Current Vascular and Endovascular Management in Diabetic Vasculopathy

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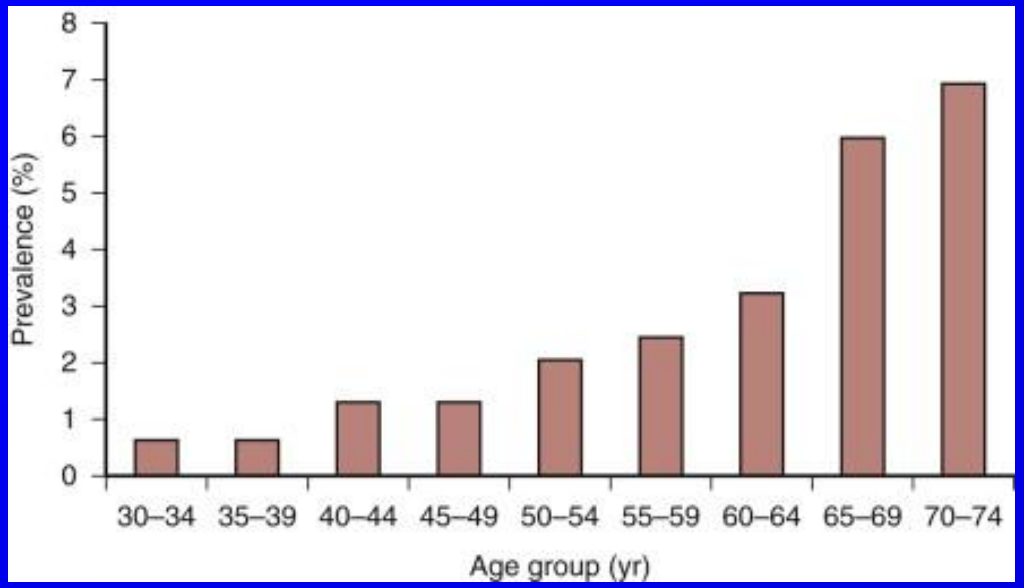
Peripheral artery disease (PAD)

- Chronic lower extremity ischemia
- Manifestations of PAD (degree of muscle ischemia)
  - Asymptomatic
  - Intermittent claudication (IC)
  - Critical limb ischemia (CLI)

Prevalence of symptomatic PAD

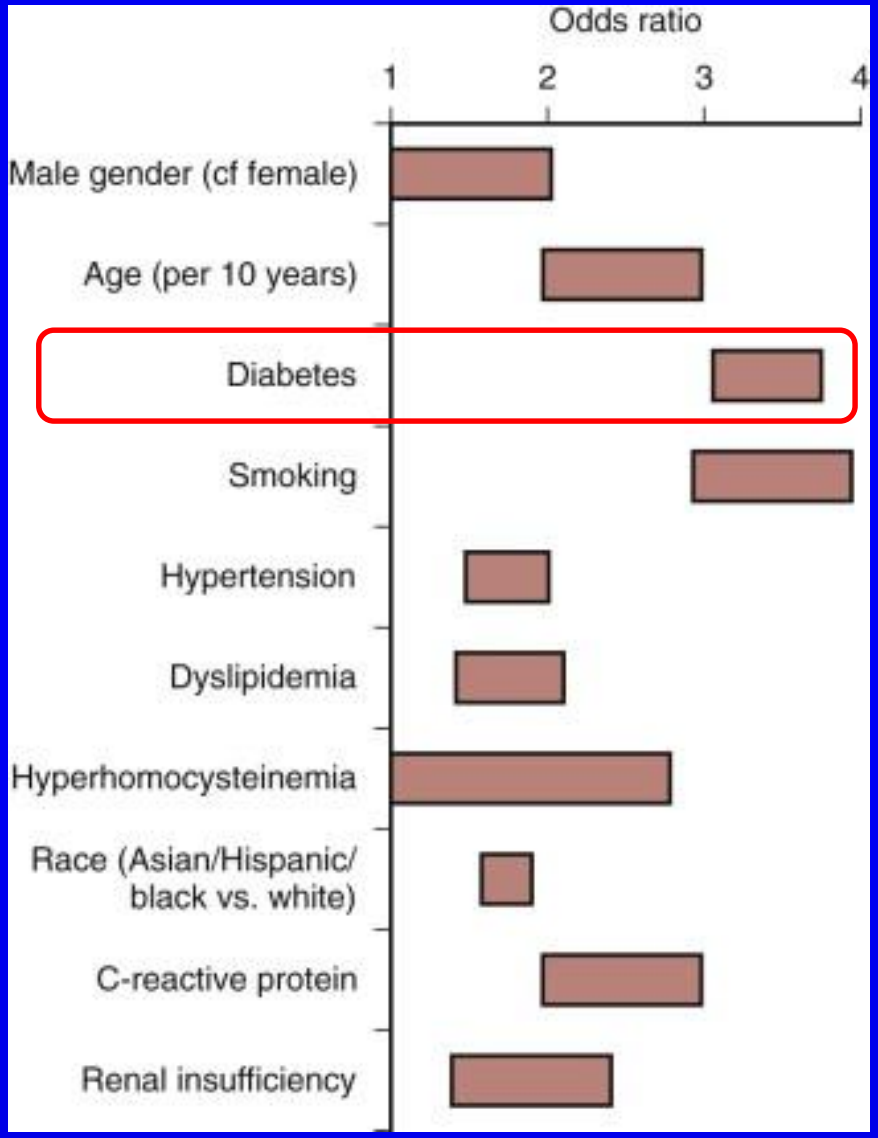


Stages of chronic limb ischemia

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

Critical limb ischemia (CLI)

Risk factors for symptomatic PAD



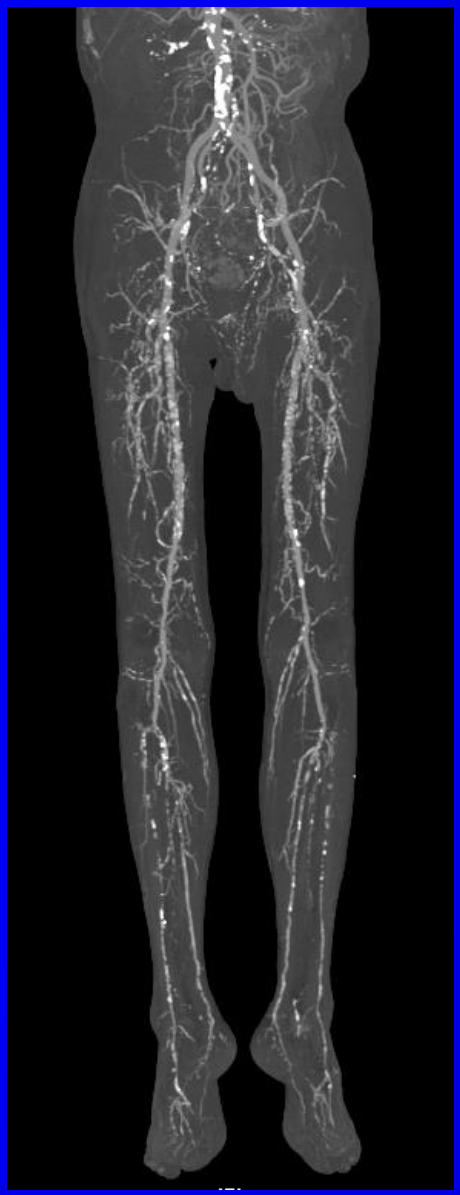
PAD in diabetes

- More common (~x2) intermittent claudication

- PAD in DM
  - 26% increased risk of PAD / 1% increase HbA1c
  - Insulin resistance
  - More aggressive compared to non-diabetes
    - early large-vessel involvement
    - major amputation risk : x5-10
  - Foot ulcers and infections
    - Peripheral neuropathy
    - ↓ resistance to infection
  - Aggressive control of blood glucose levels
    - HbA1c <7.0% or as close to 6% as possible

Characteristics of diabetes vasculopathy

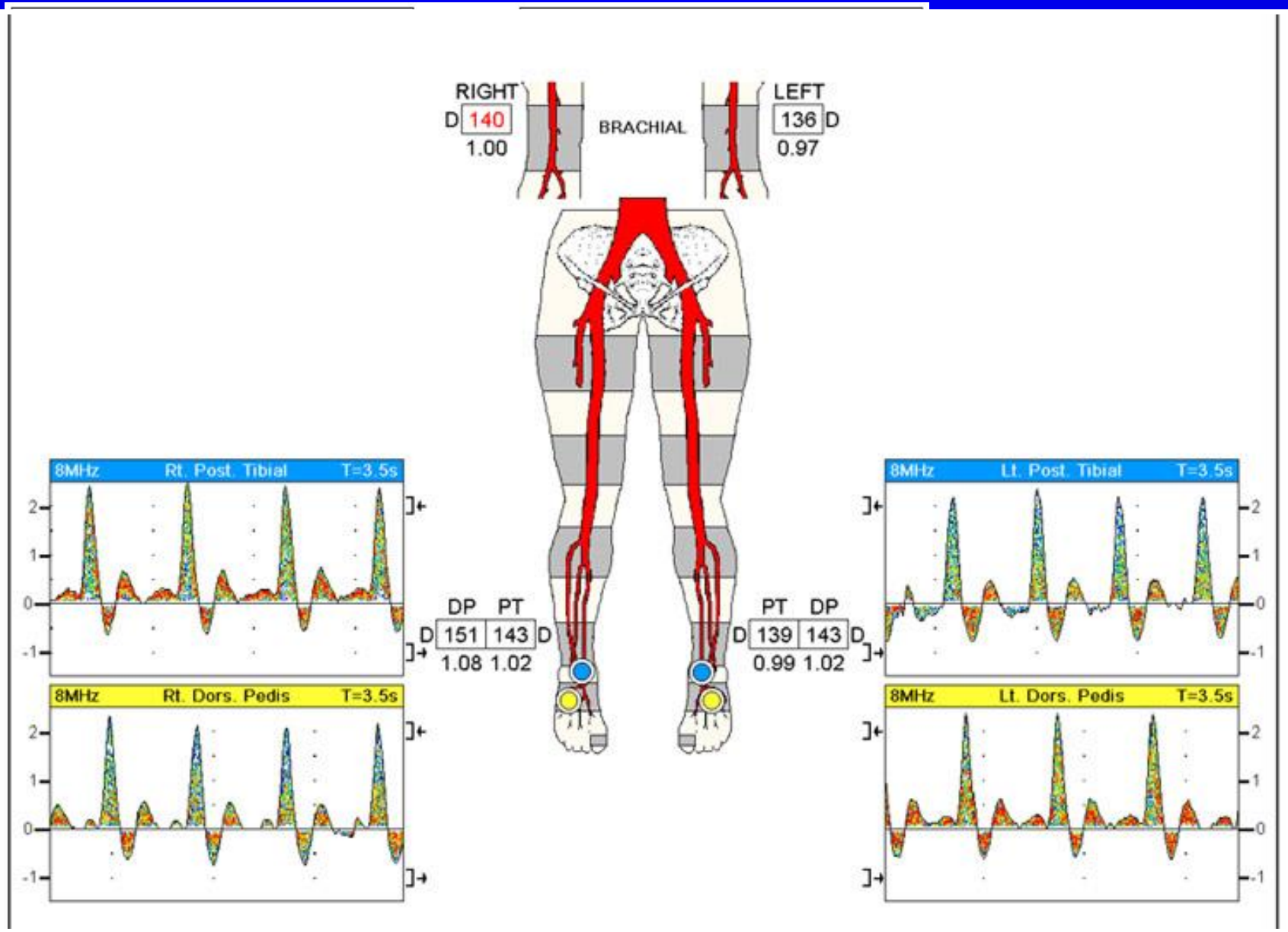
- Diffuse multilevel involvement
- Infragenicular arteries
- Heavy calcification
- Poor collateral developments
- Microangiopathy
- Macroangiopathy



Noninvasive Diagnosis of PAD

- Non-invasive vascular laboratory(혈관검사실)
  - ABI (ankle-brachia index)
  - Toe pressure or toe-brachial index (TBI)
  - Exercise treadmill test
  - Segmental limb pressure
  - Pulse volume recording (PVR)
  - Digital PPG

ABI (Ankle-brachial index)



Toe pressure & toe-brachial index

- Long-standing diabetes, renal failure
  - Incompressible tibial artery
  - Falsely high systolic pressure
  - Non-compressible
    - Ankle pressure ≥250mmHg
    - ABI >1.40
- Toe pressure
  - Useful in DM
  - 30mmHg less than ankle pressure
  - <40mmHg : impaired wound healing
  - Toe-brachial index (TBI) <0.70
  - Limitation :
    - inflammatory lesions, ulceration, tissue loss

Radiologic diagnostic modality

- Duplex scan
  - Easy to perform : accessibility
  - No contrast media and radiation
  - Operator-dependent
  - Calcium in diabetes
- MR angiography
  - No radiation
  - Gadolinium toxicity: nephrogenic systemic fibrosis
  - Overestimate stenosis
- CT angiography
  - Most-frequently used in Korea : cheap, popular, quick
  - Radiation and contrast media use
  - Calcium in diabetes
- Digital subtraction angiography
  - Most accurate in diabetes
  - Radiation and contrast media use
  - Invasive : femoral puncture
  - Pre-intervention purpose : intention-to-treat

Treatment of PAD
Claudicants

- Risk factor modification
  - Smoking cessation
  - LDL cholesterol < 100 mg/dL
  - LDL < 70 mg/dL if high risk (eg. DM)
  - HbA1c < 7.0%
  - BP < 140/90 mmHg
  - BP < 130/80 mmHg if diabetic or renal disease
  - Antiplatelet therapy

Treatment of PAD
Claudicants

- Supervised exercise therapy
  - Treadmill or track walking
  - Sufficient intensity to bring on claudication, followed by rest
  - Over the course of a 30-60 min session
  - 3 times a week for 3 months

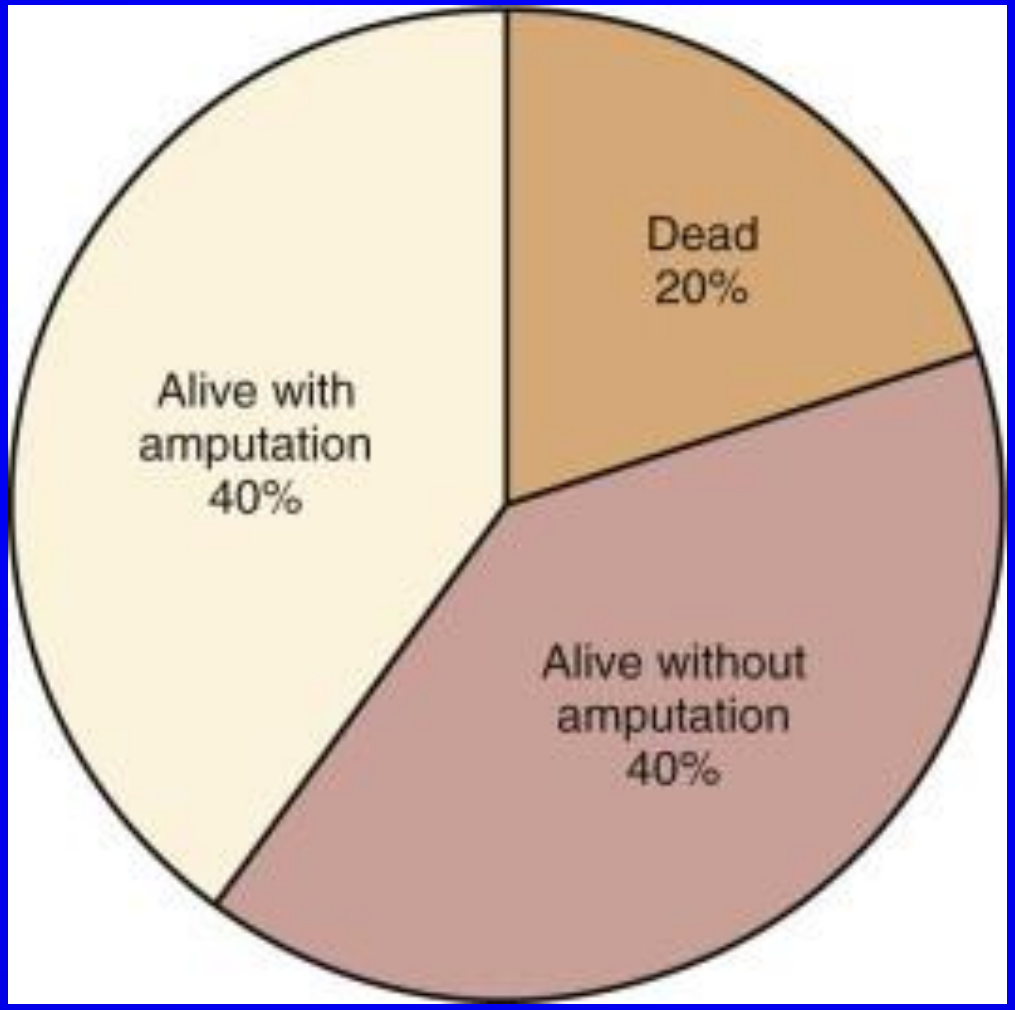
- Pharmacotherapy
  - Cilostazol (Pletaal): 1st drugs
  - Pentoxifylline (Trental)
  - Prostaglandin analogues

Critical Limb Ischemia in diabetes

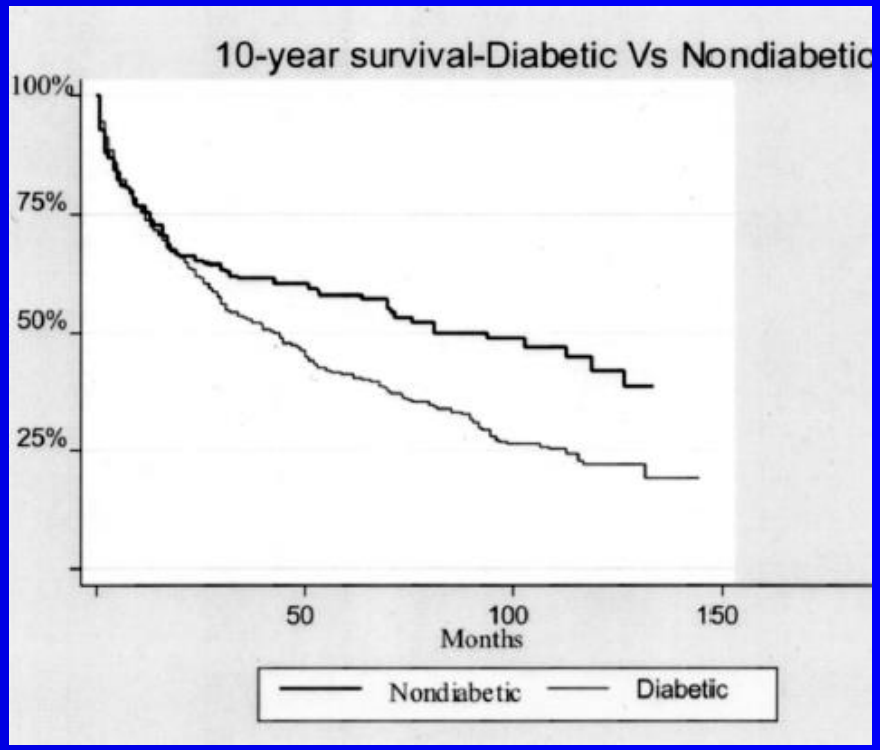
- Chracterized by
  - Occlusive rather stenotic lesions
  - Diffuse, long lesions
  - Multilevel lesions
  - Infrapopliteal lesions

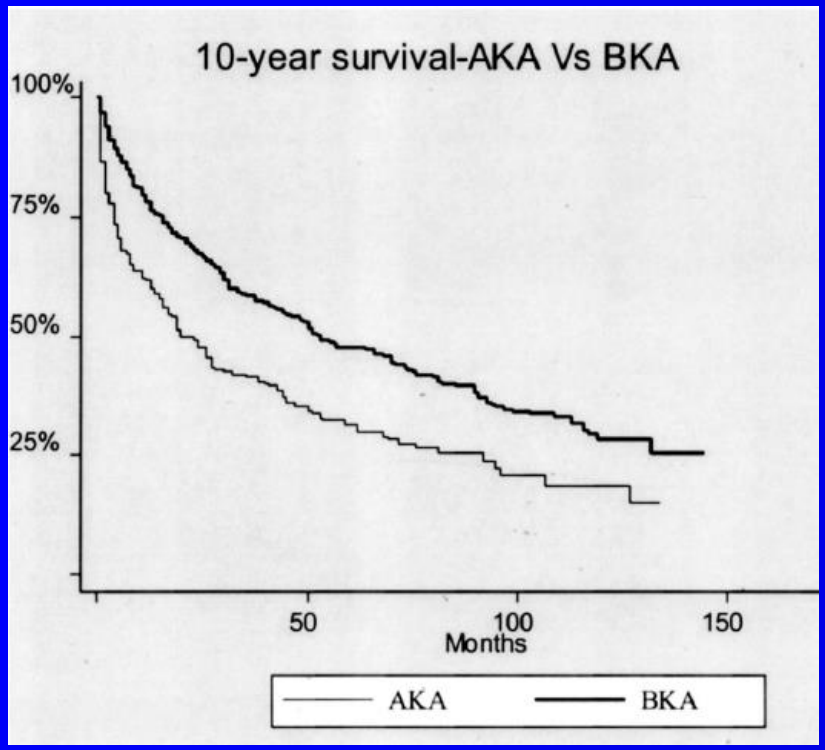
Most PAD in diabetes

1-Year Outcome of CLI



Survival of Amputees





Subramanian B, Anesth Analg 2005;100:1241-7

Indications or goals of below-the-knee (BTK) revascularization

- Indications
  - Patients with CLI for limb salvage
  - Not simple intermittent claudication

- Clinical goals
  - Limb salvage
  - Better wound healing
  - Pain relief
  - Early mobilization

Primary amputation vs. Revascularization

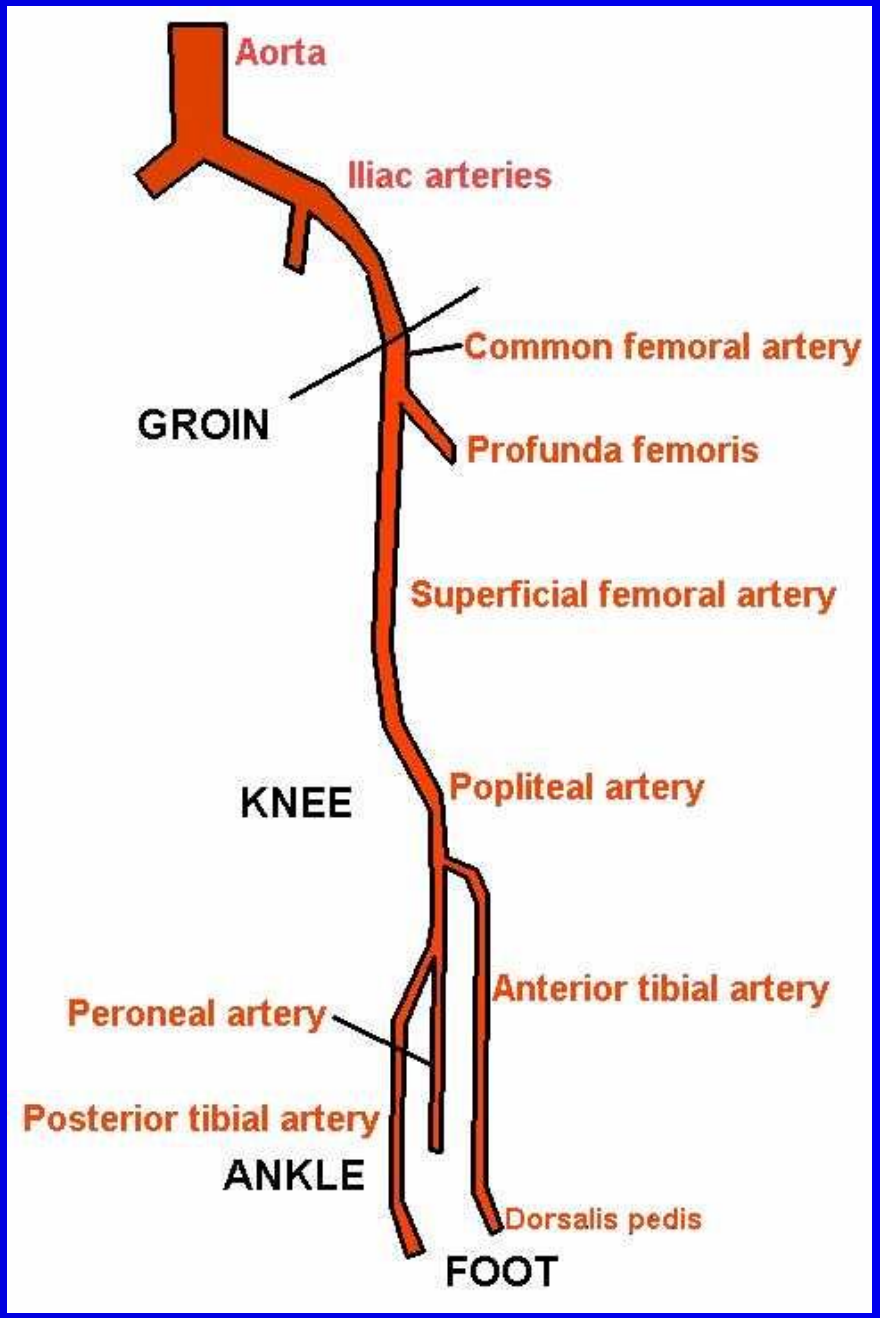
- Lower Extremity Grading System (LEGS) Score
  - Arteriographic findings
    - Stenosis or occlusion
    - Lesion length
  - Presentation
    - Claudication or critical limb ischemia
  - Functional status
    - Ambulatory or non-ambulatory
  - Comorbidities
    - Obesity, CAD, old age
  - Technical factors
    - Redo-procedure, available vein conduit, target vessel status, infection
- Recommended treatment
  - Low score : open surgery
  - Intermediate score : endovascular intervention
  - High score : primary amputation

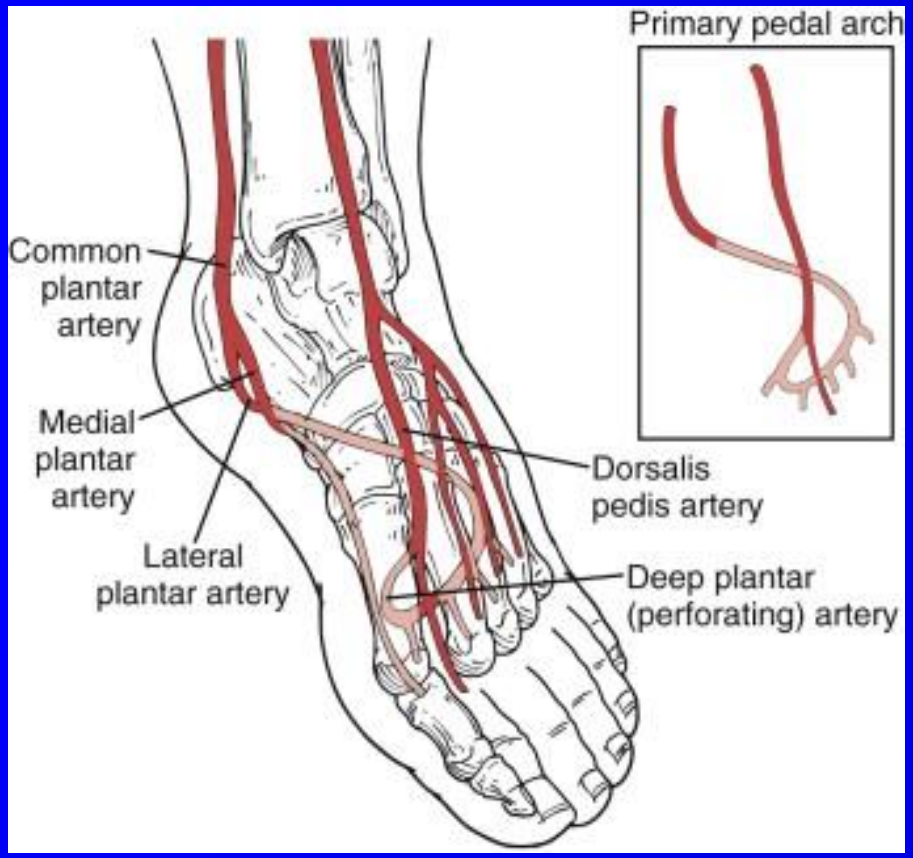
WIFI Classification for Risk of Amputation

Component	Score	Description		
W (Wound)	0	No ulcer (ischaemic rest pain)		
	1	Small, shallow ulcer on distal leg or foot without gangrene		
	2	Deeper ulcer with exposed bone, joint or tendon ± gangrenous changes limited to toes		
	3	Extensive deep ulcer, full thickness heel ulcer ± calcaneal involvement ± extensive gangrene		
I (Ischaemia)		ABI	Ankle pressure (mmHg)	Toe pressure or $TcPO_2$
	0	≥0.80	> 100	≥60
	1	0.60—0.79	70—100	40—59
	2	0.40—0.59	50—70	30—39
	3	<0.40	<50	<30
fI (foot Infection)	0	No symptoms/signs of infection		
	1	Local infection involving only skin and subcutaneous tissue		
	2	Local infection involving deeper than skin/subcutaneous tissue		
	3	Systemic inflammatory response syndrome		

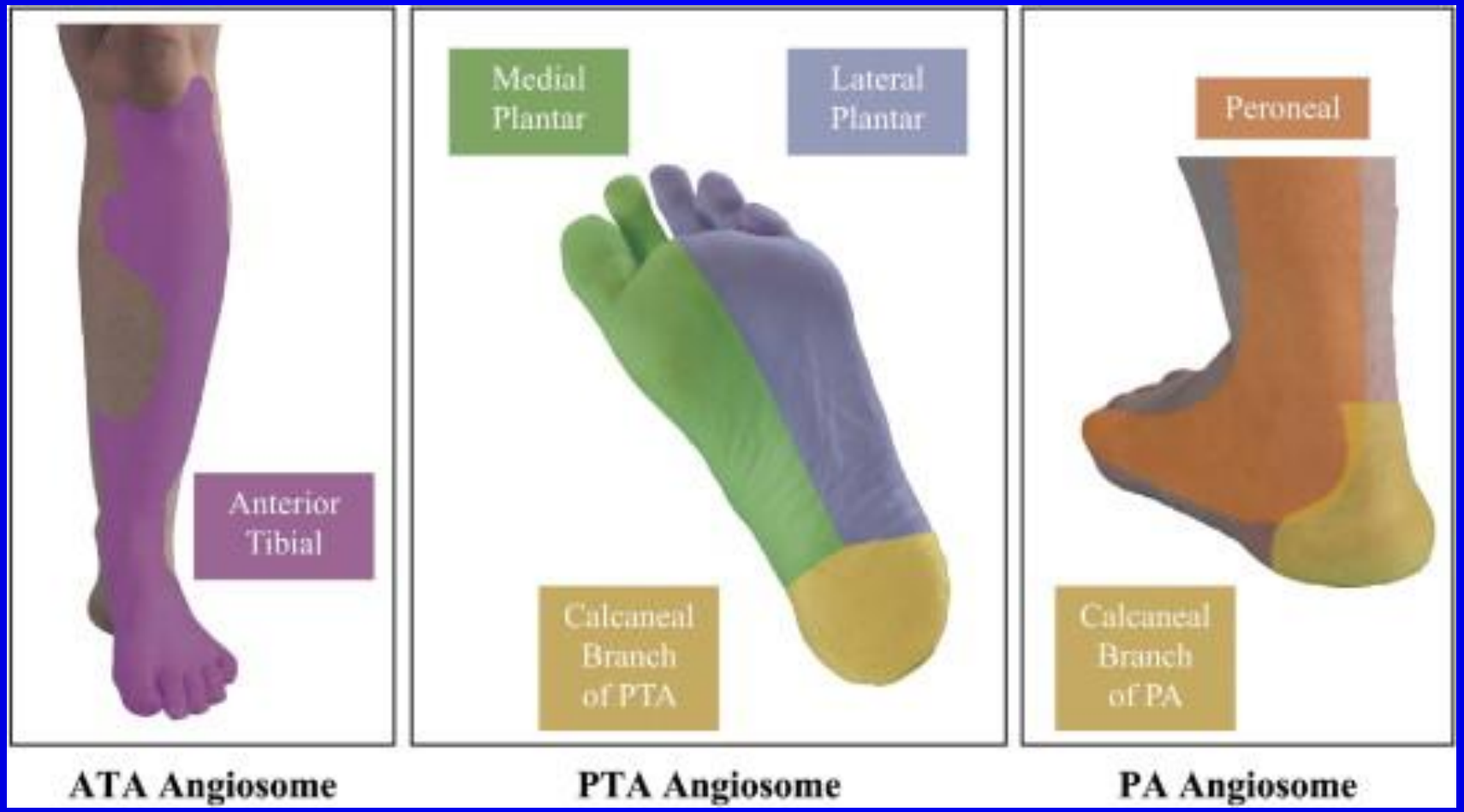
J Vasc Surg 2014;**59**:220—234

Vascular anatomy of leg





Angiosome concept



Revascularization option of PAD

- Endovascular intervention
- Surgical bypass
- Angiogenesis
  - Gene therapy
  - Stem cell

Endovascular Therapy for Limb Salvage

- Relatively new and continually evolving technology
  - **Recent advances**: DES, DCB hold promise
- Potential advantages
  - Less invasive: mortality and morbidity (?)
  - Fast recovery
- Potential disadvantage
  - Reduced efficacy: hemodynamics, durability
  - Risk of limb deterioration
  - May affect surgical options
  - Cost: frequent repeated treatments, symptom-free intervals
- Outcomes **poor** for more extensive disease, multi-level disease, major tissue loss, possibly diabetics

Infrainguinal Bypass Surgery for CLI

- Bypass with autogenous vein is the "gold standard"
- Results well documented in hundreds of reports:
  anecdotal > retrospective > randomized trials
- Versatile: results in complex situations (anatomic, patient related) well established
- Low mortality, good durability
- BUT-there are **limitations** and **risks**:
  - Wound and other complications
  - Prolonged recovery
  - Vein quality and availability
  - Technically demanding procedures
- Outcomes **poorer** for <u>suboptimal conduit, higher medical risk</u>

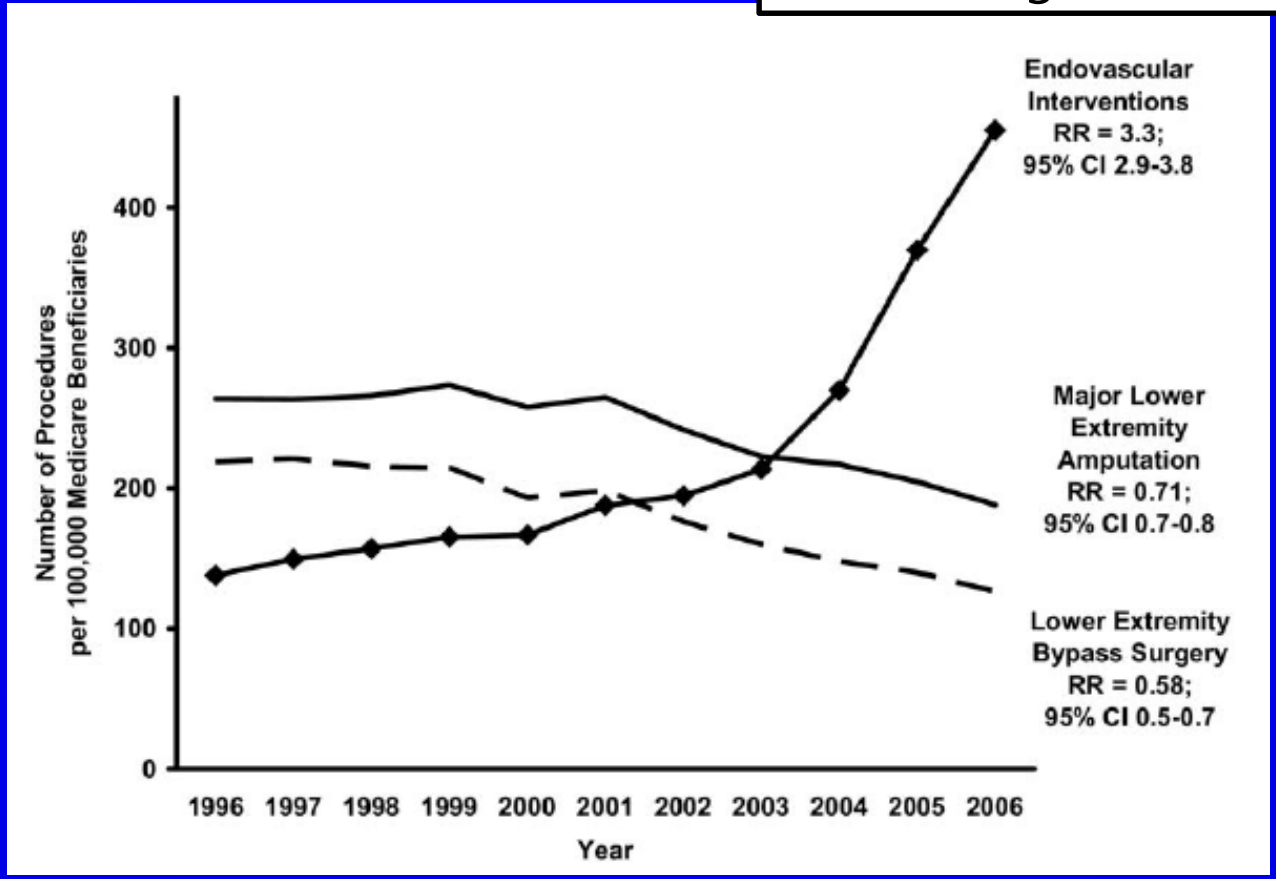
2011 ESC recommendation for PAD
Critical Limb Ischemia

Recommendations	Class[a]	Level[b]	Ref[c]
For limb salvage, revascularization is indicated whenever technically feasible.	I	A	302, 331, 336
When technically feasible, endovascular therapy may be considered as the first-line option.	IIb	B	302, 331
If revascularization is impossible, prostanoids may be considered.	IIb	B	338, 339

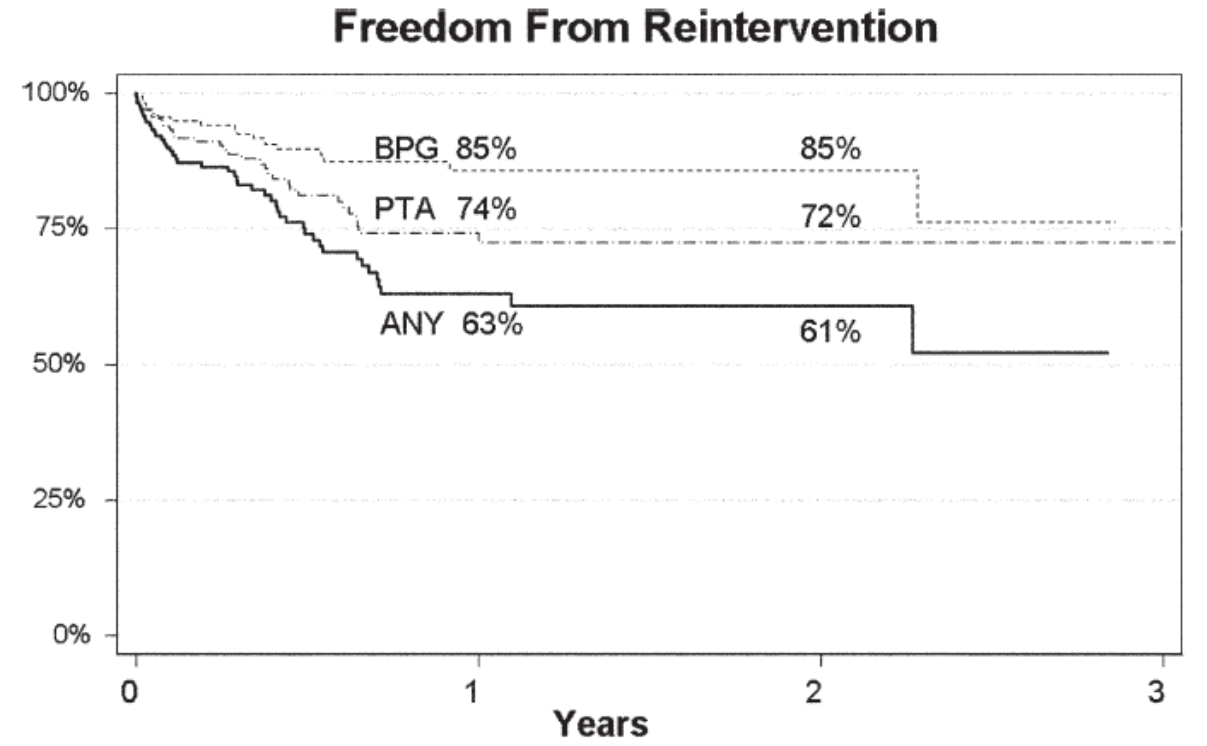
National trends in lower extremity bypass surgery, endovascular interventions, and major amputations

Philip P. Goodney, MD, MS,[a,b,c] Adam W. Beck, MD,[a] Jan Nagle, MS, RPh,[d] H. Gilbert Welch, MD, MPH,[b,c] and Robert M. Zwolak, MD, PhD,[a] *Lebanon and Hanover, NH; White River Junction, Vt; and Chicago, Ill*

J Vasc Surg 2009;50:54-60



Angioplasty is not durable



15% need BPG

26% need redo PTA @ 1 yr

41% failure rate

J Vasc Surg 2008;48:128-

Prior failed ipsilateral percutaneous endovascular intervention in patients with critical limb ischemia predicts poor outcome after lower extremity bypass

Brian W. Nolan, MD, MS,[a] Randall R. De Martino, MD,[a] David H. Stone, MD,[a] Andres Schanzer, MD,[b] Philip P. Goodney, MD, MS,[a] Daniel W. Walsh, MD,[a] and Jack L. Cronenwett, MD,[a] for the Vascular Study Group of New England, *Lebanon, NH; and Worcester, Mass*

J Vasc Surg 2011.;54:730-6

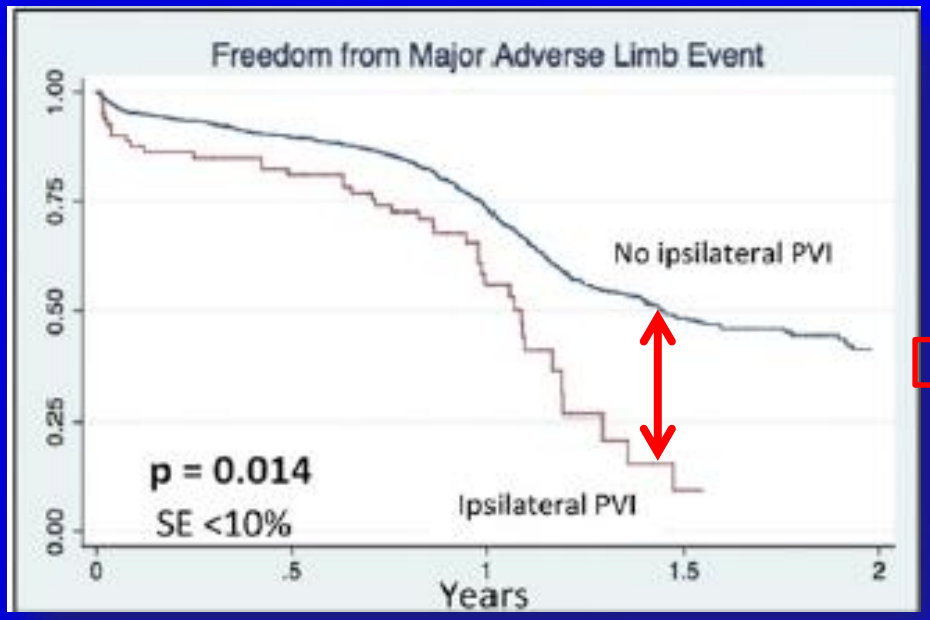
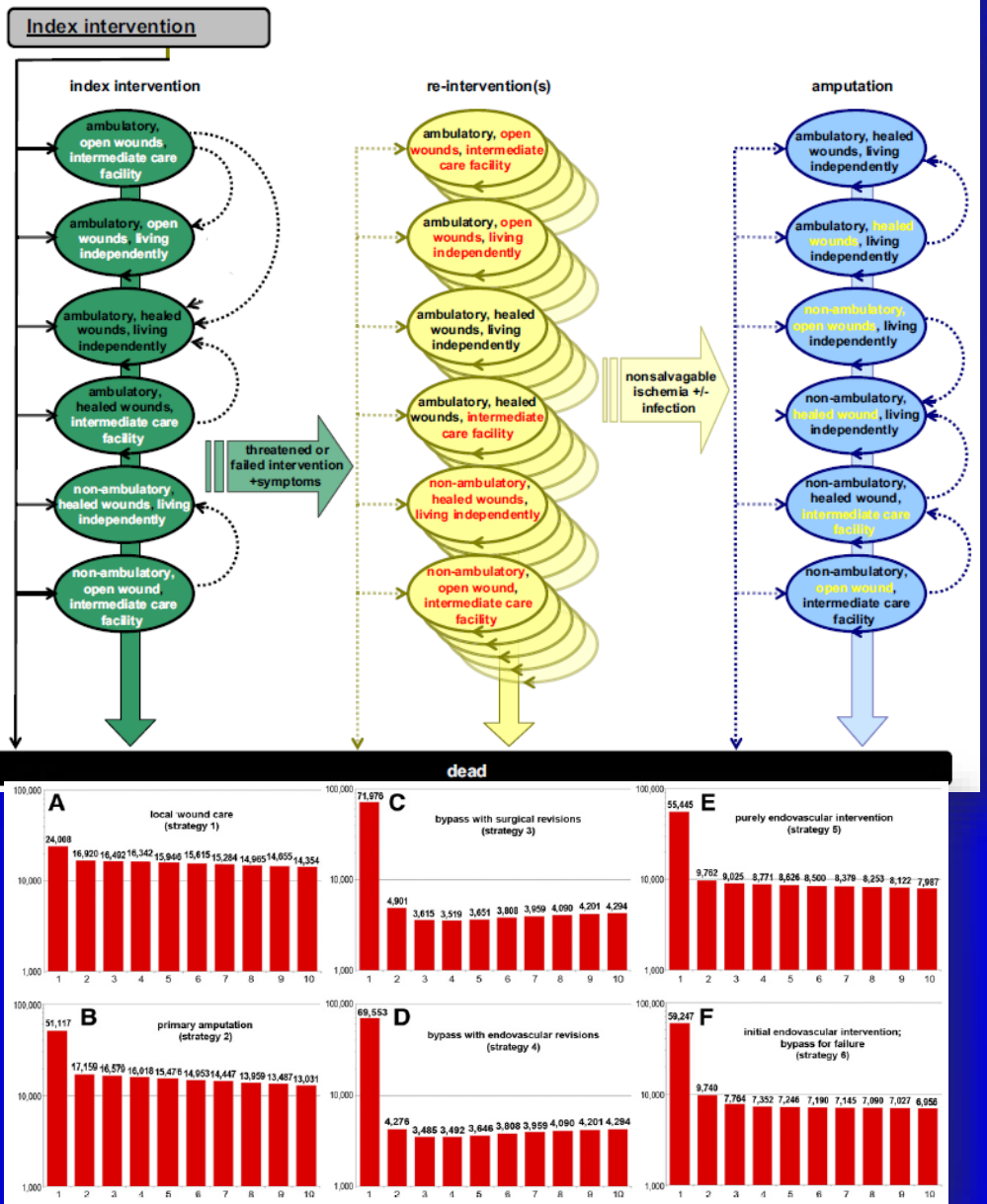


Table III. Independent predictors of major amputation at 1 year

	HR	*95% CI*	
Dialysis	2.7	2.2	3.3
Prosthetic conduit	2.1	1.3	3.4
Prior ipsilateral PVI	1.5	1.1	2
Prior ipsilateral bypass	1.4	1.1	1.7
Tibial target	1.4	1.2	1.7
Aspirin	0.8	0.7	0.9

Cost-effectiveness in the contemporary management of critical limb ischemia with tissue loss

Neal R. Barshes, MD, MPH,[a] James D. Chambers, PhD, MPharm, MSc,[b] Joshua Cohen, PhD,[b] and Michael Belkin, MD,[c] on behalf of the Model To Optimize Healthcare Value in Ischemic Extremities 1 (MOVIE) Study Collaborators,* *Houston, Tex; and Boston, Mass*



Cost-effectiveness

Best: Bypass with interventional revisions

Endovascular-first is not cost-effective

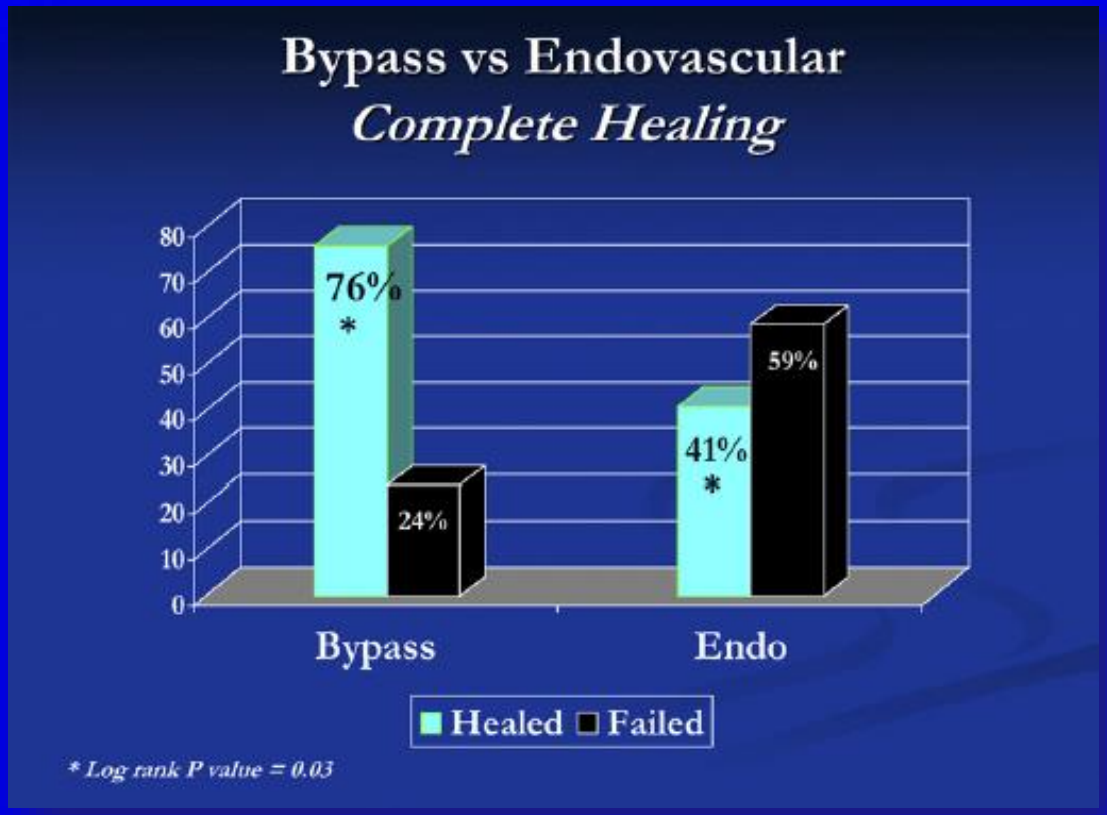
Must identify cost-drivers!

- ✓ Slow wound healing
- ✓ Procedural costs

J Vasc Surg 2012;56:1015-24

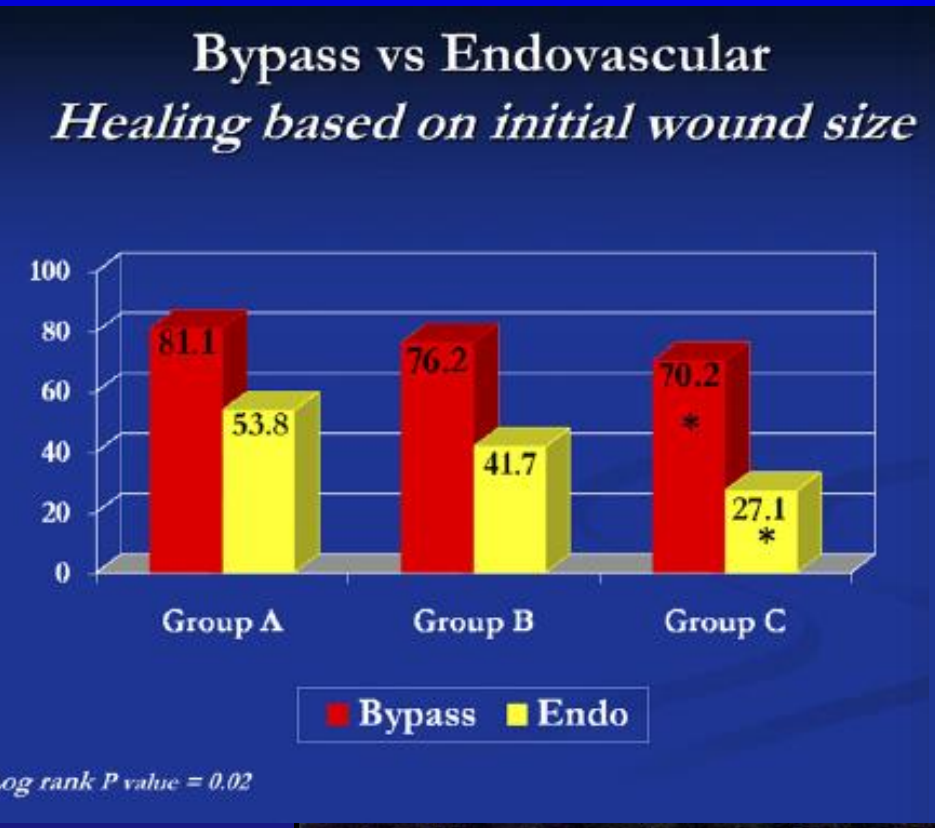
Surgical Bypass: When Is It Best and Do Angiosomes Play A Role?

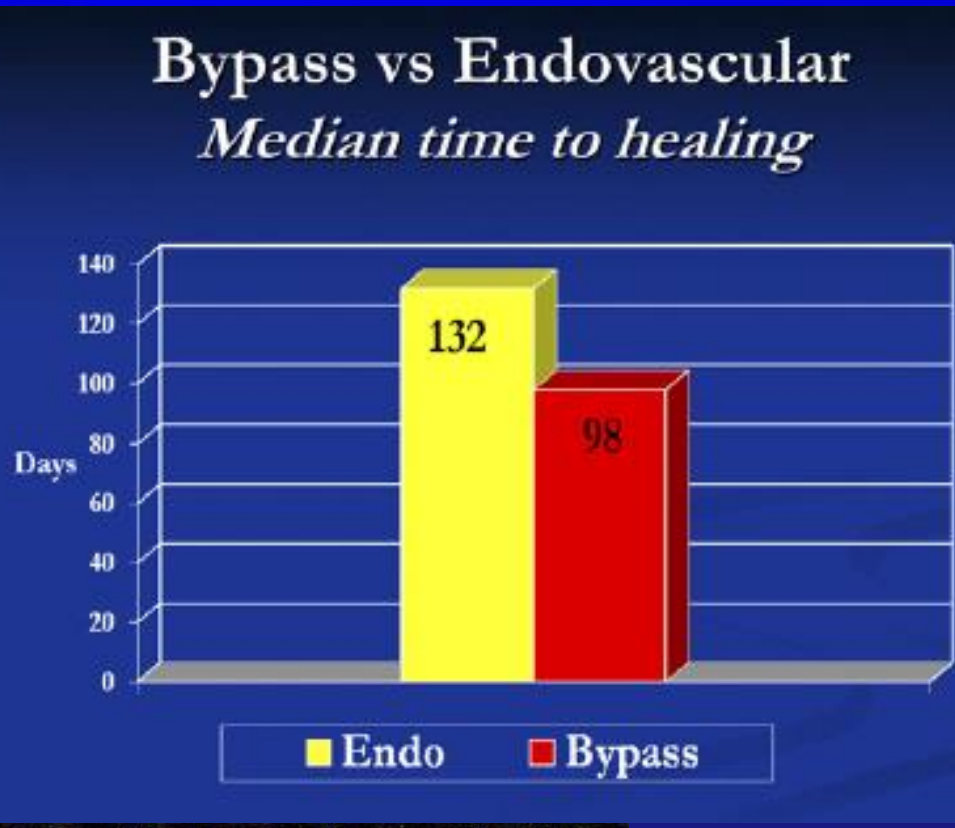
Richard F. Neville, MD and Anton N. Sidawy, MD, MPH



Semin Vasc Surg 25:102-107, 2012

Wound healing: Size and Time to healing





Group	Bypass	Endovascular	P value
	142	148	
A (0 – 5mm)	84 days	105 days	P = NS
B (5mm – 20mm)	102 days	128 days	P = NS
C (> 20mm)	115 days	164 days	P = 0.01

Semin Vasc Surg 25:102-107, 2012

“Factors influencing wound healing of critical ischemic foot after bypass surgery: is the angiosome important in selecting bypass target artery?”

- 249 distal bypasses: 81% diabetics, 49% ESRD
- Healing rate in indirect revascularization was slower than in direct revascularization, especially in ESRD patients ($P<0.001$)
- No difference after propensity scoring ($P=0.185$)
- Conclusion:

“ The angiosome concept seems unimportant, at least in non-ESRD cases”

Azuma, Eur J Vasc Endovasc Surg, 2012

CASE 1

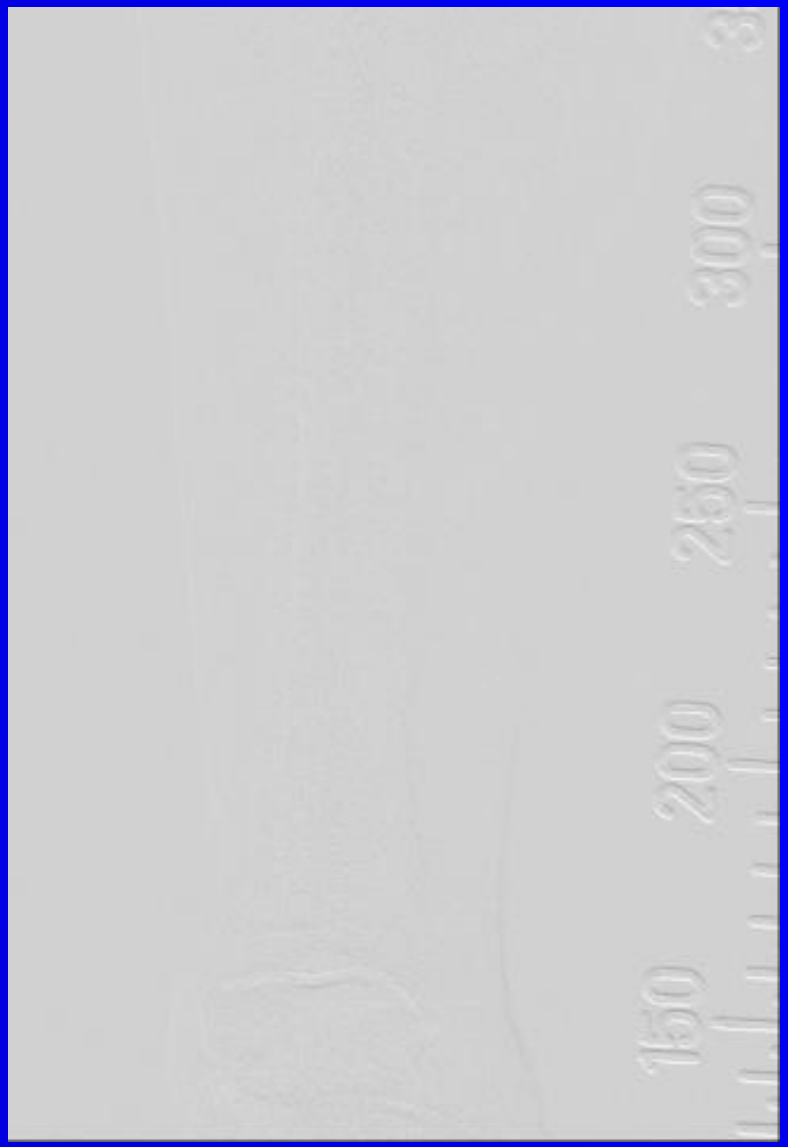
- F/61
- CC : infected ulcer, rt. foot (1WA)
- BHx:
  - Known DM patient with insulin (40y, type 1)
  - s/p rt. 4-5 toe amputation d/t trauma (40YA)


I 666

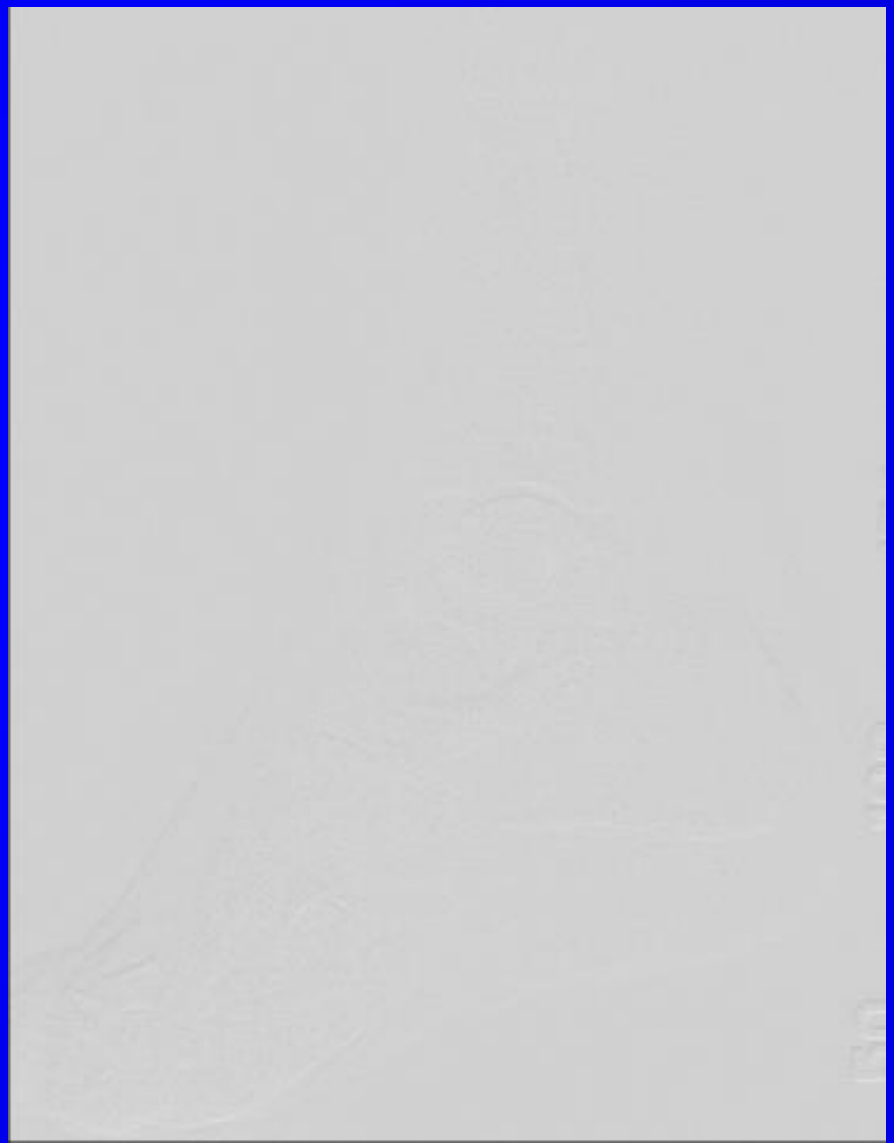

HD MIP No cut
Non GE image
DFOV 52.0 cm
B30f
Ex: May 12 2012
Calcif. included
R
L
I 900
HD MIP No cut
Non GE image
DFOV 52.0 cm
B30f
No VOI
1.0mm /1.0sp

Femoral angio via 5F sheath
BTK angio via 4F shuttle

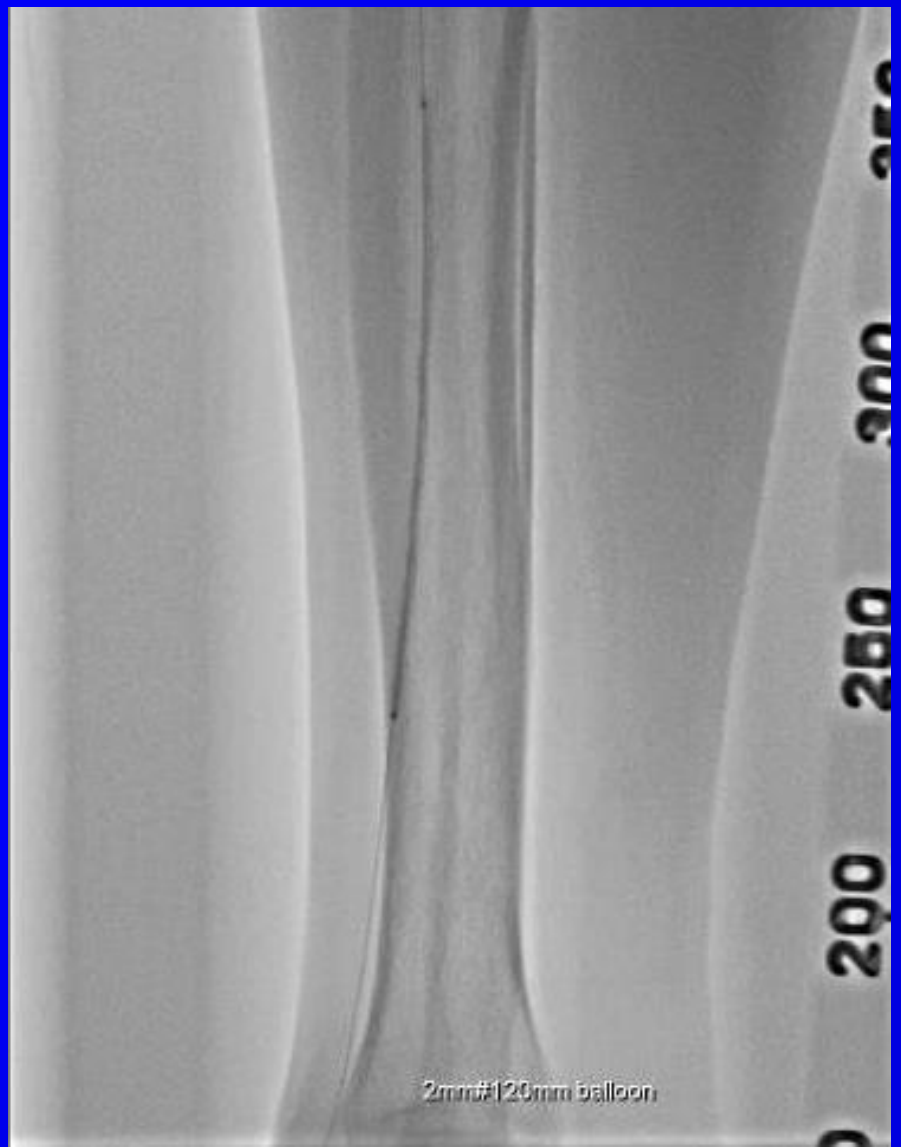
Ankle AP



Ankle lateral



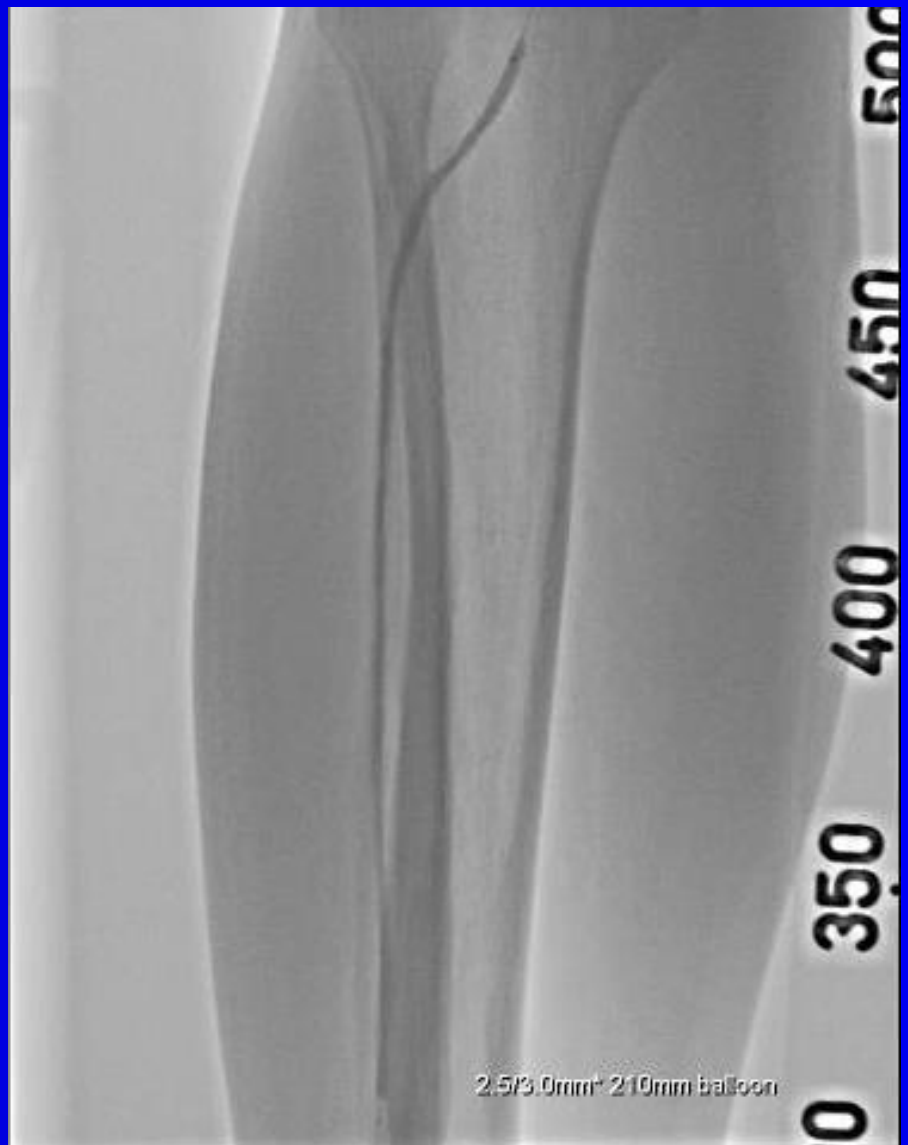
True luminal passage using V18 + microcatheter change to 0.14GW & BAP with 2mm*120mm

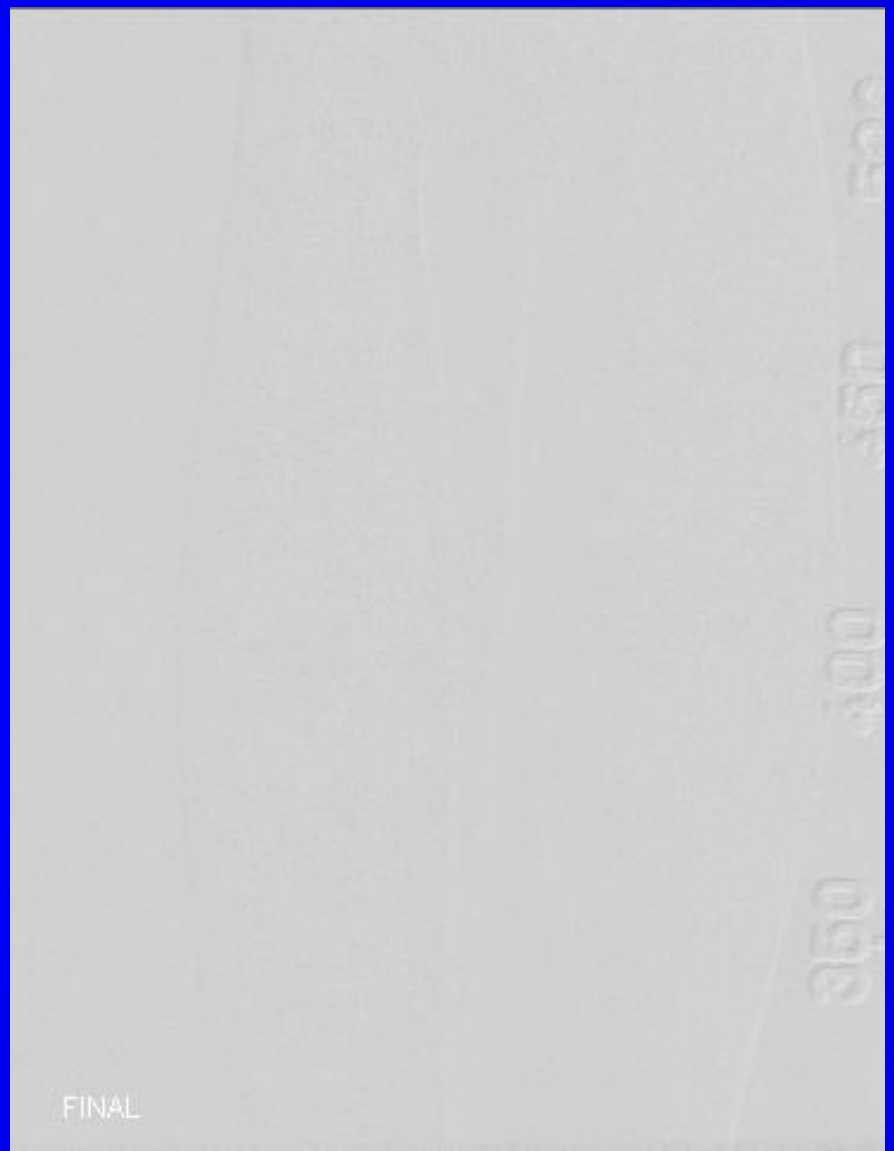



500
450
400
350


2.0mm post

BAP with 2.5-3mm*210mm





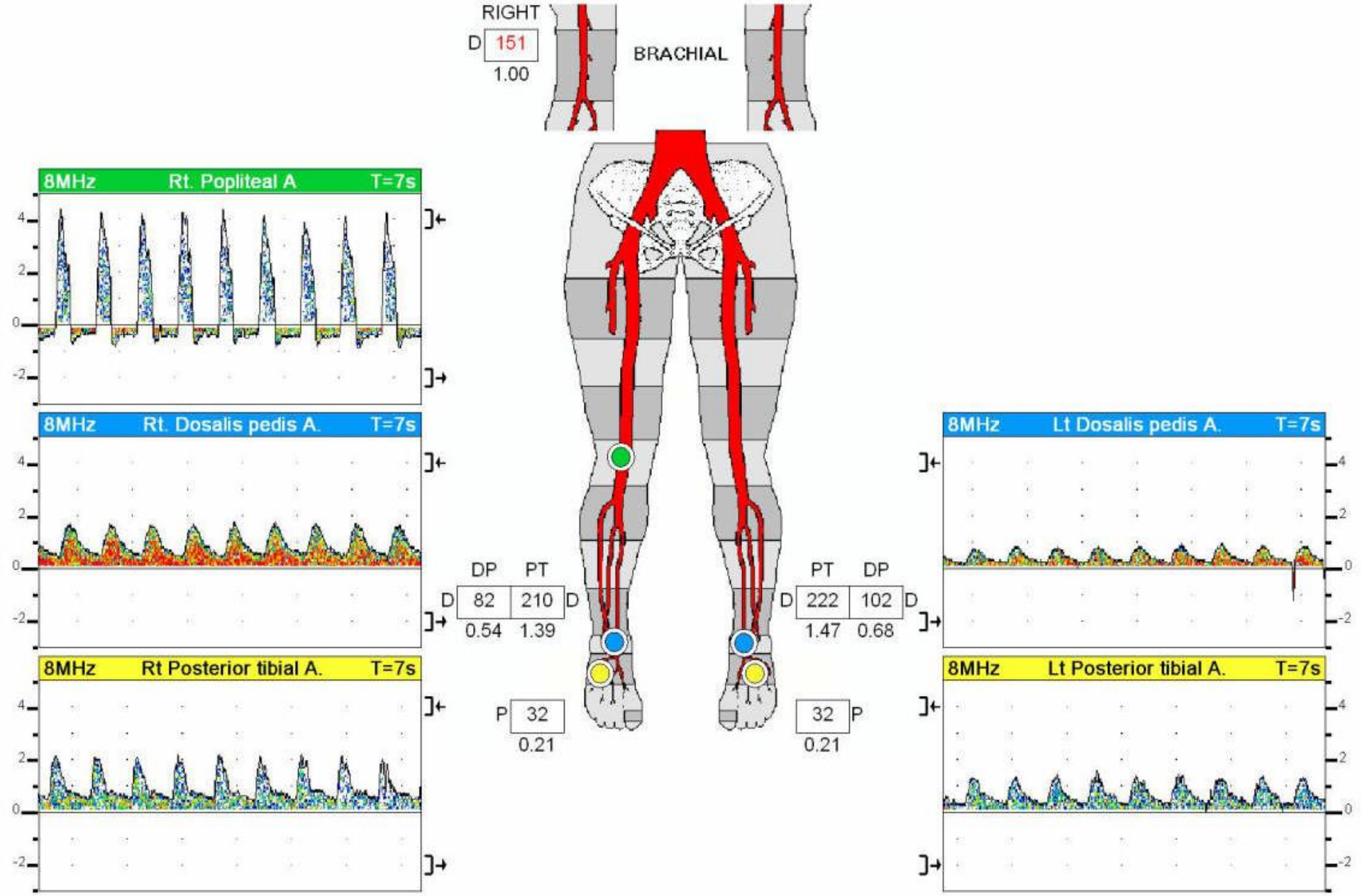
Final angiography

Post-intervention course

- IV antibiotics
  - Wound culture : MRCNS, Pseudomonas,Citrobacter, Corynebacterium
  - Vancomycin, Tazocin
- Daily I & D at OR
- Ray amputation at POD#7
- Clean wound and well-healed

CASE 2

- M/72
- DM CRF on HD
- HTN
- DM foot at 5th toe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BRACHIAL
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8MHz Rt. Dosalis pedis A. T=7s
8MHz Rt Posterior tibial A. T=7s
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D 82 210 D
0.54 1.39
P 32
0.21
PT DP
D 222 102 D
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8MHz Lt Dosalis pedis A. T=7s
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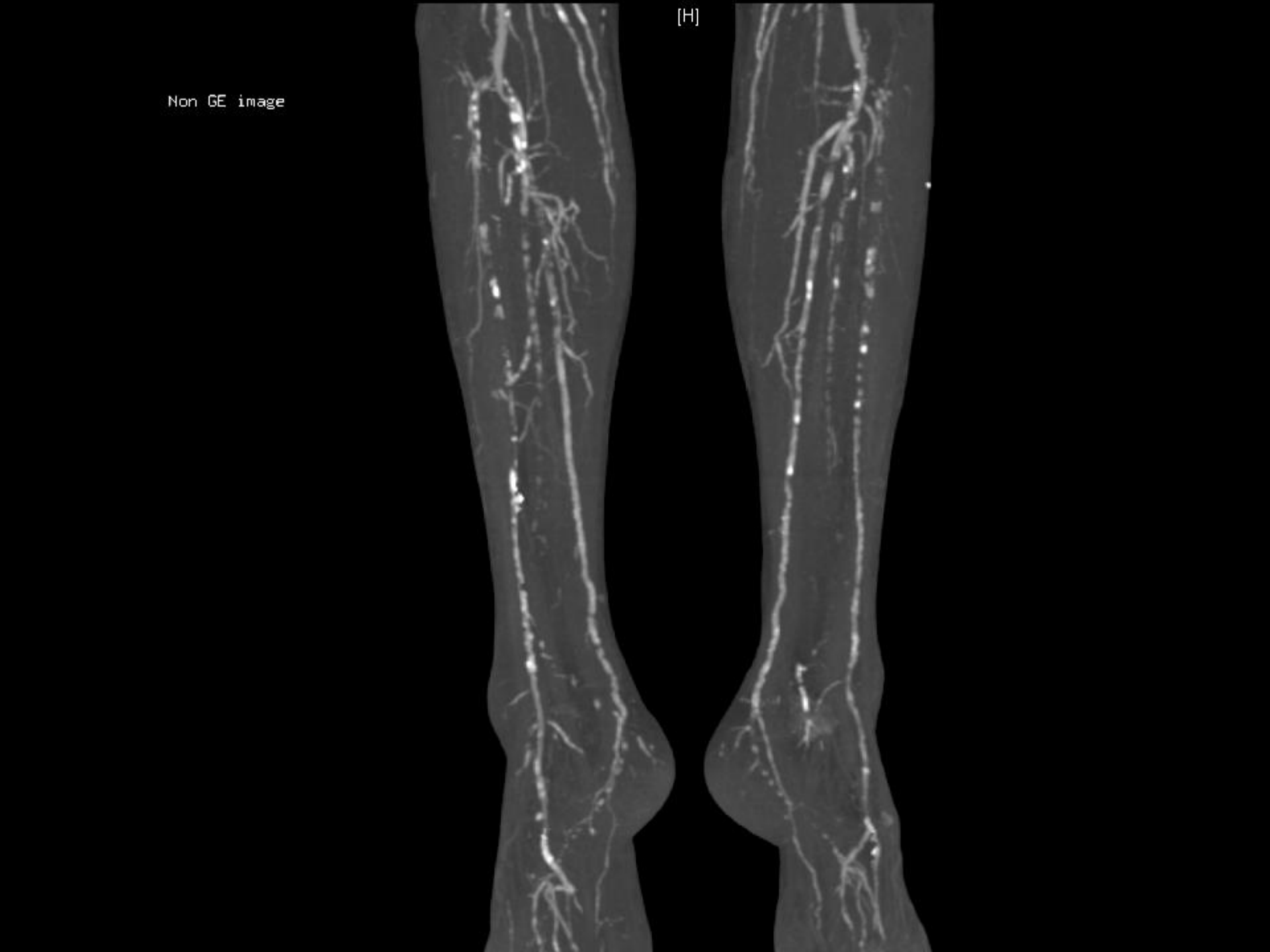
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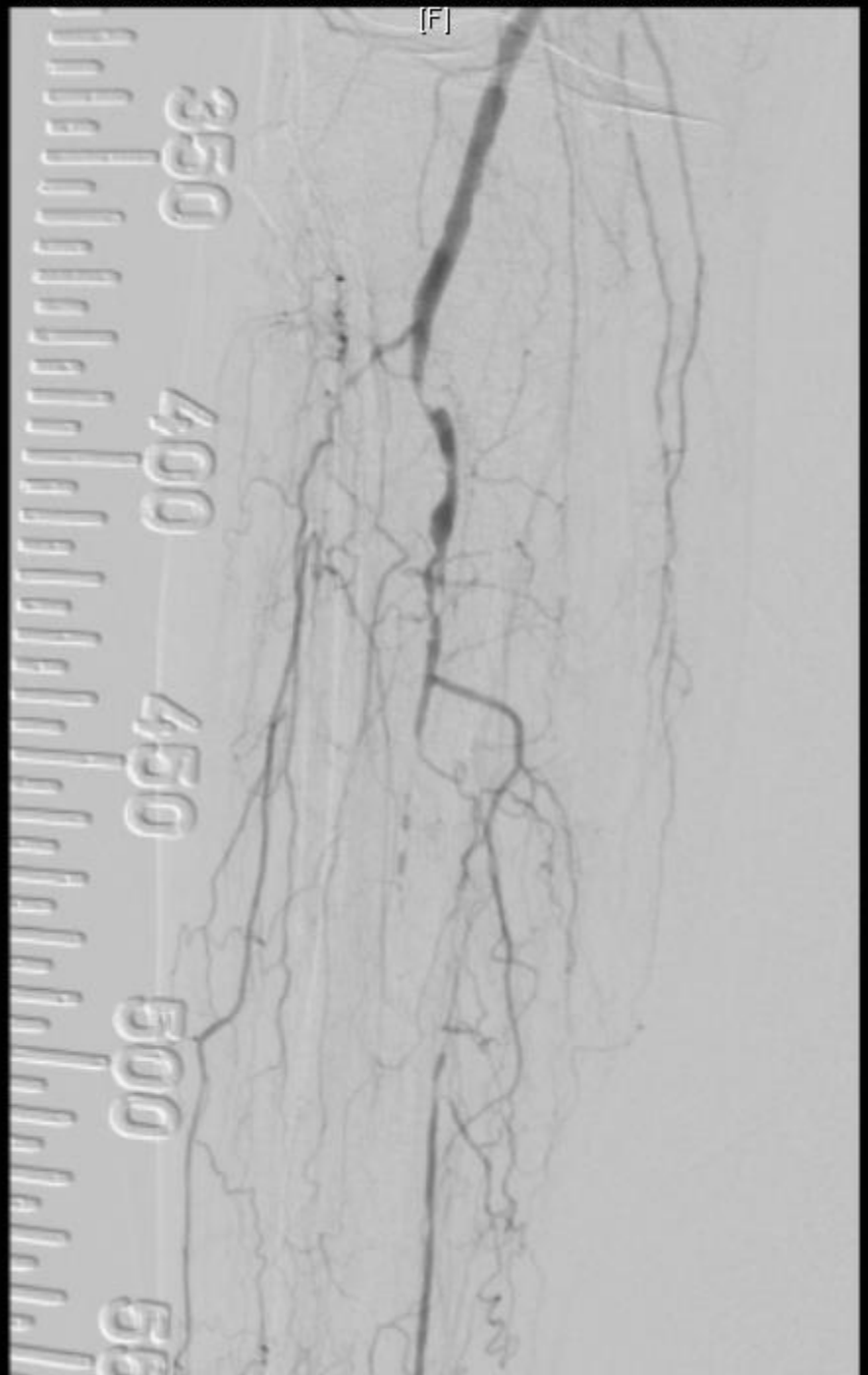
Study Time:11
MRN:062



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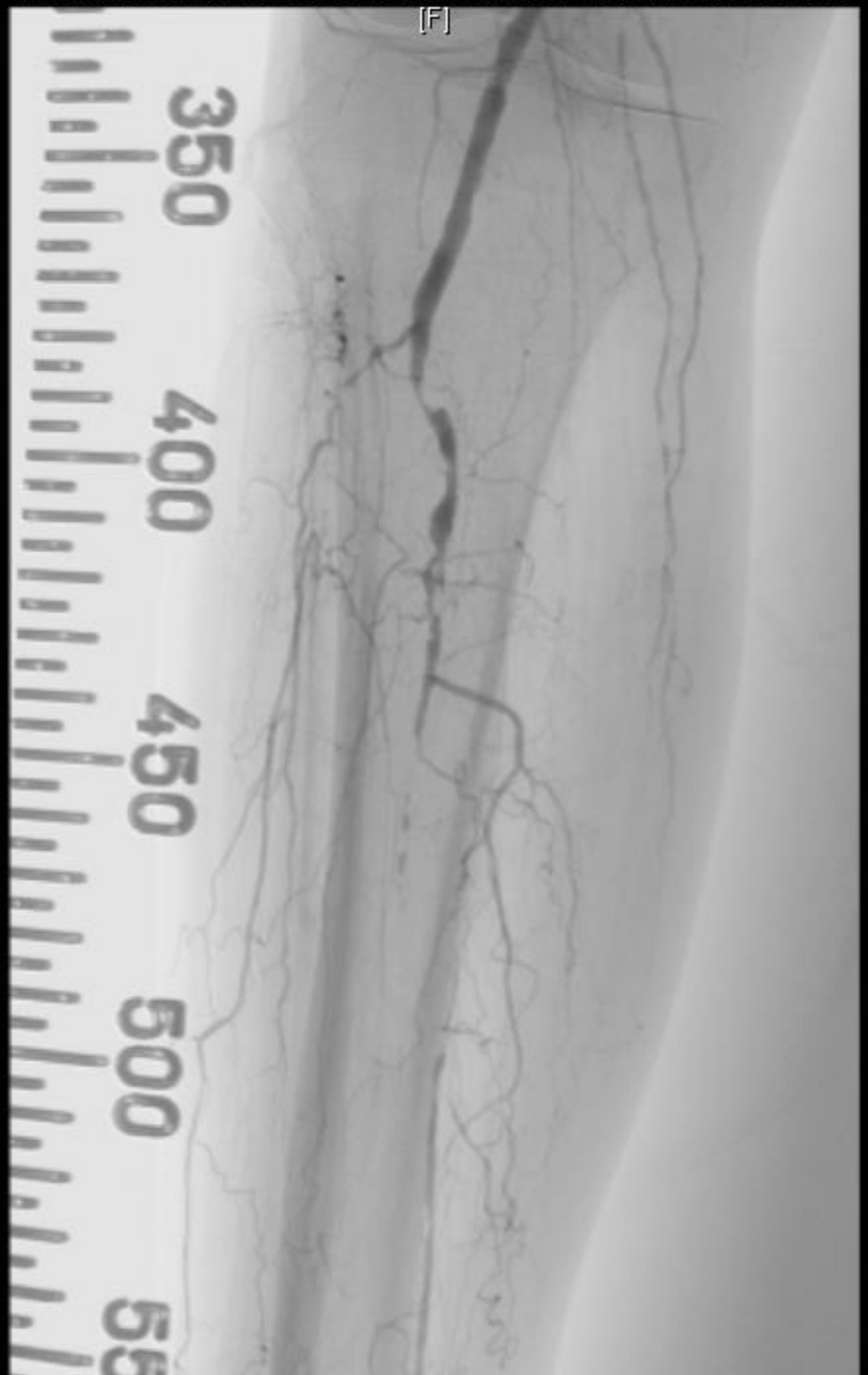
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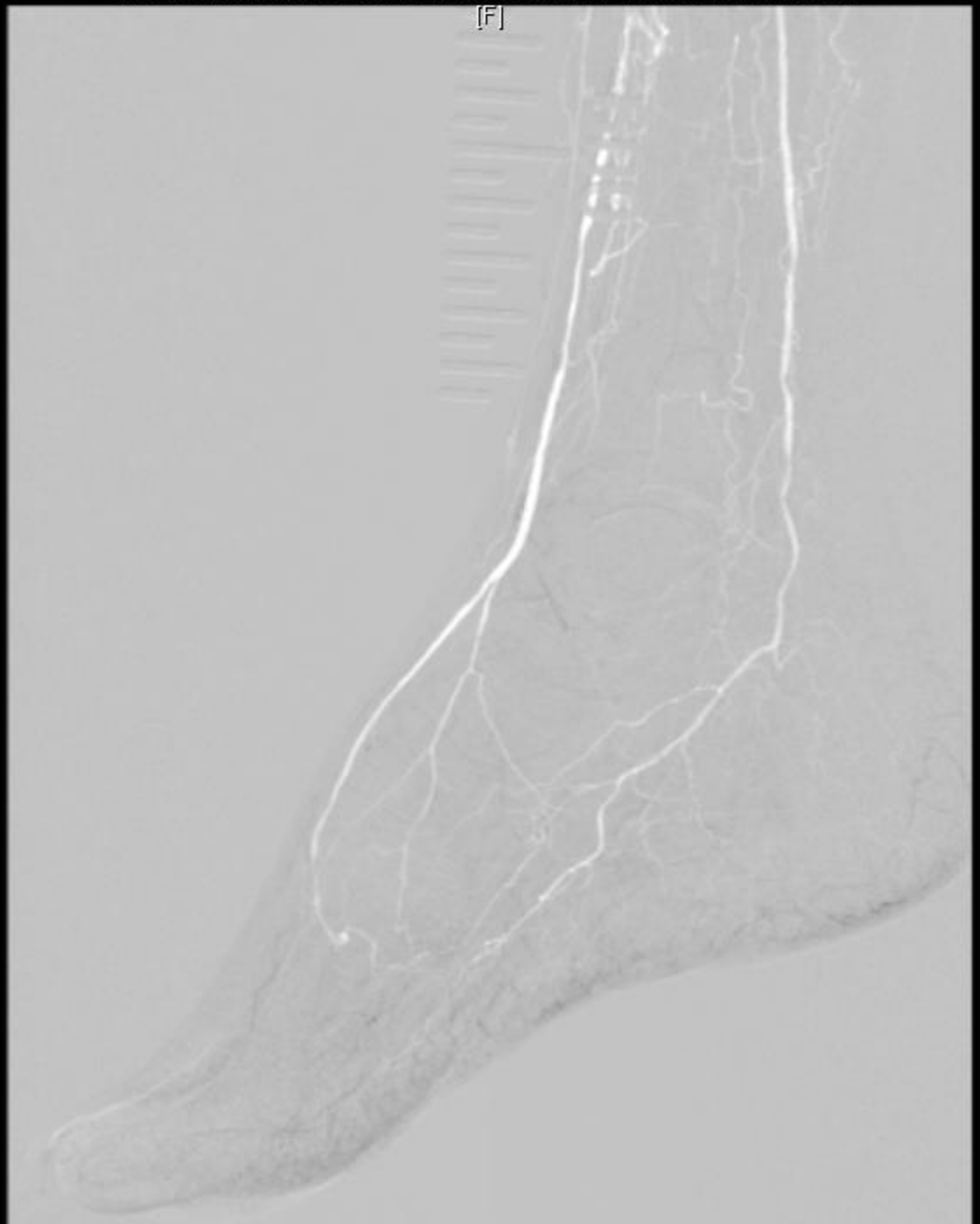

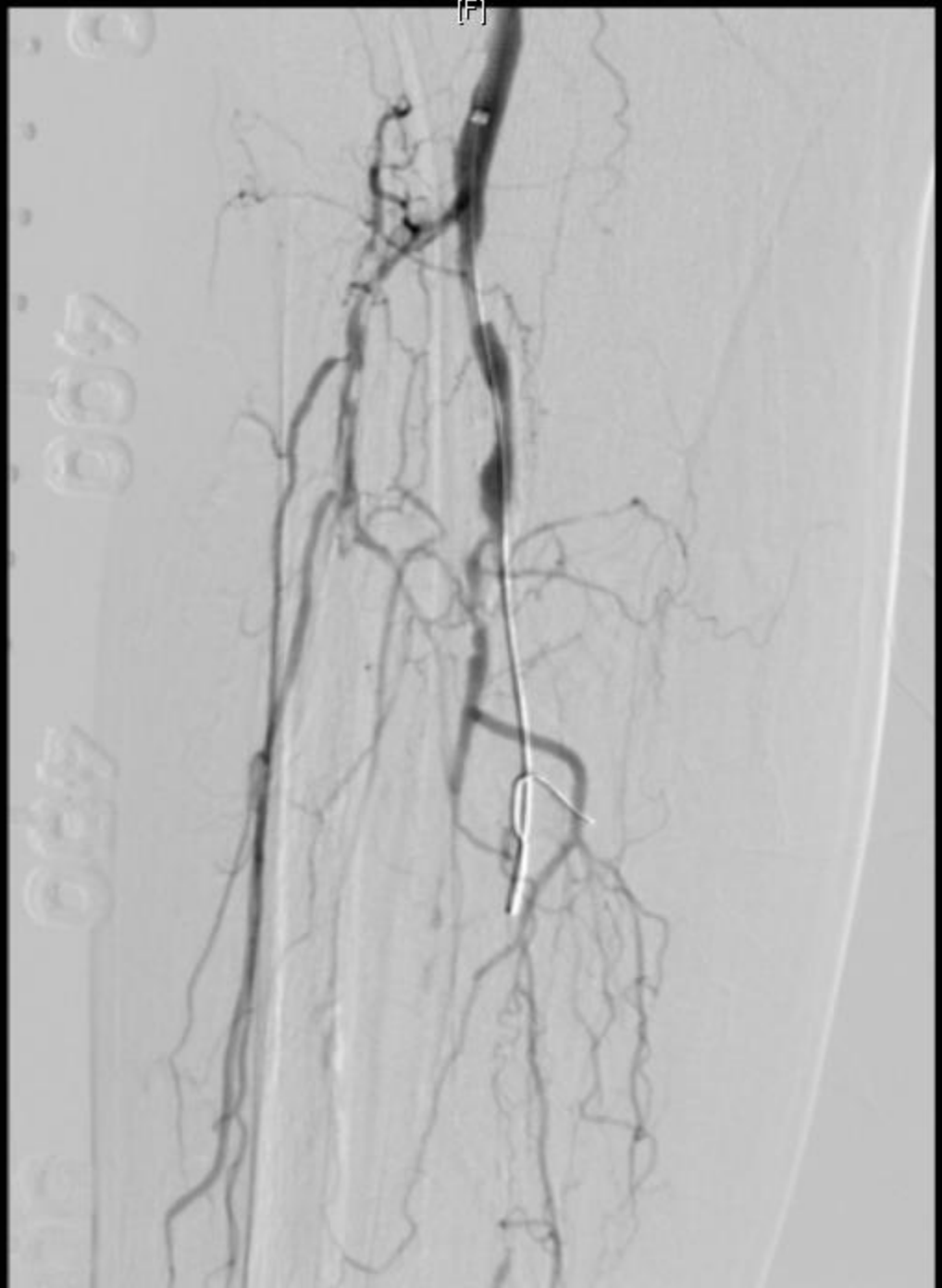

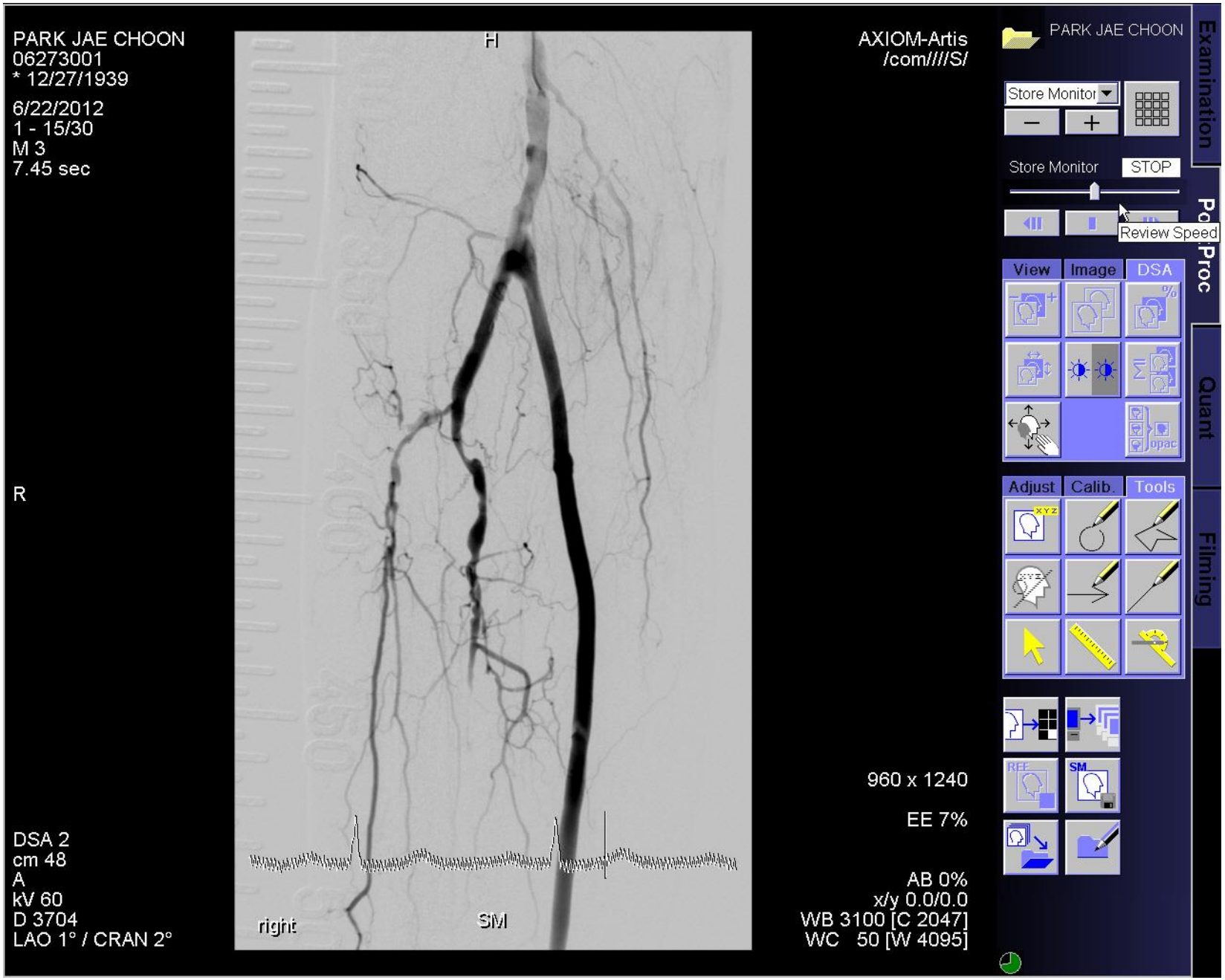
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Post Proc
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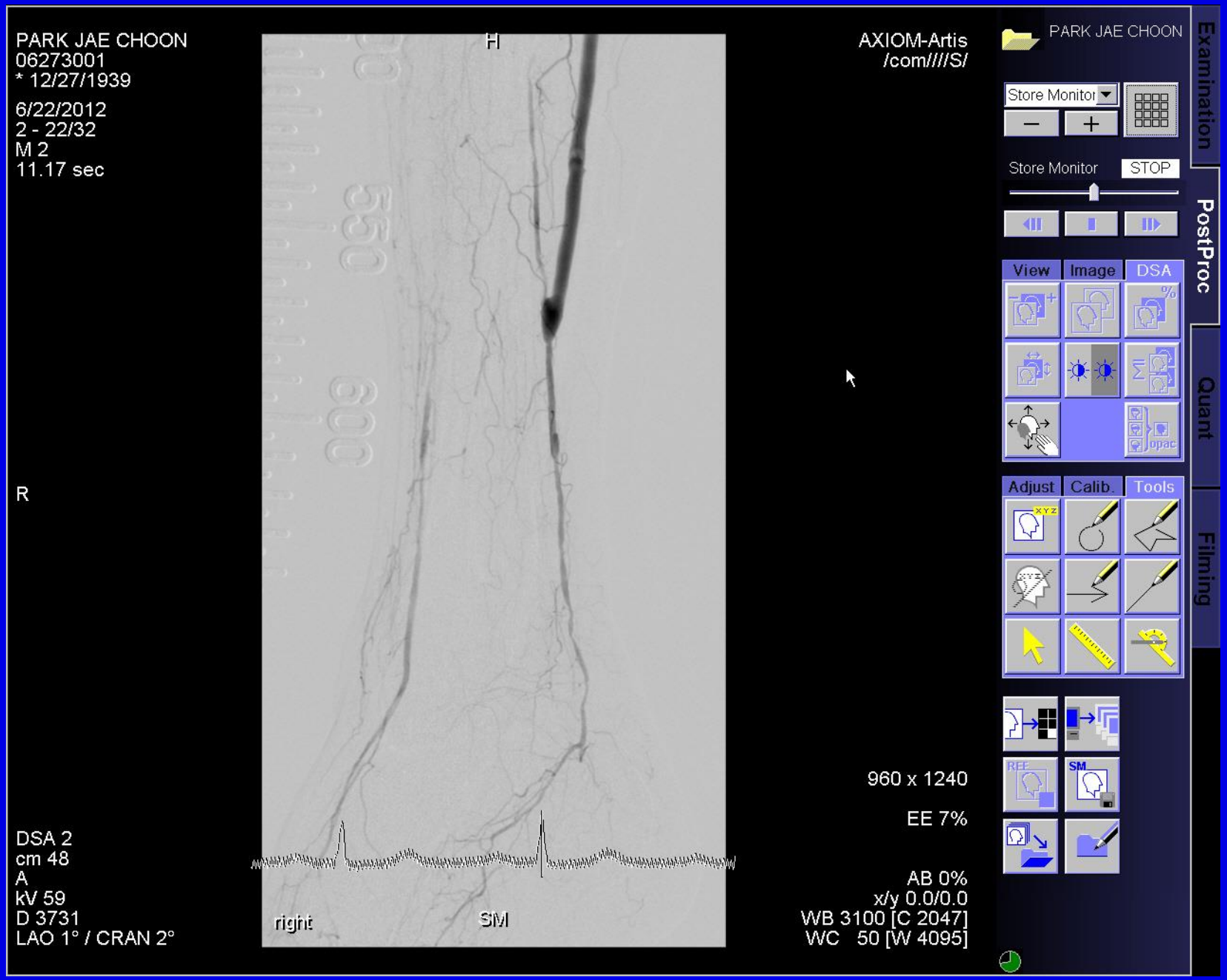
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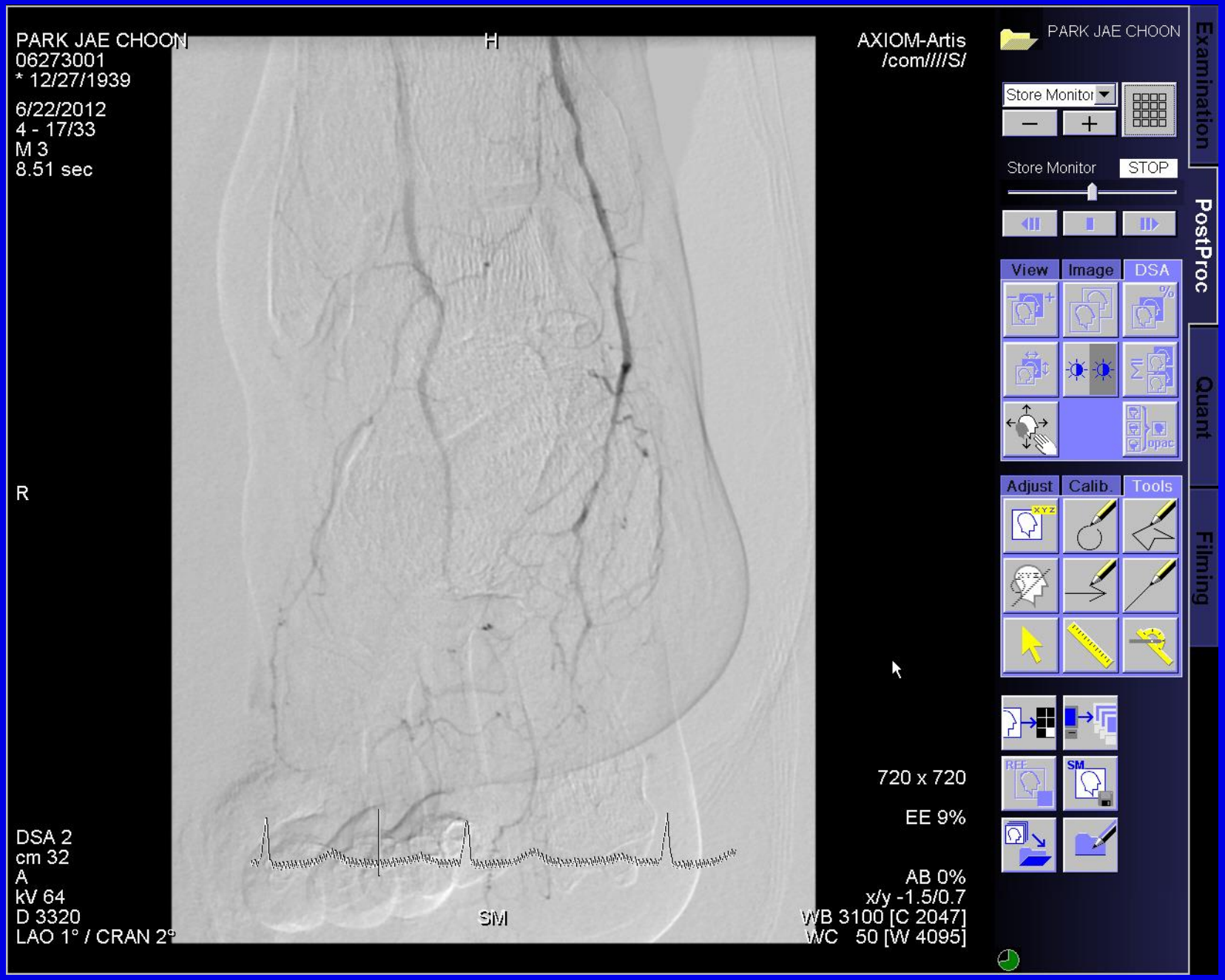
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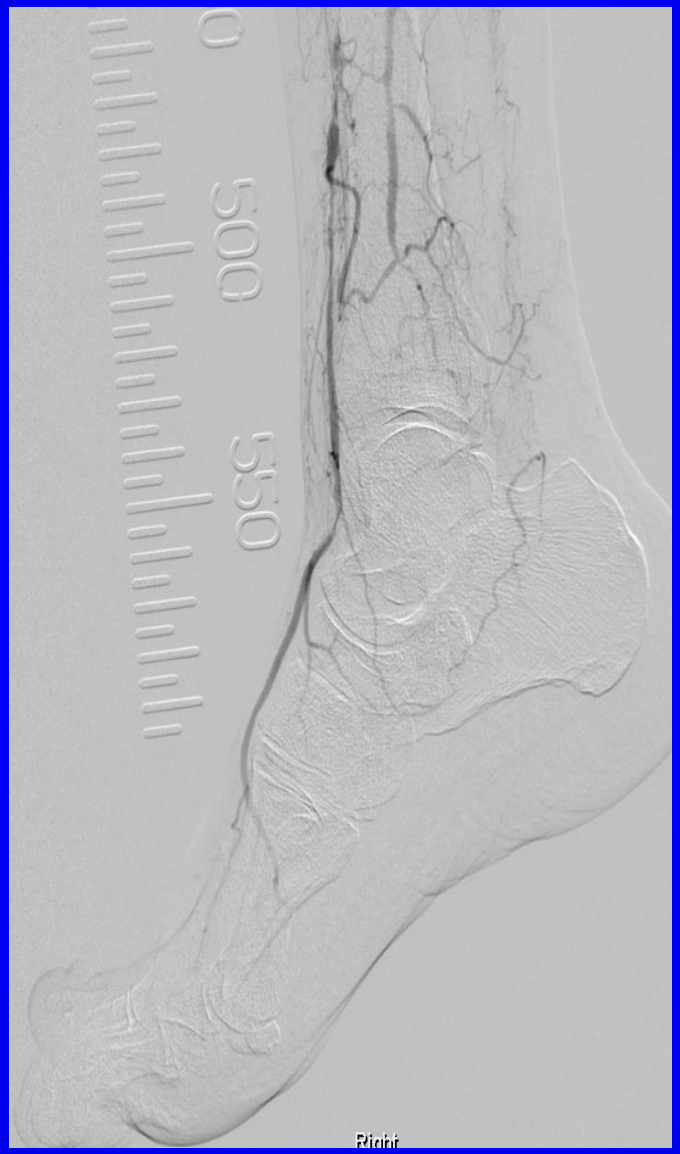
DSA 2
cm 32
A
kV 64
D 3320
LAO 1° / CRAN 2°
SM
720 x 720
EE 9%
AB 0%
x/y -1.5/0.7
WB 3100 [C 2047]
WC 50 [W 4095]
PARK JAE CHOON
Store Monitor
Store Monitor
STOP
View
Image
DSA
Adjust
Calib.
Tools
Examination
PostProc
Quant
Filming

CASE 3

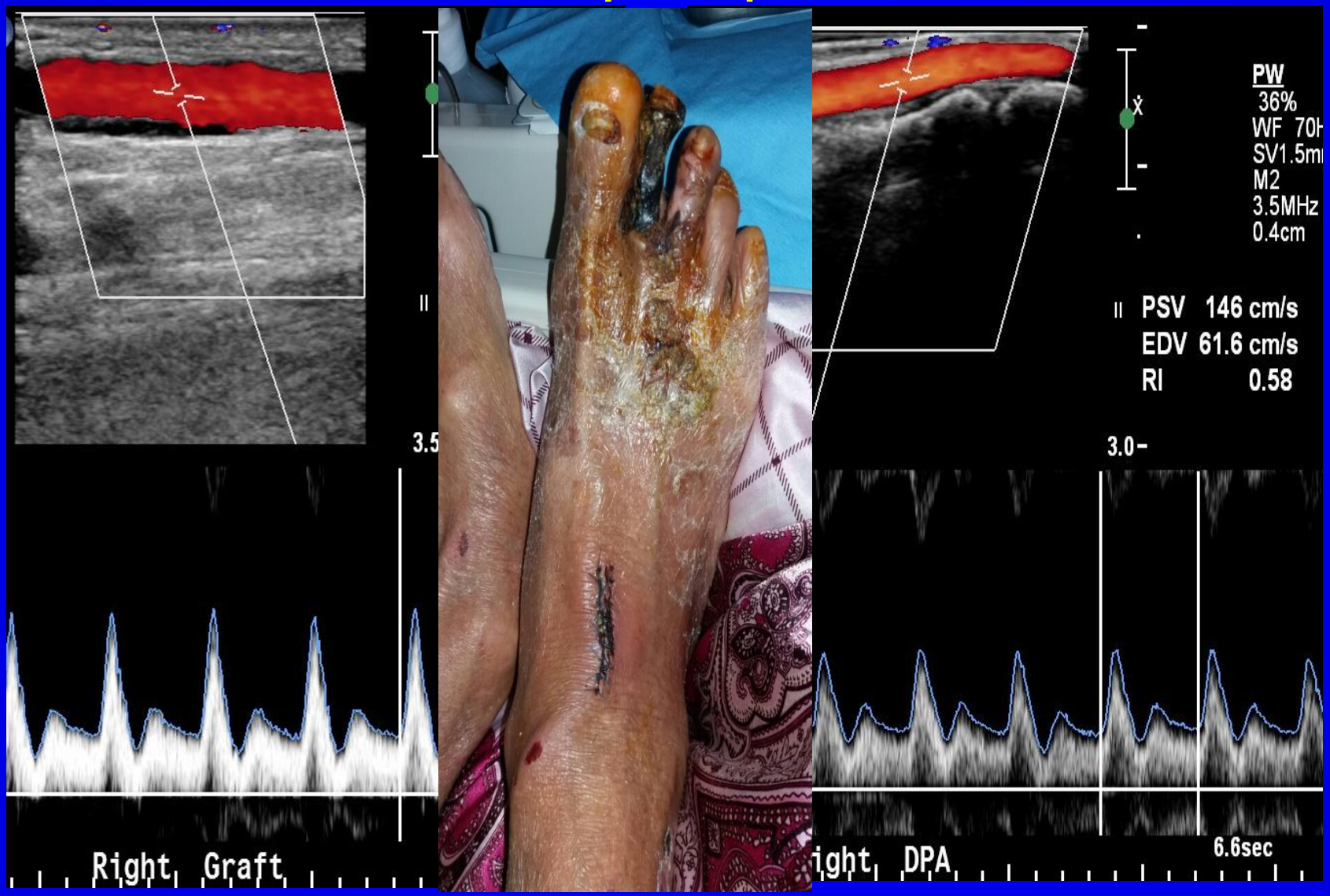
- M/81, Rt. 2nd toe unhealing wound and pain
- HTN, s/p CABG, CRF on HD
- Un-healing wound and pain at Rt. 2nd toe for 4 months

DSA



Infrapop-DPA bypass

Follow-up Duplex scan



CASE 4

- M/81
- DM CRF on HD
- HTN
- Unhealing wound at 1st toe, right

- 2012. 4 endovascular intervention : failed

- 2012. 8 aggravated wound infection after minor trauma

Updated 2017 ESC guideline for PAD

Recommendations on revascularization of infra-popliteal occlusive lesions

Recommendations	Class[a]	Level[b]
In the case of CLTI, infra-popliteal revascularization is indicated for limb salvage.[320–326]	I	C
For revascularization of infra-popliteal arteries:		
• bypass using the great saphenous vein is indicated	I	A
• endovascular therapy should be considered.[320–326]	IIa	B

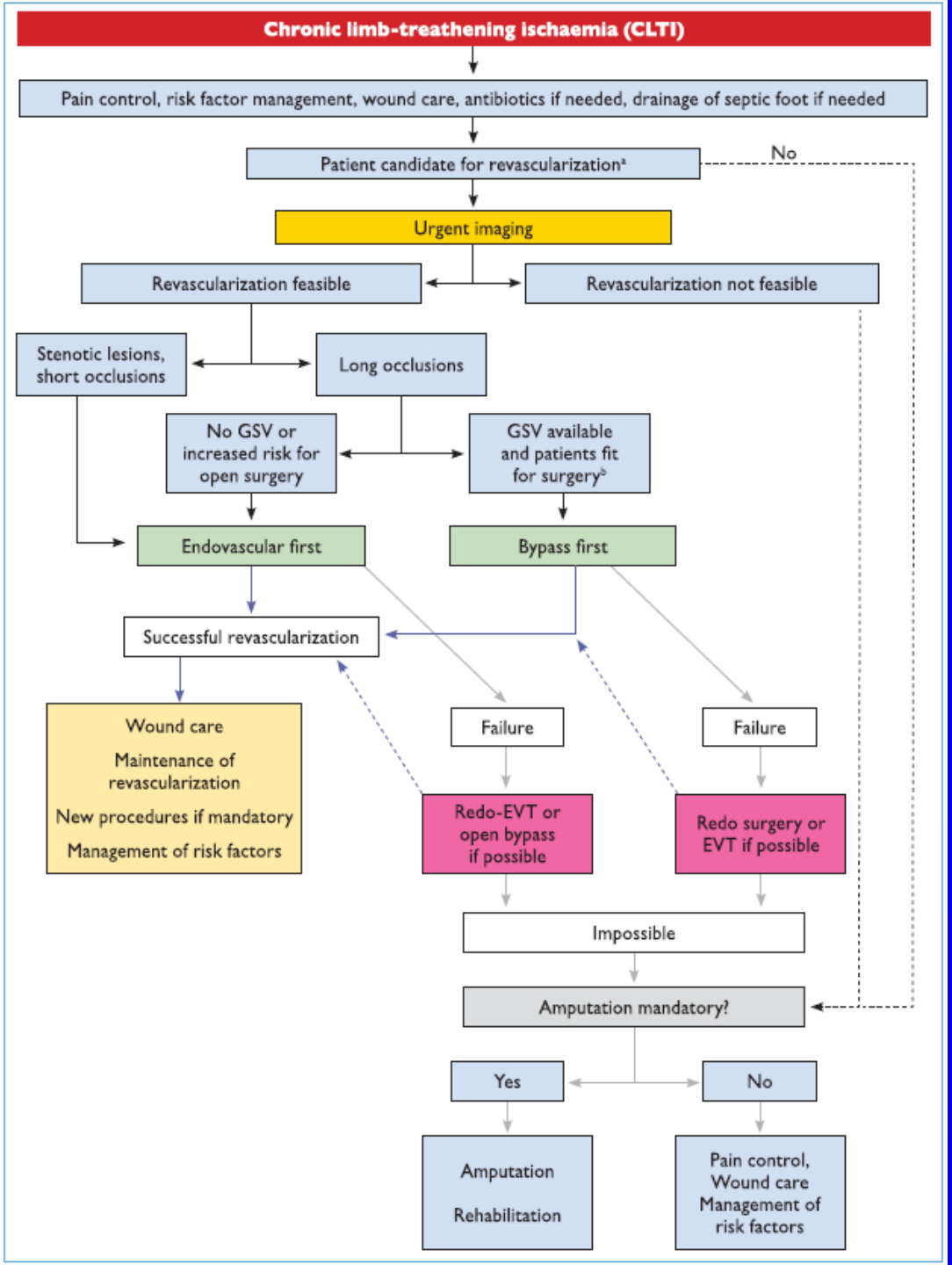
CLTI = chronic limb threatening ischaemia.

[a] Class of recommendation.

[b] Level of evidence.

CHANGE IN RECOMMENDATIONS

2011	2017
Lower Extremity Artery Disease	
Infra-popliteal lesions	
• Endovascular first	• Bypass using GSV
	• Endovascular therapy[320-326]


Chronic limb-treathening ischaemia (CLTI)
Pain control, risk factor management, wound care, antibiotics if needed, drainage of septic foot if needed
Patient candidate for revascularization[a]
No
Urgent imaging
Revascularization feasible
Revascularization not feasible
Stenotic lesions, short occlusions
Long occlusions
No GSV or increased risk for open surgery
GSV available and patients fit for surgery[b]
Endovascular first
Bypass first
Successful revascularization
Wound care
Maintenance of revascularization
New procedures if mandatory
Management of risk factors
Failure
Failure
Redo-EVT or open bypass if possible
Redo surgery or EVT if possible
Impossible
Amputation mandatory?
Yes
No
Amputation
Rehabilitation
Pain control, Wound care Management of risk factors

Summary

- All diabetic patients with ischemic symptom or unhealing ulceration
  - objective testing for PAD
- Early identification of PAD at risk
  - Essential for limb salvage
- Multidisciplinary approach
  - Organized and systematic management for PAD in diabetics
  - Diabetic foot clinic

Thank you for your attention

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