



Pulse low-intensity electromagnetic field as prophylaxis of heterotopic ossification in patients with traumatic spinal cord injury

Pulsno elektromagnetno polje niskog intenziteta u prevenciji heterotopske osifikacije kod bolesnika sa traumatskim povredama kičmene moždine

Aleksandar Đurović*, Dejan Miljković*, Zorica Brdareski*,
Aleksandra Plavšić†, Miodrag Jevtić‡

Military Medical Academy, *Clinic for Physical Medicine and Rehabilitation, †Head Office, Belgrade, Serbia; ‡Tor Vergata University, Rome, Italy

Abstract

Background/Aim. Heterotopic ossification (HO) is an important complication of head and spinal cord injuries (SCI). Pulse low-intensity electromagnetic field (PLIMF) therapy increases blood flow to an area of pain or inflammation, bringing more oxygen to that area and helps to remove toxic substances. The aim of this study was to determine the effect of PLIMF as prophylaxis of HO in patients with SCI. **Methods.** This prospective random control clinical study included 29 patients with traumatic SCI. The patients were randomly divided into experimental ($n = 14$) and control group ($n = 15$). The patients in the experimental group, besides exercise and range of motion therapy, were treated by PLIMF of the following characteristics: induction of 10 mT, frequency of 25 Hz and duration of 30 min. Pulse low-intensity electromagnetic field therapy started in the 7th week after the injury and lasted 4 weeks. The presence or absence of HO around the patients hips we checked by a plane radiography and Brookers classification. Functional capabilities and motor impairment were checked by Functional Independent Measure (FIM), Barthel index and American Spinal Injury Association (ASIA) impairment class. Statistic analysis included Kolmogorov-Smirnov test, Shapiro-Wilk test, Mann Whitney Exact test, Exact Wilcoxon signed rank test and Fischer Exact test. Statistical significance was set up to $p < 0.05$. **Results.** At the end of the treatment no patient from the experimental group had HO. In the control group, five patients (33.3%) had HO. At the end of the treatment the majority of the patients from the experimental group (57.14%) moved from ASIA-A to ASIA-B class. **Conclusion.** Pulse low-intensity electromagnetic field therapy could help as prophylaxis of HO in patients with traumatic SCI.

Key words:
spinal cord, injuries; ossification, heterotopic;
electromagnetic fields; physical medicine.

Apstrakt

Uvod/Cilj. Heterotopska osifikacija (HO) glavna je komplikacija povrede glave i kičmene moždine (*spinal cord injury* – SCI). Terapija primenom pulsno elektromagnetnog polja niskog intenziteta (*pulse low-intensity electromagnetic field* – PLIMF) ubrzava protok krvi u zoni bola ili upale, dovodeći više kiseonika u tu zonu i pomažući u uklanjanju toksičnih materija. Cilj ove studije bio je da se odrede efekti primene PLIMF u prevenciji HO kod bolesnika sa SCI. **Metode.** U ovu prospektivnu randomiziranu kliničku studiju bilo je uključeno 29 bolesnika sa traumatskim SCI. Bolesnici su randomizirani u eksperimentalnu ($n = 14$) i kontrolnu ($n = 15$) grupu. Bolesnici iz eksperimentalne grupe, osim vežbi i terapije kretanjem, bili su podvrgnuti terapiji PLIMF indukcije 10 mT, frekvencije 25 Hz u trajanju od 30 min. Primena PLIMF počela je u sedmoj nedelji od povrede i trajala je četiri nedelje. Prisustvo ili odsustvo HO oko kukova bolesnika proveravano je radiografskim snimkom i Brookersovom klasifikacijom. Funkcionalne mogućnosti i oštećenje motorike proveravni su primenom *Functional Independent Measure* (FIM), *Barthel* indeks i klasom oštećenja prema *American Spinal Injury Association* (ASIA). Statistička analiza vršena je testovima *Kolmogorov-Smirnov*, *Shapiro-Wilk*, *Mann-Whitney Exact*, *Exact Wilcoxon Signed Rank* i *Fischer Exact*. Statistička značajnost bila je do vrednosti $p < 0,05$. **Rezultati.** Na kraju lečenja nijedan bolesnik iz eksperimentalne grupe nije imao HO. U kontrolnoj grupi pet bolesnika (33,3%) imalo je HO. Na kraju lečenja većina bolesnika eksperimentalne grupe (57,14%) prešla je iz klase ASIA-A u ASIA-B. **Zaključak.** Primena PLIMF pomaže u profilaksi HO kod bolesnika sa traumatskim SCI.

Ključne reči:
kičmena moždina, povrede; osifikacija, patološka;
elektromagnetna polja; medicina, fizikalna.

Introduction

Heterotopic ossification (HO) is an important complication of head and spinal cord injuries (SCI). Heterotopic ossification produces metaplastic formation of new bone in connective tissues and muscles surrounding joints^{1,2}. In patients with SCI, HO is usually found in muscles below the level of injury. In adult patients with SCI, the incidence of HO is approximately from 11 to 75%¹⁻⁵. The onset of HO, regardless of its origin, ranges from 4–12 weeks. A peak occurrence is at 2 months after the head trauma, SCI or specific insult⁶. The rehabilitation process of patients with SCI is disturbed by the presence of HO. Approximately one third of SCI patients develop restricted hip motion or ankylosis, more frequently in patients with cervical than thoracic and lumbar injuries³. Because of that, they need more time for a successful rehabilitation, which is also more expensive. Fiedler et al.⁸ found that \$ 2 million were spent because of medical complications in postacute stage of the 115 persons with SCI. Medicaments, range of motion (ROM) and exercise therapy and radiation therapy are used for prophylaxis of HO formation^{2,4,5,9,10}. The treatment of HO consists of ROM and exercise, medicaments, radiation therapy and surgery^{2,4,5,9,11}.

Magnets and electromagnetic fields have been used for a long time in clinical medicine. Electromagnetic fields can be static or pulse¹². It has been estimated that \$ 500 million is spent on magnetic devices annually in the United States and Canada¹³. Several brands of static magnets are currently available on the market: such as magnetic necklaces or magnetic insoles^{13,14}. A dosage of static magnets implies the strength of magnetic fields and length of the magnetic procedure. Electromagnetic fields therapy mostly means pulse low-intensity electromagnetic field (PLIMF) therapy^{12,15}. A dosage of PLIMF implies induction around the inductor, frequency of the field, length of the procedure and number of the procedures. Magnets appear to increase blood flow to an area of pain or inflammation, bringing more oxygen to the area and removing toxic substances. Magnets seem to affect positive and negative charges of sodium and potassium ions within the membranes around blood vessels and nerves and to relax small smooth muscle valves in the capillaries¹⁶. The results of the experimental investigations demonstrate possibilities of PLIMF in the treatment of damaged parts of the spinal cord¹⁷.

There are different opinions in the review literature about HO in patients with SCI. Beside the fact that in the classic rehabilitation textbooks HO is discussed as an important complication of SCI, this complication was not reported in some professional reports^{4,11,18-20}. In the large data review from the American National SCI Center, in patients who had injuries between 1973 and 1998, McKinley et al.²¹ did not find HO as long-term medical complication. Many authors consider a radiation therapy as indivisible part of HO prophylaxis^{4,5,9-11}. McKinley et al.²¹, however, explicitly claim that only biphosphonates may prevent tissue ossification. The role of physical therapy in the treatment of patients after SCI is still controversial. Functional electrical stimulation (FES) is used for motor skill improvement in a late stage of rehabilitation¹⁸. Triceps surae electrical stimulation re-

duces spasticity in the patients after SCI²². Exercise is the first line in prophylaxis or treatment of HO. Unfortunately exercise has little or no direct effect on blood volume or hemoglobin content²³. Investigators believe that ROM activity provided by physical therapy and occupational therapy can minimize the risk of joint ankylosis without promoting HO^{4,6,11}. On the other hand, there are authors who have experimentally established that forcible manipulation induced heterotopic bone formation⁵. Serial casting and dynamic splinting are used to maintain joint motion in the presence of HO²⁴. There is no evidence about efficiency of these treatments. Miller et al.²⁵ speak about good treatment effect of iontophoresis with dexamethasone in patients with myositis ossificans. In the available literature we have not found anything about the use and efficiency of magnetic fields in the prophylaxis of HO. Etiology of HO is not yet known. Decreased blood flow and changes in pH may be important¹. Taking into consideration a well proved influence of magnetic fields on blood flow, circulation and inflammation, we presume that magnetic fields could be useful in prophylaxis of HO^{12,15-17,26,27}. The aim of this study was to determine the effect of PLIMF as prophylaxis of HO in patients with traumatic SCI.

Methods

We performed a prospective random control clinical study. The patients were recruited from the Neurosurgery Clinic and Clinic for Physical Medicine and Rehabilitation, Military Medical Academy, Belgrade. To be eligible, they had to be between 18 and 45 years of age, have completeness or incompleteness traumatic SCI, have no HO in 2 months after SCI, have no other prominent complications in acute stage of rehabilitation, were not taking medications which influence HO, have no any contraindications for the treatment by the PLIMF^{5,12}. Patients were excluded if they had pressure ulcer or severe spasticity because of these conditions are positively related to the formation of HO⁴.

The study protocol consisted of determining demographic characteristics of patients, some biochemistry parameters (erythrocyte sedimentation rate – ESR, serum calcium – Ca, serum alkaline phosphatase – ALP), functional capabilities of patients defined by the Functional Independent Measure (FIM) and the Barthel index, neurological deficit defined by the American Spinal Injury Association (ASIA), and presence or absence of HO around patients hips toward Brookers classification^{2,5,7,28}. The study protocol was approved by the local ethic committee. All the patients gave the written consent before participating in the study.

The patients who met inclusion criteria were randomly divided into the experimental and control group. They started with ROM and exercise therapy in both groups as soon as they achieved their vital steady state. The patients in the experimental group, besides ROM and exercise therapy, were treated by PLIMF. This treatment started on the average in seventh week after the injury. The treatment by PLIMF lasted four weeks and was performed by the use of an apparatus “Magnemed MT-91, Electromedicina Nis”. This apparatus is solenoid, so a patient can comfortably lie

(Figure 1). A dosage of PLIMF implied: induction of 10 mT (miliTesla), frequency of 25 Hz and duration of 30 min. We performed this therapy five times a week. We checked the presence and grade or absence of HO at the start and the end of the treatment. The plain radiographies were read by the same radiologist. Functional capabilities of the patients were checked by the same physiotherapist at the start and the end of the treatment.

domized. One patient from the experimental group was withdrawn because of the lack of protocol compliance. A total of 29 patients participated in the study. The groups were homogeneous in terms of age and sex of the patients. The majority of the patients in the experimental group (50%) had cervical level of SCI; the majority of the patients in the control group (53.3%) had thoracic level of SCI (Table 1).



Fig. 1 – A patient during the treatment with pulse low-intensity electromagnetic field (PLIMF) (“Magnemed MT-91, Electromedicina Nis”)

Table 1

Characteristics of the patients			
Patients characteristics	Experimental group (n = 14) $\bar{x} \pm SD$	Control group (n = 15) $\bar{x} \pm SD$	<i>p</i>
Mean age (years), $\bar{x} \pm SD$	30.57 \pm 11.97	31.47 \pm 10.78	0.64*
Sex [n (%)]			
male	14 (100)	14 (93.3)	1.0 [†]
female	0 (0)	1 (6.67)	
Start of magnetotherapy (week), $\bar{x} \pm SD$	7.43 \pm 3.25		
Duration of magnetotherapy (week), $\bar{x} \pm SD$	4.21 \pm 0.58		
Level of spinal cord injury [n (%)]			
cervical	7 (50)	2 (13.3)	
thoracic	4 (28.5)	8 (53.3)	
lumbosacral	1 (7.14)	1 (6.60)	
cervical-thoracic	1 (7.14)	2 (13.3)	
thoracic-lumbosacral	1 (7.14)	2 (13.3)	

* Analysis conducted using Mann Whitney Exact Test

[†] Analysis conducted using Fischer Exact Test

Statistic analysis included Kolmogorov-Smirnov test, Shapiro-Wilk test, Mann Whitney Exact test, Exact Wilcoxon signed rank test and Fischer's Exact test. Statistical significance was set up to $p < 0.05$. The data was assessed by SPSS version 10.0 for Windows.

Results

A total of 33 patients were recruited by a rehabilitation specialist, neurosurgical specialist and physiotherapist. Out of them three refused to participate. Thirty patients were ran-

domized. There was no significant difference between the groups in terms of functional capabilities: at the end of the treatment, the patients of both groups achieved a significant functional improvement (Table 2).

There were significant differences between the groups in terms of ASIA impairment class. At the end of the treatment the majority of the patients from the experimental group (57.14%) moved from the ASIA-A to the ASIA-B class; at the end of the treatment the majority of the patients from the control group (60%) remained in the ASIA-A class (Table 3).

Table 2
Functional capability defined by the Functional Independent Measure (FIM) and the Bartel Index

Clinical test	Experimental group		Control group		p*
	start x̄ ± SD	end x̄ ± SD	start x̄ ± SD	end x̄ ± SD	
FIM	51.64 ± 11.71	78.07 ± 23.10	61.31 ± 20.84	78.54 ± 26.00	WEG = 0.001 WCG = 0.008 BGS = 0.16 BGE = 0.62
Bartel Index	17.14 ± 11.04	62.50 ± 29.66	28.46 ± 26.25	54.62 ± 28.54	WEG = 0.001 WCG = 0.008 BGS = 0.32 BGE = 0.63

* Mann Whitney Exact Test and Exact Wilcoxon Signed Rang Test; WEG – within experimental group; WCG – within control group; BGS – between groups at the start; BGE – between groups at the end

Table 3
American Spinal Injury Association (ASIA) impairment at the start and at the end of the treatment

ASIA class	Experimental group		Control group		p*
	start n (%)	end n (%)	start n (%)	end n (%)	
A	13 (92.87)	2 (14.29)	13 (86.67)	9 (60.00)	BGS = 1.0
B		8 (57.14)		1 (6.67)	
C	1 (7.14)	2 (14.29)	2 (13.33)	2 (13.33)	BGE = 0.01
D		1 (7.14)		1 (6.67)	
E		1 (7.14)		2 (13.33)	

* Fischer Exact Test. BGS – between the groups at the start; BGE - between groups at the end

There were significant differences between the groups in terms of the presence of HO at the end of the treatment. In the experimental group, no one had HO. In the control group, five patients (33.3%) had several grades of HO (Table 4). These HO were mostly in the Brooker classes I and II (Figure 2).

Discussion

This study showed that the patients with traumatic SCI, who were treated by PLIMF, had no HO at the end of the treatment. On the other hand, 33.33% of the patients who

Table 4
Heterotopic ossification at the end of the treatment

Grade	Experimental group (n = 14) n (%)	Control group (n = 15) n (%)	p*
0	14 (100)	10 (66.67)	0.04
1	0 (0)	2 (13.33)	
2	0 (0)	2 (13.33)	
3	0 (0)	1 (6.67)	
4	0 (0)	0 (0)	

*Fischer Exact Test. Abbreviations



Fig. 2 – A patient with Brooker class I/II

were not treated by the PLIMF had HO around their hips. Inflammation was significantly diminished by PLIMF treatment. The majority of patients who were treated by PLIMF moved into the better ASIA class. These results could be explained by the biological effect of magnetic field. Pathophysiology of HO is not clear. Important contributing factors include tissue hypoxia, hypercalcemia, and changes in sympathetic nerve activity, prolonged immobilization and mobilization after that, disequilibrium between parathyroid hormone and calcitonin. Metabolic and vascular changes resulting from autonomic nervous system alterations might play a major role in HO metaplasia. Eicosanoids (prostaglandins and leukotriens) are important factors in bone metabolism. Subcutaneous injection of prostaglandin E2 induces HO bone formation. An important step in the ossification process is fibroblastic metaplasia⁵. The membranous ossification usually predominates in the process of HO for-

mation⁴. Rehabilitation, in terms of ROM and exercise therapy, drug treatment and radiation therapy are considered the mainstay of HO prevention^{1,4,5}. However, all of these therapies have the notable side effects. An experimental investigation was demonstrated that forcible manipulation during ROM and exercise therapy can induce HO formation⁴. Nonsteroidal anti-inflammatory drugs (NSAIDs) have well-known side effects that most commonly affect the gastric, hepatic and renal systems. A treatment with bisphosphonate, etidronate disodium (EHDP), generally is a safe method of prevention and treatment of HO. But, there is a potential risk of bone fracture when it is used for prolonged periods. A "rebound ossification" secondary to prolonged osteoclast inhibition has also been postulated. Radiation therapy is rarely associated with malignancy. However, increased rates of trochanteric non-union with high dose fractionated radiotherapy in populations following total hip arthroplasty were found². Magnetic fields, like other physical procedures, have common and specific contraindications, but their side effects are minimal^{12,15}. Mild insomnia or some kind of psychological disturbances, were described mostly at the elderly¹².

The fact that we have not recorded any side effect during the magnetic field therapy, testifies that PLIMF is safe and useful physical procedure. Before creation of the study we had a few dilemmas regarding the biological effect of PLIMF. Namely, in Western medicine magnets are not considered as medical remedy¹⁶. In some well designed clinical studies the value of magnetic fields were not confirmed^{13,14}. In the absence of randomized, placebo control trials, the medical community is understandably skeptical regarding to acceptance of magnets as a valid option. We believed that PLIMF can help in prevention of HO formation, but, on the other hand, we were aware about the influence of PLIMF on the bone adhesion¹². Histologically, HO cannot be differentiated from calus formation of a healing fracture. Nevertheless, the results of this study confirmed our assumptions that PLIMF can help in prevention of HO formation in patients with traumatic SCI. Therefore, we chose high-dosage PLIMF. We suppose that the main reason for the prevention HO in this study was the effect of magnetic field on micro-circulation and cell membranes. Contributing factors in HO formation, a tissue hypoxia and sympathetic nerve activity, in the first place, were diminished or eliminated by PLIMF. Pulse low-intensity electromagnetic field promoted blood flow and red cell increase in the treated area. It is possible that the influence on the central nervous system and local effect on intra- and extracellular water were achieved. There is a theoretical possibility that magnetic fields could realign chromosomes⁵. This possibility could be important due to a link of some ligaments ossification with a genetic locus to the HLA region on the short arm of chromosome Gp⁵. A very important step in the ossification process is fibroblastic metaplasia. It is possible that PLIMF inhibited this process changing an arrangement of ions in the cell membranes¹². Phospholipids in cell membranes have both diamagnetic and paramagnetic properties. We explain significant reduction of

inflammation in the experimental group by the fact that magnetic field can increase the partial pressure of tissue oxygen and improve oxygen delivery to tissues. It is also known that magnetic field can raise the common adaptation capabilities of organism^{12,15,17,26,27}. In such a way, we can explain significantly higher number of patients in the experimental group who moved from A to B ASIA class at the end of the treatment.

We could not compare our results directly with those of other studies. Many authors researched HO in different conditions. Massive ectopic calcification of muscles is possible after the injury of femoral artery²⁹. Incidence of HO in some neurological diseases, such as Guillain-Barre Syndrome (41.6%), was higher than the incidence of HO after SCI toward the statements of some authors^{5,30}. However, our results confirm the statements of some authors that incidence of HO in patients with SCI are from 11 to 75%^{2,4}. Additionally, some authors compared different ways of prophylaxis of HO in several orthopedic conditions^{31,32}. The prophylaxis of HO could be incomplete in patients with internal fixation of an acetabular fracture. Contrary to our results, Schafer et al.⁹ have found that of 32 patients treated with indomethacin 14 had HO; of 36 patients treated with radiation therapy 13 had HO. In our group of patients treated with PLIMF no one had HO. We concluded that passing of a significant number of the patients in the experimental group from A to B ASIA class at the end of the treatment is important and can be related with PLIMF. This is in accordance with the results of Scivoleto et al.³³ who found that ASIA impairment designations had significant prognostic value. In subject with paraplegia proximal femoral bone mineral density (BMD) is lower than at able-bodied people. It is known that magnetic field can improve an energy cell balance and accelerate the basal metabolic rate (BMR)¹². It can be important for our study because of Yilmaz et al.³⁴ have found that BMR is closely associated with BMD. Magnets, as well as acupuncture, are a kind of complementary therapies used in rehabilitation¹⁶. Magnetic field, beside others, can act across the acupuncture points^{12,16}. This is relevant for our results as acupuncture diminishing a shoulder pain in the patient with SCI³⁵. Biochemical parameters in our study were similar to parameters of other authors. The fact that ALP was not significantly different between the groups at the start and the end of the treatment is in accordance with the opinion that elevated ALP has no value in predicting HO³. These results confirmed our assumptions that PLIMF can help in prophylaxis of HO after traumatic SCI. Regarding a record that treatment of HO by the combination of NSAIDs, radiation therapy and surgery have well-known side effect and serious limitations, the question is if PLIMF treatment of HO could be successful.

Limitations of this study come out of a relatively small sample size that may reduce interpretation of the same observations. We did not carry out the most accurate diagnostics. Ultrasonography, computed tomography (CT), or bone scintigraphy have an important role in the diagnosis of early unmineralised HO. Although plain radiography is highly specific in the diagnosis of HO, this method lacks sensitivity

in early diagnosis. Similarly, an increased ECR is an important mark of inflammation. But C-reactive protein (CRP) may also be elevated in acute HO⁴. We did not check serum creatine phosphokinase (CPK) as well, beside the fact that elevated CPK have value in predicting HO³. At the end, as mineralization and true bone formation are usually completed in 6–18 months after SCI, there is a need for further follow-up with intention to answer the question of the even-

tual remote effects of PLIMF on the HO in patients with traumatic SCI².

Conclusion

Pulse low-intensity electromagnetic field therapy can help as prophylaxis of HO in the patients with traumatic SCI.

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