

A Randomized Control Trial of the Effectiveness of Magnetotherapy with Conventional Exercise on Pain, Functions and Lumbar Range of Motion of Persons with Non-specific Low Back Pain

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Abstract

Background: Non-specific low back pain is defined as low back pain not attributable to a known cause. Magnetotherapy is an alternative physical agent providing beneficial effects by its ability to penetrate deeply in the tissue in repair process as the patient's whole body was immersed on a magnetic field.

Objectives: To determine the effect of magnetotherapy and conventional exercise on the improvement of pain, Lumbar range of motions and functions in the persons with non-specific low back pain

Method: 60 subjects were randomly divided into 2 groups. group A, received Magnetotherapy and conventional exercise and group 2 received Sham magnetic field with conventional exercise. Pain, Lumbar range of motion and Modified Oswestry disability Index were evaluated at baseline and after 3rd week.

Results: There was significant difference found in within group comparison and there was no significant difference found in between group analysis of pain, lumbar range of motion and Modified disability index

Conclusion: The magnetotherapy with the dose of 31mT/10% intensity and 55.55 Hz frequency for 30 minutes have not additional beneficial effect on reduction of pain, lumbar range of motion and functions of the patients with non- specific low back pain.

Keywords: Magnetotherapy, Nonspecific low back pain.

1.INTRODUCTION

Spinal stability is described in three subsystems: passive (inert structure / bones and ligaments) Active(muscles) and neural control. Instability of the spinal segment is often a combination of tissue damage, insufficient muscular strength or endurance and poor neuromuscular control. ⁽¹⁾

The lumbar region is capable of movement in flexion, extension, lateral flexion and rotation. The amount of flexion varies at each interspace of the lumbar vertebrae, but most of the flexion takes place at the lumbosacral joint. Lateral flexion and rotation are most free in the upper lumbar region and progressively diminished in the lower lumbar region. ⁽²⁾

low back pain is the leading contributor to years lived with disability. ⁽³⁾ Non-specific low back pain is defined as low back pain not attributable to a known cause. ⁽⁴⁾ And represents 90 to 95% of the cases of LBP. ⁽⁵⁾ and 85% of back pain is associated with myofascial pain syndrome (MPS). ⁽⁶⁾

Low back pain (LBP) is a common condition that affects most people at some point in their lives, with up to an 84% lifetime prevalence. ⁽⁷⁾ The prevalence depends on factors such as sex, age, educational level and occupation. ⁽⁸⁾ Low back pain was more common in females than males' individuals and those aged 40-69 years than in other age groups and prevalence was greater in high income (30.3%) countries than middle income (21.4%) or low income (18.2%) countries ⁽⁹⁾⁽¹⁰⁾

Non-specific low back pain may be classified by duration as acute (Pain lasting less than 6 weeks), Sub-chronic (6-12 weeks) or chronic (more than 12 weeks). The condition may be further classified by the underlying cause as either mechanical, non-mechanical or referred pain. Acute low back pain can be triggered by physical factors (e.g., Lifting awkwardly) or psychosocial factor (e.g., Being fatigue or tired) or by a combination of the two (e.g., Being distracted while lifting). New episodes are more likely to begin early in the morning. ⁽¹¹⁾

Magnetotherapy is a treatment that is based on the application of continuous electromagnetic fields that stimulate the cells of our body. it restores the correct electrical potential, both intracellular and extracellular, that has been lost due to injury, trauma or illness. ⁽¹²⁾ some natural materials possess magnetic properties that might be used for the healing of specific health problems in different parts of the world.

Magnetotherapy began in Japan immediately after World War II by introducing both magnetic and electromagnetic fields (EMFs) in clinical practice. There is a large body of basic science and clinical evidence that time-varying magnetic fields can modulate molecular, cellular and tissue functions in a physiologically and clinically significant manner. ⁽¹³⁾

During nearly seven decades of development of contemporary magnetotherapy more than a million patients have been treated worldwide for pain, many musculoskeletal injuries, postsurgical and traumatic wounds. Magnetic/ electromagnetic stimulation was proven to enhance such fundamental properties as nerve repair and regeneration, as well as immune and endocrine functions. There are three general types of magneto therapeutic devices: (a) solenoid, (b) two coils and (c) flat mattress. In the solenoid approach the limb or part of the torso inserted into EMF generating system. The two-coil approach is based of placing two coils on both sides of the limb. This provides conditions for creation of homogenous EMF secured by both coils. The flat mattress is mostly used in home settings and for wellness purposes. ⁽¹³⁾

Magnetotherapy includes at least seven groups of EMFs, developed and utilized in different countries of the world during the last 50 years ⁽¹⁷⁾; (a) Static/permanent magnetic fields created by various permanent magnets as well as by passing direct current (DC) through a coil.(b)Low-frequency sine wave EMFs mostly utilize 60 Hz (in the USA and Canada) and 50 Hz (in Europe and Asia) frequency in distribution lines.(c)Pulsed Electromagnetic field (PEMF) are usually low-frequency fields with various specific shapes and amplitudes.(d)PRF utilizes the selected frequencies in the radiofrequency range: 13.56, 27.12, and 40.68MHz.(e) Transcranial magnetic/electric stimulation is a method of treatment of selected areas of the brain with short but intensive magnetic pulses.(f)Millimeter waves have a very high-frequency range of 30–100 GHz. In the last 10 years this modality has been used for treatment of a number of diseases. (g)Ultrashort pulses were developed and investigated in the recent decade. ⁽¹⁴⁾

Electromagnetic field help in wound healing, bone unification, in reducing pain, edema and inflammation, in increasing blood circulation; in stimulation of immune and endocrine systems. Since cells involved in tissue repair are electrically charged, some endogenous EMF signals may facilitate cellular migration to the injured area, thereby restoring normal electrostatic and metabolic conditions. ⁽¹⁵⁾ Magnetotherapy has very few contraindications like pregnancy, pacemaker, metal plates in the body, tuberculosis, neurological or infectious disease, some type of cancer and coronary problems. ⁽¹²⁾ The purpose of the study is to determine the effect of magnetotherapy and conventional exercise on the improvement of pain, Lumbar range of motions and functions in the persons with non-specific low back pain. To determine if the specific magnetotherapy with conventional therapy will be capable to effect on persons with non-specific low back pain by decreasing the pain and improving the functions and improvement in the lumbar range of motion. Previous studies have shown that electromagnetic field therapy can be useful tool when used to facilitate the healing of skin ulcer, manage diabetic neuropathic pain, and facilitate functional improvement in patients with fibromyalgia. Electromagnetic field has been shown to significantly reduced pain in patients suffering from a number of conditions like carpal tunnel syndrome, shoulder impingement syndrome, rotator cuff pathology, osteoarthritis of knee, cervical radiculopathy, lower back pain. However, the effect of magnetotherapy in patients with non-specific low back pain is controversial as there is no fix dose of magnetotherapy for treatment. As we are using the BTL magnetotherapy machine with inbuilt program for low back pain treatment but right now we have not that much amount of literature for the effect of magnetotherapy and also lack of evidence related this BTL magnetotherapy machine program effect on conditions. Due to lack of evidence we are not clear about the effect of magnetotherapy on non-specific low back pain. To Determining the effectiveness of inbuilt dose of BTL magnetotherapy device as a treatment for nonspecific low back pain can significantly improve the management of nonspecific LBP patients.

2. MATERIALS AND METHOD

In this double blind, randomized placebo-control study, volunteer patients between 18 to 70 years of age who had non specific low back pain were included. Before the study, approval was obtained from the Ethics committee of Guru Govindsingh government hospital, Jamnagar. After the approval was given by the ethical committee (Ref. No. IEC/Certi/154/09/2018). 90 subjects were assessed based on the eligibility criteria of the study. Based on that criteria, those who were not matched they were excluded from the study. All subjects were asked to read patient information and proper explanation regarding purpose and procedure of the study were given in vernacular language. All the recruited subjects signed an informed consent form before participating. The detailed anamnesis of the patients was obtained, and their demographic characteristic were recorded. Numerical pain rating scale (NPRS), Lumbar range of motions and Modified Oswestry low back pain analyses were determined. Testing environment was quite with well-ventilated and natural lighted room and absence of outside noises. 70 subjects who met the eligibility criteria were randomly allocated to either Magnetotherapy group or Sham magnetotherapy group. Randomization was applied by the simple random method. Group 1 received therapy consisting Magnetotherapy and Conventional exercise and Group B received a sham Magnetotherapy with conventional exercise. The patient did not know what treatment they were receiving. The treatment was applied by the one physician and evaluation of the patient was performed by another physician who did not know the which groups patients were in.

The treatment was given in the well-ventilated room. After all the completion of demographic data and pre-examination patient were asked to lying prone on the magnetotherapy mat. All the contraindications were check and any other metallic or radioactive things were placed away from the treatment table. Treatment area were open and cylindrical solenoid coil was placed over it. The power cable was on and machine was start. The pre decided program was set and treatment stated for 30 min. The same technique and program were used for group B, but intensity was changed to 1% for 30 minutes.

Table 1: Treatment protocol used of BTL Magnetotherapy machine

PROTOCOL	
NAME	VERTEBRO ALGIC SYNDROME
CURRENT	SERIES OF MAGNETIC PULSE
SHAPE OF PULSE	RECTANGULAR PROTRACTED
INTENSITY	31 mT/10 %
FREQUENCY	55.55 Hz
TIME	30 MINUTES



Figure 1: Treatment of Magnetotherapy

The conventional exercise were isometric abdominals, isometric back extensors, curl ups, single knee to chest, double knee to chest, prone on elbow/hand and hot pack given to both the groups.

3. RESULTS AND DISCUSSION

Table 2: Shapiro-wilk normality test result at 95% confidence interval.

SR. NO.	VARIABLES	p value	Normality
1	Numerical pain rating scale	0.002	Normality rejected
2	Lumbar flexion	0.000	Normality rejected
3	Lumbar extension	0.000	Normality rejected
4	Right side bending	0.010	Normality rejected
5	Left side bending	0.020	Normality rejected
6	Oswestry disability index	0.146	Normality Accepted

Table 3: Within group and between group comparison

VARIABLES	WITH IN GROUP COMPARISON					BETWEEN GROUP COMPARISON	
	GROUP A (MEAN± SD)		P VALUE	GROUP B (MEAN± SD)		P VALUE	P VALUE
	PRE	POST		PRE	POST		
NPRS	7.10±1.95	3.17±2.67	0.000	6.80±1.78	3.07±2.30	0.000	0.976
Lumbar Flexion ROM	5.06±1.38	5.78±1.37	0.000	5.38±1.42	6.43±1.49	0.000	0.080
Lumbar Extension ROM	1.33±0.44	1.45±0.46	0.020	2.10±0.90	2.46±0.98	0.001	0.000
Lumbar Right-side bending	18.25±3.13	19.48±3.34	0.000	18.86±2.64	20.83±2.71	0.000	0.104
Lumbar Left-side bending	18.25±3.10	19.38±3.22	0.000	18.90±2.56	20.80±2.71	0.000	0.080
MODI	39.53±14.21	17.50±14.62	0.000	40.30±17.90	23.66±17.41	0.000	0.143

Interpretation: p Value >0.05 suggestive of no significant difference found and p Value <0.05 suggestive of significant difference found.

The intent of the study was to find out the effect of Magnetotherapy on pain, lumbar range of motion and functions of the patients with non-specific low back pain. The result of this study suggests that there is significant improvement in both the groups. There was no significance difference between the groups except in lumbar extension. In lumbar extension range, there were significance difference between the groups. In the present study total 60 subjects were taken and they were divided in to two groups. Group A (Magnetotherapy plus conventional exercise and group B (sham Magnetotherapy plus conventional exercise). Pain was assessed by the NPRS scale, lumbar range was assessed by the modified modifies Schober test and functional status was assessed by the Modified Oswestry disability index.

The result of the present study shows Mean difference of NPRS in group A is 3.93±2.01 and p value is 0.000(p<0.05) and in group B is 3.73±2.57 and p value is 0.000(p<0.05). So, there is significant reduction of pain within both the groups but there is not statistically significance difference between the groups as the p value is 0.97(p>0.05). Mean difference of lumbar flexion in group A is 0.717±0.63 and p value is

0.000($p < 0.05$). In group B mean difference is 1.05 ± 1.24 and p value is 0.000($p < 0.05$). So, there is significance improvement lumbar flexion range in both the groups but There is no significance improvement of lumbar flexion range between the group as the p value is 0.08($p > 0.05$). Mean difference of right side bending in group A is 1.233 ± 0.92 and p value is 0.000($p < 0.05$) and in group B mean difference of lumbar right-side bending is 1.96 ± 1.51 and p value is 0.000($p < 0.05$) which is suggestive of significance improvement in the lumbar right side bending but there is no significance improvement between two group as the p value is 0.10($p > 0.05$). For lumbar left side bending in group A is 1.13 ± 0.91 and p value is 0.000($p < 0.05$) and for group B mean difference is 1.90 ± 1.59 and p value is 0.000($p < 0.05$), which is suggestive of improvement in the lumbar left side bending with in the groups but there is no significance improvement of lumbar left side bending between two groups as p value is 0.08($p > 0.05$). Lumbar extension mean difference for group A is 0.11 ± 0.25 and p value is 0.02($p < 0.05$) and for group B is 0.36 ± 0.49 and p value is 0.001($p < 0.05$) which states that there is significance improvement in both the group and there is also significance improvement of lumbar extension between group as the p value is 0.000($p < 0.05$). But, for lumbar extension baseline data are also shows significance difference. So, we cannot comment on the lumbar extension range improvement as the lumbar extension baseline data was not equally distributed in two groups. Modified Oswestry low back pain index score Mean difference for group A is 22.03 ± 12.45 and p value is 0.000($p < 0.05$) and for group B is 16.63 ± 14.07 and p value is 0.000($p < 0.05$) which shows there is significance improvement in the functional status of the patients in both the groups but in between group comparison p value is 0.14($p > 0.05$) which shows there is no significance improvement of functions in patients with non-specific low back pain.

Mechanical back pain is resulting from inherent susceptibility of spine to static load due to muscle gravitational force and to kinetic deviation from normal function⁽¹⁸⁾. Male adolescent suffer from back pain less than female adolescent may be due to several factors including difference in physical structure, muscle mass and hormonal setting. And women have a greater sensitivity to noxious stimuli.⁽¹⁹⁾ People with low back pain have reduced spinal motion. Spinal extension is more limited than the spinal flexion. Reduced spinal extension led to pain and stiffness. The functions, co-ordinations of muscle and stabilization of spine is impaired.⁽¹⁸⁾ The primary mechanisms of the production of pain in local tissue in response to cell injury include, to varying degrees, edema, apoptosis or necrosis, diminished vascular supply, reduced cellular energy production, and impaired repair processes. PEMF therapies address many of these different aspects of cell injury. Magnetic therapy increases the threshold of pain sensitivity and activates the anticoagulation system which increases circulation to tissue. PEMF treatment stimulates production of opioid peptides, activates mast cells and increases electric capacity of muscular fibers, helps with edema and pain before or after a surgical operation increases amino acid uptake and induces changes in transmembrane energy transport enzymes, allowing energy coupling and increased biological chemical transport work.⁽¹⁴⁾ The different results were obtained from the previous studies with different types of parameters. Some studies done with Low frequency magnetotherapy and some studies done on the high frequency magnetotherapy. The present study was conducted with a frequency of 55.55 Hz with 31mT/10(3.1 mT) intensity for 30 min for 5 days in a week for 3 weeks. Which is the inbuilt machine dose of the BTL Magnetotherapy for back pain.

Result of our study is similar to Ann Marie Nayback-Beebe et al. (2017)⁽²⁰⁾ studied on the effect of pulsed electromagnetic frequency therapy on health-related quality of life in 75 military service members with chronic low back pain. They divide the patients in to two groups. experimental group received

Microcurrent levels between 20 and 500 microampere PEMF and usual care and control group received usual care only. Both the groups received 30 min treatment for 3 times per week for 4 weeks. They compute the pre post and 1 month follow up pain logs in both the groups. For PEMF + UC group, there was a statistical non-significance decrease in mean pain intensity score from 4.3 at baseline to 3.9 post treatment and for UC group, there was a statistically non-significance increase in mean pain scores from 3.5 to 3.8. At the 4 weeks follow up period in PEMF group 3.9 to 3.8 and in UC group 3.8 to 3.4. that was non significance in both the groups also and the between group comparison was also not significance. According to Richard Carter et al. ⁽²¹⁾ who studied on the 30 carpal tunnel patients. Out of them 15 received 100 Gauss magnet therapy and 15 were received placebo treatment. In the magnet group baseline pain was 5.9(2.6) and post treatment pain was 3.6(3.1). so, there is significance reduction of pain. In placebo group baseline pain score was 5.0(2.4) and post treatment pain was 2.6(2.7). so, there is also significance reduction pain. But between group comparison there is no significance difference found. And they conclude that magnets were not effective in treating low back pain. Although they proposed that the depth of the pain source might have played a role in the outcome of their study. Similar result was demonstrated by the Anita krammer et al. ⁽²²⁾ who studied on the electromagnetic field effect on the acute low back pain patient by applying the low dose PEMF (0.03 mT) with a frequency of 27.12 MHz with routine physical therapy and they measure the Oswestry disability index (ODI). And they conclude the group treated with active pulsed electromagnetic energy failed to demonstrate any significant additional improvements in Oswestry Disability Index. Richard Leclaire et al. ⁽²³⁾ also conclude that magnetotherapy failed to reduced pain, increase range of motion and improved the functional status of periartthritis shoulder patients compared to control group. They were used 30 Gauss intensity with 10 Hz frequency, 40 Gauss intensity with 15 Hz frequency and 60 Gauss intensity with 30 Hz frequency for 1 to 6 sessions, 7 to 16 sessions and beyond 17 sessions respectively.

In contrast to our result, Anthony J. Lisi et al. ⁽¹⁷⁾ studied on the pulsed electromagnetic field device on the 42 patients with non-specific low back pain. Experimental group received the PEMF therapy plus usual care and control group received sham PEMF therapy plus usual care. They were used extremely low intensity electromagnetic field (nT; 10^{-9}) at a set of low (range 1-100 Hz) frequencies. Participants were instructed to self-treat with the device for 30 min. Total 96-102 sessions in 12 weeks. They conclude that patients in the experimental group reported a more rapid decrease in pain between baseline and week 6 compared with patients in the sham group. Ahmed Mohamed Elshawi et al. ⁽¹⁶⁾ studied on the effect of electromagnetic field on 50 nonspecific low back pain patients with 20 Gauss (2 mT) intensity and 50 Hz frequency for 20 min in the experimental group and sham electromagnetic field therapy in the control group. Both the groups received conventional physical therapy protocol. Both the groups received 12 sessions over 4 weeks period. They conclude that there was a significance difference of pain, functional disability and lumbar right and left side bending increase between both the groups. Significance improvement in lumbar flexion and extension in favor to the experimental group. In contrary to our result Diego galace de Freitas et al. ⁽²⁴⁾ studied on the patients with shoulder impingement syndrome with 9 sessions of 50 Hz frequency with an intensity of 20mT for 30 minutes. They conclude that combination of Pulsed electromagnetic field (PEMF) with shoulder exercise is effective improving functions, muscle strength and decreasing pain in the patients with shoulder impingement syndrome. Dalia M. Kamel et al. ⁽²⁵⁾ conclude that PEMF has a significance and superior effect on carpal tunnel syndrome in postnatal women, as compared to therapeutic Ultrasound (US). The PEMF dose was 80 Gauss intensity with 50 Hz

frequency with 30 minutes for 3 times per week for 4 weeks. Maria Grazia Benedetti et al. ⁽²⁶⁾ who studied the effect of Bio- Electro-Magnetic Energy regulation (BEMER) for the treatment of type 1 complex regional pain syndrome with very low intensity (Body:7-35 microTesla, Pad:60-100 microTesla) and <33.3 Hz frequency. And they conclude that group treated with BEMER combined with rehabilitation yield better result in pain reduction and functional improvement of both upper and lower limb. Ekram HATTAPOGLU et al. ⁽²⁷⁾ also studied on the effect of pulsed electromagnetic field on patients with cervical disc herniation with the low frequency (50 Hz) and 0.6 mT intensity for 20 minutes with the TENS and Hot pack in both the groups. And they conclude that a significant improvement was found in neck pain, disability, depression, anxiety and quality of life in both the groups. And improvement in VAS and Nottingham health profile sleep sub parameter in the 12th week after treatment in between the groups.

4. CONCLUSION

The findings of the present study confirmed that Magnetotherapy along with conventional exercise is equally effective in reduction pain and improvement in the functions of the patients with non-specific low back pain. So, current dose of magnetotherapy does not have additional beneficial effect. Future study with other doses of magnetotherapy may be done to find its effectiveness. There are some limitations in this study like the use of medication before the study start was not recorder, resting pain was not accounted, limited sample size, unequal male and female distribution, Lumbar extension baseline data had significant difference in both the groups and long term follow up was not taken.

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