Peripheral Artery Disease

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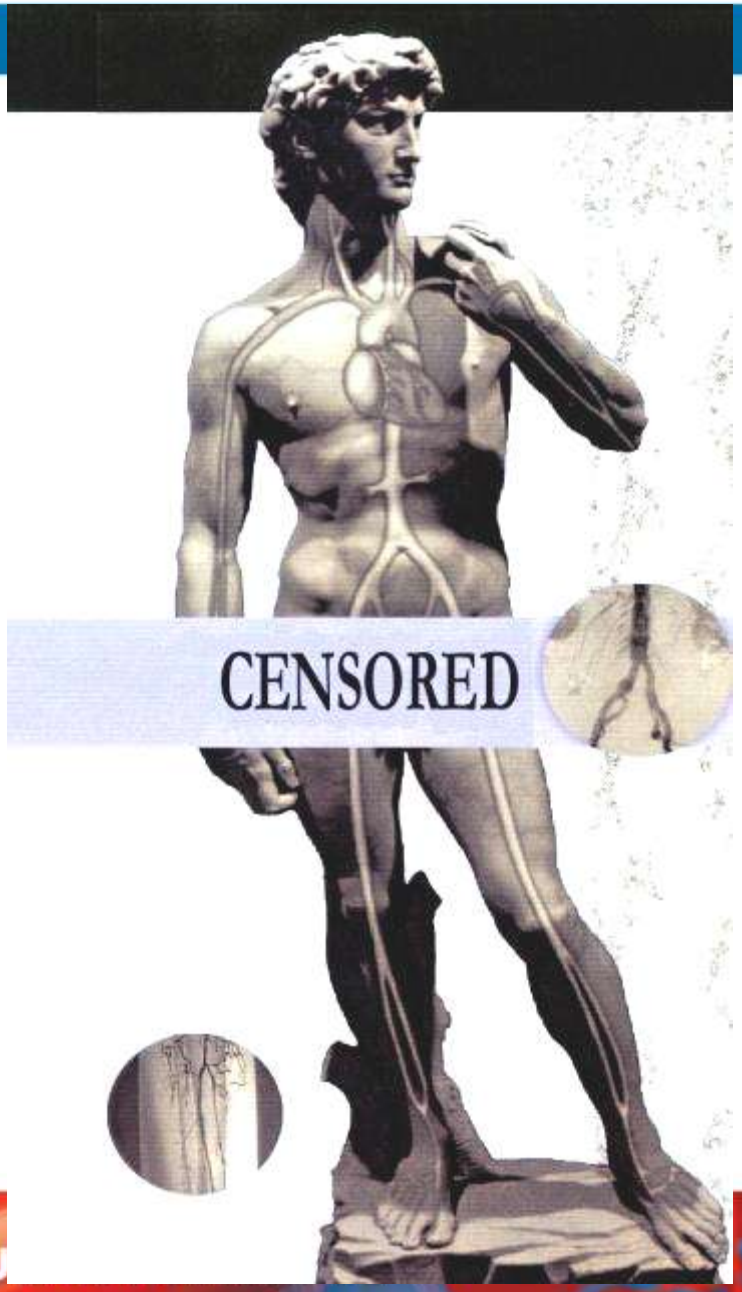
Disclosure Statement of Financial Interest

- **Advisory**
  - **Boston Scientific**
  - **Abbott Vascular**
  - **Atheromed**
  - **Endologix**
- **Training/Speaking**
  - **Endologix**
  - **Cook Medical**
  - **Cardinal Health**
- **Royalties**
  - **Cook Medical**
- **Research/National PI**
  - **CSI**
- **Stock**
  - **Embolitech**
  - **Enable Injections**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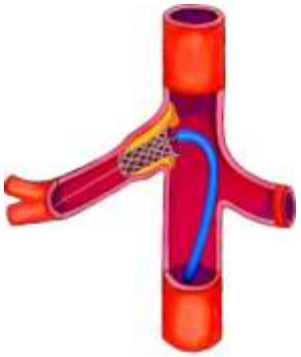


Encompassing Vascular Disease

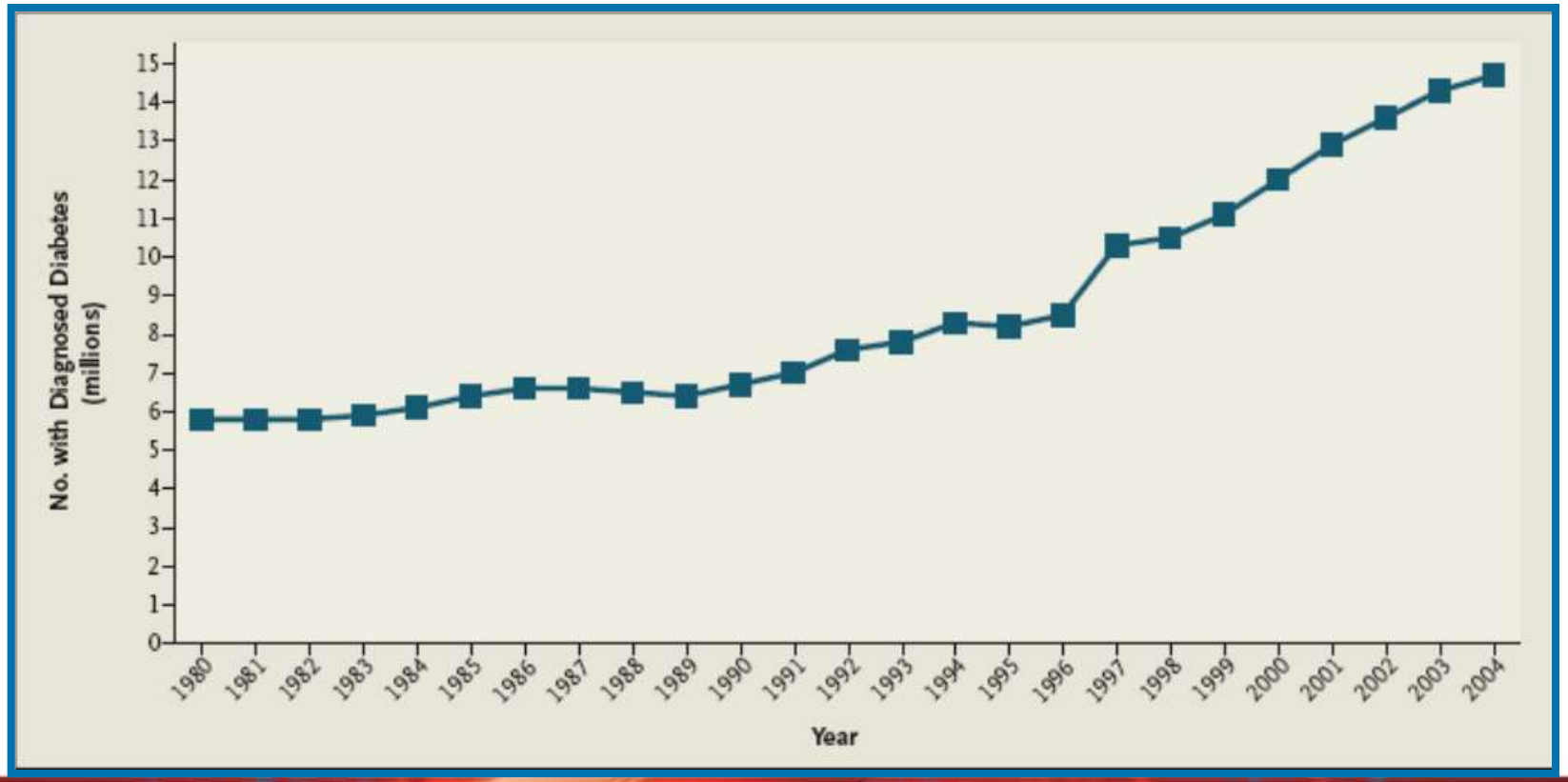
- PAD
- AAA
- Renal artery stenosis
- Subclavian artery stenosis
- Carotid artery disease
- Venous diseases
- Vasculitis

When To Suspect multi-organ Vascular Involvement ?

ALWAYS !!!!!!

The Evolution of America

Persons Diagnosed with DM in US



N Engl J Med 2006;354:545.

Peripheral Arterial Disease

- Patients present with
  - Classic Intermittent Claudication(~30%)
  - Atypical Symptoms (~50%)
  - Critical Limb Ischemia (~10%)
    - Ischemic Rest Pain
    - Ischemic Ulceration
    - Gangrene
  - No symptoms with abnormal arterial circulation (~10%)

Peripheral Arterial Disease

Tests Available

- Bedside Ankle-Brachial Index
- ABI, Segmental Pressures, PVR
  - Treadmill
- Arterial Duplex Ultrasonography
- Magnetic Resonance Arteriography
- CT Angiography
- Contrast Arteriography
- CO2 arteriography

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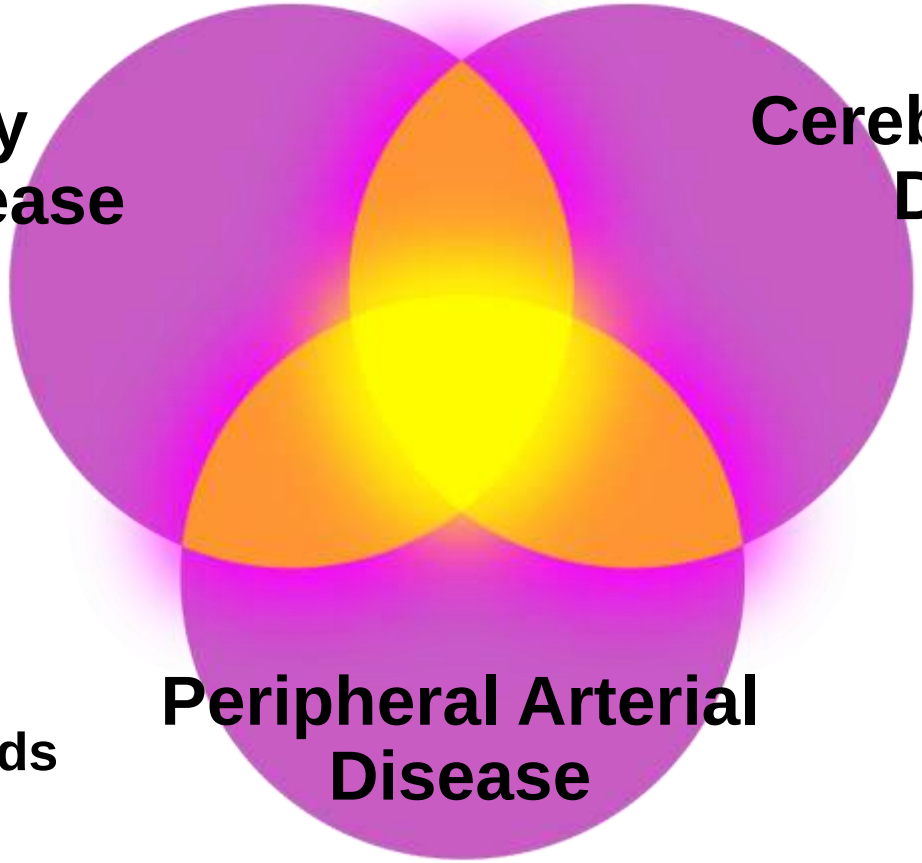
APPROPRIATE USE CRITERIA

ACCF/ACR/AIUM/ASE/ASN/ICAVL/SCAI/SCCT/SIR/SVM/SVS 2012 Appropriate Use Criteria for Peripheral Vascular Ultrasound and Physiological Testing Part I: Arterial Ultrasound and Physiological Testing

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, American College of Radiology, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Nephrology, Intersocietal Commission for the Accreditation of Vascular Laboratories, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Interventional Radiology, Society for Vascular Medicine, and Society for Vascular Surgery

Endorsed by the American Academy of Neurology, American Podiatric Medical Association, Society for Clinical Vascular Surgery, Society for Cardiovascular Magnetic Resonance, and Society for Vascular Ultrasound

Overlap of Atherosclerotic Disease



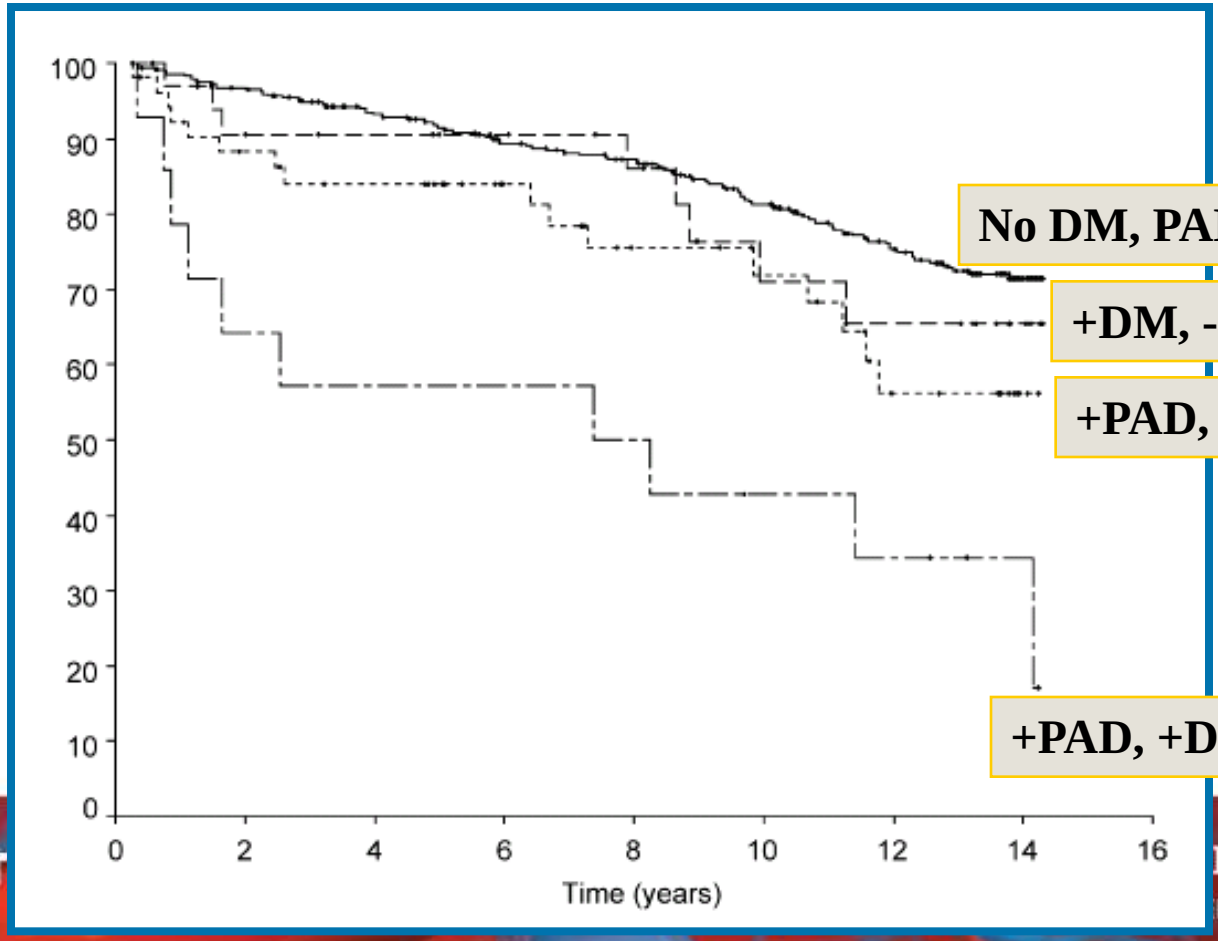
38% overlap
≥2 vascular beds

Patients with one manifestation
often have coexistent disease in other vascular beds.

Ness J, Aronow WS. *J Am Geriatr Soc*. 1999;47:1255-1256.

PAD, DM, and Cardiac Mortality

474 Men Age 68 Followed Prospectively for 14 Years



Eur J Vasc Endovasc Surg 2005;29:182-9

Differential Diagnosis of PAD

Condition	*Location*	*Prevalence*	*Characteristic*	*Effect of exercise*	*Effect of rest*	*Effect of position*	*Other characteristics*
Calf IC	Calf muscles	3–5% of adult population	Cramping, aching discomfort	Reproducible onset	Quickly relieved	None	May have atypical limb symptoms on exercise
Thigh and buttock IC	Buttocks, hip, thigh	Rare	Cramping, aching discomfort	Reproducible onset	Quickly relieved	None	Impotence May have normal pedal pulses with isolated iliac artery disease
Foot IC	Foot arch	Rare	Severe pain on exercise	Reproducible onset	Quickly relieved	None	Also may present as numbness
Chronic compartment syndrome	Calf muscles	Rare	Tight, bursting pain	After much exercise (jogging)	Subsides very slowly	Relief with elevation	Typically heavy muscled athletes
Venous claudication	Entire leg, worse in calf	Rare	Tight, bursting pain	After walking	Subsides slowly	Relief speeded by elevation	History of iliofemoral deep vein thrombosis, signs of venous congestion, edema
Nerve root compression	Radiates down leg	Common	Sharp lancinating pain	Induced by sitting, standing or walking	Often present at rest	Improved by change in position	History of back problems Worse with sitting Relief when supine or sitting
Symptomatic Bakers cyst	Behind knee, down calf	Rare	Swelling, tenderness	With exercise	Present at rest	None	Not intermittent
Hip arthritis	Lateral hip, thigh,	Common	Aching discomfort	After variable degree of exercise	Not quickly relieved	Improved when not weight bearing	Symptoms variable History of degenerative arthritis
Spinal stenosis	Often bilateral buttocks, posterior leg	Common	Pain and weakness	May mimic IC	Variable relief but can take a long time to recover	Relief by lumbar spine flexion	Worse with standing and extending spine
Foot/ankle arthritis	Ankle, foot, arch	Common	Aching pain	After variable degree of exercise	Not quickly relieved	May be relieved by not bearing weight	Variable, may relate to activity level and present at rest

J Vasc Surg 2007;45:S5A-S67A

The Most Important Aspect of the Diagnostic Evaluation of PAD

- History
  - Location of Symptoms
  - Description of Discomfort
  - Exacerbating/Ameliorating Characteristics
  - Reproducible Symptoms
- Physical Examination

Interesting PAD Diagnoses

Identify the vascular problem:

1. Raynaud's phenomenon
2. Spontaneous venous hemorrhage
3. Livedo reticularis
4. Acrocyanosis

Acrocyanosis

- Symmetric reddish-blue discoloration of the hands & feet
- Discoloration exacerbated by cold
- Acrocyanosis extends *proximal* to the wrist and dorsal foot
- Discoloration is *persistent* rather than episodic
- Venous pooling of the elderly also benign and looks the same
- Improves with limb elevation and goes to normal pink

Acrocyanosis: *Differential Diagnosis*

- Anorexia nervosa
- Mononucleosis
- Lymphoreticular/solid malignancies
- Cold agglutinin disease
- Interferon alpha
- POTS
- Methemoglobinemia
- Sulfhemoglobinemia
- Multiple sclerosis
- Myeloproliferative syndrome
- APAS
- Arsenic poisoning
- Arteritis
- Parvovirus B19
- Fabry's disease
- Paroxysmal cold hemoglobinuria
- Spinal cord injury
- Stroke

Acrocyanosis in Anorexia Nervosa

- Occurs in *severely* anorectic patients
- May represent an extreme form of an energy saving mechanism
- Sometimes associated with clubbing and swelling of the digits
- Univ of Basle- 33%
- Univ of Ferrara- 29%
- Univ of Innsbruck- 56%; associated with leukopenia and low eosinophils.

Strumia, *Dermat* 2001;203:314-7
Hediger, *Schweiz Med Wochenschr* 2000;130:565-75
Klein-Weigel, *J Psychosom* 2001;51:145-8.

?

Acrocyanosis: *Therapy*

- No evidence-based guidelines
- Eliminate underlying cause
- Reassurance
- Vasodilator therapy

A 33 y.o. non smoker presents with pruritic, swollen toes in November.
What is the diagnosis?

1. Raynaud's
2. Acrocyanosis
3. Pernio
4. Atheroemboli

Pernio

Overview: A superficial, localized inflammatory skin disorder

History : Exposure to humid, *non freezing* cold; previous hx of similar manifestations (late fall/early spring)

Symptoms: burning; intense pruritus

Clinical: erythematous/violaceous patches, plaques, and/or papules; bulbous digits; blisters, ulcerations → *Toes* and/or fingers

Pernio

Associated Diseases:

Vasospastic disorders (Raynaud's, acrocyanosis)

Chronic ischemia (PAD, erythermalgia)

Hyperviscosity syndromes (cryopathies, leukemia)

Abnormal fat distribution (obesity; anorexia)

Pernio

Laboratory:

- Not required in uncomplicated cases
- Complicated- autoimmune & cryopathy serology

Differential Dx:

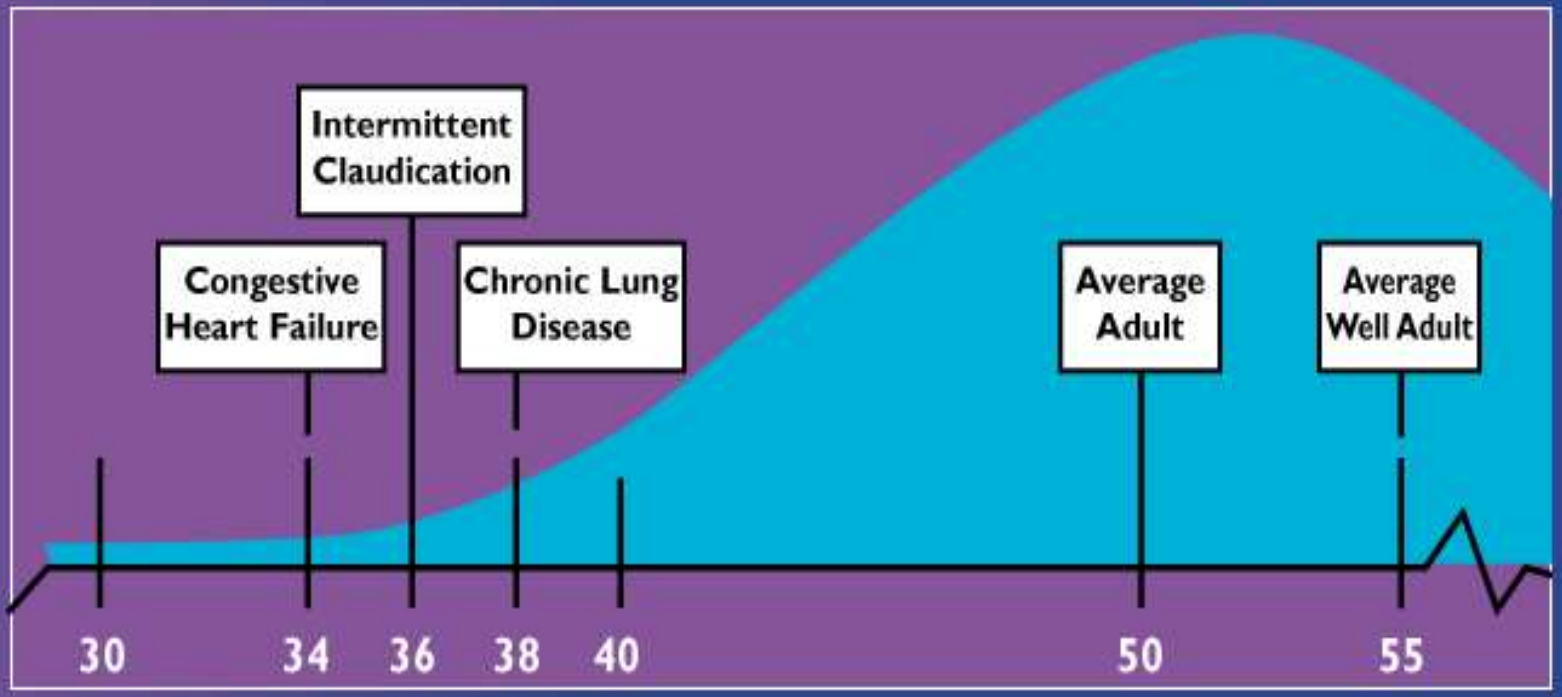
- Arterial ischemia (*athero*/thromboemboli)
- Vasculitis
- Vasospastic diseases

Therapy: supportive care; Ca^{2+} channel blockers; PD III/V inhibitors; topical steroids

Now for Symptomatic PVD

Peripheral Arterial Disease

Comparing Physical Health for Chronically Ill U.S. Adults



Source: Adapted from Ware et al., 1994.

Prognosis for CLI Patients

- Within 3 months of presentation:
  - death in 9%
  - MI in 1%
  - stroke in 1%
  - amputation in 12%
  - persistent CLI in 18%
- 1-year mortality: 21.0%
- 2-year mortality: 31.6%

The Ankle-Brachial Index

- Simple, painless, accurate, highly reproducible examination
- Indications
  - Any patient suspicious of PAD
  - Any patient at risk of PAD
    - Age 50 or greater with history of DM or Tobacco Use
    - Age 70 or greater regardless of risk factors

ABI as a Screening Test

Table 1. Effectiveness of the ABI vs Other Common Screening Tests

Diagnostic Test	Sensitivity, %	Specificity, %
Pap smear[37]	30-87	86-100
Fecal occult blood test[38]	37-78	87-98
Mammography[39]	75-90	90-95
ABI[5,35,36]	95	100

Abbreviation: ABI, ankle-brachial index.

Belch JJF et al. Arch Intern Med 2003;163:884-92

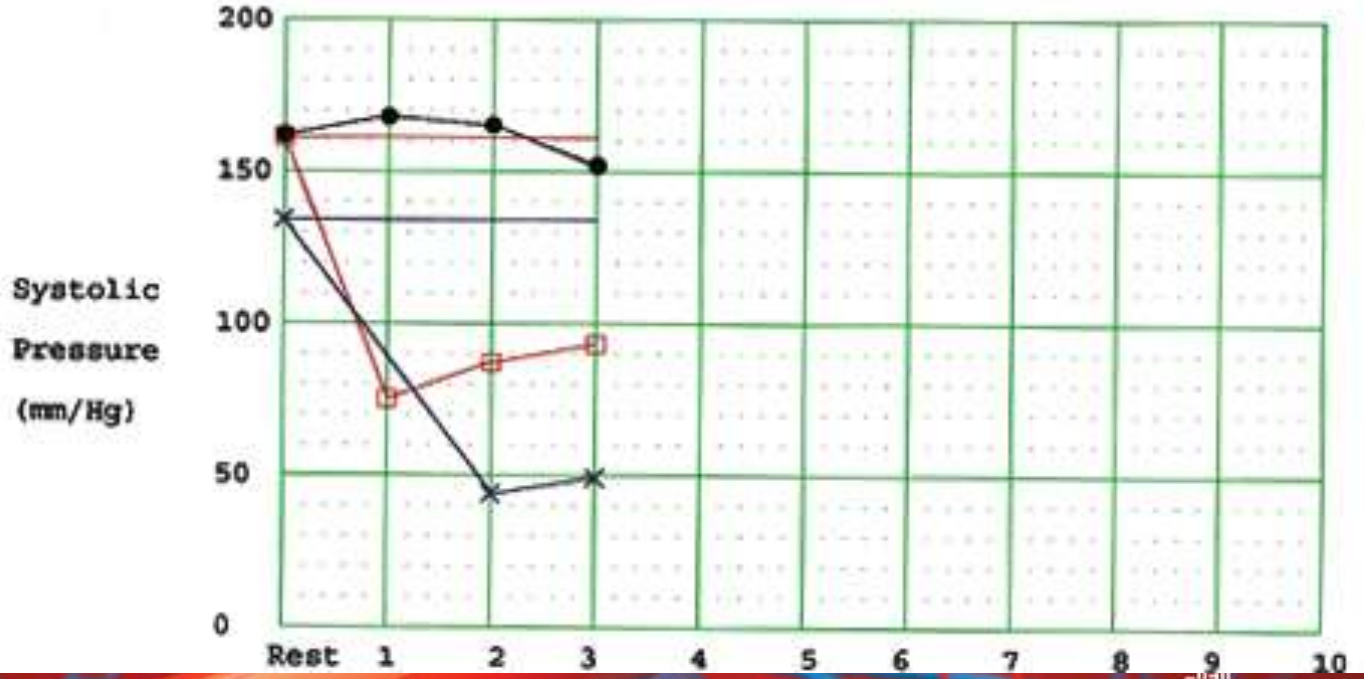
Indications for Treadmill Vascular Test

- Any patient with atypical exertional limb symptoms—
  - Determine IC vs Pseudoclaudication
- Measure true functional impact of PAD
- Demonstrate impact of revascularization
- May uncover occult angina pectoris/CAD

Exercise

Exercise

	Rest	1	2	3	4	5	6	7	8	9
Brachial BP	162	168	165	152						
R Ankle BP	161	75	87	93						
L Ankle BP	134		44	49						
R ABI	0.99	0.45	0.53	0.61						
L ABI	0.83		0.27	0.32						



Is It Vascular Limb Pain?

Historical Clue	Vascular Etiology	Neurogenic Etiology
Onset	Predictable	Variable
Only With Walking?	Yes	No
Relief With Stopping/Standing?	Yes	Variable
Absent Pedal Pulses at Rest	Variable	Variable

Therapy for Intermittent Claudication

Symptom/Limb

- Tobacco Cessation
- Foot Care
- Control of DM
- Reduction in Cholesterol
- Antiplatelet Agents
- Exercise
- Cilostazol
- Angiogenesis
- Gingko Biloba

Life

- Tobacco Cessation
- Control of DM
- Reduction in Cholesterol
- Reduction in BP
- Ace inhibition
- Antiplatelet Agents
- Evaluation for CAD
- Exercise

LOWER EXTREMITY REVASCULARIZATION

INDICATIONS

- Lifestyle-interfering intermittent claudication
- Limb-threatening ischemia
  - Ischemic rest pain
  - Non-healing ulceration
  - Gangrene

Therapeutic Crossroads (Variables)

Patient Goals

Typically in 2016 Revascularization is Endo First

Peripheral Vascular Disease

Surgical Revascularization: Currently Venus Bypass Considered Most Durable Treatment

- **Life-Style Disabling Claudication**
- **Rest Pain**
- **Tissue Necrosis or Infection**
- **Limb-threatening Ischemia**

Morbidity and Mortality Should Prevent Indications from Being Expanded

InfraInguinal Surgery

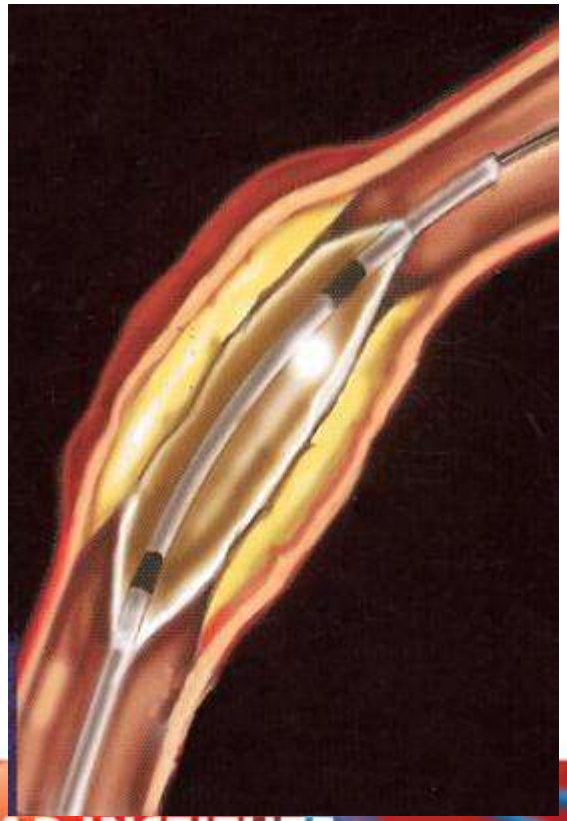
- Serious Wound Infection 1 - 6%
- Myocardial Infarction 1.9 - 3.4%
- Early graft failure 0 - 24%
- Acute leg ischemia 1.0 - 2.0%

- Op. Mortality 1.3 - 6%
- Surgical Revision rate > 20%

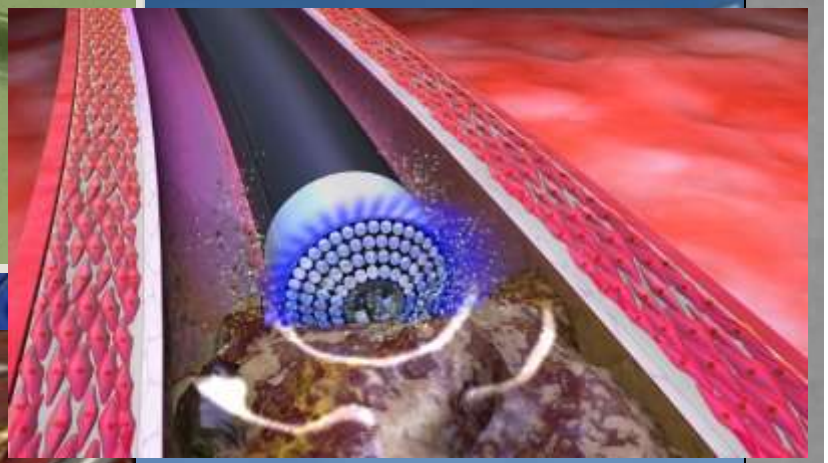
ENDOVASCULAR TECHNIQUES

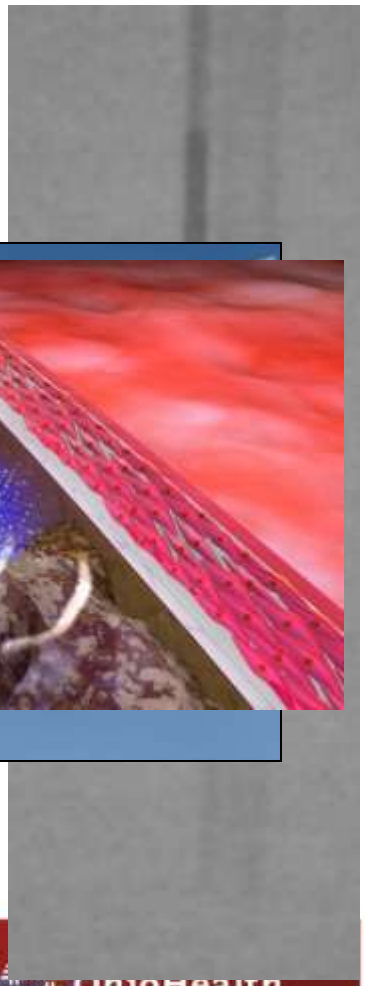
What Can Be Accomplished in 2016

Higher Success Rates and Prolonged Patency



Tools for CTO Intervention
Success Rates > 95%



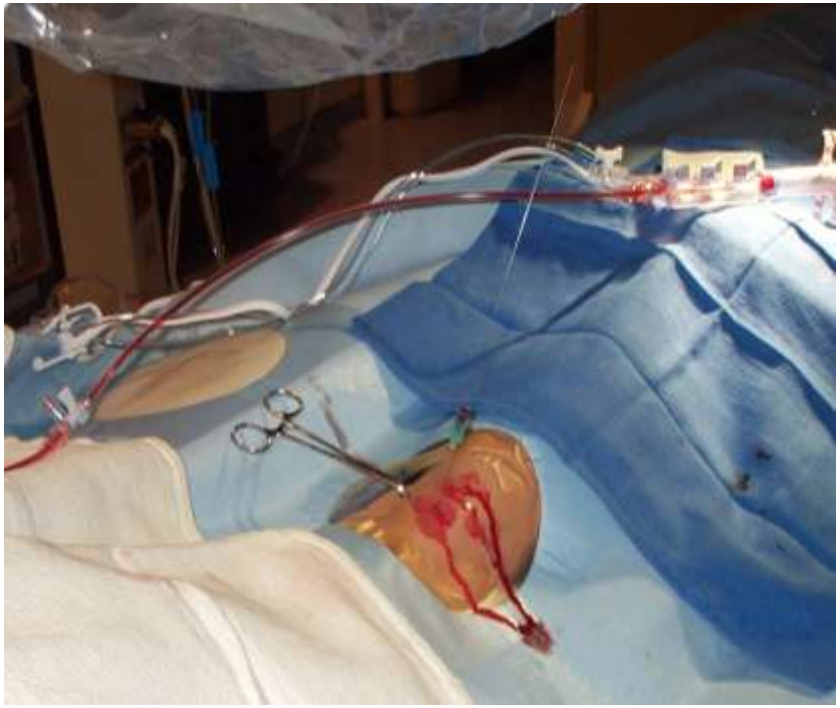


Case

- Male, Age 80, HTN and CAD. Smoker
- ABI = .32
- CLI: rest pain
- *Previous; Aortobifem bypass. Femtibial bypass x2 with multiple thromboses*
-

Case

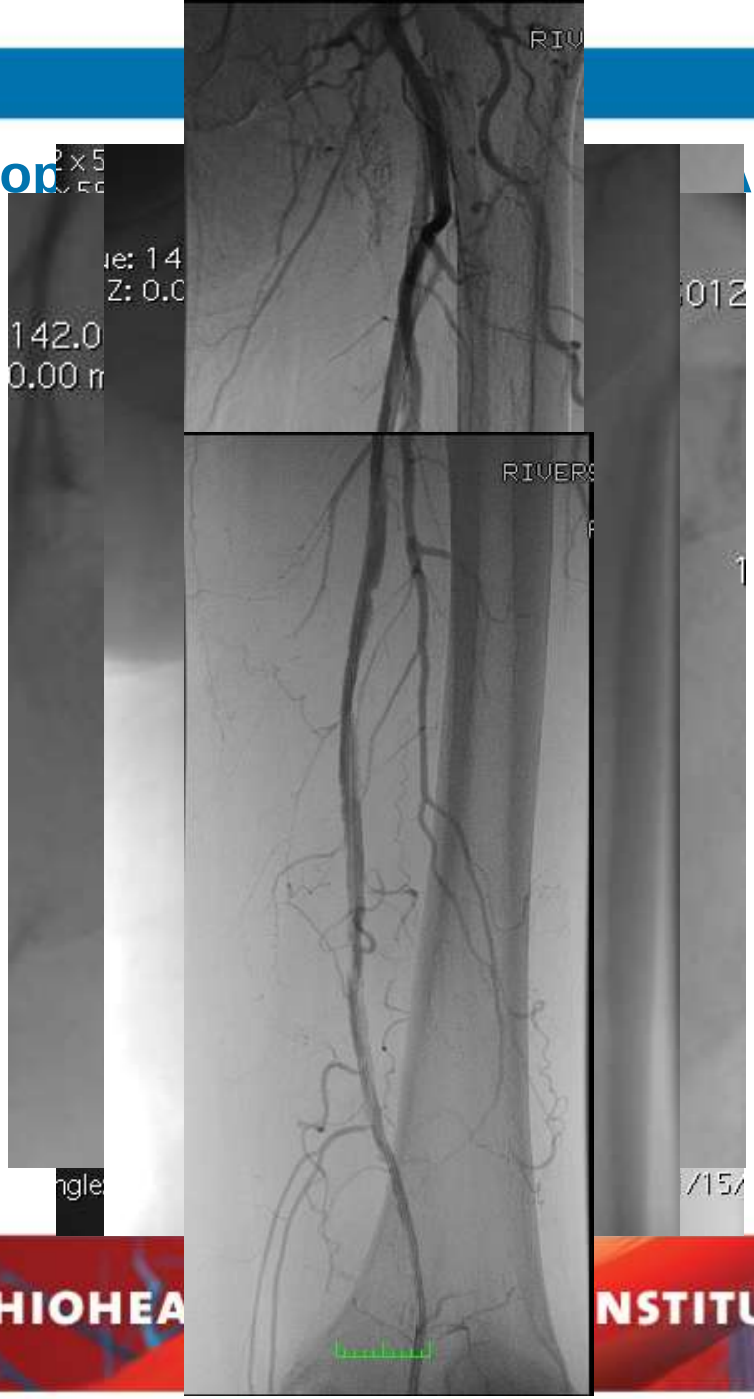
- Plan combined contralateral and popliteal access
- Difficult to go contralateral with aortobifemoral bypass
- Plan utilization of popliteal access



Access and Wire manipulation

- Flipped to prone position
- 5 french popliteal ulstrasound guided access
- 4 french catheter over .035 straight hydrophilic guidewire
- Traversed to area of common femoral artery
- .035 wire replaced by .014 guide wire
- CTO devices advanced

Adop[illegible] of AT and DP arteries

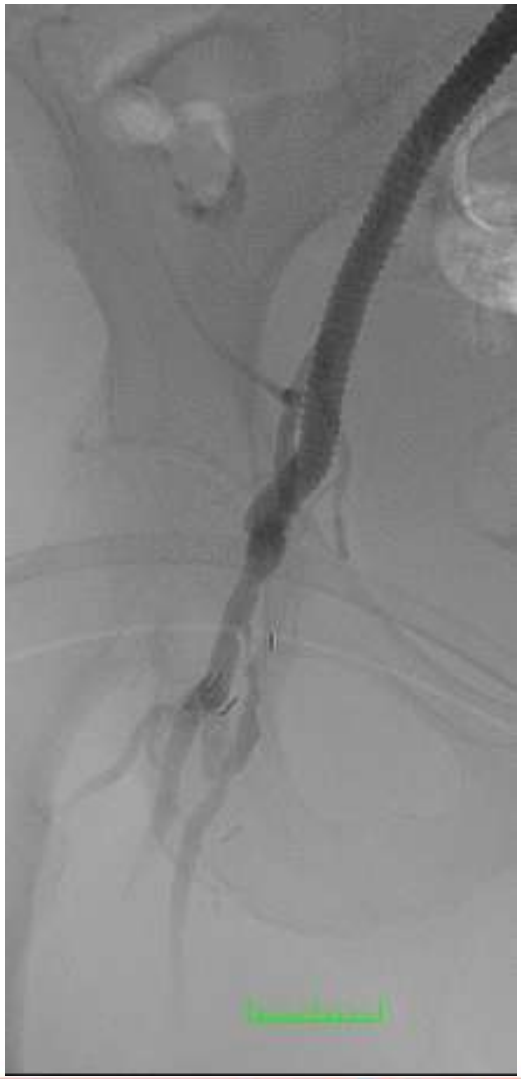


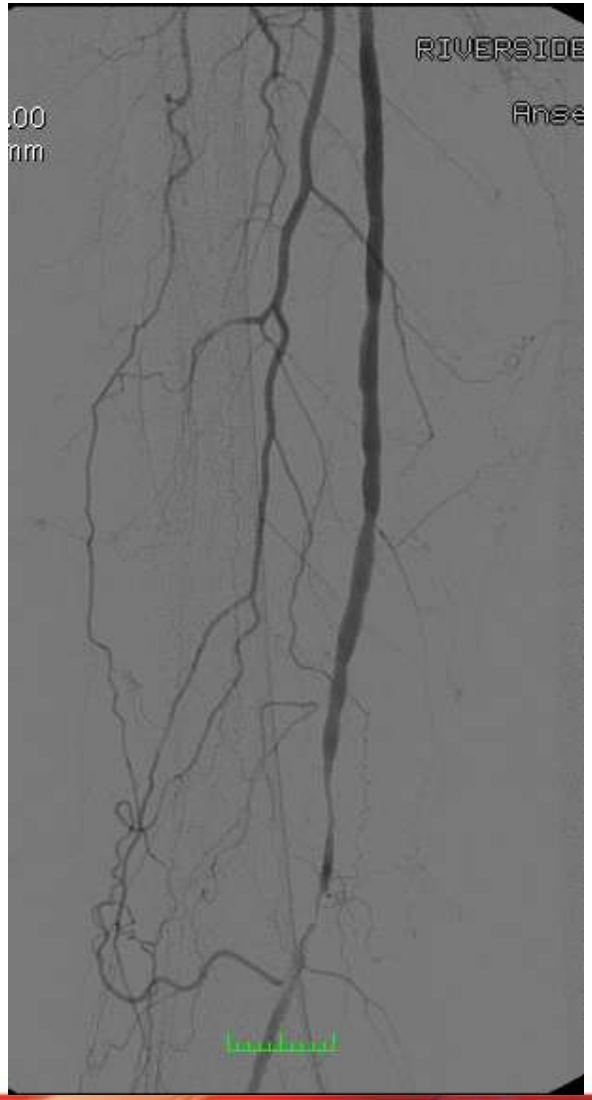
Rational

+ **Further bypass futile**
+ **Endovascular relief of symptoms higher than restenosis rate**
+ **Discrepency of SFA to popliteal size**
+ **Repeatable**

6 months later

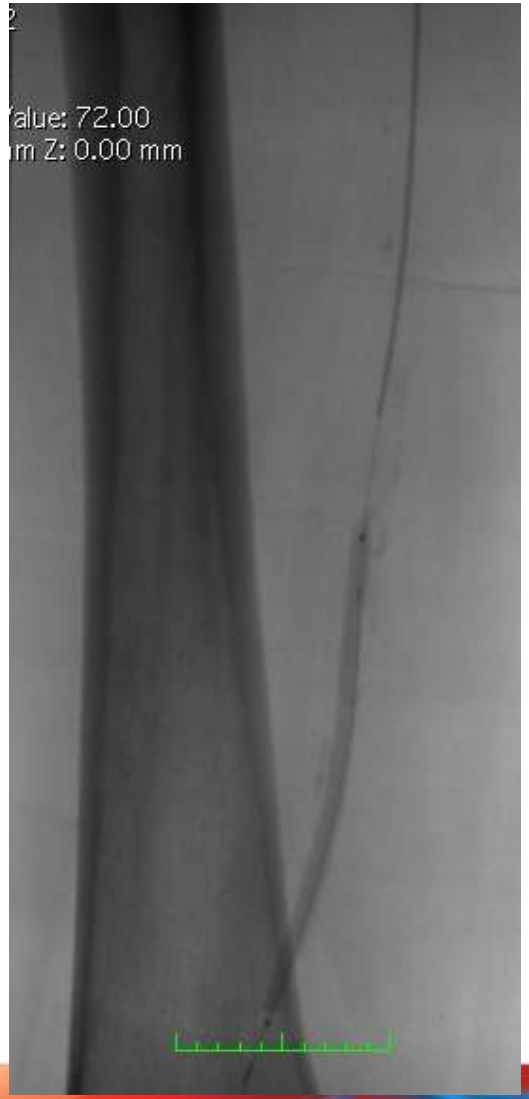
- Patient without rest pain but developed a large wound secondary to self-removal of a callous
- ABI .6 and no palpable pulse
- What now?

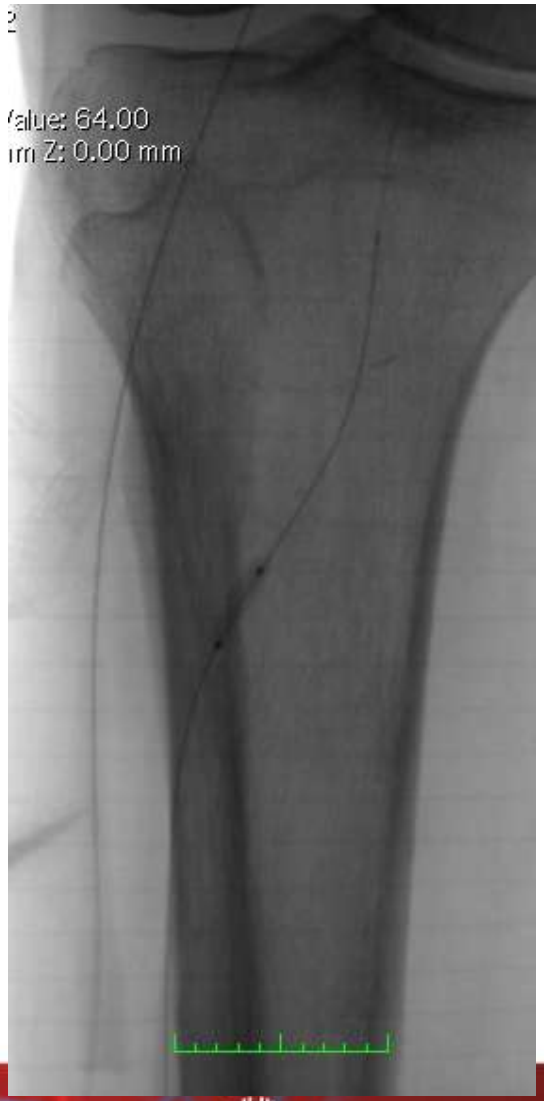



RIVERSIDE

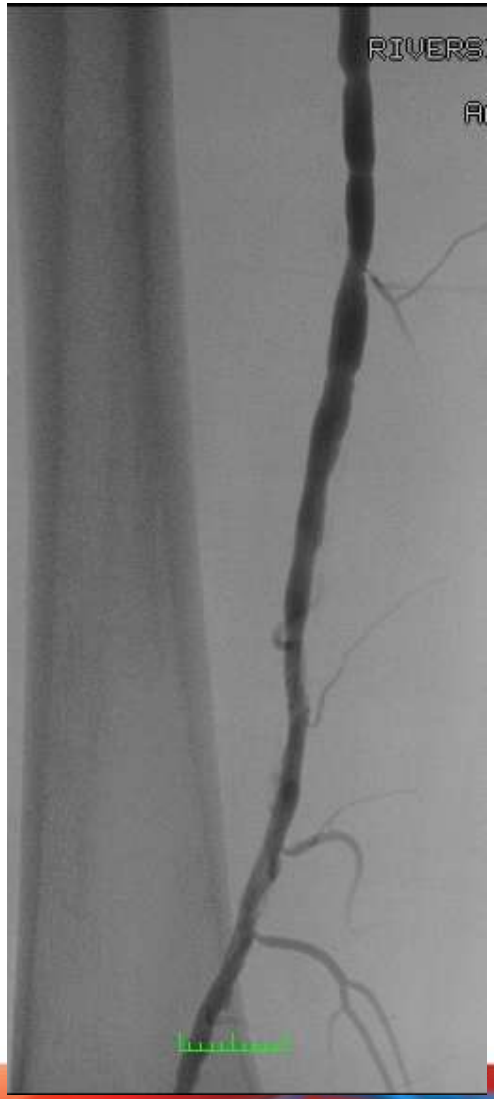

PTA


x Value: 142.00
) mm Z: 0.00 mm


alue: 72.00
m Z: 0.00 mm


alue: 64.00
m Z: 0.00 mm


RIVERS

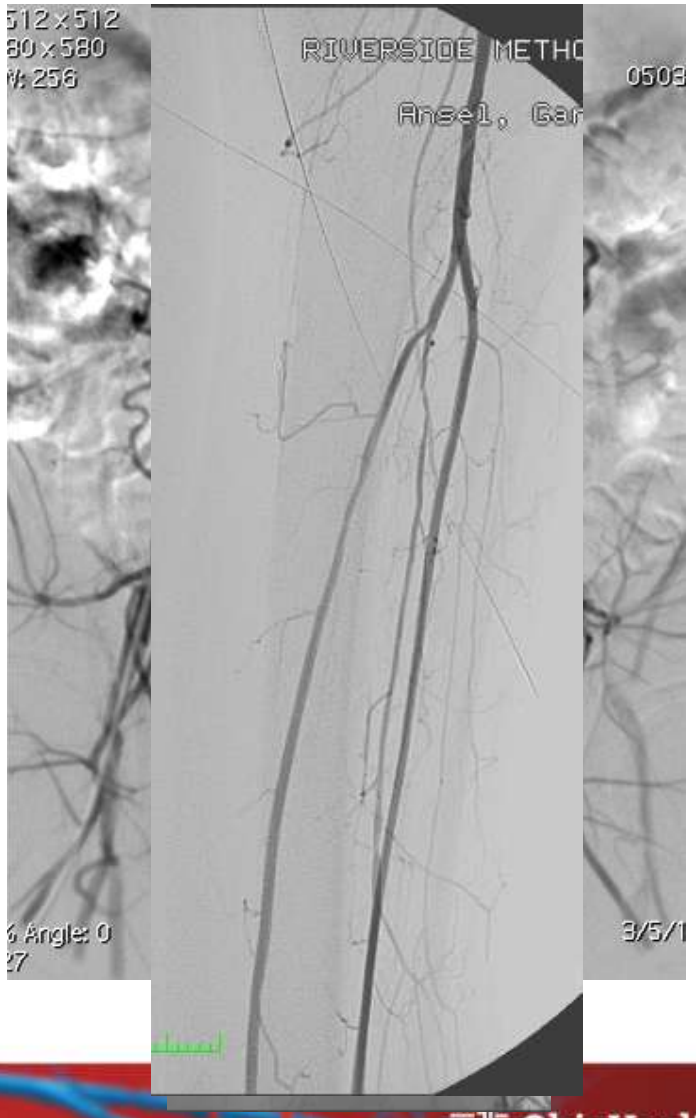

RIVERS

CASE

- ABI .89
- Palpable DP pulse
- Still healed for 5 years before sudden death

Case

- Male, Age 60, HTN and CAD. Smoker,
- CLI: toe gangrene
- ABI .28
- CTA
  - *Rt common iliac ostial 90%*
  - *Lt common iliac 100%*
  - *Lt SFA distal 100%*
- Plan Contralateral access to begin and bilateral access to finish



How to proceed ?

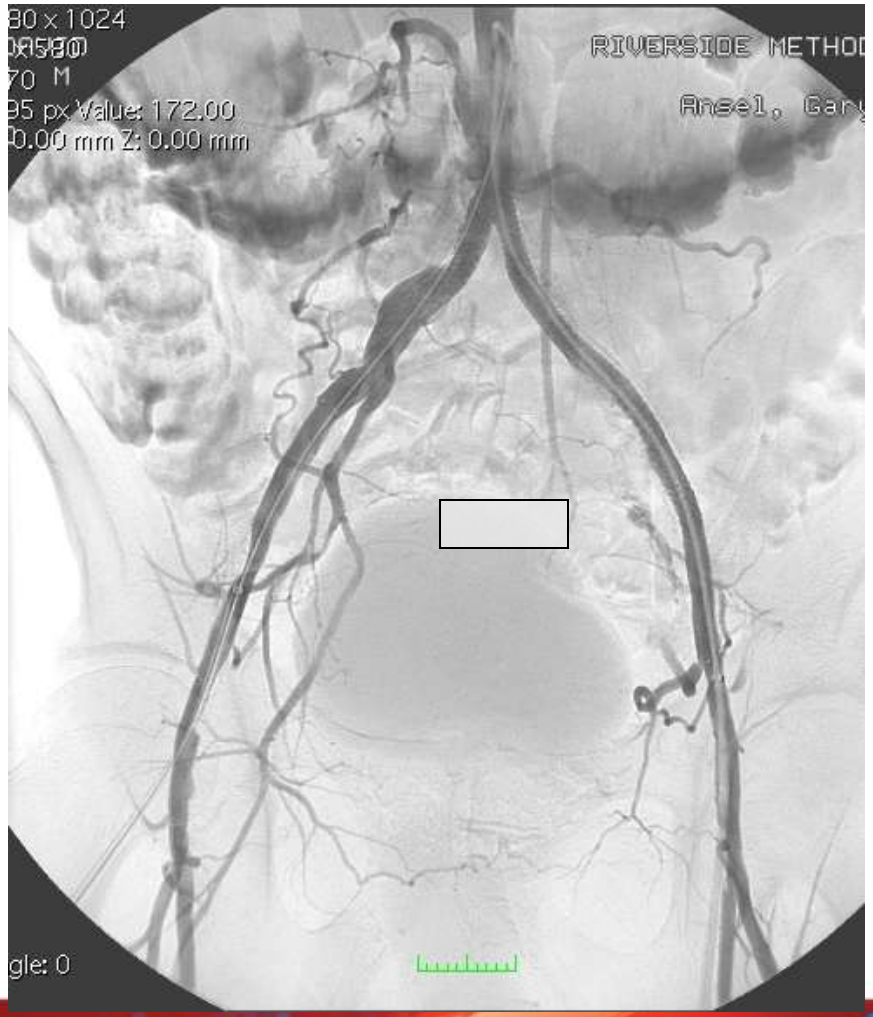
1. Conservative Treatment ?
2. Aortobifemoral bypass with fempop bypass
3. Iliac stenting with SFA PTA/stent

Adopted Strategy: Option 3, Bilateral iliac stenting with Lt SFA Intervention

Rational

+ **Poor surgical candidate**
+ **Durable iliac procedure**
+ **Endo outpt and low risk**

Adopted Strategy: Option 3, Bilateral iliac stenting with Lt SFA Interventi

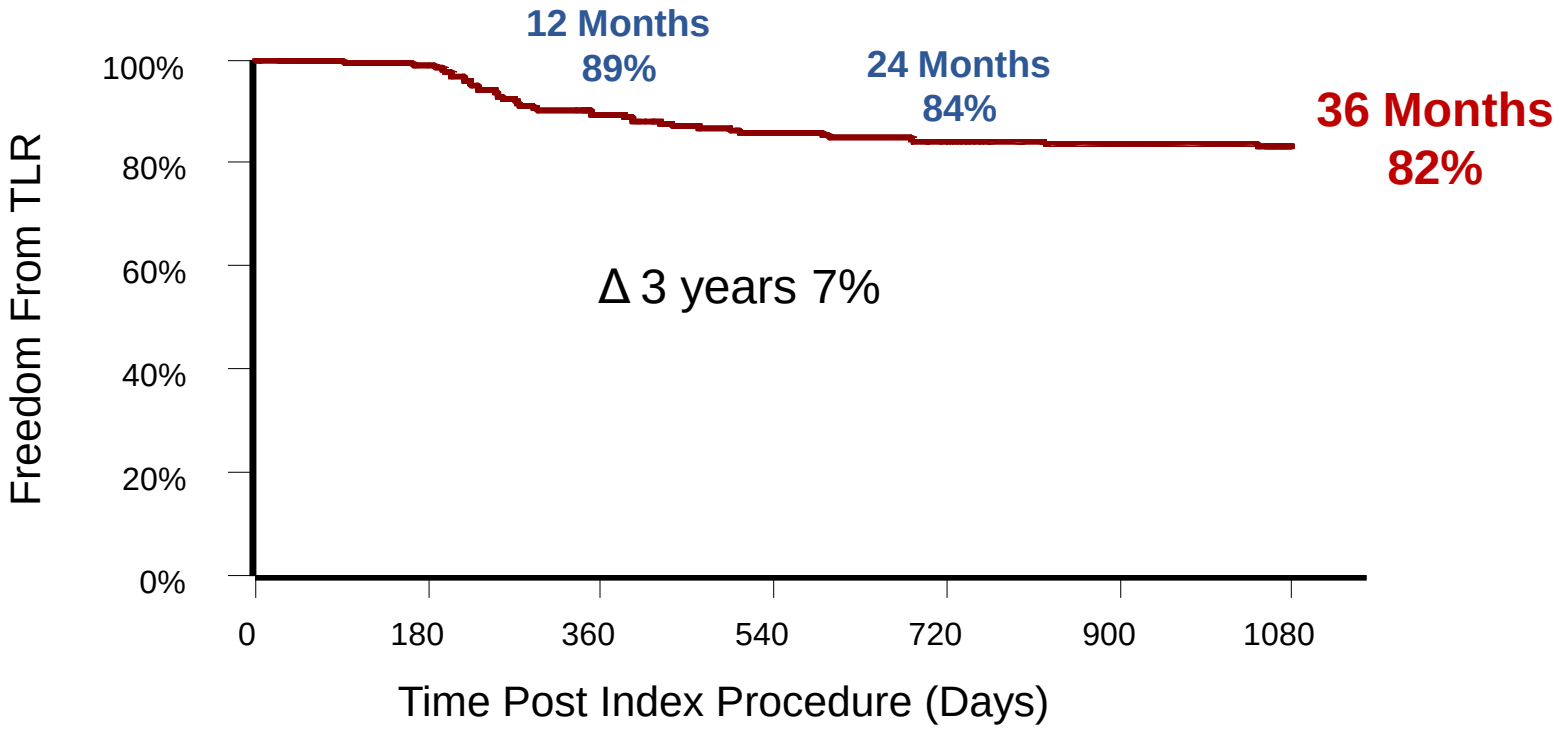


Outpatient Procedure

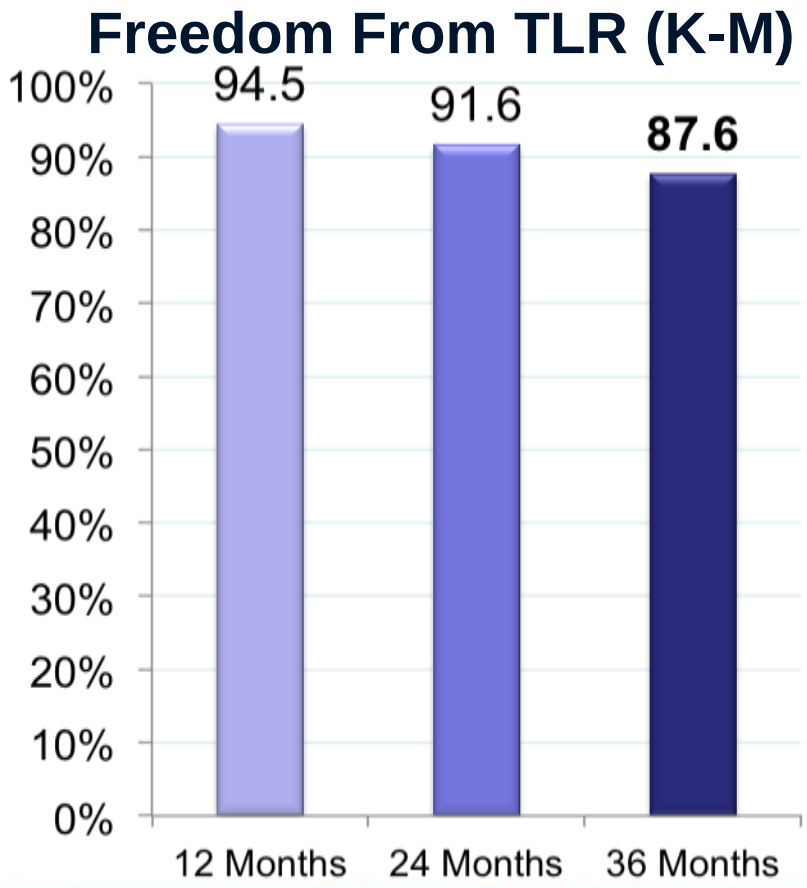
Technology Changes that Have Improved Outcomes

Compression Resistant Stent

SUPERB TRIAL:
Maintained Patency from 1 to 3 Years



Improved outcomes in Severe Calcification



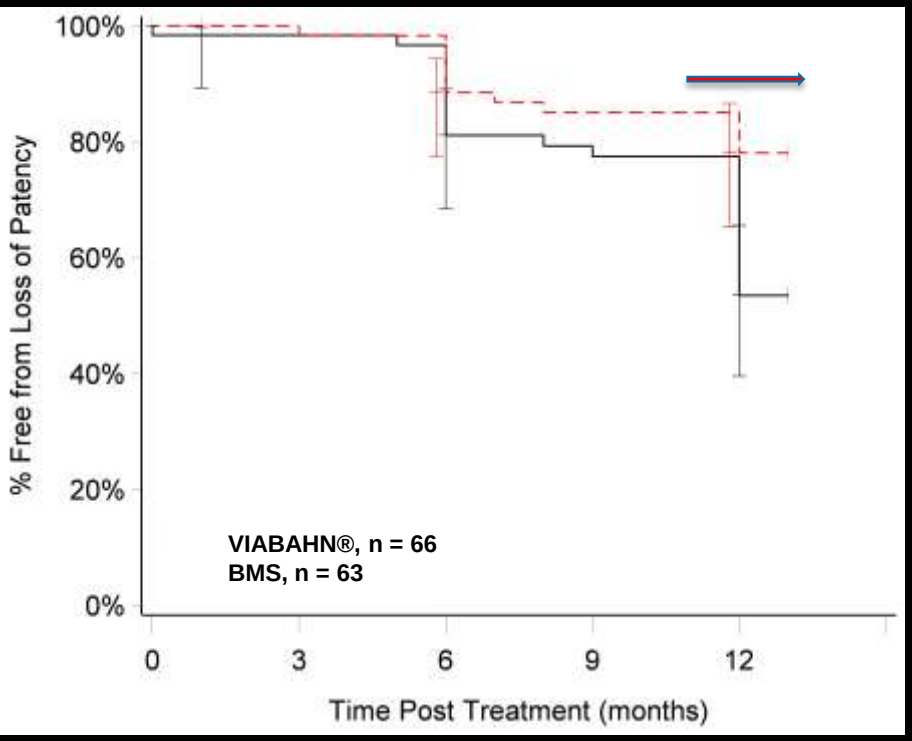
Superb Severe Calcification Subset	
Severe calcification	45%
Patency (VIVA 1 year)	89%

Severe Ca++ defined as1cm either side vessel

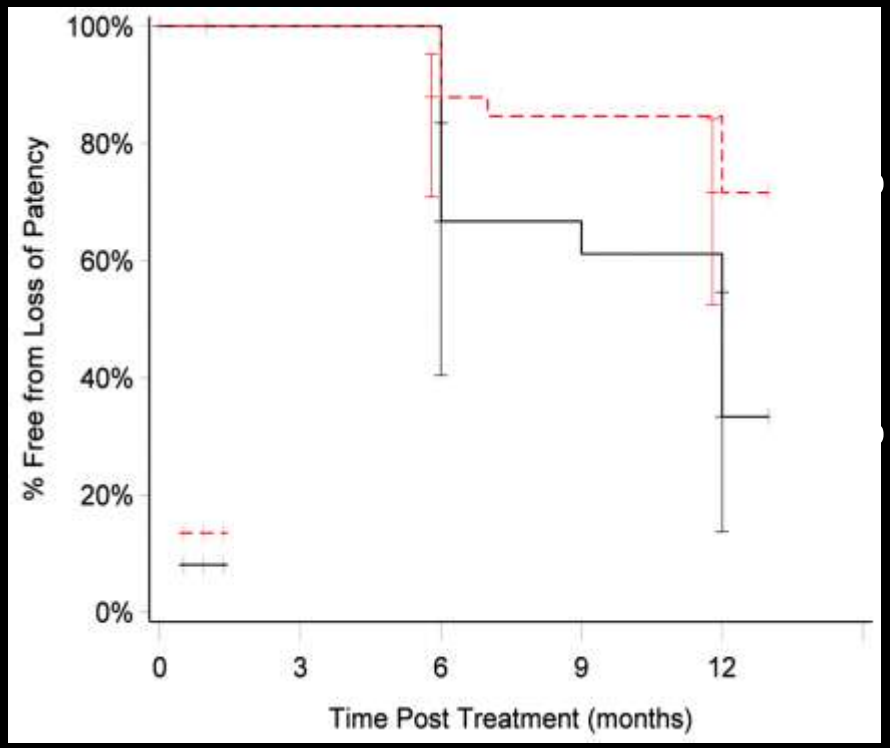
Acute Effect of Resistive Stent SUPERA

Courtesy Scheinert

Stent graft Option: VIASTAR:Primary Patency



All Lesions



Lesions ≥ 20 cm

Time Post Treatment (months)

SG (non-heparin) Randomized Comparison to Surgical Prosthetic Bypass

N = 86 pts (100 limbs)
- Stent graft 50
- Surgical bypass 50

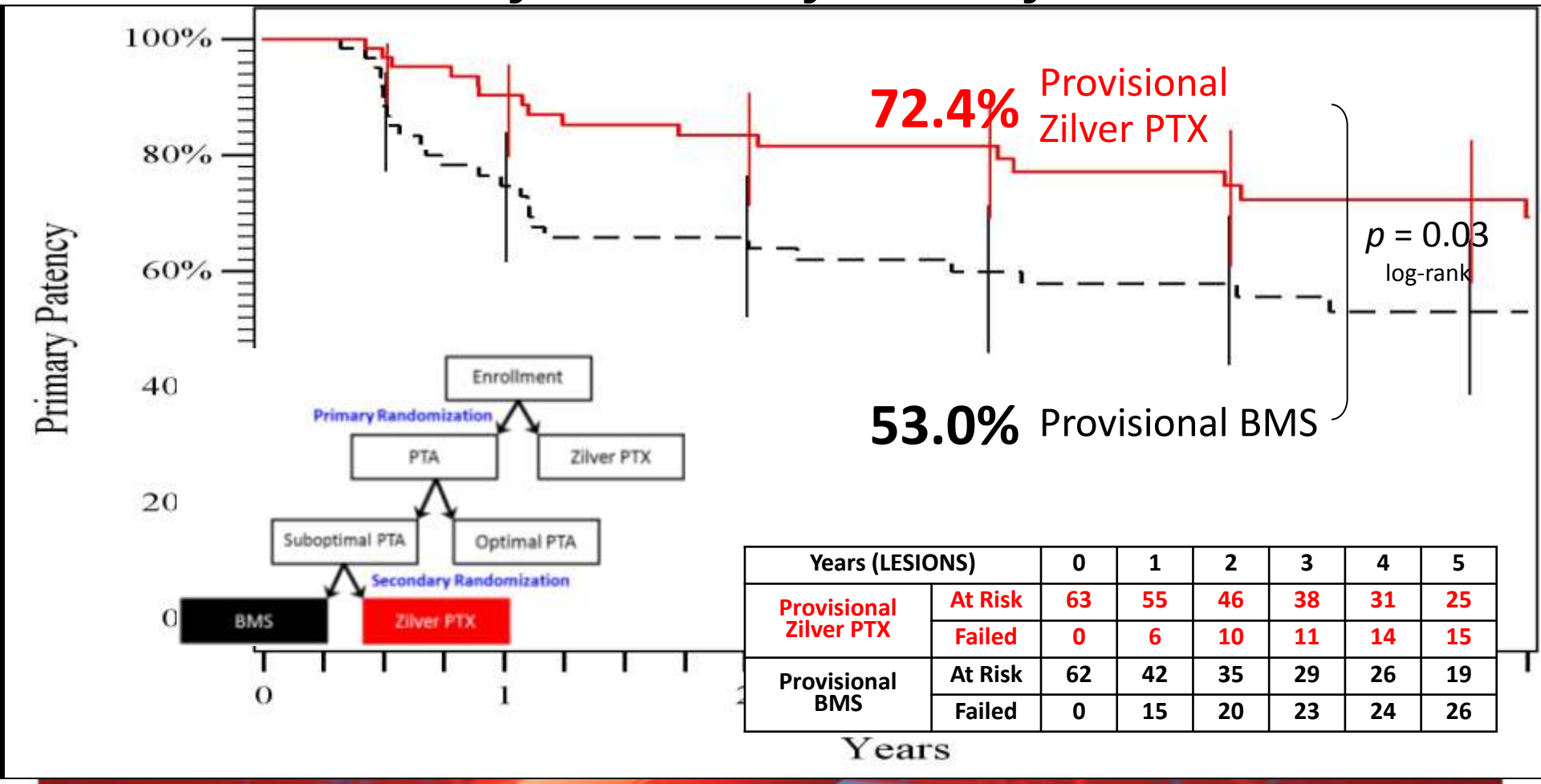
Mean stent graft treatment length = 25.6 cm

	SG	Bypass
1-year patency		
+ **Primary**	**73.5%**	**74.2%**
+ **Secondary**	**83.9%**	**83.7%**
2-year patency		
+ **Primary**	**62%**	**65%**
+ **Secondary**	**73%**	**75%**

Kedora et al J Vasc Surg 2007;45:10-16

McQuade et al. J Vasc Surg. 2009 Jan;49(1):109-15

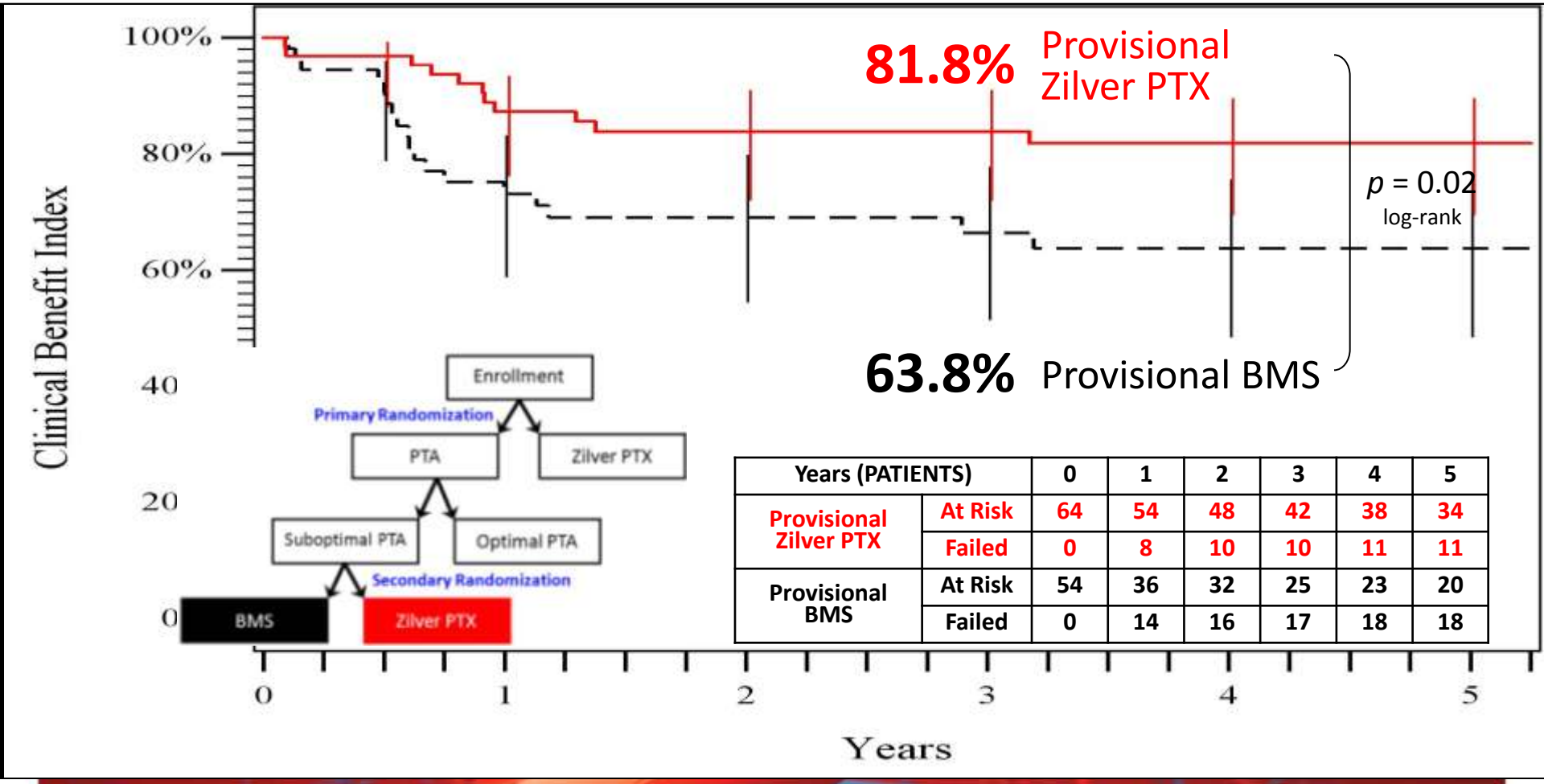
Druge Coated Stents Now in PV as well
5-year Primary Patency



Years (LESIONS)		0	1	2	3	4	5
Provisional Zilver PTX	At Risk	63	55	46	38	31	25
	Failed	0	6	10	11	14	15
Provisional BMS	At Risk	62	42	35	29	26	19
	Failed	0	15	20	23	24	26

At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to BMS

DCB 5-yr Results: Provisional Zilver PTX vs. BMS



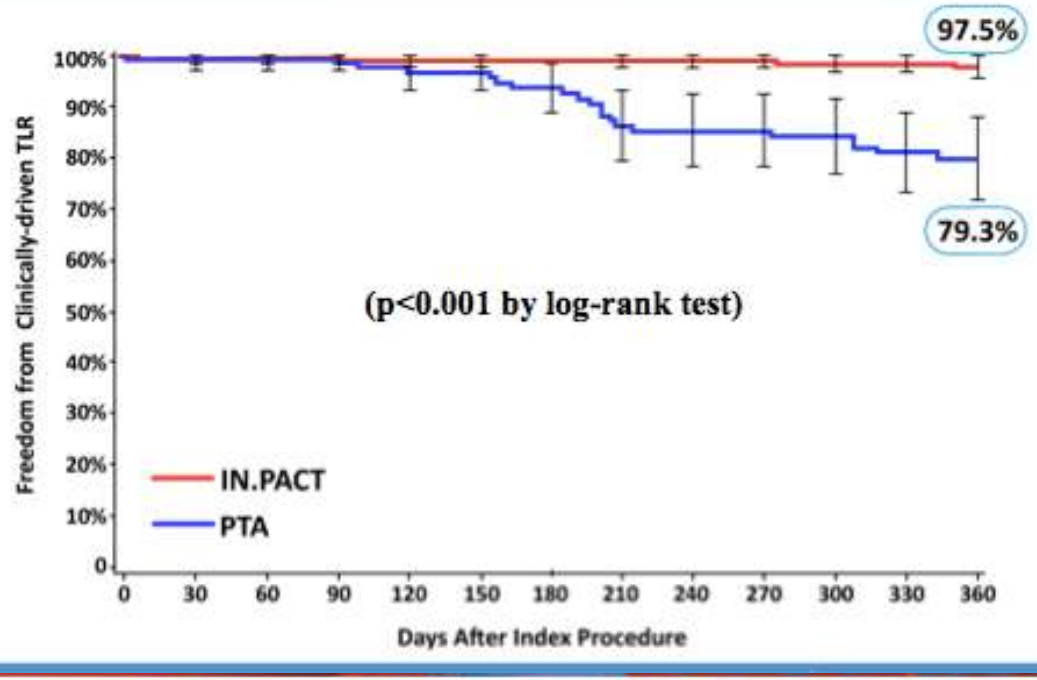
Years (PATIENTS)		0	1	2	3	4	5
Provisional Zilver PTX	At Risk	64	54	48	42	38	34
	Failed	0	8	10	10	11	11
Provisional BMS	At Risk	54	36	32	25	23	20
	Failed	0	14	16	17	18	18

At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss

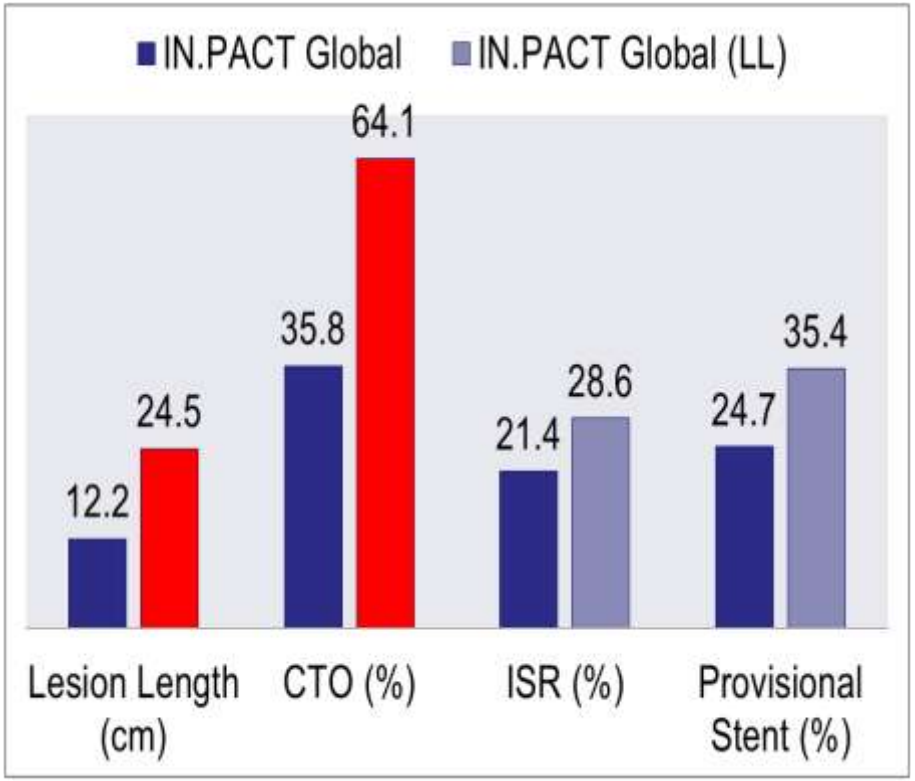
Drug Coated Balloons Leaving Nothing Behind

ALL ITT, 12-month Clinically-driven TLR

	IN.PACT	PTA	*p*
Clinically-driven TLR [1]	2.4%	20.6%	*<0.001* [2]



(≥15cm) Long Lesion Subset



- TLR for long lesion subset compares favorably to full cohort
  - *2-fold increase in lesion length*
  - *~ 2-fold increase % CTO*
- Longer lesions require more use of provisional stents

IN.PACT Global Full Cohort vs. (≥15cm) Lesion Subset 12-months Results

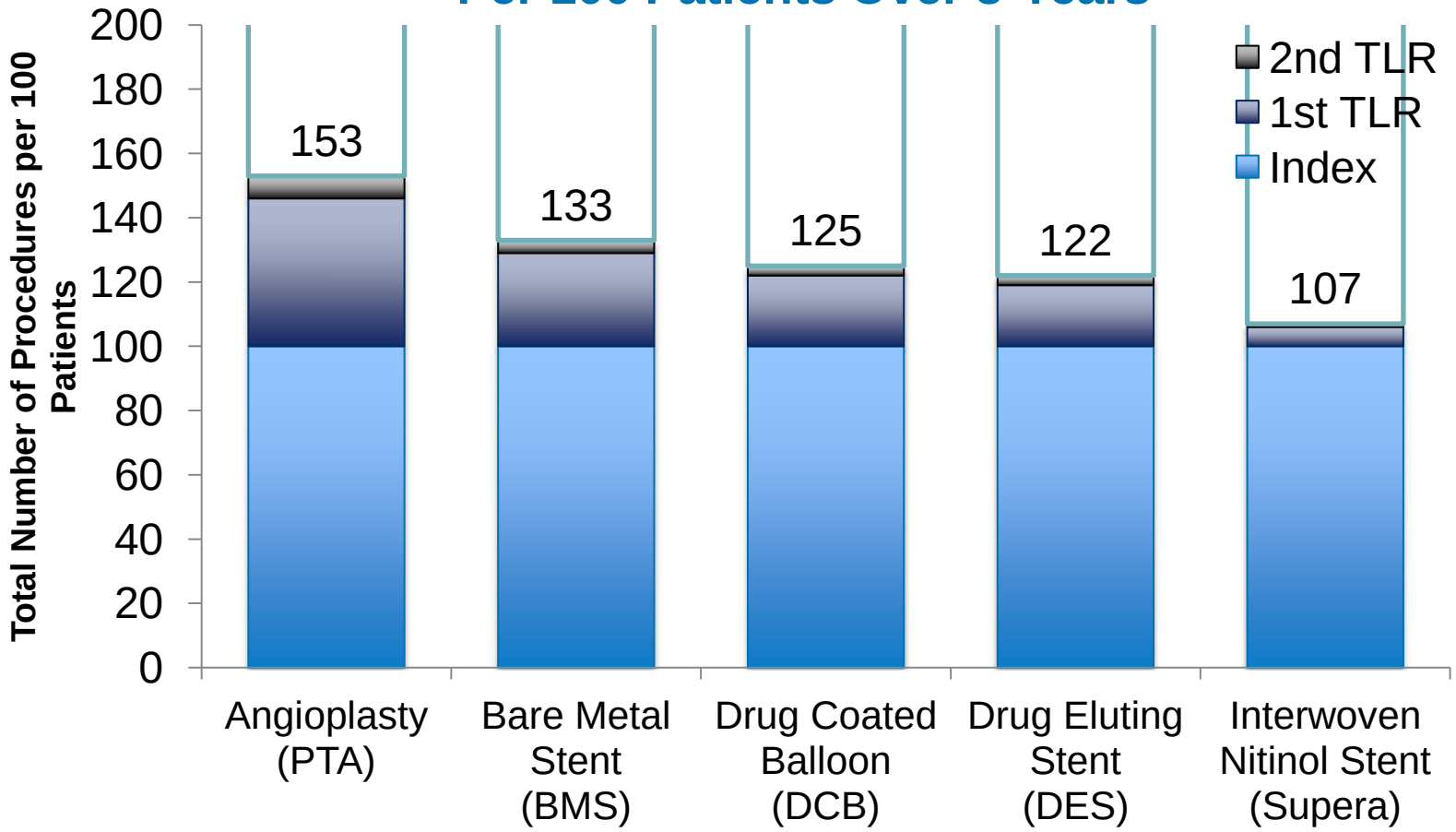
	IN.PACT Global Long Lesion subset N=227	IN.PACT Global N=655
CD-TLR	11.7%	8.7%
CD-TVR	12.2%	9.5%
Thrombosis	5.1%	3.8%
Target Limb Major Amputation	0.0% (0)	0.3% (2)

What of the Economics of All of This?

Pass through for DCB

- Have to use new fee code
- Variables
  - Cost to charge ratio from hospital
  - Medicare cost factor then calculated
  - Also takes into account device offset
    - PTA approx $1830
    - Stent approx $3000
    - Atherectomy $3600

Results: Total Number Of Procedures Per 100 Patients Over 3-Years



Number of revascularization procedures calculated using economic model

Risk of a second TLR is assumed to be the same as the risk of the first TLR for a given therapy

Results: Payer Perspective
Cost To Medicare Per Patient Over 3-Years

Treatment	Cost to Medicare Per Patient Over 3-Years
Bare Metal Stent (BMS)	$16,158
Angioplasty (PTA)	$15,166
Drug Eluting Stent (DES)	$14,845
Drug Coated Balloon (DCB)	$13,421
Interwoven Nitinol Stent (INS)	$13,036

Analysis based on 2015 Medicare national average payment rates

Results: Provider Perspective
Hospital Remaining Payment Over 3-Years

Treatment	Total Hospital Remaining Payment* *(per 100 patients over 3 years)*	Total Number of Procedures *(per 100 patients over 3 years)*	**Average Hospital Remaining Payment* per Procedure** *(over 3 years)*
INS	$1.06M	107	**$9,926**
BMS	$1.31M	133	**$9,885**
DES	$1.14M	122	**$9,375**
PTA	$1.31M	153	**$8,588**
DCB	$1.05M	125	**$8,442**

** Remaining payment = facility reimbursement – device costs*

Analysis based on 100 index procedures per treatment strategy

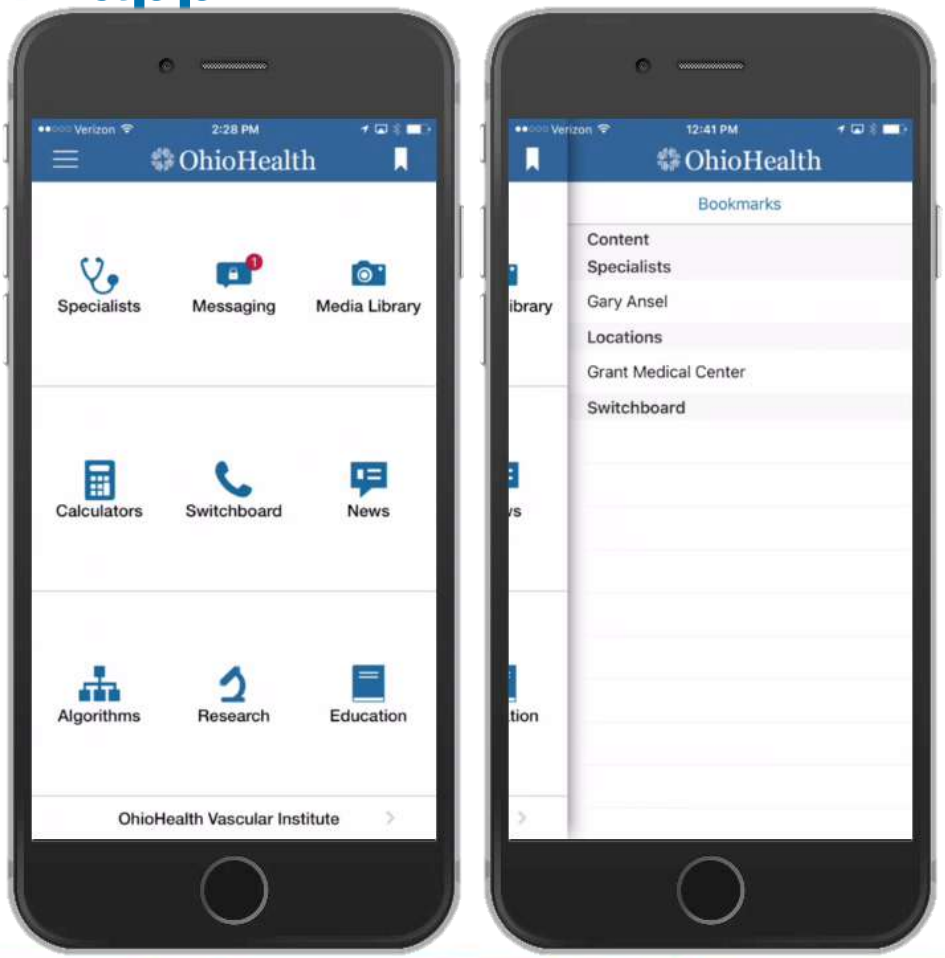
Summary

Thank You
Lets Stay in Touch

OhioHealth Vascular Institute App
OHVI app

Home Screen

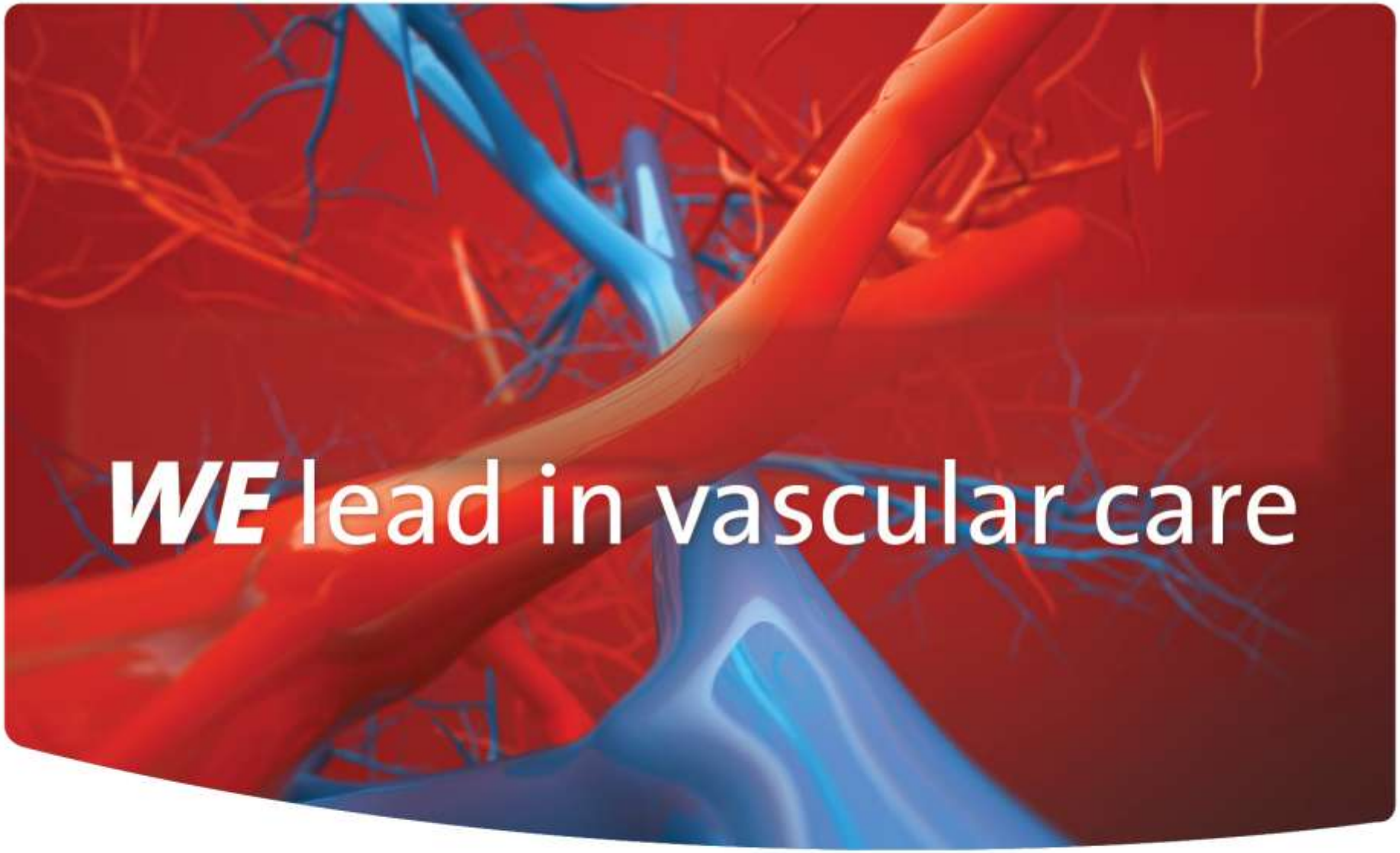
+ 9 widgets
+ Finger print sign on for Iphone
+ Bookmark tab
+ User Profile
+ Text messaging
+ Contact info and Insurance references
+ PE risk and GFR calculators



OHVI App

Instructions for Download

- For Apple users, go to the App Store and search OHVI and download
- For Android users, go to Google Play and search OHVI and download
- Requires physician NPI number to register



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