



Arterial status, angiosome, arterial calcifications:
it is possible to plan treatment at BTK level ?

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Chief: Prof. Andrea Stella

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it is possible to plan treatment at BTK level ?

Disclosure

Speaker name: **Mauro Gargiulo**

I have the following potential conflicts of interest to report:

X Consulting: William Cook Europe, Medtronic Vascular Inc.

- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
-

I do not have any potential conflict of interest

Tibial Artery Angioplasty with Uncoated Balloon in CLI

	n.	%
Limbs	249	100
▪ Fontaine Stage		
III	20	8
IV	229	92



Tibial Artery Angioplasty with Uncoated Balloon in CLI

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Limbs	249	100
▪ Fontaine Stage		
III	20	8
IV	229	92



Validation of a diabetic wound classification system

Armstrong DG et al Diabetes Care 1998;21:855-859

Grade Stage	0	I	II	III
A	Pre or post-ulcerative lesion	Non-infected, non-ischemic, superficial ulceration	Non-infected, non-ischemic, ulcer that penetrates to capsule or bone	Non-infected, non-ischemic, ulcer that penetrates to bone or deep
B	With infection	With infection	With infection	With infection
C	Without infection, With ischemia	Without infection, With ischemia	Without infection, With ischemia	Without infection, With ischemia
D	With infection, With ischemia	With infection, With ischemia	With infection, With ischemia	With infection, With ischemia

Tibial Artery Angioplasty with Uncoated Balloon in CLI

	n.	%
Limbs	249	100
▪ Fontaine Stage		
III	20	8
IV	229	92
▪ TUC Grade		
< III	53	21.3
III	176	70.7
▪ TUC Stage		
C	70	28.1
D	159	73.9

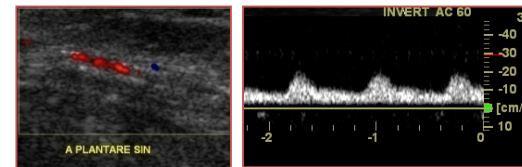


Path of treatment of CLI

CLI



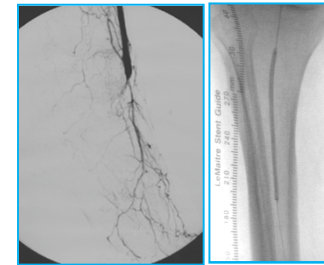
PAOD evaluation



Treatment of trophic lesions



Limb revascularization



Foot surgery
Treatment of trophic lesions
Adjuvant therapy



Limb salvage and Wound Healing



Treatment of trophic lesions
Functional rehabilitation



Ability to walk



To plan treatment at BTK level

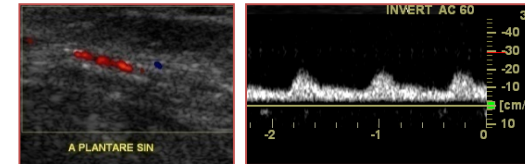
CLI



PAOD evaluation



Treatment of trophic lesions



Limb revascularization

Foot surgery
Treatment of trophic lesions
Adjuvant therapy



Limb salvage

Treatment of trophic lesions
Functional rehabilitation



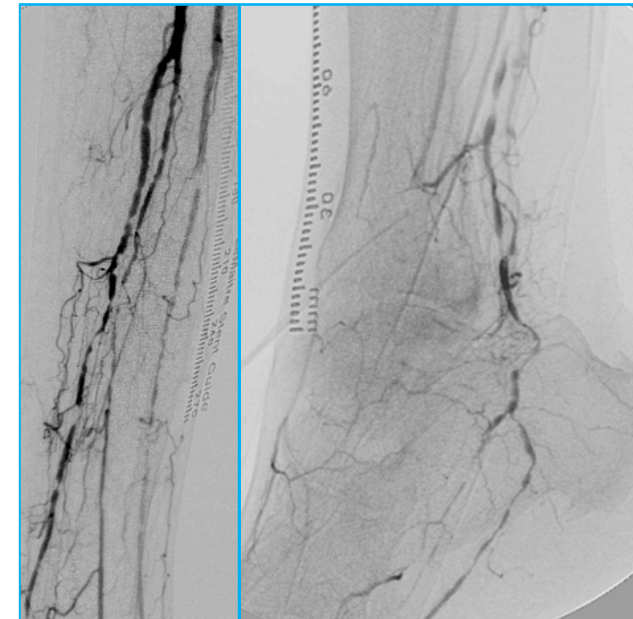
Ability to walk

To plan treatment at BTK level – PAOD evaluation

- Clinical evaluation
 - Fontaine stage III / IV
 - Neuro-ischemic ulcers
 - . TWC
 - . angiosome



- Arterial disease evaluation

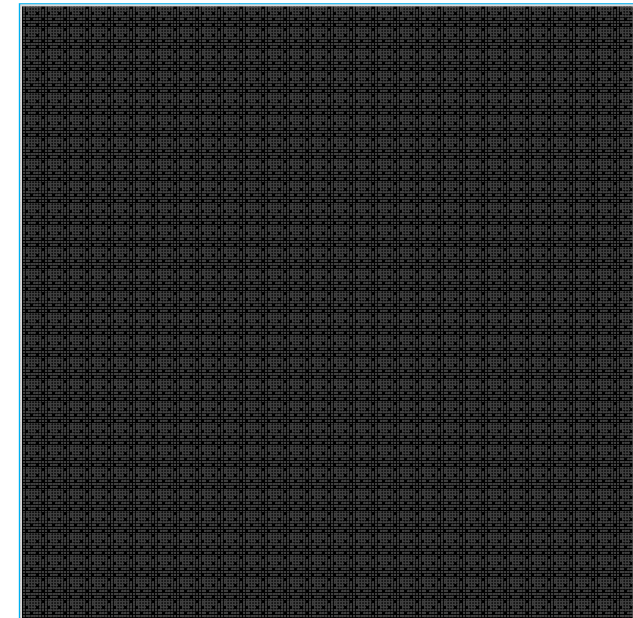


To plan treatment at BTK level – PAOD evaluation

- **Clinical evaluation**
 - Fontaine stage III / IV
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- Arterial disease evaluation



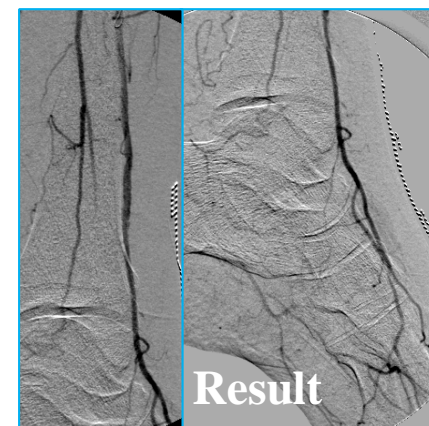
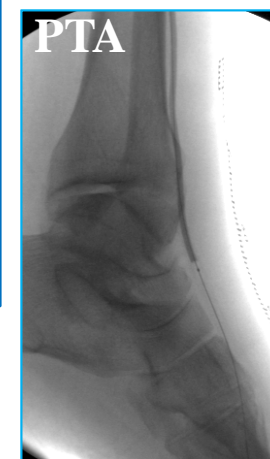
BTK revascularization – Fontaine Stage III

Primary end-point

Re-establishment of
pulsatile, straight-line **flow to the foot**



- Remove ischemic pain
- Prevent limb loss
- Improve quality of life
- Prolong survival

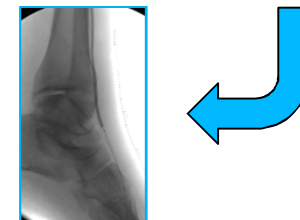


BTK revascularization – Fontaine Stage IV

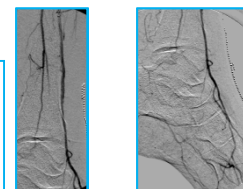
Ischemic Foot – revascularization according the **Angiosome-Model**

Primary end point

Re-establishment of pulsatile, straight-line **flow to the angiosome**



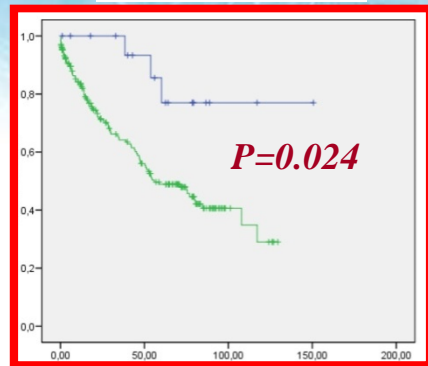
- Healing of (neuro)ischemic ulcers
- Regression of ischemic pain
- Limb salvage
- Improve quality of life
- Prolong survival



Tibial Artery Angioplasty with Uncoated Balloon in CLI

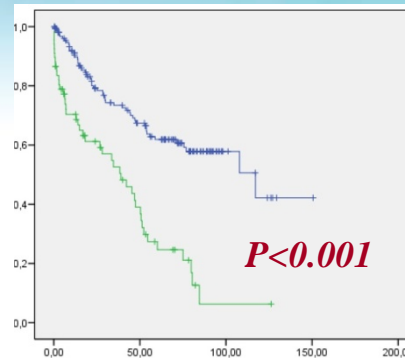
Survival

Fontaine stage



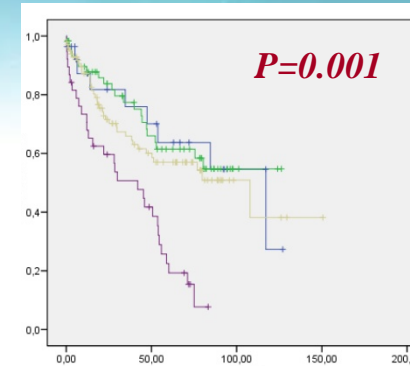
■ III
■ IV

ESRD



■ NO
■ YES

AGE



■ < 60 years
■ 61-70 years
■ 71-80 years
■ > 80 years

Variables	Univariate	Multivariate	HR (95% CI)
Fontaine: IV vs III	0.017	0.024	2.63 (0.83-8.36)
ESRD: Yes vs No	< 0.001	< 0.001	3.41 (2.28-5.1)
Age (years)	0.001	0.001	10.42 (10.18-10.67)
> 80 vs			
- ≤ 60			
- 61-70			
- 71-80			

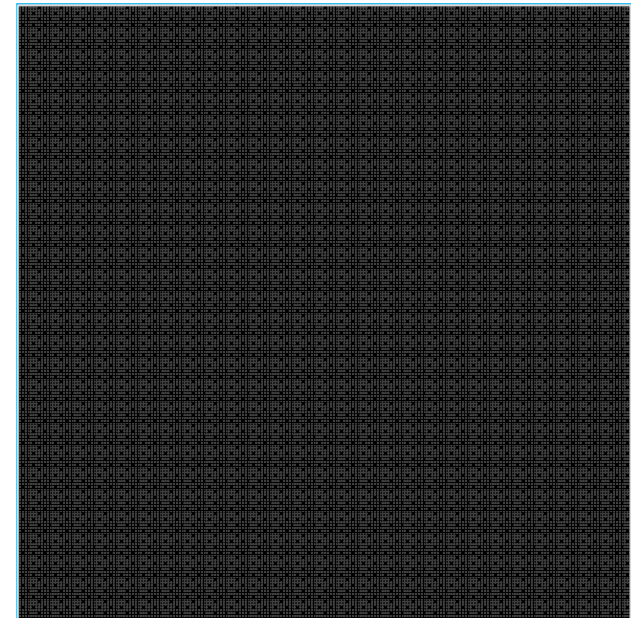


To plan treatment at BTK level – PAOD evaluation

- **Clinical evaluation**
 - Fontaine stage III / IV
 - **Neuro-ischemic ulcers**
 - . TWC
 - . angiosome



- Arterial disease evaluation



Validation of a diabetic wound classification system

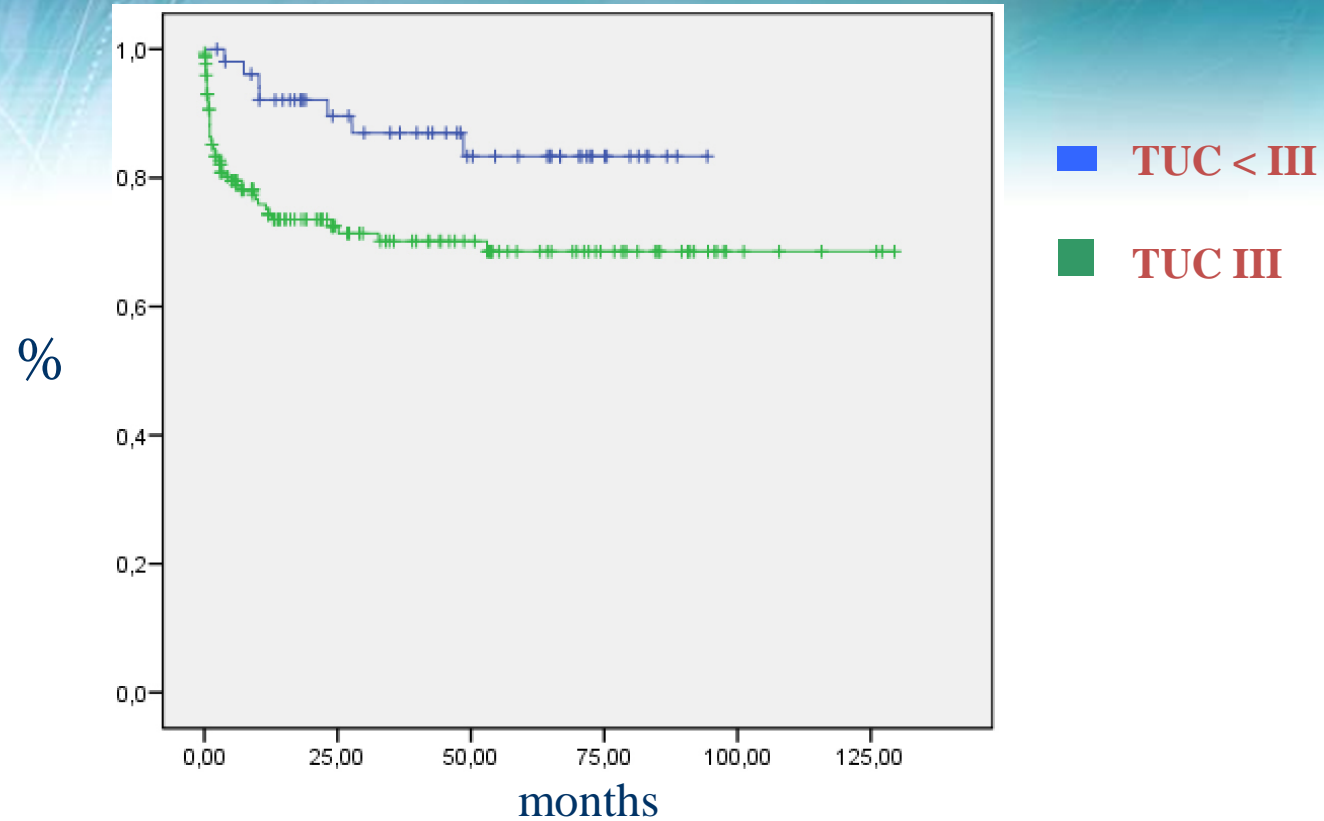
Armstrong DG et al Diabetes Care 1998;21:855-859

Grade Stage	0	I	II	III
A	Pre or post-ulcerative lesion 0%	Non-infected, non-ischemic, superficial ulceration 0%	Non-infected, non-ischemic, ulcer that penetrates to capsule or bone 0%	Non-infected, non-ischemic, ulcer that penetrates to bone or deep 0%
B	With infection 12.5%	With infection 8.5%	With infection 28.6%	With infection 92%
C	Without infection, With ischemia 25%	Without infection, With ischemia 20%	Without infection, With ischemia 25%	Without infection, With ischemia 100%
D	With infection, With ischemia 50%	With infection, With ischemia 50%	With infection, With ischemia 100%	With infection, With ischemia 100%

The amputation risk is presented as %

Tibial Artery Angioplasty with Uncoated Balloon in CLI

Limb Salvage



Variables	Univariate	Multivariate	HR (95% CI)
TUC: III vs <III	0.018	0.050	3.82 (1.72-8.47)
ESRD: Yes vs No	0.023	-	-

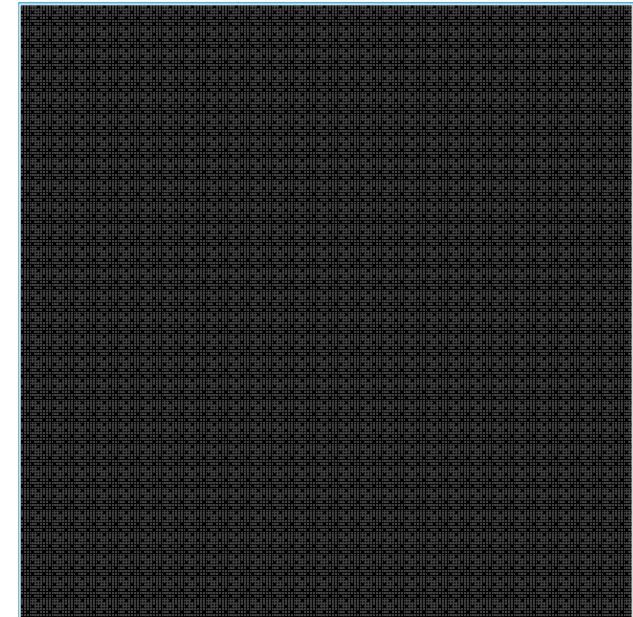


To plan treatment at BTK level – PAOD evaluation

- **Clinical evaluation**
 - Fontaine stage III / IV
 - **Neuro-ischemic ulcers**
 - . TWC
 - . angiosome



- Arterial disease evaluation



Angiosome of the leg: Anatomic study and clinical implications

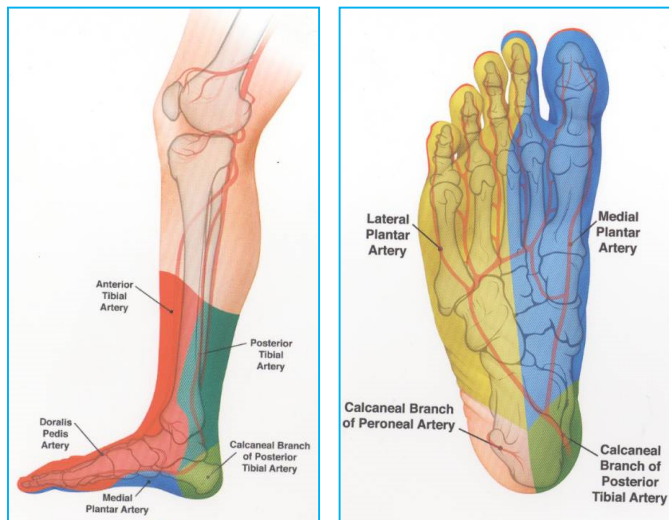
MEET 2015
MULTIDISCIPLINARY EUROPEAN
ENDOVASCULAR THERAPY

Taylor GI, Pan WR.
Plast Reconstr Surg 1998;102-599.

Ankle/Foot: 6 angiosomes

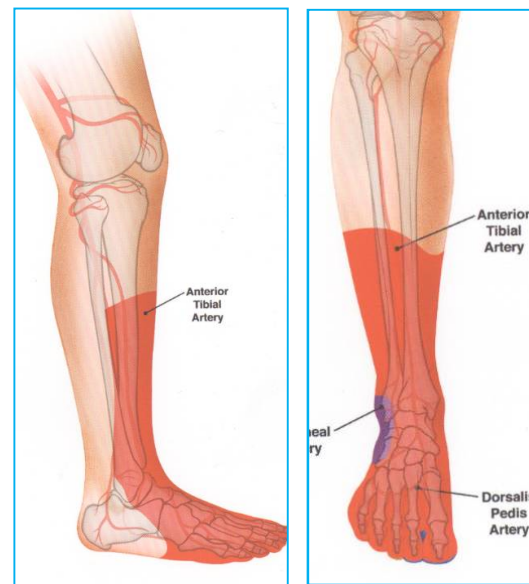
Posterior Tibial Artery (# 3)

- . Calcaneal artery
- . Medial plantar artery
- . Lateral plantar artery



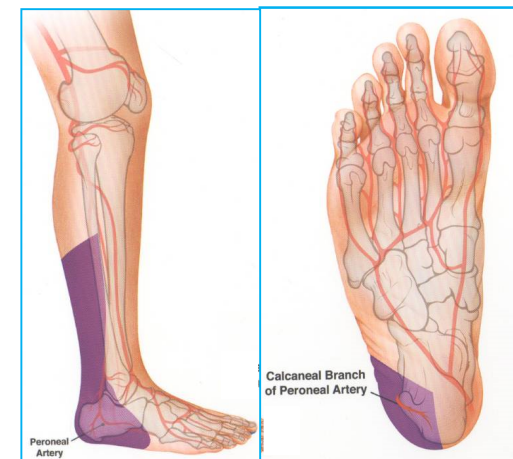
Anterior Tibial Artery (#1)

- . Dorsalis pedis artery



Peroneal Artery (#2)

- . Calcaneal artery
- . Anterior perforating artery

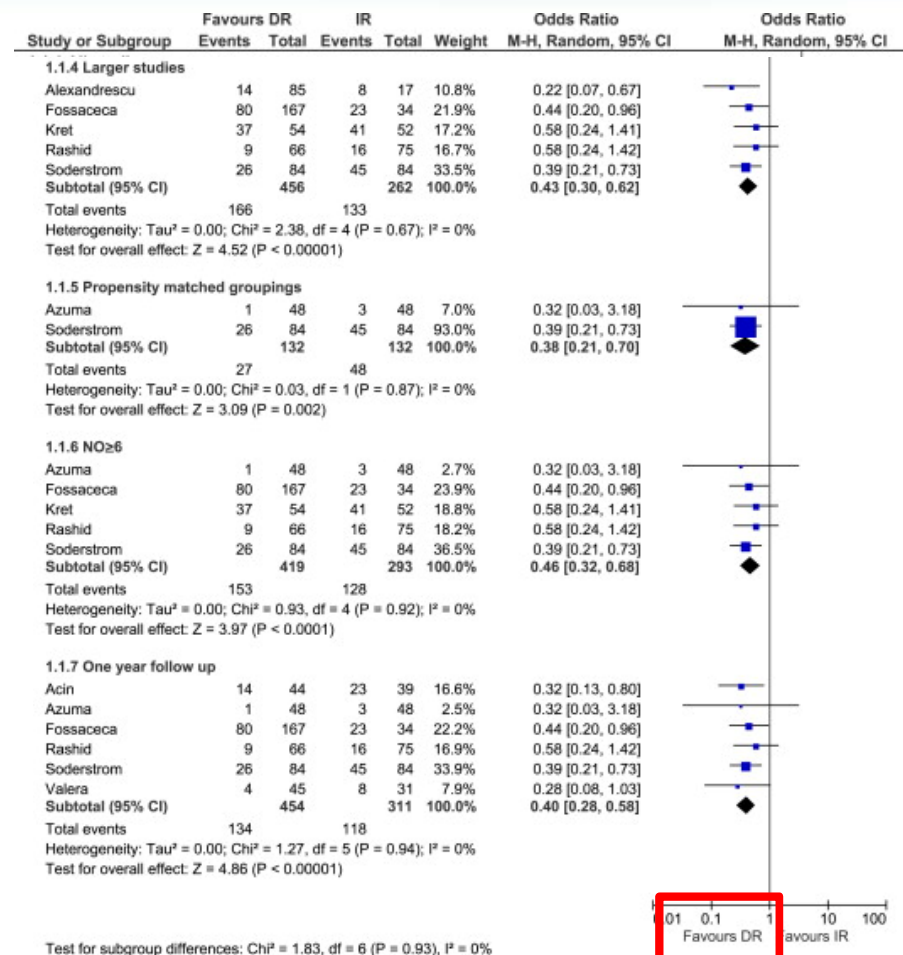
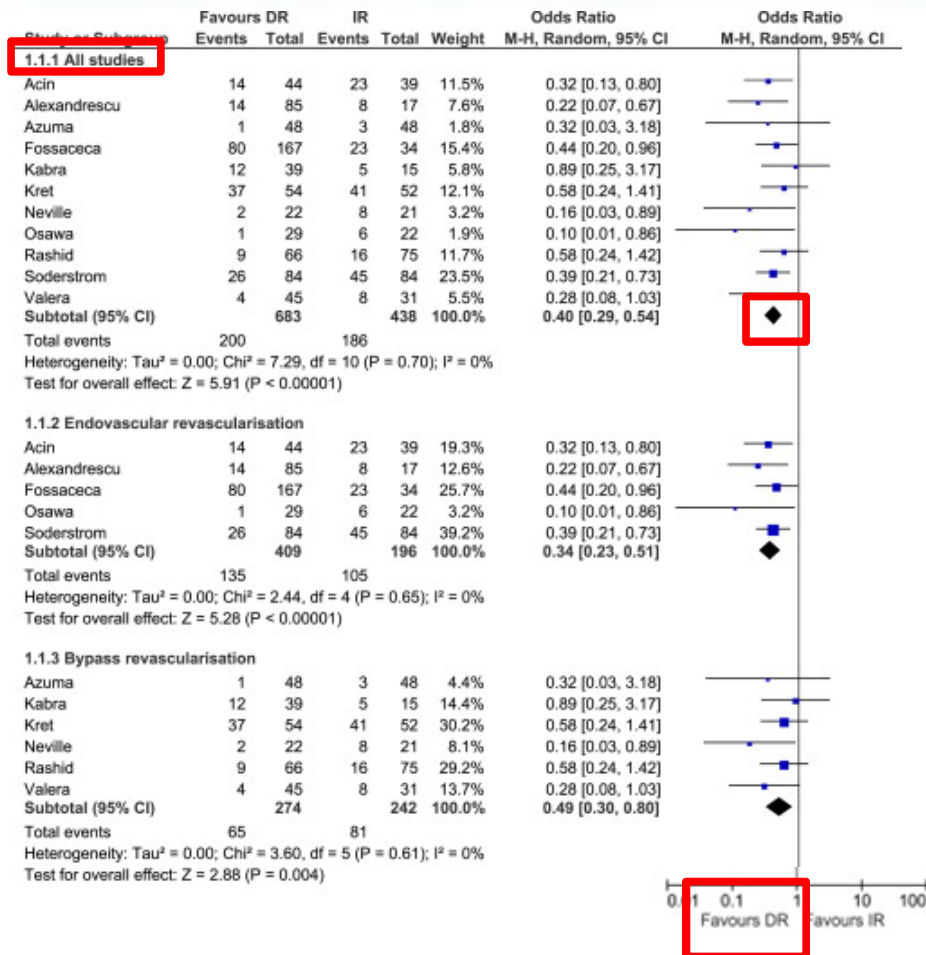


Systematic Review and Meta-analysis of Direct versus Indirect Angiosomal Revascularisation of infrapopliteal arteries

Bosanquet DC et al.

Eur J Vasc Endovasc Surg 2014; 48: 88-97

Wound healing

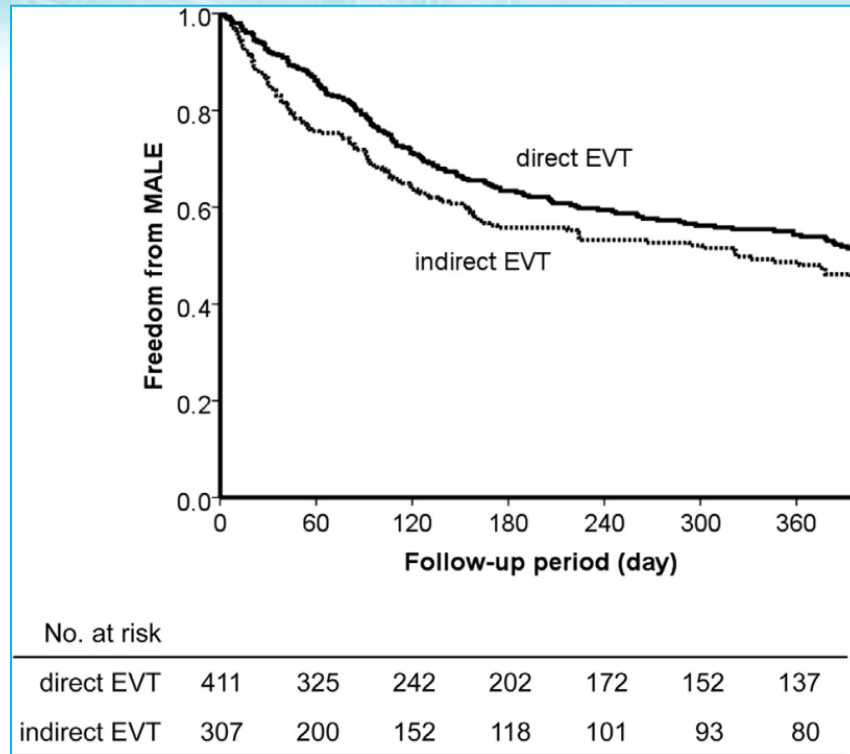


Test for subgroup differences: Chi² = 1.83, df = 6 (P = 0.93), I² = 0%

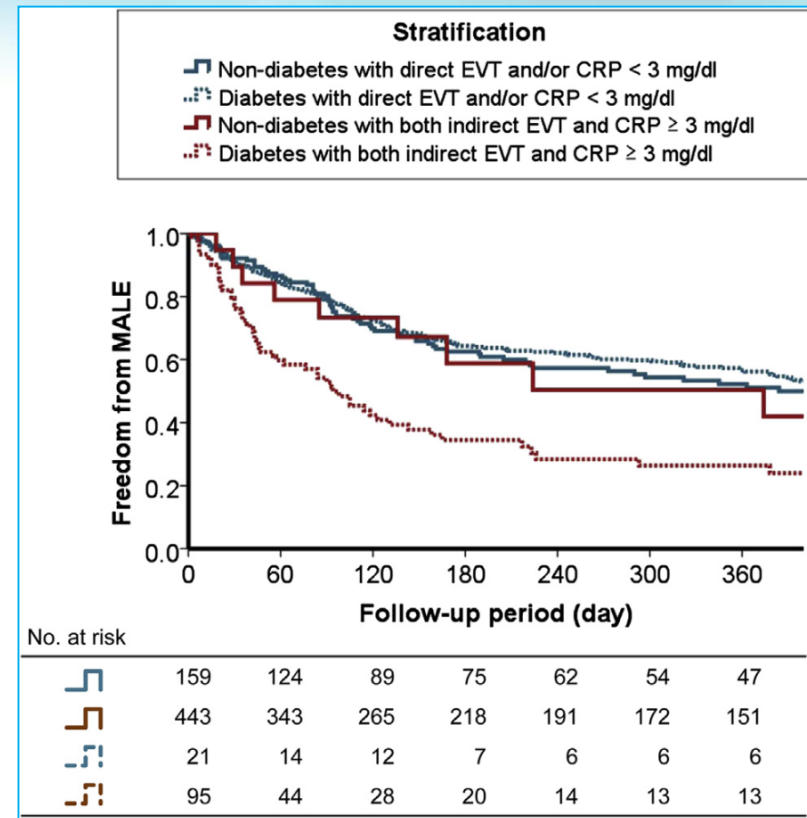
Worse Limb Prognosis for Indirect versus Direct Endovascular Revascularization only in Patients with Critical Limb Ischemia Complicated with Wound Infection and Diabetes Mellitus

Iida O et al.

Eur J Vasc Endovasc Surg 2013, 46(5): 575-82



MALE: major amputation or any reintervention

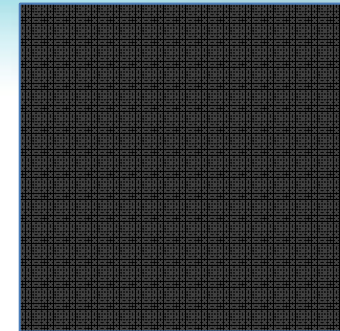


Conclusion: indirect EVT in patients with Diabetes and Wound Infection had a significant association with MALE

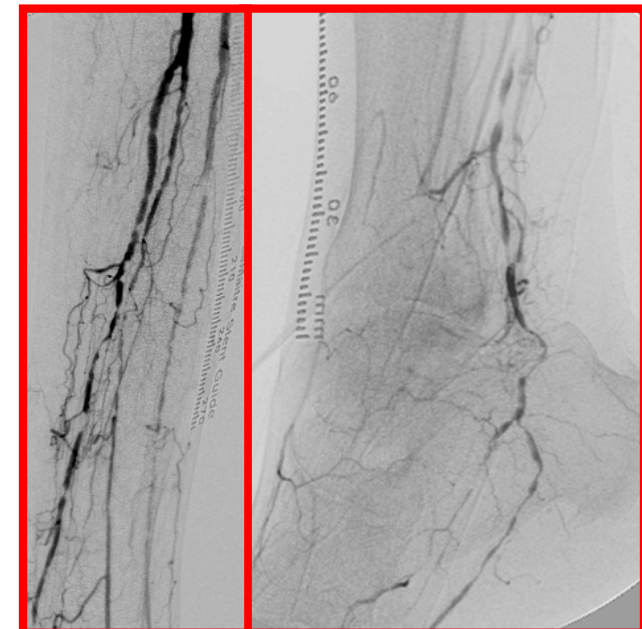


To plan treatment at BTK level – PAOD evaluation

- Clinical evaluation
 - Fontaine stage III / IV
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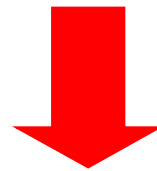
- Arterial disease evaluation



To plan treatment at BTK level – Arterial disease evaluation

Imaging - End-points

- To define the presence of pathology
- To define the extension of pathology
- Run in, Run off (morphology and haemodynamic aspects)



Imaging of femoro-popliteal-tibial axis
Imaging of foot arteries

To plan treatment at BTK level – Arterial disease evaluation

Imaging

- Doppler CW, ABI
- Duplex
- TcPO₂
- Angio MRI, Angio CT
- Angiography



To plan treatment at BTK level – Arterial disease evaluation

Imaging

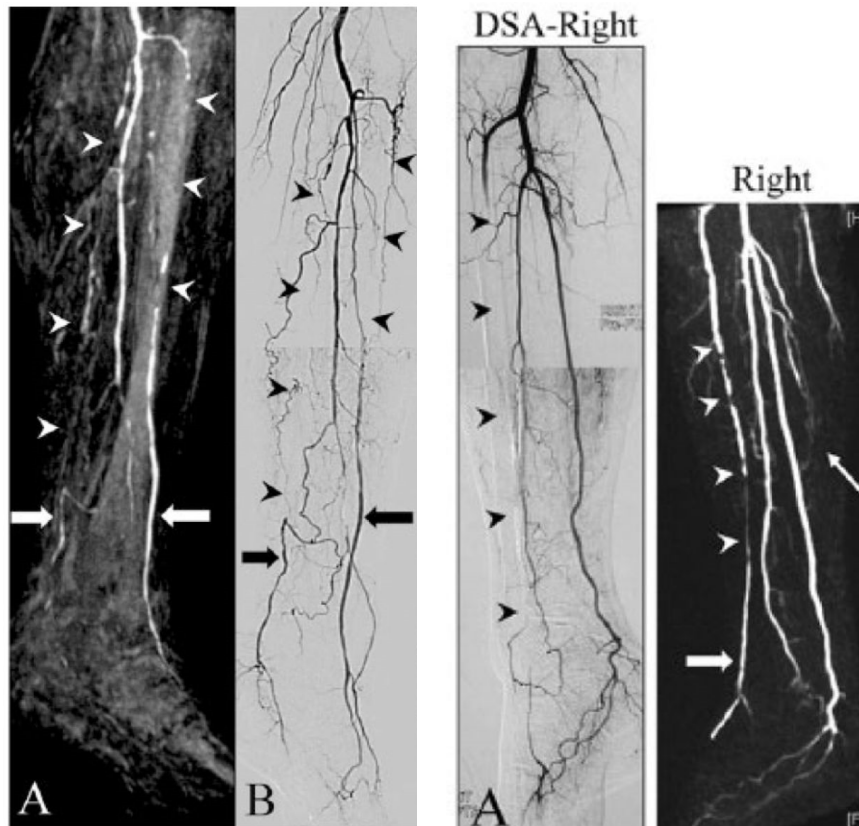
- Doppler CW, ABI
- Duplex
- TcPO₂
- **Angio MRI**, Angio CT
- Angiography



To plan treatment at BTK level – Arterial disease evaluation

Imaging – MR Angiography

- Lapeyre M et al *Am J Roentgenol* 2005; 185: 1641-1650
- Diehm N et al *Invest Radiol* 2007; 42: 467-476



- DSA may fail to correctly depict tibial artery especially distal to long-segment occlusions.

- Late contrast enhancement of distal runoff vessels with retrograde filling via collaterals may also not be visible on DSA images.

YQ Zhu et al.

J Endovasc Ther 2015;22:243-251

N. Diehm

J Endovasc Ther 2015: 22; 252-253

To plan treatment at BTK level – Arterial disease evaluation

Imaging

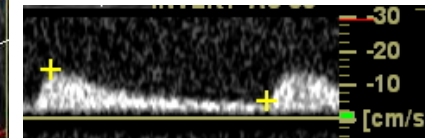
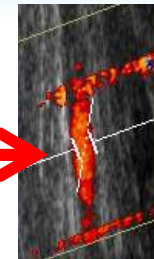
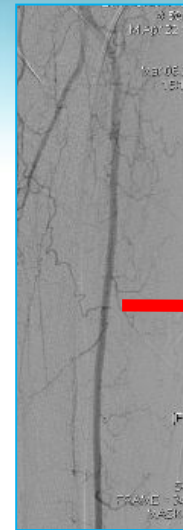
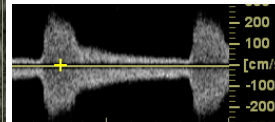
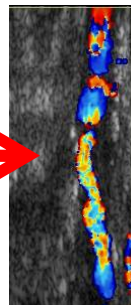
- Doppler CW, ABI
- **Duplex**
- TcPO₂
- Angio MRI, Angio CT
- Angiography



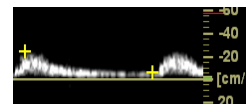
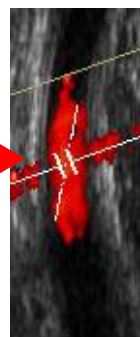
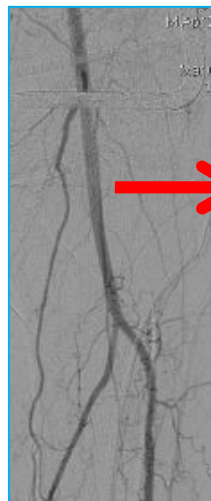
Tibial arteries disease: Ultrasound evaluation



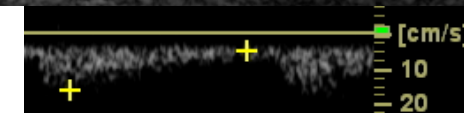
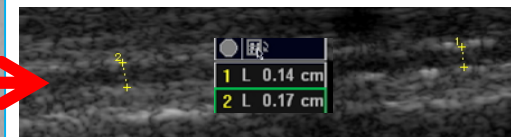
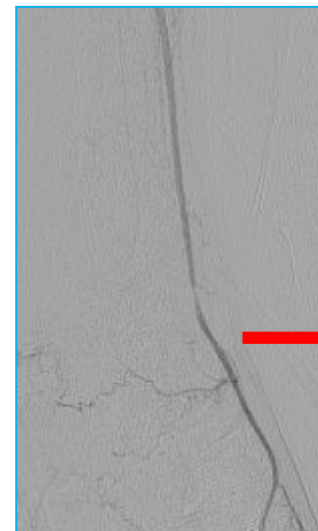
SFA



Anterior tibial A.



Popliteal A.



Dorsalis pedis A.



DUS assessment of tibial arteries in patients with arterial disease:

a Systematic Review

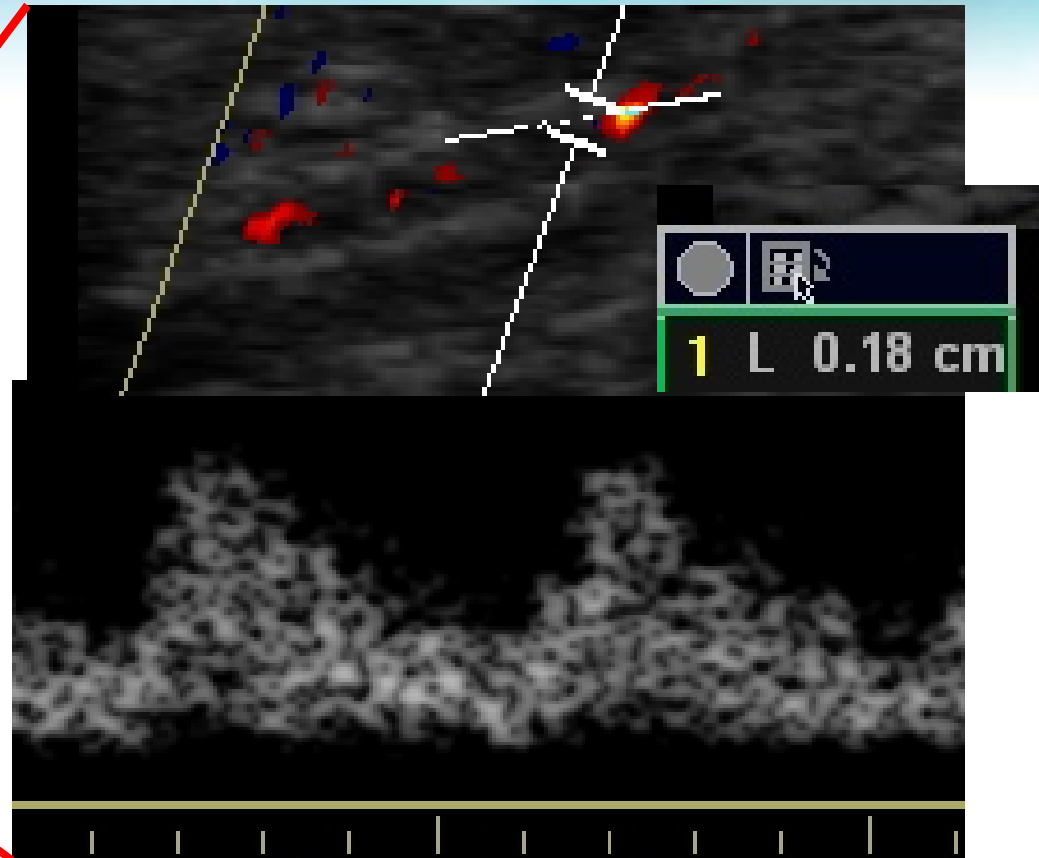
Artery	Sensitivity (%)	Specificity (%)
TPT	25-71	87-100
ATA	72-98	35-100
Peroneal a.	89-94	21-58
PTA	79-100	40-100
Dorsalis pedis	33-85	76-89
Plantar arteries	43-78	76-100

Bianchini Massoni C. 2014



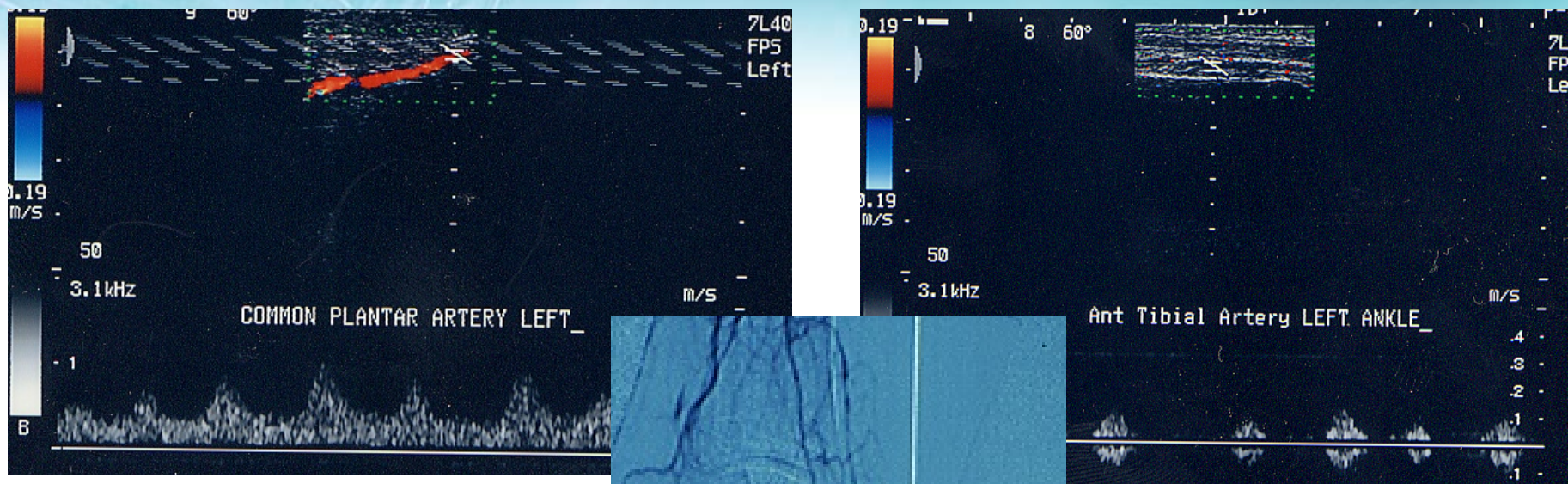
Neuroischemic foot – TUC III C

Angio: Posterior tibial artery, Peroneal artery and Anterior tibial artery long occlusion, no foot arteries

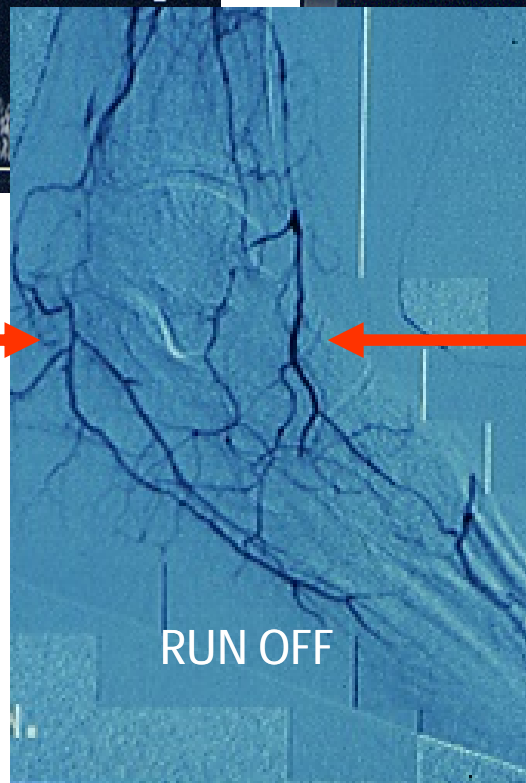


Tibial arteries disease in diabetic patients: Can colour duplex mapping of the ankle and foot arteries improve the vascular program?

M Gargiulo, A Stella, S Tarantini et al ESVS 2000



**GOOD
RUN OFF**

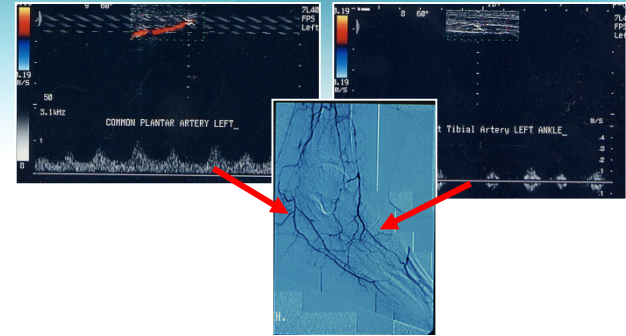


**POOR
RUN OFF**

Neuro-ischemic foot

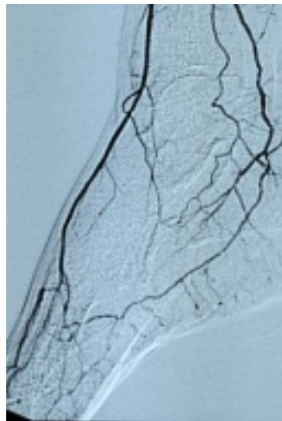


Duplex ultrasound arterial mapping
from the EIA to the pedal arteries

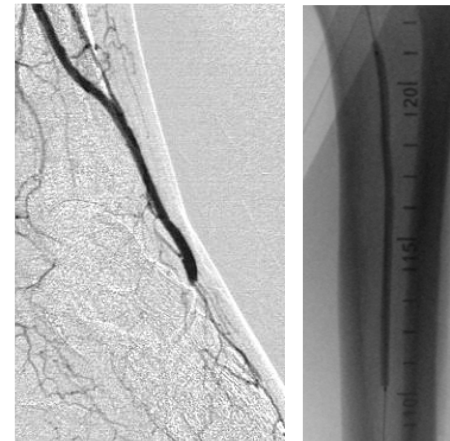


Arterial wall calcification
Extensive ulcers
Edema
Very poor run in or run off

Arteriography



Lower Extremity
Revascularization



Angiosomes: How Do They Affect My Treatment?

LM Palena et al.

Tech Vasc Intervent Radiol 2014; 17:155 - 169

Targets for revascularization in CLI

1. Complete revascularization

1 vessel better than 0
2-3 vessels better than 1
Tibial arteries better than peroneal

2. Wound related artery revascularization

Direct revascularization better than indirect revascularization

Treatment at BTK level

Step-by-step crossing strategy

Antegrade approach

1. Endoluminal approach
 2. Subintimal approach
- Impossibility to cross?*

Retrograde approach

1. Pedal-Plantar Loop Technique
2. Trans-collateral approach
3. Retrograde percutaneous puncture

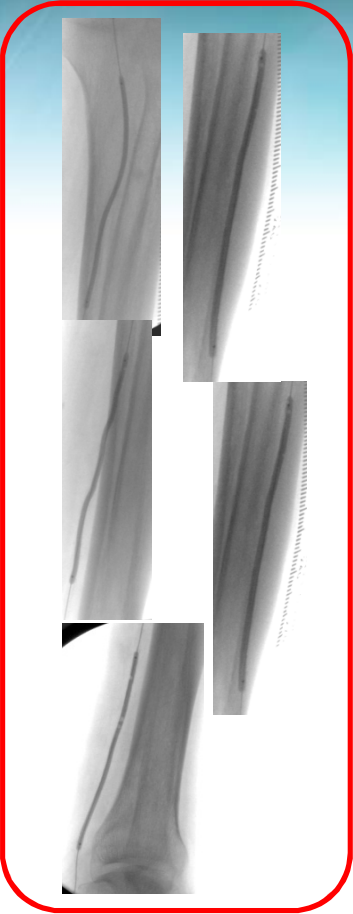
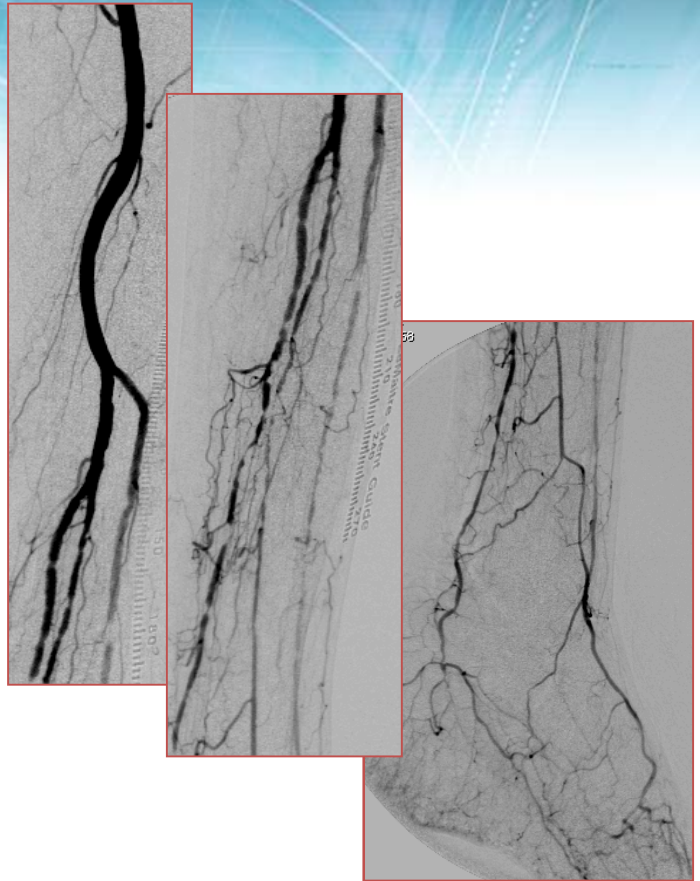
R. Ferraresi et al

J Cardiovasc Surg 2013; 54: 685-711

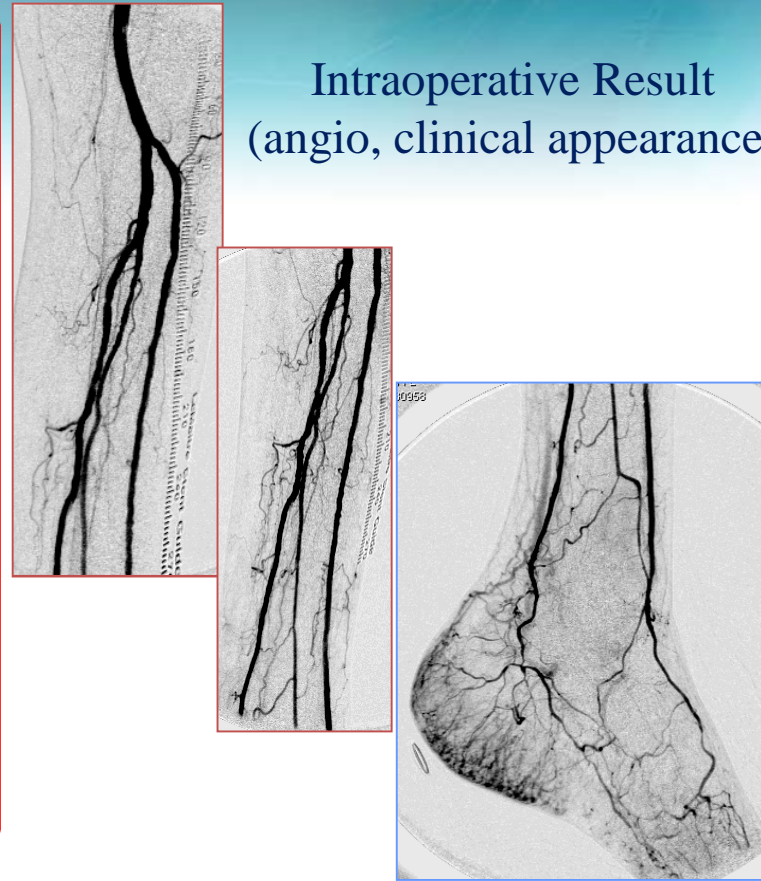
LM Palena et al.

Tech Vasc Intervent Radiol 2014; 17:155 - 169

Case # 1 - Tibial arteries stenosis - PTA

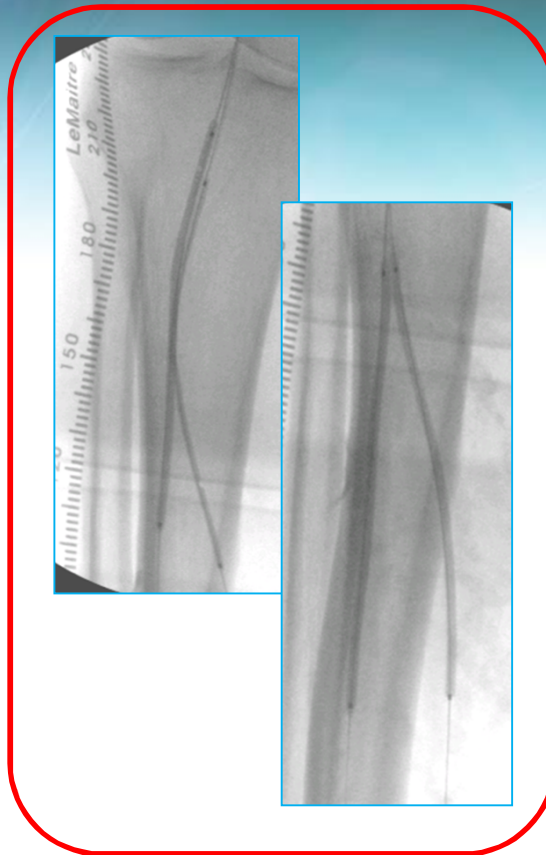


Intraoperative Result
(angio, clinical appearance)



Follow up 1 month

Case # 2 – Tibial-peroneal trunk obstruction - PTA



Intraoperative Result



TUC III D



Kissing balloon technique
Gargiulo M et al
Eur J Vasc Endovasc Surg 2008; 36:197-202



Follow up 10 months

CLI and tibial arteries disease – Endovascular treatment Results

Authors	Limbs	Technical success
Schwarten 1988	114	97%
Saab 1992	14	100%
Matsi 1993	84	83%
Durham 1994	14	100%
Hauser 1996	47	80%
Lofberg 1996	86	88%



Technical Failure 0-20%

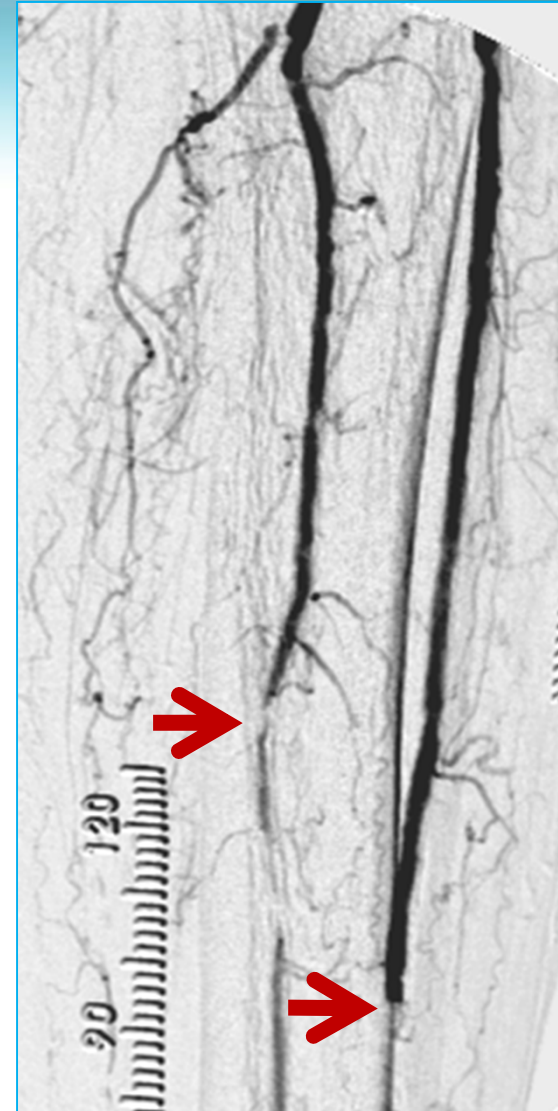
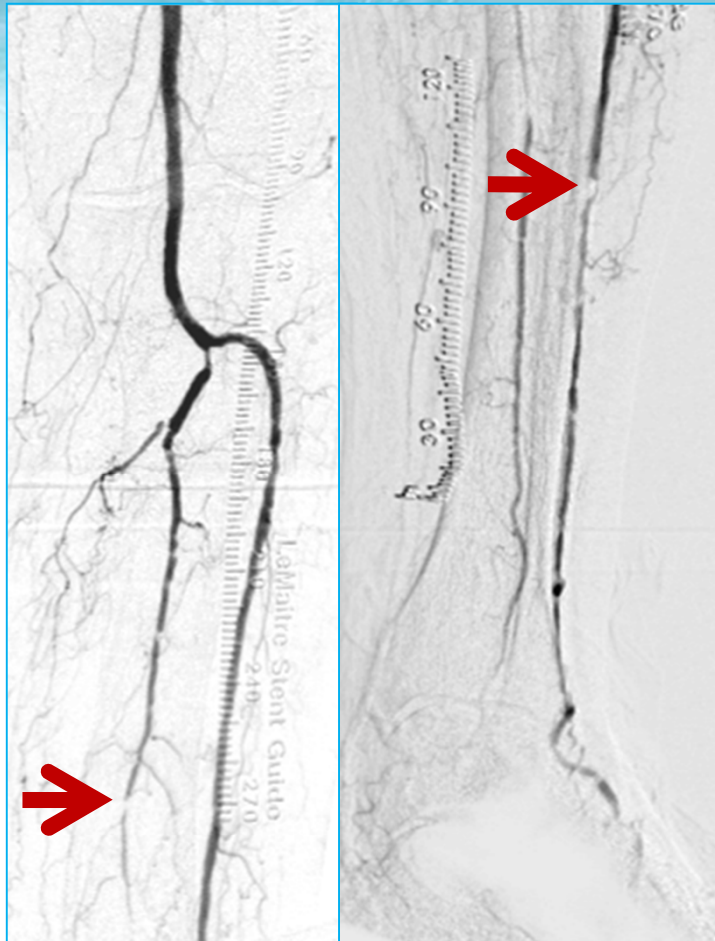
CLI and tibial arteries disease – Endovascular treatment Results

Authors	Limbs	Technical Success
Faglia E. et al <i>Eur J Vasc Endovasc Surg 2005</i>	1188	83.6%
Romiti M et al. <i>J Vasc Surg 2008</i>	2693	89%
Ferraresi R. et al <i>Eur J Vasc Endovasc Surg 2009</i>	107	93.5%
Alexandrescu V et al <i>J Endovasc Ther 2011</i>	232	80%
Our Experience 2012 <i>Not published data</i>	249	97.2%



Technical Failure 3-20%

Arterial calcification and PAOD



Arterial calcification and PAOD

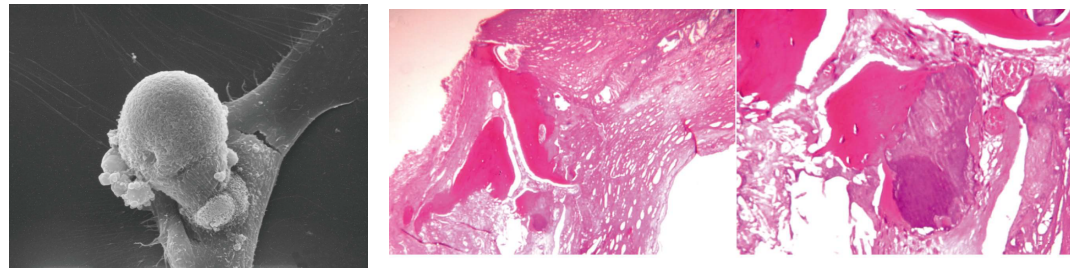
Peripheral arterial calcification: prevalence, mechanism, detection and clinical implications

Rocha-Singh K et al.

Catheterization and Cardiovasc interventions 2014; 83: E212-E220

Vascular Calcification

- **Passive process:** the results of Calcium and Phosphate ions exceeding solubility in tissue fluid, inducing the precipitation and deposition of hydroxyapatite crystals
- **Active process:** VC is a result of intracellular molecular process involving the differentiation of macrophages and VSMCs into osteoclast-like cells



Diabetic PAOD

1. Macroangiopathy is most often seen in popliteal and tibial arteries

2. The lesions tend to be more extensive

3. Histopathological lesions

- Macroangiopathy

atherosclerosis

diffuse intimal fibrosis

medial calcific sclerosis

- Microangiopathy

no small artery or arteriolar occlusive lesion

4. Patency of the ankle and foot arteries

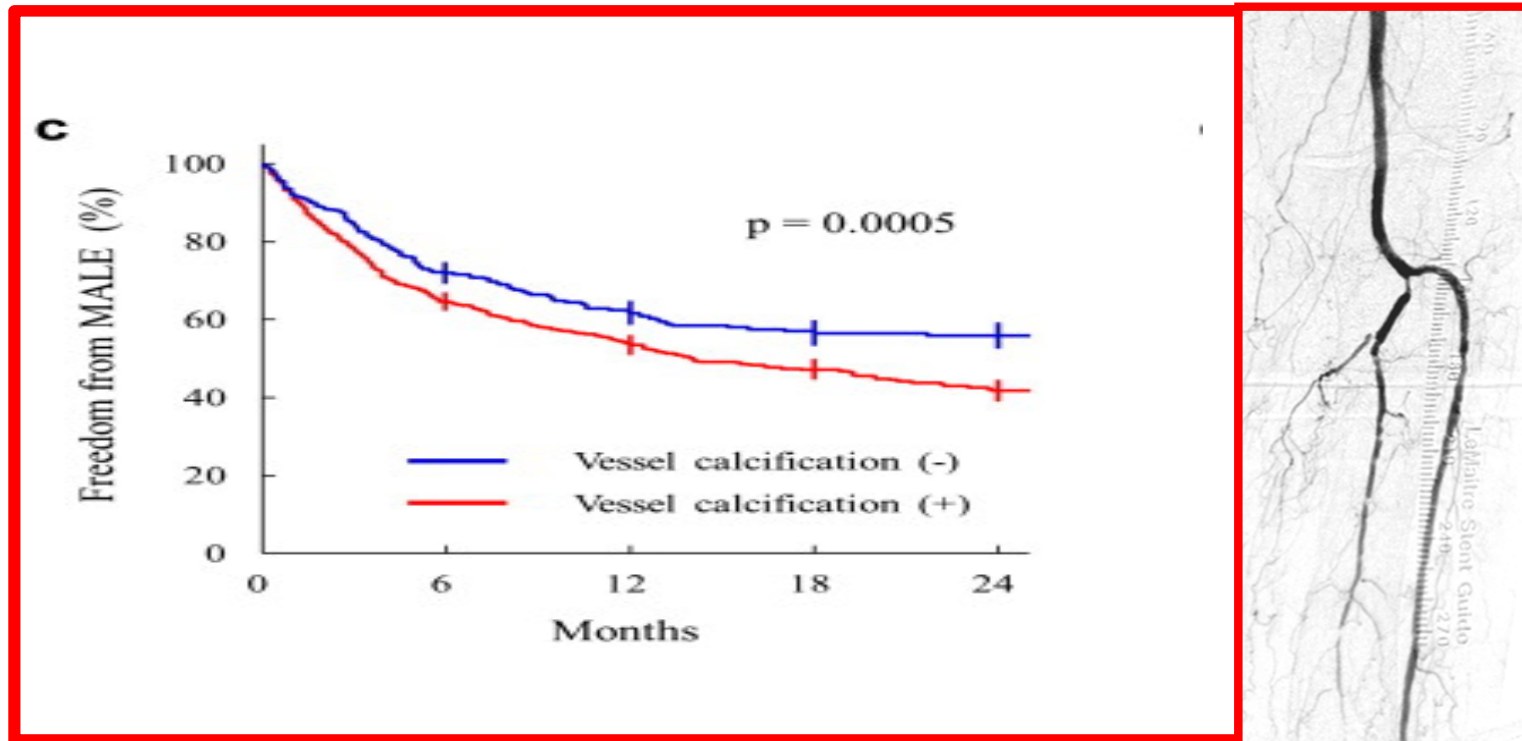
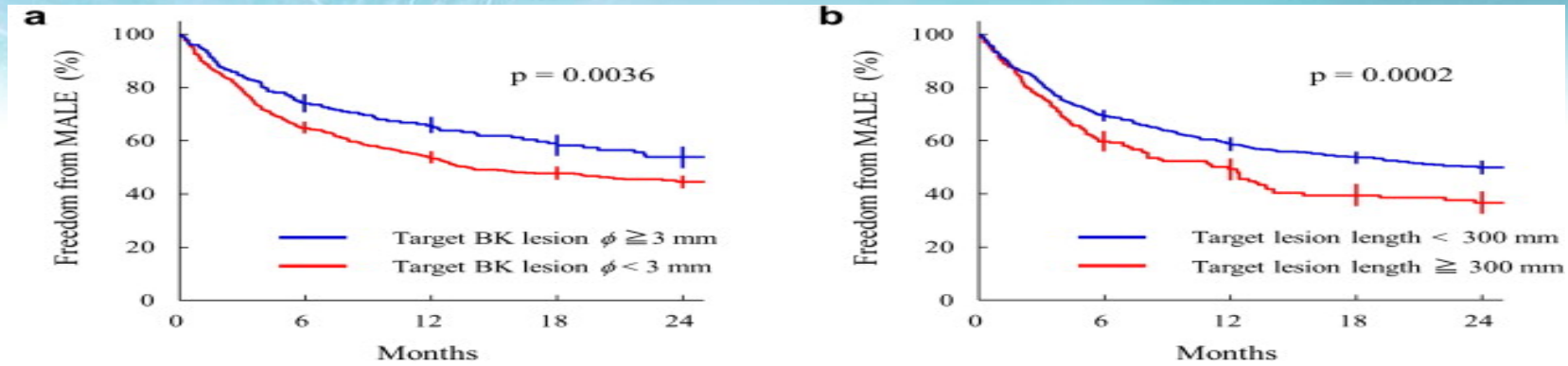


LoGerfo FW

J Vasc Surg 1987; 5: 793-6

Anatomical Predictors of Major Adverse Limb Events after Infrapopliteal Angioplasty for Patients with Critical Limb Ischaemia due to Pure Isolated Infrapopliteal Lesions

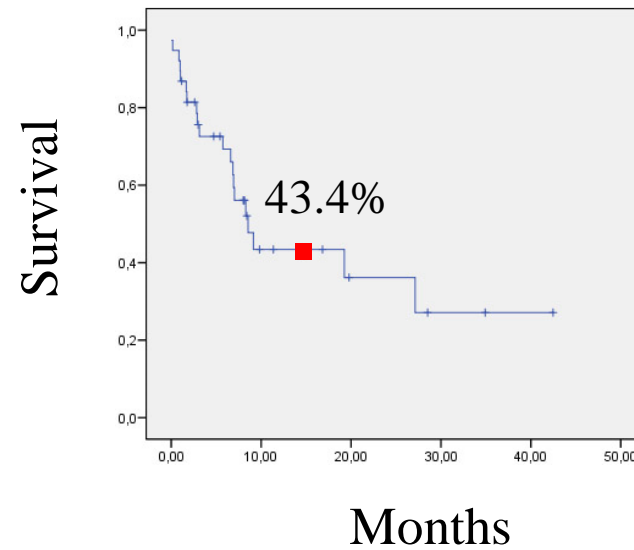
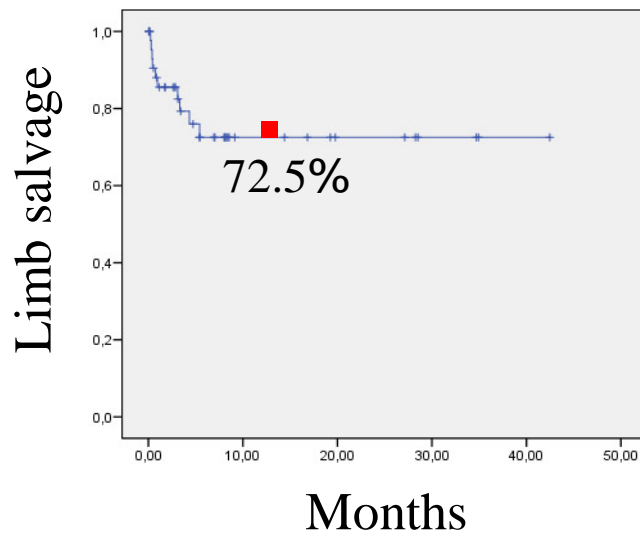
Iida O et al.
EJVES 2012; 44: 318 - 324



Endovascular treatment of the tibial arteries in hemodialysis patients with critical limb ischemia: is it justified?

*C. Bianchini Massoni et al
Ann Vasc Surg 2014*

Pts	39
Limbs	46
Infrapopliteal target arteries	91
Technical Success	89%



Arterial calcification and PAOD

Peripheral arterial calcification: prevalence, mechanism, detection and clinical implications

Rocha-Singh K et al.

Catheterization and Cardiovasc interventions 2014; 83: E212-E220

Proposed Peripheral Arterial Calcium Scoring System (PACSS)

Grade 0: No visible calcium at the target lesion site

Grade 1: unilateral calcification < 5cm; a) intimal calcification; b) medical calcification; c) mixed type

Grade 2: unilateral calcification \geq 5cm; a) intimal calcification; b) medical calcification; c) mixed type

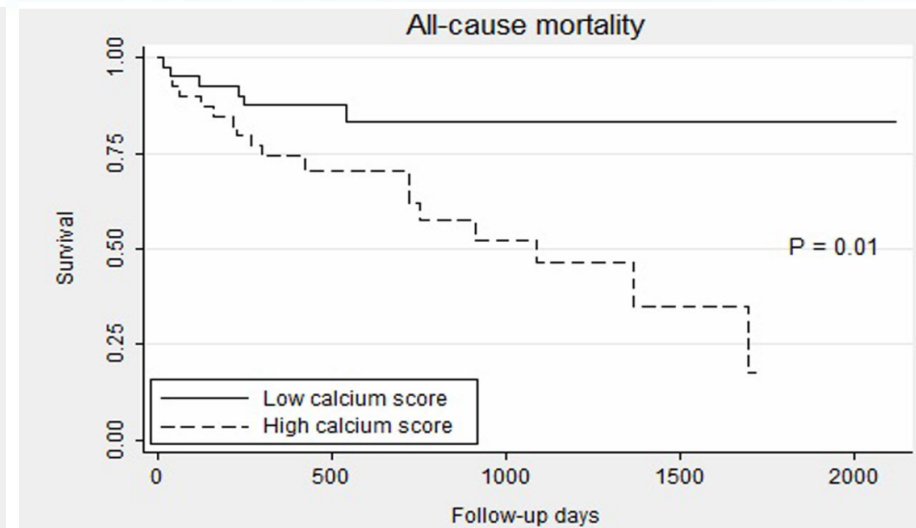
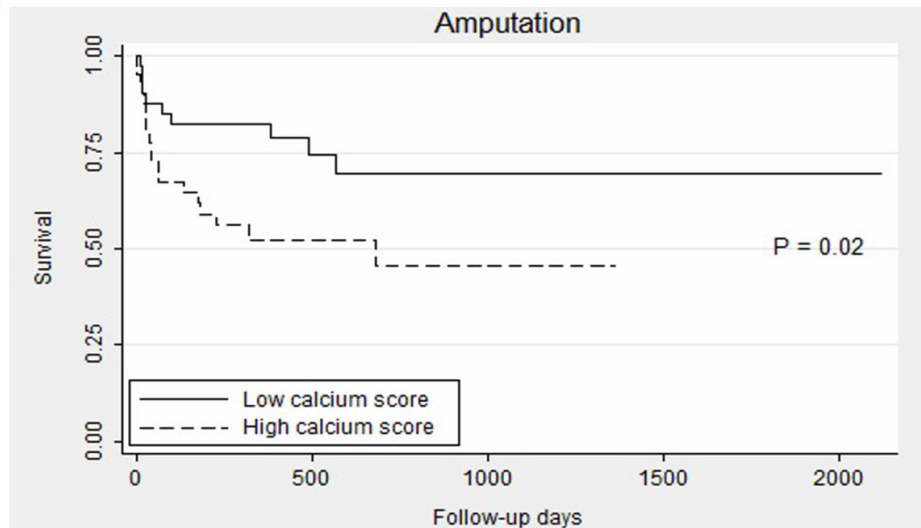
Grade 3: bilateral calcification < 5cm; a) intimal calcification; b) medical calcification; c) mixed type

Grade 4: bilateral calcification \geq 5cm; a) intimal calcification; b) medical calcification; c) mixed type

This scoring system is based only on the length of the calcified portion but do not take in consideration the circumferential distribution

Association of lower extremity arterial calcification with amputation and mortality in patients with symptomatic peripheral artery disease.

Huang CL et al.
Plos 2014; 9: 1-6



Arterial status, angiosome, arterial calcifications:
it is possible to plan treatment at BTK level ?

Conclusion

Arterial status, angiosome, arterial calcifications:
it is possible to plan treatment at BTK level ?

Conclusion

YES

Arterial status, angiosome, arterial calcifications:
it is possible to plan treatment at BTK level ?

Conclusion

YES

- Clinical evaluation
 - Fontaine stage III / IV
 - Neuro-ischemic ulcers
 - . TWC
 - . angiosome
- Arterial disease evaluation
 - Extension
 - Run in, run off
 - Tibial and foot arteries calcium score

To plan treatment at BTK level – Arterial disease evaluation

Imaging

- Doppler CW, ABI
- Duplex
- TcPO₂
- Angio MRI, Angio CT
- Angiography
- **Tibial and foot arteries X-Ray**

