Contents lists available at ScienceDirect

Primary Care Diabetes

journal homepage: http://www.elsevier.com/locate/pcd

Original research

Effects of a pulsatile electrostatic field on ischemic injury to the diabetic foot: Evaluation of refractory ulcers

Mario Liani[a,*], *Ernesto Trabassi*[a], *Claudio Cusaro*[b], *Elisabetta Zoppis*[b], *Elisabetta Maduli*[b], *Roberto Pezzato*[c], *Paola Piccoli*[c], *Maddalena Maraschin*[c], *Piero Bau*[d], *Pietro Cortese*[d], *Albero Cogo*[e], *Filippo Salvati*[f], *Rossella Liani*[g]

[a] *"S. Massimo" Hospital, Department of Nephrology and Dialysis, Penne, PE, Italy*
[b] *"Maggiore della Carità" Hospital, University of Eastern Piedmont "Amedeo Avogadro", Diagnostic and Interventional Radiology, Novara, NO, Italy*
[c] *HUB Unit Health Bio, Policlinic and Analysis, Vicenza, VI, Italy*
[d] *"San Bassano" Hospital, Department of Geriatrics, Bassano del Grappa, VI, Italy*
[e] *Diabetic Foot Unit, Villa Berica Hospital, Department of Endocrinology and Metabolism, Vicenza, VI, Italy*
[f] *"Ortona and Guardiagrele" Hospital, Department of General Medicine, Guardiagrele, CH, Italy*
[g] *Ce.S.I., Center of Excellence on Aging, University of Chieti "G. d'Annunzio", Department of Medicine and Science of Aging, Chieti, CH, Italy*

ARTICLE INFO

Article history:
Received 4 July 2013
Received in revised form
27 November 2013
Accepted 30 November 2013
Available online 13 January 2014

Keywords:
Type 2 diabetes mellitus (T2DM)
Ulcers
Foot

ABSTRACT

Aims: The macro- and microcirculation disease, in patients with type 2 diabetes mellitus (T2DM), induces ischemic wounds of the lower limbs. We have tried to reduce the aggregation of red blood cells and to improve the O_2 supply to the tissues and speed the healing of ulcers in T2DM patients.

Methods: We enrolled 25 obese subjects without glucose intolerance (group A; BMI greater than 30 kg/m^2), 20 obese adults intolerant to glucose (group B) and two subgroups, groups C and D, with T2DM and with leg ulcers. The groups A, B and C were treated with PESF. Body weight, O_2 extraction, the capillary pulse, blood pressure and the surface of the ulcers were monitored.

Results: The technique PESF shows to have positive effects on the metabolism, on the reduction of body weight in the groups A and B, increasing extraction of O_2 in group C and increase the speed of healing of wounds in group C compared to group D. In group A, there was a significant reduction in systolic and diastolic blood pressure.

Conclusions: The technique PESF has affected the metabolic processes and the speed of wound healing ulcer in patients with T2DM.

* *Corresponding author*. Tel.: +39 0858276349; fax: +39 0858276393.
E-mail address: mario.liani@tin.it (M. Liani).
1751-9918/$ – see front matter © 2013 Primary Care Diabetes Europe. Published by Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.pcd.2013.11.009

1. Introduction

Whilst the incidence of patients with type 2 diabetes mellitus (T2DM) is constantly increasing in countries with a high standard of living [1], there is still no conclusive evidence that primary prevention associated with the administration of antiplatelet drugs confers any significant clinical benefits with a gradual increase in those who develop disabling cardiovascular complications [2]. The aim of available therapies in T2DM patients is to achieve better control of carbohydrates and lipid metabolism. Modification of some risk factors have resulted in an extension of life expectancy by reducing and or delaying complications such as renal, cardiac, vascular disease and hypertension [3,4]. However despite the widespread use of antiplatelet, vasodilators and hemorheological drugs, ischemic ulcers of the lower limbs [5] are frequent in T2DM and do not eliminate the risk from revascularization procedures or interventions that compromise the autonomy of patients. This problem occurs with greater frequency and severity in those with T2DM that have severe renal failure necessitating hemodialysis.

The prevalence of foot ulcers in T2DM patients ranged from 4% to 10% and 85% of these can involve to amputations [6].

The reduced tissue perfusion leads to a decreased O_2 supply to peripheral tissues by the red blood cells. This contributes to ischemic pathology and to endothelial dysfunction characterized by macro- and micro-angiopathy in T2DM. Hemorheologic alterations may be caused by altered plasticity with consequent reduction of the deformability of the red blood cells membrane, and by altered aggregation caused by the inflammatory in T2DM [7–9]. Aggregation of red blood cells, rouleaux formation and alteration of vascular reactivity can be related to an alteration of the electric charge on the surface of the blood cells and the endothelium [7,8,10,11]. This effect is believed to be due to the glycation in diabetes mellitus and carbamylation in uremia.

The aim of the study is to evaluate a non-pharmacological approach to improve the hemorheology of the microcirculation by the O_2 supply to the peripheral tissues and the restoration of vascular reactivity in T2DM patients with and without leg ulcers. We have tried to modify the electrical charges present on the surface of the membrane of the blood cells [7,8,10–12] and to improve the vasomotor performance through the use of an electrostatic pulsating field generator. A secondary objective was to verify whether this procedure had effects on the healing rate of ulcers in T2DM. In some obese patients this technique has been shown to induce improvement in the patho-physiology of the microcirculation as well as on the formation of rouleaux and vasomotor activity [12].

2. Materials and methods

We enrolled 25 obese subjects without glucose intolerance (group A); 20 adults with a concentration of fasting plasma glucose greater than 110 mg% and less than 126 mg% (IFG WHO classification) who were not taking hypoglycemic drugs (group B). We also enrolled 56 patients with T2DM treated with hypoglycemic drugs and with ischemic lesions in the lower limbs that were divided randomly into two subgroups: the first (group C) was composed of 29 patients and the second (group D) with 27 patients. All groups, healthy and diabetics, were matched for age and gender; in our study the patients were included in each group consecutively as they enter: patients with odd numbers were assigned to the group C while those with pair numbers to the group D. We compared groups treated with matching the 95% confidence for age and body mass index (BMI) (see Table 1).

Table 1 – Analysis of variance (ANOVA) of groups A, B, C and D (CI, confidence interval).

Groups	Age		BMI	
	Male	Female	Male	Female
A				
95% CI upper	67,989	61,045	28,665	30,517
95% CI lower	49,211	53,455	23,715	26,133
B				
95% CI upper	75,339	75,040	35,812	34,946
95% CI lower	64,376	51,817	30,878	26,597
C				
95% CI upper	75,842	79,540	31,009	35,112
95% CI lower	63,682	66,793	27,372	29,132
D				
95% CI upper	81,500	76,977	31,810	33,777
95% CI lower	69,000	64,148	26,607	27,198

Groups A and B were selected in our nephrology clinic on "World Kidney Day 2011" dedicated to obesity management. T2DM patients (groups C and D) with ulcers were selected from our specialized clinic dedicated to the care of the diabetic foot.

The ulcers were located in the pre-tibial region of the heel or in the foot arch and some patients with T2DM had more than one ischemic injury.

The groups A, B and C were designated for a treatment cycle with Pulsating Electrostatic Field (PESF) generated from a medical device (NewHealth 9000, Akern srl, Pontassieve, Italy). Group D served as a control for group C. PESF permeate the body and stimulate the metabolism.

NewHealth 9000 is able to generate PESF inducing a negative charge with an intensity varying from 2000 to 9000 V at extremely low current levels and is proven to be safe with a pulsatile frequency of 50 Hz. PESF generated is applied by means of a mat consisting of plastic material capable of conducting current (conductivity equal to 200 Ω/cm) and covered with a double layer insulating PVC of 0.5 mm of thickness on which the subject can sit (see Fig. 1), or lie. The patient and ionizing mat must be adequately insulated from ground. Before and during the session, the patients were monitored for body weight, heart rate, blood pressure and hemoglobin saturation (% SpO_2). Fig. 1 illustrates the insulated subject and the theoretical electrical ionic field.

The device is safe, simple, not invasive and is supported by clinically valid documentation and has been granted a European safety certificate (CE).

None of participants had altered the medical or surgical treatment program during PESF. Before the PESF cycle all study participants were informed of the aims and procedures of the study and gave their consent.