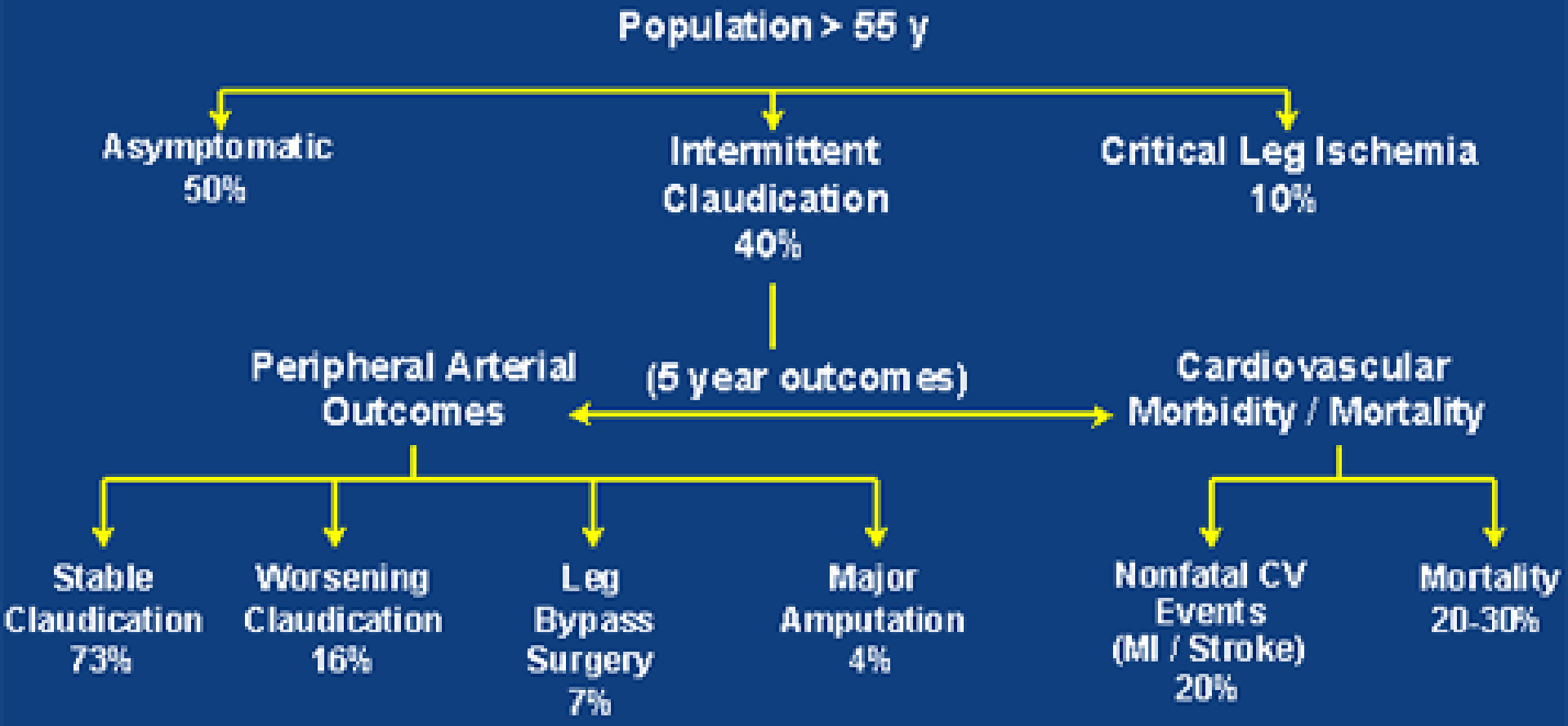
Arteries of the Pelvis and Lower Extremity

Problem Sites



Obstruction in:	Ischemia in:
Aorta or Iliac Artery	Buttocks, Penis, Thighs
Femoral Artery or Branches	Thigh, Calf
Popliteal Artery	Calf, Ankle, Foot

PAD Natural History

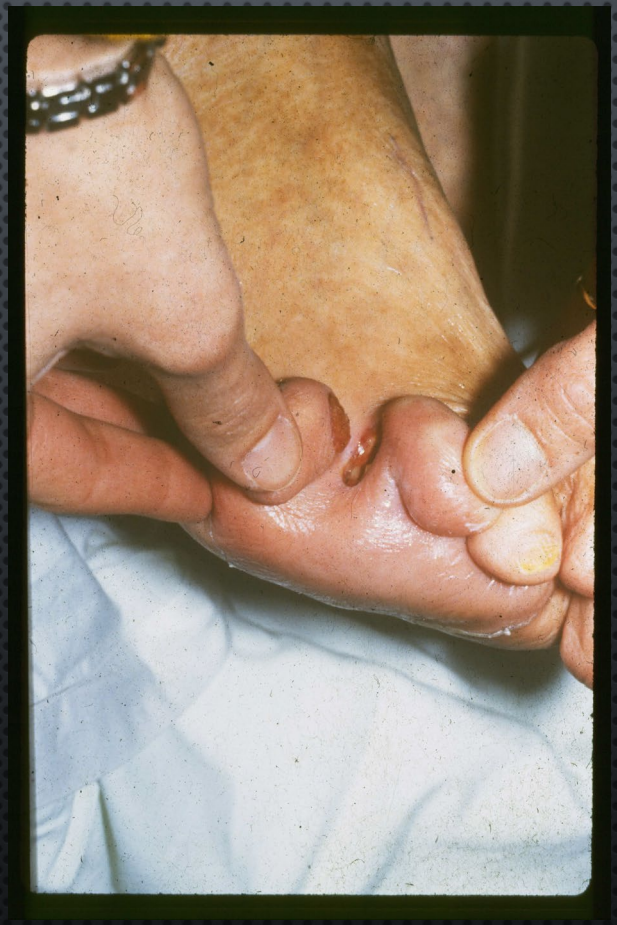


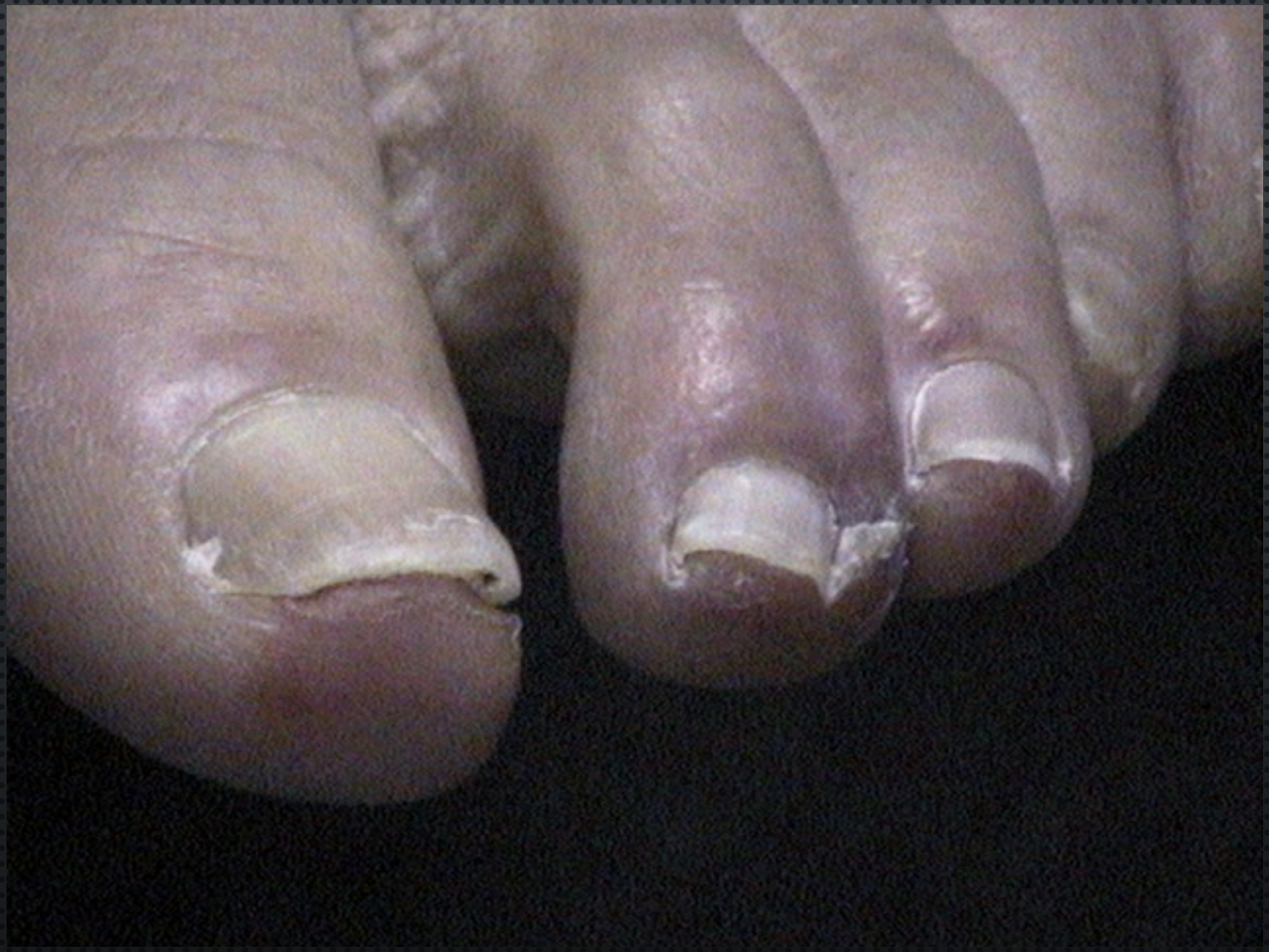
Weitz JI. *Circulation*. 1996;94:3026-3049.

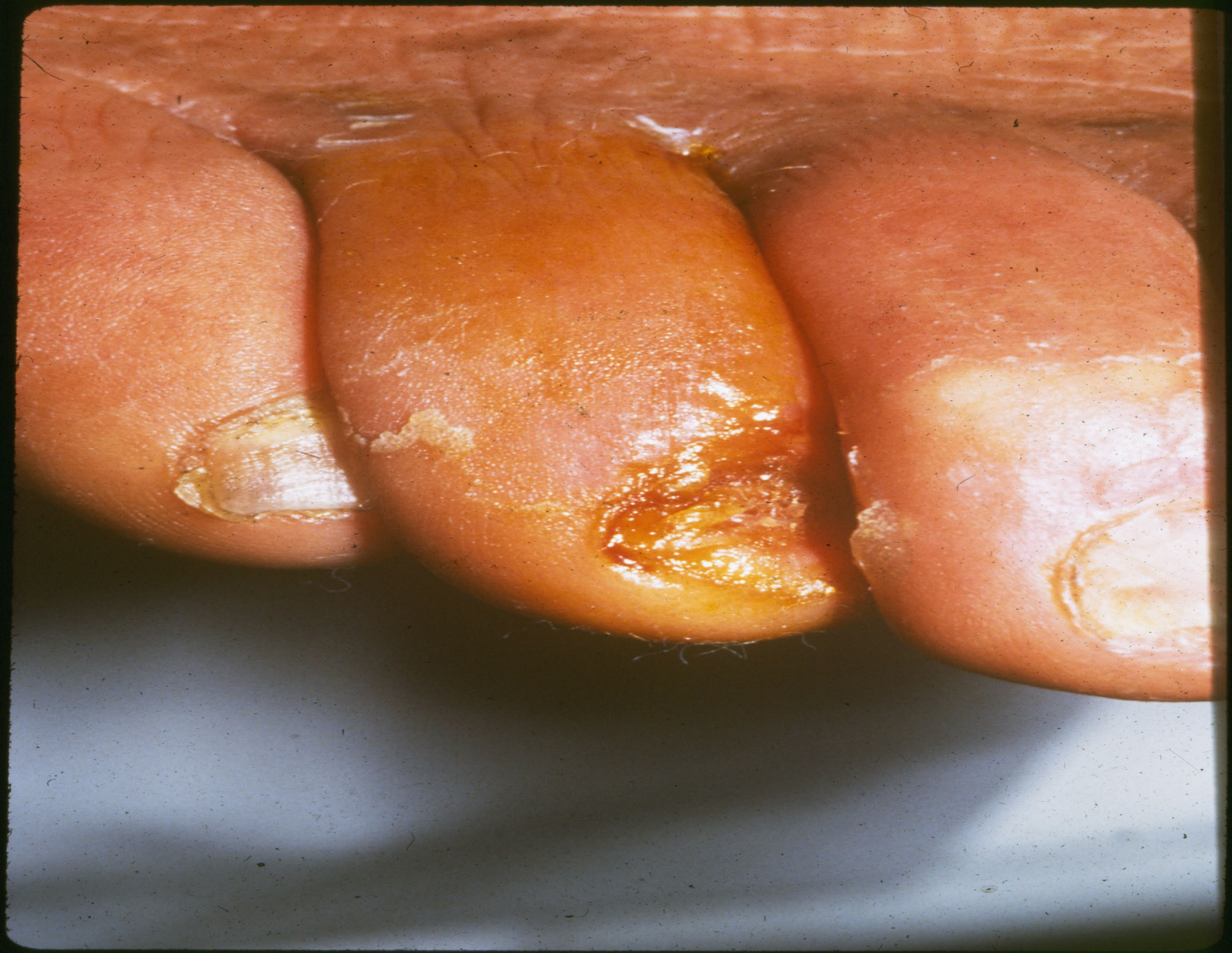
Diagnosis of PAD

- Vascular history
- Physical examination
  - Assess pulses
- Ankle-brachial index measurement
- Noninvasive vascular laboratory
- Arteriography

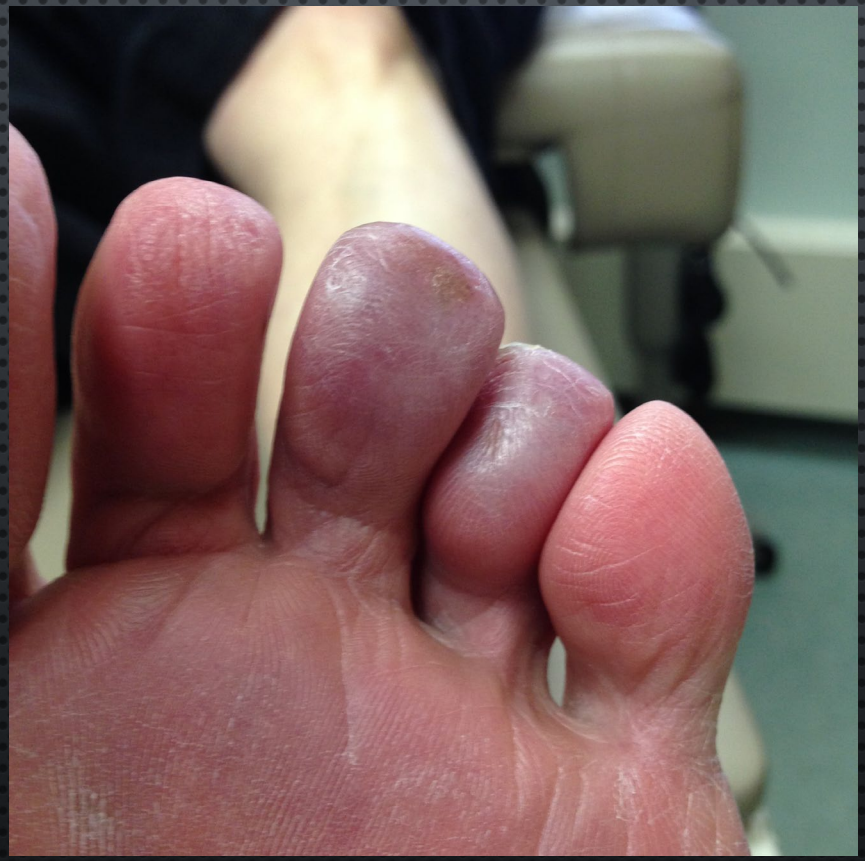
KISS ULCERATION



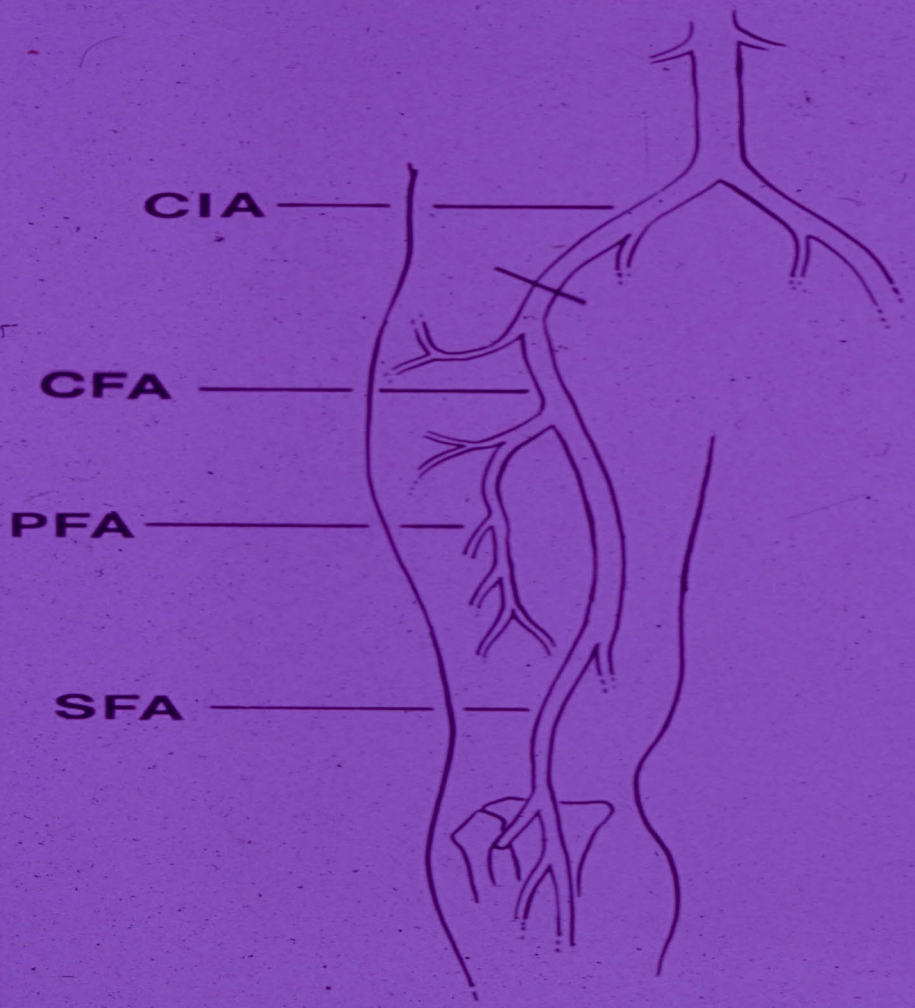




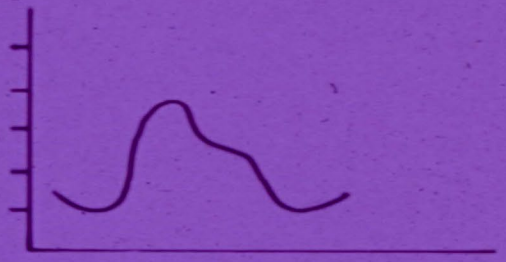
BLUE TOE SYNDROME



NORMAL ARTERIAL SUPPLY TO RIGHT LEG WITH SEGMENTAL LIMB PRESSURES (SLP) AND PULSE VOLUME RECORDINGS (PVR)



ARM BP
130mmHg

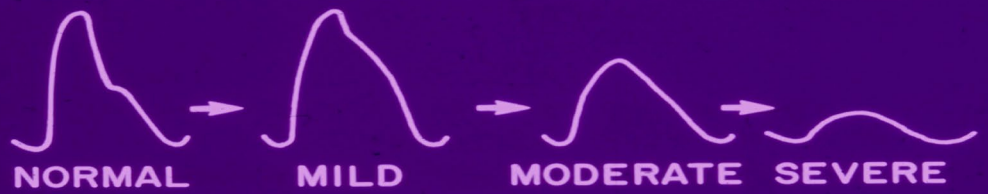


130mmHg

130mmHg

PULSE VOLUME RECORDINGS

PULSE VOLUME RECORDINGS
CHANGES WITH PROGRESSIVE ARTERIAL NARROWING

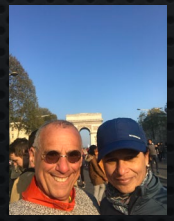


COST OF CVD IN THE USA

- ESTIMATED 151 BILLION IN DIRECT AND INDIRECT COSTS.
- COST-EFFECTIVENESS OF TREATING RISK FACTORS(SMOKING,HTN,LIPIDS)LESS THAN $20,000 PER YEAR OF LIFE SAVED

SOMETIMES YOU HAVE TO MOVE WITH THE TARGET.

Sometimes things are exactly as they appear!



SOMETIMES THINGS ARE EXACTLY AS THEY APPEAR!!!!

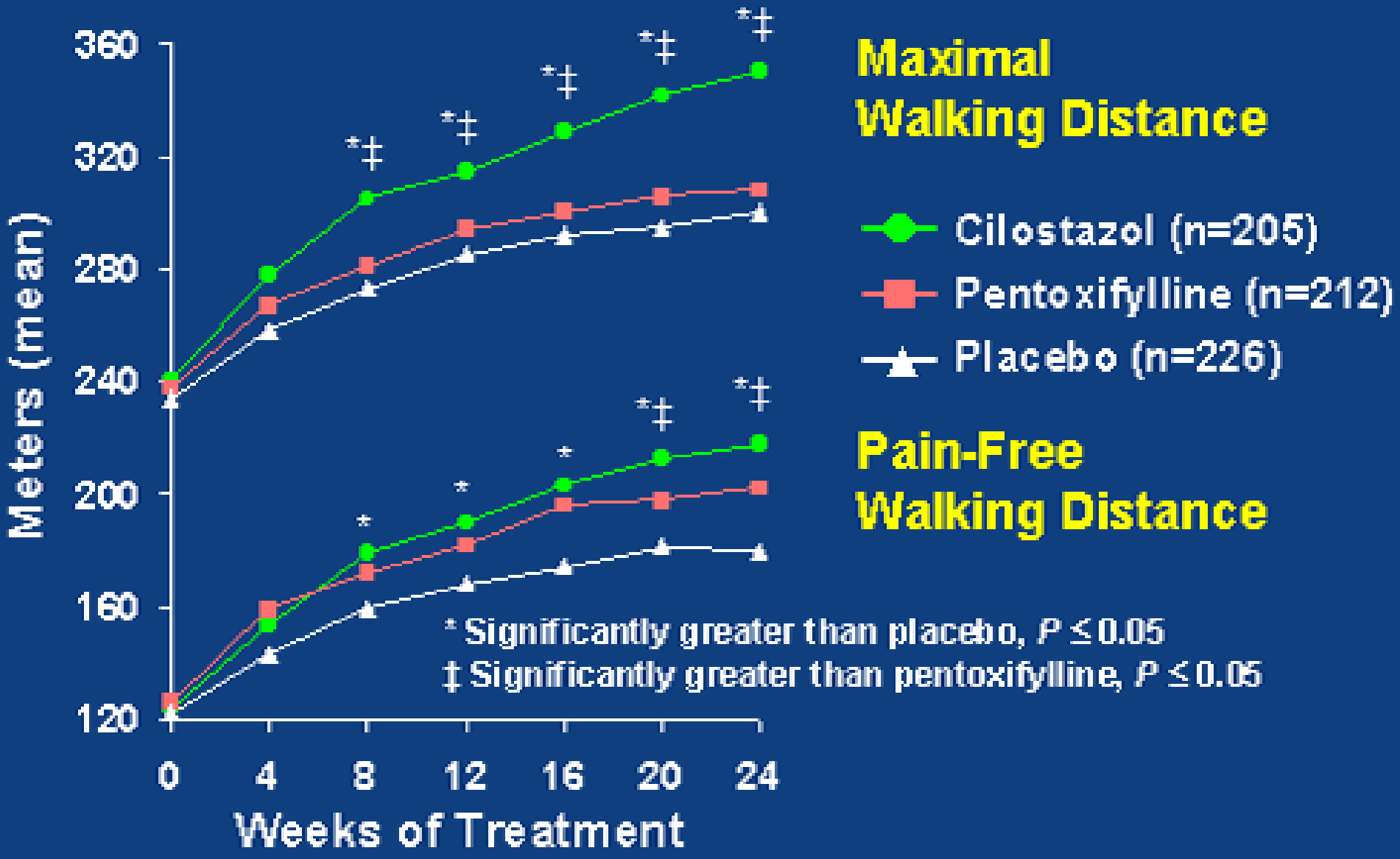
“TELL THE TRUTH. IF YOU DO YOU DON’T HAVE TO REMEMBER ANYTHING”

MARK TWAIN

“TELL THE TRUTH , IT IS EASIER TO REMEMBER”

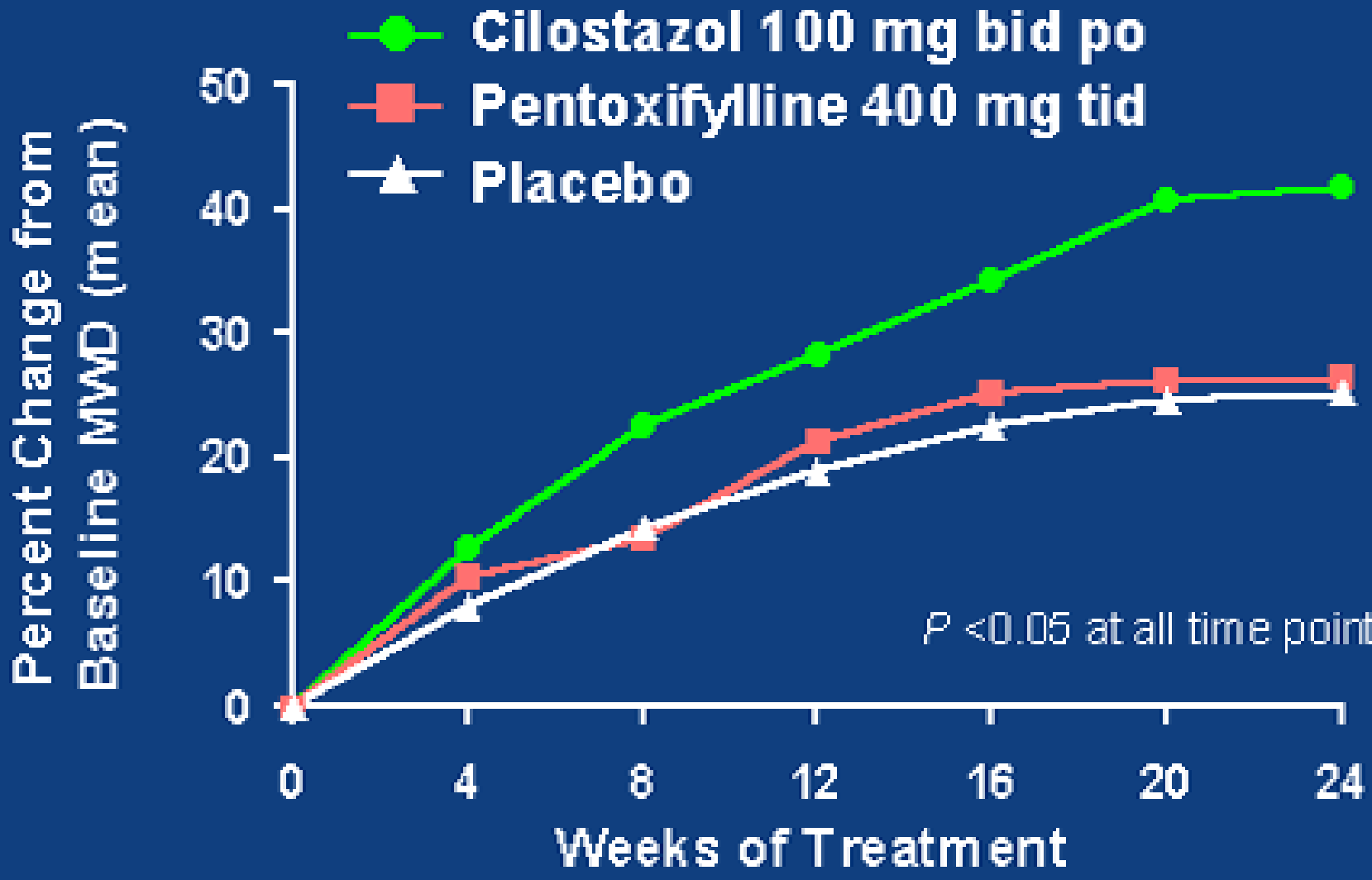
My Wife

Comparison to Standard Therapy



Dawson, et al. *Circulation*. 1998;98(17):I-12. Cardiovascular and Renal Drugs Advisory Committee. 85th Meeting US DHHS, FDA. Bethesda, MD; July 9,1998.

Improvement in Maximal Walking Distance
% Change from Baseline



Dawson, et al. *Circulation.* 1998;98(17):1-12.

HEART PROTECTION STUDY(HSP)

- SIMVASTATIN ASSOC WITH:
- 12% REDUCTION IN TOTAL MORTALITY
- 17% REDUCTION IN VASCULAR MORTALITY
- 27% REDUCTION IN ALL STROKES
- 16% REDUCTION IN NON-CORONARY REVASCULARIZATIONS
- NO THRESHOLD CHOLESTEROL VALVE BELOW WHICH STATIN NOT ASSOC. WITH BENEFIT.
- NO BENEFIT OR HARM FOUND WITH ANTIOXIDANT VITAMINS TO PREVENT ISCHEMIA

HYPERLIPIDEMIA

- Reduction of total Cholesterol
- Reduction in LDL
- Lipid lowering agents

- Homocysteine

HOPE TRIAL

- 4,046 patients with PAD
- 22% reduction in PAD in diabetics randomized to Ramipril and Placebo

This establishes the ACE inhibitor independent of BP control as a cardio-protective agent.

CAPRIE TRIAL/ CHARISMA TRIAL

- CLOPIDOGREL WAS SHOWN TO REDUCE RISK IN CVD IN THE PAD POPULATION OF 24%
- ?????

CHARISMA

3/12/2006 NEJM CLOPIDOGREL AND ASPIRIN VERSUS ASPIRIN ALONE FOR THE PREVENTION OF ATHEROTHROMBOTIC EVENTS.

- 15,603 PATIENTS DOUBLE BLINDED AND PROSPECTIVELY RANDOMIZED WITH EITHER EVIDENT CVD OR MULTIPLE RISK FACTORS
- TREATMENT=CLOPIDOGRIL 75MG PLUS ASA 75-162MG
- CONTROL =PLACEBO PLUS ASA 75-162MG

- CONCLUSION NO DIFFERENCE IN OUTCOME!

TARGET BEDS

- Carotid disease Antiplatlet therapy
- AAA Anti- Platlet therapy
- Cardiac arrhythmia Anticoagulation
- Arterial Dissection (no diferance between ASA and Anticoagulation
- Thrombophilia Antiphosphlipid antibody ACA,LA, SLE Combined Antiplatlet anticoagulation ?
- PAD ???

- **Presentation, treatment, and outcomes in patients with spontaneous isolated celiac and superior mesenteric artery dissection**
- **Charles DeCarlo1, Suvranu Ganguli2, Jorge C Borges3, Robert M Schainfeld3, Ari J Mintz4, Jessica Mintz4, Michael R Jaff5 and Ido Weinberg3**

BACKGROUND FOR COMPASS

- Aspirin significantly reduces both primary and secondary cardiovascular events events (***Antithrombotic Trialist Collaboration Lancet 2009***)

- Oral anticoagulation +/- ASA reduces secondary events vs ASA alone with a probitively high bleeding risk (***Meta-analysis. JACC 2003***)

- Rivaroxaban had improved mortality in in patients after acute coronary syndromes with increased bleeding rate vs placebo (***ATLAS ACS-TIMI 46 NEJM 2012***)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Rivaroxaban with or without Aspirin in Stable Cardiovascular Disease

J.W. Eikelboom, S.J. Connolly, J. Bosch, G.R. Dagenais, R.G. Hart, O. Shestakovska, R. Diaz, M. Alings, E.M. Lonn, S.S. Anand, P. Widimsky, M. Hori, A. Avezum, L.S. Piegas, K.R.H. Branch, J. Probstfield, D.L. Bhatt, J. Zhu, Y. Liang, A.P. Maggioni, P. Lopez-Jaramillo, M. O'Donnell, A. Kakkar, K.A.A. Fox, A.N. Parkhomenko, G. Ertl, S. Störk, M. Keltai, L. Ryden, N. Pogosova, A.L. Dans, F. Lanas, P.J. Commerford, C. Torp-Pedersen, T.J. Guzik, P.B. Verhamme, D. Vinereanu, J.-H. Kim, A.M. Tonkin, B.S. Lewis, C. Felix, K. Yusoff, P.G. Steg, K.P. Metsarinne, N. Cook Bruns, F. Misselwitz, E. Chen, D. Leong, and S. Yusuf, for the COMPASS Investigators*

Is rivaroxaban plus aspirin or rivaroxaban alone better than aspirin alone in the prevention of MI, stroke, or cardiovascular death in those with stable CAD and/or PAD?

ANTICOAGULATION IN STABLE PAD
COMPASS - PAD

45% relative risk reduction in major adverse limb events

Outcome	ASA + riva 2.5 mg BID (%)	Riva 5 mg BID (%)	ASA (%)	ASA + Riva vs ASA alone		Riva vs ASA alone	
	N=2,492	N=2,474	N=2,504	HR (95% CI)	P	HR (95% CI)	P
MALE	**30 (1.2)**	35 (1.4)	**56 (2.2)**	0.54 (0.35-0.84)	0.005	0.63 (0.41-0.96)	0.03
Major amputation	**5 (0.2)**	8 (0.3)	**17 (0.7)**	0.30 (0.11-0.80)	0.01	0.46 (0.20-1.08)	0.07

COMPASS Investigators. NEJM. 2017

Compass Trial

Inclusion Criteria

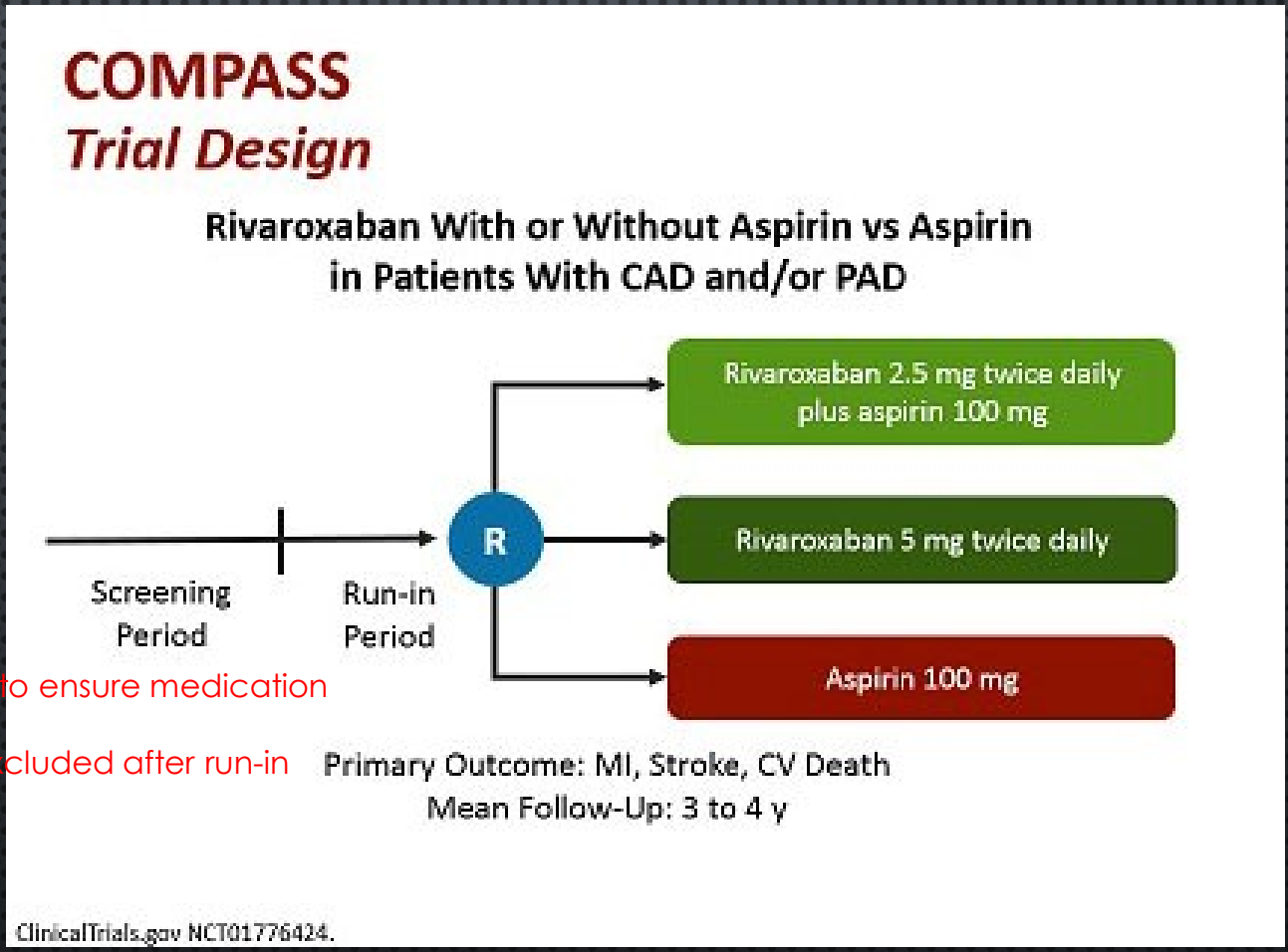
- ***Presence of CAD or PAD***
  - CAD defined as any of:
    - Myocardial infarction within the last 20 years
    - Multivessel coronary disease with symptoms or with history of stable or unstable angina
    - Multivessel PCI
    - Multivessel CABG
  - PAD defined as any of:
    - Previous aorto-femoral bypass surgery, limb bypass surgery, or PTCA of the iliac, infra-inguinal arteries
    - Previous limb or foot amputation for arterial vascular disease
    - History of claudication (peripheral extremity pain with either of ABI < 0.90 or ≥ 50% stenosis of peripheral artery by angiography or duplex ultrasound)
    - Previous carotid revascularization or asymptomatic carotid stenosis ≥ 50% by either angiography or duplex ultrasound
- If included for CAD, also requires either of:
  - Age ≥ 65 years
  - Age < 65 years with documented atherosclerosis or revascularization involving at least 1 additional vascular bed or presence of at least 2 of:
    - Current smoker
    - Diabetes
    - Renal dysfunction with eGFR < 60mL/min
    - Heart failure
    - Non-lacunar stroke ≥ 1 month prior to randomization

Exclusion Criteria

- High risk of bleeding
- Stroke within 1 month or any history of hemorrhagic or lacunar stroke
- Severe heart failure with known LVEF < 30% or NYHA III or IV
- Estimated GFR < 15mL/min
- Need for dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or oral anticoagulant therapy
- Known non-cardiovascular disease associated with poor prognosis or increases risk of adverse effect from study medications
- History of hypersensitivity or known contraindication to rivaroxaban, aspirin, pantoprazole, or excipients or study procedures
- Systemic treatment with strong inhibitors of CYP3A4
- Any known hepatic disease with coagulopathy
- Subject who are pregnant, breastfeeding, or are of childbearing potential and sexually active without contraception34erc

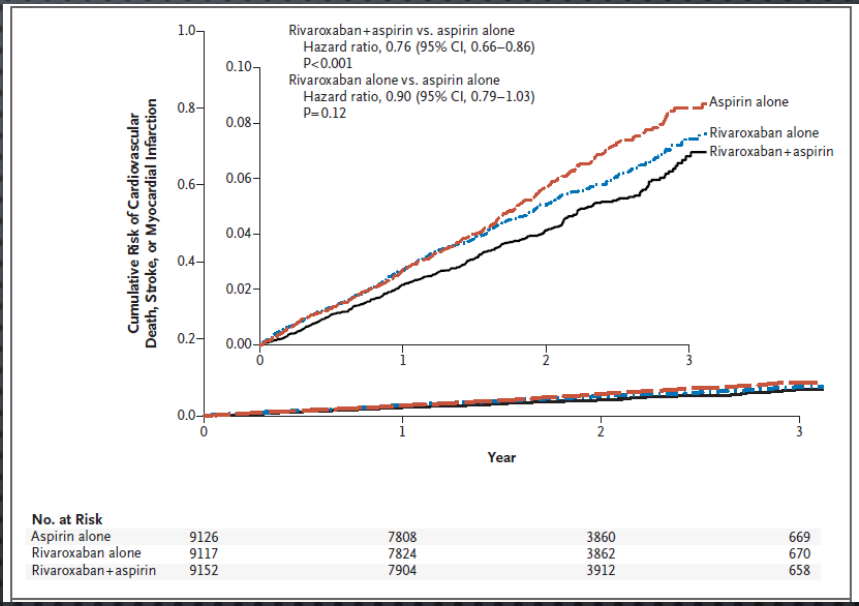
- Randomized placebo-controlled phase III study
- Event driven
- 27,400 patients

Run in period to ensure medication adherence:
~8% excluded after run-in



24% relative risk reduction in combine rivaroxaban + ASA vs ASA alone

Efficacy	ASA + riva 2.5 mg BID (%)	Riva 5 mg BID (%)	ASA (%)
1° outcome (CV death, MI, stroke)	**4.1** *HR 0.76 (0.66-0.86)* **NNT 77**	4.9 *p=0.12*	**5.4**
CV death	1.7	2.1	2.2
MI	**1.9** *p=0.14*	2.0	**2.2**
Stroke	**0.9** *HR 0.58 (0.44-0.76)*	1.3	**1.6**
Death	**3.4** *HR 0.82 (0.71-0.96)* **NNT 143**	4.0	**4.1**



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Major	**5 (0.2)**	8 (0.3)	**17 (0.7)**	0.30	0.01	0.46	0.07

70% increased risk in bleeding

Safety	ASA + riva 2.5 mg BID (%)	Riva 5 mg BID (%)	ASA (%)
Major bleed (modified ISTH)	**3.1** *HR 1.70 (1.40-2.05)* **NNH 84**	**2.8** *HR 1.51 (1.25-1.84)* **NNH 112**	**1.9**
Symptomatic intracranial hemorrhage, or fatal bleed	0.4 *HR 1.23 (0.76-2.01)*	0.5 *HR 1.59 (1.00-2.53)* **NNH 500**	0.3
GI	**1.5** *HR 2.15 (1.60-2.89)*	**1.0** *HR 1.40 (1.02-1.93)*	**0.7**
Minor bleed	**9.2** *HR 1.70 (1.52-1.90)* **NNH 28**	**8.1** *HR 1.50 (1.34-1.68)* **NNH 39**	**5.5**

Net clinical benefit favoring rivaroxaban + ASA
Absolute net-benefit: 1.2%
Relative net-benefit: 20%

Table 3. Bleeding Events and Net Clinical Benefit.*

Outcome	Rivaroxaban plus Aspirin (N=9152)	Rivaroxaban Alone (N=9117)	Aspirin Alone (N=9126)	Rivaroxaban plus Aspirin vs. Aspirin Alone		Rivaroxaban Alone vs. Aspirin Alone	
				Hazard Ratio (95% CI)	P Value	Hazard Ratio (95% CI)	P Value
	number (percent)						
Major and minor bleeding							
Major bleeding	288 (3.1)	255 (2.8)	170 (1.9)	1.70 (1.40–2.05)	<0.001	1.51 (1.25–1.84)	<0.001
Fatal bleeding†	15 (0.2)	14 (0.2)	10 (0.1)	1.49 (0.67–3.33)	0.32	1.40 (0.62–3.15)	0.41
Nonfatal symptomatic ICH†	21 (0.2)	32 (0.4)	19 (0.2)	1.10 (0.59–2.04)	0.77	1.69 (0.96–2.98)	0.07
Nonfatal, non-ICH, symptomatic bleeding into critical organ†	42 (0.5)	45 (0.5)	29 (0.3)	1.43 (0.89–2.29)	0.14	1.57 (0.98–2.50)	0.06
Net-clinical-benefit outcome: CV death, stroke, myocardial infarction, fatal bleeding, or symptomatic bleeding into critical organ	431 (4.7)	504 (5.5)	534 (5.9)	0.80 (0.70–0.91)	<0.001	0.94 (0.84–1.07)	0.36
Transfusion within 48 hr after bleeding	87 (1.0)	66 (0.7)	44 (0.5)	1.97 (1.37–2.83)	<0.001	1.50 (1.03–2.20)	0.03
Minor bleeding	838 (9.2)	741 (8.1)	503 (5.5)	1.70 (1.52–1.90)	<0.001	1.50 (1.34–1.68)	<0.001
Site of major bleeding							
Gastrointestinal	140 (1.5)	91 (1.0)	65 (0.7)	2.15 (1.60–2.89)	<0.001	1.40 (1.02–1.93)	0.04
Intracranial	28 (0.3)	43 (0.5)	24 (0.3)	1.16 (0.67–2.00)	0.60	1.80 (1.09–2.96)	0.02
Skin or injection site	28 (0.3)	28 (0.3)	12 (0.1)	2.31 (1.18–4.54)	0.01	2.34 (1.19–4.60)	0.01
Urinary	15 (0.1)	30 (0.3)	21 (0.2)	0.61 (0.31–1.23)	0.16	1.43 (0.82–2.50)	0.20
Net-clinical-benefit outcome: CV death, stroke, myocardial infarction, fatal bleeding, or symptomatic bleeding into critical organ	431 (4.7)	504 (5.5)	534 (5.9)	0.80 (0.70–0.91)	<0.001	0.94 (0.84–1.07)	0.36

* ICH denotes intracranial hemorrhage, and ISTH International Society on Thrombosis and Haemostasis.
† If a participant had more than one event of major bleeding, only the most serious bleeding event was counted in these analyses.

Limitations

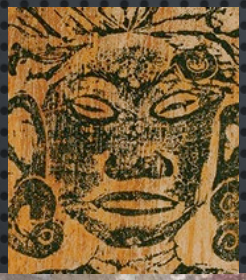
- Small differences in absolute risk reduction
- Trial was stopped early and therefore limits long-term bleeding complication rates.

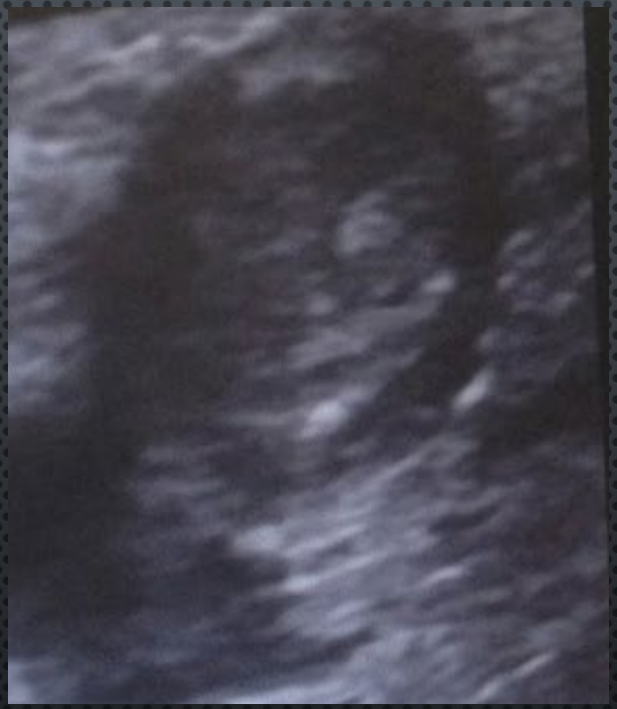
Though the data is statistically significant most specialists have held back engaging this therapy choosing to stratify these patients based upon severity of disease and their experience

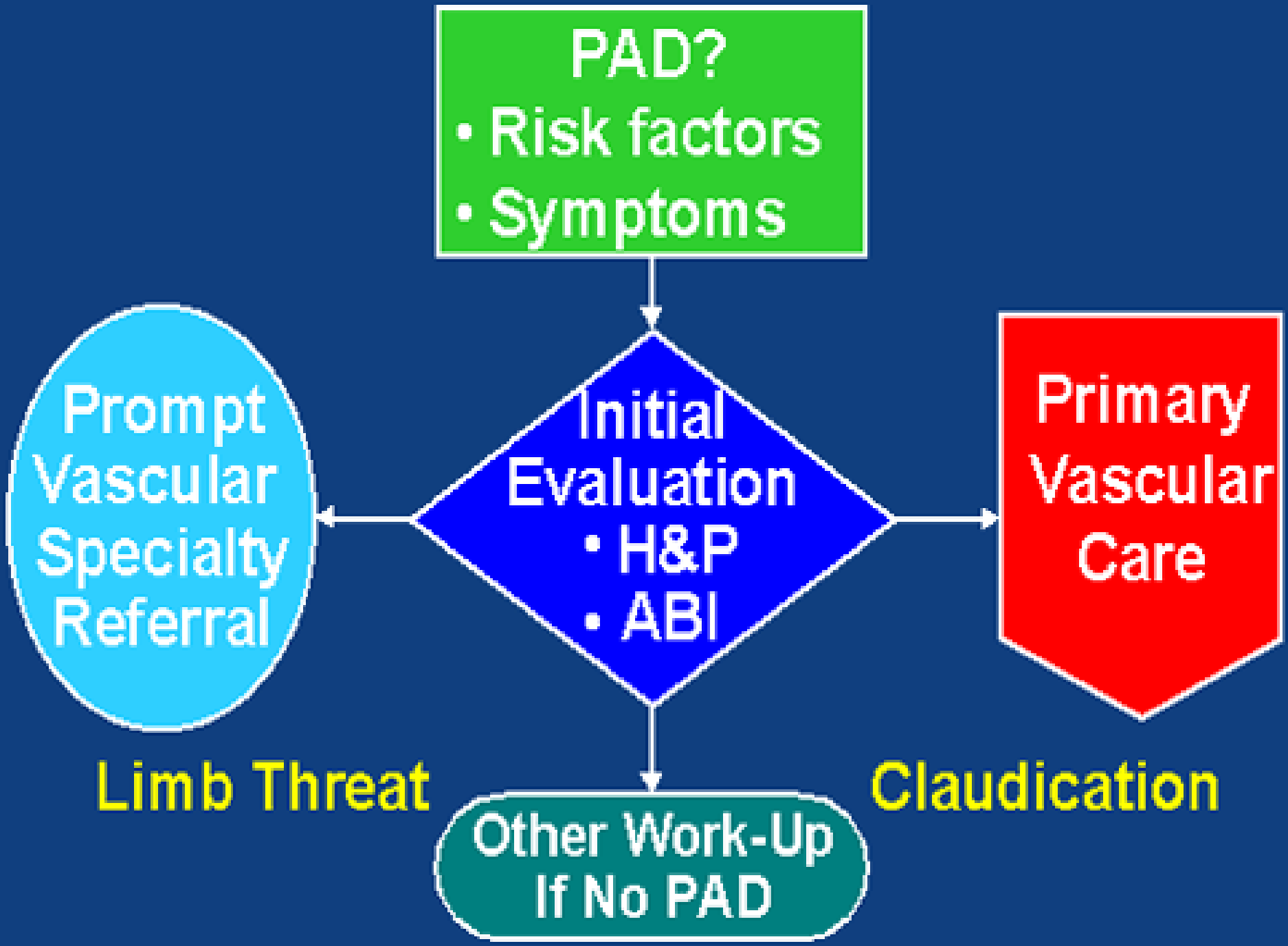
100 year old Cave Drawing

52 year old with h/o temporal wasting neurotrophic ulcer lymphedema right a swollen right arm

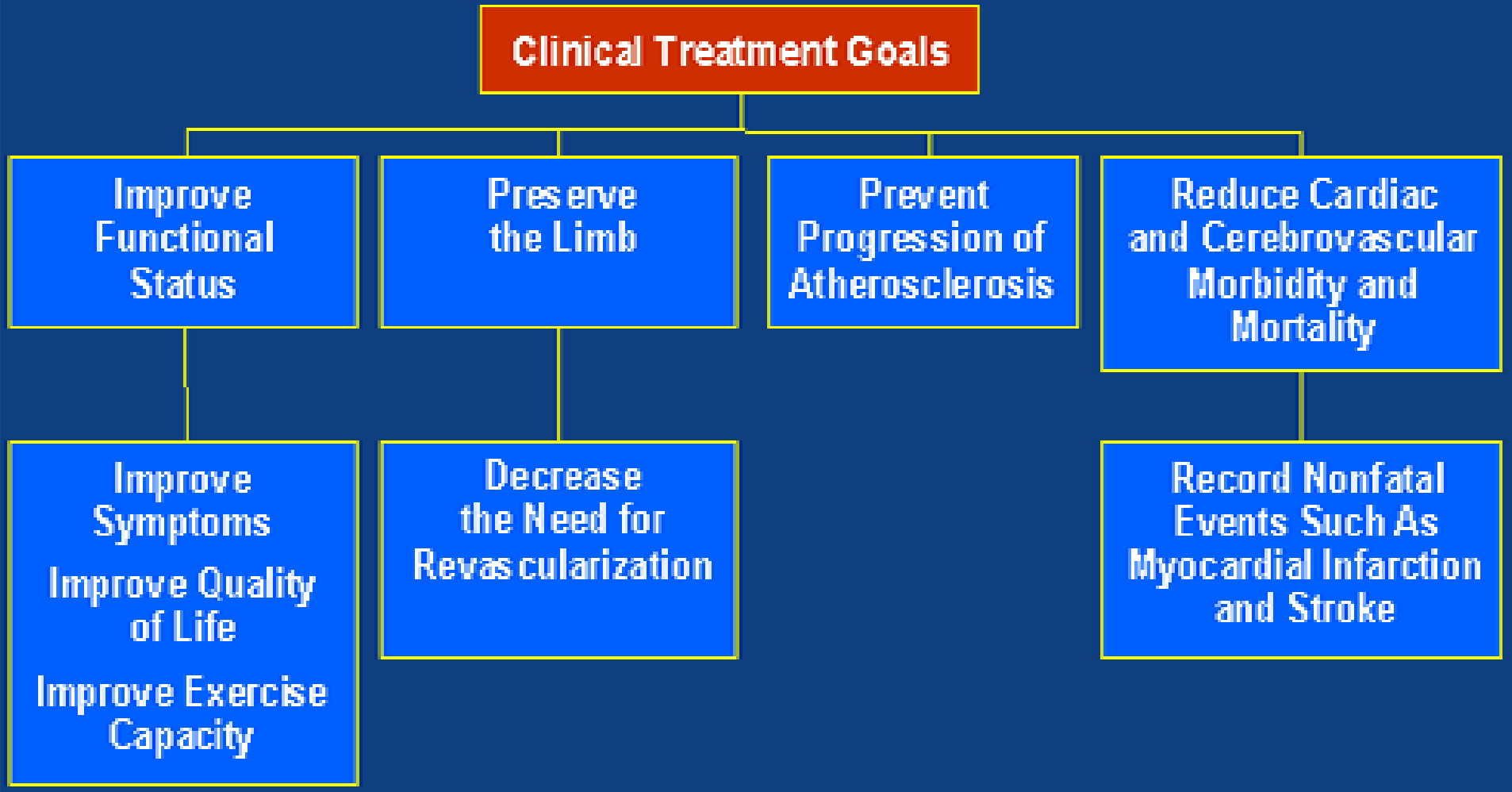
ARCHETYPES VOODOU AND THE COGNITIVE DESISTENCE
IT IS ALWAYS DATA VS VOODOU AND FAITH





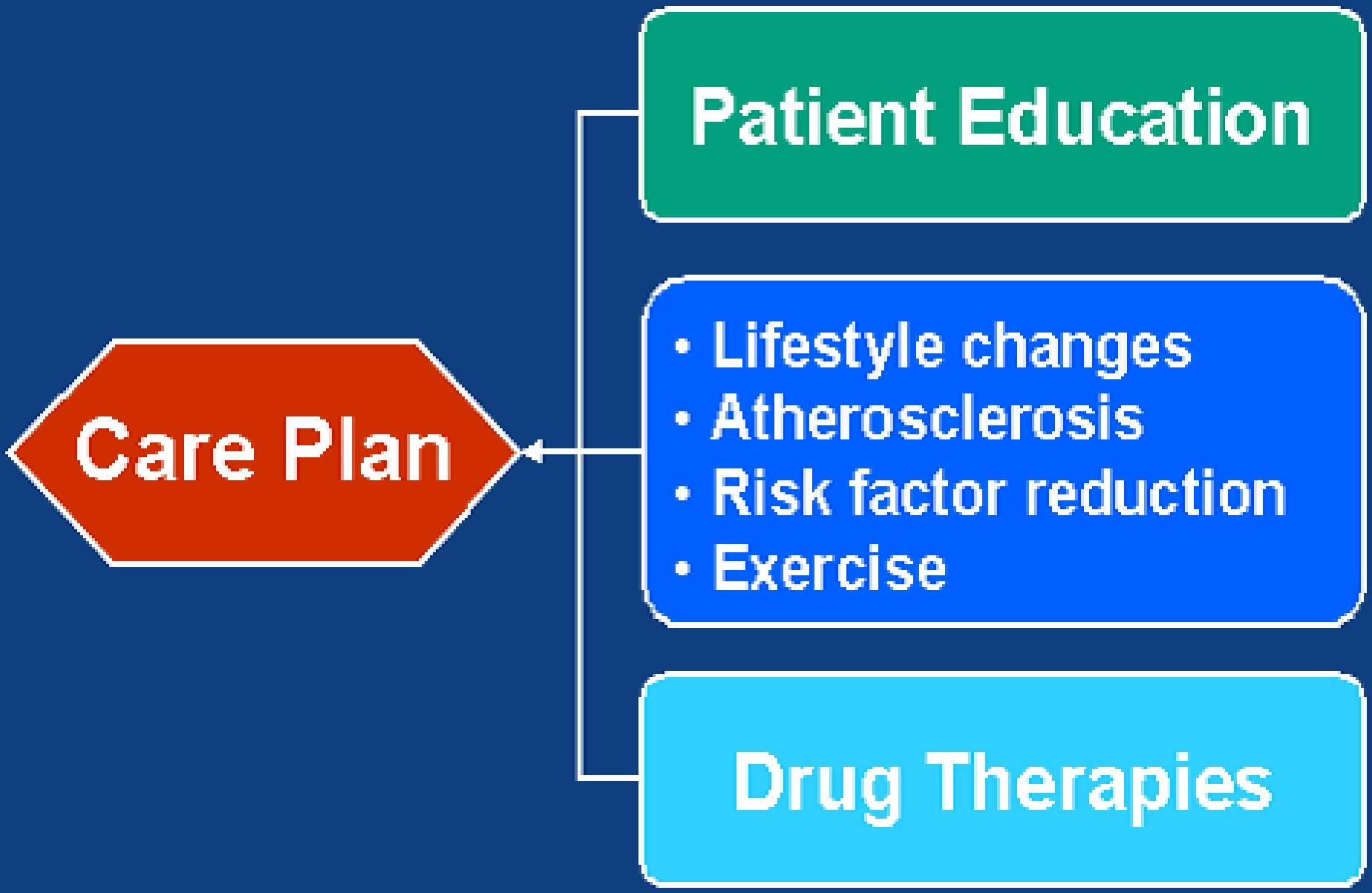

PAD?
• Risk factors
• Symptoms
Prompt Vascular Specialty Referral
Initial Evaluation
• H&P
• ABI
Primary Vascular Care
Limb Threat
Claudication
Other Work-Up If No PAD

Treatment Goals for the Patient with Peripheral Arterial Disease



Factors That May Improve the Natural History of Atherosclerosis and Prevent Acute Ischemic Events

- Stop smoking
- Achieve ideal body weight
- Exercise
- Control blood pressure
- Control cholesterol and triglycerides
- Control diabetes
- Antiplatelet therapy


Care Plan
Patient Education
• Lifestyle changes
• Atherosclerosis
• Risk factor reduction
• Exercise
Drug Therapies

"It has been said that a little exercise never hurt anyone, but I say why take the chance."
Ronald Reagan

"Trickle down economics "

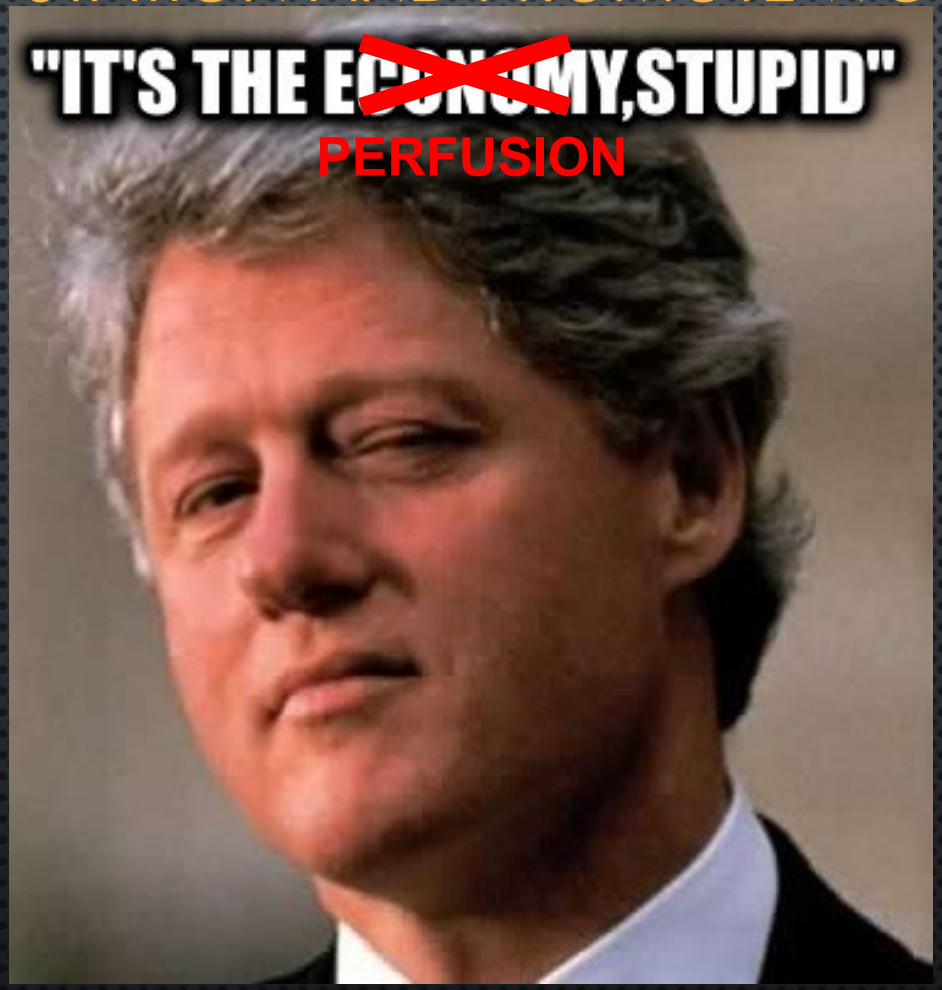
EVERYBODY HAS A GAME PLAN UNTIL THEY GET PUNCHED IN THE FACE

MIKE TYSON

CONCLUSIONS

- EARLY IDENTIFICATION OF CLINICAL FEATURES AND ESTABLISHMENT OF RISK FACTOR REDUCTION IS PARAMOUNT
- MEDICAL THERAPY WORKS, BUT MAY NOT BE ENOUGH IN CLI
- REVASCULARIZATION IS STILL THE CORNERSTONE OF THERAPY TO RELIEVE REST PAIN, IMPROVE WOUND HEALING, AND REDUCE AMPUTATION
- DEVELOP PATIENT SPECIFIC GOALS FOR REVASCULARIZATION
  - WHEN IN DOUBT, ESTABLISH STRAIGHT, IN-LINE, PULSATILE FLOW TO THE FOOT
- RECOGNIZE WHAT IS SALVAGEABLE AND WHEN TO GET OUT OF DODGE!!!

WHAT IS THE BEST WAY TO PREVENT AMPUTATION AND PROMOTE WOUND



10% OF THOSE UNDERGOING LOWER EXTREMITY REVASC WILL HAVE A MALE IN 1 YEAR.

CENTRAL ILLUSTRATION 1-Year Outcomes After Peripheral Artery Revascularization

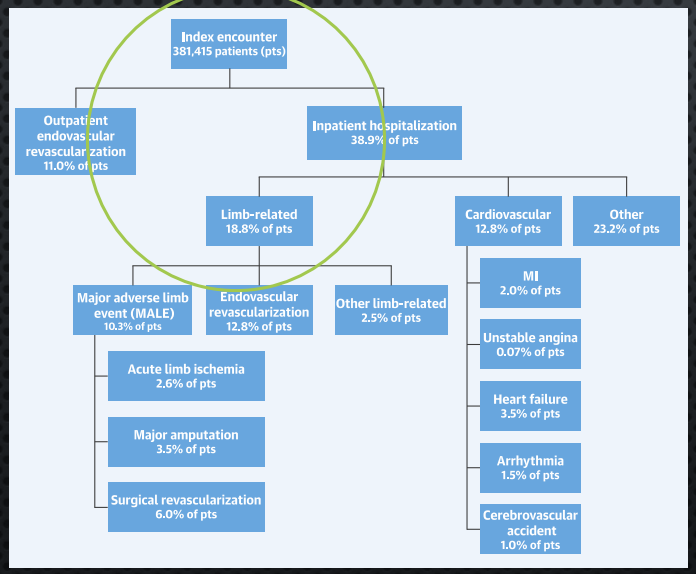


TABLE 2 Factors Associated With 1-Year Hospitalization for MALE

	OR (95% CI)	p Value
Demographics		
Age		
65–74 yrs vs. <65 yrs	0.82 (0.79–0.84)	<0.0001
≥75 yrs vs. <65 yrs	0.63 (0.61–0.65)	<0.0001
Female	0.91 (0.89–0.93)	<0.0001
Black vs. white race	1.27 (1.24–1.31)	<0.0001
Indication for revascularization		
ALI vs. symptomatic PAD	1.39 (1.31–1.47)	<0.0001
CLI vs. symptomatic PAD	2.24 (2.19–2.30)	<0.0001
Obesity	0.91 (0.88–0.94)	<0.0001
Diabetes	1.20 (1.17–1.23)	<0.0001
Hyperlipidemia	0.93 (0.91–0.96)	<0.0001
Procedure operator specialty		
Vascular surgery vs. cardiology	2.13 (2.06–2.20)	<0.0001
General surgery vs. cardiology	2.09 (2.01–2.18)	<0.0001
Radiology vs. cardiology	2.11 (2.02–2.21)	<0.0001
Thoracic surgery vs. cardiology	1.86 (1.77–1.97)	<0.0001
Other vs. cardiology	1.58 (1.52–1.65)	<0.0001
Procedure operator specialty		
Vascular surgery vs. cardiology	2.13 (2.06–2.20)	<0.0001
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Thoracic surgery vs. cardiology	1.86 (1.77–1.97)	<0.0001
Other vs. cardiology	1.58 (1.52–1.65)	<0.0001
Discharge to skilled nursing facility vs. home	1.10 (1.07–1.14)	<0.0001
Hospital characteristics		
Midwest vs. Northeast region	0.96 (0.92–0.998)	0.04
Bed size		
350–549 beds vs. <350 beds	1.14 (1.11–1.17)	<0.0001
>550 beds vs. <350 beds	1.05 (1.02–1.09)	0.002

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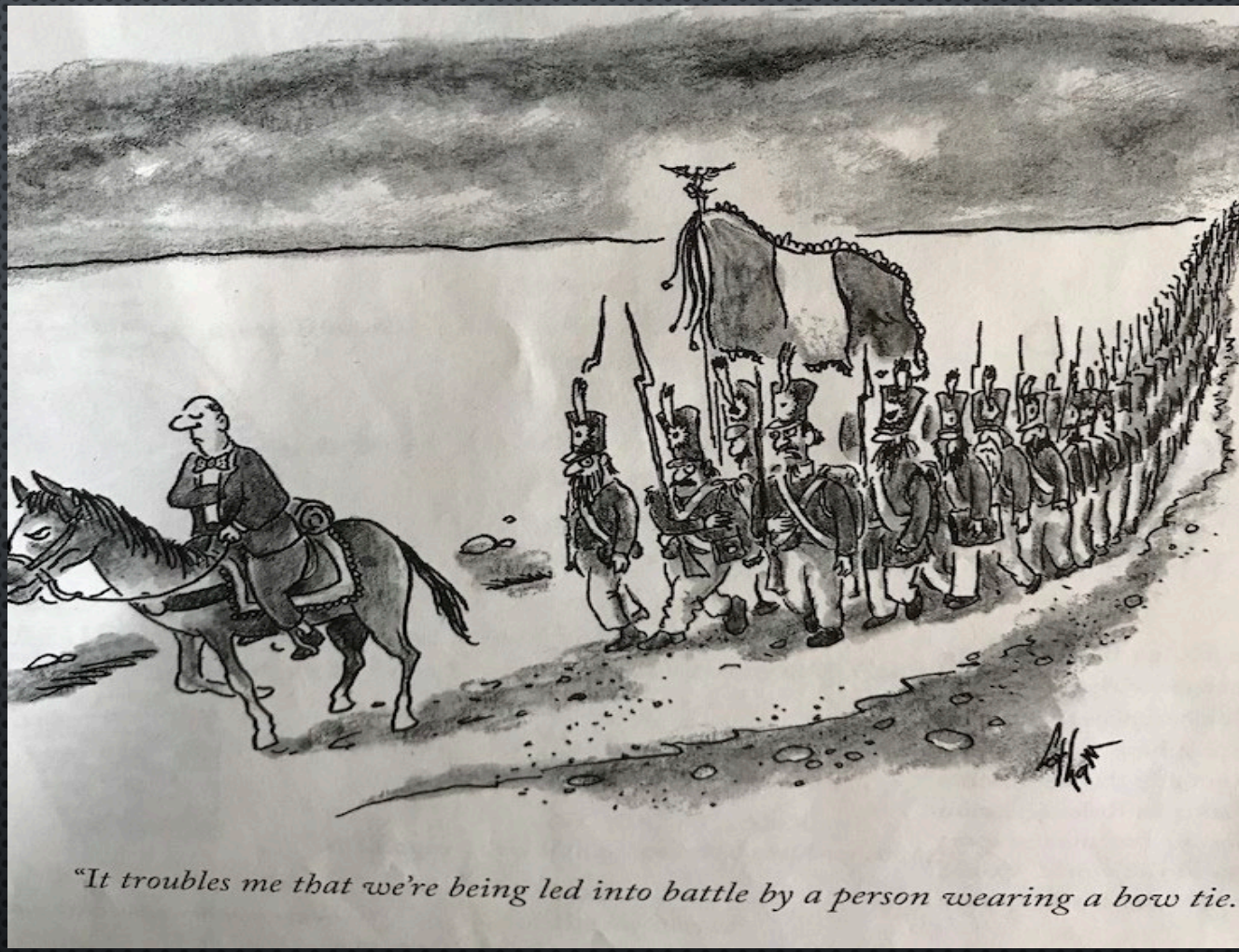
DATA CAN BE CONFUSING

- DATA CAN BE RAW
- DATA CAN BE MANIPULATED
- DATA CAN BE MADE UP
- DATA CAN COUNTERINTUITIVE



Call to Action

- Increase awareness and consequences of PAD.(education)
- Improve identification of symptomatic PAD.(public Awareness)
- Initiate Screening for PAD.
- Improve Treatment rates.
- Increase early detection in asymptomatic population.
- Understand and pursue evidence based recommendation
- Combine reproducible data with best Judgement

"DON'T BE SURPRISED IF YOU DRAIN THE PACIFIC OCEAN IF THE ISLANDS ARE CONNECTED"

JUDA FOLKMAN MD

“ IT IS NOT THE ANSWER THAT ENLIGHTENS , BUT THE QUESTION”
EUGENE IONESCO

Thank you

Commonly asked questions

- Should I anticoagulant
- What dose
- Should I use antiplatelet therapy
- Is there an optimal dose

TARGET BEDS

- Carotid disease Antiplatlet therapy
- AAA Anti- Platlet therapy
- Cardiac arrhythmia Anticoagulation
- Arterial Dissection (no diferance between ASA and Anticoagulation
- Thrombophilia Antiphosphlipid antibody ACA,LA, SLE Combined Antiplatlet anticoagulation ?
- PAD ???