SVM Fellows Course Handouts Table of Contents
Sunday, March 17, 2024

* Handout not included in packet

Diagnosing PAD

March 2024

Bryan J. Wells, MD

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Learning Objectives

- Discuss differential of PAD and other possible diagnoses of LE pain
- Review classic presentation/ physical exam in PAD
- Role of ABI and other vascular testing in diagnosis

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Case

- 57-year-old man with a history of tobacco abuse presents to the clinic c/o calf pain
- States that after he walks in the parking lot, he gets a burning sensation in the back of his legs
- This is worse with hills and resolves completely after 30 seconds of rest
- Past Medical and Social History
  - Tobacco Abuse
    - Tried to quit with Chantix but failed
  - HLD
  - EtOH
  - HTN
  - Works as a bartender and is on his feet most of the day

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Case Continued

MEDS
- Aspirin
- Atorvastatin
- Ibuprofen
- Cyclobenzaprine

EXAM
- 2+ DP/PT bilaterally
- No peripheral edema
- No abdominal bruits

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Why Screen for PAD?

- To identify disease and prevent progression and complications related to PAD
- To identify patients at high risk for other forms of cardiovascular disease and aggressively treat risk factors to prevent cardiovascular events

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Question 1

- What is the differential diagnosis for lower extremity pain?

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Lower Extremity Pain

- History and physical is important to determine the etiology
- Differential diagnosis is broad
  - Acute versus Chronic
  - Resting versus exertional
  - Positional, location, associated signs/symptoms
- 3 main categories
  - Vascular
  - Neurological
  - Musculoskeletal

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VASCULAR CAUSES	
DVT	Unilateral pain, swelling, discoloration; risk factors include smoking, recent travel, cancer, etc
Peripheral vascular disease	Bilateral claudication; history of smoking, atherosclerosis
Arterial endofibrosis	Associated with repetitive hip flexion, unilateral, most common in cyclists; ischemic pain and loss of power
Cystic adventitial disease	Men in mid-40s, intermittent claudication with activity
Popliteal artery aneurysm	Most common peripheral aneurysm, more common in males, associated with smoking and HTN; acute or chronic ischemic pain or arterial insufficiency, often asx
Popliteal artery entrapment syndrome	Lower limb pain and ischemia with high-intensity exercise associated with excessive dorsiflexion and plantar flexion of ankle

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NEUROLOGICAL CAUSES	
Lumbar radiculopathy	Possible association w/ low back pain, sx in distribution of dermatome, often unilateral
Peripheral neuropathy	History of DM, vitamin deficiency, or other systemic disease; pain and sensory loss
Spinal stenosis	Age >/- 50, lower back pain, symptoms worse with activity, relieved with sitting or flexing spine; numbness and tingling from buttocks into legs
Nerve entrapment	Pain and tingling worse with activity in distribution of affected nerve; trauma more likely than overuse

MUSCULOSKELETAL CAUSES	
CECS	Consistent bilateral symptoms; numbness and weakness may occur
MTSS	Common in runners, often bilateral, diffuse tenderness
Muscle strain	Immediate onset of symptoms, unilateral, no pain at rest
Stress fracture	Common in athletes, especially female athlete triad; unilateral, focal pain, tenderness
Tendinopathy	Gradual onset of symptoms related to overuse

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True or False

- The majority of patients with peripheral arterial disease will have typical claudication symptoms

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PAD Symptoms

- Classic claudication symptoms
  - Exertional leg pain that resolves within 10 minutes of rest
  - Present in only 32% of patients; 20% have no leg pain, 48% have atypical symptoms
- Rest pain
- Ulcer
- Gangrene
- Leriche's syndrome

McDermott, et al. JAMA. 2001: 286:1599.

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	Claudication	Pseudoclaudication
Characteristic of discomfort	Cramping, tightness, aching, fatigue	Same as claudication + tingling, burning, numbness
Location of discomfort	Buttock, hip, thigh, calf, foot	Same as claudication
Exercise-induced	Yes	Variable
Distance	Consistent	Variable
Occurs with standing	No	Yes
Action for relief	Stand	Sit, change position
Time to relief	<5 minutes	≤30 minutes

Hirsch AT, et al. J Am Coll Cardiol. 2006;47:1239-1312.

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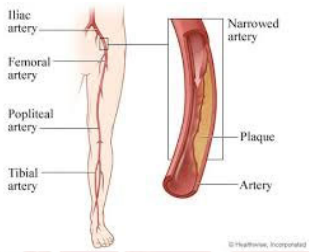
Lower Extremity Peripheral Arterial Disease (PAD)



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Question 2

- What are the risk factors for peripheral arterial disease?

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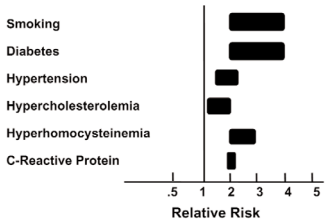
Risk Factors for PAD



Dormandy JA, et al. J Vasc Surgery, 2000, 31.

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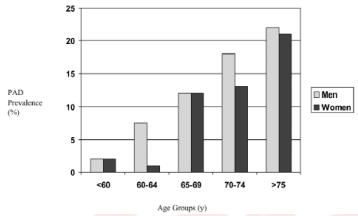
PAD Prevalence Increases with Age



Criqui. Circulation 1985;71:510-5 (77).

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Question 3

- What are the physical examination findings associated with PAD?

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PAD Physical Exam Findings

- Peripheral pulses
- Skin temperature
- Skin color
- Bruits
- Hair loss
- Tissue loss
- Signs of infection

Khan NA, JAMA 2006; 295:536.

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Question 4

- What diagnostic testing is available to evaluate for PAD?

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AHA/ACC 2016 Guidelines

Recommendations for Resting ABI for Diagnosing PAD		
COR	LOE	Recommendations
I	B-NR	In patients with history or physical examination findings suggestive of PAD (Table 4), the resting ABI, with or without segmental pressures and waveforms, is recommended to establish the diagnosis (60-65).
I	C-LD	Resting ABI results should be reported as abnormal (ABI ≤0.90), borderline (ABI 0.91–0.99), normal (1.00–1.40), or noncompressible (ABI >1.40) (46, 63-66).
IIa	B-NR	In patients at increased risk of PAD (Table 3) but without history or physical examination findings suggestive of PAD (Table 4), measurement of the resting ABI is reasonable (41, 42, 67-89).
III: No Benefit	B-NR	In patients not at increased risk of PAD (Table 3) and without history or physical examination findings suggestive of PAD (Table 4), the ABI is not recommended (87, 90).

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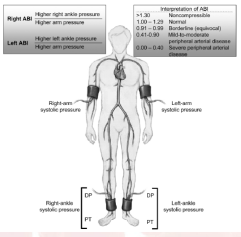
Ankle-Brachial Index

$$ABI = \frac{\text{Ankle systolic pressure}}{\text{Brachial systolic pressure}}$$

- ABI has excellent accuracy in detecting stenosis **>50%**



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Diagnostic Performance of the ABI

TEST	SENSITIVITY	SPECIFICITY
ABI	**95-97%**	**99-100%**
PULSE EXAM (DP)	50%	73%
PULSE EXAM (PT)	71%	91%
Rose Claudication Questionnaire	20%	96%

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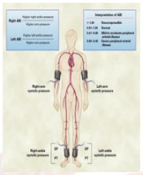
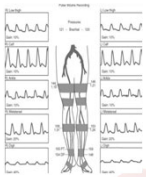
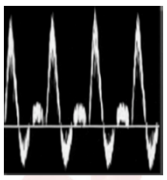
Diagnostic studies to evaluate for PAD



Ankle-Brachial Index



Segmental Pressures & Pulse Volume Recordings



Spectral Doppler Waveforms

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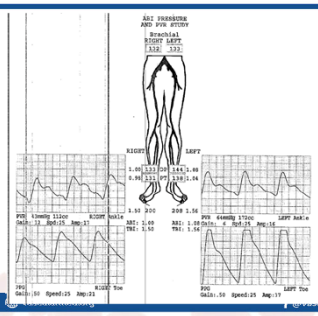
Our Patient's Resting ABI



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Exercise ABI

POST EXERCISE ANKLE PRESSURES

	BRACHIAL	TIME	RIGHT ANKLE	RIGHT ABI	RIGHT TIME	LEFT ANKLE	LEFT ABI	LEFT TIME
RESTING								
IMMEDIATE	163	02:09	59	0.36	00:55	148	0.91	01:30
PERIOD 1			75		02:53			
PERIOD 2								
PERIOD 3								
PERIOD 4								
PERIOD 5								

Total Exercise Time: 05:14
RIGHT CALF symptomatic at: 01:36

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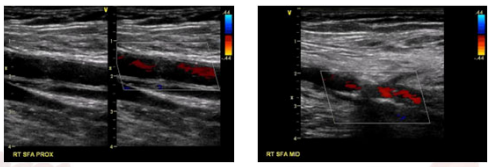
Arterial Duplex



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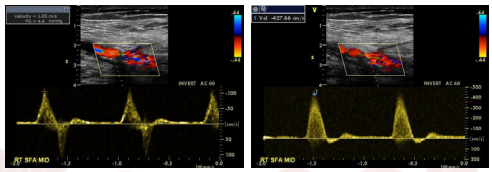
Arterial Duplex



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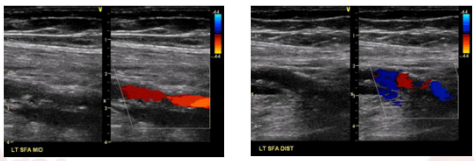
Arterial Duplex



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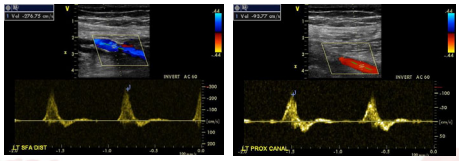
Arterial Duplex



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Lower Extremity Angiogram

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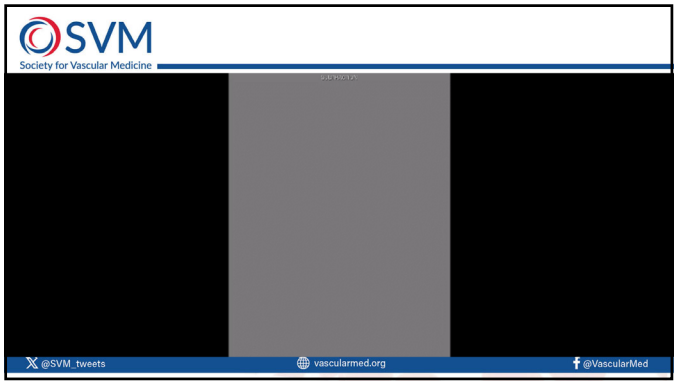
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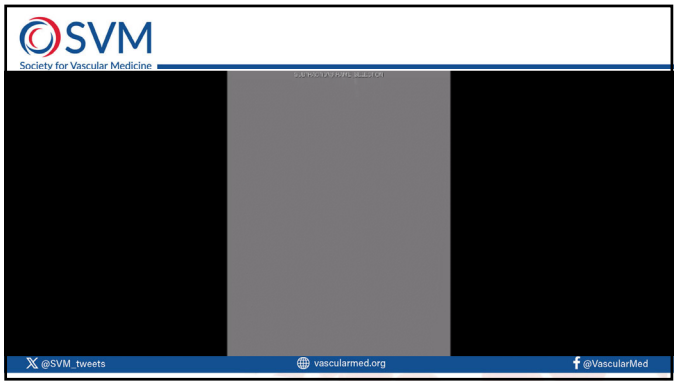
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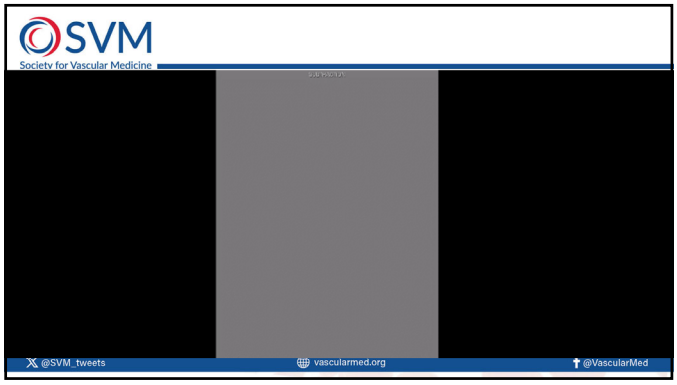
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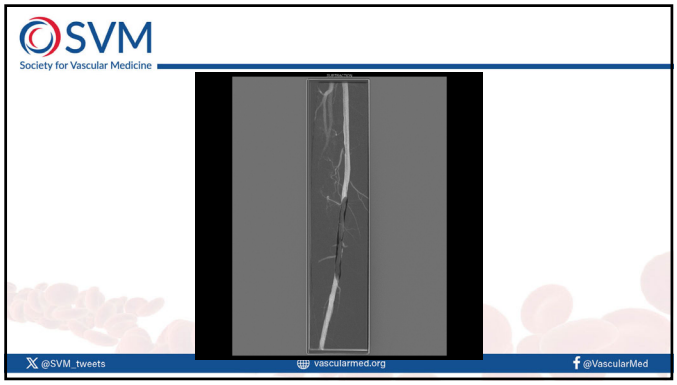
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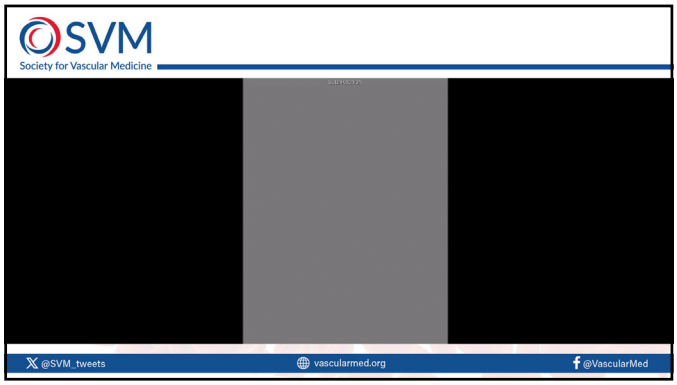
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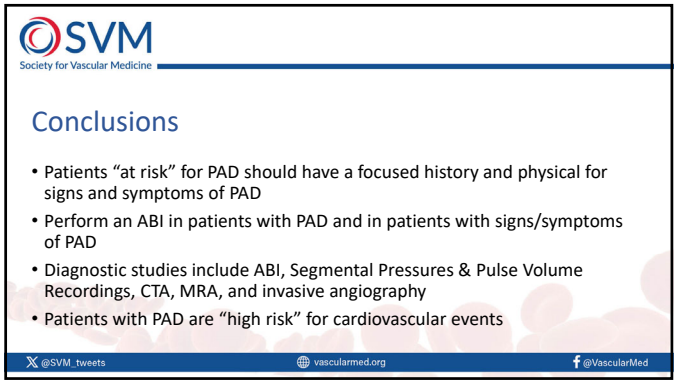
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Conclusions
• Patients “at risk” for PAD should have a focused history and physical for signs and symptoms of PAD
• Perform an ABI in patients with PAD and in patients with signs/symptoms of PAD
• Diagnostic studies include ABI, Segmental Pressures & Pulse Volume Recordings, CTA, MRA, and invasive angiography
• Patients with PAD are “high risk” for cardiovascular events
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Preserving Life and Limb in PAD

Aditya Sharma, MBBS, FSVM
Director, Vascular Medicine
Associate Professor of Medicine
University of Virginia
adityasharmamd

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Disclosures

- Research funding:
  - PI: Boston Scientific (HI-PEITHO)
  - PI: Vascular Medcure
  - PI: NIH (C-TRACT)
  - Co-I: Thrombolex (RESCUE) and NIH (ATTRACT)
- Speakers bureau and consulting:
  - Boston Scientific
  - enVVeno
- Clinical Excellence Committee:
  - Thrombolex

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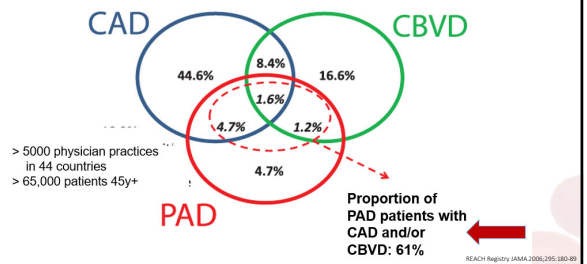
PAD: A POLYVASCULAR DISEASE



REACH Registry JAMA 2006;295:180-89
EUCLID JACC 2020;75:498–508

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Not ALL PAD is the SAME

Patients with PAD who have undergone a REVASCULARIZATION: Very high risk for major adverse cardiovascular events (MACE) and major adverse limb events (MALE)

Compared to stable PAD
→4x higher risk of ALI
→> 30% increased risk of MI

J Am Coll Cardiol. 2016;67:2719–2728

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PAD patient

- Antithrombotics
- Hyperlipidemia
- Diabetes
- Diet and Smoking
- Hypertension
- Exercise therapy

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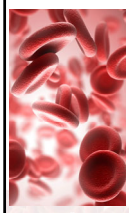
Antithrombotic Therapy



- ATT data: Reduced CV event rate by 22% ↓ in large meta-analysis
- CAPRIE trial: Incremental benefit of clopidogrel vs. aspirin (8.7 RR reduction)
- Berger et al: 2009 meta-analysis suggests aspirin not adequately proven to be anti-platelet agent of choice for preventing CV events in PAD patients
- EUCLID trial: ticagrelor monotherapy not superior to clopidogrel
- Path specimens: plaque thrombosis and microembolism
  - 2/3rd of infrapopliteal lesions are thrombosis without atherosclerosis

N Engl J Med 2017; 376:32-40
JACC Cardiovasc Imaging. 2019;12:1501–1513.
BMJ. 2002;324:71.
Lancet. 1996;348:1329
Eur Heart J. 2009;30:192.

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Combination Therapies

	Aspirin+ticagrelor 60 mg twice daily vs aspirin
Pivotal studies	PEGASUS-TIMI 54[125,126]
Population	Prior MI with symptomatic PAD subgroup†
Effects for MACE	15% relative risk reduction
Effects for MALE	35% relative risk reduction
Bleeding	2.32-fold relative excess in TIMI major bleeding

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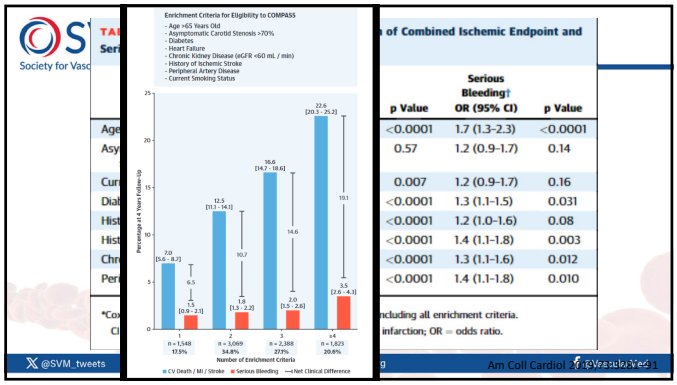

of Combined Ischemic Endpoint and

p Value	Serious Bleeding† OR (95% CI)	p Value
<0.0001	1.7 (1.3-2.3)	<0.0001
0.57	1.2 (0.9-1.7)	0.14
0.007	1.2 (0.9-1.7)	0.16
<0.0001	1.3 (1.1-1.5)	0.031
<0.0001	1.2 (1.0-1.6)	0.08
<0.0001	1.4 (1.1-1.8)	0.003
<0.0001	1.3 (1.1-1.6)	0.012
<0.0001	1.4 (1.1-1.8)	0.010

ncluding all enrichment criteria.
infarction; OR = odds ratio.

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Individualized Approach of Antithrombotic Therapy in PAD

Increase Ischemic Events (MACE)	Increase Limb Events (MALE)	Increase bleeding events
Polyvascular disease (CAD/CVD)	Prior bypass (especially prosthetic or below the knee bypass) or Prior revascularization	Recent major bleeding
Diabetes Mellitus	Prior amputations / tissue loss	Prior Intracranial bleeding
Old age	Below the knee disease/ multilevel disease	Chronic anticoagulation (A fib/VTE)
Active smoking	CLI (ARR higher 5.7% vs. 3.9%)	Anemia
Heart failure / Renal disease	Prior arterial thrombotic events	Fragility / old age

J Am Coll Cardiol. 2018;71(21):2450-67

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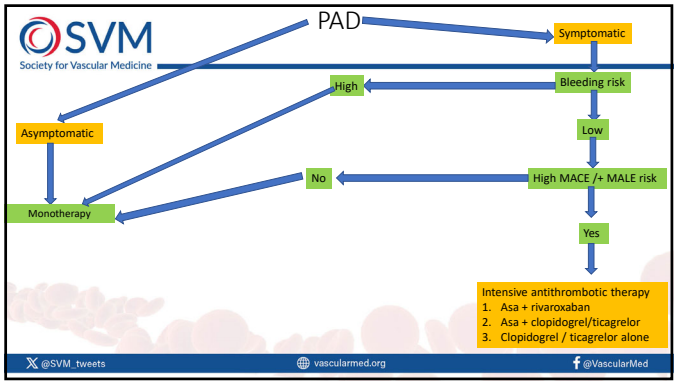
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PAD
Symptomatic
Bleeding risk
High
Low
Asymptomatic
No
High MACE /+ MALE risk
Monotherapy
Yes
Intensive antithrombotic therapy
1. Asa + rivaroxaban
2. Asa + clopidogrel/ticagrelor
3. Clopidogrel / ticagrelor alone
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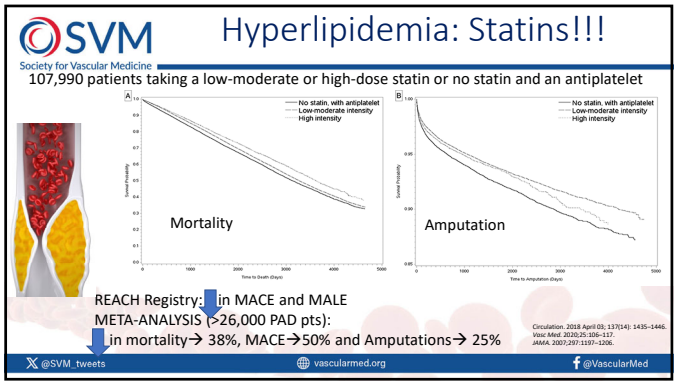
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Hyperlipidemia: Statins!!!
107,990 patients taking a low-moderate or high-dose statin or no statin and an antiplatelet
No statin, with antiplatelet
Low-moderate intensity
High intensity
Mortality
Amputation
REACH Registry: in MACE and MALE
META-ANALYSIS (>26,000 PAD pts):
in mortality→ 38%, MACE→50% and Amputations→ 25%
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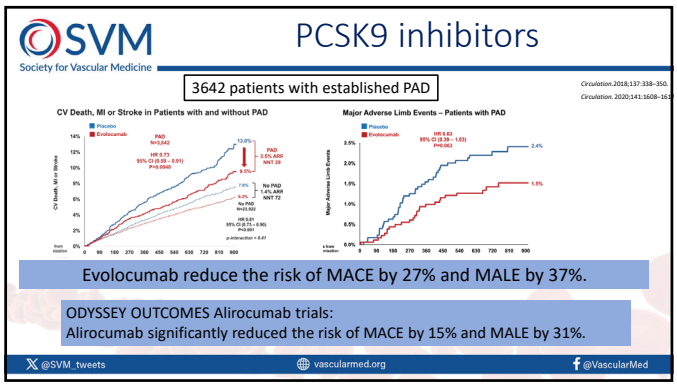
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PCSK9 inhibitors
3642 patients with established PAD
CV Death, MI or Stroke in Patients with and without PAD
Major Adverse Limb Events – Patients with PAD
Evolocumab reduce the risk of MACE by 27% and MALE by 37%.
ODYSSEY OUTCOMES Alirocumab trials:
Alirocumab significantly reduced the risk of MACE by 15% and MALE by 31%.
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SVM Approach to Lipid management

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- ALL PATIENTS WITH PAD -HIGH INTENSITY STATINS
  - Atorvastatin 40 to 80 mg or Rosuvastatin 20-40 mg
- PCSK9i considered in some scenarios
  - LDL > 70 or less than 50% reduction from base LDL on high intensity statins
  - Statin intolerance
- It reasonable to have a low LDL even up to 25 mg/dl
- GOAL is to keep < 70 mg/dl

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SVM Diabetes Management: More than LOWERING GLUCOSE !!! SGLT2 inhibitors and GLP-1 agonists

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- GLP-1 agonists: Liraglutide and Semiglutide

- Liraglutide: LEADER trial (>9000 patients)
  - Lower MACE (HR, 0.87; $p < 0.001$) and CV death (HR, 0.78; $p = 0.00$
  - Amputation reduction by 35% (HR, 0.65; $p = 0.03$)
- Semiglutide:
  - SUSTAIN-6 trial: (>3000 patients), lowered MACE (HR, 0.74; $p < 0.001$)
  - POST HOC ANALYSIS OF ONLY PAD patients (>1500 patients): MACE is 35% higher in PAD and greater benefits seen compared to non-PAD patients.
  - Taiwan National database: Lower risk of MALE and MACE

Vascular Medicine 2023, Vol. 28(1) 62–76c

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SVM SGLT2 inhibitors

	Empaglifozin	Canagliflozin	Dapagliflozin
Trial			
CV or renal Outcome			
Limb outcomes			

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Approach to Diabetes

- At risk for amputations (previous amputation, CLI or neuropathy): GLP-1 agonists
- Heart failure and/ renal disease: SGLT2 inhibitors

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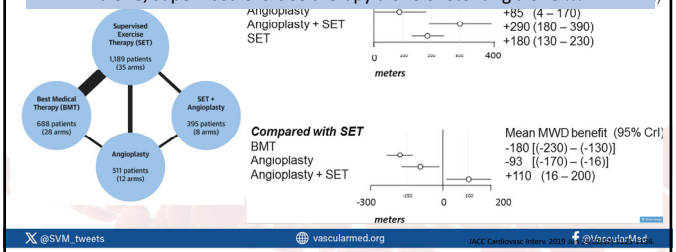
Supervised Exercise Therapy and Revascularization for Intermittent Claudication

Network Meta-Analysis of Randomized Controlled Trials

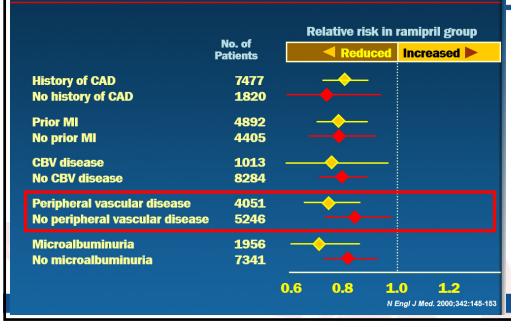
Stenting with supervised exercise therapy is superior to medical therapy alone, supervised exercise therapy alone or stenting alone !!!



@SVM_tweets vascularmed.org @VascularMed

17

HOPE: Benefits in CV Risk Subgroups



- ACEI and ARB are first line anti-hypertensive therapies for hypertension in PAD patients.
- CV event risk reduction seen independent of BP reduction.

@VascularMed

18

Minimizing Tissue Loss in Patients With PAD

- Counsel your patients on ***daily*** self-foot examination
- Prompt diagnosis and treatment of foot infection
- Biannual foot examination by a clinician is reasonable for patients with PAD and diabetes mellitus

Circulation 2017;135:e726

@SVM_tweets vascularmed.org @VascularMed

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Take Home Points

Save Limbs

Save Lives

- All patients with PAD require medical therapy and risk factor modification
- Select patients will benefit from intensive antithrombotic therapy
  - These includes those with polyvascular disease, CLI, HF, DM, prior LER
- Hyperlipidemia:
  - High intensity statins for ALL
  - If intolerant or LDL > 70 mg/dl on statins → PCSK9i
- Diabetes:
  - Goal HbA1c < 7
  - Prior amputations or CLI: GLP1 agonists
  - Heart failure or kidney disease: SGLT2i (avoid canaglifazon)
- Exercise therapy, diet and smoking cessation for ALL
- Hypertension: Consider ACEI/ ARB

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20

I think we need to revascularize!

What about medications?

Not just a procedure!!

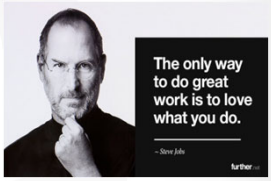
Andrew J. P. Klein, MD, FACC, FSCAI
Interventional Cardiology
Vascular and Endovascular Medicine
Piedmont Heart Institute
Atlanta, GA

Piedmont HEART

1

Disclosure

- No Financial Disclosures
- I am
  - **An Internist**
  - A Cardiologist
  - An Interventional Cardiologist
  - A Vascular and Endovascular Specialist



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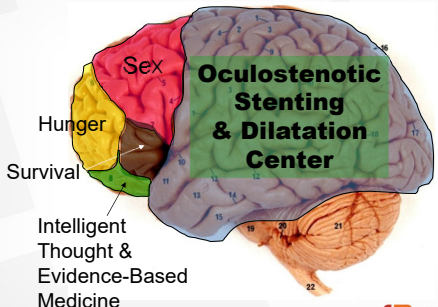
2

DISCLAIMER

Interventional Cardiology Brain



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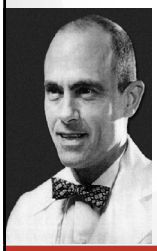
Slide compliments of Jim Hermiller and Chris White

3

"My favorite conceptual trademark is a sketch that I did years ago of a crossed pipe and wrench. It's a gross oversimplification, of course, but what it means to me is that if a plumber can do it to pipes, we can do it to blood vessels"



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Dotter CT, Judkins MP. Transluminal treatment of arteriosclerotic obstruction. Description of a new technic and a preliminary report of its application. Circulation. 1964;30:654–70.

4

Objectives

1. PVD care is a medical disease!
2. Revascularization techniques are **complimentary not competitive**
3. "Right procedure for the right patient at the right time"

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5

PAD

Symptom Terminology

Intermittent Claudication

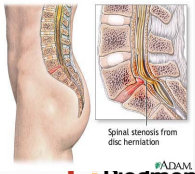
- Cramping pain
- One or both legs, foot/calf moving up
- Occurs with walking consistent distance
- Does not resolve with continued activity
- Abates with rest (standing) or reduction in walking speed

Pseudocladication

- Spinal stenosis
  - Sharp/paresthetic pain, numbness
  - Variable walking distance
  - Relief with sitting or leaning forward
  - Thigh or back moving downward

Miscellaneous

- FMD, Iliac syndrome in cyclist, Buerger's disease, Large vessel vasculitis (Takayasu's, Giant cell arteritis)



Spinal stenosis from disc herniation

©ADAM.

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www.sscfund.org/claudication.html

6

Lower Extremity PAD
Terminology

Critical Limb Threating Ischemia

- Limb pain that occurs at rest or impending limb loss that is caused by severe compromise of blood flow to the affected extremity.
- Chronic versus acute limb ischemia


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Hirsch AT, et al. ACC/AHA Guidelines for the Management of Patients with PAD 2005.

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PAD vs. CAD
Terminology Comparison

CAD		PAD	
STEMI	ACS	CLI	Gangrene
NSTEMI			Wound
Unstable Angina			Rest Pain
Stable Angina			Claudication

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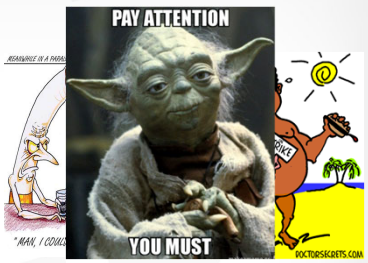
Slide compliments of Ivan Casserly

8

PAD
Risk Factors

- **Smoking**
- **Diabetes**
- **Age**
- Male gender
- Race
- HTN
- Hyperlipidemia
- Hyperhomocystenemia



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Peripheral Arterial Disease

Prevalence

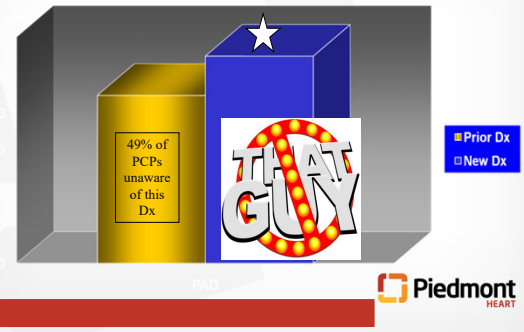
- PARTNERS Program (PAD Awareness, Risk, and Treatment: New Resources for Survival)
  - 350 Primary care sites
  - Patients (n=~7,000)
    - >70 yrs
    - 50-69 yrs with history DM or smoking
  - PVD diagnosis
    - ABI <0.9
    - Previous documentation
    - Abnormal vascular studies
    - Prior revascularization
  - **PAD detected in 1865 patients (29%)**

Hirsch AT, JAMA 2001;286:1317-1324

10

Peripheral Arterial Disease

Prevalence

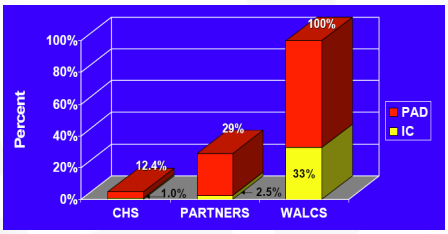


Hirsch AT, JAMA 2001;286:1317-1324

11

PAD

Asymptomatic is the rule!



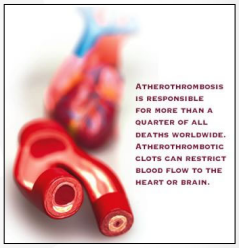
1. Newman A J Clin Epi 2001;54:294-300
2. Hirsch A JAMA 2001;286:1317-1324
3. McDermott M JAMA 2001;286:1599-1606

Graph Courtesy of McDermott, M

12

PAD
Clinical Impact

- **Mortality 2-3x higher than age and sex-matched controls[1]**
- 5 Year Mortality 30%[2]
- 15 year Mortality 70%[2]
- 60-80% of patients with PAD have CAD in at least 1 vessel[3,4]
- ~25% of PAD patients have a carotid stenosis of >70%[5]



1. Dormandy J J Cardiovasc Surg (Torino) 1989;30:50-57
2. Weitz JI et al. Circulation. 1996;94:3026.
3. Valentine RJ, et al. J Vasc Surg. 1994 Apr;19(4):668.
4. McFalls EO, et al. CARP Trial. N Engl J Med. 2004 Dec 30;351(27):2795.
5. Cheng Sw, et al. Cardiovasc Surg. 1999 Apr;7(3):303

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13

PAD
Clinical Significance

- Major Risk Factor for Amputation
  - Diabetes
- Quality of Life
  - **More severe than that of CHF or recent MI[3]**
  - CLI patients~Terminal Cancer
- Functional impairment and decline is common even in asymptomatic patients[2,3]

1. Schneider JR et al. Ann Vasc Surg. 1993;7:419.
2. McDermott MM et al. Ann Intern Med. 2002;136:873.
3. McDermott MM, et al. JAMA 2004 292;453-461.

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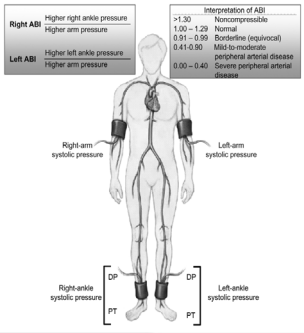
Ankle-Brachial Index

R brachial
150 mmHg

R DP 150
R PT 160

Right ABI
160/150=1.06



L brachial
145

L DP 140
L PT 150

Left ABI
150/150=1.00

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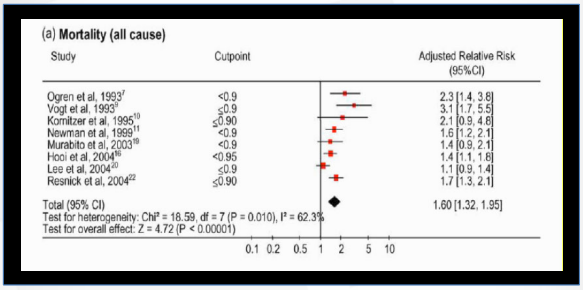
Abnormal ABI and Mortality



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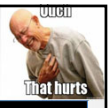
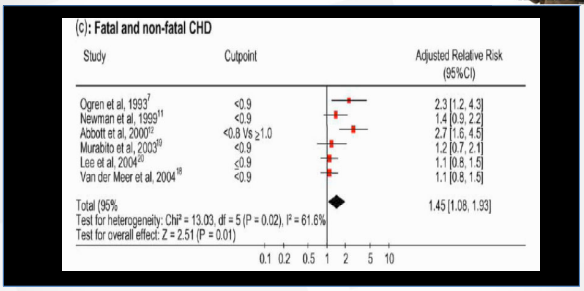
Heald C Atherosclerosis 2006 189;61-69

16

Abnormal ABI and CHD





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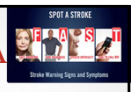
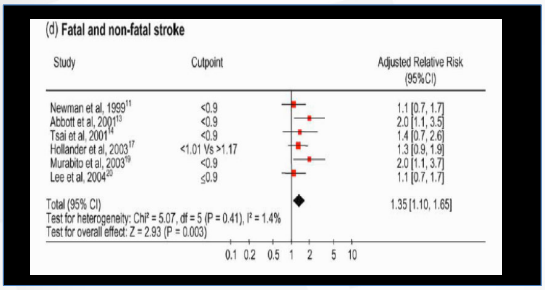
Heald C Atherosclerosis 2006 189;61-69

17

Abnormal ABI and CVA





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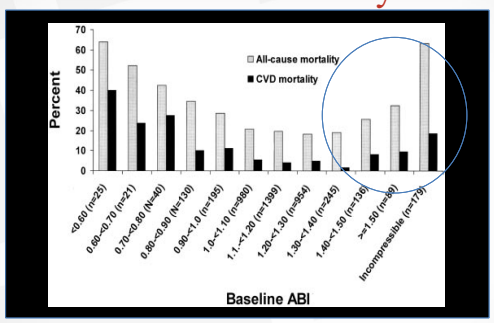
Heald C Atherosclerosis 2006 189;61-69

18

ABI and Mortality



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Resnick H Circulation. 2004 Feb 17;109(6):733-9

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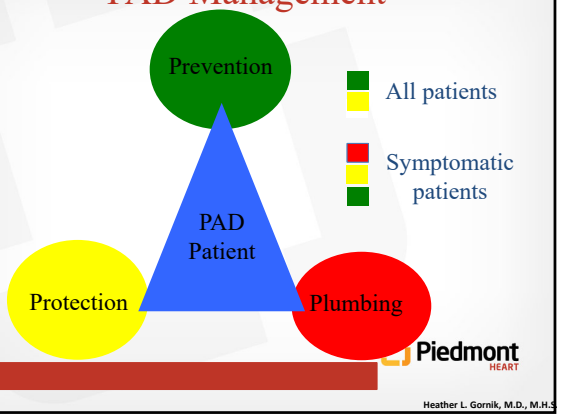
PAD Management



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Heather L. Gornik, M.D., M.H.S.

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Newer Guidelines

2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Developed in Collaboration With the American Association of Cardiovascular and Pulmonary Rehabilitation, Society for Cardiovascular Angiography and Interventions, Society for Clinical Vascular Surgery, Society of Interventional Radiology, Society for Vascular Medicine, Society for Vascular Nursing, Society for Vascular Surgery, Trans-Atlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease, and Vascular and Endovascular Surgery Society

WRITING COMMITTEE MEMBERS*

Marie D. Gerhard-Herman, MD, FACC, FAHA, Chair
Heather L. Gornik, MD, FACC, FAHA, FSVM, Vice Chair*

2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Arterial Disease Circulation. 2016 Nov 13 And JACC 2016 Nov

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PROTECTION

Foot Care

- Meticulous foot and nail care
- Daily foot self-inspection
- Appropriate footwear
- DM patients
  - Podiatry consultation/collaboration
  - Review warning signs of critical limb ischemia (CLI)
  - Reinforce importance of foot care at each office visit

NEW GUIDELINES

I	C-LD	Patients with PAD and diabetes mellitus should be counseled about self-foot examination and healthy foot behaviors (222, 223).
I	C-LD	In patients with PAD, prompt diagnosis and treatment of foot infection is recommended to avoid amputation (224-228).

2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Arterial Disease

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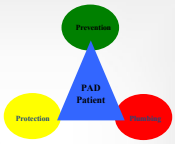
PREVENTION



- Smoking cessation
- Anti-platelet therapy
- Lipid lowering therapy
  - Statins
- Antihypertensive therapy
- Ace-inhibitors/ARBs
- Glycemic control

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Prevention

Smoking Cessation

I	A	Patients with PAD who smoke cigarettes or use other forms of tobacco should be advised at every visit to quit (170-172).
I	A	Patients with PAD who smoke cigarettes should be assisted in developing a plan for quitting that includes pharmacotherapy (i.e., varenicline, buproprion, and/or nicotine replacement therapy) and/or referral to a smoking cessation program (170, 180-182).
I	B-NR	Patients with PAD should avoid exposure to environmental tobacco smoke at work, home, and public places (185, 186).

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Prevention
Anti-platelet Therapy

- Meta-analysis of anti-platelet therapy for cardiovascular disease
- 42 clinical trials enrolled patients with PAD
  - Major reductions in Vascular Event rate with Aspirin therapy
  - Benefits similar among PAD subtypes (intermittent claudication, peripheral grafting, and peripheral angioplasty)
- CAPRIE Trial
  - Benefit of clopidogrel over ASA in symptomatic PAD patients with respect to CV risk reduction

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Antithrombotic Trialists' Collaboration. BMJ. 2002;324:71.

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Updated Anti-Platelet Statements

Recommendations for Antiplatelet Agents		
COR	LOE	Recommendations
I	A	Antiplatelet therapy with aspirin alone (range 75–325 mg per day) or clopidogrel alone (75 mg per day) is recommended to reduce MI, stroke, and vascular death in patients with symptomatic PAD (139-142).
IIa	C-EO	In asymptomatic patients with PAD (ABI ≤0.90), antiplatelet therapy is reasonable to reduce the risk of MI, stroke, or vascular death.
IIb	B-R	In asymptomatic patients with borderline ABI (0.91 to 0.99), the usefulness of antiplatelet therapy to reduce the risk of MI, stroke, or vascular death is uncertain (75, 76, 139, 142).
IIb	B-R	The effectiveness of dual antiplatelet therapy (DAPT) (aspirin and clopidogrel) to reduce the risk of cardiovascular ischemic events in patients with symptomatic PAD is not well established (143, 144).
IIb	C-LD	DAPT (aspirin and clopidogrel) may be reasonable to reduce the risk of limb-related events in patients with symptomatic PAD following lower extremity revascularization (145-148).
IIb	B-R	The overall clinical benefit of vorapaxar in patients with symptomatic PAD is uncertain (149-152).

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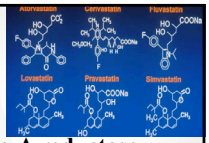
Prevention
Statins



CLASS I

- **Treatment with an HMG coenzyme-A reductase inhibitor (statin) medication is indicated for all patients with peripheral arterial disease to achieve a target LDL cholesterol of less than 100 mg/dl.**

NEW GUIDELINES

I	A	Treatment with a statin medication is indicated for all patients with PAD (96, 153-157).

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Hirsch AT, et al. ACC/AHA Guidelines for the Management of Patients with PAD 2005.

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Prevention
HTN Treatment

Class I
Benefit >>> Risk
Procedure/Treatment SHOULD be performed/administered

Class I

- **Antihypertensive therapy should be administered to hypertensive patients with lower extremity PAD**
- **Beta-adrenergic blocking drugs are effective antihypertensive agents and** are not contraindicated in patients with **PAD.**

NEW GUIDELINES

I	A	Antihypertensive therapy should be administered to patients with hypertension and PAD to reduce the risk of MI, stroke, heart failure, and cardiovascular death (158-162).

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Prevention
HTN Treatment

ACE-Inhibitors and ARBS

- **HOPE trial: Beneficial in PAD patients**
- **ONTARGET Trial: Benefit of Telmisartan in PAD**
- **Also have been shown to increase walking distance versus placebo**

NEW GUIDELINES

IIa	A	The use of angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers can be effective to reduce the risk of cardiovascular ischemic events in patients with PAD (161, 168, 169).

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Ahimastos AA, et. al. Ann Intern Med. 2006;144:660 AND JAMA. 2013 Feb 6;309(5):453-60.
2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Arterial Disease

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Prevention
Diabetes Therapies

Class I

- **Proper foot care, including use of appropriate footwear, chiropody/podiatric medicine, daily foot inspection, skin cleansing, and use of topical moisturizing creams, should be encouraged and skin lesions and ulcerations should be addressed urgently in all diabetic patients with lower extremity PAD. *(Level of Evidence: B)***

NEW GUIDELINES

I	C-LD	Patients with PAD and diabetes mellitus should be counseled about self-foot examination and healthy foot behaviors (222, 223).
I	C-EO	Management of diabetes mellitus in the patient with PAD should be coordinated between members of the healthcare team.

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Hirsch AT, et al. ACC/AHA Guidelines for the Management of Patients with PAD 2005.
2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Arterial Disease

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Prevention
Diabetes Therapies

Class IIa

- **Treatment of diabetes in individuals with lower extremity PAD by administration of glucose control therapies to reduce the hemoglobin A1C to less than 7% can be effective to reduce microvascular complications and potentially improve cardiovascular outcomes. *(Level of Evidence: C)***

NEW GUIDELINES

IIa	B-NR	Glycemic control can be beneficial for patients with CLI to reduce limb-related outcomes (191, 192).

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Hirsch AT, et al. ACC/AHA Guidelines for the Management of Patients with PAD 2005.
2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Arterial Disease

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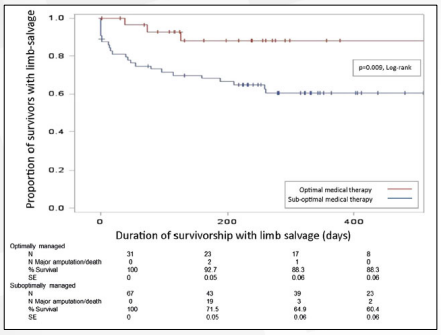
Guideline Concordance Saves Limbs



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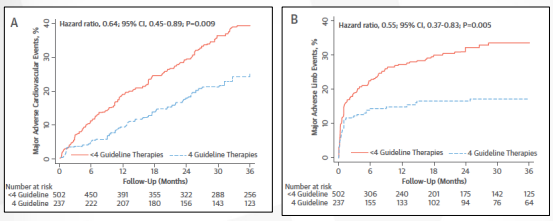
Chung et al. JVS 2013 58:792-80

32

Guideline Concordance Saves Lives



ASA Rx 88%; Smoking Abstinence 71%; ACE 60%; STATIN 67%

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Armstrong EJ et al. J Am Heart Assoc 2014;3

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Plumbing
Symptomatic Patient

- **Medical Therapy**
- **Exercise Therapy**
- **Endovascular Therapy**
- **Surgical Therapy**

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Plumbing
Symptomatic Patient
Medical Treatment

Cilostazol

- Mechanism of Action: Phosphodiesterase inhibitor
- Extensive metabolism issues
  - Diltiazem, Fluoxetine, Omeprazole
  - Consider 50 mg BID starting dose
- Side effects of cilostazol are common; 20% DC Rate
  - Headaches (25-35%)
  - Abnormal stools or diarrhea (~15-20%)
  - Palpitations or tachycardia (~15%)
- **Cilostazol is contraindicated in patients with congestive heart failure of any severity**

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Plumbing
Symptomatic Patient
Medical Treatment

CLASS IA

- **Cilostazol (100 mg orally 2 times per day) is indicated as an effective therapy to improve symptoms and increase walking distance in patients with lower extremity PAD and IC.**
- **A therapeutic trial of cilostazol should be considered in all patients with lifestyle-limiting claudication (in the absence of heart failure).**

NEW GUIDELINES

COR	LOE	Recommendation
I	A	Cilostazol is an effective therapy to improve symptoms and increase walking distance in patients with claudication (199, 200).

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Hirsch AT, et al. ACC/AHA Guidelines for the Management of Patients with PAD 2005.

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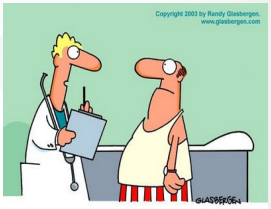
Plumbing

Symptomatic Patient

Exercise Treatment

- Improves
  - Exercise performance
  - Walking ability
  - Physical functioning
  - Quality of Life
- Highly cost-effective
- Supervised exercise



"What fits your busy schedule better, exercising one hour a day or being dead 24 hours a day?"

NEW GUIDELINES

I	A

In patients with claudication, a supervised exercise program is recommended to improve functional status and QoL, and to reduce leg symptoms (36-38, 40-46, 48, 210, 211).

2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Arterial Disease

Stewart KJ, et al. N Engl J Med. 2002;347:1941.

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Plumbing

Symptomatic Patient

Exercise Treatment

CLEVER

- RCT of aorto-iliac claudicants to Endovascular Therapy (EVT) vs. Optimal Medical Therapy (OMT) vs. Supervised Exercise Therapy (SET)
- At 18 months, the peak-walking time improved for both EVT and SET, but not OMT
- QOL was better for EVT compared with SET or OMT

ERASE

- RCT of aorto-iliac and femoral-popliteal claudicants to EVT + SET vs. SET alone
- **EVT + SET had greater improvement in walking distance and health-related QOL vs. SET alone**

CONCLUSIONS

- SET is an effective alternative to revascularization
- **SET + EVT in the presence of GDMT = best option**

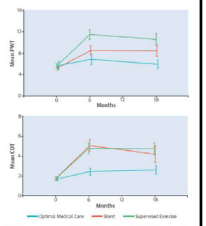

FIGURE 1 Upper panel: Peak Walking Time (PWT): Patients with 18-month follow-up visit only. Lower panel: Claudication Onset Time (COT): Patients with 18-month follow-up visit only. (Figure 1 reproduced with permission) [56]

Murphy T et al. J Am Coll Cardiol 2015;65:999–1009.

Fakhry F et al. JAMA 2015;314:1936–1944.

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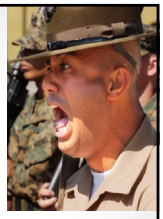
Plumbing

Symptomatic Patient

Exercise Treatment

Guidelines



- Warm-up and cool down for 5-10 minutes
- Types of Exercise
  - Treadmill and track walking most effective
  - Resistance training complementary only
- Intensity
  - Initial workload to elicit sxs within 3-5 minutes
  - Walk until moderate severity occurs, rest for brief period till sxs abide
- Duration
  - Exercise-rest-exercise; 35 minutes and increasing 5 minutes each session until 50 minutes of intermittent walking can be accomplished
- Frequency
  - Treadmill or track 3-5x per week
- Supervision
  - As ability improves, workload should be increased by increasing grade or speed to ensure stimulus of claudication pain always occurs

Stewart KJ, et al. N Engl J Med. 2002;347:1941.

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Plumbing
Symptomatic Patient
Exercise Treatment

Supervised exercise program (COR I, LOE A)

- Takes place in a hospital or outpatient facility.
- Uses intermittent walking exercise as the treatment modality.
- Program can be stand alone or within a cardiac rehabilitation program.
- Program is directly supervised by qualified health-care provider(s)
- Training performed for a minimum of 30–45 min/session; sessions performed at least 3 times/wk for a minimum of 12 wk (36-46).
- Training involves intermittent bouts of walking to moderate-to-maximum claudication alternating with periods of rest.
- Warm-up and cool-down periods precede and follow each session of walking.

Structured community or home-based exercise program (COR IIa, LOE A)

- Takes place in the personal setting of the patient rather than in a clinical setting (41, 47-51).
- Self-directed program with guidance of health-care providers.
- Health-care providers prescribe an exercise prescription similar to that of a supervised program.
- Patient counseling ensures understanding of how to begin and maintain the program and how to progress the difficulty of the walking (by increasing distance or speed).
- Program may incorporate behavioral change techniques such as health coaching and/or use of activity monitors.

COR indicates Class of Recommendation; LOE, Level of Evidence; and PAD, peripheral artery disease.

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2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Arterial Disease

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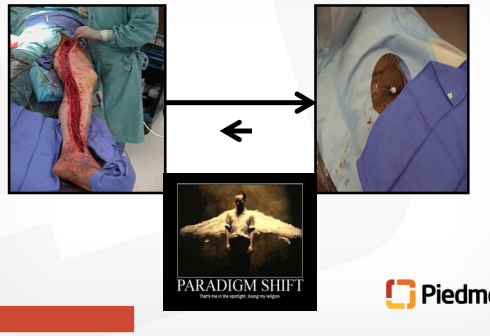
Plumbing
Symptomatic Patient
Paradigm is Changing



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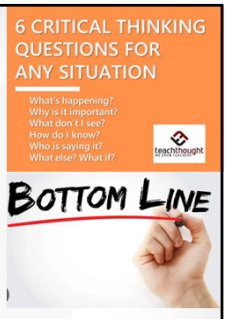
Plumbing
Symptomatic Patient

- **Should you revascularize?**
- **What is the Indication?**
- **Where is the disease?**
- **What are the patient's co-morbidities?**
- **What are you trying to achieve?**
- **What is the disease like?**
- **What is the renal function?**
- **What is the realistic long term patency?**
- **Who is your operator?**
- **What is your personal threshold?**
- **What would you do for your family or yourself?**



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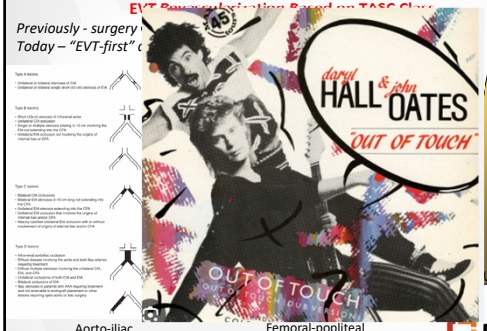
Plumbing

Symptomatic Patient

Previously - surgery
Today – "EVT-first"



TASC A

Endovascular

urgery

TASC D

Aorto-iliac

Femoral-popliteal

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TASC II Working Group JVS January 2007

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Plumbing

Symptomatic Patient

Surgical therapy: Claudication

8.1.2. Surgical Revascularization for Claudication: Recommendations

Recommendations for Surgical Revascularization for Claudication		
COR	LOE	Recommendations
I	A	When surgical revascularization is performed, bypass to the popliteal artery with autogenous vein is recommended in preference to prosthetic graft material (263-271).
IIa	B-NR	Surgical procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication with inadequate response to GDEM, acceptable perioperative risk, and technical factors suggesting advantages over endovascular procedures (232, 265, 275-277).
III: Harm	B-R	Femoral-tibial artery bypasses with prosthetic graft material should not be used for the treatment of claudication (287-289).
III: Harm	B-NR	Surgical procedures should not be performed in patients with PAD solely to prevent progression to CLI (234-237, 262).

Where are you going to suture?
Is there a suitable vein?
Perioperative risk
Wound infection risk

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Plumbing

Symptomatic Patient

Endovascular therapy: CLAUDICATION

Recommendations for Endovascular Revascularization for Claudication		
COR	LOE	Recommendations
I	A	Endovascular procedures are effective as a revascularization option for patients with lifestyle limiting claudication and hemodynamically-significant aortoiliac occlusive disease (12, 37, 38, 232, 240, 242, 246).
IIa	B-R	Endovascular procedures are reasonable as a revascularization option for patients with lifestyle limiting claudication and hemodynamically-significant femoropopliteal disease (217, 232, 243-245, 250, 251).
IIb	C-LD	The usefulness of endovascular procedures as a revascularization option for patients with claudication due to isolated infrapopliteal artery disease is unknown (256-258).
III: Harm	B-NR	Endovascular procedures should not be performed in patients with PAD solely to prevent progression to CLI (234-237, 259-261).

Where is the disease?
Who is your operator?
Periprocedural risk?

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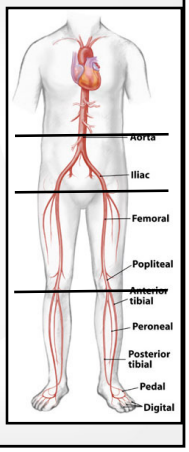
Plumbing

Symptomatic Patient

EVT Treatment

- Aorto-Iliac
  - Endovascular approach unless AAA to be also repaired or failure of EVT
- Femoral-Popliteal
  - Depends on type of disease (focal vs. diffuse), patient risk factors and comorbidities, claudicant vs. CLI, long term patency, renal function
- Infra-popliteal
  - Medical therapy for most, unless CLI
  - DES consideration
  - May change with bioasorbable scaffolds



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Plumbing

Symptomatic Patient

Aortoiliac Revascularization Indications

Aorto-iliac disease *with symptoms*

- Relieve claudication
- Wound healing in CLI
- Improve functional status and Quality of Life (QOL)

Aorto-iliac disease *without symptoms*

- Situations where large-bore arterial access is required for hemodynamic support devices (e.g., intra-aortic balloon pumps (IABP) or other catheter-based ventricular assist devices), for structural, valvular (e.g., TAVR), and vascular (e.g., endovascular aortic aneurysm repair (EVAR)) procedures

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Klein A, Jaff M, Gray B et al. Catheter Cardiovasc Interv. 2017;90:E90–E110.

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Symptomatic Patient

EVT Treatment

2005 ACC/AHA Guidelines

Class I

- **Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease). *(Level of Evidence: A)***

2016 ACC/AHA GUIDELINES

I	A	Endovascular procedures are effective as a revascularization option for patients with lifestyle limiting claudication and hemodynamically-significant aortoiliac occlusive disease (12, 37, 38, 232, 240, 242, 246).

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Hirsch AT, et al. ACC/AHA Guidelines for the Management of Patients with PAD 2005.
2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Arterial Disease

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Plumbing

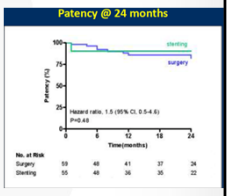
Symptomatic Patient EVT in CFA

Registry Data

- Supports EVT-first approach, 5 year f/u data on CFA stenting
  - 79% freedom form TLR

TECCO Trial

- 117 pts RCT of **common femoral endarderectomy vs. EVT** for isolated CFA disease
- 1°outcome: M&M within 30 days
  - 16 of 61 patients (26%) in the CFE group and 7 of 56 patients (12.5%) in the EVT group (odds ratio, 2.5; 95% CI, 0.9 to 6.6; p<0.05).
- The mean duration of hospitalization was significantly lower in the EVT group (3.2±2.9 days 6.3±3 days; p<0.0001).
- **At 24-months: No difference in the sustained clinical improvement, the primary patency rate, and the target lesion and extremity revascularization rates**



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Goueffic Y et al. JACC Cardiovasc Interv. 2017 Jul 10;10(13):1344-1354
Azema L et al. J Vasc Endovasc Surg 2011;41:787– 793.

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Plumbing

Symptomatic Patient
EVT in FP Disease: TASC and ACC/AHA guideline

- TASC 2015 update recommends
  - "endovascular first" recommendation for experienced operators and teams
- 2016 ACC/AHA guidelines on PAD provide a class IIA recommendation (Level of Evidence B) for EVT of FP disease

CONCLUSION

"the choice of EVT as a revascularization approach for claudication due to femoral-popliteal disease should include a **discussion of outcomes, addressing the risk of restenosis and repeat intervention, particularly for lesions with a poor likelihood of long-term durability**"

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Jaff MR et al. Catheter Cardiovasc Intervent Off J Soc Cardiac Angiogr Intervent 2015;86:611–625
Gerhard-Herman MD et al. J Am Coll Cardiol 2016;69:1465–1508

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Plumbing

Symptomatic Patient
EVT in Infrapopliteal Dz

- Generally limited to Critical Limb Ischemia (CLI) patients
- Small vessels, diffuse and long disease, high rates of restenosis
- Intervention to provide straight line flow to the foot, angiosome-based approach
- For claudicants, only moderate to severe (>50% diameter stenosis) lesions and multivessel tibial disease (2 tibial vessels) should be considered for revascularization.
- Prior to considering infra-popliteal intervention, all hemodynamically significant inflow disease should be treated to normalize inflow to the infra-popliteal circulation.

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Plumbing

Symptomatic Patient

CTLI

Guidelines

9.1. Revascularization for CLI: Recommendations

Recommendation for Revascularization for CLI		
COR	LOE	Recommendation
I	B-NR	In patients with CLI, revascularization should be performed when possible to minimize tissue loss (290).
I	C-EO	An evaluation for revascularization options should be performed by an interdisciplinary care team (Table 9) prior to amputation in the patient with CLI.

9.1.1. Endovascular Revascularization for CLI: Recommendations

Recommendations for Endovascular Revascularization for CLI		
COR	LOE	Recommendations
I	B-R	Endovascular procedures are recommended to establish in-line blood flow to the foot in patients with nonhealing wounds or gangrene (292, 293).

9.1.2. Surgical Revascularization for CLI: Recommendations

Recommendations for Surgical Revascularization for CLI		
COR	LOE	Recommendations
I	A	When surgery is performed for CLI, bypass to the popliteal or infrapopliteal arteries (i.e., tibial, pedal) should be constructed with suitable autogenous vein (263, 266, 269, 272).

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Plumbing

Symptomatic Patient

- Who is at your center?
  - Culture may drive things but don't let it
- Who is doing the procedure?
  - Experience
  - Back-up
  - Thoughtful
  - Collaborative

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PTA vs. Bypass

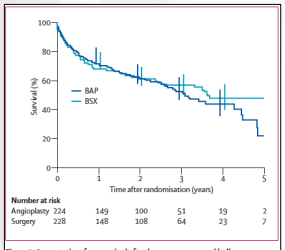

Figure 2: Amputation-free survival after bypass surgery and balloon angioplasty
Bars show 95% CIs for survival up to 1, 2, 3, and 4 years of follow-up, which were calculated from the cumulative hazards.

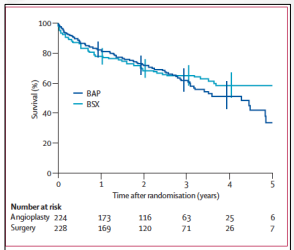

Figure 3: All-cause mortality after bypass surgery and balloon angioplasty
Bars show 95% CIs for survival up to 1, 2, 3, and 4 years of follow-up, which were calculated from the cumulative hazards.

Rates of MI, wound complications, Pulmonary comps increased in Surgery group vs. repeat revasc in PTA group

Basil Trial Lancet 2005; 366: 1925–34

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BEST-CLI

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, M.B. 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, M.C. 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†

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BEST-CLI

- **~30% of patients were dead at end of trial (3 years)** no matter what intervention

You want your leg filleted open when you have 1/3 chance of being dead soon?

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BEST-CLI: Cohort 1

- Comparison of the BEST Surgical intervention (GSV) vs. "Best Endo"
- What is 'best' Endo?
  - DCB/DES
  - Trial started in 2014
  - Trial Data
    - **52% PTA only**
    - 15% Atherectomy
    - 25% DCB
    - 22% DES

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BEST-CLI: WHO?

- Endovascular interventions were performed by:
  - **Vascular surgeons: 73%**
  - Interventional cardiologists: 15%
  - Interventional radiologists:13%
- The **technical success** of the index procedure was **98% in the surgical** group and **85% in the endovascular** group

15% failure rate in ENDO
Is this 'Best Endo"

JVS 2016;63:958-965 Large Series report Endovascular Success rates >90%

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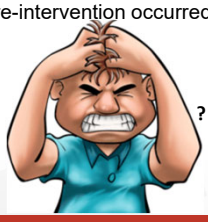
BEST-CLI: Cohort 1

- **'BEST' Endo: Success Rate equal to BASIL 1: 17 years ago !!!!!**
- 108 cases of early technical failure in the endovascular group→ 66 were treated with a bypass operation within 30 days.
- 42.5% re-intervention occurred within 30 days.



15% failure rate in ENDO
? Shocked that this led to 42.5% reintervention rate

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BEST-CLI

CONCLUSIONS

Among patients with CLTI who had an adequate great saphenous vein for surgical revascularization (cohort 1), the incidence of a major adverse limb event or death was significantly lower in the surgical group than in the endovascular group. Among the patients who lacked an adequate saphenous vein conduit (cohort 2), the outcomes in the two groups were similar. (Funded by the National Heart, Lung, and Blood Institute; BEST-CLI ClinicalTrials.gov number, NCT02060630.)

IF

1. You are at a Center with a HIGH Endo failure rate
2. Endo therapy that is given is not based on the most current evidence

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BEST-CLI: Limitations (Listed)

- White male patients
- **Majority of pts with CLTI do not have SSGSV**
- Trial ran out of funds so follow up limited on cohort 2
- MAJOR DROP IN DCB use because of Paclitaxel debate (which is now been settled) but started in 2014 so……..BS
- 66% infrapopliteal disease but lots of fem-pop bypasses?
- Angiographic analysis pending

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BEST-CLI: Limitations (not listed)

- **Majority of operators were VS**
  - Procedure 1: 98-100% Success rate
  - Procedure 2: 80-85% Success rate

    Which one were people better at ?
- **No real DCB/DES use**
- Major endpoint driven by re-intervention (not CD-TLR)
- Low enrollment of women and Black patients
- **High burden of CV disease but Medical therapy Awful:**
  - 65-70% only on ASA and/or statins

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BEST-CLI: Limitations (not listed)

- 75% of sites had some combo of IR, VS, IC
- Only 13% had all 3 and 28% of sites with only VS performing surgery and endo procedures
- *High mortality for endo procedures ??GETA for VS*
- POBA was used most of the time vs DCB/DES/atherectomy
- Enrollment was very very slow
- SUBGROUP ANALYSIS
  - COHORT 1: NO difference in
    - Age>80
    - CKD
    - Black Patients

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BEST-CLI Take Home

- GSV + Cohort did well with surgery
  - **Low periop Death rate: 1.9%**
- Comparing the **best surgical** procedure to **crappy endo** procedures
  - **80-85% Failure rate**
  - Heterogenous procedure w >50% POBA alone
- QOL showed Endo to be better
- Need better and more meds
- Cannot generalize results
  - What is your center like?
  - Who are your operators
  - What is your threshold?
  - If you have no out to the OR would you work harder at endo? Activation Energy

Simons JP, Schanzer A, Flahive JM, et al. Survival prediction in patients with chronic limb-threatening ischemia who undergo infrainguinal revascularization. J Vasc Surg 2019;69(6S):137S-151S.e3

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Which one do you want?

VS.

65

How should we best treat PAD?

Team Approach

Who is on your team?

66

Bottom Line: TEAMWORK

Table 9. Interdisciplinary Care Team for PAD

A team of professionals representing different disciplines to assist in the evaluation and management of the patient with PAD. For the care of patients with CLI, the interdisciplinary care team should include individuals who are skilled in endovascular revascularization, surgical revascularization, wound healing therapies and foot surgery, and medical evaluation and care.

Interdisciplinary care team members may include:

- Vascular medical and surgical specialists (i.e., vascular medicine, vascular surgery, interventional radiology, interventional cardiology)
- Nurses
- Orthopedic surgeons and podiatrists
- Endocrinologists
- Internal medicine specialists
- Infectious disease specialists
- Radiology and vascular imaging specialists
- Physical medicine and rehabilitation clinicians
- Orthotics and prosthetics specialists
- Social workers
- Exercise physiologists
- Physical and occupational therapists
- Nutritionists/dieticians

Faster. Stronger. Farther.

better

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2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Arterial Disease

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Conclusions

- PAD is common
- Patients with PAD die from CV complications
- Prevention, Protection, Plumbing
- Endo and Surgery are not competing but complimentary therapies
- "Right procedure for the right patient at the right time" on top of solid medical and exercise therapy

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Get the word out!!!

•70% of Americans are not familiar with PAD and its devastating risks.
•Approximately all (91%) of the survey respondents would dismiss pain as just part of getting older, although pain in the leg when walking that goes away with rest is one of the first symptoms of PAD.
•More than half (53%) of respondents would wait more than a week with ongoing leg pain before calling their doctor.
•8 in 10 Black and Hispanic respondents never had a doctor or healthcare provider talk with them about PAD.
•Amputations are 4-5x high in African Americans compared to Caucasions
•Despite 71% of Black adults having one or more risk factors for PAD or knowing someone with one or more risk factors, 65% report they are at little to no risk at all for developing PAD.
•Three-quarters of Hispanic adults have one or more risk factors for PAD or know someone with one or more risk factors but 70% think they are not at risk for developing PAD.

PADPulse.org.

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Get a Pulse on PAD
Kick Off The Conversation

PAD Pulse Alliance Founding Partners

PAD Pulse Alliance Supporting Partners

PADPulse.org.

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Thank you!

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SVM Society for Vascular Medicine

CLTI Controversies – Case CLTI – Surgical Revascularization Approach

Olamide Alabi MD MS
Chief Quality Officer, Division of Vascular Surgery and Endovascular Therapy
Emory University School of Medicine

Sunday May 17, 2024

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SVM Society for Vascular Medicine

Objectives

- Open versus Endo
- "No Stent Zones"
- Angiosome Concept

2

SVM Society for Vascular Medicine

Objectives

- Open versus Endo
- "No Stent Zones"
- Angiosome Concept

3

SVM Society for Vascular Medicine

Objectives

- ~~Open versus Endo~~ Complementary Therapies
- "No Stent Zones"
- Angiosome Concept

4

SVM Society for Vascular Medicine

Open Surgical Revascularization: Complementary Therapies

	BEST-CLI	BASIL-2
Trial Endpoint	composite of major adverse limb events or death from any cause	Composite time to above ankle amputation of the trial limb or death from any cause
Study Period	8/2014-10/2019	7/2014-11/2020
Intended N	2100	600
Actual N	1830	345
Differences in inclusion criteria	• Life expectancy 2 years • Availability of autogenous bypass conduit	• Life expectancy >6mo • Required an infrapopliteal target
Exclusions	Excessive risk for open vascular surgery	• Prior vascular intervention to infrapopliteal target within prior 12mo • Ischemic pain or tissue loss considered not primarily due to PAD

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SVM Society for Vascular Medicine

Open Surgical Revascularization: Complementary Therapies

TABLE 2. Comparison of key patient characteristics comparing BEST-CLI and BASIL-2.

	BEST-CLI COHORT 1	BEST-CLI COHORT 2	BASIL-2
Patients who did not undergo any procedure	4.3% / 1.1%	3.6% / 2.0%	8.7% / 1.2%
Cross-over to other revascularization method	3.5% / 0.4%	1.0% / 2.0%	7% / 3.5%
Median age (years)	66.9 / 67.0	68.4 / 68.8	72.4 / 72.5
Male	72% / 71.1%	71.6% / 72.4%	81% / 82%
Diabetes mellitus	72.1% / 71.6%	62.2% / 58.3%	68% / 69%
Mean eGFR (ml/min)	NA	NA	[illegible]
Chronic hemodialysis	9.4% / 11.8%	12.8% / 10.1%	6% / 3%
Previous stroke	12.8% / 13.9%	19.4% / 12.1%	15% / 20%
Coronary artery disease	42.3% / 44.4%	49.5% / 53.8%	NA
Previous MI	NA	NA	24% / 13%
Previous PCI & CABG	NA	NA	26% / 19%
Previous intervention study leg	5.6% / 5.2%	10.3% / 10.1%	31% / 39%
RBC 4	20.3%/20%	29.4%/30.2%	13% / 11%
RBC 5 (and 6)	79.7%/80%	70.6%/69.8%	87% / 89% (RBC 5 only)
ASA class 3 or 4	80.8%/75.9%	83.5%/80.9%	NA
No. patients completing the trial	560/1434 (39%)	226/396 (57.1%)	212/345 (61.4%)

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Open Surgical Revascularization: Complementary Therapies

Table 3. Comparison of key outcome characteristics comparing BEST-CLI and BASIL-2.

	BEST-CLI Cohort 1	BEST-CLI Cohort 2	BASIL-2
Bypass location			
Femoro-popliteal	40%	47.9%	1%
Femoro-popliteal AK	NA	NA	0%
Femoro-popliteal BK	NA	NA	1%
Femoro-BTK	35.7%	37.4%	59%
Popliteal-BTK	15.7%	8.4%	40%

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Table 3. Comparison of key outcome characteristics comparing BEST-CLI and BASIL-2.

	BEST-CLI Cohort 1	BEST-CLI Cohort 2	BASIL-2
Endovascular techniques			
Balloon angioplasty	52.7%	47.2%	60%
Atherectomy	13.6%	15.4%	0%
Drug-coated balloon	27.8%	25.1%	0%
Bare-metal stent	39.3%	43.1%	10%
Drug-eluting stent	24.2%	21.5%	0%
Stent graft	8.6%	12.8%	0%
Technical success	98.3% / 84.7%	100%/80.6%	96% / 80%

@SVM_tweets

7

Open Surgical Revascularization: Complementary Therapies

Table 3. Comparison of key outcome characteristics comparing BEST-CLI and BASIL-2.

	BEST-CLI Cohort 1	BEST-CLI Cohort 2	BASIL-2
Technical success	98.3% / 84.7%	100%/80.6%	96% / 80%
All cause death	33% / 37.6%	25.9% / 24.1%	53% / 45%
Major amputation (above ankle)	10.4%/14.9%	15.2%/14.1%	20%/18%
AK amputation	NA	NA	NA
BK amputation	NA	NA	NA
Amputation free survival	43.3%/52.4%	41.1%/38.2%	37%/47%
Cross-over intervention during FU	NA	NA	27% / 19%
Reintervention****	9.2% / 33.1%	14.2%/25.6%	5% / 19%

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Open Surgical Revascularization

- BEST-CLI and BASIL-2 are not really comparable
- Neither should be used as an 'end all argument'
- Lessons to learn from both:
  - Nothing beats single segment great saphenous vein….if this is available
    - Get vein mapping prior to the angiogram
  - The toolbox is large – USE IT!
  - Shared decision making
    - There is a small but not insignificant cohort of patients who would benefit from primary amputation

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Open Surgical Revascularization

- ~~Open versus Endo~~ Complementary Therapies
- "No Stent Zones"
- Angiosome Concept

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TH

- 3/2012 Left SFA stent
- 8/2012 left SFA atherectomy and BAP of stent
- 11/2012 left SFA laser and BAP of stent
- 7/2013 left SFA revascularization
- 3/2014 BAP Left SFA in-stent stenosis
- 6/2021 shockwave lithotripsy of left CFA and popliteal + DCB BAP
- 6/2023 left SFA stent recanalization
- 8/2023 left SFA stent recanalization

11

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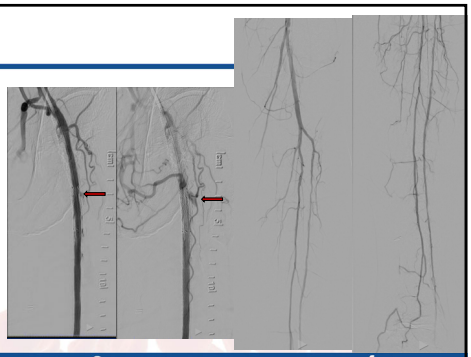
- 9/18/23 Procedure
- 1) Ultrasound guided access of the right common femoral artery
- 2) Angiogram of abdominal aorta and bilateral iliac arteries
- 3) Angiogram of the left femoral, popliteal, anterior tibial, posterior tibial, and popliteal vessels
- 4) Angiogram of the right femoral, popliteal, anterior tibial, posterior tibial, and popliteal vessels
- 3) PTA of L SFA (stents present)
- 5) Shockwave Lithotripsy
- 6) Laser atherectomy of the L SFA
- 7) Drug coated balloon of the L SFA



12

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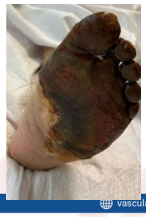
And then this happened…what would you do?



- Abi
- Lt Brachial: 118 mmHg
- Lt Posterior Tibial: 48 mmHg
- Lt Posterior Tibial: 0.41
- Lt Dorsalis Pedis: 50 mmHg
- Lt Dorsalis Pedis: 0.42

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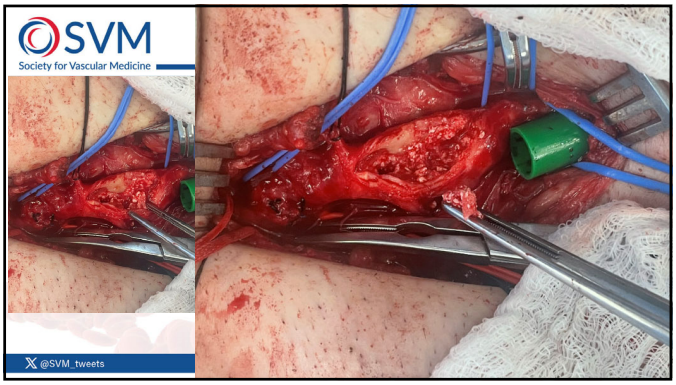

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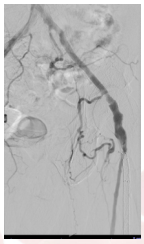

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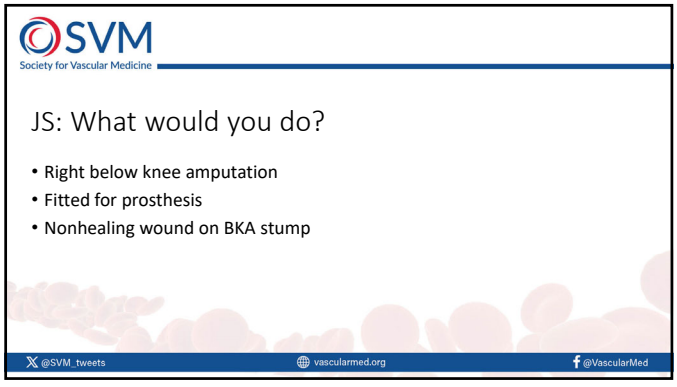
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JS: What would you do?
• Right below knee amputation
• Fitted for prosthesis
• Nonhealing wound on BKA stump
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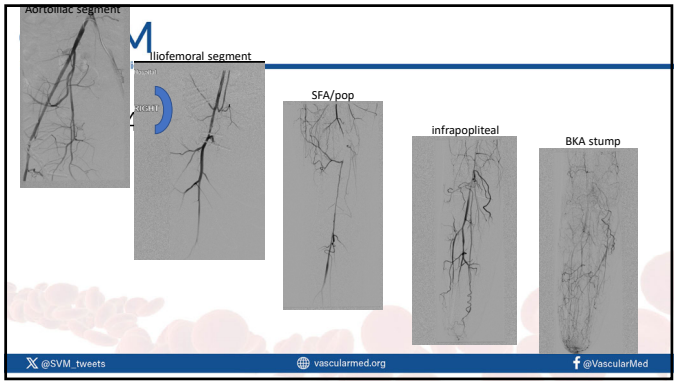
Aortoiliac segment
Iliofemoral segment
SFA/pop
infrapopliteal
BKA stump
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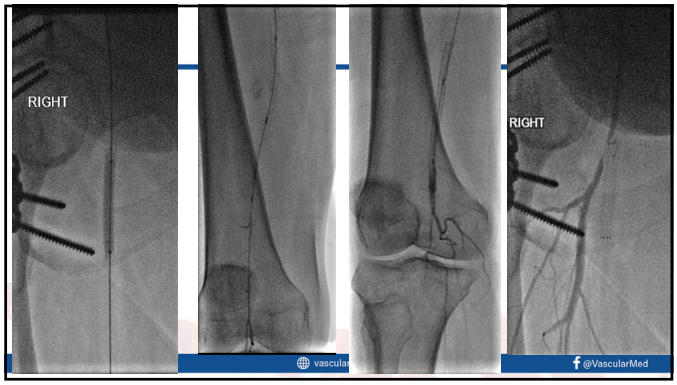
RIGHT
RIGHT
@VascularMed

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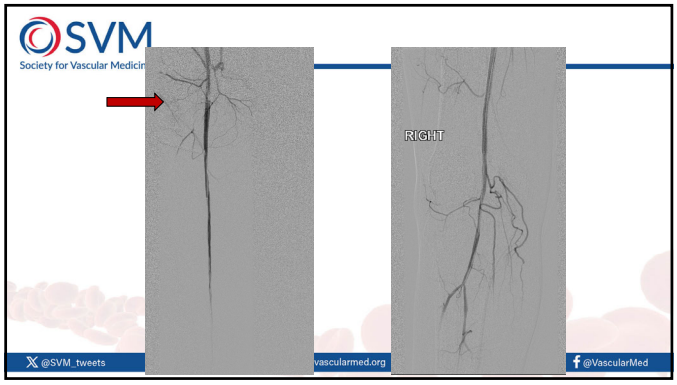
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Went to OR:

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DH: What would you do?

- 3rd toe wound with underlying osteomyelitis
- No frank cellulitis
- Vein mapping: single segment vein present
- Angiogram

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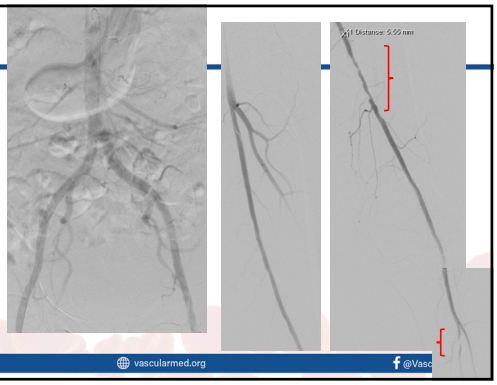
DH

- Single segment vein present…



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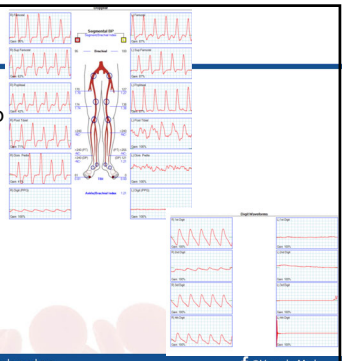
CD: What would you do?

- Chronic emboli from mitral valve vegetation over time
- Developed CLTI with lateral 5th toe wound at base of toe



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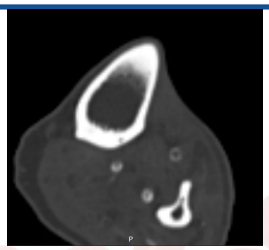

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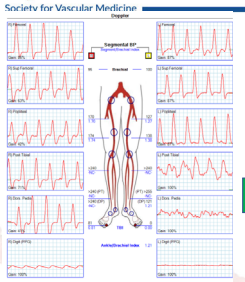

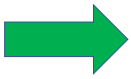

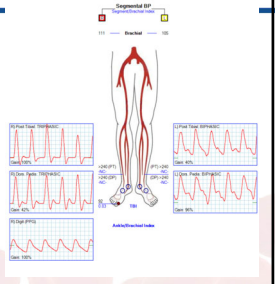

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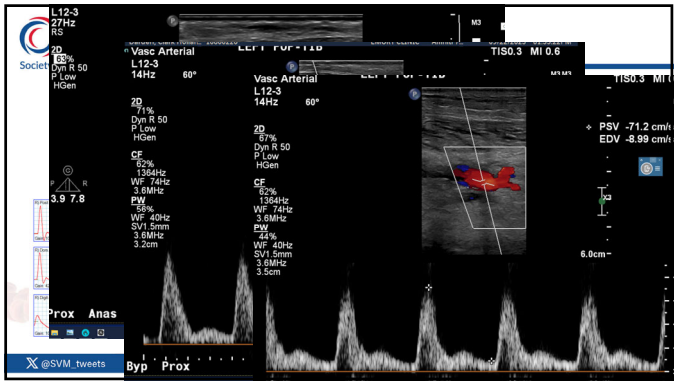

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Open Surgical Revascularization

- ~~Open versus Endo~~ Complementary Therapies
- "No Stent Zones"
- Angiosome Concept

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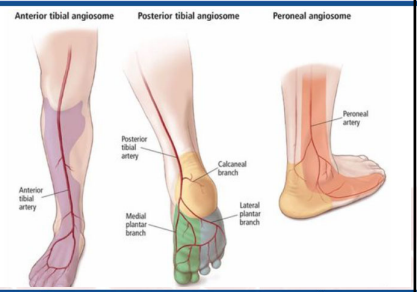
Angiosomes



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Direct versus Indirect Revascularization

- Meta-analysis. 9 studies
  - 715 direct revascularization
  - 575 indirect revascularization
- Direct revascularization associated with:
  - Lower risk of unhealed wound (HR 0.64, 95% CI 0.52-0.8, I2 0%)
  - Lower risk of major amputation (0.44, 95% CI 0.26-0.75, I2 62%)
  - Limb salvage rates
    - 1 year: 86.2% direct; 77.8% indirect
    - 2 years: 84.9% direct; 70.1% indirect

Biancari F, Juvonen T. Angiosome-targeted lower limb revascularization for ischemic foot wounds: systematic review and meta-analysis. *Eur J Vasc Endovasc Surg*. 2014;47(5):517-522.

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Open Surgical Revascularization

- ~~Open versus Endo~~ Complementary Therapies
- "No Stent Zones"
- Angiosome Concept

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Questions

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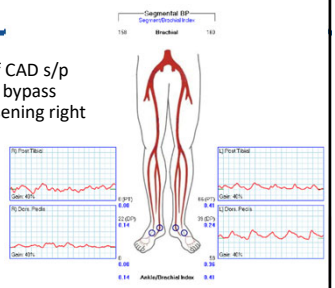
CLTI Management
Endovascular Revascularization

Yulanka Castro, MD
Clinical Assistant Professor of Medicine
University Hospitals Harrington Heart and Vascular Institute
Cleveland, OH
@YSCastroMD

1

Case

- 79-year-old woman with history of CAD s/p CABG, PAD s/p PTFE right fem-pop bypass presenting with rest pain and worsening right posterior ankle ulcer



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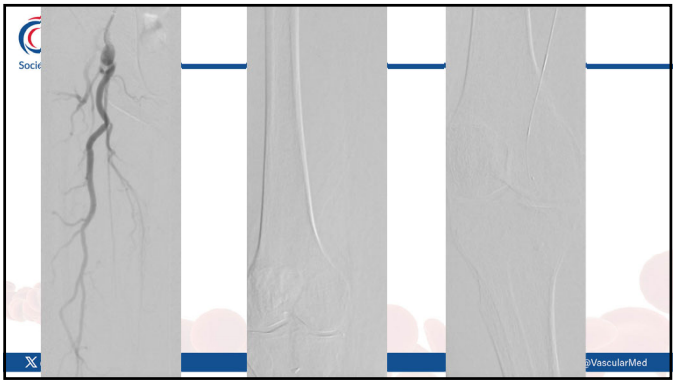

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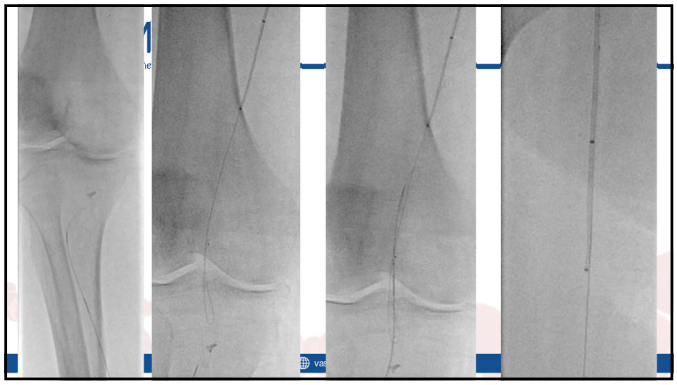

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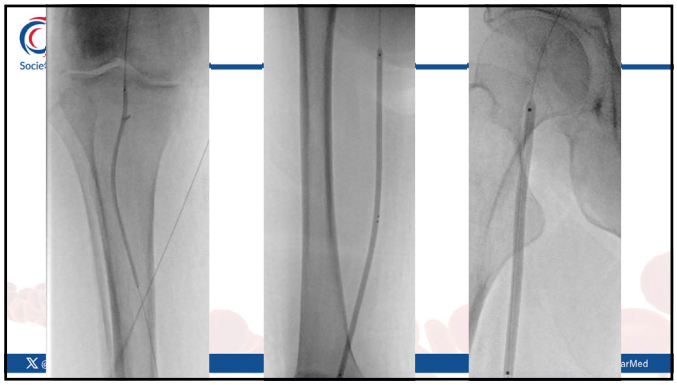

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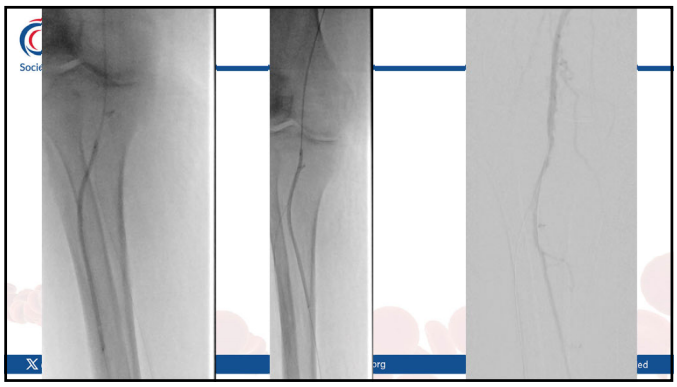

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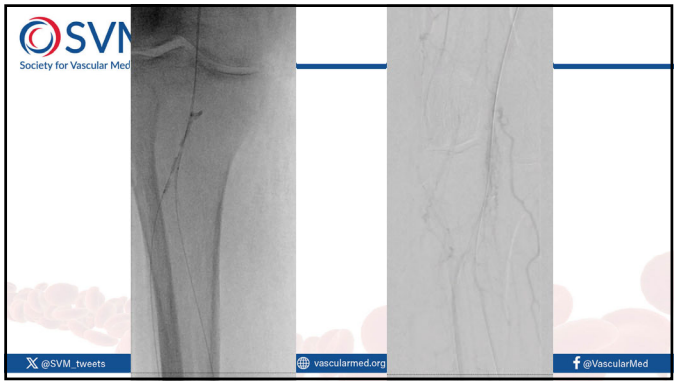
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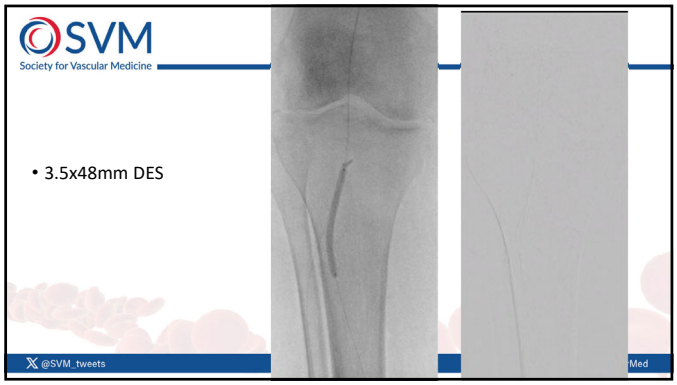
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• 3.5x48mm DES
@SVM_tweets

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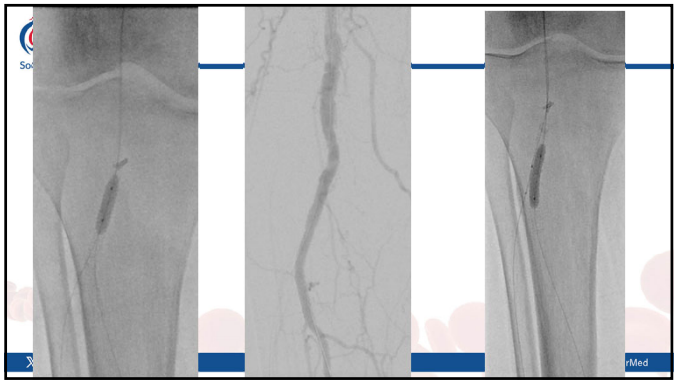

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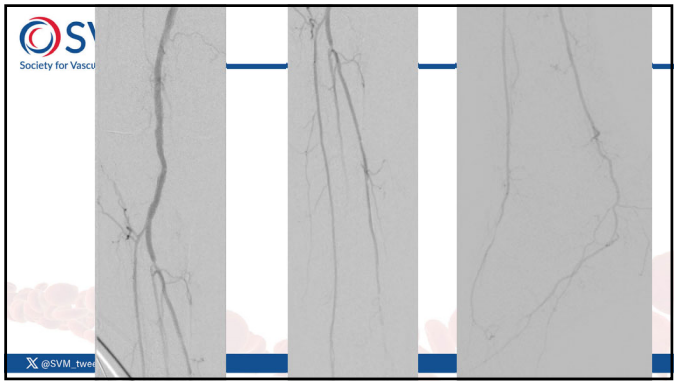
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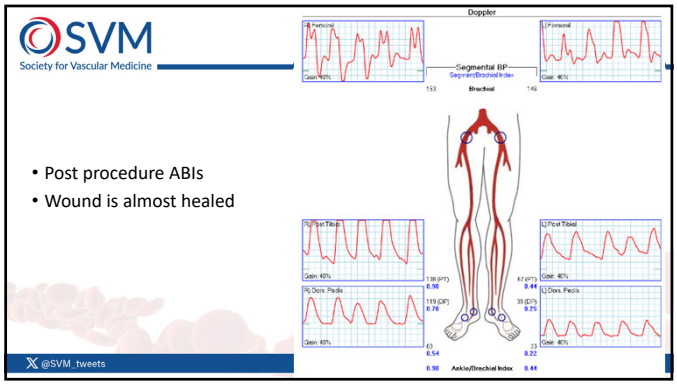
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Doppler
Segmental BP
Brachial
• Post procedure ABIs
• Wound is almost healed
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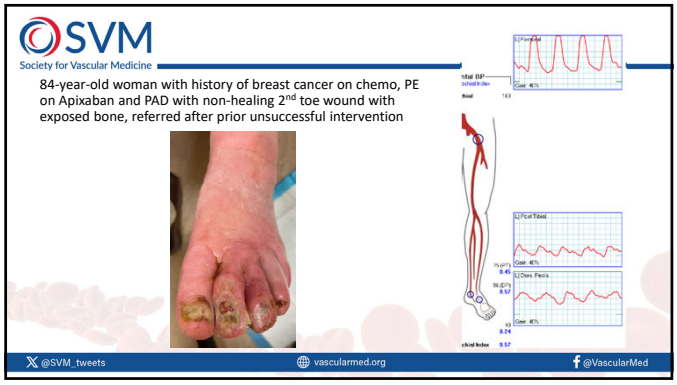
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84-year-old woman with history of breast cancer on chemo, PE on Apixaban and PAD with non-healing 2nd toe wound with exposed bone, referred after prior unsuccessful intervention
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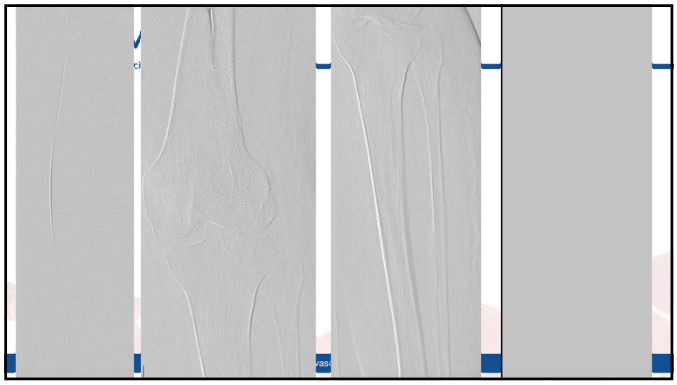

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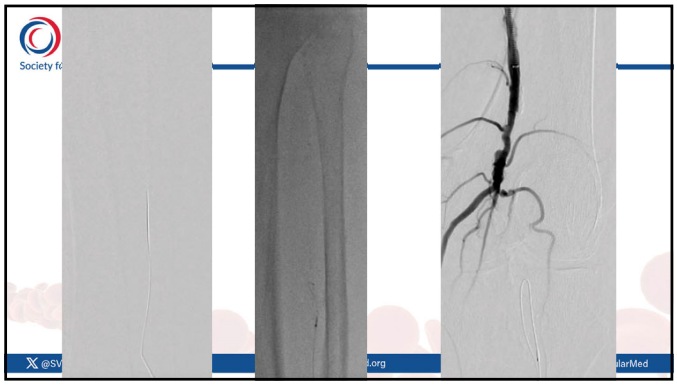

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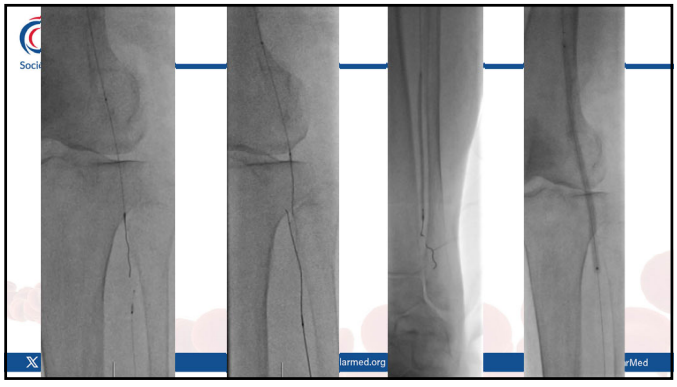

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BASIL-2 Trial

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 Popplewell, Lewis Meecham, Gareth R Bate, Lisa Kelly, Ian Chetter, Athanasios Diamantopoulos, Arul Ganeshan, Jack Hall, Simon Hobbs, Kim Houlind, Hugh Jarrett, Suzanne Lockyer, Jonas Malmstedt, Jai V Patel, Smitaa Patel, S Tawgeer Rashid, Athanasios Saratzis, Gemma Slinn, D Julian A Scott, Hany Zayed, Jonathan J Deeks, on behalf of the BASIL-2 Investigators

THE LANCET

University Hospitals Heart & Vascular Institute

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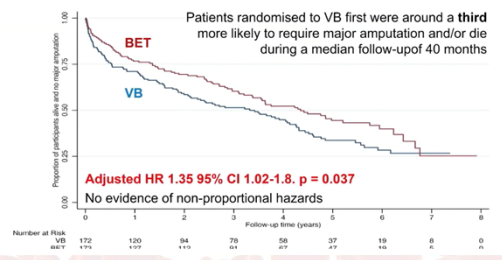
Amputation-free survival (ITT analysis)



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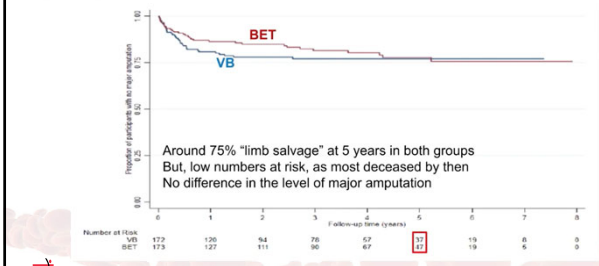
BASIL-2 Time to First Major Amputation (ITT)



19

Outcomes

- Number of re-interventions was higher in BET (19%) than in the VB (5%) (0.27 [0.13-0.55])
- Crossover interventions – more common in VB (27%) than in the BET (19%) (1.43 [0.94-2.18])
- NO differences in 30-day morbidity and death, MALE, MACE, relief of ischemic pain, or QoL

	Vein bypass group (n=172)	Best endovascular treatment group (n=173)	Estimate (95% CI)
Subsequent intervention	50 (29%)	56 (32%)	RR 0·94† (0·68 to 1·28); uRD −0·03§ (−0·13 to 0·06)
Reintervention	9 (5%)	33 (19%)	RR 0·27† (0·13 to 0·55); uRD −0·14§ (−0·21 to −0·07)
Crossover intervention	46 (27%)	33 (19%)	RR 1·43† (0·94 to 2·18); uRD 0·08§ (−0·01 to 0·17)

20

Patient Characteristics: BASIL-2 and BEST-CLI

	BASIL-2	BEST-CLI (cohort 1)	BEST-CLI (cohort 2)
Enrolled participants	345	1434	396
Median age (yrs)	73	67	68
Diabetes	68%/69%	72%/72%	62%/58%
ESRD on HD	6%/3%	13%/14%	13%/10%
Previous intervention study leg	31%/39%	10%/10%	6%/5%
Antiplatelet use	76%/80%	ASA – 67%/67% Clopidogrel 19%/25%	ASA – 71%/71% Clopidogrel 25%/28%
Cholesterol lowering agent	75%/80%	71%/70%	79%/77%
Tissue loss	87%/89%	80%/80%	71%/70%
Tibial disease treated	100%	51%/51%	46%/43%

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Primary Outcomes: BASIL-2 and BEST-CLI

- BEST-CLI
  - MALE – major amputation above ankle, major limb reintervention (new bypass graft, graft revision, thrombectomy, or thrombolysis) or death from any cause
- BASIL-2
  - Amputation-free survival – time to major amputation above ankle or death from any cause
    - What ultimately matters to patients – to avoid amputation and prolong life
    - Does not reflect burden of major reinterventions

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Key Comparisons: BASIL-2 and BEST-CLI

	BASIL-2	BEST-CLI (cohort 1)
Endo technical success	87%	85%
Bypass technical success	96%	98%
Crossover (endo to bypass)	19%	23%
Major amputation/Death		
Bypass	63%	43%
Endovascular	53%	53%

Outcome	Surgery	Endovascular Therapy	Hazard Ratio (95% CI)††
Efficacy			
Primary outcome: major adverse limb event or death from any cause — no./total no. (%)‡	302/709 (42.6)	408/711 (57.4)	0.68 (0.59–0.79)
Secondary outcomes — no./total no. (%)			
Death from any cause	234/709 (33.0)	267/711 (37.6)	0.98 (0.82–1.17)
Above-ankle amputation of the index limb	74/709 (10.4)	106/711 (14.9)	0.73 (0.54–0.98)
Intervention in index limb			
Major	65/709 (9.2)	167/711 (23.5)	0.35 (0.27–0.47)

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Data we need from BEST-CLI and BASIL-2

- Few patients with CLTI are deemed suitable and have an optimal vein for infra-popliteal bypass
  - Risk profiles of patients deemed not appropriate for surgery
- Angiographic lesion-level data and severity of disease morphology in both arms
- Registry data of patients that were treated during trial period but not enrolled – understand patients who BEST-CLI and BASIL-2 results does not apply to
  - No equipoise when disease morphology is straightforward for endo or patient unfit for open surgery

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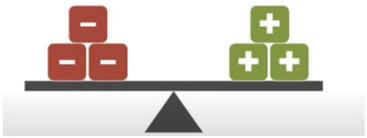
Individual Assessment



- Involvement of CFA/PFA
- Younger, low risk patient
- Suitable vein

- Extensive tibial disease with poor targets
- No suitable vein
- Older patient, poor surgical candidate

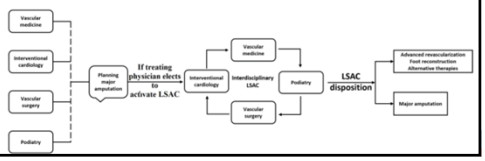
25

I | C-EO

An evaluation for revascularization options should be performed by an interdisciplinary care team (Table 9) before amputation in the patient with CLI.

Impact of Interdisciplinary System-Wide Limb Salvage Advisory Council on Lower Extremity Major Amputation

Mehdi H. Shishehbor, DO, MPH, PhD, Tarek A. Hammad, MD, Tonia J. Rhone, MS, Ahmad Younes, MD, Norman Kumins, MD, Abdullah Abdullah, MD, Jun Li, MD, Karem Harth, MD, Teresa L. Carman, MD, Heather L. Gornik, MD, Peter J. Pronovost, MD, PhD, and Vikram S. Kashyap, MD



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Learning Points

- Reminder poor prognosis of patients with CLTI. ~ 50% of patients died by 5 years
- Primary prevention – early detection of PAD and institution of GDMT and lifestyle interventions
- Saphenous vein mapping and surgical risk assessment should be more regularly considered
- Management of patients with CLTI requires multidisciplinary expertise in limb salvage programs

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Large Vessel Vasculitis

SVM Fellows Course: Non-Atherosclerotic Arterial Diseases
March 17, 2024

Deborah Hornacek, MD, FSVM
Cleveland Clinic, Section of Vascular Medicine

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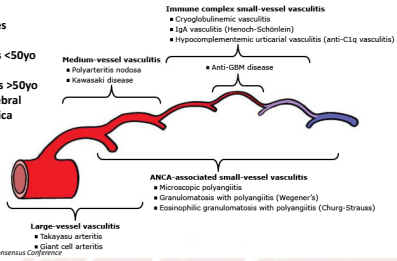
International Chapel Hill Consensus 2012

Large-vessel vasculitis: aorta and major branches

Takayasu arteritis: onset usually in patients <50yo

Giant cell arteritis: onset usually in patients >50yo
Carotid artery (temporal artery), vertebral
Associated with polymyalgia rheumatica



Jennette JC, Falk RJ, Bacon PA, et al. 2012 revised International Chapel Hill Consensus Conference Nomenclature of Vasculitides. Arthritis Rheum 2013; 65:1

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LVV: Takayasu's vs Giant Cell Arteritis

Table 1. A comparison of the significant characteristics of Takayasu's arteritis and giant cell arteritis.

	Takayasu's arteritis	Giant cell arteritis
Peak age of onset, years	15–30	60–80
Female:male ratio	9:1	3:1
Racial predisposition	Eastern Asia (Japan)	Caucasian (northern Europe)
Common presentation	Symptoms of aortic branch occlusion	Headache Visual impairment
Aorta affected, %	100%	40%
Common histological appearance	• Excessive adventitial fibrosis • Well circumscribed intimal fibrocellular hyperplasia • Increased vessel wall thickness	• Prominent inflammation of inner media and intima • Fragmentation of internal elastic laminar • Focal aortic wall inflammation with 'skip lesions'
Common genetic association	HLA-B52 Non HLA (IL12B region)	HLA-DR4
Immunopathological features	• Activation of adventitial dendritic cells • Recruitment and activation of CD4 T-lymphocytes • Macrophage activation with giant cell formation and release of pro-inflammatory cytokines • Neovascularisation and intimal hyperplasia	
Aetiological trigger	Unknown: maybe infective agent or autoantigen	

Harky A , Fok M, Balmforth B, and Bashir M. Pathogenesis of large vessel vasculitis: Implications for disease classification and future therapies. Vascular Medicine. 2019, Vol. 24(1) 79–88

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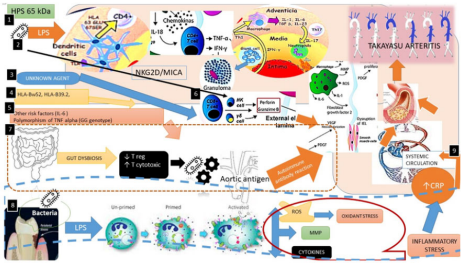
LVV: mechanism of immune stimulus

- Unclea … *sis*
- Undete … ein-65 in the aor…
  - HSP…
- HSP-65 … nd macrop…
  - Pro-… n, smooth mus…
  - Recr… odies
- Can oc… loid, sero-negativ… itosis, Sweet …



…dings in a rare case of Takayasu arteritis. IP Int J Periodontol Implantol 2023;8(4):230-236

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LVV: high morbidity and mortality

- Takayasu: Multicenter study of 318 patients, median follow-up of 6.1 years
  - 43% of patients with symptomatic relapses
  - 38% with vascular complications
  - 45% with disease progression on imaging
  - 10% with carotidynia
  - 5% mortality (median age of patients in study 36yo, range 25-47yo)
  - Factors associated with relapse of Takayasu arteritis were male sex, elevated C-reactive protein level, and carotidynia
- Takayasu pediatric cases: mortality of 10-30%
- GCA: minor decrease in longterm survival compared to age- and sex-matched controls
  - Estimated median survival time was 13.1 years (95% CI 12.6–13.5) in patients with GCA compared with 14.4 years
  - Excess mortality seen in first 2 years, and persisted > 10 years after diagnosis
  - Patients diagnosed ≤ 70 years of age are at greater risk

Circulation. 2017;136:1114–1122
Ann Pediatr Cardiol. 2013 Jan-Jun; 6(1): 52–58
J Rheum. 2020; 47(9): 1385-1391

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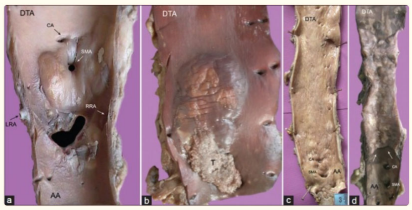
Takayasu: gross inspection of an aorta

Common to have evidence of active/inflammatory disease alongside chronic/fibrotic disease.



(a) Abdominal aorta with large, glistening intimal plaques seen around the superior mesenteric (SMA) and left (LRA), right (RRA) renal arteries

(b) single large gelatinous plaque with superimposed thrombosis (t) in descending thoracic aorta (DTA)

(c) diffuse intimal thickening with superficial scars and furrows of entire descending aorta

(d) the localized disease affecting the descending thoracic aorta (DTA) is abruptly separated from normal abdominal aorta (AA) by a distinct shelf of intimal thickening

Ann Pediatr Cardiol. 2013 Jan-Jun; 6(1): 52–58

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LVV Symptoms

- Consider in patients with systemic or constitutional symptoms and evidence of single and/or multiorgan dysfunction.
- Diagnosis is often delayed due to non-specific symptoms.
- Typical symptoms
  - Systemic: fever, fatigue, weight loss, arthralgias
  - Vague chest pain
  - Claudication of upper or lower extremities in a patient with low risk for atherosclerosis
- Features – depend on involved arteries
  - BP gradient, absent or decreased pulses, eliciting pain on pulse palpation, bruit

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LVV Differential & Mimics

- Atherosclerosis**
  - Soft plaque, mural thrombus, long stenotic lesions
- Dissection -> intramural hematoma
- Thromboembolic disease
  - Hypercoag disorders: APS, TTP
- Infectious etiology
  - Endocarditis, HBV, HCV, HIV, syphilis
- Congenital/structural
  - Coarctation, middle aortic syndrome
- Malignancy, paraneoplastic
  - Lymphomas, leukemia
- Iatrogenic
  - Drugs: ergotism (St. Antony's fire)
  - Radiation arteritis
- Multisystem inflammatory disorders
  - Sarcoidosis, Susac syndrome
  - IgG4-related disease
- Fibromuscular dysplasia
- Variable vessel vasculitis
  - Behçet syndrome, Cogan syndrome

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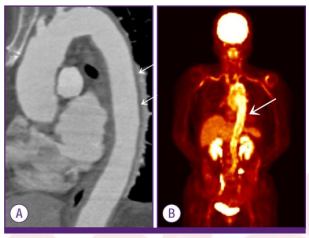
LVV Diagnosis

1. High level of suspicion!
2. Inflammatory markers
3. Imaging
   - GCA: temporal artery US -> biopsy
   - CTA
   - MRA
   - FDG PET-CT

Example: Chest CT revealed diffuse thickening of the aortic arch and the thoracic aorta (Panel A, arrows).
FDG PET-CT scan shows high uptake in aortic wall regions corresponding to thickened areas on CT (Panel B).



Infect Chemother. 2015 Sep; 47(3): 190–193.

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LVV Treatment: glucocorticoids

- New diagnosis: prednisone 1mg/kg daily (max dose 60-80mg), 2-4 weeks
  - Start tapering when clinical improvement of symptoms and ESR/CRP decrease
  - Goal: prednisone 20mg daily dose by end of 3 months
- Long-term low dose prednisone is often used to prevent constitutional symptoms
  - Common strategy for GCA – particularly when accompanied by polymyalgia rheumatica
  - Unknown whether this strategy prevents progression of arterial stenosis, particularly in young patients
- Relapse with organ-threatening disease: methylprednisolone 500-1000mg IV, 1-3 days. Then reinitiate high-dose prednisone as above.
- Initiation of glucocorticoid-sparing agent for patients with relapses

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LVV Treatment: Takayasu

- After relapse: initiate alongside prednisone
- Methotrexate, azathioprine*, mycophenolate, leflunomide, cyclophosphamide
- Biologics: depends on disease severity; primary treatment vs added to agents above
  - Anti-TNF: Remicade (infliximab*), Enbrel (etanercept), Humira (adalimumab*), Cimzia (certolizumab pegol) and Simponi (golimumab).
  - Other: Actemra (tocilizumab, IL-6 receptor inhibitor), Rituxan (rituximab, anti-CD20)
  - Mycophenolate and cyclophosphamide should not be combined with biologics
- Considerations: access (cost, availability = local infusion center?), comorbidities, plan for pregnancy (*ok to continue)

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LVV Treatment: GCA

- Older population -> increased risk of adverse steroid-related sided effects
  - osteoporosis, diabetes, hypertension, glaucoma
- 2 recommended agents: methotrexate and tocilizumab
- New ACR guidelines: all patients with GCA should receive tocilizumab
- Alternative strategy: tocilizumab at first relapse
  - SE: infection, neutropenia, elevated liver function tests, increased cholesterol, diverticulitis, gastrointestinal perforation
- Methotrexate as alternative, particularly for patients with intolerance or contraindication to tocilizumab (bowel disease in particular!)
- Note: anti- IL-6 treatment completely normalizes ESR and CRP. Surveillance of disease activity relies on clinical evaluation and interval imaging studies.

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LVV: patient case

- 27yo F
  - PMHx significant for migraines.
  - Rx: OCP, vit D supplement
  - No tobacco, etoh, or illicit drug use.
- Saw PCP: reported poor activity tolerance, vague chest pain.
- Noted cardiac murmur and asymmetric radial pulses on exam.
- EKG normal -> referred for echo, Vasc Med evaluation for possible TOS.

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LVV: patient case

- Emigrated from Vietnam to US in 2017 after coming to play soccer in college.
- Recently increased headaches; attributed to chronic sinusitis given thickening of maxillary sinuses seen on CT brain without contrast.
- Hard time completing shifts at Amazon Warehouse because arms and legs are sore.
- Recently had to give up recreational soccer league.
- Notes easy fatiguability, some night sweats. Vague non-exertional chest pain x4 weeks.

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LVV case: exam

- VS: 5'2", 114lb (BMI 20). 100% on RA; BP right 105/75, left 93/70, HR 110
- Gen: NAD, appears fatigued
- HEENT: No saddle nose deformity, no lymphadenopathy. No JVD.
- Heart: Decrescendo murmur heard through diastole at RMSB
- Lungs: Clear to auscultation. Abdomen: Normal bowel sounds.
- Vascular: Bruit vs murmur over bilateral carotids and subclavian arteries.
  Right radial 2+, left radial 1-2+/2.
  No appreciable bruit over abdominal aorta or iliac arteries.
  DP and PT 1+/2 bilaterally.
- Extremities: Warm and pink. No edema, rashes, petechiae, or synovitis.

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- The patient is called to echo down the hall—

  What other testing do you want to obtain?

Before you finish putting in orders, the echo tech finds you to discuss results.

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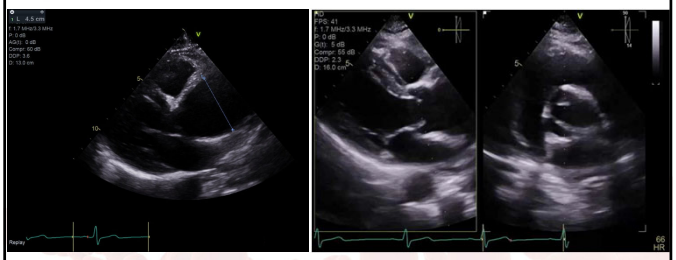
Echo



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Do the echo findings explain her symptoms?

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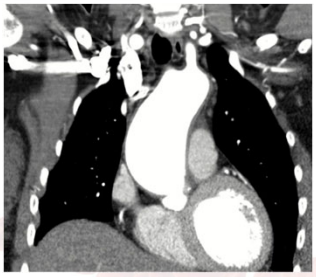
CTA chest with IV contrast



AORTIC VALVE: Bicuspid with fusion of the left and right coronary cusp
Mild leaflet thickening, with incomplete diastolic coaptation suggesting at least mild aortic regurgitation. No leaflet calcification

AORTIC ROOT: UPPER NORMAL SIZE; Diameter: 3.7 cm

ASCENDING THORACIC AORTA: aneurysmal dilatation 5.1 x4.9 cm

Diffuse Circumferential Wall Thickening with trivial calcification, thickening measuring about 3 mm.
Extends from the arch and descending aorta and involves the ostial arch branch vessels

Diffuse small size of subclavian arteries measuring approximately 3 mm. Pattern is nonspecific and could be consistent with early atherosclerotic changes. However inflammatory changes of aortitis can have similar appearance.

CORONARY ANATOMY: not optimized for assessment, however, no appreciable calcification or aneurysmal changes to coronary arteries.

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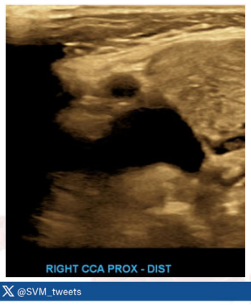
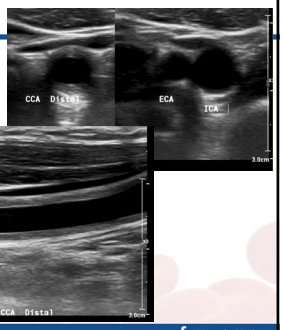
Carotid duplex





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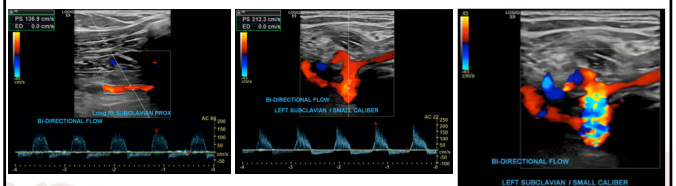
Carotid duplex: subclavian arteries



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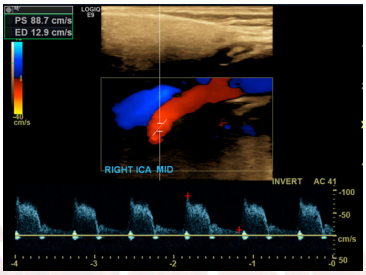
Carotid duplex: R ICA



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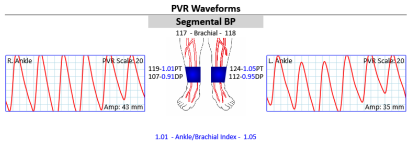
PVR

Lower Arterial Segmental Pressures

Right Pressure	Right Index		Left Pressure	Left Index
117	- 0.99	Brachial	118	- 1.00
119	- 1.01	Ankle (PT)	124	- 1.05
107	- 0.91	Ankle (DP)	112	- 0.95



Patient declined exercise portion of exam.

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Labs

WSR	0 - 20 mm/hr	**46 (H)**
CRP	<0.9 mg/dL	**8.9 (H)**

Hepatitis acute and chronic panel			Negative
HSV IgG 1	**Positive**	IgM	Negative
HSV IgG 2	Negative	IgM	Negative
CMV IgG	Negative	IgM	Negative
V.zoster IgG	**Positive !**	IgM	Negative
EBV VCA IgG	**Positive !**	IgM	negative
HIV1&2 Combo (Ag/Ab)	Non Reactive		
Syphilis Screen Result	Non Reactive		
Quantiferon gold (TB)	Negative		
Bacterial, fungal cultures	No growth		

Complete metabolic panel -- normal ranges, Cr 0.4
CBC with diff – platelet count 98k, other results within range
Urine analysis -- normal ranges, bland sediment

ANA		Negative
Proteinase 3 Antibody		Negative
Myeloperoxidase AutoAb		Negative
c-ANCA Fluorescence		Negative
p-ANCA Fluorescence		Negative
Anti-RNP		Negative
Anti-Centromere Ab		Negative
Scl-70 Abs		Negative
C3	86 - 166 mg/dL	101
C4	13 - 46 mg/dL	10 (L)

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What should we do at this point?

A. Take to OR urgently for aortic valve replacement and repair of ascending aortic aneurysm.

B. Start prednisone 60mg daily – this treats vasculitis which is the underlying cause of her aneurysm.

C. Treat active vasculitis with prednisone first, with plan for aortic valve and aneurysm surgery promptly in a few weeks - months.

D. Call Rheumatology!

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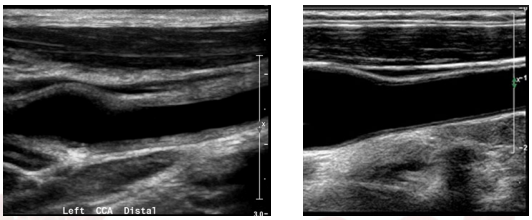
Carotid duplex post-treatment



Pre- and post-treatment (different patient – only 6yo at time of scan!)

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Case: clinical course

- Prednisone 60mg daily -> tapered to 20mg at 10 weeks.
- Normalization of inflammatory markers.
- Aortic valve repair, ascending aortic replacement frozen elephant trunk, and left subclavian artery stenting.
- Post-op:
  - Noted persistently elevated/increasing LFT.
  - Positive anti-smooth muscle antibodies = diagnosis of autoimmune hepatitis
- Addition of azathioprine.
- Prednisone fully stopped after 6 months.

- 1-year later: c/o orthopnea, dyspnea on exertion, increased fatigue

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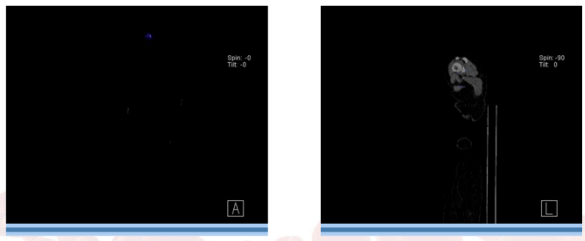
Case: PET for new symptom evaluation



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1-year: New symptom evaluation

- ESR 22, CRP 1.0
- CT PET: Mild FDG activity around the ascending aorta surgical graft and at the graft/stent anastomosis at the mid arch. Represents postsurgical granulation tissue formation.
  No suspicious FDG activity in the walls of native aorta or visualized arch branch vessels.
- Prior graft stuck to posterior sternum.

- Echo shows interval increase in residual aortic valve anterior leaflet prolapse

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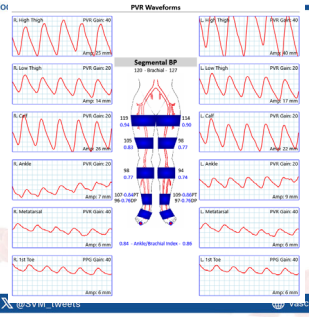
PVR: 1 year



- Prior ABI 1-year ago: 1.0 bilaterally.

- Now ABI 0.8 bilaterally.
- Inflammatory markers have been low.
  - Represent under-treatment of active disease?
  - Represent progression of fibrotic remodeling? …probably yes…

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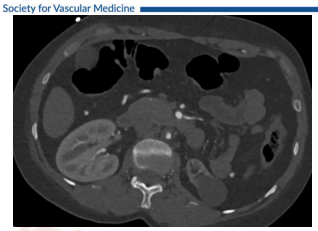
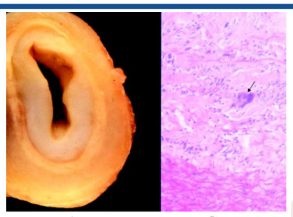
Chronic fibrotic stage



Abdominal aorta measurements:
1.6 cm at the supramesenteric segment
0.8 cm at the renal segment
0.7 cm at the mid infrarenal segment
0.9 cm at the aortic bifurcation



A B

Pathological findings in Takayasu arteritis, Extensive intimal thickening is seen with attenuation of the media and adventitial fibrosis (A). Histology revealed degeneration of the media with a dense inflammatory infiltrate, including giant cells (arrow). Circulation. 2008;117:3039–3051

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Disease-related complications

Due to lifestyle limiting symptoms from aortic insufficiency--

- Redo sternotomy, lysis of adhesions, AVR (#21 OnX mechanical)
- Readmitted 2 days post-discharge: Pericardial effusion with clinical tamponade, no windows for pericardiocentesis. Return to OR for drainage and evacuation of clots.
- Recovered well, discharged without further events.

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Treatment and Surveillance

- Now has been 4 years since original presentation—
  - Maintained on azathioprine for Takayasu's and autoimmune hepatitis
  - Inflammatory markers remain low /stable
  - Serial imaging: extensive changes, but stable
  - 4-limb BP readings – difficult to determine accurate BP
  - Aspirin 81mg
  - On beta blocker (aorta, and headaches)
  - On statin, target LDL <100
  - Migraine abortive: Rimegepant – avoid triptans d/t dissection risk

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Takeaways

- Patients can have non-specific symptoms for weeks to years prior to disease recognition.
- Multidisciplinary care is essential.
- Imaging is important for surveillance to detect subclinical disease progression and fibrotic remodeling. Use ESR/CRP, but no disease-specific markers.
- Glucocorticoid-sparing agents are now considered standard part of long-term therapy for many patients.
  - Consider access, comorbidities, and potential for pregnancy when selecting agent.
- Takayasu's: high morbidity/mortality – endovascular intervention and surgery is more complex and higher risk in these patients
- GCA: small decrease in longterm survival, don't rely on ESR/CRP if on tocilizumab

Peripheral Artery Dissections

Daniella Kadian-Dodov, MD
Associate Professor of Medicine
Program Director, Vascular Medicine Fellowship
Mount Sinai Fuster Heart Hospital

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Disclosures

Consulting, Honoraria:
- Boston Scientific
- Abbott

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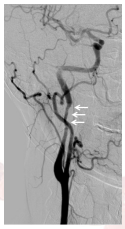
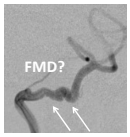
39 yo F p/w HA and Pulsatile Tinnitus

Cervical artery dissection (CeAD) accounts for up to 25% of stroke in patients ≤ 45 years old





15-20% are FMD-related, with higher overlap rates when below neck imaging is obtained

Intimal tear or rupture of the vaso vasorum that allows blood flow and separation of the wall layers

J Neurol 2003; 250:1179-1184, Stroke 2014;45:37-4
Vasc Med 2019;24:112-119

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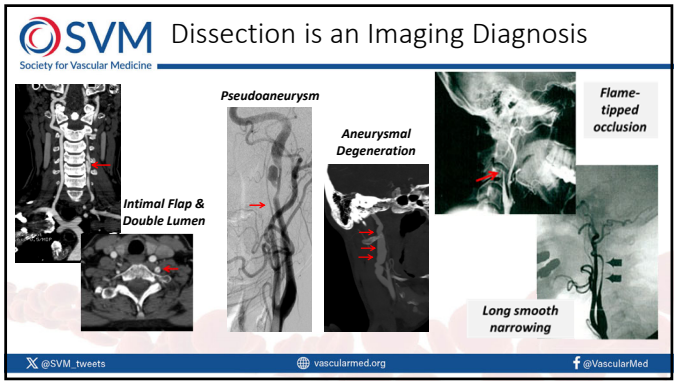
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Dissection is an Imaging Diagnosis
Intimal Flap & Double Lumen
Pseudoaneurysm
Aneurysmal Degeneration
Flame-tipped occlusion
Long smooth narrowing
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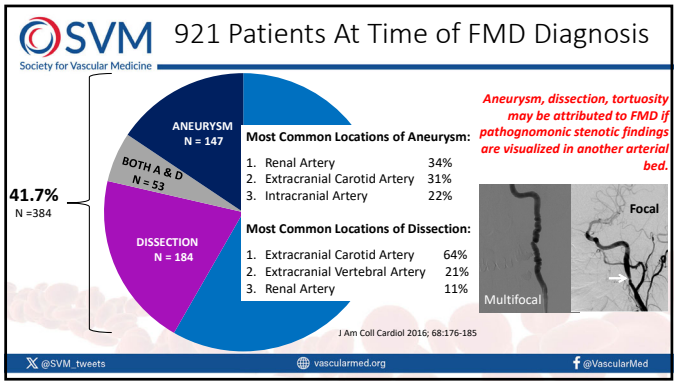
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921 Patients At Time of FMD Diagnosis
41.7%
N =384
ANEURYSM N = 147
BOTH A & D N = 53
DISSECTION N = 184
Most Common Locations of Aneurysm:
1. Renal Artery 34%
2. Extracranial Carotid Artery 31%
3. Intracranial Artery 22%
Most Common Locations of Dissection:
1. Extracranial Carotid Artery 64%
2. Extracranial Vertebral Artery 21%
3. Renal Artery 11%
Aneurysm, dissection, tortuosity may be attributed to FMD if pathognomonic stenotic findings are visualized in another arterial bed.
Multifocal
Focal
J Am Coll Cardiol 2016; 68:176-185
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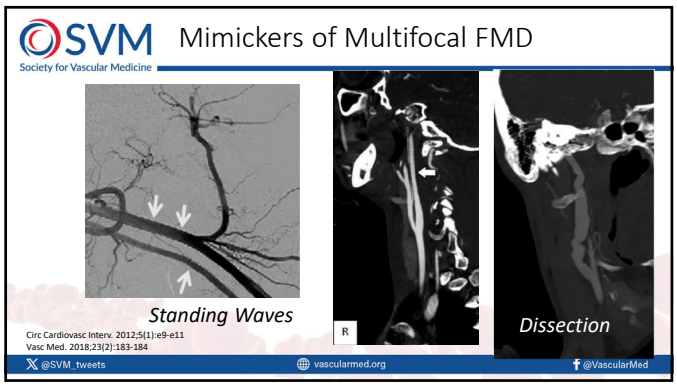
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Mimickers of Multifocal FMD
Standing Waves
R
Dissection
Circ Cardiovasc Interv. 2012;5(1):e9-e11
Vasc Med. 2018;23(2):183-184
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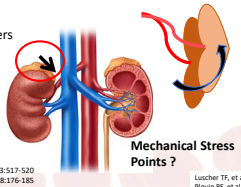
Fibromuscular Dysplasia

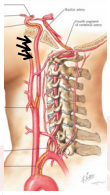
- Non-atherosclerotic, non-inflammatory arterial disease of the mid-distal (usually) artery
- Predominantly identified in women (94%) age 40s-50s, but men and peoples of any age can be affected
- Usually affects the carotid and renal arteries, but any artery can be affected

No difference in OCPs or parity when FMD patients matched to controls

Higher rates of aneurysm and more severe disease in smokers



Mechanical Stress Points ?



Bofinger A, et al. J Hum Hypertens. 1999;13:517-520
Kadian-Dodov D, et al. J Am Coll Cardiol. 2016; 68:176-185

Luscher TF, et al. Mayo Clin Proc. 1987;62:931-952
Plouin PF, et al. Orphanet J Rare Dis. 2007;2:28.

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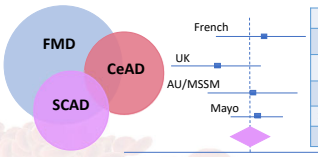
7

Genetics of Disease

PHACTR1 rs9349379[A] allele:
↓ risk of MI, CAD
↑ **risk of CeAD, FMD, migraine, SCAD**



OR (95%CI)	P-value
1.81 (1.39-2.35)	0.00001
1.38 (1.09-1.75)	0.007
1.66 1.27-2.15)	0.00016
1.77 (1/51-2.07)	10^{-12}
1.67 (1.50-1.86)	6.7×10^{-21}

J Am Coll Cardiol 2019;73:58-66

Two small cerebral aneurysms
Bilateral ICA
Bilateral vertebral

Vasc Med 2019;24:162-163

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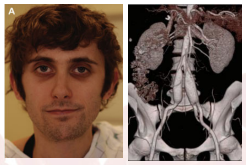
8

Back To The Case – 3 Years Later

- Represented with severe abdominal pain, nausea, vomiting and found to have **bilateral renal artery dissections with renal infarct**
- Sent to genetics and found to have a pathogenic variant in COL3A1 gene consistent with vEDS

Ehlers-Danlos Type IV, Vascular Type
COL3A1, rarely COL1A1

- Arterial dissection, aneurysm, rupture; intestinal and uterine rupture
- Haploinsufficiency vs Minimal Production normal collagen dictates course of disease



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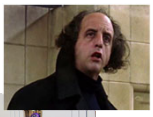
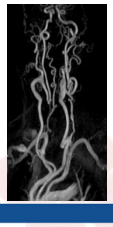
9

Other Syndromic Arteriopathies

Marfan Syndrome
FBN1
Ectopia lentis, enlarged aortic root, systemic signs of CTD



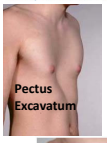
Loeys-Dietz Syndrome
TGFBR 1 and TGFBR 2
SMAD 3, TGFB 2, TGFB3
Triad: Arterial tortuosity, Bifid uvula, hypertelorism



Germain DP. Orphanet J Rare Dis 2007; 2:32.
Chu LC, et al. Am J R 2014;202(5):1120-1129
Loeys BL, et al. J Med Genet 2010;47(7):476-485
Deveraux RB, et al. J Cardiol 2012; 110(8):1189-1194

10

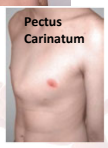
Systemic Signs of Connective Tissue Disease

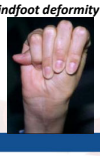

Pectus Excavatum


Curved spine

Thumb and Wrist Sign

Hindfoot deformity

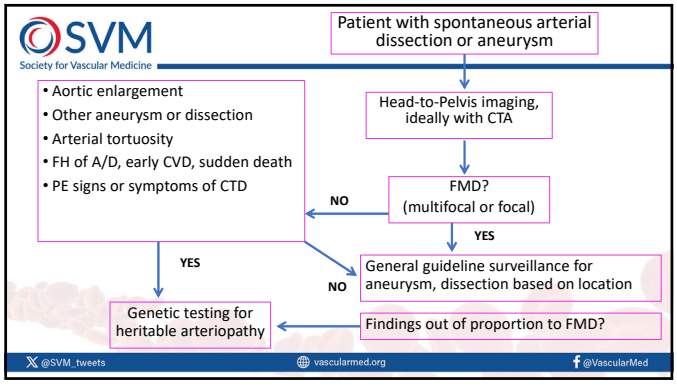

Pectus Carinatum



Beighton Score ≥ 5/9 defines hypermobility

Beighton et al. Am J Med Genet. 1998; 77(1):31-37
Loeys BL, et al. J Med Genet 2010;47(7):476-485

11



12

Management of Vascular Findings

1. Aneurysm
   - Depends on location, size (surveillance vs repair)
   - There are no FMD specific recommendations and general guidelines apply (identification of heritable arteriopathy may change repair thresholds)
2. Dissection
   - Incidental extracoronary dissections: ASA 81 mg daily
   - Acute, symptomatic extracoronary dissections: Antiplatelet vs Anticoagulation
   - Imaging type and surveillance intervals dependent on location and high risk features (e.g. pseudoaneurysm)
3. Any findings (A/D, tortuosity, aortic arch anomaly)
   - Lifestyle modifications
   - ASA 81 mg daily

Gornik HL, et al. Vasc Med. 2019;24(2):164-189
Hayes SN, et al. J Am Coll Cardiol. 2020;76:961-984

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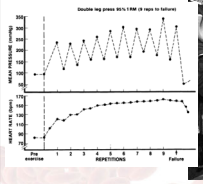
Lifestyle Modification (Don't Do This)

Avoid intense isometric exercise, extreme valsalva



Paul Anderson – USA Olympic Champion 1956, World Champion and Original World's Strongest Man

Chiropractic neck manipulation

Cardio Exercise
- **Warm up, cool down**
- **MaxHR = 80%MPHR**
- **Complete a sentence without gasping for air**

High G-force activities
(roller coasters, etc)

J Appl Physiol 1985; 58:785-790

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FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients

FDA Drug Safety Communication

- Epidemiologic studies and the FDA Adverse Event Reporting System database revealed an association between **fluoroquinolones and aortic aneurysm/dissection risk (~2x Risk)**
- Risk appears time-sensitive (first 10 days) and related to treatment duration (e.g. > 14 days exposure), underlying risk for aneurysm/dissection (***genetic arteriopathy, elderly, cardiovascular risk factors***)

www.fda.gov/drugs/drugs-safety-and-availability/fda-warns-about-increased-risk-ruptures-or-tears-aorta-blood-vessel-fluoroquinolone-antibiotics accessed May 5, 2021

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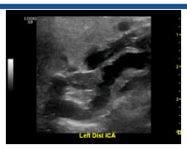
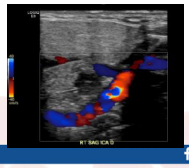
15

Faces of Fibromuscular Dysplasia

47 year old woman with hypertension, carotid bruit on exam





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Faces of Fibromuscular Dysplasia

47 year old woman with hypertension, carotid bruit on exam

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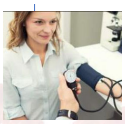
Faces of Fibromuscular Dysplasia

Hypertension
Renal & Carotid FMD



47 years old

45 years old

Spontaneous Coronary Artery Dissection
Carotid multifocal FMD

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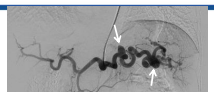
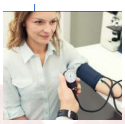
Faces of Fibromuscular Dysplasia



Hypertension
Renal & Carotid FMD

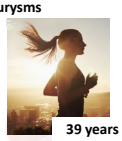


47 years old

45 years old

Spontaneous Coronary Artery Dissection
Carotid FMD

Splenic artery aneurysms



39 years old

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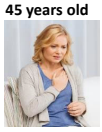
Faces of Fibromuscular Dysplasia

Takatsubo Cardiomyopathy
1990s – Age 50s

Hypertension
Renal & Carotid FMD

47 years old

45 years old



Spontaneous Coronary Artery Dissection
Carotid FMD

Splenic artery aneurysms

39 years old

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"FMD-Like" or Arteriopathy NOS

- Arterial dissection, aneurysm, and/or tortuosity **WITHOUT** multifocal or focal lesions
- Negative genetic testing for heritable arteriopathies
- **On paper, look like an FMD patient**: middle aged, often women who are otherwise healthy
- Diagnosis of exclusion

Splenic artery aneurysms

39 years old

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Should we be screening more patients?

YES!

Consider in all patients or first degree family members with:

- cervical (high) or abdominal bruits
- early onset hypertension (age < 40 years)
- difficult to control or labile hypertension
- severe migraine headaches
- pulsatile tinnitus
- spontaneous dissection, arterial tortuosity, aneurysms

**NB if you screen prior to mean age of FMD diagnosis (age 54 years), it is not a guarantee that the patient will remain free of vascular findings throughout their life

Gornik HL, et al. Vasc Med. 2019;24(2):164-189

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THANK YOU!

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23

The Blue Finger

Stanislav Henkin, MD, MPH, RPVI, FSVM
Senior Associate Consultant
Mayo Clinic

@stanhenkin

1

Learning Objective

Develop an evidence-based algorithm for work-up and management of "the blue finger"

2

Case 1

- 45 year old woman presents for finger discoloration in last 2 years
  - Initially was a few fingers, now all
  - Fingers turn white then blue – well demarcated
  - Worse in the winter
- PMH
  - Supraventricular tachycardia
- Medications:
  - Bisoprolol
- Exam: "Normal"
- Labs: "Normal"

3

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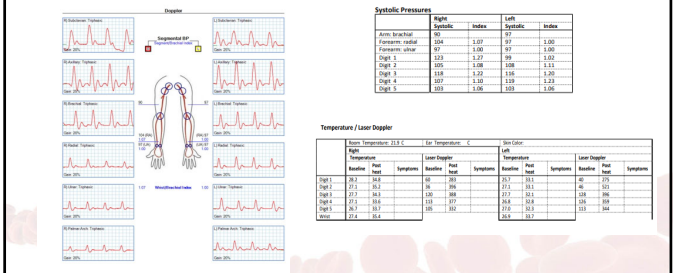

Systolic Pressures

	Right		Left	
	Systolic	Index	Systolic	Index
Arm: brachial	90		97	
Forearm: radial	104	1.07	97	1.00
Forearm: ulnar	97	1.00	97	1.00
Digit 1	123	1.27	99	1.02
Digit 2	105	1.08	108	1.11
Digit 3	118	1.22	116	1.20
Digit 4	107	1.10	119	1.23
Digit 5	103	1.06	103	1.06

Temperature / Laser Doppler

Room Temperature: 21.9 C Ear Temperature: C Skin Color:

	Right						Left					
	Temperature			Laser Doppler			Temperature			Laser Doppler		
	Baseline	Post heat	Symptoms	Baseline	Post heat	Symptoms	Baseline	Post heat	Symptoms	Baseline	Post heat	Symptoms
Digit 1	28.2	34.8		68	283		25.7	33.1		40	275	
Digit 2	27.3	35.2		36	396		27.1	33.5		46	521	
Digit 3	27.7	34.3		130	388		27.7	32.1		128	396	
Digit 4	27.1	33.0		113	377		26.8	32.8		126	359	
Digit 5	26.7	33.7		105	332		27.0	32.3		113	344	
Wrist	27.4	35.4					26.9	33.7				

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4

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What do you recommend?

- A: Recommend placing hands in hot water when symptoms occur
- B: Botox injection
- C: Start sildenafil
- D: Switch bisoprolol to diltiazem
- E: Referral to rheumatology for evaluation of connective tissue disorder

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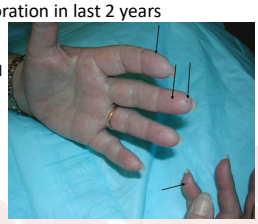
Case 2

- 35 year old woman presents for finger discoloration in last 2 years
  - Initially was a few fingers, now all
  - Fingers turn white then blue – well demarcated
  - Developed left index finger ulceration that healed
- PMH
  - None
- Medications:
  - Amlodipine
- Exam: Chest and digital telangiectasias
- Labs: ANA 1:2560, + centromere antibody



Choi and Hemkin, Vascular Medicine 2021; 26:56-70

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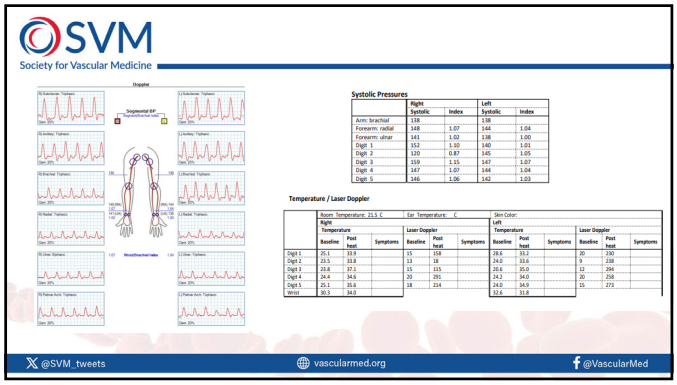
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Doppler
Segmental BP
Waveform/brachial index
Systolic Pressures
Right
Systolic
Index
Left
Systolic
Index
Arm: brachial 138 138
Forearm: radial 148 1.07 144 1.04
Forearm: ulnar 141 1.02 138 1.00
Digit 1 152 1.10 140 1.01
Digit 2 120 0.87 145 1.05
Digit 3 159 1.15 147 1.07
Digit 4 147 1.07 144 1.04
Digit 5 146 1.06 142 1.03
Temperature / Laser Doppler
Room Temperature: 21.1 C
Ear Temperature: C
Skin Color:
Right
Left
Temperature
Laser Doppler
Baseline
Post heat
Symptoms
Digit 1 25.1 33.9 15 158 28.6 33.2 20 230
Digit 2 21.5 33.8 13 38 24.0 33.6 9 238
Digit 3 21.8 37.1 15 115 20.6 35.0 12 294
Digit 4 24.4 34.6 20 291 24.2 34.0 20 258
Digit 5 25.1 35.6 18 214 24.0 34.9 15 273
Wrist 30.3 34.0 32.6 31.8
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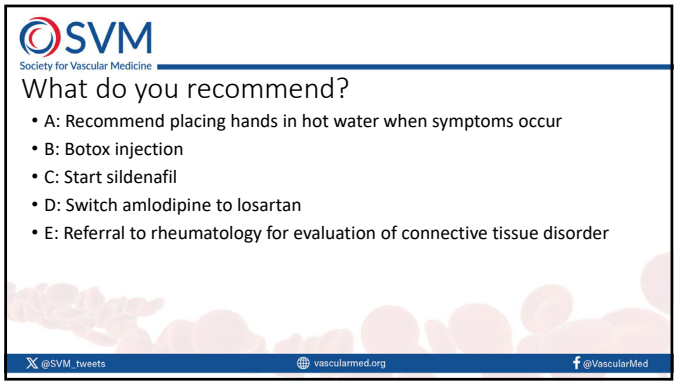
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Society for Vascular Medicine
What do you recommend?
• A: Recommend placing hands in hot water when symptoms occur
• B: Botox injection
• C: Start sildenafil
• D: Switch amlodipine to losartan
• E: Referral to rheumatology for evaluation of connective tissue disorder
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Causes of “blue fingers”
• Obstruction
  • Emboli, thrombosis
• Vasospasm
  • Primary vs secondary
• Hemorrhage
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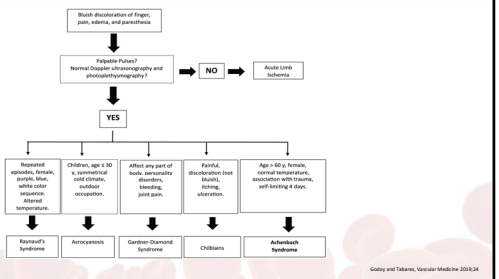
9

History and exam



Godoy and Tabares, Vascular Medicine 2016;24

10

Atheroembolism

Shepherd, R. Chapter 45, Atheroembolism. Vascular Medicine: A Companion to Braunwald's Heart Disease. Published 2016

11

Emboli "blue finger syndrome"

- Variation of acute limb ischemia – but size of embolic material is smaller and travels into end arteries
  - Intact large vessels and pulses
  - Extremely painful
  - Toe/finger becomes discolored
  - End-organs most commonly are fingers and toes but can also include brain, eye, kidney, GI tract, skin
- Abdominal aorta is most common origin – but any artery with atherosclerosis can be culprit
- Spontaneous vs iatrogenic
- Many present with multisystem involvement

12

Treatment

- Stabilize plaque
  - Statin, antiplatelet agents, smoking cessation
  - Anticoagulation only if mobile atheroma
- Wound care
- Pain control
- Infection treatment
- Pneumatic arterial pump
- Hyperbaric oxygen therapy
- Operative management

13

Paroxysmal finger hematoma

Godoy and Tabares, Vascular Medicine 2019;24

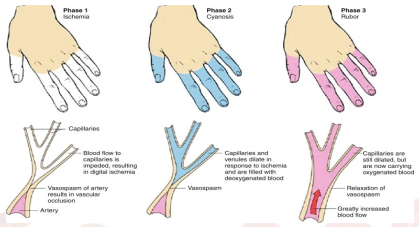
14

Vasospasm

Choi and Hankin, Vascular Medicine 2021;26:56-70
Weinberg, Blue Toe and Blue Toes: Causes, Diagnosis and Treatment (angiologist.com), Accessed 2/23/24

15

Raynaud Phenomenon



Henkin and Creager. Chapter 46, Raynaud Phenomenon. Vascular Medicine: A Companion to Braunwald's Heart Disease. Published 2019.

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Primary vs Secondary

- Primary (idiopathic; Raynaud disease)
  - Up to 8% of US population, higher prevalence in cooler climates
  - Women >> men
  - 3rd or 4th decade of life
  - Genetic predisposition - ~40% have relatives
  - Start with 1-2 fingers → symmetric bilaterally
  - 40% involve toes (but <2% only involve toes)
- Secondary (Raynaud syndrome)
  - Consequence of systemic disease
  - Digital pitting, ulceration, gangrene
  - Transition rate from primary to secondary depends on study – anywhere from 1% per year to 13% total

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Thermal/Ice Challenge

Choi and Henkin, Vascular Medicine 2021; 26:56-70

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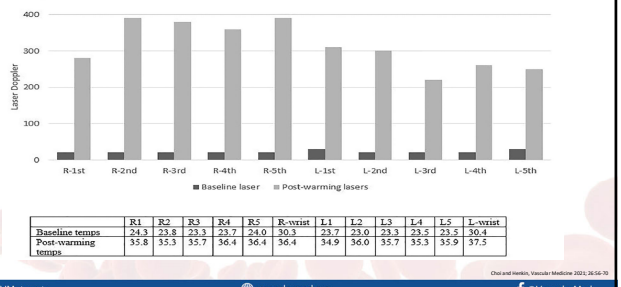
Laser Doppler – Primary



	R1	R2	R3	R4	R5	R-wrist	L1	L2	L3	L4	L5	L-wrist
Baseline temps	24.3	23.8	23.3	23.7	24.0	30.3	23.7	23.0	23.3	23.5	23.5	30.4
Post-warming temps	35.8	35.3	35.7	36.4	36.4	36.4	34.9	36.0	35.7	35.3	35.9	37.5

Choi and Henkin, Vascular Medicine 2021; 26:56-70

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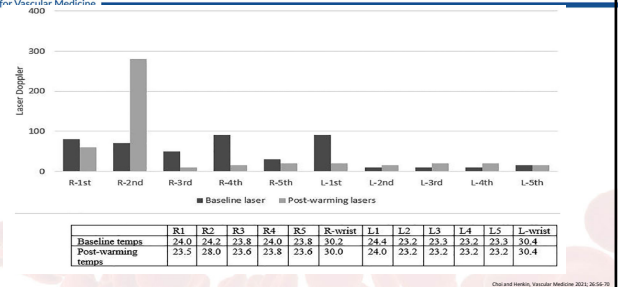
Laser Doppler – Secondary



	R1	R2	R3	R4	R5	R-wrist	L1	L2	L3	L4	L5	L-wrist
Baseline temps	24.0	24.2	23.8	24.0	23.8	30.2	24.4	23.2	23.3	23.2	23.3	30.4
Post-warming temps	23.5	28.0	23.6	23.8	23.6	30.0	24.0	23.2	23.2	23.2	23.2	30.4

Choi and Henkin, Vascular Medicine 2021; 26:56-70

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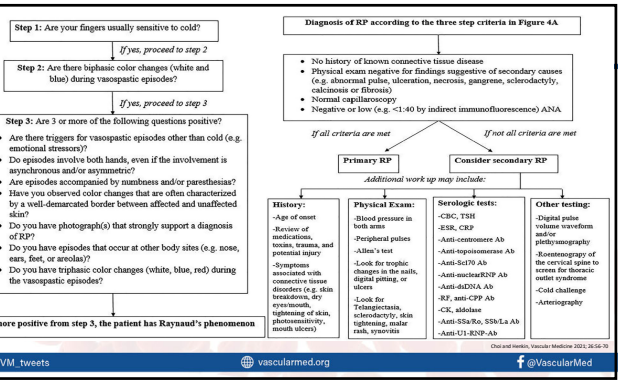

Choi and Henkin, Vascular Medicine 2021; 26:56-70

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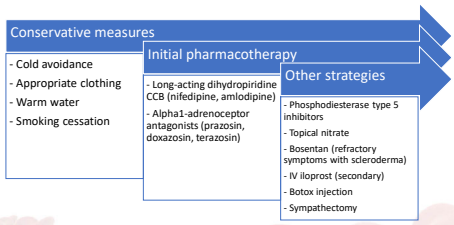
Often overlooked secondary causes

- Medications
  - Beta-blockers
  - Chemotherapy – bleomycin, vinblastine, gemcitabine
  - Estrogen
  - Pseudoephrine
- Cocaine, amphetamine
- Low BMI
- Carpel tunnel syndrome

22

Treatment



23

Acrocyanosis

- Primary vs Secondary
  - Autoimmune disease (APLA, connective tissue disease)
  - Hematologic disorder (Cold agglutinin, cryoglobulinemia, myeloproliferative disorder)
  - Neurologic disorder (paraplegia, multiple sclerosis, POTS)
  - Eating disorders
  - Malignancy
  - Infection
  - Drugs (vasoconstrictors, inferferon, chemotherapy, biological agents)

Eberhardt. Chapter 47, Acrocyanosis. Vascular Medicine: A Companion to Braunwald's Heart Disease. Published 2016.

24

Treatment

- Reassurance
- Avoidance of cold exposure
- Medications rarely necessary (and usually don't work)
- Treat primary condition, if present!

25

Pernio

- Treatment
  - Prevention
  - Avoid cold and damp conditions, appropriate showewear/gloves
  - Consider dihydropyridine CCB to treat and prevent pernio

Olin JW. Chapter 49, Pernio (Chilblains). Vascular Medicine: A Companion to Braunwald's Heart Disease. Published 2013.

26

	Primary RP	Primary acrocyanosis	Pernio	Primary LR
Demographic	Female predominance Age before 40 years[1]	Female predominance Age 20–30 years[60]	Female predominance Any age with exposure[90]	Female predominance Age 20–60 years[111]
Trigger/ exposure	Cold, emotional stress	Cold, emotional stress	Cold, damp, non-freezing temperature	Cold exposure
Symptom duration	Episodic	Persistent over time (not triggered); improves with rewarming and elevation of limbs	Occurs during cold months and lasts days to several weeks[84]	Episodic; improves with rewarming and elevation of limbs[126]
Clinical features	Bi/triphasic color change with pain/paresthesia;[7] absence of ulcer/necrosis	Painless cyanosis; absence of ulcer/necrosis; associated with hyperhidrosis in the hands and feet[69]	Erythematous or purple lesions accompanied by pain, burning sensation, ulcer or necrosis[80,81]	Violaceous reticular, 'net-like' mottling encircling a pallor central core
Distribution	Symmetric; commonly seen in hands (thumbs are often spared) and feet; less commonly seen in tongue, earlobes, nose, nipples	Symmetric; commonly seen in hands and feet; less commonly seen in tongue, earlobes, nose, nipples	Depends on exposure; commonly seen in finger pads, toe pads, nailfolds, dorsum of the hands/ feet, face, ears	Symmetric; more frequently seen in the lower limbs, but may be seen in upper limbs or torso
Treatment	Cold avoidance; dihydropyridine CCB (nifedipine, amlodipine), α_1-adrenoceptor antagonists[85,125]	Cold avoidance, elevation Medications rarely indicated	Cold avoidance Medications rarely indicated	Cold avoidance, elevation Medications rarely indicated

CCB, calcium channel blocker; LR, livedo reticularis; RP, Raynaud's phenomenon.

Choi and Henion, Vascular Medicine 2021; 26:56-70

27

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Conclusions

- History, history, history
  - Then exam and better exam
- Develop an approach for every patient you see with “blue finger”
- Conservative measures before other stuff

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Thank you!
Henkin.Stanislav@mayo.edu

@stanhenkin

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Consultant Case Files: Compression Syndromes

Aaron W. Aday, MD, MSc, RPVI, FSVM
Assistant Professor of Medicine
Vanderbilt University Medical Center

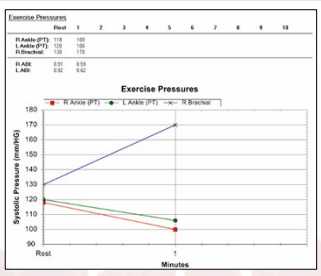
1

Case #1

- 24-year-old healthy man
- Typically runs 3-4 miles several days per week
- Starts training for a marathon→exertional leg pain as he builds up distance
- Pain feels like aching and burning in both calves, relieved by resting ~2 minutes
- Normal cardiovascular exam

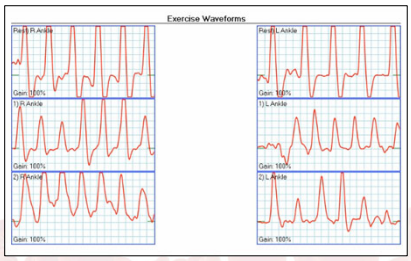
2

Exercise ABI



3

Doppler Waveform Pre- and Post-Exercise



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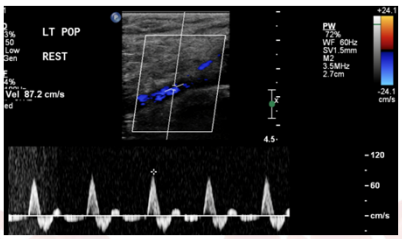
Popliteal Artery Duplex at Rest



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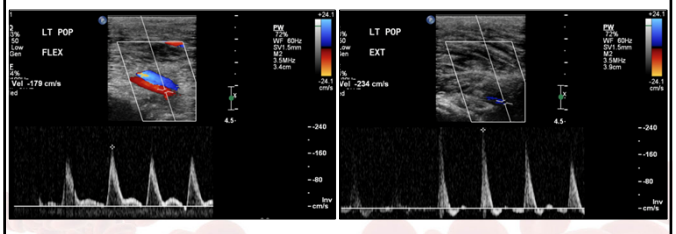
Popliteal Artery Duplex with Ankle Flexion



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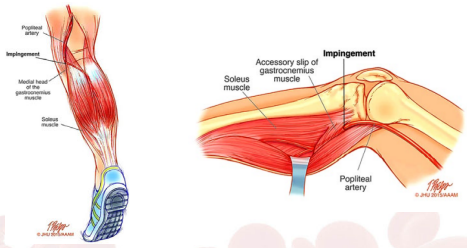
Popliteal Artery Entrapment Syndrome



Hicks CW et al. *Vasc Med* 2019;24(20):190-194

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Case #2

- 28-year-old healthy woman
- Former collegiate athlete, now competes in triathlons
- Progressive cramping in R leg with cycling or long runs
- Some pain in R buttock, thigh, and calf
- Normal cardiovascular exam

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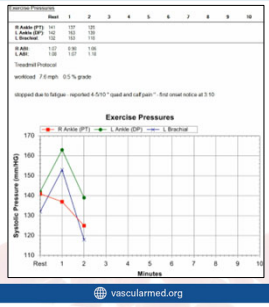
Exercise ABI



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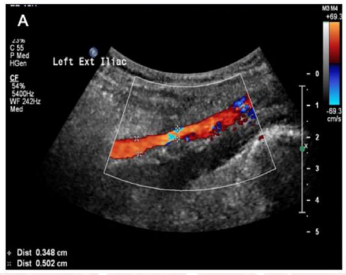
LE Arterial Duplex



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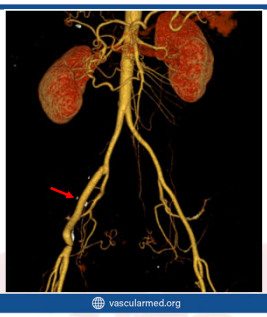
External Iliac Artery Endofibrosis



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Case #3

- 27yo house painter
- Progressive numbness and tingling in his right (dominant) hand
- Exacerbated by overhead work
- Right arm easily fatigues
- Fingers stiff and pale in the cold

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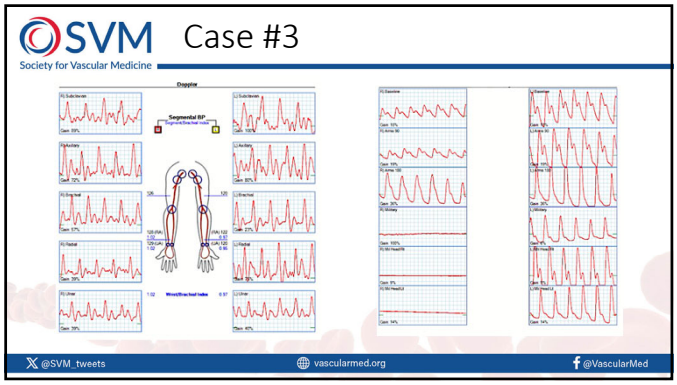
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Case #3
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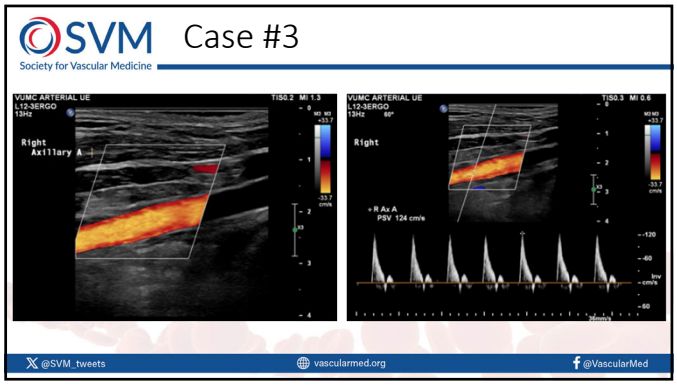
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Case #3
Right
Axillary A
Right
R Ax A
PSV 124 cm/s
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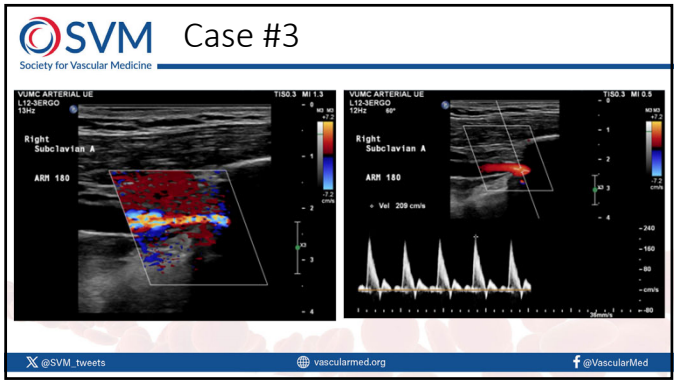
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Case #3
Right
Subclavian A
ARM 180
Right
Subclavian A
ARM 180
Vel 209 cm/s
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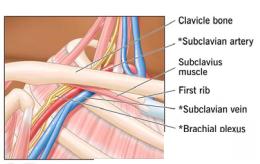
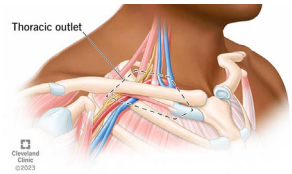
Thoracic Outlet Syndrome





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Thoracic Outlet Syndrome

Table 1. Types of thoracic outlet syndrome (TOS).

Types of TOS	Neurogenic *Most common form of TOS*	Venous *Involvement of the subclavian vein*	Arterial *Involvement of the subclavian artery*
Sex	More common in females (3.5:1)	More common in males	Females/males equally
Typical age	20–40 years	20–30 years	20–30 years
Risk factors	• Repetitive movements • Previous trauma	• Strenuous work using arms • Athletics	• Vigorous arm activity • Trauma
Symptoms	• Pain down arm, forearm, ring finger, and little finger • Tingling/numbness at night • Arm/hand weakness • Arm/hand swelling • Loss of dexterity • Cold intolerance • Headache	• Pain in affected arm often associated with strenuous work • Arm/hand swelling • Veins of shoulder and chest appear more visible • Hand/arm appears blue in color • Blood clot (DVT) may develop	• Pain at rest • Pain with arm activity • Hand appears white in color • Hand/arm cool • Decreased pulse • Aneurysm of subclavian artery may be present • Thrombosis (blood clot) may develop
Lab studies	None	Coagulation studies if DVT develops	Coagulation studies if blood clot develops
Imaging studies	Chest X-ray	Chest X-ray Ultrasound Venography or angiography	Chest X-ray Ultrasound Angiography

Grunebach G et al. *Vasc Med* 2015;20(5):493-495

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Arterial TOS Treatment

- Thoracic outlet decompression +/- arterial reconstruction
- Thrombectomy/thrombolysis in some cases
- Anticoagulation and/or antiplatelet therapy
- Physical therapy

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Case #4

- 45yo woman with hypertension, hyperlipidemia, and fibromyalgia
- 6 months of abdominal pain
- Primarily after eating, but sometimes after vigorous exercise
- Nausea, lost 7 pounds
- Soft epigastric bruit on exam
- Extensive GI testing negative

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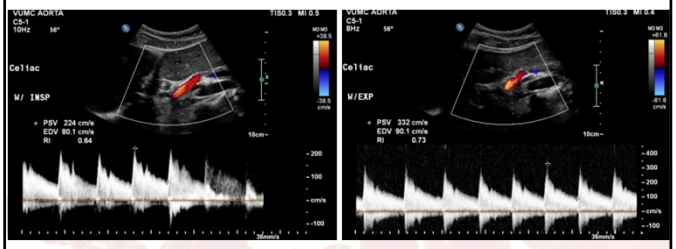
Case #4



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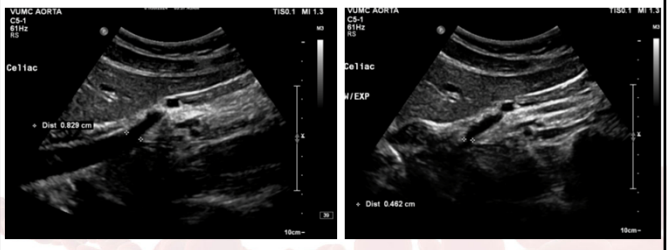
Case #4



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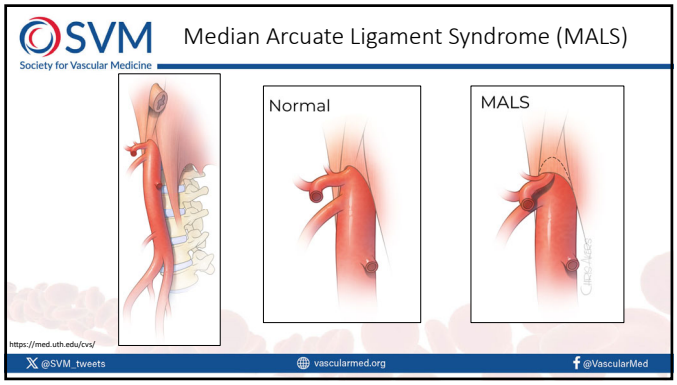
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Median Arcuate Ligament Syndrome (MALS)
Normal
MALS
https://med.uth.edu/cvs/
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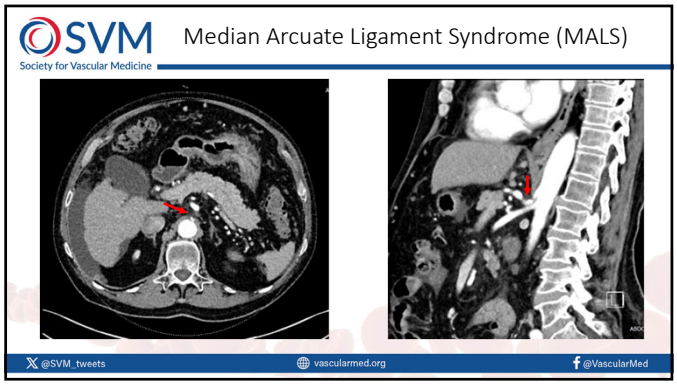
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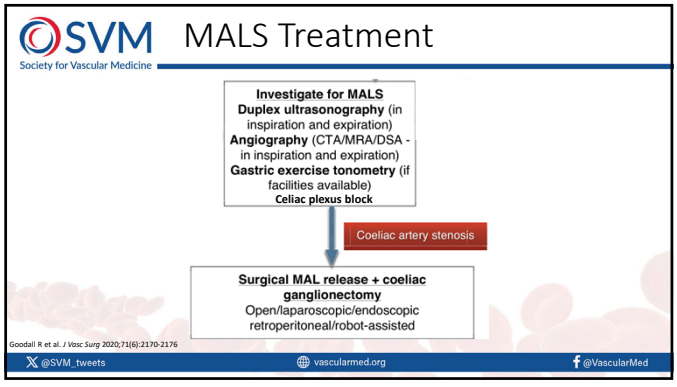
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MALS Treatment
Investigate for MALS
Duplex ultrasonography (in inspiration and expiration)
Angiography (CTA/MRA/DSA - in inspiration and expiration)
Gastric exercise tonometry (if facilities available)
Celiac plexus block
Coeliac artery stenosis
Surgical MAL release + coeliac ganglionectomy
Open/laparoscopic/endoscopic retroperitoneal/robot-assisted
Goodall R et al. J Vasc Surg 2020;71(6):2170-2176
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Questions?

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Asymptomatic Carotid Artery Disease – Surgical Revascularization…and TCAR

Olamide Alabi MD MS
Chief Quality Officer, Division of Vascular Surgery and Endovascular Therapy
Emory University School of Medicine

Sunday May 17, 2024

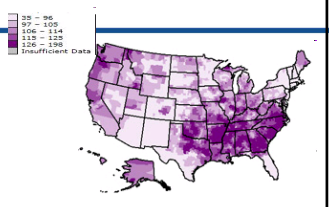
1

Disclosures

- No relevant disclosures
- Some slides related to TCAR were provided by SilkRoad Medical but I have no personal or financial relationship with them

2

Epidemiology



- 3rd leading cause of death in the US
- 800,000 stroke victims per year
- 1/3 die
- 1/3 permanently disabled
- COSTS ~$70 BILLION annually
- 85% strokes are ischemic
- Carotid disease is responsible for 20% of strokes

3

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Management of Carotid Stenosis

- Antiplatelet Therapy
- High intensity Statin Therapy
- Risk Factor Modification

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Management of Carotid Artery Stenosis

Carotid Intervention to prevent stroke is recommended for:

- ***asymptomatic*** patients with carotid stenosis (60% to 99%) who are expected to live ≥5 years if the perioperative (30-day) stroke and death rate was *<3%*.
- *symptomatic* patients with carotid stenosis (50% to 99%) if the 30-day stroke and death risk is *<6%*.

- CAS is a reasonable alternative to CEA for stroke prevention when performed within these standards

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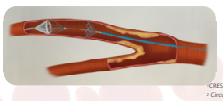
Gold Standard Carotid Endarterectomy	**Less Invasive Alternative** Transfemoral, Filter Protected CAS

• Low stroke risk, but…
• Invasive; risk of surgical complications
  • Risk of cranial nerve injury
  • MI rates 2X that of TF-CAS
	• Patient friendly, long-term durability, **but…**
	• Excess procedural stroke risk
	  • Unprotected arch and disease navigation; lower embolic capture rate from misaligned filters



CREST Trial. N Engl J Med 2010;363:11-2
Circulation. 2012;125:2256-2264

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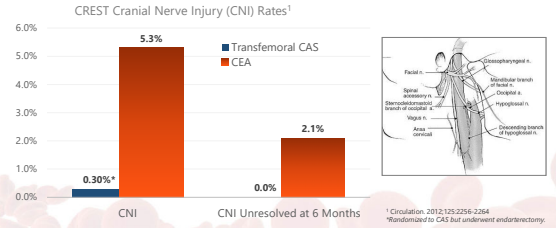
Increased Cranial Nerve Injury Rates for CEA in CREST



[1] Circulation. 2012;125:2256-2264
*Randomized to CAS but underwent endarterectomy.

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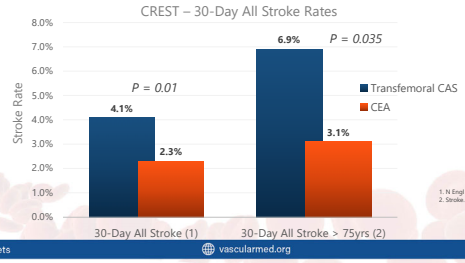
Higher Stroke rate after Transfemoral CAS



1. N Engl J Med 2010;363:11-23.
2. Stroke. 2011 Dec;42(12):3484-90.

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Carotid stents are durable

Trial	Type	n	< 30 day Stroke and Death		> 30 day Ipsilateral Stroke		Follow Up
			CEA	CAS	CEA	CAS	
SPACE	RCT, Symp	1183	6.5%	7.7%	1.9%ǂ	2.2%ǂ	2 years
CREST	RCT	2502	2.3%	4.4%	2.4%	2.0%	Median 2.5 years
EVA-3S	RCT, Symp	527	3.9%*	9.6%*	3.1%⁺	2.4%⁺	Median 7.1 years
SAPPHIRE	RCT	334	5.4%	4.8%	3.6%	3.6%	3 years

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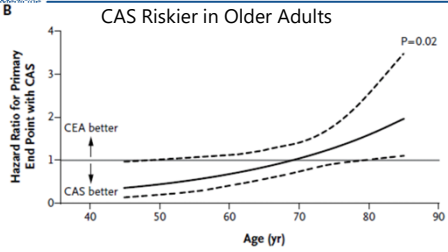
B

CAS Riskier in Older Adults



1. N Engl J Med 2010;363:11-23.
2. Stroke. 2011 Dec;42(12):3484-90.

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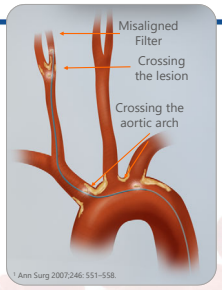
Challenges in Transfemoral CAS

- Excessive arch vessel or carotid artery tortuosity and lesion angulation
- Excessive aortic arch plaque burden
- Difficult femoral vascular access



1 Ann Surg 2007;246: 551–558.

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TCAR Case

- 69F, Asymptomatic. Bilateral carotid stenosis identified by surveillance duplex ultrasound
- PMH: Tongue Cancer sp partial glossectomy, neck dissection and radiation in 1994
- Duplex:
  - right 421/134 (cm/s) , left 319/101 (cm/s)
- CTA:
  - LEFT 80% RIGHT 90%

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Transcarotid artery revascularization with flow reversal

Temporary occlusion of the CCA
+
reversal of antegrade flow in the CCA/ ECA/ ICA

Protection against embolization:
- avoids manipulation within the aortic arch
- robust flow reversal before lesion manipulation.

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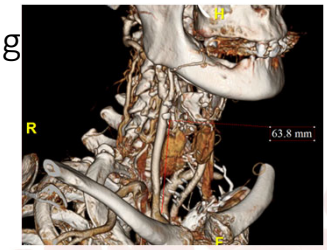
Pre TCAR planning

- ≥5cm working length (clavicle to bifurcation)
- Standard stent considerations



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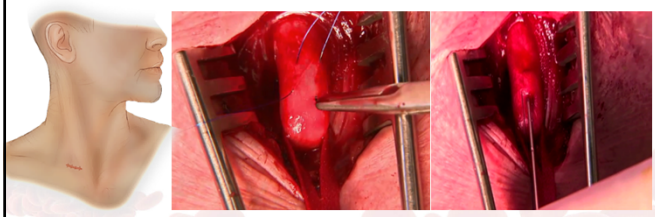
TCAR Technique: CCA Access



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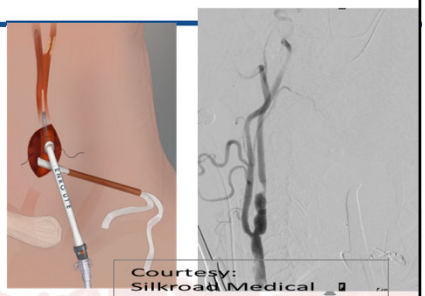
TCAR Technique: Engage the ECA



Courtesy: Silkroad Medical

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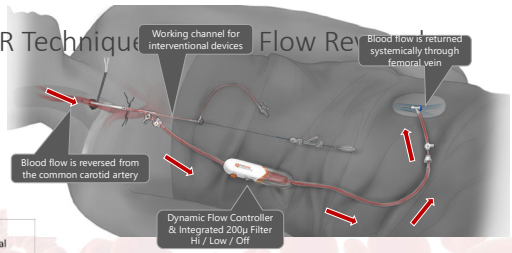
TCAR Technique: Flow Reversal



Courtesy: Silkroad Medical

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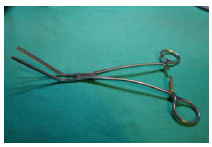
TCAR Technique: CCA Occlusion (Clamp) Active Flow Reversal



- **Confirm Flow reversal by injecting heparinized saline in the venous line**

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TCAR Technique: Considerations

Blood Pressure

- **140-160mmHg Systolic**
  hypotension must be avoided
- delta between arterial and venous blood pressure

Systemic Heparin

ACT>250

Treat bradycardia

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TCAR Technique: Flow controller and Flow Line Prep

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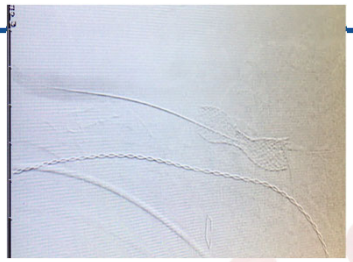

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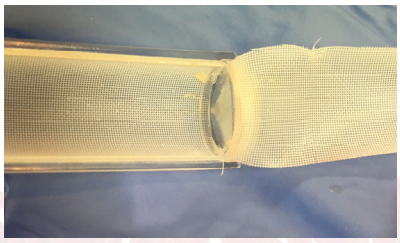
TCAR Technique: Filter retrieval



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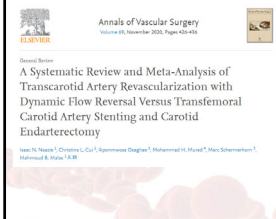
TCAR: How does it compare?



- 9 non-randomized studies, total 4021 TCAR patients
- 2 studies compared TCAR to TF-CAS

	TCAR	TF-CAS	OR (95%CI)
30-d stroke	1.33%	2.55%	.52 (.36-.74)
30-d death	.76%	1.46%	.52 (.32-.84)

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When is CEA Preferable?

1. Symptomatic or asymptomatic
2. Age>65
3. Absence of anatomic high risk criteria

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When might CAS be Appropriate?

1. Asymptomatic
2. Younger than 65
3. Hostile Neck: Radiation with skin changes
   Prior CEA with recurrent stenosis
   Prior neck surgery
   Tracheostomy or stoma
4. Contralateral recurrent laryngeal nerve injury (VC paralysis)
5. High bifurcation (C2)

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Conclusions

1. We need to be aggressive with primary stroke prevention
2. Keep up the GREAT work with OMT
3. If asymptomatic carotid stenosis >70%, CREST2 trial consideration
   a) Can be considered for CEA, TCAR, TF-CAS
4. CEA is primary treatment for asymptomatic and symptomatic carotid artery disease
5. TCAR is preferred over TF-CAS and CEA in anatomically high risk patients
6. In symptomatic patients with high risk features, CAS can be considered
   a) But patients >80yo should get CEA over CAS

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Questions

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Asymptomatic Carotid Artery Disease: Endovascular Revascularization

Herbert D. Aronow, MD, MPH, FSVM, FSCAI, FACC
Past President, Society for Vascular Medicine
Professor, College of Human Medicine, Michigan State University
Medical Director, Heart & Vascular Services
Henry Ford Health, Detroit, MI

1

Disclosures

- Consultant – Philips (ILLUMENATE Trials DSMB)
- Consultant – Silk Road Medical (NITE trial CEC)

2

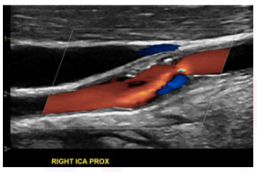
Vascular Medicine Clinic Referral

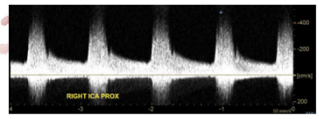
- 62M tobacco use d/o, HTN, HLD, DM
- Referred for evaluation of a carotid bruit
- No amaurosis fugax, TIA, stroke in past 6 months
- On aspirin, statin, ACEI, SGLT2 inhibitor
- HR 70, BP 155/85, RICA bruit
- Hgb 14, eGFR 49,
- Counseled about smoking cessation
- Referred for CDUS

3

Carotid Duplex Ultrasound

- Proximal RICA PSV 498 cm/s
- Proximal RICA EDV 164 cm/s
- Proximal RCCA PSV 70 cm/s
- ICA/CCA PSV 7.15
- ICA Stenosis 70-99%





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Return Office Visit

- CDUS results consistent with severe RICA stenosis
- Yearly stroke risk estimated at ~2% on medical therapy alone
- Counseled on R/B/A CAS vs. CEA vs. TCAR and opted for CAS
- Prescribed clopidogrel and statin dose optimized

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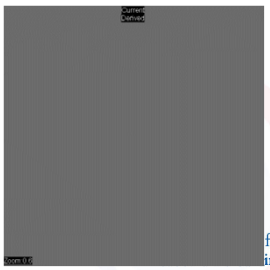
Ultrasound-Guided Micropuncture Access RCFA



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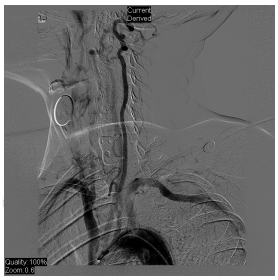
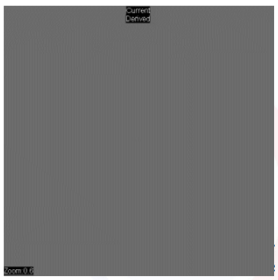
Arch Aortogram





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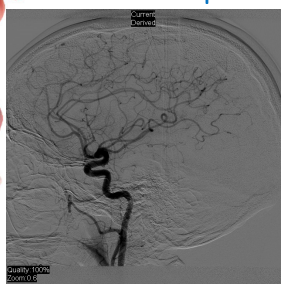
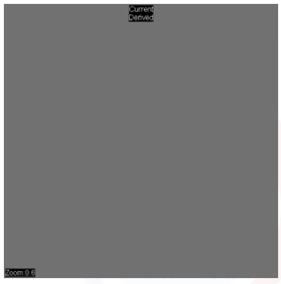
L Hemisphere - Lateral Intracranial





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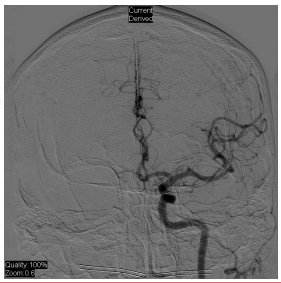
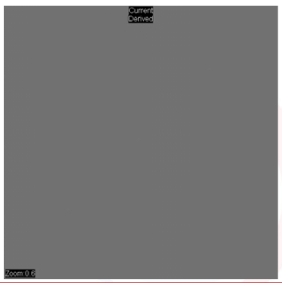
L Hemisphere - AP Intracranial





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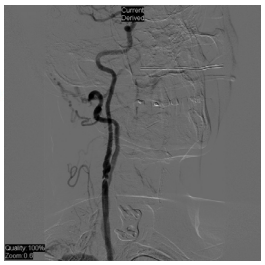
Selective RCCA



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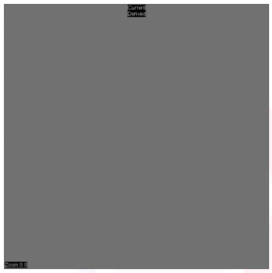
R Hemisphere - AP Intracranial



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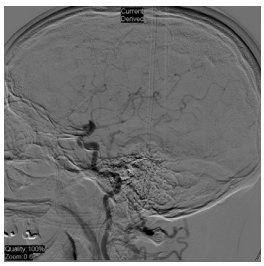
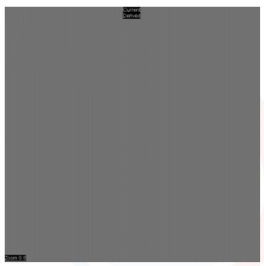
R Hemisphere - Lateral Intracranial





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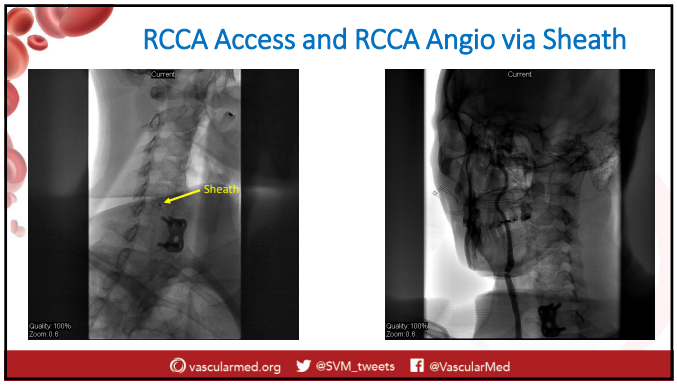
RCCA Access and RCCA Angio via Sheath
Sheath
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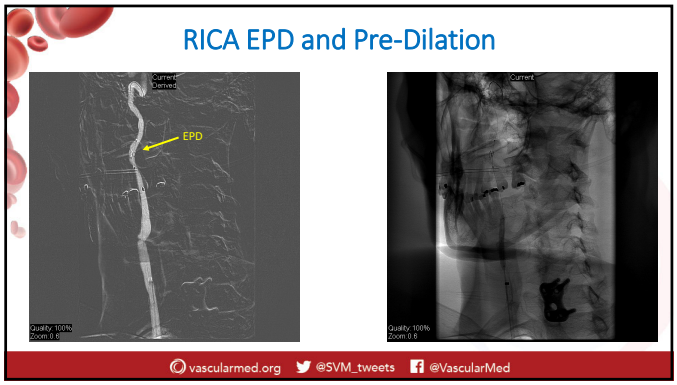
RICA EPD and Pre-Dilation
EPD
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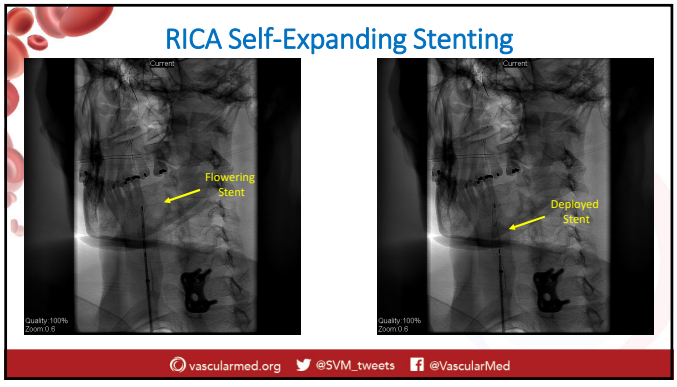
RICA Self-Expanding Stenting
Flowering Stent
Deployed Stent
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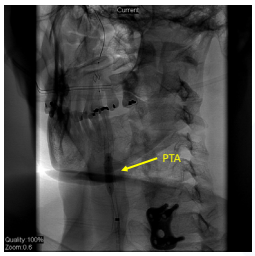
Stent Post-Dilation



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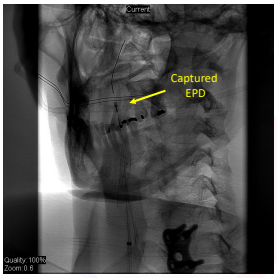
Unsubtracted Angio & EPD Removal



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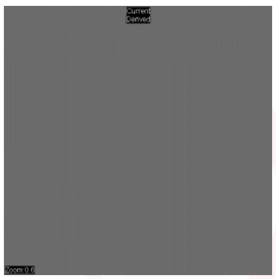
Selective RCCA



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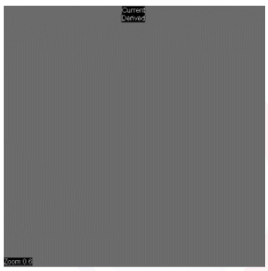
Selective RCCA



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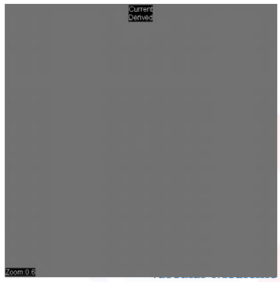
R Hemisphere – Lateral Intracranial



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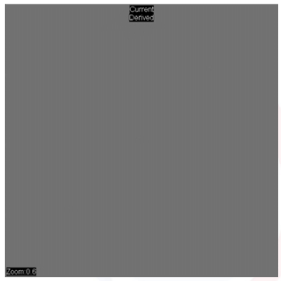
R Hemisphere - AP Intracranial



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Hospital Course

- Admitted overnight to CICU
- No bradycardia
- BP meds held for relative hypotension
- Prescribed DAPT x 1 month
- Follow up CDUS scheduled for coming week and at 30 days
- Counseled on importance of short-term BP control and provided with parameters for upper/lower BP limits for which to call office

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30-Day Follow Up

- No interval neurological events
- HR 65, BP 132/70
- RICA bruit
- Follow up CDUS results reviewed
- Risk factor management reviewed
- Scheduled for 6 month follow up

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4- Week Return Office Visit

- No interval neurological events
- HR 65, BP 132/70
- RICA bruit
- Follow up CDUS results reviewed
- Risk factor management reviewed
- Scheduled for 6 month follow up

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Questions

- Legacy evidence base for treatment of asymptomatic carotid stenosis?
- Contemporary understanding of stroke risk?
- Definition of OMT?
- Evolution of carotid revascularization?
- How do we reconcile and reboot?

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What Do We Know About Management of Asymptomatic Carotid Stenosis?

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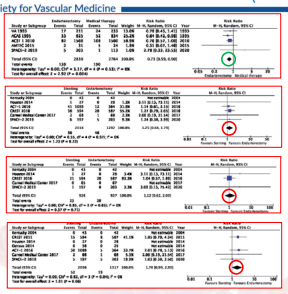
Meta-analysis of RCTs in *Asymptomatic* Disease

CEA vs. BMT (n=5,594) and CAS vs. CEA (n=3,310)



CEA vs. BMT: long-term risk of ipsilateral stroke, including peri-procedural stroke in any territory, or peri-procedural death

CAS vs. CEA: long-term risk of ipsilateral stroke, including peri-procedural stroke in any territory, or peri-procedural death

CAS vs. CEA: long-term risk of post-procedural ipsilateral stroke

CAS vs. CEA: risk of peri-procedural stroke

European Stroke Organisation guideline on endarterectomy and stenting for carotid artery stenosis. Eur Stroke J 2021;6:I–XLVII

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2011 US Multispecialty Guideline Indications for Carotid Revascularization

ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS

	Symptomatic Patients		Asymptomatic Patients:
	50% to 69% Stenosis	70% to 99% Stenosis*	70% to 99% Stenosis*
Endarterectomy	Class I LOE: B	Class I LOE: A	Class IIa LOE: A
Stenting	Class I LOE: B	Class I LOE: B	Class IIb LOE: B

Brott TG et al. J Am Coll Cardiol 2011;57:e16-94.

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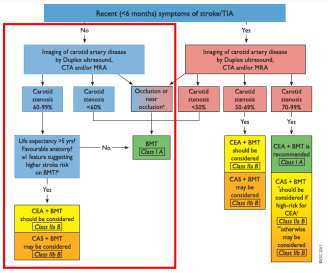
2017 ESC Guidelines: PAD Diagnosis/Treatment/Carotid Revascularization



European Heart Journal (2018) 39, 763–821

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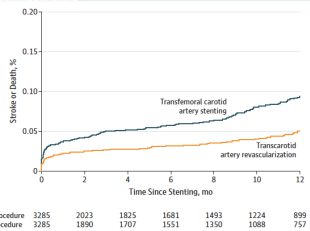
SVS VQI TCAR Surveillance Project and TF CAS Registry 2016-2019 (n=6,572)



Limitations

- Operator-reported outcomes
- Despite propensity-matching TF CAS population appeared sicker
  - Different discharge disposition (13% vs. 7% failed d/c home)
  - KM curves continue to separate over time despite stenting in both arms
- CAS stroke rates were > 3x higher than observed for skilled operators in RCTs

Schermerhorn ML, et al. JAMA 2019;322(23):2313-2322

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SVS VQI TCAR Surveillance Project and TF CAS Registry 2016-2019 (n=6,572)

Results by Symptom Status

Outcome[a]	Symptomatic Patients (n = 3658)					Asymptomatic Patients (n = 2876)				
	Transcarotid Artery Revascularization[b] (n = 1829)	Transfemoral Carotid Artery Stenting[b] (n = 1829)	Absolute Difference (95% CI), %	Relative Risk (95% CI)	*P* Value	Transcarotid Artery Revascularization[b] (n = 1438)	Transfemoral Carotid Artery Stenting[b] (n = 1438)	Absolute Difference (95% CI), %	Relative Risk (95% CI)	*P* Value
Stroke or death	39 (2.1)	76 (4.2)	−2.02 (−3.21 to −0.83)	0.51 (0.35 to 0.75)	<.001	15 (1.0)	21 (1.5)	−0.42 (−1.30 to 0.47)	0.71 (0.37 to 1.39)	.32
Stroke or death, 30 d	47 (2.6)	88 (4.8)	−2.22 (−3.53 to −0.96)	0.53 (0.38 to 0.76)	<.001	18 (1.3)	26 (1.8)	−0.56 (−1.53 to 0.42)	0.69 (0.38 to 1.26)	.23
Stroke	36 (2.0)	56 (3.1)	−1.10 (−2.17 to −0.02)	0.64 (0.42 to 0.97)	.04	10 (0.7)	18 (1.3)	−0.56 (−1.35 to 0.23)	0.56 (0.26 to 1.20)	.13
Stroke, 30 d	36 (2.0)	58 (3.2)	−1.20 (−2.29 to −0.12)	0.62 (0.41 to 0.94)	.02	11 (0.8)	20 (1.4)	−0.63 (−1.45 to 0.20)	0.55 (0.26 to 1.15)	.11
Transient ischemic attack	14 (0.8)	25 (1.4)	−0.60 (−1.33 to 0.12)	0.56 (0.29 to 1.08)	.08	6 (0.4)	6 (0.4)	0.00 (−0.54 to 0.54)	1.00 (0.32 to 3.10)	>.99
Death	9 (0.5)	28 (1.5)	−1.04 (−1.74 to −0.33)	0.32 (0.15 to 0.68)	.002	6 (0.4)	3 (0.2)	0.21 (−0.27 to 0.69)	2.00 (0.50 to 8.00)	.32
Death, 30 d	17 (0.9)	39 (2.1)	−1.20 (−2.06 to −0.35)	0.44 (0.25 to 0.77)	.003	8 (0.6)	6 (0.4)	0.14 (−0.44 to 0.72)	1.33 (0.46 to 3.84)	.59
Myocardial infarction	1 (0.1)	6 (0.3)	−0.27 (−0.61 to 0.06)	0.17 (0.02 to 1.38)	.06	4 (0.3)	5 (0.3)	−0.07 (−0.55 to 0.41)	0.80 (0.21 to 2.98)	.74

Schermerhorn ML, et al. JAMA 2019;322(23):2313-2322

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SVS VQI 2016-2019 TCAR vs CEA (n=12,768) Propensity Adjusted In-hospital and One-Year Outcomes

Results by Symptom Status

	Symptomatic (N = 3333)				Asymptomatic (N = 9435)			
	CEA (N = 1675)	TCAR (N = 1658)	TCAR Versus CEA[a]		CEA (N = 4709)	TCAR (N = 4726)	TCAR Versus CEA	
In-hospital Outcomes	N (%)	N (%)	Relative Risk (95% CI)	*P*-value	N (%)	N (%)	Relative Risk (95% CI)	*P*-value
Stroke/death	43 (2.6)	36 (2.2)	0.85 (0.55–1.31)	0.458	60 (1.3)	68 (1.4)	1.13 (0.80–1.59)	0.490
Death	8 (0.48)	9 (0.54)	1.14 (0.44–2.94)	0.792	14 (0.3)	16 (0.3)	1.14 (0.56–2.33)	0.722
Ipsilateral Stroke	33 (2.0)	31 (1.9)	0.95 (0.58–1.54)	0.835	33 (0.7)	49 (1.0)	1.48 (0.95–2.30)	0.080
Stroke	37 (2.2)	34 (2.1)	0.93 (0.59–1.47)	0.754	52 (1.1)	57 (1.2)	1.09 (0.75–1.59)	0.641
Myocardial infarction	17 (1.0)	8 (0.5)	0.47 (0.20–1.10)	0.075	41 (0.9)	23 (0.5)	0.56 (0.34–0.93)	0.025
Stroke/death/Myocardial infarction	57 (3.4)	43 (2.6)	0.76 (0.51–1.12)	0.172	96 (2.0)	87 (1.8)	0.90 (0.68–1.20)	0.486
Cranial nerve injury	52 (3.1)	5 (0.3)	0.12 (0.05–0.29)	<0.001	121 (2.6)	13 (0.3)	0.14 (0.08–0.25)	<0.001
Post-procedural Hypotension	203 (12.1)	250 (15.2)	1.25 (1.05–1.49)	0.010	482 (10.2)	809 (17.2)	1.67 (1.51–1.86)	<0.001
Post-procedural Hypertension	366 (21.9)	255 (15.5)	0.71 (0.61–0.82)	<0.001	886 (18.8)	613 (13.0)	0.69 (0.63–0.76)	<0.001
Bleeding with intervention	35 (2.1)	21 (1.3)	0.61 (0.35–1.04)	0.068	70 (1.5)	63 (1.3)	0.90 (0.64–1.26)	0.527
LOS more than 1 day	756 (45.1)	655 (39.5)	0.87 (0.81–0.95)	0.001	1418 (30.1)	1250 (26.4)	0.88 (0.82–0.94)	<0.001
Non-Home Discharge	237 (14.2)	249 (15.1)	1.06 (0.90–1.25)	0.464	213 (4.5)	195 (4.1)	0.91 (0.75–1.10)	0.343

1-year freedom from ipsi stroke or death - no different between CEA and TCAR

Malas MB, et al. Ann Surg 2022;276:398-403

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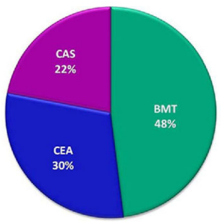
Shared Decision Making in Management of Asymptomatic Carotid Stenosis: Patient Preference Survey (n=102)



Charing Cross Patient Survey

Jayasooria GS, et al. J Vasc Surg 2011;53:1466-1472

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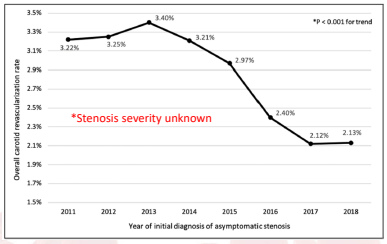
Revascularization Rate for Newly Diagnosed Asymptomatic Carotid Stenosis: Medicare FFS (n = 795,512)



Sorber R. Ann Vasc Surg 2021;71:132-44

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Is What We Knew Before Still True Today (e.g., stroke risk, OMT, revascularization) ?

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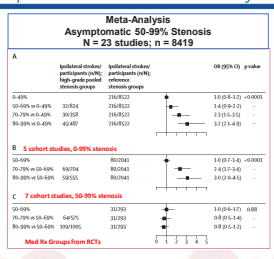
Stroke Risk on Medical Therapy Alone

Population Based Estimates for Asymptomatic Disease



Howard DPJ, et al. Lancet Neurol 2021;20:193–202

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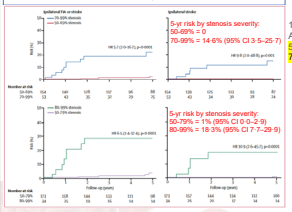
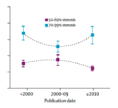
Stroke Risk on Medical Therapy Alone

Population Based Estimates for Asymptomatic Disease

Prospective Oxford Vascular Study (OxVasc)
Asymptomatic 50-99% Stenosis
N = 207



15 cohort studies (n=8,419)
Annual ipsilateral stroke risk
50-69% = 1·23% [1·1–1·37]
70-99% = 2·81% [2·54–3·08]



Retrospective Kaiser Permanente Northern CA
Asymptomatic 70-99% Stenosis
N = 3737

Outcomes	Cohort, % (95% CI) (N=4230)
Unadjusted overall crude rates, No. (%)	
Ipsilateral carotid-related stroke	133 (3.1)
All-cause mortality	2353 (55.6)
Mean yearly crude rates	
Ipsilateral carotid-related stroke	0.9 (0.7-1.2)
All-cause mortality	13.6 (12.6-14.7)
Kaplan-Meier unadjusted cumulative probabilities at 5 y	
Risk of ipsilateral carotid-related stroke	4.7 (3.9-5.7)
All-cause mortality	45.2 (43.4-46.9)
Unadjusted cumulative incidence of ipsilateral stroke (competing risk analysis), y	
1	1.0 (0.8-1.4)
2	1.6 (1.3-2.0)
3	2.1 (1.7-2.5)
4	2.5 (2.0-3.0)
5	2.7 (2.2-3.2)
6	2.8 (2.3-3.4)
7	2.9 (2.5-3.5)
8	3.2 (2.7-3.8)

Howard DPJ, et al. Lancet Neurol 2021;20:193–202

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Optimal Medical Therapy Has Evolved…

- More potent antiplatelet agents
- Statins
- RAAS inhibors
- PCSK9i, GLP-1, SGLT2i?

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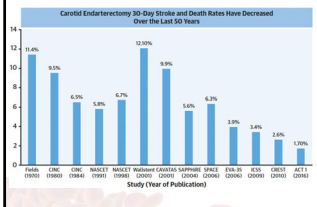
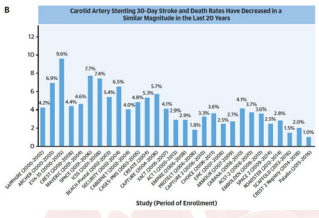
Revascularization Outcomes Are Better:
Perioperative Stroke and Death Rates for CAS and CEA





White CJ, et al. J Am Coll Cardiol 2022;80:155–170

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How Do We Account for Changing Risks and Over Time?

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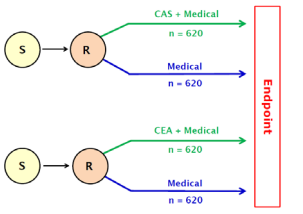
CREST-2

Patients with ≥70% asymptomatic stenosis:

CREST-2



Endpoint = all stroke & death in first 30 days and ipsilateral stroke thereafter up to 4 years.

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Conclusions

- Uncertainty around risk of asymptomatic carotid stenosis.
- Newer medical regimens may reduce risk further.
- Risk of carotid revascularization has decreased over time.
- CREST-2 may provide new direction for clinicians.
- In the interim, both CAS and CEA (TCAR too?) remain reasonable options for management of asymptomatic carotid stenosis.

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Is All Hypertension Essential?

Aaron W. Aday, MD, MSc, RPVI, FSVM
Assistant Professor of Medicine
Vanderbilt University Medical Center

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How to Measure Blood Pressure

www.heart.org

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Blood Press Categories

TABLE 6 Categories of BP in Adults*

BP Category	SBP		DBP
Normal	<120 mm Hg	and	<80 mm Hg
Elevated	120–129 mm Hg	and	<80 mm Hg
Hypertension			
Stage 1	130–139 mm Hg	or	80–89 mm Hg
Stage 2	≥140 mm Hg	or	≥90 mm Hg

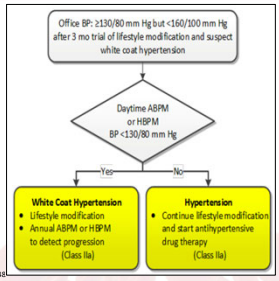
*Individuals with SBP and DBP in 2 categories should be designated to the higher BP category.

BP indicates blood pressure (based on an average of ≥2 careful readings obtained on ≥2 occasions, as detailed in Section 4); DBP, diastolic blood pressure; and SBP, systolic blood pressure.

Whelton PK et al. *J Am Coll Cardiol* 2018;71(19):e127-248

3

White Coat Hypertension



Whelton PK et al. *J Am Coll Cardiol* 2018;71(19):e127-248

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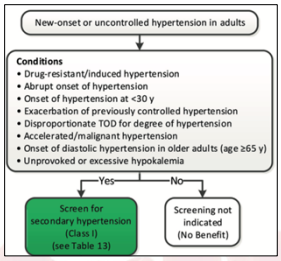
Secondary Hypertension



Whelton PK et al. *J Am Coll Cardiol* 2018;71(19):e127-248

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Resistant Hypertension Prevalence

Table 1. Prevalence of aTRH in Adults With Treated Hypertension as Reported From Selected Population-, Clinic-, and Intervention-Based Studies

Population Based	Time Period	n	Uncontrolled With ≥3 BP Medications, %	Controlled With ≥4 BP Medications, %	aTRH, %
NHANES[3]	1988–1994	2755	8.3	1.1	9.4
NHANES[3]	1999–2004	3031	8.8	2.9	11.7
NHANES[4]	2003–2008	3710	…	…	12.8
NHANES[5]	2005–2008	2586	9.7	4.8	14.5
REGARDS[6]	2003–2007	14731	9.1	5.0	14.1
REGARDS[6] (CKD)*	2003–2007	3134	…	…	28.1
Clinic based					
EURIKA[7] (diabetes mellitus)	2009–2010	5220	13.0†	3.1	16.1
Spanish ABPM[8]	2004–2009	68 045	12.2	2.6	14.8
CRIC (CKD)[9]‡	2003–2008	3939	21.2	19.2	40.4
South Carolina[10]§	2007–2010	468 877	9.5	8.4	17.9
Clinical trials					
ALLHAT[11]	1994–2003‖	14 684	11.5	1.2	12.7
ASCOT[12]	1998–2005	19 527	48.5	…	…
ACCOMPLISH[13]	2003–2006¶	10 704	39	…	…
INVEST[14]	1997–2003#	17 190	25.1	12.6	37.8

Uncontrolled aTRH is defined as BP ≥140 mm Hg systolic and/or ≥90 mm Hg diastolic on ≥3 BP medications. Controlled aTRH is defined as BP <140 mm Hg systolic and <90 mm Hg diastolic on ≥4 BP medications unless otherwise specified.

Carey RM et al. *Hypertension* 2018;72:e53-e90

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Causes of Resistant Hypertension

- Inadequate adherence
- Incorrect blood pressure measurement technique
- White-coat hypertension
- Undertreatment
- Obesity
- Dietary sodium
- Obstructive sleep apnea
- Medications

Carey RM et al. *Hypertension* 2018;72:e53-e90

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Medications Causing Resistant Hypertension

NSAIDs
Oral contraceptives
Sympathomimetic
Cyclosporine, tacrolimus
Erythropoietin
VEGF inhibitors
Alcohol
Cocaine
Amphetamines
Antidepressants
Glucocorticoids, mineralocorticoids

Carey RM et al. *Hypertension* 2018;72:e53-e90

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Secondary Hypertension

Common causes
Renal parenchymal disease
Renovascular disease
Primary aldosteronism
Obstructive sleep apnea
Drug or alcohol induced
Uncommon causes
Pheochromocytoma/paraganglioma
Cushing's syndrome
Hypothyroidism
Hyperthyroidism
Aortic coarctation (undiagnosed or repaired)
Primary hyperparathyroidism
Congenital adrenal hyperplasia
Mineralocorticoid excess syndromes other than primary aldosteronism
Acromegaly

Whelton PK et al. *J Am Coll Cardiol* 2018;71(19):e127-248

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Secondary Hypertension Workup

Condition	Who	How	Special considerations
Primary aldosteronism	• All with resistant HTN • Hypokalemia • Adrenal mass	• Morning plasma aldosterone/renin ratio, pt seated for >30 minutes	• Correct hypokalemia • Stop spiro, eplerenone, or amiloride 1 month prior • Other med interactions
CKD	• All with resistant HTN	• BMP + urinalysis	
Renal artery stenosis	• Early onset HTN • Bruits	• Renal artery duplex • CTA/MRA	• Suspect if AKI to modest ACEi/ARB doses
Pheochromocytoma	• All with resistant HTN • Episodic HTN with diaphoresis, headache, palpitations	• Plasma catecholamine measurement	• Obesity, OSA, and TCAs can modestly increase catecholamine (<4X ULN)
Cushing syndrome	• Mood disorders, muscle weakness • Signs: weight gain, striae, hirsutism, fat pad, hyperglycemia	• Dexamethasone suppression test	• Rare
Coarctation	• Prior coarct repair, discrepant BPs	• CTA/MRA	

Carey RM et al. *Hypertension* 2018;72:e53-e90

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Case

- 50yo man with hypertension
  - Began in his mid 40s
  - Initially treated with HCTZ, but stopped due to hypokalemia (2.5 mEq/L)
  - Now on lisinopril, amlodipine
  - Systolic BP 140-150 on home monitor
- Exam
  - BMI 31 kg/m^2
  - Soft systolic murmur at the base
  - Normal vascular exam with no bruits

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Case (cont)

- Workup
  - No OSA on sleep study
  - TTE with mild left ventricular hypertrophy
  - Creatinine 1.2 mg/dL
  - Potassium 3.9 mEq/L

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Case (cont)

- Additional Workup
  - Serum metanephrines normal
  - Renal artery duplex normal
  - Aldosterone:renin ratio 30, aldosterone 18 ng/dL

13

Case (cont)

- Next step
  - Confirmatory test
    - IV saline infusion with plasma aldosterone drawn 4h later
    - Oral sedum loading test with 24h urinary aldosterone measurement
  - Adrenal imaging
  - Specialist referral

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Primary Aldosteronism

COR	LOE	Recommendations for Primary Aldosteronism
I	C-EO	In adults with hypertension, screening for primary aldosteronism is recommended in the presence of any of the following concurrent conditions: resistant hypertension, hypokalemia (spontaneous or substantial, if diuretic induced), incidentally discovered adrenal mass, family history of early-onset hypertension, or stroke at a young age (<40 years).
I	C-LD	Use of the plasma aldosterone: renin activity ratio is recommended when adults are screened for primary aldosteronism.

Whelton PK et al. *J Am Coll Cardiol* 2018;71(19):e127-248

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Questions?

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Renal artery stenosis: is intervention still a thing?

Vivian Bishay, MD
Associate Professor, Vascular and Interventional Radiology
Mount Sinai Hospital

1

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Why is there all this controversy surrounding renal artery stenting?

- No good data
- No clear indications
- No clear techniques
- No clear predictors of outcomes


Increase in Utilization of Percutaneous Renal Artery Interventions by Medicare Beneficiaries, 1996-2000


The Renal Stenting Downturn

2

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Three modern randomized trials for Renal Artery Revascularization

1. STAR
2. ASTRAL
3. CORAL

3

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STAR

ARTICLE | Annals of Internal Medicine

Stent Placement in Patients With Atherosclerotic Renal Artery Stenosis and Impaired Renal Function

A Randomized Trial

Liesbeth Bax, MD, PhD; Arend-Jan J. Woittiez, MD, PhD; Hans J. Kouwenberg, MD; Willem P.T.M. Mali, MD, PhD; Erik Buskens, MD, PhD; Frederik J.A. Beek, MD, PhD; Branko Braam, MD, PhD; Frans T.M. Huysmans, MD, PhD; Leo J. Schultze Kool, MD, PhD; Matthijs J.C.M. Rutten, MD; Cornelius J. Doorenbos, MD, PhD; Johannes C.N.M. Aarts, MD; Ton J. Rabelink, MD, PhD; Pierre-François Plouin, MD; Alain Raynaud, MD; Gert A. van Montfrans, MD, PhD; Jim A. Reekers, MD, PhD; Anton H. van den Meiracker, MD, PhD; Peter M.T. Pattynama, MD, PhD; Peter J.G. van de Ven, MD, PhD; Dammis Vroegindeweij, MD, PhD; Abraham A. Kroon, MD, PhD; Michiel W. de Haan, MD, PhD; Cornelis T. Postma, MD, PhD; and Jaap J. Beutler, MD, PhD*

- Randomized
- 10 centers
- 140 patients, CrCl < 80, ARAS 50% or greater
- Stent vs. Medical Rx
- Medical Rx: HTN meds, Statin, ASA
- Primary endpoint: 20% or more decrease in CrCl
- Secondary endpoints: safety, CV morbidity and mortality

4

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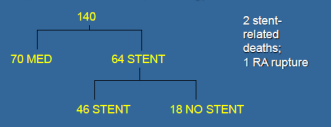
Randomized Trials of Stent vs. Meds

STAR

- n=140 Patients, Cr_{Cl} <80; RAS > 50%
- Primary endpoint: ≥ 20 % ↓ in Cr_{Cl}



2 stent-related deaths; 1 RA rupture

Bax L, et al. Ann Intern Med 2009;150:840-8.

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STAR

- Primary endpoint in 22% medical, 16% stent
- p=.06, 27% treatment effect
- "A considerable number of stent-related complications occurred, including 2 procedure-related deaths…suggesting that renal stenting for ARAS may cause more harm than benefit in a community setting."

Bax L, et al. Ann Intern Med 2009;150:840-8.

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Revascularization versus Medical Therapy for Renal-Artery Stenosis

The ASTRAL Investigators*

ABSTRACT

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ASTRAL

Diagnosis of significant ARVD
(Unilateral or Bilateral)
Revascularization not contraindicated

↓

Uncertain whether to revascularize
Randomisation

↓

Revascularization
with angioplasty and/or stent
(and medical treatment)

No revascularization
Medical Treatment only

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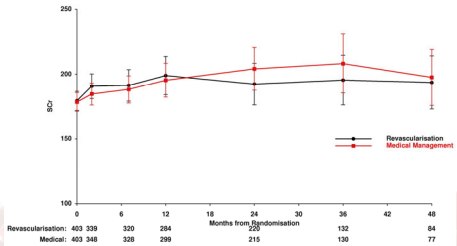
ASTRAL



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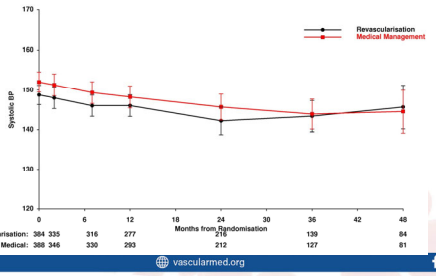
ASTRAL



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CORAL

ORIGINAL ARTICLE

Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis

Christopher J. Cooper, M.D., Timothy P. Murphy, M.D., Donald E. Cutlip, M.D., Kenneth Jamerson, M.D., William Henrich, M.D., Diane M. Reid, M.D., David J. Cohen, M.D., Alan H. Matsumoto, M.D., Michael Steffes, M.D., Michael R. Jaff, D.O., Martin R. Prince, M.D., Ph.D., Eldrin F. Lewis, M.D., Katherine R. Tuttle, M.D., Joseph I. Shapiro, M.D., M.P.H., John H. Rundback, M.D., Joseph M. Massaro, Ph.D., Ralph B. D'Agostino, Sr., Ph.D., and Lance D. Dworkin, M.D., for the CORAL Investigators*

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CORAL

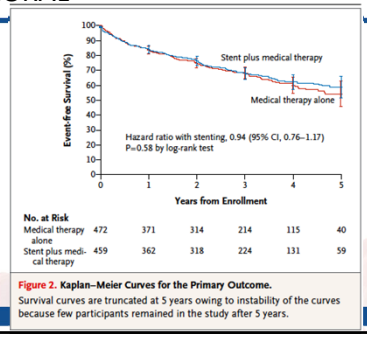

Figure 2. Kaplan–Meier Curves for the Primary Outcome.
Survival curves are truncated at 5 years owing to instability of the curves because few participants remained in the study after 5 years.

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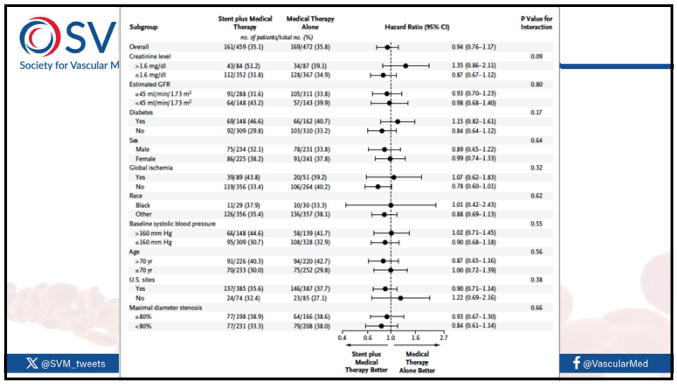

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SVM Current Data Supporting PTA and Stenting

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- Only anecdotal or descriptive evidence supports it, but the RCT's say:
- "…renal stenting for ARAS may cause more harm than benefit in a community setting."1
- "…substantial risks but no evidence of a worthwhile clinical benefit"2

1. Bax L, et al. Ann Intern Med 2009;150:840-8.
2. N Engl J Med 2009;361:1953-62.

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How can we select patients who are
MOST LIKELY
to benefit from RAS?

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What predictors can be used?

- Biomarkers
- Hemodynamic
- Imaging
- Technique

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What predictors can be used?

- Biomarkers
- Hemodynamic
- Imaging
- Technique

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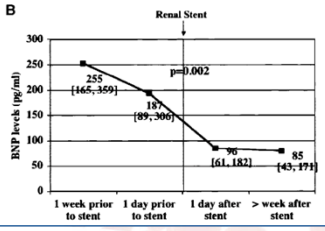
Elevated Brain Natriuretic Peptide Predicts Blood Pressure Response After Stent Revascularization in Patients With Renal Artery Stenosis

Jose A. Silva, MD; Albert W. Chan, MD; Christopher J. White, MD; Tyrone J. Collins, MD; J. Stephen Jenkins, MD; John P. Reilly, MD; Stephen R. Ramee, MD



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Use of B-Type Natriuretic Peptide to Predict Blood Pressure Improvement after Percutaneous Revascularisation for Renal Artery Stenosis

D. Staub [a,1], T. Zeller [b,1], D. Trenk [b], C. Maushart [c], H. Uthoff [a], T. Breidthardt [c], T. Klima [c], M. Aschwanden [a], T. Socrates [c], N. Arenja [c], R. Twerenbold [c], A. Rastan [b], S. Sixt [b], A.L. Jacob [d], K.A. Jaeger [a], C. Mueller [c,*]

[a] Department of Angiology, University Hospital Basel, Basel, Switzerland
[b] Herz-Zentrum Bad Krozingen, Bad Krozingen, Germany
[c] Department of Internal Medicine, University Hospital Basel, Basel, Switzerland
[d] Division of Interventional Radiology, University Hospital Basel, Petersgraben 4, CH-4031 Basel, Switzerland

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Table 3 Diagnostic performance of BNP levels for the prediction of blood pressure improvement during follow up.

	Sensitivity	Specificity	NPP	PPV
Overall cohort (n = 120)				
BNP >50 pg/ml pre-intervention	79%	44%	63%	62%
BNP decrease >20 pg/ml	59%	61%	54%	65%
Patients with ≥70% atherosclerotic RAS (n = 91)				
BNP >50 pg/ml pre-intervention	83%	42%	69%	62%
BNP decrease >20 pg/ml	58%	66%	55%	64%
Patients with refractory hypertension (n = 30)				
BNP >50 pg/ml pre-intervention	100%	50%	100%	70%
BNP decrease >20 pg/ml	56%	54%	50%	60%

NPP indicates negative predictive value; PPV, positive predictive value; BNP, B-type natriuretic peptide; RAS, renal artery stenosis.

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Herculink Elite Cobalt Chromium Renal Stent Trial to Demonstrate Efficacy and Safety (HERCULES)

OBJECTIVE
Evaluate the safety and effectiveness of RX Herculink Elite Renal Stent System in the treatment of suboptimal post-procedural PTA of atherosclerotic de *novo* or restenotic RAS in patients with uncontrolled hypertension

202 patients at 37 US sites treated from August 2007 to October 2009

PRIMARY ENDPOINT: 9M Restenosis Rate (Performance Goal 28.6%)

Clinical, lab and DUS follow-up at 1, 6, 9,12 mos, 2Y and 3Y

BNP measurement at baseline, 24 hrs and 1 month

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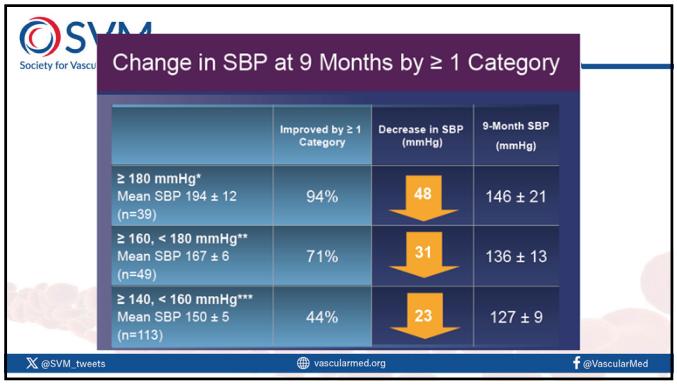
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Change in SBP at 9 Months by ≥ 1 Category
Improved by ≥ 1 Category
Decrease in SBP (mmHg)
9-Month SBP (mmHg)
≥ 180 mmHg*
Mean SBP 194 ± 12
(n=39)
94%
48
146 ± 21
≥ 160, < 180 mmHg**
Mean SBP 167 ± 6
(n=49)
71%
31
136 ± 13
≥ 140, < 160 mmHg***
Mean SBP 150 ± 5
(n=113)
44%
23
127 ± 9
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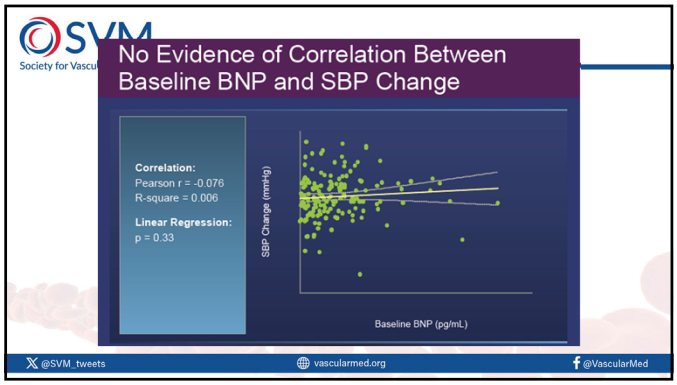
Society for Vascu
No Evidence of Correlation Between Baseline BNP and SBP Change
Correlation:
Pearson r = -0.076
R-square = 0.006
Linear Regression:
p = 0.33
SBP Change (mmHg)
Baseline BNP (pg/mL)
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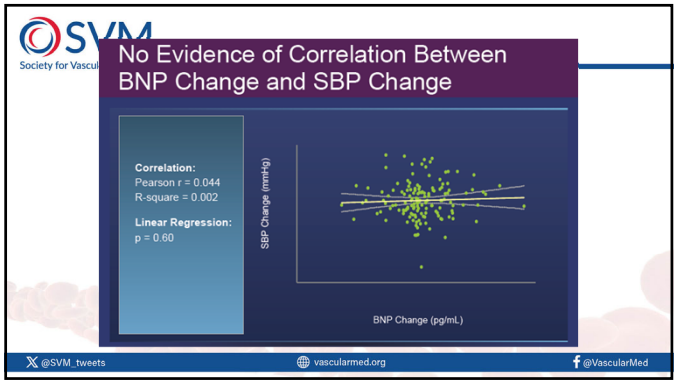
23


Society for Vascu
No Evidence of Correlation Between BNP Change and SBP Change
Correlation:
Pearson r = 0.044
R-square = 0.002
Linear Regression:
p = 0.60
SBP Change (mmHg)
BNP Change (pg/mL)
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24

What predictors can be used?

- Biomarkers
- Hemodynamic
- Imaging
- Technique

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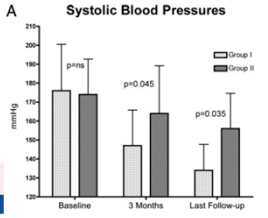
Predicting Blood Pressure Improvement in Hypertensive Patients After Renal Artery Stent Placement: Renal Fractional Flow Reserve

Jason A. Mitchell,[1] MD, Rajesh Subramanian,[2] MD, Christopher J. White,[3*] MD, Peter A. Soukas,[4] MD, Yaron Almagor,[5] MD, Richard E. Stewart,[6] MD, and Kenneth Rosenfield,[7] MD

Group 1: FFR<0.8

Group 2: FFR>0.8



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What predictors can be used?

- Biomarkers
- Hemodynamic
- Imaging
- Technique

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27

Prediction of Hypertension Improvement After Stenting of Renal Artery Stenosis

Comparative Accuracy of Translesional Pressure Gradients, Intravascular Ultrasound, and Angiography

Massoud A. Leesar, MD,* Jai Varma, MD,* Adam Shapira, MD,* Ibrahim Fahsah, MD,*
Seyed T. Raza, MD,† Ziad Elghoul, MD,* Anthony C. Leonard, PhD,‡
Karthikeyan Meganathan, MS,‡ Sohail Ikram, MD*
Louisville, Kentucky; and Cincinnati, Ohio

Parameters	AUC	95% Confidence Interval	Cutpoint	Sensitivity, %	Specificity, %	Predictive Accuracy, %
Renal pressure measurements						
HSG	0.87	0.72–0.96	21 mm Hg	82	84	84
FFR	0.85	0.76–0.94	0.90	73	88	79
HMG	0.81	0.70–0.91	6.0 mm Hg	80	76	79
RSG	0.81	0.71–0.92	7.0 mm Hg	78	76	77
IVUS parameters						
MLA	0.86	0.76–0.96	7.8 mm^2	78	80	79
Area stenosis	0.82	0.71–0.92	67%	75	80	77
MLD	0.78	0.67–0.90	2.7 mm	70	76	72*
Plaque plus media area	0.73	0.60–0.85	9.0 mm^2	73	68	70*
Angiographic parameters						
Diameter stenosis	0.74	0.61–0.86	60%	68	72	69*
MLD	0.69	0.55–0.82	2.25 mm	51	80	62*†
Clinical parameters						
Systolic blood pressure	0.55	0.41–0.70	170 mm Hg	43	68	53*†
Diastolic blood pressure	0.51	0.36–0.66	95 mm Hg	41	64	50*†
Mean blood pressure	0.54	0.39–0.68	118 mm Hg	51	60	54*†

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What predictors can be used?

- Biomarkers
- Hemodynamic
- Imaging
- Technique

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Guarding Against Atheroembolism

- Meticulous “no touch” technique
- Aortography before cannulation
- Use of low profile, atraumatic catheters
- Limited catheter manipulation
- Primary stenting when feasible
- GP 2b3a Antagonists
- Distal protection devices

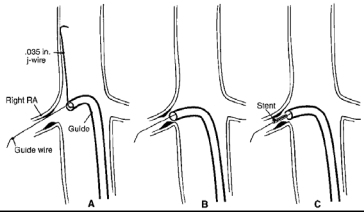
30

Pearls

No-Touch Technique for Reducing Aortic Wall Trauma During Renal Artery Stenting

Robert L. Feldman, MD, Thomas J. Wargovich, MD, and John A. Bittl,* MD

Cholesterol embolism, a serious but infrequent complication of renal artery stenting, may be avoided by minimizing contact between the guide catheter and the atherosclerotic aorta. In this report, we illustrate the "no-touch" technique for stenting renal arteries. By placing a second 0.035-inch J-wire within the guide catheter during cannulation of the renal artery to prevent the tip of the guide from rubbing the aortic wall, we minimize the contact between the guide catheter and atherosclerotic plaques and reduce the potential for intimal disruption and cholesterol embolization. *Cathet. Cardiovasc. Intervent.* 46:245–248, 1999.



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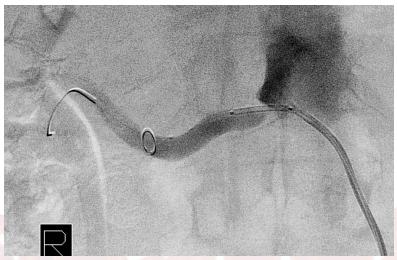
Embolic Protection



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Embolic Protection Devices

- Work best when they fit
- Early side branches = BAD!
- Distal vessel often too large
- Room for stent device?
- EPD wire enough support?
- Increased time, contrast , cost?
- How do we know if they work?

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When to Consider Renal EPD?

- Poor renal reserve and favorable anatomy
  - Single kidney
  - Poor GFR
  - Long standing DM
  - Bulky plaque, high risk lesions
  - Distal disease
- Clinical Trials

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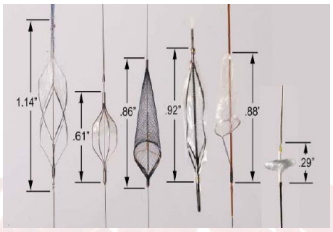
Best Options for Renal Protection

- Shorter basket and larger diameter better for renal artery



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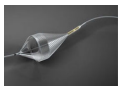
EPD Options

- NAV 6 (Abbott)
  - Short Basket, 7.2mm diameter vessels
  - Independent (SS) wire not "connected" to basket-advantage!



- Angioguard (Cordis)
  - Multiple sizes, up to 8mm diameter
  - Short basket

- Fibernet (Medtronic)
  - Shortest device, conformability
  - Multiple sizes, up to 7.0mm diameter

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PERIPHERAL VASCULAR DISEASE

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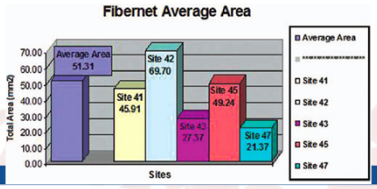
Original Studies

Feasibility of FiberNet® Embolic Protection System in Patients Undergoing Angioplasty for Atherosclerotic Renal Artery Stenosis

John R. Laird,[1*] MD, Faramarz Tehrani,[1] MD, Peter Soukas,[2] MD, James D. Joye,[3] DO, Gary M. Ansel,[4] MD, and Krishna Rocha-Singh,[5] MD



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RESIST Trial

Interventional Cardiology

Embolic Protection and Platelet Inhibition During Renal Artery Stenting

Christopher J. Cooper, MD; Steven T. Haller, MS; William Cohyer, MD; Michael Steffes, MD; Mark W. Burket, MD; William J. Thomas, MD; Robert Safian, MD; Bhagat Reddy, MD; Pamela Barewster, MA; Mary Ann Ankenbrandt, RN; Ronn Virmani, MD; Eric Dippel, MD; Krishna Rocha-Singh, MD; Timothy P. Murphy, MD; David J. Kennedy, PhD; Joseph I. Shapiro, MD; Ralph D. D'Agostino, PhD; Michael J. Poncina, PhD; Sadik Khuder, PhD

Background—Preservation of renal function is an important objective of renal artery stent procedures. Although atheroembolization can cause renal dysfunction during renal stent procedures, whether adjunctive use of embolic protection devices or glycoprotein IIb/IIIa inhibitors improves renal function is unknown.

Methods and Results—One hundred patients undergoing renal artery stenting at 7 centers were randomly assigned to an open-label embolic protection device, Angioguard, or double-blind use of a platelet glycoprotein IIb/IIIa inhibitor, abciximab, in a 2×2 factorial design. The main effects of treatments and their interaction were assessed on percentage change in Modification in Diet in Renal Disease–derived glomerular filtration rate from baseline to 1 month using centrally analyzed creatinine. Filter devices were analyzed for the presence of platelet-rich thrombus. With stenting alone, stenting and embolic protection, and stenting with abciximab alone, glomerular filtration rate declined ($P<0.05$), but with combination therapy, it did not decline and was superior to the other allocations in the 2×2 design ($P<0.01$). The main effects of treatment demonstrated no overall improvement in glomerular filtration rate; although abciximab was superior to placebo (0±37% versus −18±29%; $P<0.05$), embolic protection was not (−1±24% versus −10±29%; $P=0.06$). An interaction was observed between abciximab and embolic protection ($P<0.05$), favoring combination treatment. Abciximab reduced the occurrence of platelet-rich emboli in the filters from 42% to 7% ($P<0.01$).

Conclusions—Renal artery stenting alone, stenting with embolic protection, and stenting with abciximab were associated with a decline in glomerular filtration rate. An unanticipated interaction between Angioguard and abciximab was seen, with combination therapy better than no treatment or either treatment alone. (*Circulation*. 2008;117:2752-2760.)

Key Words: kidney ■ peripheral vascular disease ■ platelets ■ stenosis ■ stents

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RESIST Trial

- Multicenter, prospective, randomized trial in 100 patients with renal artery stenosis
  - Control (n = 28)
  - Angioguard only (22)
  - Abciximab only (25)
  - Angioguard and Abciximab (25)
- Baseline creatinine ~1.2 mg/dL

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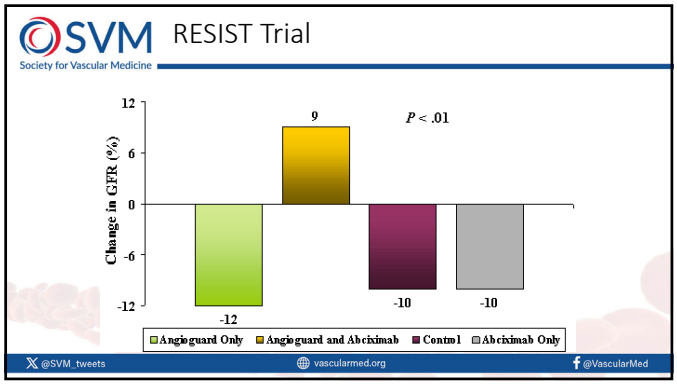
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RESIST Trial
Change in GFR (%)
12
6
0
-6
-12
9
P < .01
-12
-10
-10
Angioguard Only
Angioguard and Abciximab
Control
Abciximab Only
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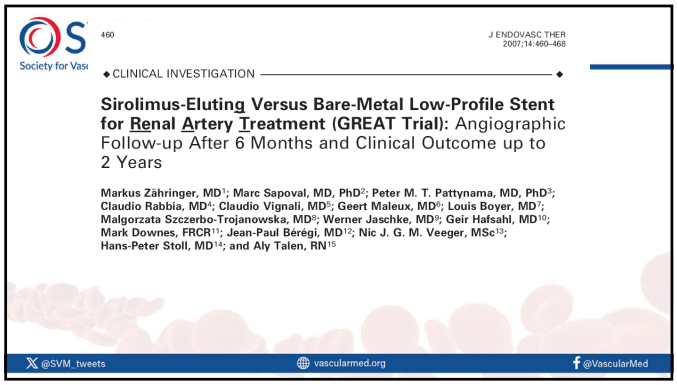
460
J ENDOVASC THER
2007;14:460–468
CLINICAL INVESTIGATION
Sirolimus-Eluting Versus Bare-Metal Low-Profile Stent for Renal Artery Treatment (GREAT Trial): Angiographic Follow-up After 6 Months and Clinical Outcome up to 2 Years
Markus Zähringer, MD[1]; Marc Sapoval, MD, PhD[2]; Peter M. T. Pattynama, MD, PhD[3]; Claudio Rabbia, MD[4]; Claudio Vignali, MD[5]; Geert Maleux, MD[6]; Louis Boyer, MD[7]; Malgorzata Szczerbo-Trojanowska, MD[8]; Werner Jaschke, MD[9]; Geir Hafsahl, MD[10]; Mark Downes, FRCR[11]; Jean-Paul Bérégi, MD[12]; Nic J. G. M. Veeger, MSc[13]; Hans-Peter Stoll, MD[14]; and Aly Talen, RN[15]
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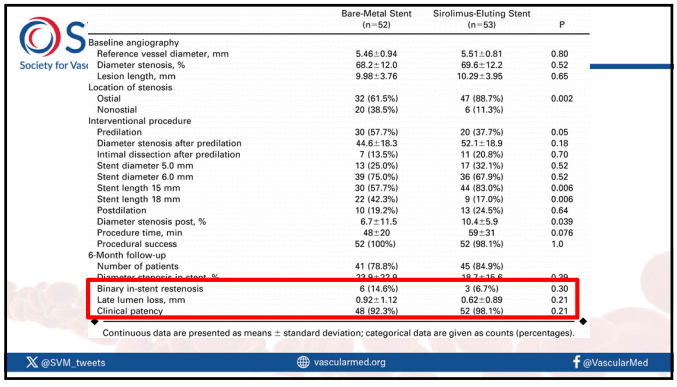
Bare-Metal Stent (n=52)
Sirolimus-Eluting Stent (n=53)
P
Baseline angiography
Reference vessel diameter, mm 5.46±0.94 5.51±0.81 0.80
Diameter stenosis, % 68.2±12.0 69.6±12.2 0.52
Lesion length, mm 9.98±3.76 10.29±3.95 0.65
Location of stenosis
Ostial 32 (61.5%) 47 (88.7%) 0.002
Nonostial 20 (38.5%) 6 (11.3%)
Interventional procedure
Predilation 30 (57.7%) 20 (37.7%) 0.05
Diameter stenosis after predilation 44.6±18.3 52.1±18.9 0.18
Intimal dissection after predilation 7 (13.5%) 11 (20.8%) 0.70
Stent diameter 5.0 mm 13 (25.0%) 17 (32.1%) 0.52
Stent diameter 6.0 mm 39 (75.0%) 36 (67.9%) 0.52
Stent length 15 mm 30 (57.7%) 44 (83.0%) 0.006
Stent length 18 mm 22 (42.3%) 9 (17.0%) 0.006
Postdilation 10 (19.2%) 13 (24.5%) 0.64
Diameter stenosis post, % 6.7±11.5 10.4±5.9 0.039
Procedure time, min 48±20 59±31 0.076
Procedural success 52 (100%) 52 (98.1%) 1.0
6-Month follow-up
Number of patients 41 (78.8%) 45 (84.9%)
Binary in-stent restenosis 6 (14.6%) 3 (6.7%) 0.30
Late lumen loss, mm 0.92±1.12 0.62±0.89 0.21
Clinical patency 48 (92.3%) 52 (98.1%) 0.21
Continuous data are presented as means ± standard deviation; categorical data are given as counts (percentages).
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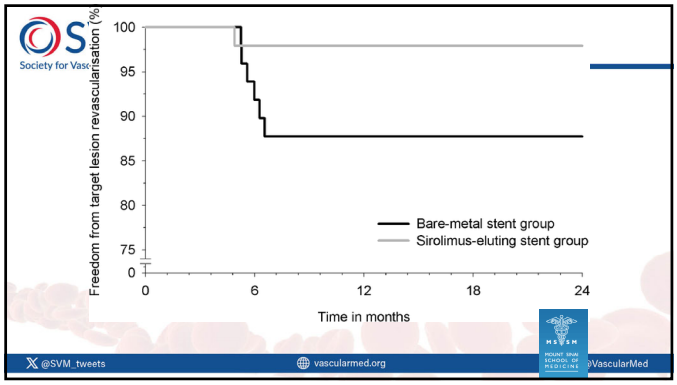
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Freedom from target lesion revascularisation (%)
100
95
90
85
80
75
0
0
6
12
18
24
Time in months
Bare-metal stent group
Sirolimus-eluting stent group
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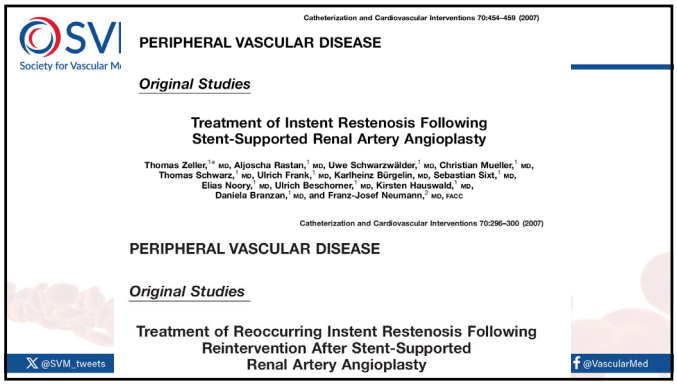
Society for Vascular M
Catheterization and Cardiovascular Interventions 70:454–459 (2007)
PERIPHERAL VASCULAR DISEASE
Original Studies
Treatment of Instent Restenosis Following Stent-Supported Renal Artery Angioplasty
Thomas Zeller, MD, Aljoscha Rastan, MD, Uwe Schwarzwälder, MD, Christian Mueller, MD, Thomas Schwarz, MD, Ulrich Frank, MD, Karlheinz Bürgelin, MD, Sebastian Sixt, MD, Elias Noory, MD, Ulrich Beschorner, MD, Kirsten Hauswald, MD, Daniela Branzan, MD, and Franz-Josef Neumann, MD, FACC
Catheterization and Cardiovascular Interventions 70:296–300 (2007)
PERIPHERAL VASCULAR DISEASE
Original Studies
Treatment of Reoccurring Instent Restenosis Following Reintervention After Stent-Supported Renal Artery Angioplasty
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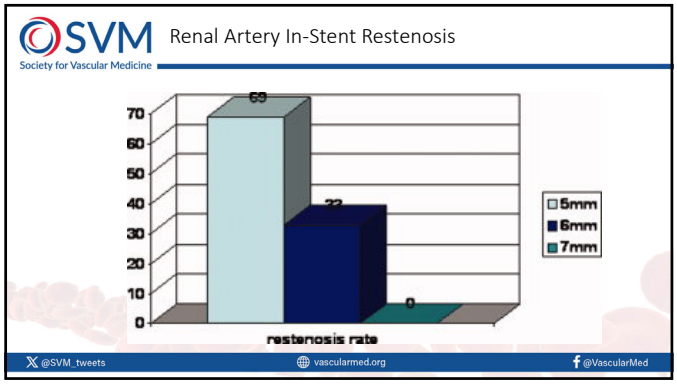
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Renal Artery In-Stent Restenosis
70
60
50
40
30
20
10
0
69
0
5mm
6mm
7mm
restenosis rate
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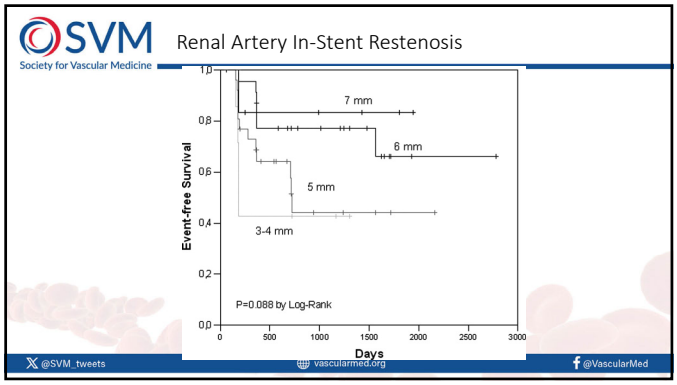
SVM
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Renal Artery In-Stent Restenosis
7 mm
6 mm
5 mm
3-4 mm
Event-free Survival
P=0.088 by Log-Rank
Days
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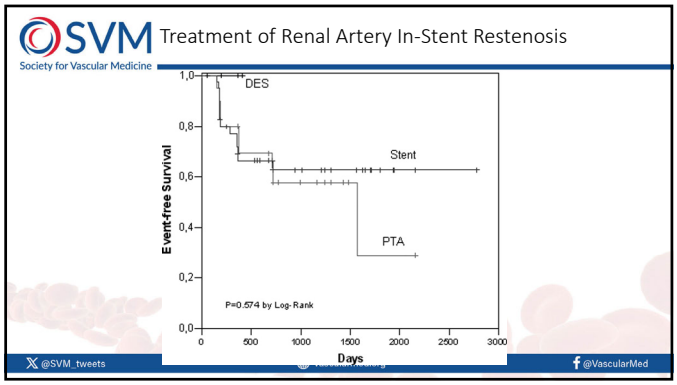
SVM
Society for Vascular Medicine
Treatment of Renal Artery In-Stent Restenosis
DES
Stent
PTA
Event-free Survival
P=0.574 by Log-Rank
Days
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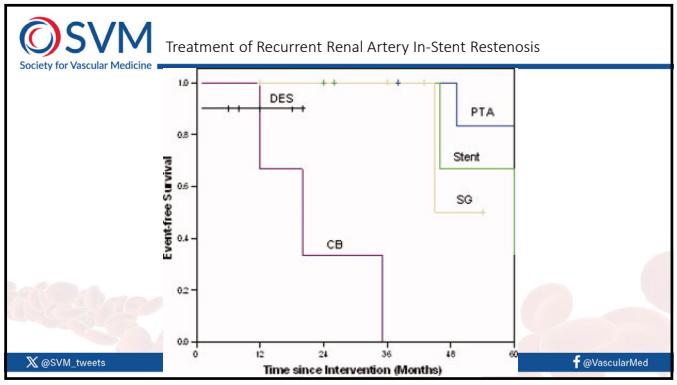
SVM
Society for Vascular Medicine
Treatment of Recurrent Renal Artery In-Stent Restenosis
DES
PTA
Stent
SG
CB
Event-free Survival
Time since Intervention (Months)
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RESIST – What does it mean?

- Why no increase with EPD alone?
- Possible emboli before or after filter deployment
- Or alternate mechanism…

- Risk of Reopro vs. supposed benefit?
- Cost Issues

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CLINICAL STUDY

Roll-in Experience from the Cardiovascular Outcomes with Renal Atherosclerotic Lesions (CORAL) Study

Timothy P. Murphy, MD, Christopher J. Cooper, MD, Donald E. Cutlip, MD, hn Rundback, MD, Kenneth MD, Joseph Shapiro, MD, Yen, MS, Holly Burtch, RN, D, and Lance Dworkin, MD

Table 7. Angiographic Complications Reported by the Angiographic Core Laboratory

Angiographic Complication	No. (%)
Dissection	11 (4.5%)
Embolus	9 (3.7%)
Occlusion	9 (3.7%)
Incomplete deployment or maldeployment of DPD	1 (0.4%)
Thrombus	3 (1.2%)
Vessel rupture	2 (0.8%)
Wire perforation	2 (0.8%)
Pseudoaneurysm	1 (0.4%)

Angiographic complications were seen in 13% of cases

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Table 2. Change Score from Baseline to Short-Term Follow-up (2–4 Weeks)

Change Score from Baseline to 2 Weeks	DPD (n = 161)	No DPD (n = 78)	Total Population (n = 239)	Difference [95% CI]	P Value
Kidney function—creatinine					
Mean ± SD (no.)	−0.01 ± 0.26 (124)	−0.02 ± 0.26 (56)	−0.01 ± 0.26 (180)	0.02 [−0.07, 0.10]	.702
Range (min., max.)	(−1.30, 0.60)	(−0.80, 0.60)	(−1.30, 0.60)		
Kidney function—MDRD eGFR					
Mean ± SD (no.)	0.23 ± 12.27 (124)	−0.30 ± 11.43 (56)	0.07 ± 11.98 (180)	0.53 [−3.28, 4.35]	.783
Range (min., max.)	(−50.09, 58.19)	(−49.17, 28.58)	(−50.09, 58.19)		
Systolic blood pressure					
Mean ± SD (no.)	−14.15 ± 23.34 (129)	−15.51 ± 25.36 (60)	−14.58 ± 23.94 (189)	1.37 [−6.03, 8.76]	.716
Range (min., max.)	(−90.00, 61.33)	(−74.33, 35.00)	(−90.00, 61.33)		

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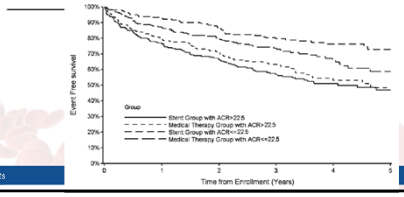
Clinical Trial: CORAL

Relationship of Albuminuria and Renal Artery Stent Outcomes

Results From the CORAL Randomized Clinical Trial (Cardiovascular Outcomes With Renal Artery Lesions)

Timothy P. Murphy, Christopher J. Cooper, Karol M. Pencina, Ralph D'Agostino, Joseph Massaro, Donald E. Cutlip, Kenneth Jamerson, Alan H. Matsumoto, William Henrich, Joseph I. Shapiro, Katherine R. Tuttle, David J. Cohen, Michael Steffes, Qi Gao, D. Christopher Metzger, William B. Abernethy, Stephen C. Textor, John Briguglio, Alan T. Hirsch, Sheldon Tobe, Lance D. Dworkin



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Hypertension

AHA SCIENTIFIC STATEMENT

Revascularization for Renovascular Disease: A Scientific Statement From the American Heart Association

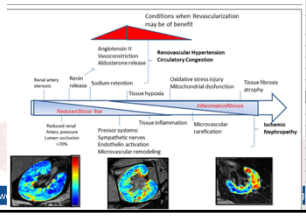

Table 2. Populations and Characteristics Considered for Renal Revascularization

Clinical populations
Unilateral renal artery stenosis with characteristic syndromes (see below)
Fibromuscular dysplasia with hypertension*
High-risk clinical syndromes*
Rapidly progressive hypertension*
Rapidly declining estimated glomerular filtration rate*
Flash pulmonary edema*
Bilateral renal artery stenosis with progressive loss of renal functional mass
Single native kidney renal artery stenosis
Special populations:
Renal allograft: transplant renal artery stenosis with or without calcineurin inhibitors
Episodic, circulatory congestion with bilateral atherosclerotic renovascular disease
Progressive loss of glomerular filtration rate with occlusive atherosclerotic renovascular disease and no other kidney disease (ischemic nephropathy)
Aortic disease with renovascular protection as part of endovascular repair
Left-ventricular assist device
Radiation-induced renovascular disease with clinical syndromes
Other diseases: eg, Takayasu arteritis, extrinsic vascular compression
Pediatric patients with mid aortic syndrome or fibromuscular variants
Characteristics suggestive of clinical benefit from revascularization
Recent onset or exacerbation (<1 y) of hypertension*
Absence of proteinuria*
Identifiable activation of renin-angiotensin system*
Hyperkalemia*
With unilateral renal artery stenosis, lateralization of renal vein renin*
Younger age
Radiographic evidence of progressive renal artery occlusion
Treatment-resistant hypertension (documentation of hypertension by ambulatory blood pressure and medication adherence)
Angiotensin-dependent glomerular filtration rate

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SVM Case

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- 73 year old female was transferred from an outside hospital to the Mount Sinai coronary care unit
  - She was in acute pulmonary edema and on an FiO2 of 50%
  - The blood pressure was 180/104 mmHg on:
    - Furosemide 120 mg BID
    - Metolazone 5 mg daily
    - Atenolol 100 mg daily
    - Hydralazine 100 mg TID
    - Clonidine patch 0.3 mg weekly
    - Isosorbide mononitrate 90 mg daily

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SVM Case

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- Despite large doses of diuretics, her urine output over the last several days was 250 cc/24 hours
- The serum creatinine 4 weeks ago was 1.6 mg/dL and on transfer to the CCU it was 3.9 mg/dL.
  - She underwent hemodialysis and ultrafiltration
- Four weeks ago she had a stress thallium test that was negative for ischemia and an echocardiogram with LVH, normal systolic LV function and diastolic dysfunction.
- A renal artery duplex ultrasound demonstrated a >60% stenosis on the left renal artery and the right renal artery was poorly visualized due to bowel gas and inability to breath hold.

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SVM Renal Artery Duplex

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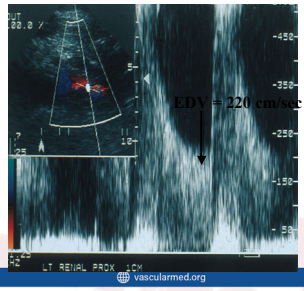

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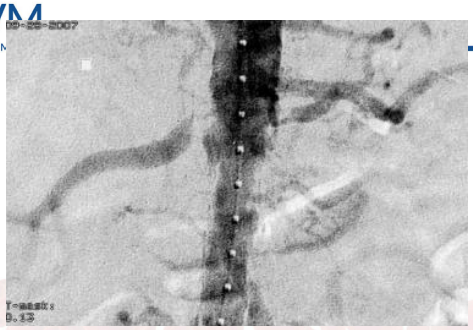

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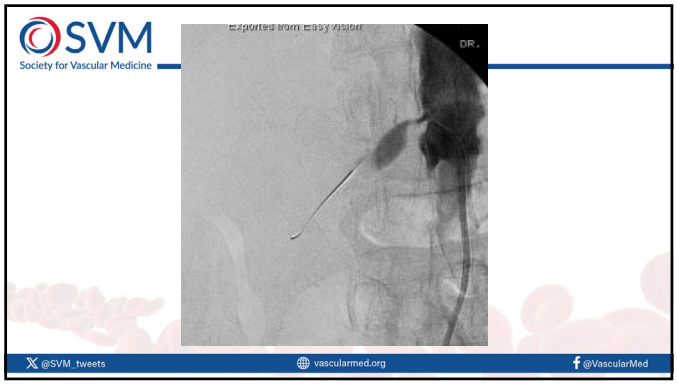
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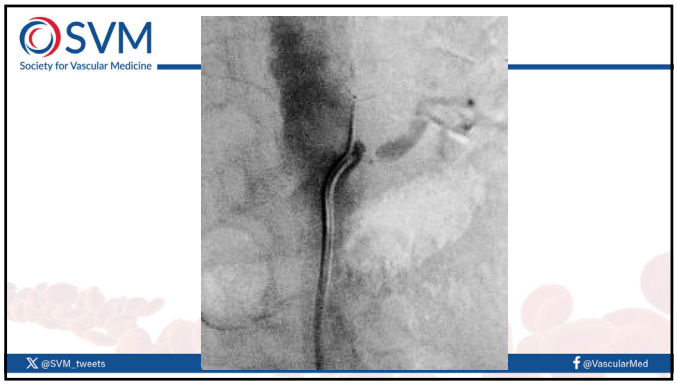
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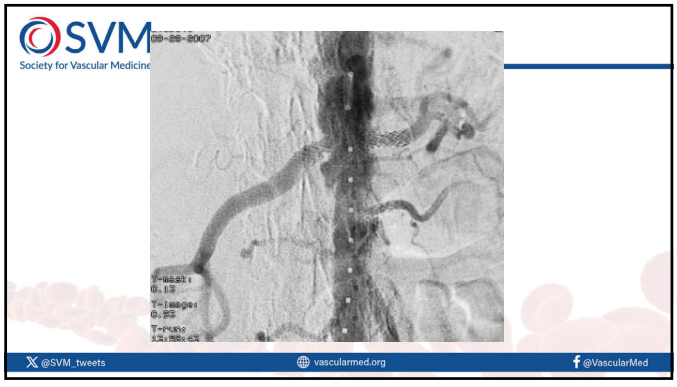
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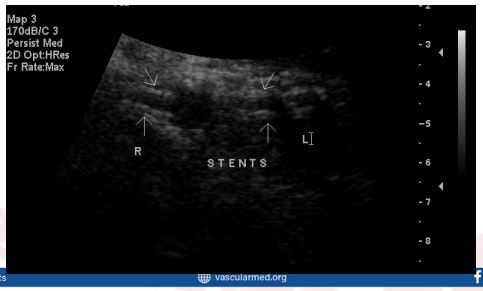
Post Renal Artery Stent



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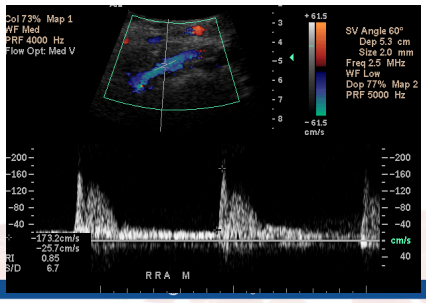
Post Renal Artery Stent



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Case Summary

- Post stenting she required no dialysis
- The serum creatinine was 1.2 mg/dL four days after renal artery stent implantation
- The blood pressure was 130/70 on:
  - HCTZ 25 mg daily
  - Lisinopril 20 mg BID
  - Atenolol 100 mg daily
- She returned in 2 weeks for the first surveillance duplex ultrasound and all three stents were patent
  - Blood pressure was 120/60 on meds as above
  - Serum creatinine was 1.2 mg/dL (GFR, 45 ml/min/1.73m2)

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Summary: current indications for RAS?

- Bilateral high grade disease with a significant translesional gradient/FFR:
  - Refractory hypertension (medical failure)
  - Renal insufficiency with acute deterioration
  - Flash pulmonary edema with cardiac disturbance syndrome
  - NO/LOW Albuminuria
- Unilateral disease with a significant translesional gradient/FFR:
  - Solitary kidney
  - Renal Transplant
  - Refractory hypertension

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