

Added value of non invasive tissue perfusion imaging during endovascular interventions for CLI patients

MAC-conference, Munich 2019



Jean-Paul de Vries, Head Department of Surgery
University Medical Centre Groningen
The Netherlands



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Disclosures

- Cofounder of Endovascular Diagnostics B.V.
- Consultant for Bentley Innomed
- Advisory board member Getinghe
- Research Grants Cardionovum, Lijf & Leven



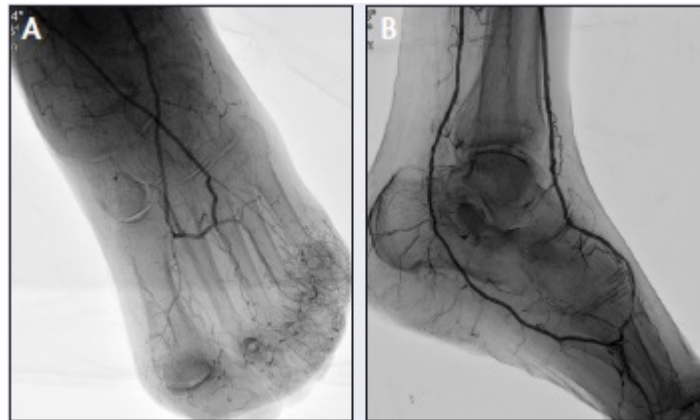
Introduction

- 15% of PAOD will progress to chronic limb threatening ischemia
- 22% of CLTI patients will undergo major amputation
- 15% of amputees will need 2nd amputation
- Treatment options
 - Bypass surgery
 - Endovascular treatment (PTA/stent)
- Both with substantial comorbidity, expenses and need for reinterventions



Introduction

- Current diagnostics
 - eg. ABI, doppler ultrasound, CTA, MRA, DSA
- Determination of macrovasculature
- Focus on stenosis or occlusion of arteries



Introduction

- What do we also (really) want to know:
 - Determination of tissue perfusion (TP)/oxygenation
 - Real time monitoring TP during interventions
 - TP values to predict (un)successful outcomes
 - TP monitoring during complete care process
 - Even at home during follow-up
- At every location of the lower limb / foot



Current tissue perfusion measurements

A systematic review of diagnostic techniques to determine tissue perfusion in patients with peripheral arterial disease

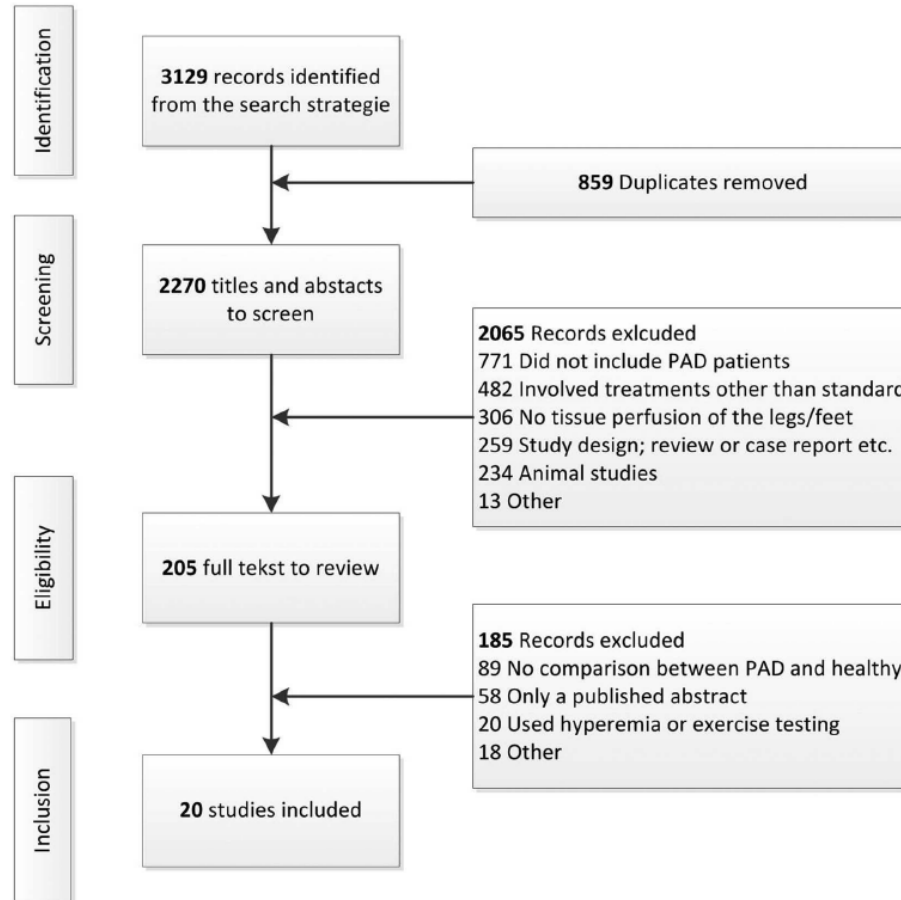
Kirsten F. Ma, Simone F. Kleiss, Richte C.L. Schuurmann, Reinoud P.H. Bokkers, Çağdas Ünlü & Jean-Paul P.M. De Vries

<https://doi.org/10.1080/17434440.2019.1644166>

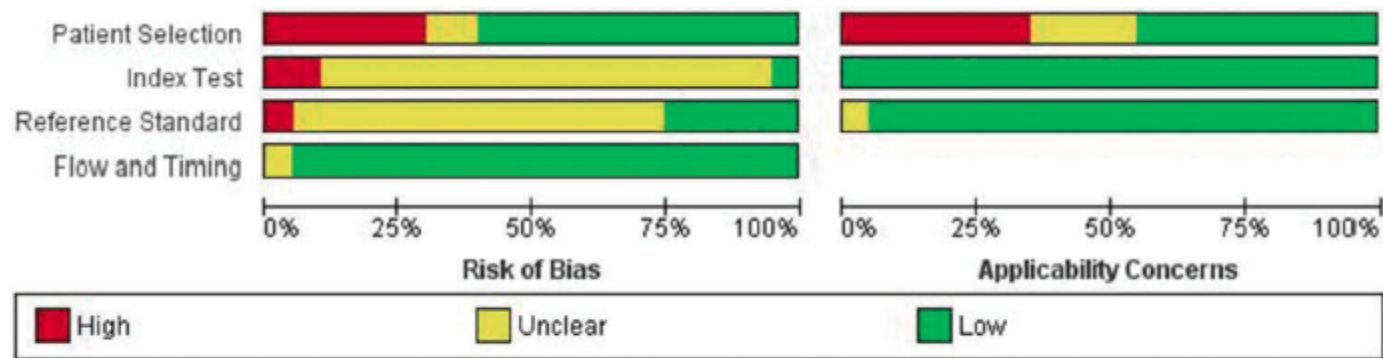


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Current tissue perfusion measurements



Current tissue perfusion measurements



Graphical display is bias and quality assessment according to QUADAS-2.



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Current tissue perfusion measurements

- Transcutaneous oxygen measurement (tcPO₂)
- NIRS
- Hyperspectral imaging
- Laser speckle contrast imaging
- Laser Doppler perfusion monitoring



Current tissue perfusion measurements

- Transcutaneous oxygen measurement (tcPO₂)
- Considered as a gold standard
- Time consuming, operator dependent
- Not 'idiot prove' and 'real-time'
- No measurements at home



Hyperspectral imaging

- With the HyperView™ system
- Visible light spectroscopy
 - Oxyhemoglobin, deoxyhemoglobin and oxygen saturation
- Non-invasive and transcutaneous measurements
- Easy to use, hand-held camera
- Applicable in hospital and in home setting



REVIEW

RECENT DEVELOPMENTS IN THE MANAGEMENT OF CRITICAL LIMB ISCHEMIA

Hyperspectral imaging for noninvasive tissue perfusion measurements of the lower leg: review of literature and introduction of a standardized measurement protocol with a portable system

Simone F. KLEISS ¹ *, Kirsten F. MA ¹, Richte C. SCHUURMANN ¹, Mostafa EL-MOUMNI ², Clark J. ZEEBREGTS ¹, Reinoud P. BOKKERS ³, Çağdas ÜNLÜ ⁴, Jean-Paul de VRIES ¹

- 9 manuscripts (3 on PAOD, 4 on DM)
- In 5 of 7 patient studies HSI was associated with
 - Wound healing
 - Severity of peripheral ischemia
- No robust validation of technique



Validation study

- 43 healthy volunteers
- Plantar side of both feet
- Lateral side of the calves
- Standardized conditions
- 90° angulation Hyperview with skin
- Skin temperature



Validation study

- Repeated measurements (3 at each location)



Results

Intra Class Correlation (95% CI) of 3 repeated measurements			
	Oxyhemoglobin	Deoxyhemoglobin	Saturation
Right leg			
Plantar	0,86 (0,78-0,92)	0,87 (0,79-0,92)	0,86 (0,78-0,92)
Lateral calf	0,83 (0,70-0,91)	0,87 (0,78-0,93)	0,81 (0,69-0,89)
Left leg			
Plantar	0,84 (0,76-0,91)	0,89 (0,83-0,93)	0,85 (0,77-0,91)
Lateral calf	0,87 (0,79-0,93)	0,89 (0,82-0,94)	0,82 (0,71-0,90)



Results

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Left leg			
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Lateral calf	0,87 (0,79-0,93)	0,89 (0,82-0,94)	0,82 (0,71-0,90)

ICC > 0,81



Results

Location	N.	OxyHb (a.u.)	DeoxyHb (a.u.)	Saturation (%)
Right leg				
Plantar	43			
Lateral calf	32			
Left leg				
Plantar	43			
Lateral calf	32			



Results

Location	N.	OxyHb (a.u.)	DeoxyHb (a.u.)	Saturation (%)
Right leg				
Plantar	43	85,2 ± 24,9	54,1 ± 15,4	60,5 ± 11,7
Lateral calf	32	41,9 ± 11,4	37,8 ± 9,9	52,4 ± 10,6
Left leg				
Plantar	43			
Lateral calf	32			

P < 0.001



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Results

Location	N.	OxyHb (a.u.)	DeoxyHb (a.u.)	Saturation (%)
Right leg				
Plantar	43			
Lateral calf	32			
Left leg				
Plantar	43	80,4 ± 23,1	57,3 ± 15,9	57,9 ± 11,7
Lateral calf	32	39,8 ± 10,5	38,3 ± 9,8	50,9 ± 10,3

P < 0.001



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Results

Location	N.	OxyHb (a.u.)	DeoxyHb (a.u.)	Saturation (%)
Right leg				
Plantar	43	85,2 ± 24,9	54,1 ± 15,4	60,5 ± 11,7
Lateral calf	32			
Left leg				
Plantar	43	80,4 ± 23,1	57,3 ± 15,9	57,9 ± 11,7
Lateral calf	32			

P < 0.05



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Results

Location	N.	OxyHb (a.u.)	DeoxyHb (a.u.)	Saturation (%)
Right leg				
Plantar	43			
Lateral calf	32	41,9 ± 11,4	37,8 ± 9,9	52,4 ± 10,6
Left leg				
Plantar	43			
Lateral calf	32	39,8 ± 10,5	38,3 ± 9,8	50,9 ± 10,3

P < 0.05



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Conclusions

- Tissue perfusion measurements in its infancy
- Hyperspectral imaging might be an option
- ICC of repeated HSI measurements good
- However, each measurement location should be used as its own reference



The **SPECTACULAR** study

- Validation of the Hyperview™ system in:
 - Clinical setting
 - Home monitoring
- Collecting values of tissue oxygenation during all phases of treatment
- Predictive value of hyperspectral imaging for clinical outcome
 - Wound healing



Design – Prospective cohort study

- Pre- and post-interventional diagnostics per current protocol
 - Collecting data of standard diagnostics
- Standard treatment according to guideline
 - PTA/Bypass surgery
- Additional diagnostics throughout the complete process (also at home)



Methods – patient inclusion

- Chronic limb threatening ischaemia
 - Rutherford 4, 5 and 6
- Standard diagnostic
- PTA/bypass
- ...
- ...
- ... temperature measurements

Start inclusion Nov 29th 2019



Measurements at home



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