

Efficacy and safety of a musically modulated electromagnetic field (TAMMEF) in patients affected by knee osteoarthritis

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Abstract

Objective

Numerous studies have demonstrated the utility of extremely low frequencies (ELF) electromagnetic fields in clinical practice. Moreover, the effects of these fields seems to depend on their respective codes (frequency, intensity, waveform). In our study we want to value the effects of the TAMMEF (Therapeutic Application of a Musically Modulated Electromagnetic Field) system, which field is piloted by a musical signal.

Methods

Ninety subjects, affected by primary osteoarthritis of the knee, were enrolled in the study and randomly divided into three groups of 30 patients each: A exposed to TAMMEF, B exposed to ELF, C exposed to a simulated field. All subjects underwent a cycle of 15 daily sessions of 30 minutes each and a clinical examination upon enrolment, after 7 days of therapy, at the end of the cycle and at a follow-up 30 days later.

Results

All the patients of groups A and B completed the therapy without the appearance of side effects: they presented a significant improvement of the subjective pain and the functional limitation, which remained stable at the follow-up examination. In group C, there was no improvement of the pain symptoms or articular functionality.

Conclusions

This study suggests that the TAMMEF system is efficacious in the control of pain symptoms and in the reduction of functional limitation in patients with knee osteoarthritis. Moreover, the effects of the TAMMEF system cover those produced by the ELF field.

Key words

Electromagnetic fields, therapy, osteoarthritis, analgesic-antiinflammatory activity, TAMMEF.

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This study was supported in part by a contribution from the "Fondazione del Monte dei Paschi di Siena", Siena, Italy.

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Received on November 24, 2003; accepted in revised form on June 16, 2004.

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Introduction

The effects of the various types of low frequency electromagnetic fields used in clinical practice depend on their codes (frequency, intensity, waveform, the number of impulses per train and the interval between one train and another). The electromotor forces induced at a given point of a biological system act on the electric charges present which respond, causing functional modifications in the cellular microenvironment (1-3).

The overall biophysical effect can be appreciated only by observation, since the level of complexity of the system does not allow one to predict what mechanisms of action will predominate. However, it is possible to compare the effects of a certain field with those of an all-inclusive reference field whose parameters continually change in time so that all possible codes can occur in a single application.

Our group has already shown the efficacy and tolerability of the extremely low frequency (ELF) field in patients affected by osteoporosis (4), rheumatoid arthritis (5) and osteoarthritis (6). Recently to evaluate the utility of applying the widest possible magnetic field, we introduced the new TAMMEF (Therapeutic Application of a Musically Modulated Electromagnetic Field) system. The field is obtained from recorded musical passages; thus its parameters (frequency, intensity, waveform) are modified in time, randomly varying within the respective ranges, so that all possible codes can occur during a single application(6).

The aim of this study is to evaluate the efficacy of the TAMMEF system in the treatment of knee osteoarthritis. In particular, we wished to ascertain if the effects of the field piloted by a musical signal are comparable with those of field with frequency of 100 Hz and a sinusoidal waveform. Both fields are generated by an opposing pair of heteronomous polar expansions and thus present the characteristic spatial conformation.

Methods and patients

Methods

The instruments used to generate the

ELF and TAMMEF fields are similar.

An audiotape player sends the relative monochannel-microphone signal to two low frequency amplifiers A and B, both with adjustable gain. The current from amplifier A, modulated according to the recorded signal, feeds two electromagnets with iron-silicon cores joined posteriorly by a ferromagnetic arc. The anatomical region to be treated is placed between the opposing faces (3x4 cm) of the polar expansions. The current from amplifier B feeds a loudspeaker that plays the pilot musical passage. The music can also be heard through headphones, with automatic exclusion of the loudspeaker. The gain of amplifier A is regulated so that when the audiotape contains a sinusoidal signal with frequency of 100 Hz, the electromagnetic field is equal to the ELF field used (about 3 gauss midway between the poles when this distance is 30 cm). This set-up is then left unchanged whatever the contents of the audiotape used subsequently. The patient is allowed to regulate the gain of amplifier B, with the volume preferred, whether the music is being transmitted over a loudspeaker or into a headset.

Patients

Ninety subjects (63 females and 27 males), between 59 and 76 years old, affected by primary osteoarthritis of the knee, were enrolled in the study (Table I) and randomly divided into three groups: A =30 patients subjected to TAMMEF, B=30 patients subjected to ELF and C=30 patients subjected to a simulated field. Group C was introduced because of the possibility that the TAMMEF effects would be indistinguishable from those of the ELF, and thus to test for the presence of a substantial placebo effect. All the patients including in group C listened to the music.

The diagnosis of osteoarthritis of the knee was made according to the criteria of the American College of Rheumatology (7). Evaluation of the stage of the disease was based on the radiographic system of Kellgren and Lawrence(8). The clinical examination was based on the Lequesne index of algo-functional severity (9), a validated questionnaire

Table I. Personal and clinical characteristics of the examined patients.

Sex	Pt. no. (%)	Mean age (yrs.)	Disease duration
M	27 (30%)	53.5 ± 7.6	10.8 ± 2.3
F	63 (70%)	59.4 ± 7.1	11 ± 3.5
Total	90 (100%)	58.9 ± 7.4	11 ± 3.1

Table II. Clinical characteristics of the examined patients (Pts) according to the Lequesne index of algo-functional severity.

	Pt. no. (%)			Slight disease (%)			Moderate disease (%)			Serious disease (%)		
	A	B	C	A	B	C	A	B	C	A	B	C
	Pts with knee osteoarthritis (%)	30	30	30	15	13	15	12	13	12	3	4
	100%	100%	100%	50%	43%	50%	40%	43%	40%	10%	14%	10%

specific for knee osteoarthritis. On the basis of the point of the score of the Lequesne index, the patients were divided

into three subgroups, as shown in Table II. All the subjects were out-patients and, correctly informed of the experi-

mental plan, gave their written consent. All the patients underwent a cycle of 15 daily sessions of 30 minutes each, with application of the magnets in contact with the lateral zones of the knee. In the past, all the patients had been treated occasionally or cyclically with analgesic (paracetamol) or non-steroidal anti-inflammatory drugs (diclofenac, or piroxicam, or celecoxib, or rofecoxib), but they had suspended any drug at least 15 days before the beginning of the cycle. The clinical examination was performed when the patients were enrolled in the study, after 7 days of therapy, at the end of the cycle and at a follow-up, 30 days later (10).

The evaluation of the possible therapeutic effects has been effectuated using the Lequesne test as modified by the authors: we have divided the evaluation of pain from the evaluation of articular function because of the well-known subjectivity of pain to the placebo effect (11).

Statistical analysis

The differences between the means of the various parameters at 0, 15 and 45 days were tested by Student's t test or Mann-Whitney-U test as appropriate.

Results

Above all, we specified that no significant differences were found between the three groups of patients, concerning private data and their degree of disease. All the patients of group A and B completed the therapeutic cycle, without side-effects that might have required suspension of the treatment. With regard to the efficacy of the therapy, it should be underlined that none of these patients had to take analgesic-anti-inflammatory drugs during the cycle and that all the patients presented a significant improvement of both subjective pain and regional functional limitation. In particular, in the TAMMEF group, the subjective pain progressively decreased in all subjects even after the first week and regressed completely at the end of treatment in 27 (90%) of the 30 patients. In the remaining 3 patients (10%), the pain symptoms, albeit not totally regressed, decreased significantly with respect to the basal values and

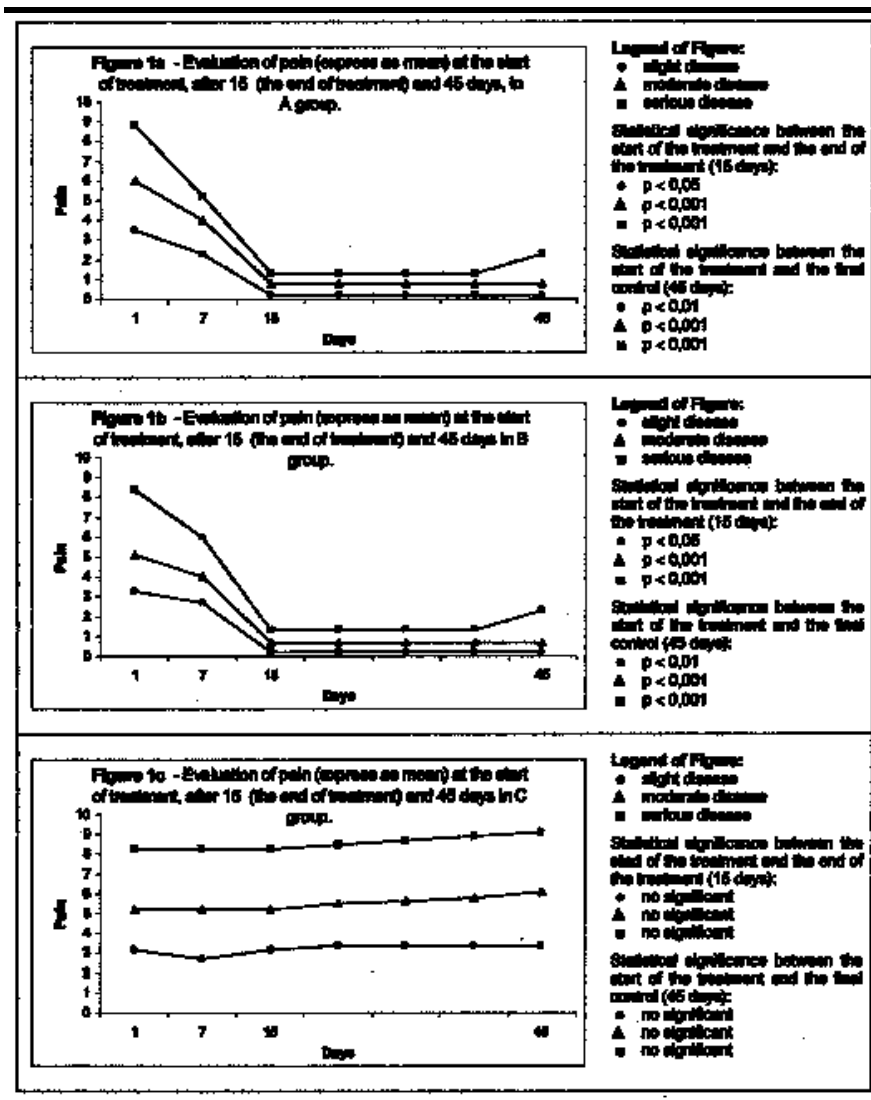
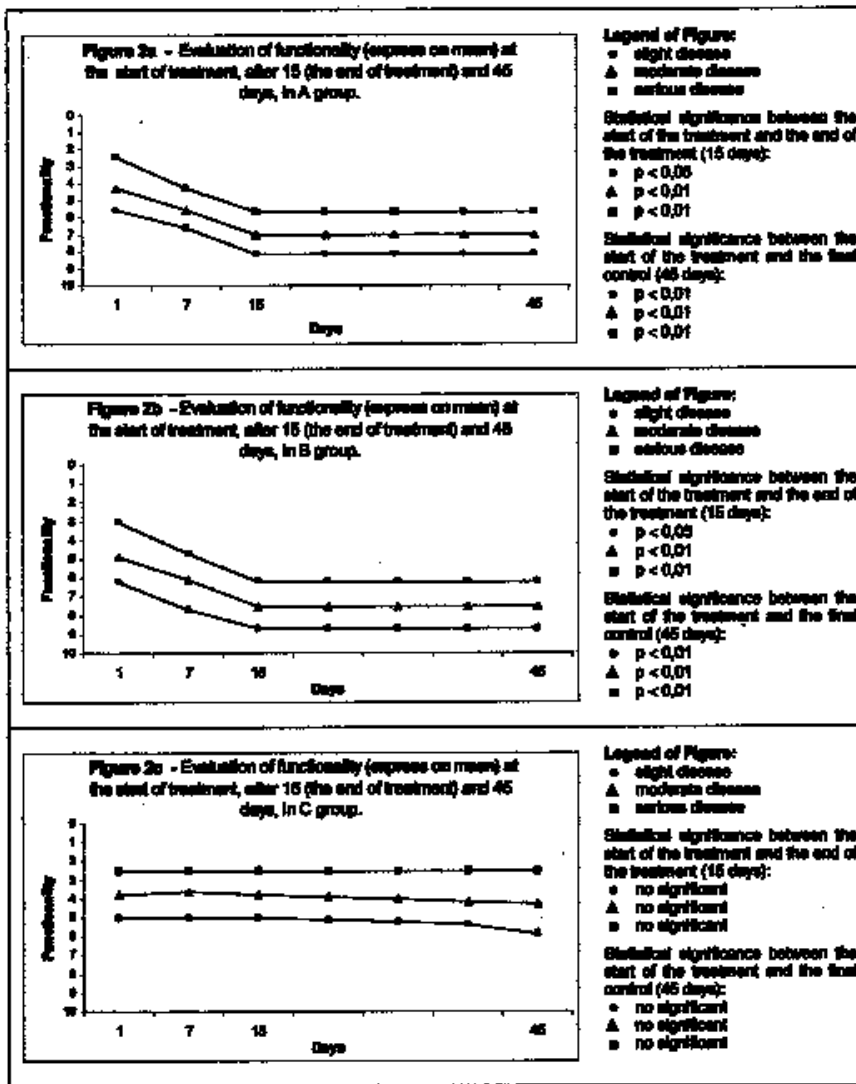


Figure 2 Evaluation of functionality



to those recorded after the first week (Fig. 1a). In the ELF group, the time course of subjective pain was equivalent to that of the TAMMEF group, with complete regression in 23 patients (76.6%) and a significant reduction in the remaining 7 patients (23.4%) (Fig. 1b).

With regard to the evaluation of articular functionality, there was a significant partial recovery of mobility in all patients, starting from the first week (thus concomitant with the improvement of subjective pain). At the end of the cycle, in the TAMMEF group, 21 patients (70%) manifested a total recovery of the partially compromised articular functionality, while 9 patients (30%) showed a significant further improvement with respect to the already

positive trend recorded after the first week of therapy, although they did not achieve a total functional recovery (Fig. 2a). In the ELF group, there was a total functional recovery in 19 patients (63.3%), while in 11 patients (36.7%) the change was similar to that of the TAMMEF group (Fig. 2b).

The clinical follow-up, one month after the end of the cycle, revealed that in 28 group A patients (93.3%), there was no appreciable variation in the regression or improvement of pain symptoms from what was recorded at the end of the magnetotherapy; in the other 2 subjects (6.7%), affected by severe osteoarthritis, there was a clear relapse of pain. However, this was not accompanied by a concomitant worsening of articular functionality, which continued

to show the same recovery as recorded at the end of the therapy one month previously. There was a very similar pattern in group B: in 27 patients (90%), there was no change from the situation at the end of therapy, whereas 3 subjects (10%) reported a relapse of the pain symptoms.

The time course of the articular pathology was clearly different in the 30 subjects of group C. Only 3 of them (10%) presented a slight subjective improvement of the symptoms in the first 5 days of the cycle, while the other 27 patients (90%) reported no significant pain reduction. After the first week, application of the simulated magnetic field had to be suspended in 12 group C patients (40%) because of its ineffectiveness, while the remaining 18 patients (60%) completed the cycle. At the end of treatment and at the clinical follow-up one month later, all the patients who completed the cycle reported no improvement of pain symptoms or articular functionality; indeed, there was a slight worsening of pain (Figs. 1c-2c).

Discussion

All the patients treated with TAMMEF or ELF completed the therapeutic cycle and manifested a significant improvement of the clinical picture. The two electromagnetic fields had equivalent effects and produced a so-called "tail effect", continuing after the suspension of therapy, as if the biophysical action interfered with the pathogenetic mechanisms of the disease, probably by inhibition of the inflammatory process(4, 5). Moreover, the effects of low frequency electromagnetic fields on cartilage have been evaluated recently by various authors (12,13): they demonstrated *in vitro* that electromagnetic fields exposure exerts a chondroprotective effect on articular cartilage, increase the rate of differentiation of these cells and enhance synthesis of normal matrix proteins. The lack of efficacy in the group C patients confirms the therapeutic effects of the two fields. Indeed, considering the known relationship between the pain pathways and the psychic habitus of the patient (14-16), only the slight improvement of pain

symptoms initially shown by the group C subjects could be attributed to the placebo effect.

It should be mentioned that all the patients subjected to TAMMEF applications stated that they enjoyed listening to the music and they manifested a psychological attitude of trust and satisfaction. It also seems that these patients showed more evident and quicker responses, although this was not statistically significant and is reported only as an impression and a possible topic for future research.

Our results confirm the efficacy and tolerability of low frequency magnetic fields as previously reported (4-6, 10, 17), also support the hypothesis that the effects of magnetic fields with parameters that change in time, like those produced by the music-piloted TAMMEF system, are equivalent to the effects of the ELF field(6).

Moreover, in relation to current studies on interactions between the nervous, endocrine and immune systems (18, 19), it may be possible to combine the electromagnetic stimulus with the corresponding acoustic stimulus, i.e. listening to the pilot musical passage. In fact, the two mechanisms, triggered in different sites and acting by different but simultaneous and coherent channels, might produce responses that reinforce one another(20).

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