



Turkish Journal of Geriatrics  
DOI: 10.31086/tjgeri.2018.62  
2018;21 (4):557-64

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Received: 27/08/2018  
Accepted: 19/11/2018

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#### RESEARCH

## EFFICACY OF PULSED ELECTROMAGNETIC FIELD THERAPY IN PATIENTS WITH LUMBAR SPINAL STENOSIS: A RANDOMISED CONTROLLED STUDY

### ABSTRACT

**Introduction:** Lumbar spinal stenosis is a disorder that may cause low back and/or leg pain. This study aimed to evaluate the efficacy of pulsed electromagnetic field therapy in lumbar spinal stenosis.

**Materials and method:** This study is single-blind randomised controlled study. Fifty patients diagnosed with lumbar spinal stenosis were randomised into two groups. Patients in the first group [median age 61 (51-84) years] underwent 10 sessions of active pulsed electromagnetic field therapy (25 Hz, 80 gauss) for 15 minutes a day, whereas those in the second group [median age 64 (55-77) years] were controls and underwent 10 sessions of placebo pulsed electromagnetic field therapy. The patients were assessed with VAS, the Timed Up and Go test, Oswestry Disability Index and EQ5D-VAS. All tests were completed at baseline, after treatment and at a 3-week follow-up.

**Results:** Forty-nine patients completed the study. The pulsed electromagnetic field therapy group significantly improved VAS score, Oswestry Disability Index and EQ5D-VAS ( $p<0.05$ ) after treatment. Significant improvement was sustained after 3-week follow up. In the placebo group, there was no significant change in VAS score, Oswestry Disability Index or EQ5D-VAS ( $p>0.05$ ) after treatment. Pulsed electromagnetic field therapy group showed significant improvement than placebo group in terms of pain severity, Oswestry Disability Index, EQ5D-VAS and Timed Up and Go after treatment and at follow-up ( $p<0.05$ ).

**Conclusion:** Pulsed electromagnetic field therapy appears to be useful in terms of back and/or leg pain, functional mobility, physical disability and general health-related quality of life in lumbar spinal stenosis patients.

**Keywords:** Spinal stenosis; Magnetic fields; Back pain; Quality of life

#### ARAŞTIRMA

## LOMBER SPİNAL STENOZLU HASTALARDA PULSE ELEKTROMANYETİK ALAN TERAPİSİNİN ETKİNLİĞİ: RANOMİZE KONTROLLÜ ÇALIŞMA

### Öz

**Giriş:** Lomber spinal stenoz bel ve/veya bacak ağrısına neden olabilen bir rahatsızlıktır. Bu çalışma lomber spinal stenozda pulse elektromanyetik alan terapisinin etkinliğini değerlendirmeyi amaçladı.

**Gereç ve Yöntem:** Bu çalışma tek kör randomize kontrollü bir çalışmadır. Lomber spinal stenoz tanısı konulan 50 hasta 2 gruba randomize edildi. 1. gruptaki hastalar [ortanca yaş 61 (51-84) yıl] 10 seans, günde 15 dakika pulse elektromanyetik alan terapisi (25 Hz, 80 gauss) aldı, 2. grup kontrol grubuydu [ortanca yaş 64 (55-77) yıl] ve 10 seans plasebo pulse elektromanyetik alan terapisi aldı. Hastalar VAS, Süreli Kalk ve Yürü testi, Oswestry Disabilite İndeksi ve EQ5D-VAS skalası ile değerlendirildi. Tüm değerlendirmeler başlangıçta, tedavi sonrası ve tedaviden 3 hafta sonra tamamlandı.

**Bulgular:** 49 hasta çalışmayı tamamladı. Pulse elektromanyetik alan terapisi grubunda tedavi sonrası VAS skoru, Oswestry Disabilite İndeksi'nde ve EQ5D-VAS anlamlı olarak iyileşmişti ( $p<0.05$ ). Anlamlı iyileşme tedaviden 3 hafta sonrada sürdürüldü. Kontrol grubunda tedavi sonrası VAS, Oswestry Disabilite İndeksi veya EQ5D-VAS'da anlamlı değişim olmadı ( $p>0.05$ ). Pulse elektromanyetik alan terapisi grubunda plasebo gruba göre ağrı şiddeti, Oswestry Disabilite İndeksi, EQ5D-VAS, Süreli Kalk ve Yürü testi tedavi sonrası ve kontrolde anlamlı gelişim gösterdi ( $p<0.05$ ).

**Sonuç:** Pulse elektromanyetik alan terapisi uygulaması lomber spinal stenozlu hastalarda bel/bacak ağrısı, fonksiyonel mobilite, fiziksel dizabilite ve genel yaşam kalitesi açısından yararlı olduğu ortaya çıkmıştır.

**Anahtar sözcükler:** Spinal stenoz; Manyetik alanlar; Bel ağrısı; Yaşam kalitesi

## INTRODUCTION

Lumbar spinal stenosis (LSS) is one of the major causes of back pain, ranging in incidence between 1.7%–8% (1). The diagnosis of LSS is usually made with history and clinical findings. Magnetic resonance imaging (MRI) provides information about the level and severity of stenosis (2). Although measuring spinal canal diameter is advantageous for diagnosis, the severity of symptoms is not necessarily always proportional to the canal diameter (2).

Due to the increase in the elderly population, diagnosis and treatment of LSS has become even more important today. In patients with mild to moderate symptoms, conservative treatment methods are preferred initially (3). Physiotherapy modalities are commonly used as non-pharmacological treatments are less likely to have systemic side effects (4). However, treatment of pain associated with spinal stenosis is challenging, and therefore, new treatment methods are needed.

Pulsed electromagnetic field therapy (PEMF) has been used and found to be useful in the treatment of pain due to different causes such as degenerative arthritis, lateral epicondylitis, and fibromyalgia (5-8). To our knowledge, there is no previous study on PEMF in cases with LSS. The magnetic field treatment created by passing a continuous current through a coil has analgesic and anti-inflammatory effects. Macrophage stimulation provides an anti-inflammatory effect by changing enzyme activation and pH. It creates an analgesic effect by depolarising the nociceptive C-fibres. Moreover, the high level of anti-inflammatory cytokines due to increased blood flow because of vasodilatation may also play a role in the analgesic effect (9). It is possible to avoid undesirable side effects, such as heating in pulsed magnetic fields created by conducting discrete electrical currents

through the coil (5). Different devices for magnetic field treatment have been developed for this purpose. The strongest magnetic fields are the spiral electrodes surrounding the body (10).

The aim of this study was to investigate the efficacy of PEMF in patients with back and/or leg pain associated with LSS.

## MATERIALS AND METHOD

This study is single-blind randomised controlled study. Fifty patients who were admitted to hospital outpatient clinic presenting with complaints of back and/or leg pain between 15 November, 2015 and 15 November, 2016 and diagnosed with LSS based on clinical findings and lumbar MRI were included in this study. A diagnosis of the clinical syndrome of LSS requires both the presence of characteristic symptoms (low back pain, neurogenic claudication, lower extremity pain, numbness) and signs and radiographic or anatomic confirmation of narrowing or stenosis (central canal<10mm, lateral recess<3mm) of the lumbar spinal canal (11).

The inclusion criteria were: Patients aged>50 years, having chronic back pain, capable of independent ambulation, absence of visual disturbances and hearing impairments, good mental and cognitive health, having central and/or lateral recess stenosis on spinal stenosis on MRI and not having a physical therapy programme in the last 3 months. The exclusion criteria were: back pain for<3 weeks, inconsistent clinic findings although the detection of LSS on MRI, presence of progressive neurological deficit, primary or metastatic spinal malignancy or history, infectious spondylodiscitis such as tuberculosis, brucellosis, inflammatory spondylitis, uncontrolled systemic disease, history of lumbar surgery, the presence of acute lumbar trauma, lower limb operation



or unhealed fracture, pregnancy, epilepsy and implanted medical devices, such as pacemaker, insulin pump or hepatic artery infusion pump.

The history of physiotherapy in the last year, walking distance, duration of low back pain, number of sessions, and the use of analgesics, braces and canes were noted. In MRI, the level of lumbar central stenosis of all patients was determined, and central canal and lateral recess diameters were measured. Central canal measured distance between middle of vertebral body and middle of basis processus spinosus at border of dural sac. Lateral recess measured distance between superior articular facet and the top part of the pedicle. Measures were recorded in millimetres (12). All patients were examined by the same physician, and all of them experienced an increased pain with back extension. Patients were randomly assigned to each group. The treatment group received PEMF for 15 minutes in each session. Patients in the placebo group were laid on PEMF table for 15 minutes, but did not receive treatment; they received magnetic field therapy for 2 weeks. Patients in both groups were trained in lumbar flexion exercises, and advised to do these exercises every day for 10 times, twice a day throughout the study. Patients in both groups were allowed to use paracetamol for pain if needed. Physical examination was performed in the patients in both groups before therapy, at the end of 10 sessions of therapy and 3 weeks after therapy.

Visual analogue scale (VAS: 0–10cm) was used to assess the severity of resting low back pain or leg pain with 0 (no pain) to 10 (worst pain ever). Timed Up and Go (TUG) test was used for functional mobility. The TUG uses the time that a person takes to rise from a standard 45 cm chair, walk 3 m, turn around, walk back to the chair, and sit down (13). Two trials performed and the faster of the two is recorded. The Oswestry Disability Index

(ODI; range 0-100) was used for physical disability. It is a self-administered questionnaire divided into ten sections designed to assess limitations of various activities of daily living. Each section is scored on a 0–5 scale, 5 representing the greatest disability. The index is calculated by dividing the summed score by the total possible score, which is then multiplied by 100 and expressed as a percentage (14). The overall quality of life was assessed using the EuroQol-5D VAS (EQ5D-VAS) index scale. EQ5D-VAS was presented as a vertical line, marked from 100 (best imaginable health state) to 0 (worst imaginable health state) in the centre of page. Respondents were asked to draw a line to the EQ5D-VAS to indicate how good or bad health state.

MAG-Expert with coil Ø 60 cm (Physiomed, Germany, AC input 230V/1-100Hz, intensity 1-100 gauss, input power 400VA) magnetotherapy unit was used for PEMF administration in the study. PEMF for a total of 10 sessions was administered to the lumbar region for two weeks, 15 minutes per day and five sessions per week.

Patients were treated at the same specific time each day. All applications were carried out by the same person during the therapy. Patients were laid in a comfortable supine position on the treatment table. Channel 1 was selected from the device touch screen, and the frequency was set manually to 25 Hz and intensity to 80 gauss.

Patients in both the PEMF and placebo groups received therapy (or sham) in the same manner for the same amount of time. Patients in the placebo group were placed in supine position into the solenoid coil. The written consents of all the patients enrolled in the study were obtained after they were informed of the study and relevant general information about their disease. This study was approved by the hospital ethics committee on 08.04.2016. (Number:2016-202)

### Statistical analysis

The mean, standard deviation, median lowest, highest, frequency and ratio values were used in the descriptive statistics of the data. The distribution of the variables was measured by the Kolmogorov-Smirnov test. Mann-Whitney U test and independent samples t test were used in the analysis of quantitative data. Chi-square test was used in the analysis of qualitative data. The SPSS

22.0 software package was used in the analyses, and a P value of <0.05 was considered statistically significant. Clinical parameter values (VAS, ODI, TUG, EQ5D-VAS) were assessed at baseline, posttherapy, and at the 3 weeks follow-up period in PEMF and placebo groups (Table 2). Posttherapy and control period clinical parameter values were compared to pretreatment (Table 3). Differences were calculated and the group comparison was made (Table 3).

**Table 1.** Demographic characteristics, duration of low back pain, walking distance and MRI findings related with LSS.

Characteristics		PEMF Group			Placebo Group			P
		Mean±sd	Median (min-max)		Mean±sd	Median(min-max)		
Age (years) §		61.6±8.6	61 (50-84)		64.6±5.0	64 (55-77)	0.061	
Sex (F/M)**		18/7			17/7		0.928	
BMI (kg/m <sup>2</sup> )*		28.2±4.1	28.3 (22-38)		29.2±3.9	29 (19-36)	0.327	
Profession**	Housewife	10			8		0.151	
	Retired	12			16			
	Working	3						
Walking Distance (m)*		1802±2110 (500-5000)	500 (100-)		1092±708	1000 (100-2000)	0.936	
Duration of low back pain* (Year)		4.9±3.1	5 (1-10)		7.3±1.9	7 (3-11)	0.003‡	
Level of stenosis	L1-2	2 (8%)			5 (20.8%)			
	L2-3	2 (8%)			12(50%)			
	L3-4	8 (32%)			3 (12.5%)			
	L4-5	7 (28%)			3 (12.5%)			
	L5-S1	6 (24%)			1 (4.5%)			
Central canal diameter (mm)*		8.9±0.6	9 (8-9.8)		8.8±0.6	9 (8-9.8)	0.847	
Lateral recess diameter (mm)*		2.5±0.2	2.5 (2.1-2.9)		2.4±0.3	2.5 (1.8-2.8)	0.245	

Abbreviations: BMI, body mass index; F, female; M, male; SD, Standard Deviation

\*Mann-Whitney U test \*\*Chi-square test § t test ‡P value of <0.05 statistically significant



**Table 2.** Change in Clinical parameters at the end of therapy and at 3 weeks of control period.

Characteristics		PEMF Group			Placebo Group			P
		Mean±sd	Median (min-max)		Mean±sd	Median (min-max)		
VAS*	Baseline	6.1±1.8	6 (3-9)		6.2±1.6	6 (3-8)	0.878	
	Posttherapy	4.5±2.5	4 (0-9)		6±1.6	6 (3-8)	0.024‡	
	Control	4.5±2.5	4 (0-9)		6±1.6	5 (3-8)	0.032‡	
ODI*	Baseline	46.2±17.2	44 (2-68)		47±17.5	45 (26-82)	0.857	
	Posttherapy	40.8±19.3	42 (0-68)		46.9±17.5	44 (24-82)	0.028‡	
	Control	39.5±19.4	36 (0-68)		46.3±17.4	45 (24-82)	0.018‡	
TUG*	Baseline	13.8±3.4	14 (8-21)		14.5±3.2	14 (10-21)	0.747	
	Posttherapy	13.1±3.6	13 (8-21)		14.6±3.2	14 (10-21)	0.141	
	Control	12.8±4.3	13 (7-21)		14.6±3.0	15 (10-21)	0.155	
EQ5D-VAS*	Baseline	57.4±14.7	60 (30-90)		52.7±15.9	55 (30-80)	0.280	
	Posttherapy	63.4±15.9	70 (30-95)		52.9±15.9	55 (30-80)	0.029‡	
	Control	64±16.3	70 (30-95)		52.9±15.9	55 (30-80)	0.023‡	

Abbreviations: VAS, visual analogue scale; ODI, oswestry disabilite indeks; TUG, timed up and go test;EQ5D-VAS, EuroQoL-5D visual analogue scale;SD,Standard Deviation \*Mann–Whitney U test ‡P value of<0.05 statistically significant

**Table 3.** Change in clinical parameters at the end of therapy and at 3 weeks of control period.

Change Compare to Baseline		PEMF Group			Placebo Group			P
		Mean±sd	Median (min-max)		Mean±sd	Median (min-max)		
VAS*	Posttherapy	-1.6±1.3	-2 (-4-0)		-0.2±0.4	0 (-1-0)	0.001‡	
	Control	-1.6±1.3	-2 (-4-0)		-0.5±0.8	0 (-2-0)	0.0004‡	
ODI*	Posttherapy	-5.4±8.4	-2 (-26- -6)		-0.1±1.4	0 (-2- -4)	0.011‡	
	Control	-6.8±7.8	-2 (-26-0)		-0.7±2.3	0 (-6- -5)	0.004‡	
TUG*	Posttherapy	-0.7±1.1	-0,4 (-2,5- +1,5)		0.1±0.8	0 (-1-+3)	0.001‡	
	Control	-1±2.1	-0,4 (-2,5- +1.3)		0.2±1.0	0 (-2-+3)	0.002‡	
EQ5D-VAS*	Posttherapy	6±7.6	5 (0- +30)		0.2±2.3	0 (-5- -10)	0.001‡	
	Control	6.6±8.1	5 (0- +30)		0.2±2.3	0 (-5- -10)	0.001‡	

Abbreviations: VAS, visual analogue scale; ODI, oswestry disabilite indeks; TUG, timed up and go test;EQ5D-VAS, EuroQoL-5D visual analogue scale; SD,Standard Deviation \* Mann–Whitney U test ‡P value of<0.05 statistically significant.

## RESULTS

Forty nine patients who were clinically diagnosed with LSS and confirmed by MRI completed this single-blind, prospective placebo randomised controlled study. One patient in the placebo group discontinued the treatment because of moving to another city. The demographic characteristics of the patient and walking distances are summarised in Table 1. There was no statistically significant difference between the age and gender distribution and body mass index (BMI) values of the treatment and placebo groups ( $p>0.05$ ). Antihypertensives were the most commonly used drug in both groups. 14 patients in the PEMF group (56%) and 17 in the placebo group (70.8%) were using antihypertensive drugs.

There was no statistically significant difference between the walking distances in PEMF and placebo groups ( $p>0.05$ ).

The spinal canal diameter measurements of patients in the PEMF and placebo groups are summarised in Table 1. In the PEMF group, the most frequent level of absolute central stenosis was L3-4 by 32%, whereas the most common level involved in the placebo group was L2-3 by 50%. There was no significant difference between the diameters of antero-posterior central canal and lateral recess in PEMF and placebo groups ( $p>0.05$ ). Mean duration of low back pain was shorter in the PEMF group than that in control ( $p<0.05$ ).

Pain intensity measured by VAS before therapy, ODI scores, duration of TUG test and EQ5D-VAS are summarised in Table 2. There was no significant difference between PEMF and placebo groups in terms of pretreatment VAS, ODI, EQ5D-VAS and TUG scores ( $p>0.05$ ). In the PEMF group, improvement in VAS, ODI, EQ5D-VAS and TUG values after treatment and after 3 weeks compared to the placebo group ( $p<0.05$ ). The improvement in VAS, ODI and EQ5D-VAS values after treatment and 3 weeks control in the PEMF group was significantly

better according to the baseline values ( $p<0.05$ ). In the placebo group, VAS, ODI, TUG and EQ5D-VAS scores did not show any change after treatment ( $p>0.05$ ). There was no significant difference in term of baseline TUG values between the groups ( $p>0.05$ ). However, the decrease in TUG values was significantly higher in PEMF group than that of controls' immediately after treatment and after 3 weeks later ( $p<0.05$ ).

## DISCUSSION

In this study, our treatment intervention (10 sessions of 15-minute PEMF) improved low back and leg pain, disability, functional mobility and general health condition in LSS patients, which was sustained even after 3 weeks. No significant improvements were noted in the placebo group.

Chronic pain is related to depression, disability and reduced quality of life (15). We believe that PEMF has positive effects on disability and quality of life parameters due to decreased back pain. In this study, there was significant relief in low back and leg pain after treatment in the PEMF group with LSS. The magnetic field affects cell membrane potential causing depolarisation in the nociceptive C-fibres, resulting in an analgesic effect (9). In a plethysmographic study, blood flow in the applied magnetic field region is increased by 45% and oxygenation is increased by 25%. Increased blood flow in the tissues creates an anti-inflammatory effect (16).

Khoromi et al., assessed the pain relieving efficacy of low intensity permanent magnets in a double-blind, randomized study in patients with lumbar radicular pain. They concluded that relative treatment effect of the 200 G magnets appeared to increase throughout the 5-week period and for this reason this type of therapy may be considered in patients with lumbar radicular pain (17).



In a randomised controlled study in patients with discogenic lomber radiculopathy by Omar et al., severity of low back pain was reduced with 3 weeks of PEMF (18), as well as improvements in hypoesthesia, achilles reflex, and straight leg raise tests.

In current study, there was a significant increase in functional mobility after treatment in the PEMF group compared to control. The increase in mobility was sustained after three weeks. In the placebo group, there was no change in mobility after treatment or after three weeks.

An important finding of this study was that the improvement in the physical disability measured by ODI in the PEMF group was significantly better after treatment and at 3 weeks of control. However, there was a significant decrease in physical disability after treatment in both PEMF and placebo groups, and was sustained for the 3-week post-treatment period. This suggests that PEMF treatment in patients with lumbar radiculopathy provides a significant improvement in the disability scores measured by modified ODI (18).

In our study, the improvement in health condition as measured by EQ5D-VAS after treatment in the PEMF group was significantly better than placebo. This situation also continued after the 3-week control period. There was an insignificant improvement in the placebo group after treatment and 3 weeks follow-up period.

Chao et al., suggested that cervical and lumbar radicular pain decreased by 53.6% and 50.8%, respectively, after one week of PEMF treatment. In the same study, the relief of pain was reported in 55% and 45.8% of patients with cervical and lumbar radiculopathy after 3 months of treatment, respectively (19). Also, in a randomised double-blind controlled study in patients with knee osteoarthritis by Bognatove et al., 12-hour therapy sessions of PEMF a significant improvement in the placebo group was reported

in terms of VAS and WOMAC values in the 12-hour therapy in PEMF group per day for 30 days. It was also reported that 26% of the patients in the PEMF group had discontinued the analgesic medication (20). In a study conducted by Harper et al., PEMF administered twice daily in patients with failed back surgery syndrome, reduced back and leg pain by 44% and 55%, respectively, by the third week of treatment. Those improvements in pain were maintained during 45 days of treatment. In the same study, analgesic use was decreased in 22 patients, and 50% of patients had a significant improvement in physical function (21). In a prospective, randomised controlled study by Nayback-Beebe et al., PEMF three times a week for a month reduced chronic low back pain in US army workers, and also significantly improved health-related quality of life immediately after treatment and one month post-treatment (22).

This study has some strengths and some limitations. One of the strength is being the first study to examine the effects of PEMF in LSS patients as our knowledge. The other strengths are its prospective design, radiographic assessments of all patients were carried out by the same physician, low experimental mortality in the PEMF group, and only one patient drop out in placebo the group. The limitation of this study was being single blind with a relatively short follow-up period. However, the duration of low back pain due to LSS was shorter in the PEMF group, all the patients had chronic low back pain more than a year.

In conclusion, there was a significant improvement in back and leg pain, functional mobility, disability and general state of health in patients with LSS compared with the placebo group. There is a need for additional studies to with varying numbers of sessions and different treatment durations.

#### **Conflict of interest**

None.

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