

Original article

Impact of low frequency pulsed magnetic fields on pain intensity, quality of life and sleep disturbances in patients with painful diabetic polyneuropathy

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Abstract

Aim. – The aim of this randomized, placebo-controlled, double-blind study was to assess whether a low frequency magnetic field can influence pain intensity, quality of life and sleep, and glycaemic control in patients with painful diabetic polyneuropathy.

Methods. – Sixty-one patients were randomized into two groups: the study group comprised 32 patients exposed to a low frequency magnetic field, average pain duration 23 months; the control group included 29 patients who received sham exposure, average pain duration 28 months. Patients were exposed for three weeks, 20 min a day, five days a week. The magnetic field generator was a Viofor JPS device (Med & Life, Komorow, Poland). All subjects filled out the following questionnaires five times (at the beginning and after one, two, three and five weeks): SFMPQ-VAS (pain evaluation), EuroQol EQ-5D and MOS Sleep Scale. HbA_{1c} was evaluated at baseline and after five weeks.

Results. – Significant reductions in pain intensity were seen in both the study group (visual analogue scale [VAS] value of 73 mm at baseline versus 33 mm after three weeks) and controls (VAS 69 mm at baseline versus 41 mm after three weeks). The extent of pain reduction did not differ significantly between the groups at any time. Also, both groups had similar improvements in EuroQol, MOS and HbA_{1c} values.

Conclusion. – Genuine magnetic field exposure has no advantage over sham exposure in reducing pain intensity, improving quality of life, and decreasing sleep disturbances and HbA_{1c}.

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Résumé

Effet des champs magnétiques en basse fréquence sur l'intensité des douleurs, la qualité de vie et les troubles de sommeil chez des patients souffrant de neuropathie diabétique douloureuse.

Objectif. – L'objectif de cette étude randomisée, en double insu et contrôlée contre placebo, était d'estimer si un champ magnétique en basse fréquence influençait l'intensité des douleurs, la qualité de vie et celle du sommeil, ainsi que l'équilibre glycémique chez des patients souffrant de neuropathie diabétique douloureuse.

Méthodes. – Soixante et un patients ont été répartis de façon aléatoire en deux groupes, un groupe de 32 patients, exposés à un champ magnétique en basse fréquence (souffrant depuis 23 mois en moyenne) et un groupe témoin, composé de 29 patients soumis à une exposition simulée (dont les douleurs duraient depuis 28 mois en moyenne). Les expositions étaient effectuées pendant trois semaines, 20 minutes par jour, cinq jours par semaine. Le champ magnétique était généré par VIOFOR JPS (Med & Life, Pologne). Tous les participants ont rempli les questionnaires suivants: SFMPQ-VAS (évaluation de douleur), EuroQol EQ-5D et MOS Sleep Scale. L'HbA_{1c} a été évaluée au début et cinq semaines après le début de l'étude.

Résultats. – Une réduction comparable et significative de l'intensité des douleurs a été observée dans les deux groupes, dans le groupe exposition réelle (valeur de VAS s'abaissant de 73 à 33 mm après trois semaines) et dans le groupe exposition simulée (valeur du Visual Analogue Scale [VAS] s'abaissant de 69 à 41 mm après trois semaines). À aucun moment de l'étude le degré d'amélioration n'a été différent entre les deux groupes. De même, une amélioration similaire de EuroQol, de MOS et du taux d'HbA_{1c} a aussi été observée dans les deux groupes.

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Conclusion. – L'exposition à un champ magnétique en basse fréquence n'est pas supérieure à une exposition simulée pour réduire l'intensité des douleurs, améliorer la qualité de vie et réduire les troubles de sommeil et le taux d'HbA_{1c} de patients atteints de neuropathie diabétique douloureuse. © 2008 Elsevier Masson SAS. All rights reserved.

Keywords: Diabetes mellitus; Painful diabetic polyneuropathy; Treatment; Low frequency magnetic fields

Mots clés : Diabète sucré ; Polyneuropathie diabétique douloureuse ; Traitement ; Champ magnétique de fréquence basse

1. Introduction

Diabetic peripheral neuropathy (DPN) is one of the most common microvascular complications of both type 1 and type 2 diabetes. Depending on the criteria used, it occurs in 5–100% of diabetic patients [1]. The most common type of DPN is distal diabetic polyneuropathy with symmetrical involvement of sensory and/or motor nerves. Patients with this complication may report no symptoms or complain of numbness and other sensation disturbances [2–4]. The main clinical problem is pain that has a major effect on the quality of life and can even lead to depression and suicide attempts in extreme cases. Current therapy for painful diabetic neuropathy (PDN) is mainly the symptomatic use of typical analgesics (nonsteroidal anti-inflammatory drugs [NSAID] or opioids) or coanalgesics (such as antidepressants and antiepileptics) [5–7]. As a causal treatment, alpha-lipoic acid appears to be the most effective [8]. However, despite a wide range of pharmacological agents, effective analgesic treatment of PDN is still a challenge. Various nonpharmacological symptomatic treatments of PDN have been attempted, including homoeopathy, acupuncture, low-intensity laser therapy as well as static and pulsed magnetic fields [9–11]. Of the physical methods, low frequency pulsed magnetic fields (PMF) are currently of clinical interest [12].

The effect of low frequency magnetic fields on human tissues has been reported in many studies. PMF have analgesic, vasoactive, neurostimulatory and trophic effects, among others, in humans [13]. By inducing low frequency currents, PMF can depolarize, repolarize and hyperpolarize neurons and, in this way, modulate neuropathic pain. The influence of low frequency magnetic fields on pain intensity has not been objectively examined so far in patients with painful diabetic polyneuropathy. Indeed, for years, diabetes has been considered a contraindication for magnetic therapy mainly due to a lack of research into its effects on glucose metabolism. However, the results of recent trials show positive effects of such therapy on glucose utilization [14].

The aim of the present randomized, placebo-controlled, double-blind study was to assess whether magnetic fields influence pain intensity, the quality of life and sleep, and glycaemic control in patients suffering from painful diabetic polyneuropathy.

2. Patients and methods

2.1. Study design and patients

From February 2004 through to October 2005, 61 patients with symptomatic diabetic polyneuropathy were recruited from

the Silesia region of Poland. Enrollment criteria required that all patients have a diagnosis of diabetes (any type) and painful diabetic polyneuropathy with pain disturbing their sleep at night. The diagnosis of diabetic polyneuropathy was based on simple clinical tests, including pinprick, temperature and vibration perception (using a 128 Hz tuning fork), 10 g monofilament pressure sensation at the distal halluces and ankle reflexes [15], and was also confirmed by electroneurography (NC). All patients had to mark at least 40 mm on a 100 mm visual analogue scale (VAS) of pain intensity, where zero (0) meant no pain and 100 mm was the worst possible pain [16]. Patients were excluded if there were other causes of neuropathic pain (such as alcohol or drugs). As a safety precaution, pregnant women and those diagnosed with neoplasm or using cardiac pacemakers were also excluded. Analgesics or other drugs taken for the treatment of chronic neuropathic pain were continued, but no new drugs were allowed during the study period.

Patients were randomized into two groups. The study group consisted of 32 people with painful diabetic polyneuropathy who had an average pain duration of 23 months and who were exposed to low frequency magnetic fields. The control group consisted of 29 patients who had an average pain duration of 28 months and who received sham exposures to magnetic fields. Table 1 shows the general characteristics of the study participants. The study protocol was approved by the ethics committee of the Medical University of Silesia in Katowice, and written informed consent was obtained from all patients before enrollment. All enrolled patients agreed to blood tests, neurophysiological examination (at the neurology department) and filling in questionnaires periodically during the five-week study (VAS Short-Form McGill Pain Questionnaire, EuroQol EQ-5D VAS worksheet questionnaire and MOS Sleep Scale).

2.2. Experimental treatment

Magnetic field exposure was performed with the use of a Viofor JPS device (Med & Life, Komorow, Poland), which is commercially available (shaped like a bed) and generates a low frequency magnetic field of up to 100 μ T [17]. This level is defined as magnetostimulation in contrast to magnetotherapy, where induced field values are above 100 μ T. The electromagnetic waves generated by the Viofor JPS are a complex sequence of pulses at a frequency of about 180–195 Hz. Electrical field intensity is about 130 V/m and is similar to the earth's electrical field. The way in which the Viofor JPS is constructed allows its use in a double-blind manner. Depending on the type of code pre-entered, the device works in a genuine or sham exposure mode and neither the observer nor the subject knows which mode is truly active. The device was precoded by the manufacturer prior

Table 1
General characteristics of the study participants

	All (N=61)	Study group (N=32)	Control group (N=29)
Age	54.5 ± 12.2	53.6 ± 13.6	55.5 ± 10.4
Duration of diabetes (years)	15.2 ± 9.0	17.1 ± 9.1	12.9 ± 8.5
Diabetes type 1/type 2 (N/N)	21/40	12/20	9/20
Duration of pain (months)	25.4 ± 21.7	23.1 ± 23.1	28.1 ± 20.2
Gender (M/F)	25/36	12/20	13/16
BMI (kg/m ²)	29.2 ± 6.0	29.1 ± 6.0	29.3 ± 6.1
WHR	0.909 ± 0.092	0.910 ± 0.093	0.908 ± 0.092
VAS baseline (mm)		73 (54–83)	69 (62–77)
EuroQol baseline (points)		45 (30–80)	50 (37–70)
MOS baseline (%)		58 (50–66)	54 (38–66)

Values are means ± standard deviation medians (interquartile range) for VAS, EuroQol and MOS. No significant differences between groups in baseline characteristics.

to the start of the study. Active and placebo codes were randomly divided into two equal parts (in blocks for 10 people) and were only disclosed after the study had been completed by all participants.

2.3. Magnetostimulation scheme

Each patient was exposed to a genuine or sham magnetic field for a period of 15 days (three weeks, excluding Saturdays and Sundays). Each session lasted 20 min and consisted of two 10 min exposures according to the following application parameters: trunk: M1, P2; intensity 4; lower limbs: M1, P2; intensity 6. M1 is an application of constant intensity of a selected field throughout the entire exposure time, and P2 is a JPS system using ionic cyclotron resonance.

2.4. Measures of outcome

The primary outcome measures were changes in:

- pain intensity;
- quality of life;
- quality of sleep.

Secondary outcome measures were changes in conduction parameters in the peripheral nerves of the lower limbs and in HbA_{1c}. The study period included three weeks of genuine (low frequency magnetic field) or sham exposures and two weeks of follow-up. Pain was measured on a 100 mm linear VAS (Short-Form McGill Pain Questionnaire) [16]. Quality of life was assessed using EuroQol EQ-5D VAS worksheet questionnaire, which records the respondent's self-rated health status on a vertical scale of 0–100 (where 0 is the worst and 100 the best health status) [18]. Sleep assessment was performed using the MOS Sleep Scale questionnaire, in which answers are converted into percentages (0–100%) and the greater the score, the greater the sleep disruption [19,20]. Patients' answers to all the questionnaires were evaluated five times: at baseline; at the end of each week of exposure (Weeks 1, 2 and 3); and at the end of the study (Week 5). Electroneurography (NC) was used to measure motor and sensory nerve conduction velocity (MNCV, the peroneal and tibial nerves; SNCV, the sural nerve),

according to the standard procedure (Counterpoint MK2, Dantec, Denmark). The amplitude of evoked potentials and their latency were also measured in all patients. Electroneurography was performed at baseline and after three and five weeks. In all patients, assessment of diabetic autonomic neuropathy was performed once, using an Ewing battery [20]. HbA_{1c} was measured by high performance liquid chromatography (HPLC; Variant Biorad) at baseline and at the end of the study (Week 5).

2.5. Statistical analyses

Data are presented as means ± standard deviation for parametric data and as medians (interquartile range) for non-parametric data. The Shapiro-Wilk test for normality was used to evaluate the distribution of data, and between-group differences were analyzed by the Mann-Whitney *U*-test. Wilcoxon's test was used to assess differences between baseline and each week of the study.

3. Results

3.1. Efficacy

The baseline characteristics of the 61 study participants were similar in both groups (Table 1). We observed a significant reduction in pain intensity after Week 1 with both genuine and sham exposures that persisted until the end of the follow-up observation period ($P < 0.05$ or $P < 0.01$ versus baseline at any time point). As shown in Fig. 1A, the extent of pain reduction was similar in both the study and control groups, with VAS values at baseline and after three weeks of 73 mm versus 33 mm and 69 mm versus 41 mm in the two groups, respectively. There were no statistically significant differences between the groups at any time during the study. Similar improvements were observed for quality of life (Fig. 1B) and sleep (Fig. 1C), with no significant differences between the groups throughout the study period. In addition, there were no statistically significant differences in conduction velocity, amplitude of evoked potentials and latency of peripheral nerves (data not shown).

Although no specific attempt was made to improve diabetes control during the study, HbA_{1c} significantly decreased

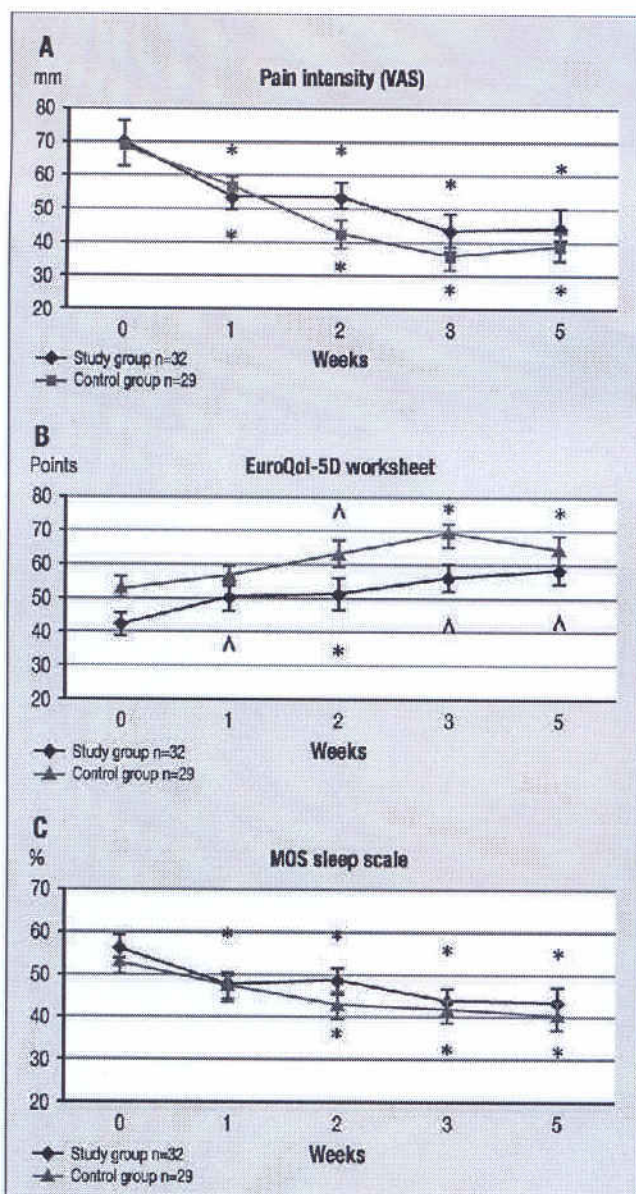


Fig. 1. A. Pain intensity, B. Quality of life, C. Sleep disturbances. Values are means \pm standard error of mean; * $P < 0.01$; $P < 0.05$ versus baseline. No significant differences between groups for all presented parameters at any time during the study.

($P < 0.01$) from baseline to the end of study, most likely as a trial effect (Table 2).

3.2. Safety

No side effects were recorded during the study.

4. Discussion

Our results show that low frequency magnetic fields have a positive impact on pain, quality of life and sleep, and HbA_{1c} values, but are no better than a placebo. A search through the

Table 2
HbA_{1c} value (%) at baseline and after Week 5

	Study group (N = 32)	Control group (N = 29)	Statistical significance
HbA _{1c}			
Baseline	8.7 (7.0–9.7)	8.1 (7.2–9.4)	$P = 0.41$
Week 5	7.8 (7.2–8.6)*	7.6 (6.9–8.4)*	$P = 0.78$

Values are medians (interquartile range); * $P < 0.01$ versus baseline.

literature revealed no study in which the effect of low frequency magnetic fields in painful diabetic polyneuropathy was assessed in a randomized, double-blind, placebo-controlled trial.

In all of our studied patients, previous analgesic pharmacological treatments were ineffectual. The key inclusion criterion, other than clinical confirmation of diabetic polyneuropathy, was a value greater than or equal to 40 mm on a self-rated VAS of pain intensity. As already known from clinical practice, such a VAS range corresponds to pain that disturbs sleep at night and has a major impact on the patient's feeling of well-being. VAS, a standard tool in clinical trials to assess the efficacy of analgesic treatments, allows for maximum sensitivity, and comparisons of pain intensity and between-patient scores [13,21,22]. It also eliminates the potential bias arising from memorization of responses given on previous questionnaires, which is often the case with descriptive scales [23].

Our results show that a low frequency magnetic field generated by a Viofor JPS device according to fixed parameters of exposure (M1, P2, and intensity 4 and 6) has no advantage over the placebo effect. Such a programme of exposure is commonly used as analgesic therapy for musculoskeletal pain. Our results do not correlate with results of other studies evaluating the impact of magnetic fields in patients with painful diabetic polyneuropathy. Two small-scale studies ($N = 31$ and $N = 21$) reported subjective pain reduction and improvement in vibration sensation (measured with a tuning fork) [23,24]. However, these studies were open and mainly assessed the impact of magnetotherapy, not magnetostimulation. Furthermore, electroneurography (NC), an objective tool to assess neuropathy, was not performed. There was also no information regarding the use of an objective pain scale [24,25]. In a different study ($N = 121$), the authors observed a 54% reduction in pain (by VAS), but magnetotherapy was not the only intervention: all subjects had also received therapeutic massage and exercises [13]. Positive effects of PMF, including pain reduction, were also demonstrated in a pilot study by Weintraub and Cole [12]. However, the analyzed group was not homogeneous (not only diabetic patients were included) and there was no control group.

In our study, the reduction of pain intensity in both groups was followed by an improvement in quality of life (EQ-5D VAS) and sleep (MOS Sleep Scale). Clearly, improvement in quality of life can be largely attributed to the pain reduction. Likewise, diminished sleep disruption most likely resulted from the reduction in night-time pain, a typical feature of symptomatic diabetic polyneuropathy. The lack of differences in our questionnaire findings between the real and sham exposure groups could have

been the result of difficulties in objective assessment of pain by patients. On the other hand, pain perception is highly subjective. In the case of a chronically ill patient who suffers from neuropathic pain, simply taking an interest in his/her problem may result in subjective feelings of improvement (placebo effect). Also, it is well known that the sensation of pain differs from one person to another. Psychological studies show that many factors, such as anxiety, suggestion or attention, can influence the origin, intensity and duration of pain. Although the threshold of pain perception is relatively stable, pain tolerance depends on mental status; it decreases in depression and increases in consciousness disturbances [26]. It should also be said that a similarly strong placebo effect was observed in pharmacological trials of analgesic and coanalgesic drugs [22].

In the present study as with that of Musaev et al. [13], NC revealed a slight baseline impairment in conduction velocity for all the nerves studied (peroneal: 40.07 and 40.60 m/s, respectively; tibial: 39.2 and 39.4 m/s, respectively) along with low amplitude evoked potentials (peroneal: 1.1 and 2.4 mV, respectively; tibial: 3.0 and 2.9 mV, respectively). These data indicate lesions in the myelin sheaths and axial cylinders of the peripheral nerves in the lower limbs in both studies. Amplitude reduction is more typical for axonal polyneuropathy, as in diabetic polyneuropathy, whereas conduction velocity may be slightly diminished or even unchanged when fast fibers are relatively preserved [27]. In the Musaev et al. study, there was an improvement in the examined parameters that was more significant with a magnetic field of lower frequency (10 Hz) than with the 100 Hz field. In our study, we observed no changes in NC in either the study or control group. Weintraub et al. obtained findings similar to ours with pulsed [12] and static magnetic fields [11] in patients with neuropathic pain.

NC analysis is an objective examination of neuropathy used for DPN diagnosis as well as its progression. Many trials conducted so far confirm the high repeatability of this method [28,29]. The lack of such changes in our study suggests no impact of PMF on definite parameters on NC; however, this does not preclude a beneficial effect of PMF on pain intensity via other mechanisms such as cellular receptor modulation.

All of the above-mentioned studies assessed the effectiveness of magnetotherapy, whereas we examined the impact of magnetostimulation in patients with painful diabetic polyneuropathy. The difference between these two interventions is the frequency of the magnetic field: magnetostimulation ranges from a few to 3000 Hz and induction values are below 100 μ T; magnetotherapy uses frequencies up to 100 Hz and induction values range from 0.1–20 mT. Effects of both types of magnetic field exposure are convergent on many points. Lately, magnetostimulation is of greater interest for analgesic therapy and, unlike magnetotherapy, the data confirm that it does not affect melatonin secretion [30]. An analgesic action of melatonin has been suggested in experimental studies of rodents [31,32].

Other studies claim a positive role for PMF in glycaemic control. In experimental studies of rodents, researchers observed lowered glucose concentrations and a reduction in the insulin to glucose ratio in exposed animals compared with controls [33]. According to the authors, the underlying mechanism could be

stimulation of insulin secretion and peripheral tissue glucose uptake by PMF. In another study, a higher absorption of ^3H glucose injected into the peritoneal cavity was observed in rats exposed to magnetic fields [34]. Such effects were attributed to the field-induced changes in cell membranes and ion channels. In our pilot study ($N = 21$), we noted a significant reduction in HbA_{1c} values after five weeks (three weeks of exposure and two weeks of observation) in patients exposed to magnetic fields compared with sham exposures ($P < 0.05$) [35]. However, after increasing the study group to 61 patients, similar reductions in HbA_{1c} were observed in both analyzed groups. There was no change in hypoglycaemic treatment during the study period that could have caused these reductions in HbA_{1c} . It may be that simply participating in a trial may have resulted in an improvement in glucose control (trial effect) due to better patient compliance during the study period. Others have confirmed that HbA_{1c} reduction has a positive effect on peripheral nerve function that may result in diminished pain intensity [36,37]. In addition, pain reduction decreases stress and, thus, may also contribute to better glycaemic control. However, it is unlikely that improvement of glycaemia was responsible for the observed pain reduction seen after the first week of PMF exposure.

When considering the use of low frequency magnetic fields for painful diabetic polyneuropathy or in medicine in general, there arises not only the question of does it really work, but also of how does it work. One hypothesis to explain the effect of magnetic fields on human tissues is that it affects the plasma membrane transport of calcium ions; a resonant interaction at cyclotron frequency between calcium ions of geomagnetic densities is observed [38,39].

Comparison of our results with the above-mentioned findings of other authors is difficult because of differences between studies in terms of parameters of magnetic fields used (exposure profile), exposure duration, total exposure times and devices used to generate the magnetic fields. Moreover, only a few researchers analyzed the placebo effect [11,24]. Furthermore, it must be emphasized that, in humans, the biological response is dependent on exposure at particular magnetic field strengths. A “window” is defined as a biological response that occurs only within a specific amplitude or frequency range, being moderate or absent outside of this range. This could explain the apparently conflicting findings in the studies using different exposure profiles. Finally, it needs to be emphasized that there were no major, clinically important, side effects with the use of low frequency magnetic fields in either our study or any of the above-mentioned trials.

The results we obtained may also have been determined by the specific exposure pattern (M1, P2, intensity 4 and 6) we used. For this reason, randomized, double-blind, placebo-controlled studies using a variety of magnetic field exposure protocols (specific window) are necessary to arrive at any conclusions regarding the potential benefits of this procedure in the treatment of painful diabetic neuropathy.

5. Declaration of competing interests

None to declare.

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