Clinical Study of Applied High-induction Electromagnetic Field on Painful Conditions

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Summary

Background: A new approach to pain management appeared in a physical therapy. It is technology based on the effect of strong pulsed electromagnetic field in human tissue (the value of induction is in the order of units of tesla). This pilot study examines the analgesic effect of this technology with different diagnoses.

Objective: Verification of an analgesic effect of a strong pulsed electromagnetic field on a sufficient statistical sample in a clinical practice.

Methods: The therapy was performed with 57 randomly selected patients with chronic and acute pain of musculoskeletal system. Patients had 6 therapies in average, 1—2 times per week, 10—15 minutes according to the selected protocol. We used the combination of the Visual Analog Scale (VAS) and the Verbal Numerical Rating Scale (VNRS) to determine the analgesic effect.

Results: Regardless of diagnoses the overall decrease of pain was 37.5 %. There was significant release of pain at 46 patients. There was neither improvement nor worsening of pain in 4 of the 50 patients. Seven patients were excluded from the study.

Conclusion: We have demonstrated the analgesic effect of a strong pulsed electromagnetic field on musculoskeletal pain.

Keywords: FMS, electromagnetic induction, analgesic effect, musculoskeletal system.

Introduction

The super inductive electromagnetic field is used in research, diagnostics and treatment of various central and peripheral disorders. The technologies using this physical principle are mentioned in literature as: FMS, TMS, rTMS, MRI, ExMI, etc. For the purpose of this study, we are solely focusing on the peripheral application, which is used less widely with regard to transcranial application. Takinginto account the fact that almost every musculoskeletal disorder is accompanied by pain, other options of influencing it should be researched.

There have been several studies conducted on the specific effects of super inductive field on human tissue. The analgesic effect is described by Poděbradský (37), Lee (26) and Uher (44). In their studies they used a stimulator reaching the frequency of 50 Hz. They hence influenced the pain on the basis of endorphin theory of pain. We have applied the Super Inductive System technology, which reaches the frequency of up to 150 Hz.

Medical application

The static super inductive electromagnetic field has been used since the 70'sfor MRI examination. The pulsed super inductive electromagnetic field has been used since the 80's. The peripheral magnetic stimulation was first used in 1982. The transcranial stimulation was first used in 1985 at the University of Sheffield. The so-called rTMS (repetitive transcranial stimulation) was discovered in 1988, when it was possible to combine more pulses into one sequence for the first time. Until then it had always been application of single pulses. Transcranial, i.e. central, application is nowadays used in research and diagnostics of cerebral disorders (8), Tourette syndrome (48), ataxia (7), focal dystonia (1), multiple sclerosis (17), Parkinson's disease (2, 4), motor cortex function (3, 10, 31), motor learning (39), neuroplasticity (36) and also in treatment of conditions after cerebral stroke (15, 22), aphasia

(16, 32, 42), in treatment of blepharospasm (24), spasticity (35) and in treatment of pain (23, 41, 43). The transcranial stimulation is applied in psychiatry in treatment of depression (13, 19, 27, 46), bipolar disorder (21), obsessive-compulsive disorder (34, 38), post-traumatic disorders (19), auditory hallucinations (40), schizophrenia (9, 28) and autism (11). The peripheral application is primarily used in rehabilitation of neuromuscular disorders (5, 26, 29, 37, 44). Furthermore, it is used in research and diagnostics of muscle and nervous tissue (6, 14, 25) and in urology (30, 45, 47).

THE METHOD

Methodology

The super inductive stimulator (the BTL-6000 Super Inductive System, by BTL Industries Ltd.) was used to perform the therapy. The effectiveness of the device was checked at an orthopaedic practice in Prague, which is closely connected to an orthopaedic clinic with significant experience in physical treatment (high intensity laser therapy, low-induction magnetotherapy, contact electrotherapy). During the whole study, the device was placed in a separate space, which was solely determined for this purpose. The separate types of physical treatment of patients were not combined. Depending on the type of pathology, the following protocols were used:

Protocol 1

Protocol 1 was used with chronic pain conditions (e.g. bursitis, gonarthrosis). It consisted of 4 sections. The frequency was changed from 1 to 10 Hz. The procedure affected the tissue based on the endorphin theory and was applied using motor threshold intensity. The total therapy time was 10 minutes.

Protocol 2

Protocol 2 was used in case of acute pain (vertebrogenic algic syndrome). It was mono sectional with a constant frequency of 143 Hz. The protocol affects the tissue based on the peripheral code theory and was applied using the above motor threshold to motor threshold intensity. The total therapy time was 15 minutes.

Protocol 3

Protocol 3 was used in case of painful conditions combined with edema (in the phase of passive hyperaemia or fibroblastic conversion). It was composed of 3 frequency-modulated sections. The frequency did not reach over 10 Hz. The procedure affected the tissue based on micro-muscular pump activation and was applied using motor threshold intensity. The total therapy time was 12 minutes.

The procedures applied for specific diagnoses are stated in Tab 2.

Experimental Group

The study was conducted from the 24th November 2015 until the 31st December 2015 on randomly selected patients with various musculoskeletal system disorders. Separate diagnoses are stated in Graph 1 below. We have not compared the effect with a control group treated by a placebo (an empty device) or any other type of physical treatment. We took the anamnesis before the therapy focusing on contra-indications and we carefully conducted clinical entry examination. The criteria for entering were stated as follows: the age of more than 12 years, diagnosed with an acute or chronic musculoskeletal disorder, non-infectious, voluntary consent. Altogether 57 patients were treated (38 women/19 men). The women's average age was 53 years (+33/-36), the men's average age was 49 years (+38/-35). The study completion criterion was stated as follows: present at a minimum of 4 therapies. 7 patients have not fulfilled the completion criterion (6 women/1 man). They were excluded from the study. The patients were present at approximately 1-2 therapies per week. They did not undergo any other physical therapy. The testing was conducted in the same room with a constant temperature of 22°C +/- 1°C.

Measurement

The applicator (15x15 cm) was placed 1-3 cm above the skin surface at the painful spot. The VAS (Visual Analog Scale) and the VNRS (Verbal Numerical Rating Scale) were used to assess the level of pain prior to the therapy and immediately after the therapy. VAS and VNRS are a part of each patient's log, which contains data about their age, sex, diagnosis and a log of specific therapies.

Data Collection

The pain was evaluated based on the subjective statements of the patients before and after each therapy and at each following visit. The values were noted down in the log of each patient.

Data Analysis

The analysis was conducted based on the calculation of mean and median values of each respective data set. Except for the above mentioned pain values,

an average decrease of pain, an average number of therapies and a total decrease of pain in the whole sample of patients was observed. Furthermore, pain decrease was evaluated by respective diagnoses.

THE RESULTS

The total of 335 therapies were conducted on 57 patients. After excluding 7 patients, who took part in less than 4 sessions, the number of therapies was reduced to 317. The median of the number of therapies was 6 (see tab 4).

The range between the maximum pain value and the minimum value after the last therapy was 7. Overall average pain for all therapies was 3.95 (see Tab 3). The most often represented diagnoses were gonarthrosis (24%) and shoulder bursitis (22%), see the Tab 1 and the Graph 1.

Overall average pain before the first therapy was 4.96 (the median was 5), overall average pain after the last therapy was 3.10 (the median was 3), which is a decrease of 37.5% (see Tab 5). 4 patients had no decrease of pain. None of the patients' conditions worsened.

The entry diagnosis for 12 individuals was represented by Gonarthrosis type II-III RTG classification by Lawrence-Kellgren. No effect took place by 2 patients with severe damage of medial compartment. A decrease in pain by 35% (20-50%) took place by the 10 remaining patients. We observed a reduction of edema whilst we did not evaluate functional improvement of the joint.

11 patients have undergone application based on the indication of chronic pain of the shoulder joint meaning subacromial bursitis. The average number of sessions was 6 (3-10), the decrease in pain was 30% (20-75%). The best results were reached after taking part in 10 sessions with the decrease in pain by 75%. This happened in 2 cases. All patients have experienced improvement by at least 20%.

DISCUSSION

We have confirmed our work hypothesis by this pilot study. An analgesic effect has been marked by the majority of patients. A Quite significant relief was experienced in cases after knee distortion. One time the treatment was complemented by hemarthrosis puncture. The decrease in pain was 40% (40-60%) after 6 applications on average. A significant antiedematous effect was visible already after 2 applications. Orthosis immobilisation with preserved static joint stabilisers reached only 2.5 weeks.

We have also included enthesopathy of extensors (in the area of lateral epicondyle of the humerus – tennis elbow) in the diagnoses spectrum (6 sessions lead to pain relief of 50%). Furthermore, we have included carpometacarpal thumb joint arthrosis – rhizarthrosis (40% relief after 6 sessions), anterior ankle pain after overexertion (6 sessions lead to relief of 40%), metatarsalgia (on average a decrease in pain by 32.5% after 6 sessions), and others.

The most effective therapy was achieved by acute inflammatory conditions of soft tissue – forearm extensors tendovaginitis (pain relief of 50% after 5 sessions), tibialis anterior tendinitis (50% relief after 4 sessions) and De Quervain tendinitis (60% relief after 6 sessions). Moreover, to this group belong also aseptic necrosis – Osgood-Schlatter (50% relief after 6 sessions), plantar fasciitis (67% relief after 10 sessions) and also painful pes planus (40% relief after 7 sessions).

Linear decrease of pain took place by the majority of patients (see graph 2) during the treatment, which lasted on average 2-3 weeks. Poděbradský (37) states pain relief for up to several weeks. He evaluated pain with the aid of VAS in mm. He states the decrease by respective diagnoses. The average decrease is 26.46 mm by males, 27.25 mm by females. Lee (26) states the statistics 1 and 4 weeks after the therapy with a continuous positive effect. The decrease of pain was 2.3 one week after the application and 2.2 after four weeks. Uher (44) states a decrease in pain by 2.33 on average after a five-week treatment. All of the above mentioned results are comparable with ours, where the overall decrease of pain was 37.5%. Poděbradský worked with four different pre-set procedures with frequencies of 3 to 40 Hz. Lee worked with a procedure which alternates 5 and 10 Hz. Uher worked with the same procedures as Poděbradský. The above stated frequency values correspond to the endorphin pain theory. We have used frequency values of 1-10 Hz in our study. We have also used an extra frequency of 143 Hz, which corresponds to the peripheral code theory. Poděbradský dealt with acute and chronic conditions by changing the intensity (threshold sensitive and supraliminal sensitive respectively). Lee set intensity based on the feeling of the patient from low in the beginning to the highest that the patient could bear. Uher did not distinguish between acuteness and chronicity and he did not provide intensity. We have used the frequency of 143 Hz for acute issues with supraliminal sensitive intensity to motor threshold intensity. For chronic conditions, we have used the

frequency of 1 to 10 Hz (see procedures 1 and 3). From the data available it seems that the intensity is not important for the effect to take place. However, it is necessary to further research this notion. It is also not clear if different frequencies take different effects. We have always used a high frequency for acute pain, but never a low one, although a low frequency takes effect in case of acute pain (36). According to Poděbradský, a permanent condition improvement cannot be explained solely by the analgesic effect. As a proof he states the time the relief takes place by respective theories (gate control theory: 35-50 minutes, endorphin theory: 45-60 minutes, peripheral code theory: up to 2 hours). He did this based on his own experience. This is not being dealt with much in the literature. Poděbradský explains the long-lasting analgesic effect by the dispersion effect, which is not that well known in the foreign literature. We are theoretically able to confirm this with regard to the fact that we used muscle twitching in the procedure 3, which is a sort of mechanical tissue charge. He furthermore explains the long-lasting effect by influencing the sympathetic nerve on the spinal circuit. He does not further explain this piece of information in any way. It is possible from the anatomical and physiological point of view of the functioning of an autonomous system. We are not able to confirm or to disprove it in this study. Moreover, he has recorded antiedematous, myorelaxant and trophotropic effects.

There are several works in foreign literature dealing with the issue. Khedr (21) applied super inductive magnetic field in a transcranial way (motor homunculus – hand area) by patients with trigeminal pain and by patients after cerebral stroke. He describes the analgesic effect as far as 2 weeks after the therapy (20 Hz, rTMS, 5 consecutive days, he does not state the time the therapy lasted). The mechanism of long-lasting pain relief remains unknown also for him. He states several studies that observe an increase in blood flow through the brain in the areas of thalamus, cingulate gyrus, orbitofrontal cortex and brain stem (12). It is therefore clear that the limbic system is influenced. Whether the super inductive therapy can also peripherally influence the limbic system still remains questionable. On the other hand, in her study, Näsi (33) describes a decrease in the concentration of haemoglobin, which is connected to the change in blood volume. During the transcranial application she observed vasoconstriction in both hemispheres – the same as during the peripheral application in the shoulder area, contrary to Khedr. Knotkova (23) shortly mentions the use of rTMS during the phantom pain treatment, naturally only with a short-term effect. On the contrary, Treister (43) provides a lot of studies in his overview, where rTMS significantly relieves neuropathic pain. Short (41) focuses on the treatment of fibromyalgia (transcranial application in the prefrontal area) in his study. He reached 29% pain relief and states a side effect against depression.

Other studies are devoted to other, promising uses for the future. TMS (peripheral application) is mentioned by Lin (29). In his study, he confirms improved gastric emptying function of patients with a spinal disorder. Bustamante (5) increased the muscle strength of the quadriceps muscle of patients with COPD using peripheral rTMS application. Also Carres (6) used peripheral application to research pathophysiological muscular spasms. Harris (14) used peripheral stimulation to diagnose muscular function of patients hospitalised at ICU. Kyroussis (25) researched abdominal muscles fatigability by maximum exhalation using peripheral stimulation.

Super inductive magnetic field impacts primarily muscle and nervous tissue. This implies that when influencing motor or sensitive component, other effects can take place.

CONCLUSION

In our pilot study we have proved analgesic effect of the Super Inductive System technology. Both chronic and acute pain decrease took place for all diagnoses. The decrease in pain was recorded immediately after respective therapies, also in long term. The cause of pain was neither a determining nor a limiting factor. Acute and subacute conditions are better influenced. The condition is to respect regime measures. Younger individuals achieved better results. The number of sessions significantly influences the treatment effect. The best result takes place with soft tissue disorders and conditions after overloading, decent result appears with arthritic joints pain, decompensation and with mild to slightly severe stages. The effect takes place much faster and lasts longer than with conventional physical methods. This therapy brings an undisputable advantage in the form of contactless application, without the need to undress the patient. Application is easy and safe. No side effects were observed during the study. To confirm the results and further effects, more detailed studies need to be conducted.

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Graph description

Graph 1: Overall average pain value before the first and after the last therapy. The X-axis contains respective diagnoses and the Y-axis contains the VNRS scale.

Graph 2: Overall average decrease in pain during the first 6 therapies (procedures 1 and 3). Procedure 2 was not applied on the sufficient statistic sample compared to the other two procedures.

Tab 1: Number of patients with respective diagnoses and per-cent decrease in pain

Diagnosis	*Number of Patients*	*Decrease in pain using VNRS (%)*
Gonarthrosis	12	35.15
Shoulder Bursitis	11	29.91
Knee Joint Distortion	6	40.16
Epicondylitis	3	34.66
Low Back Pain	3	25
Hell Spur	2	32.50
Metatarsalgia	2	32.5
Traumatic Arthritis	2	62
Osgood-Schlatter Disease	1	50
De Quervain Disease	1	60
Plantar Fasciitis	1	67
Painful Pes Planus	1	40
Tendovaginitis	1	50
Tendinitis	1	50
Rhizarthrosis	1	40
AC Joint Arthritis	1	25
Anterior Ankle Pain	1	40

Tab 2: An overview of the protocols used with the respective diagnoses

Diagnosis	*Procedure no.*
Gonarthrosis	1
Shoulder Bursitis	1
Knee Joint Distortion	3
Epicondylitis	3
Low Back Pain	2
Heel Spur	3
Metatarsalgia	3
Traumatic Arthritis	3
Osgood-Schlatter Disease	3
De Quervain Disease	3
Plantar Fasciitis	3
Painful Pes Planus	1
Tendovaginitis	3
Tendinitis	3
Rhizarthrosis	1
AC Joint Arthritis	1
Anterior Ankle Pain	1

Tab 3: Average pain out of all 317 therapies conducted

Overall pain mean	3.95
Overall pain median	4
Maximum pain value	8
Minimum pain value	1
Range	7

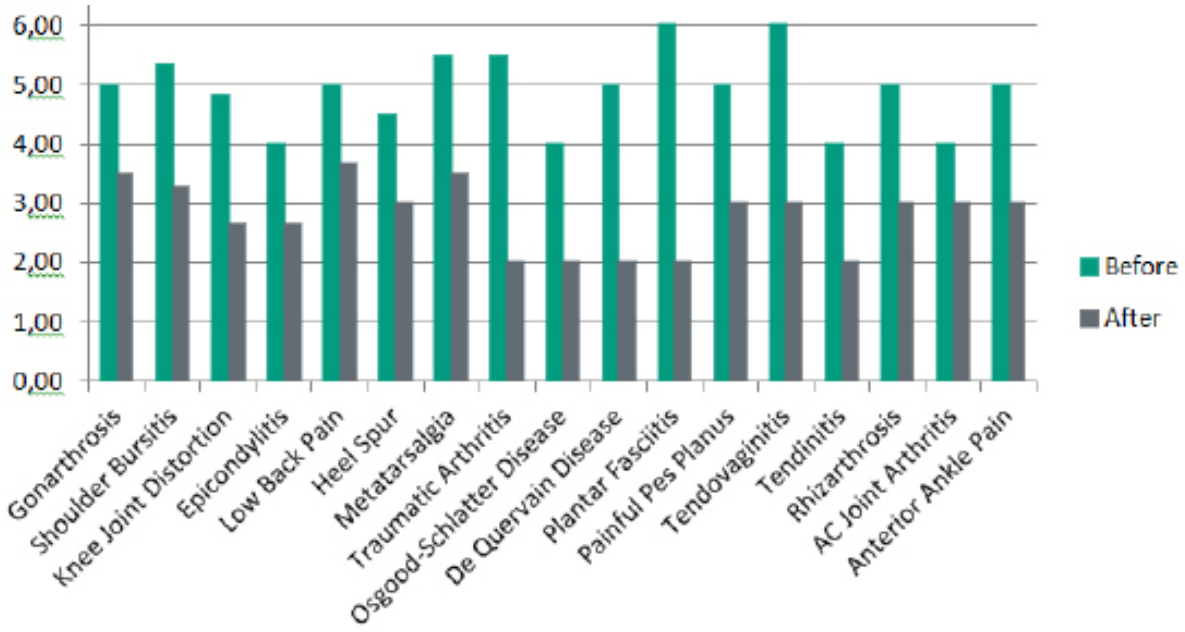
Tab 4: Average therapies conducted with one patient

Overall therapy number	317
Average number of therapies	6.34
Median of number of therapies	6

Tab 5: Comparison of VNRS values before the first and after the last therapy of the whole statistic sample.

Mean pain value before the first therapy	4.96
Median pain value before the first therapy	5
Mean pain value after the last therapy	3.1
Median pain value after the last therapy	3

Graph 1: Overall average pain value before the first and after the last therapy. The X-axis contains respective diagnoses and the Y-axis contains the VNRS scale



Graph 2: Overall average decrease in pain during the first 6 therapies (protocols 1 and 3). Protocol 2 was not applied on the sufficient statistic sample compared to the other two procedures. The X-axis contains therapy number, the Y-axis contains the VRNS scale.