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Effect of Pulsed Electromagnetic Field Treatment on Alleviation of Lumbar Myalgia; A Single Center, Randomized, Double-blind, Sham-controlled Pilot Trial Study

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The aim of this study is to investigate the efficacy of pulsed electromagnetic field (PEMF) on the alleviation of lumbar myalgia. This is a randomized, real-sham, double blind pilot study. 38 patients were divided into the PEMF group and the Sham group, each of which was composed of 19 patients (1 patient dropped out in the Sham group) of randomized allocation. The PEMF group was treated by using the PEMF device and the Sham group by using a sham device on the lumbar muscle and acupuncture points, three times a week for a total of two weeks. Evaluations of Visual Analogue Scale for bothersomeness (VASB), Visual Analogue Scale for pain intensity (VASP), Oswestry Disability Index (ODI), 36-Item Short Form Health Survey Instrument (SF-36), EuroQol-5Dimension (EQ-5D), Beck's Depression Inventory (BDI) and Roland-Morris Disability Questionnaire (RMDQ), etc. before and 1 week after treatment were carried out. The primary outcome measure was the VASB, measured 1 week after the end of the pulsed electromagnetic therapy. VASB scores for the PEMF group changed by -2.06 ± 2.12 from the baseline, and that for the Sham group changed by -0.52 ± 0.82 ($p < 0.05$). VASP scores for the PEMF group were reduced by -2.10 ± 2.12 from the base line, and that for the Sham group was reduced by -0.53 ± 1.50 ($p < 0.05$). PEMF group showed significant improvements in all VASB, VASP, ODI, SF-36, EQ-5D, BDI and RMDQ scores, while the Sham group showed significant improvements in all scores, except the VASP score. However, the VASB, VASP and RMDQ scores of the PEMF group were much lower than those of the Sham group. The two groups showed no significant difference in ODI, SF-36, EQ-5D and BDI. This study demonstrates the effectiveness of PEMF treatment for alleviating lumbar myalgia.

Keywords : pulsed electromagnetic field, lumbar myalgia, VAS

1. Introduction

Lumbago refers to the pain in the lumbar area, the most common type of back pain [1]. It is reported that 70-80% of adults will complain of lumbago at some point in their lives [2]. And chronic lumbago is known to be one of the key factors that limit the activities of the population over the age of 45 [3].

Among these, myalgia refers to the symptoms of pain in the muscles. Clinically the state in which there is sharp pain in soft tissues other than joints with unknown cause without objective sign and abnormal test findings. Lumbago is classified into 4 types, namely, muscle tension, muscular spasm, muscle deficiency and myofascial pain syndrome according to cause of myalgia and its clinical characteristics [4]. Therefore, lumbar myalgia refers to the pain in the lumbar with the characteristics described above.

Among the diverse treatments for the pain, electrical treatment (electrotherapy) is used the most frequently. Electrotherapy is used to induce muscular contraction by stimulating motor nerves or to control pain by stimulating afferent nerve fibers with large diameters [5]. However, it has the disadvantages: it cannot be applied to the parts of

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the body where an electrode cannot be attached; can damage the skin or tissues because it requires the use of electrodes; and is inconvenient for patients, who have to take their clothes off for preliminary measures before the fixation of the electrodes. Pulsed electromagnetic field (PEMF) therapy depolarizes muscles by inducing eddy currents in tissues through a pulsed magnetic field [6]. It can be applied to areas where electrodes are difficult to attach. It has been applied to various diseases since the confirmation of its efficacy in treatment of bone fracture mal-unions [7, 8].

PEMF therapy is effective for bone fractures [7, 8], arthritis [9-11], fibromyalgia [12, 13], neuropathic pain [14], postoperative pain [15], musculoskelectal pain [16, 17] and multiple sclerosis [18]. But there are few clinical trials on lumbago [19, 20]. Therefore, this study carried out a comparative analysis of the indices related to the extent of discomfort and pain before and after treatment, daily life disabilities and depression. These indices were obtained from a placebo device comparison clinical test that applied pulsed electromagnetic therapy on lumbar myalgia.

2. Subjects and Methods

2.1. Subjects

The study was conducted on 38 patients between the ages of 18 to 65 recruited from the oriental medical center at the Sangji University Hospital as well as through internet advertisement from February to May 2011.

2.2. Methods

This study was designed a single center, randomized, patient-assessor blind, two arm, sham device-controlled, pilot trial study. The patients were divided into the PEMF group and the Sham device group by random allocation, each group having 19 patients. While both the patients and outcome-assessors were blindfolded, the PEMF group was treated using a PEMF device on acupuncture points and muscles to alleviate lumbar myalgia, and the Sham device group was treated on the same areas by using a sham device, 3 times a week for a period of 2 weeks for both groups (Fig. 1). Then the extent of discomfort and pain, the extent of disability in daily life due to lumbago, health status and depression were evaluated before treatment and 1 week after treatment. This trial was carried out with approval from the Institutional Review Board (IRB) in accordance with Declaration of Helsinki 2008 and the regulations of the Good Clinical Practice principle of the Korea Food and Drug Administration. Volunteers were allowed to participate in the clinical trial after providing voluntary agreement on an informed written consent form.

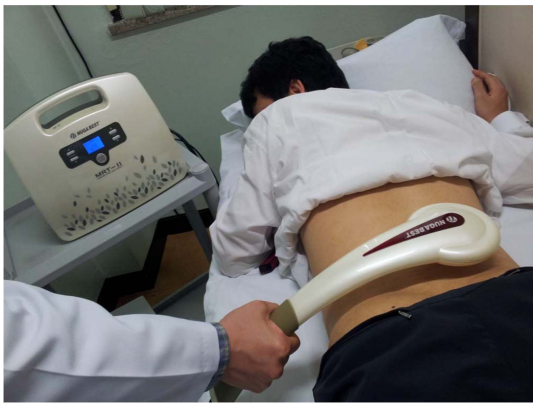

Fig. 1. (Color online) The application of PEMF (pulsed electromagnetic field device).

2.3. Criteria for inclusion, exclusion

Criteria for inclusion as a subject included male and female in the age range of 18 to 65 with lumbar myalgia that lasted for more than 3 months and with normal neurological condition. The subject had to have experienced discomfort of more than 10 cm visual analogue scale (VAS) 5 for 1 week prior to participation in the trial, to have consented not to be administered with any other treatment for the entire duration of the trial, to have voluntarily agreed to participate and to have signed an informed written consent form. Exclusion criteria included subjects as follows: those who have radicular pain, who are diagnosed with a specific disease which cause low back pain or myalgia, such as metastatic cancer, vertebral fracture, spinal infection, inflammatory spondylitis, chronic disease which could affect the result, such as cardiovascular disease, diabetic neuropathy, active hepatitis, fibromyalagia, rheumatic arthritis, dementia, haemorrhagic disease, epilepsy; who have had or would have spinal surgery; who have another skeletomucsular pain as the chief complaint; who have undergone acupuncture treatment or received pulsed electromagnetic therapy for low back pain or mylagia in the last one month; who are taking corticosteroid, narcotics, muscle relaxant, anticoagulant drug, herbal medicine for low back pain or other non-propal drugs; who have metallic artificial implants or pacemaker in the body; who is pregnant or plan to become pregnant; and who refuse the randomized allocation and the declaration of consent.

2.4. Randomization

Random numbers were allocated to the participants at their second visit. Random numbers were generated with

Fig. 2. (Color online) NUGA MRT-II (pulsed electromagnetic field device).

the SAS program with the four block size by a statistician and was tightly sealed up in double envelop to prevent the researchers from seeing them until the opening of the envelope. These random numbers were not seen until the end of the trial and analysis.

2.5. Intervention

The PEMF group was treated with NUGA MRT-II (NUGA MEDICAL, Wonju, Korea.) for a total of six times, 3 treatments per week for two weeks, with each treatment lasting 10 min, while the Sham group was treated with a sham device (Fig. 2). No other intervention was taken during the trial, and the treatment was administered by a medical specialist. The maximum strength of PEMF was 820 mT with pulse frequency of 8.56 kHz. The sham device with the same appearance and sound did not generate a magnetic field. Treating points included BL23, BL24, BL25, GV3, GV4, GV5 on the meridians of the governor vessel and bladder. These acupuncture points are located in the low back muscle and often used to treat lumbar myalgia [21].

2.6. Outcome measurements

2.6.1. Primary outcome

Visual Analogue Scale for discomfort from low back pain (VASB) [22, 23]

The changes of lumbar myalgia were evaluated by using 10 cm visual analogue scale with score of '0' (no discomfort) to the left end and score of '10' (extreme discomfort) to the right end.

VASB was measured at the baseline upon every visit to the hospital for 2 weeks and 3 weeks after (visit 8).

2.6.2. Secondary outcome

Visual Analogue Scale for pain intensity (VASP)

VASP was measured the same way as VASB's.

The Korean version of Oswestry Disability Index (ODI) [24, 25]

Disability in daily life due to lumbago was evaluated through an ODI questionnaire, made up of 10 items including extent of pain from lumbago, personal hygiene, lifting objects, walking, sitting, standing, sleeping, social life and travel. The subjects were directed to select one of the six choices given for each questions, with lower numbers indicating greater improvement in lumbago. Measurements were made at the time of the baseline, at the 6th treatment (Treatment 6) and 1 week after the conclusion of treatment (follow-up).

The Korean version of 36-Item Short Form Health Survey Instrument (SF-36) [26, 27]

Indices for evaluation of general health status and quality of life were assessed through a questionnaire survey composed of 36 questions with higher scores indicating better status of health. Measurements were made at the time of the baseline, at the 6th treatment (Treatment 6) and 1 week after the conclusion of the treatment (follow-up).

The Korean version of EuroQol-5 Dimension (EQ-5D) [28, 29]

Indices for evaluation of general health status and quality of life were assessed through a questionnaire survey composed of five questions on exercise ability, self-control, daily life activities, pain/discomfort and anxiety/depression, with lower scores indicating better health status. Measurements were made at the time of the baseline, at the 6th treatment (Treatment 6) and 1 week after the conclusion of treatment (follow-up).

The Korean version of Beck's Depression Inventory (BDI) [30]

Evaluation on depression, which is found frequently in chronic pain patients, was performed with BDI. A questionnaire survey is composed of 21 items. Lower scores signified better health status. Measurements were made at the time of the baseline, at the 6th treatment (Treatment 6) and 1 week after the conclusion of treatment (follow-up).

Roland-Morris Disability Questionnaire (RMDQ) [31]

A questionnaire survey is composed of 24 items was used to evaluate the extent of disabilities due to lumbago. Lower scores signified lower extent of disability. Measurements were made at the time of the baseline, at the 6th treatment (Treatment 6) and 1 week after the conclusion of treatment (follow-up).

2.7. Sample size

The sample size was estimated using the mean difference in VASB between the PEMF and Sham groups. We set the mean difference to 5 and the standard deviation of the VASB pooled from the two groups was 5. When a two-tailed test with a test power of 80% and significance level of 5% was applied [32], the number of subjects required for each group was 15 subjects. For a successful study, a total of 38 subjects, with a 20% dropout rate factored in, was required.

2.8. Blinding

Since it is not possible to blind-fold researchers who are administrating the treatment using a medical device, response bias and observation bias was maximally controlled through the design of the patient and outcome-assessor masking.

The administrator was only allowed to give treatment to the subjects and was instructed to minimize conversation with the subjects and not to share information on the treatment method or the assignment with other researchers. The outcome-assessor was not aware which treatment the subject received.

2.9. Statistical analysis

All data were analyzed by using SAS Version 9.13 at significance level of 0.05. Efficacy outcome measurement was analyzed with both ITT (intention to treat) and PP (per-protocol) analysis. Mean ± standard deviation (SD) or median value (1st quantile and 3rd quantile) were presented for demographic statistical characteristics (age and gender, etc.), and the quantitative data of the clinical characteristics of all the subjects were averaged depending on whether or not all variable data were normally distributed. Frequency and rate as n(%) were presented for the qualitative data. The homogeneity test between the PEMF group and the Sham group was examined. Two sample-test or Mann-Whitney U-test for the quantitative data and Chi-square test or Fisher's exact test for the qualitative data were performed for the differences in the demographic characteristics and outcome variables between the PEMF group and the Sham group.

3. Results

3.1. Participant flow and follow-up

All of the originally recruited 38 patients for the clinical test participated in the research without failure. All the selected subjects were randomly allocated to the Treatment Group and the Placebo device (sham device) group, with each group composed of 19 patients. One of the subjects in the Sham group did not receive treatment by refusal of the initial examination at the first visit following randomized allocation. The remaining subjects underwent their corresponding treatments without failure and had a follow-up after the conclusion of the treatment (Fig. 3).

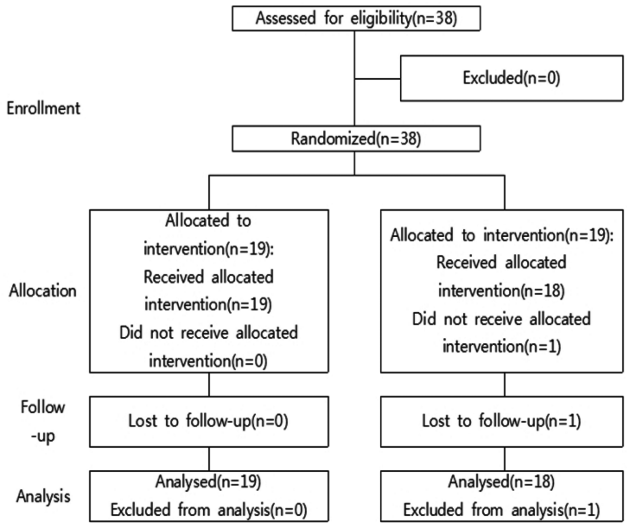

Fig. 3. Flow chart of subjects enrolled in the study.

3.2. Baseline Characteristics

At the time of the initial visit to the hospital, a basic demographics survey and physical examinations of the 38 patients in the age range of 18 to 65 were conducted. There was no significant difference between the PEMF group and Sham group at the baseline in terms of age, gender, height, weight, BMI, blood pressure, heart beat, PMS, administration of prescription drugs, VASB, VASP, ODI, SF-36, EQ-5D, BDI and RMDQ (Tables 1, 2, 3).

3.3. Efficacy Results

The PEMF group showed significant reduction in the VASB scores from that of the baseline after the 2nd treatment, while the Sham group showed significant reduction after the 3rd treatment. PEMF group showed significantly lower VASB scores after the 5th Treatment, 6th Treatment and at follow-up than the Sham group (Table 2, Fig. 4). In the follow-up, the PEMF group showed a change in the VASB scores of −2.06 ± 2.12 from that of the baseline while the Sham group showed −0.52 ± 0.82 (Table 3).

The PEMF group showed a significant reduction in the VASP scores from that of the baseline after the 3rd treatment, while the Sham group did not show any significant change throughout the entire period of treatment from that of the baseline. After the 5th treatment, the 6th treatment and in the follow-up, the PEMF group showed signifi-

Table 1. Summary of demographic variables of PEMF group and Sham group.

Variable	Total (N=38)	Sham group (n=19)	PEMF group (n=19)	p-value
Age, yrs	31.95±12.30	30.89±13.66	33.00±11.06	0.3191‡
Sex, male	11	7	4	0.2832
Job				
Office job	6	1	5	
Student	19	13	6	0.0560†
none	3	2	1	
Housewife	10	3	7	
Education				
graduate	6	3	3	
university	30	16	14	0.5776†
High school	2	0	2	
Height (cm)	163.73±7.81	164.99±8.19	162.47±7.42	0.6526‡
Weight (kg)	60.58±12.53	60.47±13.30	60.68±12.07	0.8732‡
BMI (Kg/m^2)	22.48±3.61	22.08±3.61	22.88±3.67	0.3067
SBP (mmHg)	117.32±9.45	116.21±9.62	118.42±9.39	0.2894‡
DBP (mmHg)	78.66±7.79	78.21±8.87	79.11±6.75	0.5051‡
Pulse (BPM)	76.26±5.91	74.89±5.23	77.63±6.37	0.1563
BT (^oC)	36.52±0.40	36.57±0.44	36.46±0.36	0.4360‡
PH, no	31	16	15	1.0000†
Alcohol, yes	17	10	7	0.3277
Smoking, yes	5	3	2	1.0000†
PMS				
Yes	13	6	7	
No	14	6	8	0.5541
Not Applicable	11	7	4	
Pregnancy				
Yes	0	0	0	
No	27	12	15	0.2832
Not Applicable	11	7	12	
PD, yes	6	4	2	0.6599†
NPD, yes	7	3	4	1.0000†

Data are Mean ± SD; P-value, compared with Sham group; †, Fisher's Exact Test; ‡, Mann-Whitney U-test; Continuous variables, Independent Two Samples T-test; Categorical variables, Chi-Square test; PEMF, pulsed electromagnetic field; BMI, body mass index; SBP: systolic pressure; DBP, diastolic blood pressure; BT, body temperature; PH, Past History; PMS, premenstrual syndrome; PD, prescription drugs; NPD, non prescription drugs

cantly lower VASP scores than the Sham group (Table 2, Fig. 5). In the follow-up, the PEMF group showed reduction in the VASP of -2.10 ± 2.12 from that of the base line, while the Sham group showed a reduction of -0.53 ± 1.50 (Table 3).

Although both the PEMF group and the Sham group showed significant reductions in the ODI scores and SF-36 scores from those of the baseline after the 6th treatment and during follow-up, there was no significant difference between the two groups (Table 4).

The PEMF group showed significant reduction in the EQ-5D scores from that of the baseline after the 6th treatment and during follow-up, while the Sham group showed significant reduction from that of the baseline only during the follow up period. There was no significant difference between the two groups (Table 4).

Although both the PEMF group and the Sham group showed significant reduction in BDI scores from that of the baseline only in the follow-up, there was no significant difference between the two groups (Table 4).

The PEMF group showed significant reduction in RMDQ score from that of the baseline after the 6th treatment and in follow-up, while the Sham group showed significant reduction only after the 6th treatment. PEMF group showed significantly lower RMDQ scores after the 5th treatment, the 6th treatment and during follow-up than the Sham group (Table 4).

3.4. Side-effects

There was no side effect in both groups throughout the clinical test.

4. Discussion

Randomized, double-blind and sham-controlled research that was carried out over a period of 3 weeks showed that PEMF treatment on lumbar myalgia had significant effect on the alleviation of pain.

Both the PEMF group and the Sham group showed significant improvements in the outcome measurements following the treatments or during follow-up.

PEMF group showed significant improvements in all the measured scores. Although ODI, SF-36, EQ-5D and BDI scores of both groups showed significant improvements prior to and following the treatments, there was no significant difference between the PEMF group and the Sham group. This is due to the fact that both groups had relatively intermediate level of pain with average VASB and VASP values of 6, which illustrates that both groups did not have severe daily life disabilities, adverse quality of life and degree of depression prior to the treatments. For these reasons, we assumed that there was no significant difference between the two groups following the treatment. In addition, there were some expected effects of the placebo device.

Since the finding in 1965 that bone formation is promoted through the reaction of osteoblast under an electromagnetic field [33], pulsed electromagnetic therapy has been applied mainly for the treatment of bone fractures, including nonunion, malunion and delayed union [7, 8],

Table 2. Changes of VASB and VASP at baseline, treatment and follow-up.

	Baseline	After 1st Treatment	After 2nd Treatment	After 3rd Treatment	After 4th Treatment	After 5th Treatment	After 6th Treatment	Follow-up
VASB								
PEMF	6.61±1.36	6.46±1.56	6.10±1.54*	5.84±1.68**	5.33±1.21***	5.14±1.22***	4.48±1.58***	4.54±2.15***
Sham	6.38±1.01	6.22±0.89	6.20±0.56	6.08±0.66*	5.73±0.98***	6.07±0.80	5.84±1.61	5.93±0.97*
p-value	0.8155‡	0.5655	0.7929	0.5587	0.4974‡	0.0103	0.0034‡	0.0172
VASP								
PEMF	6.63±1.54	6.39±1.58	6.18±1.59	5.79±1.65***	5.38±1.31***	5.06±1.18***	4.32±1.54***	4.53±2.29***
Sham	6.74±1.19	6.93±1.42	6.71±1.34	6.64±1.35	6.08±1.82	6.56±1.24	6.21±1.91	6.29±1.33
p-value	0.7605‡	0.4167‡	0.2853	0.1409‡	0.1902	0.0016‡	0.0007‡	0.0072

Data are mean ± SD; P-value, compared with Sham group; *p < 0.05 (compared with Baseline); **p < 0.01 (compared with Baseline); ***p < 0.001 (compared with Baseline); †, Fisher's Exact Test; ‡, Mann-Whitney U-test; PEMF, pulsed electromagnetic field; VASB, Visual Analogue Scale for bothersomeness; VASP, Visual Analogue Scale for pain

Table 3. Differences of VASB, VASP, ODI, SF-36, EQ-5D, BDI, RMDQ score between baseline and follow-up.

	PEMF Group (n=19)	Sham Group (n=18)	p-value
VASB	−2.06±2.12	−0.52±0.82	0.007**
VASP	−2.10±2.12	−0.53±1.50	0.015*
ODI	−13.37±10.13	−13.83±8.47	0.881
SF-36	12.21±18.0	14.39±11.78	0.668
EQ-5D	−1.42±1.53	−1.17±1.50	0.615
BDI	−2.74±5.14	−2.44±4.10	0.850
RMDQ	−3.74±2.66	−0.83±2.61	0.002**

Data are mean ± SD; p-value, compared with Sham group; *p < 0.05; **p < 0.01; PEMF, pulsed electromagnetic field; VASB, Visual Analogue Scale for bothersomeness; VASP, Visual Analogue Scale for pain; ODI, Oswestry Disability Index; SF-36, 36-Item Short Form Health Survey Instrument; EQ-5D, EuroQol-5Dimension; BDI, Beck's Depression Inventory; RMDQ, Roland-Morris Disability Questionnaire

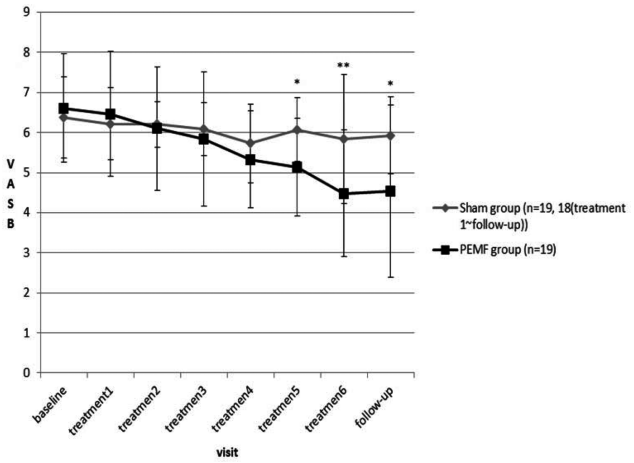

Fig. 4. Change of VASB for PEMF group and Sham group. *p < 0.05 (compared to Sham group); **p < 0.01 (compared to Sham group); PEMF, pulsed electromagnetic field; VASB, Visual Analogue Scale for bothersomeness.

Table 4. Changes of outcome parameters at baseline, after treatment and follow-up.

	Baseline	After 6th treatment	Follow-up
ODI			
PEMF	27.84±11.22	17.79±9.86***	14.47±12.39***
Sham	28.95±9.42	16.89±8.82***	16.06±8.79***
P-value	0.7442	0.7718	0.3744‡
SF-36			
PEMF	114.26±19.92	123.21±17.64*	126.47±20.96**
Sham	114.74±16.85	123.50±17.31**	127.72±17.07***
P-value	0.9374	0.9601	0.9158‡
EQ-5D			
PEMF	8.37±1.74	7.16±1.95**	6.95±2.04***
Sham	7.89±1.52	7.39±1.50	6.89±1.32**
P-value	0.3777	0.5647‡	0.7576‡
BDI			
PEMF	8.26±5.99	6.00±4.75	5.53±4.98*
Sham	8.11±5.31	7.33±5.03	6±5.03*
P-value	0.9304‡	0.4125	0.7505‡
RMDQ			
PEMF	7.21±3.58	3.42±3.53***	3.47±4.18***
Sham	5.84±3.37	5.33±2.79*	5.33±2.91
P-value	0.2532‡	0.0305‡	0.0368‡

Data are mean ± SD; P-value, compared with Sham group; *p < 0.05 (compared with Baseline); **p < 0.01 (compared with Baseline); ***p < 0.001 (compared with Baseline), †, Fisher's Exact Test; ‡, Mann-Whitney U-test; PEMF, pulsed electromagnetic field; VASB, Visual Analogue Scale for bothersomeness; VASP, Visual Analogue Scale for pain; ODI, Oswestry Disability Index; SF-36, 36-Item Short Form Health Survey Instrument; EQ-5D, EuroQol-5Dimension; BDI, Beck's Depression Inventory; RMDQ, Roland-Morris Disability Questionnaire

etc. Since approval by the US FDA, it has been applied to diverse treatments. Recent clinical researches on pain have mainly focused on knee osteoarthritis [9-11], fibromyalgia [13], diabetic neuropathic pain [14] and posto-

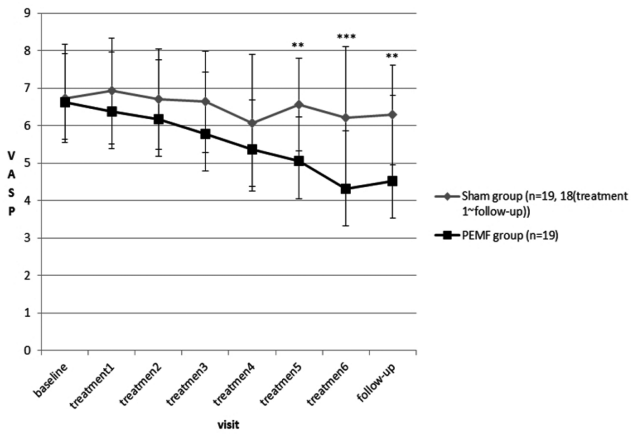

Fig. 5. Change of VASP for PEMF group and Sham group. **p < 0.01 (compared to Sham group); ***p < 0.001 (compared to Sham group); PEMF, pulsed electromagnetic field; VASP, Visual Analogue Scale for pain.

perative pain [15], rheumatoid arthritis [12] and multiple sclerosis [18] etc.

The principle of pulsated extracorporeal pulsed electromagnetic therapy is the induction of eddy currents in the body if portion of the body is within the range of formation of the magnetic field. The eddy currents will depolarize the nerve axon that is transmitted to the proximal and distal areas, thereby secreting a neurotransmitter (acetylcholine) to the motor end plate to cause the contraction of controlling muscles [34]. This therapy can be applied to areas of the body where an electrode is difficult to attach and can stimulate body tissues or nerves without contact with the skin.

In a research on pulsed electromagnetic therapy related to pain, 42 patients who received the PEMF treatment prior to surgery among 62 patients of spine fusion for discogenic low back pain showed higher success rate of union than the 19 patients who did not receive PEMF treatment [35]. In a clinical trial, the headset type of PEMF applied had significant effect on patients with chronic fibromyalgia [36].

In a pilot study on chronic back pain, when therapeutic electromagnetic fields (TEMF) and sham treatments were given for a period of 6 weeks, TEMF treatment significantly reduced the pain in comparison to the sham treatment [37].

Pulsating electromagnetic field treatment showed significant efficacy on cervicogenic headache [38], and pulsating preliminary pulsed electromagnetic therapy was effective on chronic lumbago patients [20].

In a comparative research of patients with facial sharp pain syndrome complaining of pain in the shoulder and lumbar area [39], the group that received the pulsed electromagnetic therapy showed significant improvement in the VAS and press threshold in comparison to the control group.

In contrast, pulse electromagnetic therapy and placebo device showed no significant difference in the alleviation of pain after acute pain was induced with saline in 10 volunteers [40]. In addition, flexible magnets were not effective in decreasing pain perception and recovery time after muscle micro injury [41], and pulsed electromagnetic therapy using a bipolar permanent magnet had no significant effect on chronic lumbago [42].

The effect of pulsed electromagnetic therapy on the reduction of pain still remains controversial. Therefore, there is a need for researches through numerous clinical tests.

This study examined the effect of pulsed electromagnetic therapy applied to lumbago. A clinical trial in a preliminary clinical research to examine the treatment effect of an extracorporeal pulsed electromagnetic therapy device on the alleviation of lumbar myalgia was carried out using randomization, patient/outcome-assessor blind-folding and placebo - device Sham group.

38 patients who participated in this trial were randomly allocated to the PEMF group and the Sham group, each of which had 19 patients, The PEMF group was treated with the PEMF device six times, three treatments per week for two weeks, with each treatment lasting 10 min while the Sham group was treated with a sham device. One of the patients in the Sham group was not treated after the patient refused treatment in the initial examination at the first visit to the hospital following the randomized allocation into groups. All the remaining subjects were given their respective treatments and followed up after the conclusion of the treatment.

There was no significant difference between the two groups in the demographic information and in the physical examination given prior to the clinical trial, including age, gender, height, weight, blood pressure, BMI, pulse, body temperature, drinking and smoking status. In addition, there was no significant difference between the two groups in terms of the values of VASB, VASP, ODI, SF-36, EQ-5D, BDI and RMDQ prior to the treatments. Thus, the extent of pain and disability and the quality of life due to lumbar myalgia and the physical characteristics of the subjects in the PEMF group and the Sham group were relatively similar.

Visual analogue scale (VAS) was used as the primary outcome measure for the alleviation of pain. This index was chosen because of its high level of relevance with functional disability and other evaluation indices, and its

wide use in numerous clinical trials related to pulsed electromagnetic therapy. Subjects indicated the extent of discomfort (VASB) and the strength of the pain (VASP) at the first visit and at every following visit to the hospital, and one week after the conclusion of the treatment.

VASB tended to decrease with increasing number of visits to the hospital for treatment for both the PEMF group and the Sham group. However, VASB score of the PEMF group significantly decreased more than the Sham group. The Sham group also showed less discomfort from the lumbago, presumably from the anticipatory effect of the placebo device. However, the discomfort level of the PEMF group was much lower than that of the Sham group.

Both groups showed significant improvements in ODI, SF-36, EQ-5D, BDI and RMDQ prior to and following treatment, and no significant difference between the PEMF group and the Sham group with the exception of RMDQ. This is due to the fact that both groups had a relatively intermediate level of pain with average VASB and VASP values of 6, which illustrated that both groups did not have severe daily life disabilities, adverse quality of life and degree of depression prior to the treatment. For these reasons, it is assumed that there was no significant difference between the two groups following the treatment. In addition, there were some expected effects of the placebo device.

Neither group showed abnormal reaction throughout the clinical trial. Although PEMF s safe, it safety needs to be researched further for use in long term treatment, since the six treatments over a period of two weeks is very short.

However, its efficacy on lumbar myalgia cannot be confirmed based on this preliminary clinical research. Additional researches and clinical trial study are needed. In addition, this study has limitations in that it did not present the effective frequency and the exposure mode and time for the pain. Rigorous research on the variation of frequency, continuous stimulation or discontinuous stimulation, and duration of exposure should also be carried out in the future.

5. Conclusion

38 patients were divided into the PEMF group and the Sham group, each of which was composed of 19 patients (1 patient dropped out of the Sham group) after randomized allocation.

The PEMF group was treated by using a PEMF device and the Sham group by using a sham device 3 times a week for a total of 2 weeks on the lumbar muscle and acupuncture points. We compared the change of VASB, VASP, ODI, SF-36, EQ-5D, BDI and RMDQ before and 1 week after treatment.

There was a significant lowering of VASB and VASP in the PEMF group in comparison to the Sham group. There was no significant difference between the PEMF group and the Sham group in ODI, SF-36, EQ-5D, BDI and RMDQ.

We suggest that PEMF treatment can be effective on lumbar myalgia. More clinical trials studies are needed.

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