Microwave Radiometry Thermometry: Unfolding the non-invasive differential diagnosis of arterial disease in diabetic patients with suspected critical limb ischaemia

Stavros Spiliopoulos, MD, PhD, EBIR
Asst. Professor in Interventional Radiology

2nd Radiology Department, Interventional Radiology Unit
“ATTIKON” University General Hospital
Clinical Lead: Prof. E. Brountzos
Director: Prof N. Kelekis
Background

• The number of people with diabetes has increased from 108 million in 1980 to 422 million in 2014

• Diabetes is a major cause of lower limb amputation

• New non-invasive modalities for the prompt diagnosis of CLI as to prevent amputation in people with diabetes are required
Diagnosis of vascular involvement in diabetic foot disease remains challenging.

Current non-invasive diagnostic tests include:

- Toe-brachial index: sensitivity approx. 60%
- Continuous wave Doppler: sensitivity approx. 74%

Imaging: DUS, MRA, CTA,

DSA (invasive)
Microwave Radiometry (MWR)

MWR has been widely used in ocean and atmospheric science

Applications of microwave radiometry in ocean and atmospheric science

Peter J Minnett
Rosenstiel School of Marine and Atmospheric Science,
University of Miami, USA

Global microwave SSTs
Microwave Radiometry thermometry (MWR)

In medicine
Non-invasive method for the detection of local inflammatory activation in carotid artery atherosclerotic disease, preclinical arthritis and brain temperature assessment.
Microwave Radiometry thermometry (MWR)

We conducted a multicentre, proof of concept study, to investigate the feasibility of tissue thermometry using MWR for the non-invasive diagnosis of critical limb ischemia (CLI) in subjects with diabetes.
Materials and Methods

80 patients were included, equally divided in 4 groups

Group N
- Healthy volunteers
- No PAD following clinical examination and normal DUS

Group DN
- Normal subjects with diabetes (insulin-dependent or not)
- Verified neuropathic ulcers without vascular involvement

Group DC
- Subjects with diabetes (insulin-dependent or not) with CLI
- Rutherford 5 or 6 confirmed with diagnostic digital subtraction angiography

Group NDC
- Non-diabetic subjects with CLI
- Rutherford 5 or 6 confirmed with diagnostic digital subtraction angiography
Materials and Methods

Foot MWR Thermometry

- All patients underwent MWR thermometry with the **RTM -01-RES (University of Bolton, UK)** to record the mean internal tissue temperature of the foot.
- **The RTM -01-RES is a non commercially available system**
- MWR system is consisted of an antenna, a data processing unit, a monitor and a PC equipped with dedicated software for patient and temperature documentation
Materials and Methods

- Temperature measurements were performed by 2 individual researchers, as near as possible at the site of ulceration in patients of groups DN, DC and NDC and
- In various pre-determined foot sites in healthy volunteers of group N.

- The lowest temperature of healthy volunteers was used.

- Foot measurements were performed in a room at 23-24°C.
Materials and Methods

- One-Way ANOVA and Dunn tests were performed to compare temperatures between study groups.

- Sensitivity and specificity of MWR as well as the determination of a cut-off value for diagnosis of ischemic foot disease were calculated with ROC analysis.
Results

- There were no significant differences in age ($p=0.05$), TIA/stroke ($p=0.76$), smoking habit ($p=0.21$) and hypercholesterolemia ($p=0.15$), between groups DN, DC and NDC, respectively.

- Ischemic heart disease was significantly more frequent in group DN vs. both CLI groups (DC; $p<0.001$) and NDC; $p<0.01$), but similar between CLI groups.
Results

- More dialysis patients were included in CLI diabetics (group DC) compared to diabetics without CLI (group DN); (p<0.01).

- Significantly more patients suffered from hypertension in CLI groups (DC and NDC) compared to controls (groups N and DN; p<0.001).

- Duration of diabetes (p=0.12) and IDDM rate (p=0.15) were similar between diabetic groups DN and DC.
Results

- Temperatures recorded in vicinity to foot ulcers of CLI patients were similar for diabetics and non-diabetics, but significantly lower than in patients with solely neuropathic ulcers and normal patients without vascular disease.

Inter-observer reliability analysis: excellent interclass correlation coefficient of 0.987 in average measures.
Results

- Cut off temperature to diagnose ischemic foot disease: $< 31.8^\circ\text{C}$ (area under the curve: 0.984; 95%CI: 0.965-1.00; p<0.001)
  - Sensitivity 100% (95%CI: 90.2-100)
  - Specificity 88.4% (95%CI: 74.9-96.1)
  - PPV 100%
  - NPP 87.80%

S. Spiliopoulos et al. *Journal of Diabetes and Its Complications; 2017*
Conclusions

• According to MWR, CLI patients (both diabetic and non diabetic) demonstrate significantly lower tissue temperatures at the foot, than normal subjects or subjects with diabetic foot without vascular involvement.

• MWR could be a very useful non invasive tool for the diagnosis of arterial ischemic foot disease in diabetic patients with suspected critical limb ischemia.
Advantages of MWR

- Non-invasive

- Indicates local internal tissue temperature and therefore indirectly foot perfusion.

- Safe, simple in operation, without regulators device

- MWR thermometry can be performed as office-based resting by non vascular specialists (nurses, GPs, etc.).

- Ability to monitor treatment?
MWR follow up post-angioplasty

- Ruth 6
- MWR at angiosome 3:
  - Pre PTA 25.8°
  - After PTA: 31.4°

<table>
<thead>
<tr>
<th>Location</th>
<th>Baseline</th>
<th>1m</th>
<th>6m</th>
<th>12m</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>29.2</td>
<td>33.1</td>
<td>32.2</td>
<td>30.9</td>
</tr>
<tr>
<td>2</td>
<td>25.9</td>
<td>33.8</td>
<td>34.2</td>
<td>31.9</td>
</tr>
<tr>
<td>3</td>
<td>25.8</td>
<td>31.4</td>
<td>33.7</td>
<td>32.3</td>
</tr>
<tr>
<td>4</td>
<td>27.8</td>
<td>32.3</td>
<td>34</td>
<td>33.4</td>
</tr>
<tr>
<td>5</td>
<td>26.9</td>
<td>31.7</td>
<td>34</td>
<td>32.5</td>
</tr>
<tr>
<td>6</td>
<td>25.3</td>
<td>33.2</td>
<td>33.8</td>
<td>32</td>
</tr>
<tr>
<td>Mean</td>
<td>26.8</td>
<td>32.3</td>
<td>33.6</td>
<td>32.2</td>
</tr>
</tbody>
</table>
Complete wound healing at 9 months.

25.8°

31.4°

33.7°

32.3°
Limitations

- Inflammation: measurements limited by the de facto elevated $T^\circ$
- Room temperature
- Larger trials to confirm outcomes