The REPEAT study: validation of perfusion angiography measurements for below-the-knee arteries in critical limb ischaemia

Jean-Paul P.M. de Vries, D.A.F. van den Heuvel
University Medical Centre Groningen
St. Antonius Hospital Nieuwegein, The Netherlands

8th MAC Munich
December 2018
Disclosures

Co-founder of Endovascular Diagnostics

Consultant for Medtronic, Bentley Innomed

Advisory board member: Medtronic

Research grants: Cardionovum, Stichting Lijf & Leven
Current techniques like ABI, toe pressures, TcPO2, DSA are indicative for macrovascularization

In diabetic patients pressure measurements are unreliable

Perfusion of the foot is dependent on the status of the microcirculation
2D perfusion (Philips Healthcare, Best, The Netherlands):

Obtained by post-processing software after standardized DSA (popliteal artery, 9 cc contrast, speed 3 cc/sec)

Comparison of post- and pre-intervention images
2D perfusion angiography (2DPA)

DSA → Time density curve
Color-coded perfusion image
Pros and cons of 2DPA

- Operator can choose area of interest
- No additional contrast and radiation
- 2D visualization of 3D anatomy
- No robust clinical validation performed (in CLI)
Clinical evaluation and standardization of perfusion angiography is mandatory before introduction in daily practice
REPEAT study

1. PA reproducibility

2. Intra- and inter-observer variability

3. Develop a vessel extraction method
Patient characteristics

- ✔ Non-healing ulcers or gangrene
- ✔ Below-the-knee endovascular treatment
- ✗ Severe renal failure (eGFR < 0.30 mL/1.73 m²)
- ✗ Scheduled for major amputation
Image acquisition

- Perfusion protocol
  - Minimization of patient movement
  - Constant kV and mAs
  - Equal contrast parameters
Analyses

ROI of complete image
Statistics

- Normalized root mean square error
- NRMSE ≤ 0.10

\[ \text{NRMSE} = \sqrt{\frac{\sum (TDC_{1i} - TDC_{2i})^2}{n}} / TDC_{\text{max}} \]
Results

- 11 patients included
- 64% NRMSE <0.10
Results

4 patients with NRMSE > 0.10

- In one patient caused by major movement

NRMSE = 0.30
Results

- 4 patients with NRMSE > 0.10
  - In two patients probably caused by adjustment of acquisition settings

Frame 2

Frame 60

NRMSE = 0.20
Results

- Frame selection
  - 3 out of 4 NRMSE ≤ 0.10
    - NRMSE₁ = 0.06
    - NRMSE₃ = 0.07
    - NRMSE₁₀ = 0.06
  - In total 10 out of 11 (91%) NRMSE ≤ 0.10
Observer variability

- Intra-observer variability
  - One observer
  - Five repeated measurement

- Inter-observer variability
  - Two observers
Region of interest

Complete foot with exclusion of digits

Wound area
Results: foot ROI

Intra-observer

NRMSEs < 0.10: 100% (100/100)
All parameters ICC ≥ 0.95

Inter-observer

NRMSEs < 0.10: 95% (19/20)
Conclusion

Foot ROI except digits (Reekers) preferred

But...
contains major arteries
Region growing
Results

Original image

Macrocirculation image

Microcirculation image
Conclusion

• 2D perfusion imaging may help to better interpret the microcirculation in CLI patients during revascularization.
  • No movement of the foot / leg
  • Frame selection
  • Standardized protocol of DSA
  • Foot ROI except digits (Reekers method)
  • Further development of vessel extraction method