

Open Access



# PLANTAR THERMOMETRY AND DIABETIC FOOT RISK IN PRIMARY CARE. RESULTS OF THE THERMOPIEDI STUDY.

Rafael Medrano Jiménez<sup>1</sup>, M<sup>a</sup> Mar Gili Rius<sup>1</sup>, Olga García Castillo<sup>1</sup>, María Ruiz Messeguer<sup>1</sup>, Blanca Medrano Baeza<sup>2</sup>, María Anglà Vendrell<sup>3</sup>

## SUMMARY

<sup>1</sup>UGAp Badalona 7b ICS  
Servei d' Atenció Primària  
Dap Metropolitana Nord.  
ICS

<sup>2</sup>Private centre

USR Metropolitana Nord<sup>3</sup>

**Corresponding author:**  
Rafael Medrano Jiménez

**Email:** abspie@yahoo.es

**Introduction.** This study was aimed at describing differences in foot temperature associated with neuropathy and/or arteriopathy among patients with type 2 diabetes mellitus using plantar thermometry.

**Methods.** An observational study of concordance was conducted in two primary care centres in which 532 type 2 diabetes patients >40 years of age were screened for polyneuropathy (signs and symptoms of neuropathy), arteriopathy (ankle brachial pressure index), thermometric measurements (manual infrared thermometry and thermoscale) before and after a 100-metre walk. Statistical analysis: concordance between infrared thermometer and thermoscale using the kappa index. Logistic regression analysis was performed considering neuropathy and arteriopathy as independent variables, adjusted for confounding factors.

**Results.** A total of 53.8% of the participants were men. The mean age was 67.3±7.7 years, 154 patients had no complications, 205 presented signs or symptoms of neuropathy, 99 arteriopathy, 74 had diabetic polyneuropathy 28 of whom also had arteriopathy. In patients with polyneuropathy infrared thermometry showed a mean plantar temperature difference of 0.76±0.97°C, being 0.56±0.71°C in patients without polyneuropathy (p<0.05). The maximum temperature difference between feet was 2.58±2.41°C and 1.64±1.84°C, respectively (p<0.005). After adjusting for confounding factors, mean difference between the two groups was 0,21°C (IC 95%, 0,2-0,39°C; p<0,005). Thermoscale failed to show any statistically significant differences. Concordance between the infrared thermometer and the thermoscale was low, with a kappa index of 0.08."

**Conclusions.** An increase in foot temperature according to infrared thermometry is associated with the presence of polyneuropathy.

**Termometria plantar i peu de risc diabètic a l'atenció primària. Resultats de l'estudi THERMOPIEDI.**

**Introducció.** L'objectiu fou descriure variacions de temperatura superficial del peu associades a neuropatia i/o arteriopatía en un grup de persones amb diabetis mellitus tipus 2 amb l'ús de la termometria plantar.

**Material i mètodes.** Estudi observacional de concordança fet en 2 centres d'atenció primària en que participaren 532 pacients de més de 40 anys diabètics tipus 2 a qui es va fer detecció de polineuropatia (signes i símptomes de neuropatia), arteriopatía (índex turmell-braç), mesuraments termomètrics (termòmetre infrarojos manual i bàscula termoplantar), abans i després de caminar 100 metres. Anàlisis estadístiques: concordança entre la termometria infraroja i la bàscula termoplantar mitjançant l'índex kappa. Es va fer una regressió logística considerant la neuropatia i/o arteriopatía com a variables independents, ajustant per factors de confusió.

**Resultats.** Un 53,8% van ser homes. L'edat mitjana va ser de 67,3±7,7 anys, 154 no presentaren complicacions, 205 presentaren símptomes o signes de neuropatia, 99 arteriopatía, 74 presentaren polineuropatia, dels quals 28 tingueren també arteriopatía. Entre els pacients amb neuropatia, la termometria infraroja mostrà una diferència de temperatura plantar de 0,76±0,97°C amb neuropatia i de 0,56±0,71°C entre els pacients sense neuropatia (p<0,05). La diferència de temperatures màxima entre els peus va ser de 2,58±2,41°C i de 1,64±1,84°C, respectivament (p<0,005). Després d'ajustar pels factors de confusió, la diferència mitjana entre ambdós grups fou de 0,21°C (IC 95%, 0,2-0,39°C; p<0,005). Les mateixes anàlisis amb la bàscula termoplantar no mostraren significació estadística. La concordança entre la termometria infraroja i la bàscula termoplantar fou baixa, amb un índex kappa de 0,08.

**Conclusions.** Un augment de la temperatura plantar mitjançant la termometria infraroja s'associa a polineuropatia.

### Termometría plantar y pie de riesgo diabético en atención primaria. Resultados del estudio THERMOPIEDI.

**Introducción.** El objetivo del estudio fue describir variaciones de temperatura superficial del pie asociadas a neuropatía y / o arteriopatía en un grupo de personas con diabetes mellitus tipo 2 con el uso de la termometría plantar.

**Material y métodos.** Estudio observacional de concordancia hecho en 2 centros de atención primaria en que participaron 532 pacientes diabéticos tipo 2 mayores de 40 años a los que se hizo detección de polineuropatía (signos y síntomas de neuropatía), arteriopatía (índice tobillo-brazo), mediciones termométricas (termometría infrarroja manual y báscula termoplantar), antes y después de caminar 100 metros. Análisis estadísticos: concordancia entre la termometría infrarroja y la báscula termoplantar mediante el índice kappa. Se hizo una regresión logística considerando la neuropatía y/o arteriopatía como variables independientes, ajustando por factores de confusión.

**Resultados.** Un 53,8% fueron hombres. La edad media fue de  $67,3 \pm 7,7$  años, 154 no presentaron complicaciones, 205 presentaron síntomas o signos de neuropatía, 99 arteriopatía, 74 presentaron polineuropatía, de los cuales 28 tuvieron también arteriopatía. Entre los pacientes con neuropatía, la termometría infrarroja mostró una diferencia de temperatura mediaplantar de  $0,76 \pm 0,97^\circ\text{C}$  y de  $0,56 \pm 0,71^\circ\text{C}$  entre aquellos sin neuropatía ( $p < 0,05$ ). La diferencia de temperaturas máxima entre los pies fue de  $2,58 \pm 2,41^\circ\text{C}$  y de  $1,64 \pm 1,84^\circ\text{C}$ , respectivamente ( $p < 0,005$ ). Después de ajustar los factores de confusión, la diferencia media entre ambos grupos fue de  $0,21^\circ\text{C}$  (IC 95%,  $0,2-0,39^\circ\text{C}$ ;  $p < 0,005$ ). Los mismos análisis con la báscula termoplantar no mostraron significación estadística. La concordancia entre la termometría infrarroja y la báscula termoplantar fue baja, con un índice kappa de 0,08.

**Conclusiones.** Un aumento de la temperatura plantar mediante la termometría infrarroja se asocia a la polineuropatía.

## INTRODUCTION

Diabetic foot syndrome remains a major public health problem, accounting for 15-20% of the total expenditure for diabetes mellitus<sup>1</sup>. In Spain, major and minor amputations increased 0.35% and 1.74%, respectively in type 2 diabetes mellitus during the period 2001-2008<sup>2</sup>. It is estimated that 85% of amputations are preceded by an ulcer<sup>1,2</sup>. Half of these ulcers have a neuropathic aetiology, 20% are of ischaemic

origin, and 30% present both complications, known as neuroischaemia<sup>3</sup>. Patients with diabetic foot have a higher risk of psychosocial impairments related to depression, pain and decreased quality of life<sup>4</sup>. Prevention of the development of diabetic foot requires a multidisciplinary approach, with primary care and particularly nursing staff most frequently identifying patients at risk of developing diabetic foot.

For decades assessment of diabetic foot risk in primary care has been limited to three qualitative interventions to identify the predisposing factors of diabetic foot: 1. Neuropathy: somatosensory threshold test with the use of the 5.07 Semmes-Weinstein monofilament and the vibration sensation test using a 128-Hz tuning fork; 2. Arteriopathy: palpation of the dorsalispedis and posterior tibial pulses; and 3. Deformities: foot inspection. The assessment encourages self-foot inspection, self-care and referral to a podologist, if necessary<sup>5</sup>.

The limitations of this evaluation model have led to the investigation of other objective exploratory techniques, such as plantar thermometry<sup>6</sup>. This technique consists of the measurement of the amount of heat emitted by the foot by means of high technology instruments<sup>6-13</sup>. This method is deemed to be a non-invasive, objective and reproducible exploratory technique<sup>14</sup> that allows the identification of small temperature variations which are non-detectable with manual methods<sup>14,15</sup>. Several authors have related the thermoregulatory dysfunction of the foot observed in diabetic patients to neuronal, arterial alterations and repetitive foot stress<sup>6-12</sup>.

There are currently several methods to measure foot temperature. These include thermal stimuli for assessing the integrity of the small sensory nerve fibres<sup>8-12</sup>, thermal imaging rendered by infrared radiation (infrared thermography) or direct plantar contact with liquid crystal plaques (thermal pedigraphy)<sup>6</sup>, as well as other more affordable methods, such as manual infrared thermometers applied to different sites on each foot and thermal sensors adapted to scales similar to bathroom scales, the so-called thermoscales<sup>13</sup>. These two latter instruments have been designed for use in any care setting and also for patient self-monitoring of plantar temperature allowing early identification of alarm situations among patients at high risk of presenting a diabetic foot<sup>13,14</sup>.

Numerous publications have applied this exploratory technique to the early diagnosis of diabetic neuropathy<sup>14-18</sup>, variations in arterial supply<sup>9</sup>, indicators of the outcome of diabetic foot<sup>19-21</sup>, and prevention of recurrent diabetic foot<sup>22-24</sup>. Despite these references, plantar thermometry has never been previously studied in primary care.

Since primary care plays a crucial role in the prevention of diabetic polyneuropathy and taking into account the numerous limitations of the current assessment of patients at risk of presenting diabetic foot<sup>5,25</sup>, the aim of this study (THERMOPIEDI study) was to evaluate the use of plantar

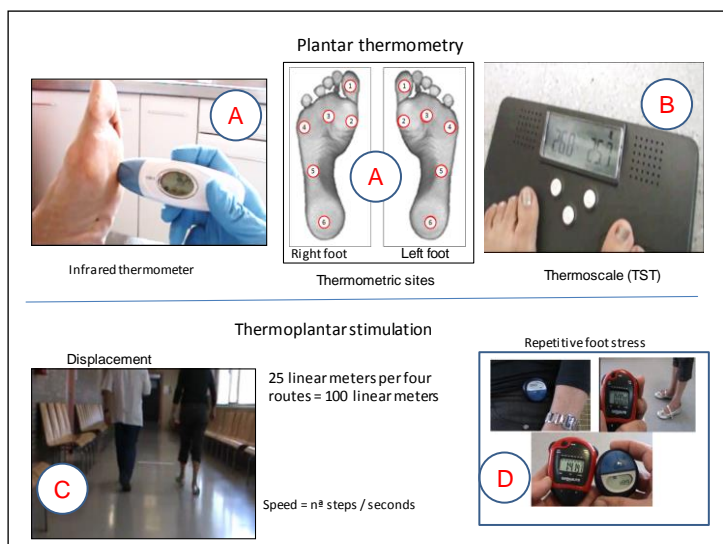
thermometry and the application of semi-quantitative evaluation models to more precisely identify patients at risk of presenting diabetic foot. The main objectives of the THERMOPIEDI study were to determine the distribution of plantar temperature in a group of patients with type 2 diabetes mellitus using two thermometric instruments - infrared thermometry and the thermoscale -<sup>13</sup> before and after thermal plantar stimuli and compare the temperature variations with the presence or absence of neuropathy and/or arteriopathy<sup>25</sup>.

The THERMOPIEDI study was approved by the Ethics Committee Board of the Institut Universitari d'Investigació Jordi Gol (reference number P13/086) and was funded by the XIV Research Grants from the Catalan Society of Family Medicine (CAMFiC) in 2013, Project FAP 1301.

## MATERIAL AND METHODS

The methodology used in the THERMOPIEDI study is described elsewhere<sup>25</sup>. Here we describe the most important parts of the protocol (**Figure 1**) and the most relevant results. The study was carried out from March to September 2014 in two primary care centres (Badalona-6 and Badalona-7b) belonging to the Catalan Institute of Health (Barcelona Nord Primary Care District). The target population was 2,500 diabetic patients older than 40 years of age identified in the e-Cap electronic clinical records and visited by nurses for foot examination and risk assessment in 2013.

**Figure 1. Illustration of thermometric interventions, thermal plantar stimuli and repetitive stress of the foot.**



- A: Plantar thermometry by infrared thermometer (TIF). Thermometric points (6 plantar points in each foot).  
 B: Plantar thermometry using a thermoplantar scale (TST).  
 C: Displacement: A distance of 25 linear meters per quarter traveled was measured. Two temperatures were obtained: TIF and TST before and after displacement (Initial temperature TIF and TST 0); (Final temperature TIF and TST 1).  
 D: Repetitive stress: measurement of steps and time used in the displacement.

A total of 702 patients who accepted to participate and fulfilled the inclusion criteria were randomly selected by phone call. The exclusion criteria were: dependent ambulation (wheelchair or leg prosthesis), important language barrier, severe cognitive impairment, serious illness preventing the patient from walking 100 metres, active ulcers with bandages covering their feet, weight greater than 150 kg, half-foot amputation, and/or failure to visit the health professional on two occasions.

## Measurements and interventions

All patients were given two 20-minute visits on different days not longer than two weeks apart. On the first visit, patients were given detailed information about the study. Informed consent was obtained with explicit authorisation to access their electronic records. Subsequently, the following interventions were carried out by healthcare professionals (doctors and nurses) trained in thermometric techniques and instrument handling:

- The clinical history was collected to detect the presence/absence of symptoms of neuropathy and arteriopathy with the use of the Neuropathy Symptom Score (NSS) questionnaire<sup>26</sup> with a score ranging from 0 to 9 points and the Edinburgh Claudication Questionnaire<sup>27</sup>, differentiating between asymptomatic, atypical symptoms or defined symptoms.
  - The thermometric measurements were made using a manual infrared thermometer (Model Fora IR10 multi-temp thermometer<sup>®</sup>)<sup>13</sup>, which was applied to six plantar sites on each foot (big toe, first, third and fifth metatarsal heads, midpoint of the external arch and centre of the heel) and thermal sensors adapted to a thermal plantar scale (OC Thermoscale<sup>®</sup> Model)<sup>13</sup>, which was previously calibrated for gender, age and height (**Figure 1**). These measurements were performed before and after thermal plantar stimuli. Two temperatures ( $T_0$  and  $T_1$ ) were obtained and differences of less than  $0.38^\circ\text{C}$  between the two feet were considered as normal<sup>28,29</sup>.
  - Thermal plantar stimuli were used to provoke a change in plantar temperature by displacement, walking a distance of 100 linear metres, with shoes and without socks or stockings. The displacement speed was calculated, being defined as the quotient between the numbers of steps measured with a Step 100<sup>®</sup> GEONAUTE pedometer and the time spent in seconds using the START 100<sup>®</sup> model GEONAUTE chronometer (**Figure 1**).
- The second visit was scheduled for the identification of high-risk foot by trained healthcare professionals (doctors and nurses):
- Neuropathy assessment was performed by the evaluation of different sensations and the Achilles reflex of each foot<sup>25,26,30-33</sup>.



1. Pressure sensation was determined by means of a 5.07 Semmes-Weinstein monofilament applied to six different plantar sites coinciding with the infrared thermometry sites. The absence of sensation in >1 site of each foot was considered as abnormal.

2. Thermal sensation was measured using a thermal bar (temperature discriminator consisting of a methacrylate bar with a metal tip) applied to the back of the foot (cold, metal; heat, methacrylate). Inability or uncertainty to distinguish the coldest object was considered as abnormal.

3. The feeling of pain was determined by applying a metallic blunt tip to the base of the first toenail. Failure to distinguish between pressure and pain was deemed abnormal.

4. The sensation of vibration was measured by means of a Rydel-Scheiffer tuning fork at the base of the great toe and malleoli. A mean score of <4/8 on the scale or 0/8 was considered as abnormal.

5. Achilles reflexes were determined with a reflex hammer hitting the Achilles tendon; the absence of involuntary movement or the presence of an abrupt involuntary movement was considered as abnormal.

In order to quantify the degree of neuropathic impairment an overall scoring system was applied to each test (0 points, normal and 1 point, abnormal) in both feet. Therefore, the total score ranged from 0 (normal) to 10 (maximal abnormality)<sup>25,26,31</sup>. The diagnosis of polyneuropathy was made by combining the score of the NSS questionnaire and that obtained in the sensory and reflex assessments<sup>26,34</sup>. A probable diagnosis of polyneuropathy was considered if either of the following assumptions was present: a) a score of signs between 3-5 points and symptoms > 5 points; or b) a score of signs > 5 points with or without symptoms<sup>25,26,30-35</sup>.

- Arteriopathy assessment was carried out by measurement of the ankle brachial pressure index following the recommendations of the American Society of Cardiology using a Huntleigh Doppler MD2<sup>®</sup> and an 8 Mhz Easy vascular probe<sup>®36</sup>. An ankle brachial pressure index <0.9 or >1.3 in either limb was considered abnormal.
- The data collected from the e-Cap electronic records included: the body mass index, metabolic control, diagnosis of diabetes complications (nephropathy, retinopathy, peripheral artery disease, neuropathy, diabetic foot and/or amputation).

### Variables

Independent variables: Thermal plantar asymmetry between the right and the left foot was evaluated (>0.38°C) by means of infrared thermometry and the thermoscale before and after walking. Dependent variables: Thermal plantar asymmetry between the right and the left foot was evaluated (>0.38°C) by infrared thermometry and the thermoscale associated with neuropathy and/or arteriopathy before and after walking. The following secondary variables were taken into account: age, gender, metabolic control (last registry of glucose levels and glycated haemoglobin), and presence of complications: nephropathy, neuropathy, arteriopathy (chronic ischemia, intermittent claudication), retinopathy, diabetic foot and amputations.

### Statistical analysis

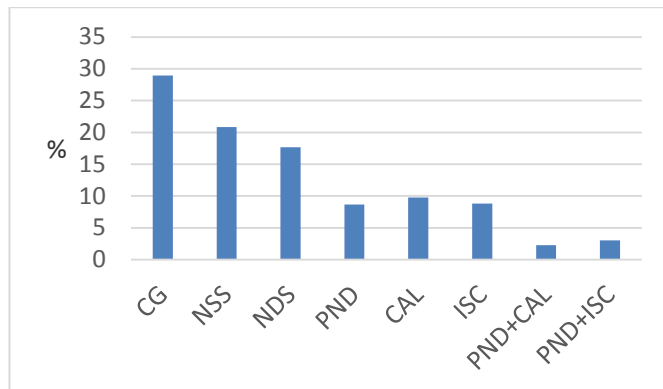
The frequencies of the continuous variables (temperature in degrees Celsius) and categorical percentages were described. Continuous variables were compared by means of ANOVA whereas categorical variables were analysed with chi-square tests. For multivariate analyses a linear regression was used when the dependent variable was continuous (difference in temperature degrees), and logistic regression was performed to analyse categorical values (plantar asymmetry, yes/no). Concordance between the two thermometric methods was analysed with the kappa index. Data were analysed with the Stata 12 statistical programme.

### RESULTS

A total of 170 patients out of the 702 contacted were excluded (24.2%): 118 missed the two scheduled visits, 20 refused to participate, 30 did not complete the data form and 2 more presented half-foot amputation. A total of 532 patients were finally recruited: 286 were men (53.8%) and 246 women (46.2%). The mean age was 67.3 years (SD 7.7 years; range: 41 to 86 years). The participation rate was 75.8%.

A total of 154 patients had no complications (29%), 251 presented signs or symptoms of neuropathy (47.2%) and constituted the neuropathy group, 127 presented arteriopathy (23.9%) and constituted the arteriopathy group, of whom 46 presented a clinically intermittent claudication. Different subgroups were identified in the neuropathy and arteriopathy groups as well (**Figure 2**). Among patients with neuropathy, 111 cases only had impaired symptoms, 94 had sensitive signs and impaired reflexes, and 46 had polyneuropathy (impaired signs and symptoms). Among patients with arteriopathy, 52 patients had an ankle brachial pressure index >1.3, 47 had an ankle brachial pressure index <0.9 and 28 with both ankle brachial pressure indexes (<0.9 and >1.3), of whom 16 had an ankle brachial pressure index <0.9 and polyneuropathy and 12 had an ankle brachial pressure index >1.3 and polyneuropathy.

**Figure 2. Distribution of the frequencies in percentages depending on the different groups and subgroups detected by neuropathy and arteriopathy assessment.**



CG: Patients without any neuropathy or arterial complications.  
 NSS: Patients with only symptoms of neuropathy (Neuropathy Symptoms Score scale score >1).  
 NDS: Patients between 2-5 points or more on the Neuropathy Disability Score scale and <5 points on the Neuropathy Symptoms Score scale.  
 PND: patients with defined polyneuropathy with normal ankle brachial pressure index.  
 CAL: Patients with ankle brachial pressure index >1.3 without neuropathy complications.  
 ISC: Patients with ankle brachial pressure index <0.9 without neuropathy complications.  
 PND+CAL: Patients with defined polyneuropathy and ankle brachial pressure index >1.3.  
 PND+ISC: Patients with defined polyneuropathy and ankle brachial pressure index <0.9.

**Table 1** shows the results of the existing diagnoses on the electronic records depending on the different groups and subgroups. 75% of the amputations and 50% of the diabetic foot registered belonged to patients of the polyneuropathy subgroup. The correlation between the recorded cases of neuropathy and arteriopathy on the electronic records and the identified cases of these complications was scarce: neuropathy ( $r=0.13$ ), arteriopathy ( $r=0.35$ ), with an agreement measurement of  $k=0.32$  and  $k=0.46$ , respectively.

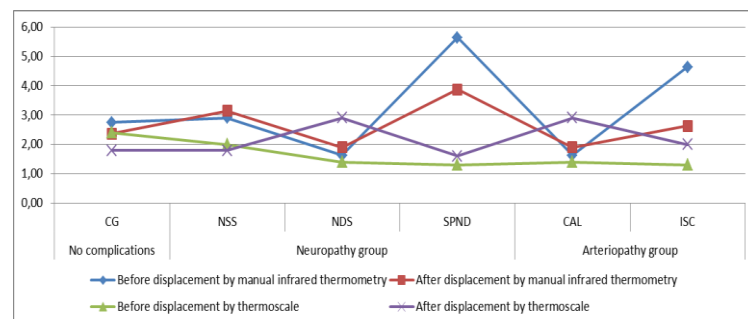
Regarding displacement, the mean number of steps was 172.9 (SD 29.2; range: 93-300). The mean time was 96.8 seconds (SD 21.4; range: 65-196) and the mean speed of displacement was 1.8 steps per second (SD 0.3; range: 0.98-2.73) without statistically significant differences between groups. Temperatures were measured in 204 patients in the morning (38.3%) and 328 in the afternoon (61.7%).

### Thermometric results

The mean temperatures in the consultations before and after the displacement tests were carried out in the consultations were 25.5°C (SD 1.7°C) and 25.3°C (SD 1.8°C), respectively. The mean temperature registered by infrared thermometry before walking was 33.8°C (SD 2.5°C) on the right foot and 33.8°C (SD 2.5°C) on the left foot. After displacement the

temperatures were 33°C (SD 2.53°C) and 33.1°C (SD 2.2°C) respectively. Before displacement, the mean temperature registered by thermoscale was 29.5°C (SD 1.37°C) on the right foot and 29.5°C (SD 1.3°C) on the left foot. After walking the temperatures were 29.4°C (SD 1.3°C) and 29.5°C (SD 1.3°C) respectively. The ANOVA analysis between mean temperatures did not show statistically significant differences. With regard to the asymmetry of temperature between feet ( $>0.38^\circ\text{C}$ ), this was present in 360 patients by means of infrared thermometry ( $p=0.66$ ) and in 366 patients with thermoscale ( $p=0.83$ ). **Figure 3** shows the concordance between both thermometric instruments, before and after displacement, which was very low ( $k=0.08$ ).

**Figure 3. Temperature differences between the right and the left foot before and after displacement measured by the thermometric instruments.**



CG: Patients without any neuropathy or arterial complications.  
 NSS: Patients with only symptoms of neuropathy (Neuropathy Symptoms Score scale score >1).  
 NDS: Patients with 2 points or more on the Neuropathy Disability Score scale and presence of symptoms.  
 SPND: Patients with polyneuropathy.  
 CAL: Patients with only ankle brachial pressure index >1.3.  
 ISC: Patients with only ankle brachial pressure index <0.9.

The association between the maximum and minimum temperature differences with the two thermometric instruments (**Figure 3**) and the presence or absence of neuropathic and/or arterial complications detected (**Table 1**) was similar, but only a statistically significant relationship was observed in the polyneuropathy subgroup when was registered by infrared thermometry ( $p<0.05$ ) (**Figure 4**).

**Table 1. Anthropometric and clinical data collected from the electronic clinical records.**

Parameter	Control group	Neuropathy group			Arteriopathy group		Total
		NSS	NDS	SPND	CAL	ISC	
Men	91	43	50	41	29	32	286
Women	63	68	44	33	23	15	246
Age	65.9 (6.5)	65.6 (6.7)	79.8 (13.1)	69.6 (8.0)	69.3 (7.7)	69.1 (7.1)	
Body mass index	30.4 (4.8)	31.1 (5.4)	31.4 (4.9)	30.8 (4.7)	31.0 (4.9)	31.1 (5.1)	
Glycaemia	145 (35.3)	150.7 (46.5)	151 (51.3)	142.4 (46.1)	162.7 (43.5)	158.9 (57.8)	
Glycated haemoglobin	6.8 (0.9)	7.1 (1.2)	7.3 (1.3)	7.2 (1.2)	7.1 (0.9)	7.4 (1.2)	
Retinopathy	7	10	5	14	0	6	42
Nephropathy	6	9	6	13	3	7	44
Neuropathy	3	5	3	23	2	6	42
Arteriopathy	4	1	5	10	1	15	36
Diabetic foot	0	0	1	10	0	0	11
Amputations	0	0	0	4	0	0	4

Note of. Standard Deviation. BMS: Body mass index.

NSS: Patients with only symptoms of neuropathy (NSS questionnaire > 1 point).

NDS: Patients who presented more than 2 points on the NDS scale and > 1 point on the NSS.

SPND: Patients with defined polyneuropathy are included (46 of the neuropathic group (PND) and 28 of the group arteriopathy with altered ABI).

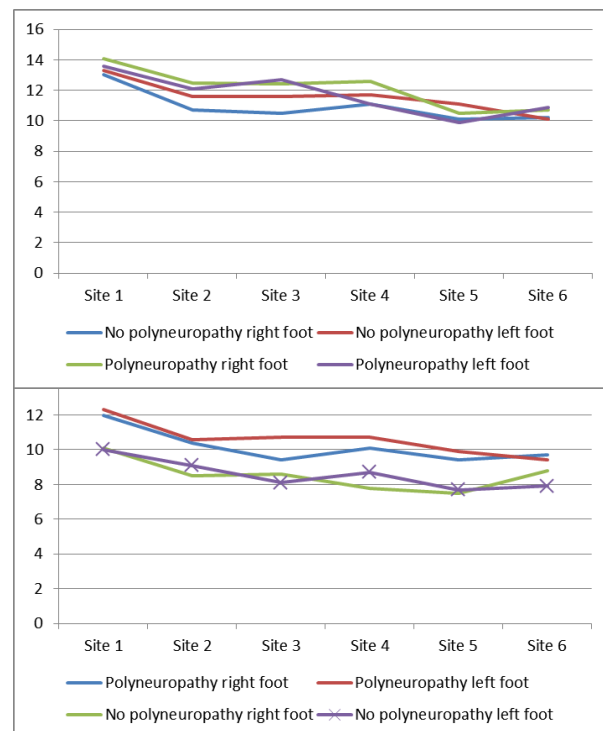
CAL: patients with ABI > 1.30 without neuropathic complications.

SSI: Patients with ABI < 0.90 without neuropathic complications.

\* 5 patients with NPD and ischemia and 2 patients with PND and calcification.

\*\* 3 patients presented PND and ischemia..

**Figure 4. Temperature differences (maximum - minimum) among thermometric sites depending on feet and presence or absence of polyneuropathy.**



A: Maximum and minimum temperatures among thermometric measuring sites by means of infrared thermometry among patients with and without polyneuropathy before walking.

B: Maximum and minimum temperatures among thermometric measuring sites among patients with and without polyneuropathy after walking.

On one hand, the mean temperature differences between the two feet in the morning were  $0.77 \pm 0.97^\circ\text{C}$  among patients with neuropathy and  $0.56 \pm 0.71^\circ\text{C}$  among those without this complication ( $p < 0.05$ ). The mean differences in maximal temperature in the morning were  $2.48^\circ\text{C}$  (SD  $2.6^\circ\text{C}$ ) among patients with polyneuropathy and  $1.82^\circ\text{C}$  (SD  $23^\circ\text{C}$ ) among patients without polyneuropathy ( $p = 0.001$ ). On the other hand, the mean temperature differences between the two feet in the afternoon were  $0.9^\circ\text{C}$  (SD  $1.18^\circ\text{C}$ ) among patients with neuropathy and  $0.5^\circ\text{C}$  (SD  $0.6^\circ\text{C}$ ) among those without this complication ( $p < 0.05$ ). The mean differences in maximal temperature in the afternoon were  $2.58^\circ\text{C}$  (SD  $2.4^\circ\text{C}$ ) among patients with polyneuropathy and  $1.64^\circ\text{C}$  (SD  $1.8^\circ\text{C}$ ) among patients without this complication ( $p < 0.005$ ). The asymmetry of temperature between the two feet ( $> 38^\circ\text{C}$ ) in the afternoon mostly occurred among patients without polyneuropathy (109, 81.3%) compared to the group of polyneuropathic patients (25 cases, 18.7%;  $p < 0.005$ ).

### Multivariate analysis

After adjusting for polyneuropathy (yes/no) and confounding factors (gender, age, body mass index, ambient temperature and speed of displacement and shift), the mean difference between the two groups of diabetics was 0.21°C (95% CI, 0.2-0.39°C;  $p < 0.005$ ) before displacement and 0.18°C (95% CI, -0.01-0.36°C;  $p = 0.06$ ) after walking. The same multivariate analysis was performed among pressure sites (0.62°C, 95% CI, 0.09-1.16°C;  $p < 0.05$ ) before walking and 0.08°C, 95% CI, -0.41-0.57°C;  $p = 0.07$  after walking) (Figure 4). The same analyses with the thermoscale failed to show any statistically significant differences.

### DISCUSSION

Body temperature is known to be a health indicator factor susceptible to environmental variations. Some variations are voluntary such as what occurs with intense physical exercise or having a sauna, while others are involuntary and are associated with physiopathological mechanisms related to decreased arterial supply<sup>9</sup>, inflammation<sup>19</sup>, wound healing<sup>20</sup> or infectious conditions<sup>21</sup>. It has been shown that diabetes can cause progressive demyelination of the peripheral nerve fibres, decreasing and even permanently impairing the physiological thermoregulatory reactions of the feet<sup>8,12,14-16</sup>.

Recent technological advances have been fostered by numerous studies aimed at providing more in depth knowledge of plantar temperature and to better identify the predisposing and aggravating factors of diabetic foot, and the tools currently developed are able to measure small variations of local temperature<sup>6-9,14-24,37</sup>. In the present study, the mean foot temperature registered by infrared thermometry among patients with polyneuropathy (main predisposing factor for the diabetic foot) was 0.21°C higher than that of patients without polyneuropathy. This finding has not been previously reported in the outpatient setting. Indeed, to our knowledge there is no study using thermometric instruments, thereby making comparison of our results difficult. However, the mean temperature of the plantar surface obtained with this instrument (29.5±1.36°C, range: 25.2°C to 35.1°C) was similar to the results reported by Van Netten *et al* with the utilisation of infrared thermography (29.4±1.8°C, range: 28.8°C to 33.9°C)<sup>15</sup>.

Considering that the interpretation of plantar thermometry is based on the differences in temperature of the contralateral limb<sup>11,14,22-24</sup>, the low concordance between infrared thermometry and the thermoscale ( $\kappa = 0.08$ ) could pose an important bias depending on the instrument applied since infrared thermometry is determined at specific pressure sites and the thermoscale shows the mean temperature of the plantar surface (Figure 3). In the present study, patients with polyneuropathy presented a reduction (measured as steps/day) and a lower intensity of physical activity (walking

speed) similar to the results of Wrobel<sup>11</sup> and Mueller *et al*<sup>38</sup>, respectively, and the mean difference in maximal temperature in the morning was 2.48°C in patients with polyneuropathy, compared to 1.82°C in patients without polyneuropathy, and 2.58°C versus 1.64°C, respectively, in the afternoon. It is important to note that according to the conclusions of Armstrong<sup>22</sup>, a single foot temperature measurement is not sufficient to assess thermoregulatory dysfunction of the foot due to diabetes. The maximum temperature differences found are not sufficient to establish a diagnosis of diabetic polyneuropathy, which is defined as temperature differences of greater than two degrees Celsius<sup>12</sup>. Neither can they determine an increased risk of ulceration, which, according to the studies of Armstrong and Lavery<sup>22-24</sup>, establish a pre-ulcer stage as a difference in temperature greater than 2.2°C.

Regarding the selection of patients to be included in our study, only those who had been screened for diabetic foot in the previous year were selected, and this may constitute a bias. Under diagnosis of complications registered in the electronic records cannot be ruled out. However, the methods used in the current study were similar to those of other studies<sup>10,30-33</sup>. With the exception of the thermal sensation tests, the remaining sensation and reflex tests have specific indicators in the electronic records that allow their application and monitoring.

In conclusion, this is the first study in primary care to describe an increase in surface temperature of the foot associated with polyneuropathy. With regard to the thermometric instruments used in the study, the thermoscale showed a mean plantar surface temperature but did not specify the area with the highest temperature and thus, could not identify the areas of highest risk of ulceration. The differences in temperature between sites were more sensitive with the use of the infrared thermometry, which was able to identify small zones with greater temperature variability. Based on these results, plantar thermometry could be applicable in primary care as a complementary technique in the assessment of diabetic foot risk, especially in patients with advanced sensory neuropathy. These results provide a solid basis for further investigation into this exploratory technique, with prospective studies being necessary for comparing these two methods for preventing diabetic foot.

### REFERENCES

1. Pompers L, Schaper N, Apelqvist J, Edmonds M, Jude E, Mauricio D, et al. Prediction of outcome in individuals with diabetic foot ulcers: focus on the differences between individuals with and without peripheral arterial disease. The EURODIAB Study. *Diabetologia*. 2008;51:747-55.
2. López de Andrés A, Martínez Huedo M, Carrasco Garrido P, Hernández Barrera V, Gil de Miguel A, Jiménez García R. Tendencias en las amputaciones de extremidades inferiores en personas con y sin Diabetes en España, 2001– 2008. *Diabetes Care*. 2011;34:1570-6.



3. Tendra M, Aboyans V, Bartelink ML, Baumgartner I, Clément D, Collet JP, et al. Guía de práctica clínica de la ESC sobre diagnóstico y tratamiento de las enfermedades arteriales periféricas. *Rev Esp Cardiol.* 2012;65:172.e1-e57.
4. Domínguez Olmedoa JM, Pozo Mendoza JA, Reina Bueno M. Revisión sistemática sobre el impacto de las complicaciones podológicas de la diabetes mellitus sobre la calidad de vida. *Rev Esp Podol.* 2017;28:30-6.
5. Alonso Fernández M, Mediavilla Bravo JJ, López Simarro F, Comas Samper JM, Carramiñana Barrera F, Mancera Romero J. En nombre del grupo de Trabajo de Diabetes SEMERGEN. Evaluación de la realización del cribado del pie diabético en Atención Primaria. *Endocrinol Nutr.* 2014;61:311-7.
6. Bharara M, Cobb JE, Claremont DJ. Thermography and thermometry in the assessment of diabetic neuropathic foot: a case for furthering the role of thermal techniques. *Int J Low Extrem Wounds.* 2006;5:250-60.
7. Rutkove SB, Veves A, Mitsa T, Nie R, Fogerson PM, Garmirian LP, et al. Impaired distal thermoregulation in diabetes and diabetic polyneuropathy. *Diabetes Care.* 2009;32:671-6.
8. Jimenez Cohol P, Grekin C, Leyton C, Vargas C, Vilaseca R. Thermal threshold: Research study on small fiber dysfunction in distal diabetic polyneuropathy. *J Diab Sci Technol.* 2012;6:177-83.
9. Peregrina-Barreto H, Morales Hernández LA, Rangel-Magdaleno JJ, Avina-Cervantes JG, Ramírez-Cortés JM, Morales-Caporal R. Quantitative estimation of temperature variations in plantar angiosomes: a case study for diabetic foot. *Comput Math Methods Med.* 2014;2014:585306.
10. Fawzy OA, Arafa AI, El WakeelMA, Abdul Kareem SH. Plantar pressure as a risk assessment tool for diabetic foot ulceration in Egyptian patients with diabetes. *Clin Med Insights Endocrinol Diabetes.* 2014;7:31-9.
11. Wrobel JS, Najafi B. Diabetic foot biomechanics and gait dysfunction. *J Diabet Sci Technol.* 2010;4:833-45.
12. García-De-La-Peña R, Benhamú S, Munuera PV. Sensitivity and specificity of a new test for thermographic evaluation of the foot in the diagnosis of diabetic peripheral polyneuropathy. *Adv Skin Wound Care.* 2014;27:491-8.
13. Blue circle medical. <http://www.bc-med.nl/>
14. Houghton VJ, Bower VM, Chant DC. Is an increase in skin temperature predictive of neuropathic foot ulceration in people with diabetes? A systematic review and meta-analysis. *J Foot Ankle Res.* 2013;6:31.
15. Van Netten JJ, Prijs M, van Baal JG, Liu C, van der Heijden F, Bus SA. Diagnostic values for skin temperature assessment to detect diabetes-related foot complications. *Diabetes Technol Ther.* 2014;16:714-21.
16. Mazilu G, Filos C, Popescu CD. Cutaneous thermographic changes in diabetic polyneuropathy. *Rev Med Chir Soc Med Nat Iasi.* 2011;115:1007-11.
17. Balbinot LF, Canani LH, Robinson CC, Achaval M, Zaro MA. Plantar thermography is useful in the early diagnosis of diabetic neuropathy. *Clinics (Sao Paulo).* 2012;67:1419-25.
18. Papanas N, Papatheodorou K, Papazoglou D, Kotsiou S, Maltezos E. Association between foot temperature and sudomotor dysfunction in type 2 diabetes. *J Diabetes Sci Technol.* 2010;4:803-7.
19. Bharara M, Schoess J, Nouvong A, Armstrong DG. Wound inflammatory index: a "proof of concept" study to assess wound healing trajectory. *J Diabetes Sci Technol.* 2011;4:773-9.
20. Bharara M, Schoess J, Armstrong DG. Coming events cast their shadows before: detecting inflammation in the acute diabetic foot and the foot in remission. *Diabetes Metab Res Rev.* 2012;28(Suppl 1):15-20.
21. Fierheller M, Sibbald RG. A clinical investigation into the relationship between increased periwound skin temperature and local wound infection in patients with chronic leg ulcers. *Adv Skin Wound Care.* 2010;23:369-79
22. Armstrong DG, Lavery LA, Wunderlich RP, Boulton AJ. Skin temperatures as a one-time screening tool do not predict future diabetic foot complications. *J Am Med Assoc Podiatr.* 2003;93:443-7.
23. Lavery LA, Higgins KR, Lanctot DR, Constantinides GP, Zamorano RG, Armstrong DG, et al. Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes Care.* 2004;27:2642-7.
24. Lavery LA, Higgins KR, Lanctot DR, Constantinides GP, Zamorano RG, Athanasiou KA, et al. Preventing diabetic foot ulcer recurrence in high-risk patients: use of temperature monitoring as a self-assessment tool. *Diabetes Care.* 2007;30:14-20.
25. Medrano Jiménez R, Pera Blanco G, Gil Valero E, Valverde Caballero I, García Castillo O, Medrano Baeza B. Termometría plantar y pie de riesgo en Atención Primaria. Estudio termopiedi. *Nure Inv.* 2015;12(77).  
<http://www.nureinvestigacion.es/OJS/index.php/nure/article/view/678/666>
26. Abbott C, Malik R, Ross E, Kukarni J, Boulton AJ. Prevalence and characteristics of painful diabetic neuropathy in a large community-based diabetic population in the UK. *Diabetes Care.* 2011;34:2220-4.
27. Leng GC, Fowkes FG. The Edinburgh Claudication Questionnaire: an improved version of the WHO/Rose Questionnaire for use in epidemiological surveys. *J Clin Epidemiol.* 1992;45:1101-9.
28. Uematsu S, Edwin DH, Jankel WR, Kozikowski J, Trattner M. Quantification of thermal asymmetry. Part 1: Normal values and reproducibility. *J Neurosurg.* 1988;69:552-5.
29. Uematsu S, Jankel WR, Edwin DH, Kim W, Kozikowski J, Rosenbaum A, Long DM. Quantification of thermal asymmetry. Part 2: Application in low-back pain and sciatica. *J Neurosurg.* 1988;69:556-61.



30. Asad A, Hameed MA, Khan UA, Ahmed N, Butt MU. Reliability of the neurological scores for assessment of sensorimotor neuropathy in type 2 diabetics. *J Pak Med Assoc.* 2010;60:166-70.
31. Boulton AJ. Management of diabetic peripheral neuropathy. *Clín Diabetes.* 2005;23:9-15.
32. Feng Y, Schlösser FJ, Sumpio BE. The Semmes Weinstein monofilament examination is a significant predictor of the risk of foot ulceration and amputation in patients with diabetes mellitus. *J Vasc Surg.* 2011;53:220-6.
33. Shakher J, Stevens MJ. Update on the management of diabetic polyneuropathies. *Diabetes Metab Syndr Obes.* 2011;4:289-305.
34. Chawla A, Bhasin G, Chawla R. Validation of Neuropathy Symptoms Score (NSS) and Neuropathy Disability Score (NDS) in the clinical diagnosis of peripheral neuropathy in middle-aged people with diabetes. *Internet J Fam Pract.* 2013;12:1.
35. Tesfaye S, Boulton AJ, Dyck PJ, Freeman R, Horowitz M, Kempner P, et al; Toronto Diabetic Neuropathy Expert Group. Diabetic neuropathies: update on definitions, diagnostic criteria, estimation of severity, and treatments. *Diabetes Care.* 2010;33:2285-93.
36. Aboyans V, Criqui MH, Abraham P, Allison MA, Creager MA, Diehm C, et al. Measurement and interpretation of the ankle-brachial index. A scientific statement from the American Heart Association. *Circulation.* 2012;126:2890-909.
37. Nishide K, Nagase T, Oba M, Oe M, Ohashi Y, Iizaka S, et al. Ultrasonographic and thermographic screening for latent inflammation in diabetic foot callus. *Diabetes Res Clin Pract.* 2009;85:304-9.
38. Mueller MJ, Zou D, Bohnert KL, Tuttle LJ, Sinacore DR. Plantar stresses on the neuropathic foot during bare foot walking. *Phys Ther.* 2008;88:1375-84.

**How to cite the article:** Medrano Jiménez R, Gili Rius M. M, García Castillo O, Ruiz Messeguer M, Medrano Baeza B, Angà Vendrell M. Plantar thermometry and diabetic foot risk in primary care. Results of the THERMOPIEDI study. Results of the THERMOPIEDI study. *But At Prim Cat* 2018;36:38.