Evaluation of the effectiveness of low frequency magnetic field treatment in patients with knee osteoarthritis – a randomized single-blind clinical trial

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DOI: https://doi.org/10.5114/phr.2022.114582

Received: 08.01.2022 **Reviewed:** 09.01.2022 **Accepted:** 10.01.2022

Abstract

Background: Knee osteoarthritis (KOA) also named as gonarthrosis, is one of the most common of all degenerative joint diseases. Ongoing research is being carried out to find effective, less expensive, and non-invasive treatments for KOA, including physiotherapy. Magnetotherapy is a treatment commonly used in the field of physiotherapy and may be clinically applicable in KOA.

Aims: This study aimed to evaluate the effectiveness of low-frequency magnetic field treatment in patients with KOA.

Material and methods: Thirty individuals with diagnosed KOA took part in the study. The participants were randomly assigned into 2 groups: study group I underwent magnetotherapy sessions and control group II was placebo. Simple randomization and single-blind method were applied. Magnetotherapy included 15 sessions. The Lysholm Knee Score (LKS), Visual Analogue Scale (VAS), and goniometer measurement of knee flexion range of motion (ROM) were used in the study. Surveys and measurements were administered on the first and last day of the treatment. Results were assessed based on 3 statistical analyses performed using IBM SPSS Statistics 23. Wilcoxon's test, Mann-Whitney U test, Chi-square, and Spearman's correlation were used.

Results: In the experimental group, the knee flexion ROM was improved after the treatments, with most people experiencing reduced pain (VAS) and improved function (LKS), whereas in the control group, a large number of subjects showed no significant changes. The results revealed that in the experimental and control groups, knee flexion ROM was associated with better function both before and after therapy and with less pain. Moreover, pain level (VAS) was strongly and negatively correlated with functional status (LKS).

Conclusion: Magnetotherapy is useful in reducing pain and improving the mobility and functional status of the knee joint in patients with KOA.

Key words

functional assessment, knee osteoarthritis, gonarthrosis, joint pain, range of motion, knee flexion, low-frequency magnetic field, low-frequency magnetic field therapy

Introduction

Knee osteoarthritis (KOA, gonarthrosis) is one of the most common of all degenerative joint diseases [1]. It is the fourth most common cause of disability in women over the age of 65 and causes knee joint impairment in about 10% of people over the age of 55 (¼ being severe disability). It also occurs in 19-28% of people over the age of 45 and in 37% over the age of 60 [2,3]. It is estimated to affect women more frequently (approximately 75%), which may be related to menopause and estrogen deficiency [4]. Based on literature review, the global prevalence of KOA was estimated to be 203 per 10,000 person-years by 2020. The results of epidemiological research on KOA suggest an enormous extent of the problem [5].

The variability of clinical symptoms of KOA may be due to the existence of different phenotypes, showing various disease mechanisms [6]. Gender, metabolic abnormalities, cartilage damage pattern, and inflammation have been indicated as the factors most crucial in distinguishing structural phenotypes [7]. KOA is also associated with stress-induced joint tissue damage caused by high BMI, among other factors. It is predicted that by 2025, 47% of men and 36% of women in the UK will be significantly overweight, and increasing global obesity is a key factor in the rising prevalence of KOA [8].

Currently, KOA is untreatable and, in its advanced stages, is associated with significant medical costs. In the United States, KOA treatment accounts for an expenditure of approximately $27 billion annually. Additionally, lost productivity generates social costs of between $560 billion and $635 billion. Health care systems are looking for less expensive and non-invasive treatments, including physiotherapy, which would help slow down the increasing economic burden [9,10].

Low-frequency magnetic field therapy (LFMFT) is a treatment commonly used in physiotherapy. It uses an alternating magnetic field with low frequency not exceeding 100 Hz, and magnetic induction not exceeding 20 mT [11]. In vitro research conducted on rats indicates that the use of magnetic fields has shown promising results in autologous chondrocyte transplants. Magnetic field stimulation has positive effects on tissue, cellular and molecular processes [12]. The magnetic induction field increases the viscosity of the joint synovial fluid and inhibits the progression of cartilage degeneration [13]. It also shows positive effects by increasing the rate of proliferation and synthesis of proteins such as collagen, aggrecan, and glycosaminoglycans, and stimulates the metabolic activity of chondrocytes [14].

For tendons, magnetic field therapy enhances tissue healing by modulating the inflammatory response. The low frequency magnetic field modulates the concentration of intracellular calcium as well as the release of reactive forms of oxygen in a time-dependent manner. Biological effects of therapy include not only local impact on individual systems but also on the whole body [15].

Aims

The aim of this study was to evaluate the effectiveness of low frequency magnetic field treatment in patients with KOA.

Material and methods

The research was performed at the Cezary Strugala's Individual Orthopedic Medical Practice based in Grudziadz, Poland. They were conducted on a group of 30 people (23 women and 7 men, aged between 38 and 83 years) diagnosed with KOA. All received information regarding the research and gave a written consent to participate in the study. The study was approved by the Bioethics Committee of the University of Bydgoszcz (number UKB 1372/21). Participants were randomly assigned into two groups. Group I (experimental-15 subjects) underwent low frequency magnetic field treatment, group II (control-15 subjects) had the treatment performed without the inclusion of a *low-frequency magnetic field* *therapy* device (placebo). Simple randomization using a computer-generated random number table was performed. Participants were not informed as to which group they were assigned to. A single-blind method was used in which *low-frequency magnetic field therapy* were simulated (sham-therapy). Both groups were compared in terms of sex, age, height, weight, and BMI to exclude the influence of these factors on further analyses of treatment effectiveness evaluation. The results demonstrated that the groups did not significantly differ. Comparisons were made using a series of analyses with Chi-square tests of independence, and the results are presented in **Table 1**.

Table 1. Results of Chi-square test analyses of independence for study group characteristics.

Character	$\chi 2$	df	p	V
Sex	0.19	1	0.666	0.08
Age	1.54	3	0.672	0.23
Body height	0.23	3	0.972	0.09
Body weight	2.42	4	0.659	0.28
BMI	5.71	3	0.127	0.44

Abbreviations: *$\chi 2$ – Chi-square statistic, df – number of degrees of freedom, p – level of statistical significance, V – strength of association.*

Subjects with good general health and no objections to *low-frequency magnetic field therapy* were qualified for the study. Participants did not receive other physical therapy or physical rehabilitation during the duration of the study. *Low-frequency magnetic field therapy* treatments had an intensity of 8-10mT, a duration of 25 minutes, and a rectangular pulse shape. Therapy included 15 treatments performed once a day, in the morning, Monday through to Friday.

A 100-point Lysholm Knee Score (LKS) form was used in the study to assess the functional status of the knee joint. The Visual Analogue Scale (VAS) was used to subjectively assess the perceived pain. The knee flexion range of motion (ROM) was measured using a goniometer. Surveys and measurements were conducted on the first and last day of *low-frequency magnetic field therapy*. They were non-invasive and safe, posing no health risks to participants.

Results were assessed using 3 statistical analyses. The first involved assessing the knee flexion ROM before and after *low-frequency magnetic field therapy*. The second one involved comparing knee joint pain before and after the treatments. The third involved the number of points obtained in the LKS before and after the treatments. Correlations between the results from the first analysis, with the results from the second and third analysis were also measured.

Statistical comparisons were performed in IBM SPSS Statistics 23 software using all statistical analysis rules. Results were characterized as minimum and maximum values and using the mean, standard deviation, and median. Comparison of initial and final results was done using the Wilcoxon test for dependent variables. Statistical examination was also performed using Mann-Whitney U test and Chi-square test. Correlation analyses were obtained using Spearman's rho correlation coefficient. Qualitative results are presented in tables or graphs. The level of statistical significance was taken as $p < 0.05$.

Results

In order to compare the knee flexion ROM before and after the treatments, Wilcoxon test analysis was performed in both groups, which indicated that *low-frequency magnetic field therapy* significantly affected the change in knee flexion ROM in the experimental group $Z = 2.03$; $p < 0.05$; $r = 0.52$, but no such change was observed in the control group $Z = 0.11$; $p = 0.916$; $r = 0.03$. In the group with magnetic field therapy, the knee flexion ROM, in degrees, at the knee joint was greater after the treatments, and the difference was large. Improvements in knee flexion ROM were reported in more than 50% of subjects in the experimental group.

In order to compare pain scores on the VAS scale, before and after surgery, the Wilcoxon test was performed for both groups. Differences between the experimental and control groups were determined by the Mann-Whitney U test results. The results of the analyses are presented in **Table 2**. They revealed that *low-frequency magnetic field therapy* significantly altered pain intensity in the experimental group $Z = 2.72$; $p < 0.01$; $r = 0.70$, but no such change was observed in the control group $Z = 1.62$; $p = 0.105$; $r = 0.42$. In the experimental group, pain was rated between 4-9 points before therapy, with a mean score of 6.27, and between 2-7 points after therapy, with a mean score of 4.80. This was a significant change. In the control group, pain changed from a mean of 6.27 points to 5.87 points. In contrast, Mann-Whitney U-test analyses showed that the experimental and control groups did not differ in their pain ratings on the VAS scale both before $Z = 0.21$; $p = 0.832$; $r = 0.04$ and after *low-frequency magnetic field therapy* $Z = 1.49$; $p = 0.137$; $r = 0.27$.

Table 2. Results of Wilcoxon and Mann-Whitney U tests analyses for VAS pain scale before and after magnetotherapy and between the comparative groups.

VAS		Z	p	r
Before-after comparison	Study group	2.72	0.006	0.70
	Control group	1.62	0.105	0.42
Between-group comparison	Before	0.21	0.832	0.04
	After	1.49	0.137	0.27

Abbreviations: *Z – Mann-Whitney or Wilcoxon U-statistics, p – level of statistical significance, r – strength of differences, VAS –Visual Analogue Scale.*

In the experimental group, the majority of subjects experienced a reduction in pain after magnetic field treatment, while in the control group, a large number of individuals assessed the occurrence of pain after *low-frequency magnetic field therapy* at a similar level as before the treatments.

Overall, the subjects could score between 0-100 points on the LKS, with a higher value indicating better functionality. The results in the experimental and control groups, before and after *low-frequency magnetic field therapy*, are provided in **Table 3**.

The results of Wilcoxon test analyses demonstrated that magnetic field therapy had a statistically significant effect on functional change in the experimental group $Z = 2.65$; $p < 0.01$; $r = 0.69$, but no such change was observed in the control group $Z = 0.00$; $p = 1.000$; $r = 0.00$. Before the treatments, the experimental group scored an average of 58.53 on the functional performance, and after *LFMFT* they scored an average of 64.57. The difference was significant.

Using a series of Spearman's rho correlation analyses, we determined whether the level of mobility and function of the knee joint in the experimental group was related to pain intensity scores. The results presented in **Table 4** revealed that in both the experimental and control groups, knee flexion ROM was associated with better function both before and after *LFMFT* and with less pain. Those who had more severe pain had a lower knee flexion ROM. It was also revealed that pain level was strongly associated with functional assessment based on the LKS. These associations were negative meaning that individuals who experienced more severe pain had reduced functionality. It was also demonstrated that those who had large reductions in pain after the treatment also had greater improvements in function and mobility in the knee joint. These associations were analogous in both groups.

Table 3. Descriptive statistics for LKS before and after magnetotherapy and between the comparative groups.

LKS		Min	Max	M	SD	Me
Study group	Before	26	80	58.53	14.98	59
	After	43	87	64.67	11.99	64
Control group	Before	55	82	69.53	8.48	70
	After	55	85	69.47	9.64	70

Abbreviations: *Min – minimum, Max – maximum, M – mean, SD – standard deviation, Me – median, LKS – Lysholm Knee Score.*

Table 4. Results of Spearman's rho correlation analyses for the relationship between mobility and functional levels and pain severity scores in the comparative groups.

		ROM before	ROM after	ROM variable	VAS before	VAS after	VAS variable	LKS before	LKS after	LKS variable
Study group	ROM before	1								
	ROM after	0.98***	1							
	ROM variable	-0.26	-0.10	1						
	VAS before	-0.77**	-0.75**	0.19	1					
	VAS after	-0.37	-0.48	-0.45	0.57*	1				
	VAS variable	-0.31	-0.17	0.71**	0.22	-0.60*	1			
	LKS before	0.87***	0.80***	-0.40	-0.71**	-0.20	-0.38	1		
	LKS after	0.78**	0.80***	-0.06	-0.80***	-0.61*	-0.08	0.83***	1	
	LKS variable	-0.27	-0.16	0.44	0.07	-0.52*	0.52*	-0.44	0.05	1
Control group	ROM before	1								
	ROM after	0.98***	1							
	ROM variable	0.39	0.55*	1						
	VAS before	-0.66**	-0.78**	-0.70**	1					
	VAS after	-0.60*	-0.73**	-0.75**	0.94***	1				
	VAS variable	0.33	0.44	0.70**	-0.54*	-0.79**	1			
	LKS before	0.43	0.51	0.31	-0.62*	-0.47	0.02	1		
	LKS after	0.60*	0.67**	0.54*	-0.73**	-0.68**	0.37	0.86***	1	
	LKS variable	0.53*	0.57*	0.62*	-0.50	-0.63*	0.76**	-0.02	0.41	1

Abbreviations: *VAS – Visual Analogue Scale, ROM – knee flexion range of motion, LKS – Lysholm Knee Score.*

Notes: **p* < 0.05; ***p* < 0.01; ****p* < 0.001.

Discussion

Based on our study, we found a significant reduction in the intensity of knee joint pain, an increase in knee flexion ROM, and an improvement in knee joint function in subjects treated with magnetic fields. After low-frequency magnetic field therapy, there was a negative correlation between pain, ROM and functional status of the knee joint in people with KOA. The results indicate that those who had a large reduction in pain after therapy also had a greater improvement in function and mobility in the knee joint. The results obtained after the completion of the study confirmed the observations of other researchers who also highlighted the effects of magnetic therapy in the treatment of KOA.

Osnovina and Alekseeva [16] analyzed the effectiveness of using different methods of *LFMFT*. The randomized placebo clinical trial included 262 patients with KOA. After the treatment, there were clear changes in terms of reduced pain intensity in the groups treated with the magnetic field. There was also a significant improvement in stiffness index and functional characteristics of the knee joint.

The effectiveness of the *LFMFT* device was tested by Karateev et al. [17], they examined 70 patients with KOA. The results showed that the use of *LFMFT* contributed to a reduction in rest pain and a significant decrease in the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index in patients with primary and secondary KOA. One year prior, a similar study was conducted on the effectiveness and safety of magnetic therapy for patients with KOA. This time, the study group consisted of 231 individuals. The therapy resulted in a statistically significant decrease in pain and stiffness and improved knee joint function. The need for non-steroidal anti-inflammatory drugs has also decreased [18].

Boerner et al. [19] evaluated the effectiveness of magnetic therapy combined with cryotherapy in patients with KOA. The study group consisted of 25 subjects. According to the researchers, the therapy significantly reduced the level of pain and had a positive effect on the knee flexion ROM. The obtained conclusions fully confirmed the results of our own research, but it should be emphasized that the study conducted by Boerner et al. [19] involved the application of magnetic therapy simultaneously with cryotherapy.

Pasek et al. [20] in their research addressed the effect of magnetoledotherapy in the treatment of pain in KOA. They examined 40 subjects, and after a 30-day treatment, high therapeutic effectiveness was obtained in the treatment of KOA. The average pain score decreased, from very severe to mild. In addition, there was also a statistically significant decrease in the degree of mobility restriction.

Gawronska [21], in a literature review, presented physiotherapeutic methods in the treatment of musculoskeletal degenerative disorders. The author emphasized that numerous studies conducted both in Poland and abroad confirm that low-frequency pulsed magnetic field together with cryotherapy and interferential currents are the best anti-inflammatory and analgesic treatments.

The effects of physiotherapy treatments on the reduction of knee joint pain were also studied by Hare et al. [22]. The effects of physiotherapy treatments on the reduction of knee joint pain were also studied. The aim of their research was also to determine the most effective treatment method based on the respondents' opinion. The study group consisted of 55 individuals. It was found that among 96% of the subjects, one of the treatments used was *LFMFT*. The obtained data revealed that pain was significantly lower after the treatments was performed. According to patients, magnetic field therapy was the most effective treatment (38% of respondents).

Taking into account the results obtained in our own study and in the studies of other researchers, it can be concluded that low frequency magnetic field demonstrates effectiveness in the treatment of KOA. *Low-frequency magnetic field therapy* is therefore a valid choice when rehabilitating people suffering from KOA.

Study limitations

Small population was a limitation, which may have affected statistical power. Moreover, the conducted study determined the therapeutic effects of the magnetic field only immediately after the therapy, which makes it impossible to assess the durability of the achieved results. Equal parameters were used for all participants in the study, which did not allow us to determine if different magnetic field doses would have led to better treatment outcomes.

Conclusions

In light of the clinical study, the following conclusions could be drawn: (1) The application of low-frequency magnetic field has an effect on reducing pain in people with KOA. (2) Use of magnetotherapy treatments improves mobility and functional status of the knee joint in patients with KOA.

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