Original Research

The Effect of Biogel Using Biomagnetic Energy in the Treatment of Acute Pain in the Upper Extremity and Spine: A Randomized Controlled Trial

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ABSTRACT

Objective: Pain is a public health problem, which is caused by various etiological factors and leads to diminished quality of life and decreased workforce. The aim of this study was to determine whether Biogel has an effect in the treatment of pain.

Methods: Patients due to acute pain in the upper extremity and/or trunk were divided into two groups as treatment and placebo by randomization method. For the patients in the treatment group, the non-interventional Biogel was applied for 10 minutes. For the control group, a non-interventional placebo was applied for 10 mins. A record was made of patient demographic data, the region of the pain, and mean arterial pressure (MAP) values before and after the application. All the patients in both groups were administered a Visual Analogue Scale (VAS) to evaluate pain severity, and the Nottingham Health Profile (NHP) before and after the applications. The data obtained were compared.

Results: In the biogel group, a statistically significant decrease was determined in the NHP-P values after treatment compared to before treatment (P<0.001). In the placebo group, no statistically significant difference was determined in the NHP-P values before and after treatment (P=0.104). In the Biogel group, a statistically significant decrease was determined in the VAS values after treatment compared to before treatment (P<0.001). In the placebo group, no statistically significant difference was determined in the VAS values before and after treatment (P=0.157).

Conclusion: These types of complementary medicine applications focussed on pain treatment can reduce the disease burden and can probably reduce costs.

Keywords: Pain, Biogel, Complementary Medicine, Traditional Medicine, Integrative Medicine

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience which identifies a type of damage or is associated with actual or potential tissue damage [1, 2]. Pain can occur for many different reasons. Acute pain is triggered by a specific disease or injury, serves a beneficial biological purpose, is associated with skeletal muscle spasm and sympathetic nerve system activation, and is self-limiting. Acute pain is short-lasting and can generally be easily described by the patient [3]. In contrast, chronic pain is a common and uncomfortable condition caused by pain which persists despite the normal healing process or which lasts for a period of longer than 3 months [4]. When pain is experienced,

it is perceived in different anatomic regions such as the head and neck region, the upper and lower back, abdomen, and chest. Abnormal signal transmission and processing in the nervous system is the true explanation of this condition [5]. Treatment of acute pain aims to treat the underlying cause and cut nociceptive signals [3].

Complementary Medicine, is a branch of science, which treats the patient holistically, providing healthcare services to patients with a patient-focussed and evidence-based approach. Traditional and Complementary Medicine (T&CM) is defined by the World Health Organisation (WHO) as "the entirety of knowledge, skills and practices based on theories, beliefs and experiences specific to different cultures, which can be explained or not, used in the prevention, diagnosis, improvement, or treatment of physical and mental diseases as well as in maintaining good health" [6]. In recent years, the interest of patients and researchers in T&CM has increased. In parallel with this, different methods have been accepted throughout the world, including phytotherapy, mesotherapy, larva application, prolotherapy, cupping applications, music therapy, hypnotherapy, homeopathy, leech therapy, ozone applications, osteopathy, reflexology, acupuncture, apitherapy, and chiropractice [6]. Another complementary medicine method that is applied worldwide is bioenergy [7].

Main Points;

- Pain is a significant public health concern, arising from a multitude of etiological variables and resulting in a notable decline in both quality of life and workforce productivity.

- Complementary medicine is a field of research that uses an evidence-based, patient-centered approach to care for patients by treating them holistically.

- Bioenergy is regarded as a therapeutic modality that promotes the principles of holistic medicine, acknowledging the potential for comprehensive treatment of ailments encompassing the physical, mental, and spiritual aspects of an individual. This approach emphasises the enhancement of the immune system and the harmonious flow of energy within the body, particularly targeting energy centres.

- The findings of this study indicate that biogel may be considered a viable adjunctive therapeutic approach for managing acute pain in the upper extremities and/or trunk.

Bioelectromagnetism is a discipline related to how the human body produces electromagnetic energy and what sort of response is given when exposed to this energy from outside. The energy area around the heart is the bio-area that was first measured in humans. Research related to this subject almost a century ago led to the invention of the electrocardiogram device. After a further twenty five years, Berger measured the bio-area around the brain and that study led to the development of electroencephalography. The studies conducted created bioelectromagnetic areas of organs such as the heart and brain and proved that the energy produced by these areas could be measured with electrodes attached to the body [7, 8].

Bioenergy is a concept coming from the words bio and energy, which have the meanings of living and life in Latin. Energy healing is currently applied for the provision of general health, well-being, and relaxation, the elimination of symptoms of several chronic diseases, for strengthening the immune system, and in the resolution of several health problems such as stress, depression, anxiety, fatigue, asthma, hypertension, cancer, arthritis, acute or chronic pain, and wound healing [9].

Treatment is applied with the harmonisation of chakras, which are accepted as aura and energy centres in bioenergy. Thus, the energy balance of the body is restored and physical and psychological diseases are treated through the activation of chakras [9]. Treatment in terms of energy applications is defined as the return of the body to a process of balance and harmony as a result of determining the causes of physical disease in the body, eliminating these and thereby regaining physical health. Energy therapies are known to have been used as healing methods since ancient times. Current modern energy therapy is known to be based on the Einstein paradigm. According to this paradigm, just as matter is composed from energy and vibrations, so the human body is also thought to be composed from energy and vibrations. In contrast to traditional drugs and surgical interventions, this approach advocates that treatment can be made with pure energy. At the same time, understanding and resolving the molecular organisation of the physical body is primarily accepted in this treatment approach, and it is believed that diseases occur when the balance of energy systems is disrupted, and thus pathological symptoms occur in physical, emotional, mental, and spiritual planes [9-11].

Bioenergy is seen as a treatment technique that advocates the understanding of holistic medicine, and it is accepted that the

treatment of diseases can be applied holistically to the body, mind, and spirit, especially strengthening the immune system and directing energy in the body in a balanced way to energy centres [12]. In diseases originating from a local weakness, acute and chronic pain, allergies, varices, constipation, and similar disorders, it is aimed to increase the energy level of cells with bioenergy and prevent recurrence of the same disease in the same area by increasing their resistance. The aim of treatment with bioenergy is not treatment of the disease itself, but to strengthen and activate the natural defence mechanisms of the body [12].

Pain is a public health problem, which is caused by various etiological factors and leads to diminished quality of life and decreased workforce. Drugs taken for treatment purposes do not always provide the desired results and this causes patients to seek different methods [13]. Pain related to the musculoskeletal system and rheumatological diseases are among the leading reasons for presentation at healthcare facilities worldwide [14]. Since ancient times many T&CM methods have been used in the treatment of pain, primarily Chinese medical acupuncture. The aim of this study was to determine whether or not there was any effect in the treatment of pain of biogel formed using amino acids and trace elements of gold, platinum, silver, and other semi-precious metal minerals processed with nano technology.

MATERIALS AND METHODS
Biogel
The biogel application performed in our study is shown in Figure 1a, and the image of the used biogel is shown in Figure 1b. The biogel (Biomagnetic Compress gel, BiogelyTM, Hitit University Technopolis Campus, Çorum, Turkey) was produced using amino acids and trace elements of gold, platinum, silver, and other semi-precious metal minerals processed with nano technology [15].

Clinical Application
The study was conducted in the Orthopaedics and Traumatology Department of Hitit University Erol Olçok Training and Research Hospital and in Mimar Sinan Family Health Centre. The study included voluntary patients aged 18-65 years who presented with the complaint of acute pain in the upper extremity and/or trunk. Patients were excluded from the study if they had a chronic disease such as diabetes mellitus, if they had a cardiac pacemaker, were pregnant, or had any psychiatric disease. Approval for the study was granted by the Local Ethics

Committee of Hitit University (decision no: 2022-28, dated: 09.01.2023).

Figure 1. a. An example application showing Biogel therapy for the treatment of pain in the shoulder area **b.** Biogel used in the research

The patients were randomly separated into two groups using randomisation software (https://www.randomizer.org) [16] as the treatment group and placebo group. With the categorisation and block randomisation method, sample size was equal between the groups and in distribution of age and gender (4 age group categories were formed of 18-29, 30-42, 42.53, and 54-65 years). The randomisation was performed by a biostatistician, using the computer-generated random numbers and the sealed envelope method.

People who met the trial inclusion criteria were invited to receive detailed written information before their written informed consent was obtained.

The study was designed to be single blind, and the patients were not aware of whether they were in the treatment or placebo group. For the patients in the treatment group, the non-interventional biogel was applied for 10 minutes. For the control group, a non-interventional placebo was applied for 10 mins (fluid not containing any substance). After the application of biogel and placebo, necessary medical treatments for pain were given to both patient groups.

After the data were obtained, routine treatments were

administered to all the patients. A record was made of patient demographic data, the region of the pain, and mean arterial pressure (MAP) values before and after the application. To determine the effect of the biogel treatment, all the patients in both groups were administered a Visual Analogue Scale (VAS) to evaluate pain severity, and the Nottingham Health Profile (NHP) before and after the applications. The data obtained were compared between and within the groups.

The NHP, developed by Hunt et al. (1980), is a scale which measures 6 areas of mobility, pain, energy, sleep, emotional reactions, and social isolation, with 38 true/false items, and contains an optional second section with items about sexual life, work, hobbies, and social relationships [17]. The NHP was adapted to Turkish by Küçükdevi et al. [18]. It is a simple, comprehensive scale, which is widely used, especially in Europe. In some conditions, the NHP can be more sensitive than the SF-36 to treatment-related changes, and compared to the SF-36, it contains a specific sleep scale and more pain items [19]. In this study, the general health profile of the patients was measured with the NHP and pain levels with the NHP- Pain (NHP-P).

Sample Size Estimations (Priori Power Analysis)

Before starting the research, power analysis was performed using Student's t-test to test the main hypothesis. In order to reach 90% power with $\alpha=0.05$ error, it was decided to include a total of 88 patients, with a minimum of 44 in each group, as a result of the power analysis using the Cohen d=0.70 effect size, which was calculated by using the literature knowledge and expert opinion. However, considering that there would be loss of patients during the research process, the sample size was increased by 10% - 20%, and as a result of randomization, a total of 100 patients, with a minimum of 50 patients in each group, were included in the study (Figure 2).
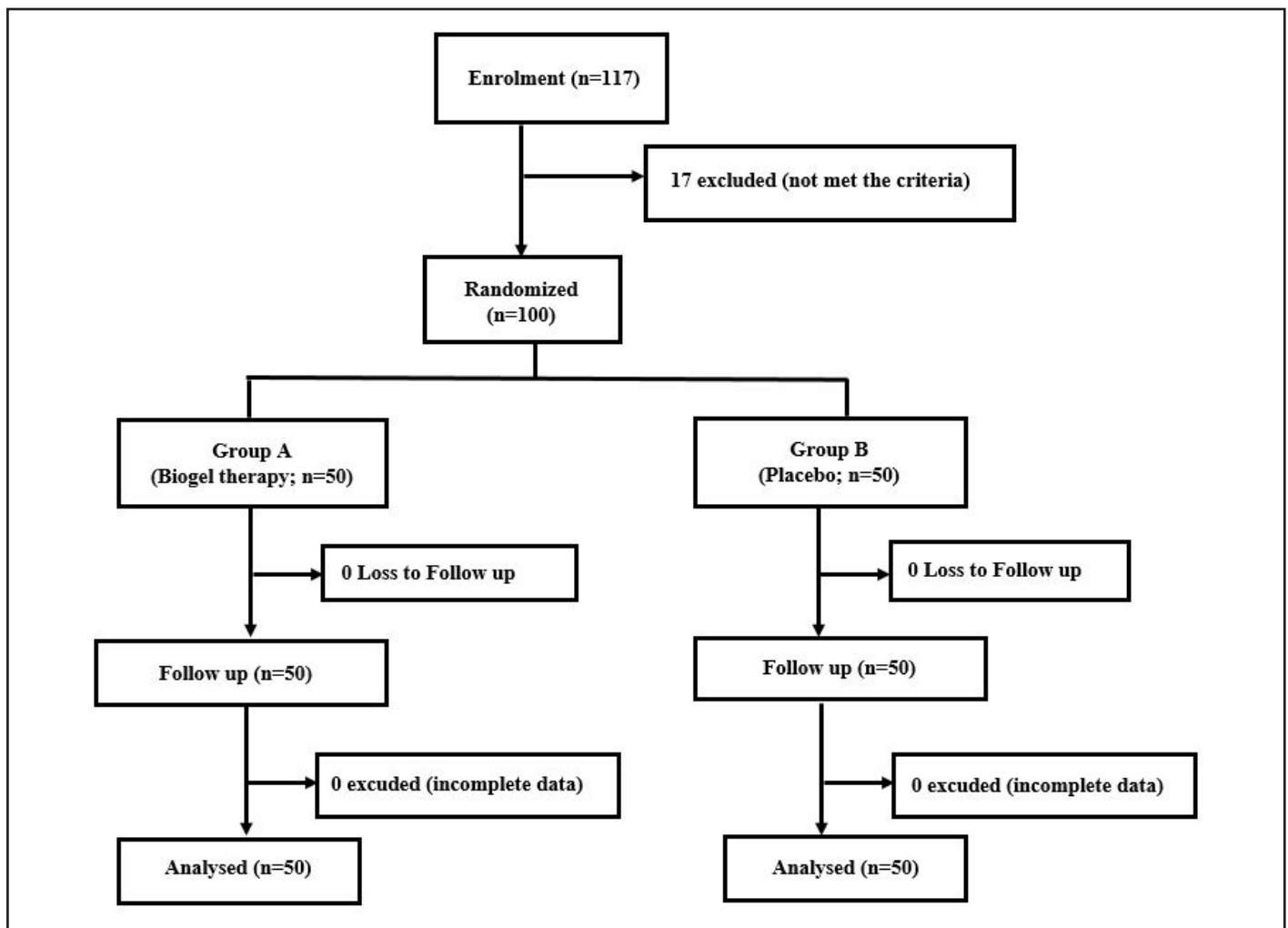
Figure 2. Consort Diagram of the block-randomized controlled trial of biogel therapy

Statistical Analysis

Statistical analyses of the data collected from the patients in our study were performed with the SPSS (Version 22.0, SPSS Inc., Chicago, IL, USA, program usage license: Hitit University) software. The normal distribution test of the data was tested with Shapiro-Wilks, Kolmogorov Smirnov and some graphical methods (Histogram and Q-Q plot). The assumption of homogeneity of variances was evaluated with the Levene test. Descriptive statistics of numerical variables were reported using mean±standard deviation or median (min-max) depending on the normal distribution of data. Descriptive statistics of categorical variables were reported using numbers (n) and percentages (%). Ratio comparisons between study groups were performed with either the Chi-square test or Fisher's exact test, depending on the sample sizes in the crosstab cells. Comparison of numerical data between research groups was performed with Student's t-test depending on parametric test assumptions. Comparison of numerical data between research groups before and after treatment was performed with the Paired t-test or Wilcoxon signed rank test, depending on parametric test assumptions. The statistical significance level was accepted as $P<0.05$.

**RESULTS**

The data of a total of 100 patients were analysed, as 50 in the biogel treatment group and 50 in the placebo group. The descriptive statistics of the sociodemographic characteristics of the patients are presented in Table 1. When the patients were assigned to the groups, randomisation was performed according to age and gender, so that gender distributions and mean ages were similar in the two groups (P=1.000, P=0.114, respectively) (Table 1). The mean age was determined as 45.28±7.13 years (range, 24-65 years) in the biogel treatment group and 47.67±7.85 years (range, 25-65 years) in the placebo group. The mean body mass index (BMI) was 29.18±4.64 (range, 18.99-36.57) in the biogel group and 28.29±4.36 (range, 19.43-40.70) in the placebo group, with no significant difference determined between the groups (P=0.325).

The distributions of education levels and marital status were similar in the two groups (P=0.773, P=0.373, respectively). The smoking status, presence of chronic disease, and history of surgery were found to be similar in both groups (P=0.488, P=0.202, P=0.295, respectively). The diagnoses of acute pain in the biogel group were arm pain in 14 patients (28%), neck pain in 6 (12%), low back pain in 20 (40%), and shoulder pain in 10 (20%). In the placebo group, the diagnoses of acute pain were arm pain in 11 patients (22%), neck pain in 9 (18%), low back pain in 18 (36%), and shoulder pain in 12 (24%). No significant difference was determined between the groups in respect of the diagnosis distribution rates (P=0.742).

In the first section of the NHP, the total mean points were 238.8±108.2 [median (min-max): 239 (60.3-497.6)] in the biogel group and 256.8±105.7 [median (min-max): 278 (32.1-400.7)] in the placebo group. In the second section of the NHP, the mean total points were 1.59±1.7 [median (min-max): 1 (0-7)] in the biogel group and 1.55±1.24 [median (min-max): 2 (0-5)] in the placebo group. No statistically significant difference was determined between the groups in respect of the points of the first and second sections of the NHP (P=0.517, P=0.781, respectively).
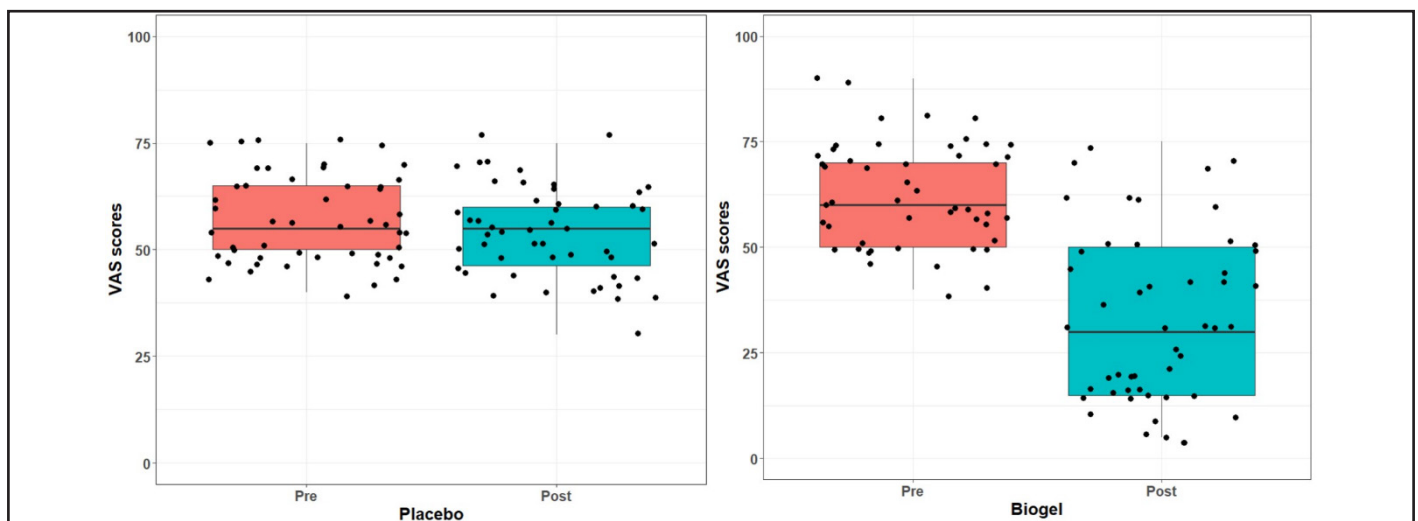
Figure 3. Line graph showing the change of VAS scores before and after biogel therapy

Table 1. Comparison of socio-demographic characteristics between research groups

		Biogel (n=50)	Placebo (n=50)	P values
Gender	Female	25 (50%)	25 (50%)	1.000[a]
	Male	25 (50%)	25 (50%)	
Age		45.28±7.13 (24-65)	47.67±7.85 (25-65)	0.114[b]
BMI		29.18±4.64 (18.99 – 36.57)	28.29±4.36 (19.43 – 40.70)	0.325[b]
Education	Primary school	5 (10%)	7 (14%)	0.773[a]
	Middle school	13 (26%)	10 (20%)	
	High school	20 (40%)	23 (46%)	
	University	12 (24%)	10 (20%)	
Marriage status	Married	38 (76%)	34 (68%)	0.373[a]
	Single	12 (24%)	16 (32%)	
Smoking	Yes	11 (22%)	14 (28%)	0.488[a]
	No	39 (78%)	36 (72%)	
Chronic disease	Yes	7 (14%)	12 (24%)	0.202[a]
	No	43 (86%)	38 (76%)	
Surgical history	Yes	15 (30%)	20 (40%)	0.295[a]
	No	35 (70%)	30 (60%)	
Diagnosis	Arm pain	14 (28%)	11 (22%)	0.742[a]
	Neck pain	6 (12%)	9 (18%)	
	Backache	20 (40%)	18 (36%)	
	Shoulder pain	10 (20%)	12 (24%)	

[a]Chi square test with n (%)

[b]Student's t-test with mean±standard deviation (min-max)

BMI: Body Mass Index

Table 2. Comparison of blood pressure, VAS, NHP-P values between research groups pre and post therapy

		Pre	Post	P values
Mean arterial pressure	**Biogel**	87.37±11.58	87.13±10.43	0.793[a]
	Placebo	95.45±8.65	93.36±8.36	0.467[a]
NHP-P	**Biogel**	59.4 (22.9 - 100)	26.01 (0 - 79.52)	**<0.001[b]**
	Placebo	59.4 (9.99-100)	50.44 (9.99 - 100)	0.104[b]
VAS	**Biogel**	62.50±12.46	32.70±20.05	**<0.001[a]**
	Placebo	57.00±10.35	54.30±10.49	0.157[a]

[a] Paired t-test with mean±standard deviation

[b] Wilcoxon signed rank test with median (min-max)

VAS: Visual Analog Scale

NHP-P: Nottingham Health Profile-Pain

The statistical findings of the within-group comparisons of MAP, VAS, and NHP-P values between the groups and within the groups before and after the application of biogel are shown in Table 2. No statistically significant difference was determined in the MAP values before and after treatment in both the biogel and placebo groups (P=0.793, P=0.467, respectively). In the biogel group, a statistically significant decrease was determined in the NHP-P values after treatment (26.01 [0-79.52]) compared to before treatment (59.4 [22.9-100]) (P<0.001). In the placebo group, no statistically significant difference was determined in the NHP-P values before and after treatment (P=0.104). In the biogel group, a statistically significant decrease was determined in the VAS values after treatment (32.70±20.05) compared to before treatment (62.50±12.46) (P<0.001). In the placebo group, no statistically significant difference was determined in the VAS values before and after treatment (P=0.157). The change in VAS scores from before to after the application of biogel is shown in graph form in Figure 3.

In the biogel treatment group, the patients were asked, "Have you benefitted from biogel?", and the responses were reported as definitely agree by 19 (38%) patients, agree by 21 (42%), undecided by 6 (12%), disagree by 3 (6%), and definitely disagree by 1 (2%).

DISCUSSION

Acute or chronic pain is one of the most common reasons for adults presenting for medical care. Many people worldwide experience pain. In a limited number of studies, the prevalence of chronic pain has been estimated to vary between 11% and 40%. According to a CDC report, it was estimated that in 2016, 1 in every 5 (20.4%) adults in the USA had chronic pain, and 8% had a chronic pain with a high impact, defined as restricting work activities on most days or every day for a period of 6 months [20, 21]. In a recent meta-analysis, the prevalence of chronic pain in developed countries was calculated as 18% (95% CI: 10-29%) [22]. A review by Gregory and McGowan (2016) reported that up to 84% of hospitalised adult patients reported acute pain and up to 36% severe pain (acute pain prevalence:37.7%-84%, severe pain prevalence: 9-36%) [23]. Acute and chronic pain have a great effect on the economy of a country. Therefore, medical and traditional treatment of pain has long been one of the most researched subjects. Since the earliest recorded times, doctors and other healing experts have applied many traditional and complementary treatments to prevent, alleviate, or cure pain [24].

In the current study, it was investigated whether or not biogel had an effect in the treatment of acute pain in the upper extremity and/or trunk. The findings demonstrated that the majoority of patients stated that they benefitted from the biogel treatment applied, and there was a significant decrease in the VAS and NHP-P scores in the biogel treatment group compared to the placebo group. No study could be found in lierature that has examined the effect on pain of a biogel directly obtained with these elements. However, there are several studies in literature about the effect of biomagnetic energy on pain.

Magnets and magnetic therapy have been used for hundreds of years in the treatment of different types of pain. Magnetic therapy is applied with static magnets which produce a therapeutic magnetic field for pain relief and healing in various problems. There are natural magnetic and electrical fields in the body, and there is a small amount of magnetic energy in all the molecules of these. The thinking behind magnetic field therapy is that some problems occur because the magnetic fields are unbalanced [25]. Ions such as calcium and potassium assist cell signal transmission and magnets have been reported to change the behaviour of these ions [26].

Conflicting results have been obtained in literature about the effect of magnetic therapy. Pawluk W. (1998) reported that magnetic therapy provided improvements in muscle strains and sprains and joint pain [25]. A systematic review published in 2020 included 21 studies (1101 patients) which focussed on electromagnetic therapy for musculoskeletal pain conditions and reported that electromagnetic therapy reduced pain and improved functions in patients with different musculoskeletal system diseases. The 21 studies examined comprised 8 which focussed on knee osteoarthritis, 2 on shoulder impingement syndrome, 1 on chronic mechanical neck pain, 4 on low back pain, 3 on fibromyalgia, 1 on patellofemoral knee pain, 1 on plantar fasciitis (heel pain), and 1 on hand osteoarthritis. This systematic review showed that electromagnetic field therapy alleviated pain and improved function in patients with various painful musculoskeletal system diseases. Studies which have analysed electromagnetic field therapy have stated that it is well tolerated without any negative side-effects reported. Thus, it has been concluded that electromagnetic therapy may be a useful component during treatment with drugs for chronic and acute pain in musculoskeletal diseases [27].

Magnetic therapy using pulsating electromagnetic field (PEMF)

treatment has been approved by the FDA for certain conditions, including postoperative oedema and pain in superficial soft tissues and the treatment of fractures that have not healed with standard medical treatment. The FDA has also approved a certain type of magnetic therapy known as transcranial magnetic stimulation, using magnetic fields to stimulate brain cells for severe migraine, depression, and obsessive-compulsive disorder. The use of FDA-confirmed magnetic therapy for these conditions is accepted as traditional medicine [28]. It has been reported in literature that PEMF has analgesic and anti-nociceptive efficacy similar to the opioid analgesic effect, although the biological and biochemical mechanism of magnetic therapy on pain is not fully understood [29]. Some researchers have shown that short-term exposure to electromagnetic fields is effective on inflammatory cellular and neurological processes such as cortical activation and inhibition models and various neurotransmitter activities [30]. In a systematic examination and meta-analysis to evaluate the clinical evidence obtained from randomised experiments of static magnets for the treatment of pain, Pittler et al. (2007) concluded that despite the widespread use of static magnets to eliminate pain, there was no evidence to suggest that static magnets could be effective in pain relief [4].

Although there is no definitive consensus in literature about the effect of biomagnetic energy on pain treatment, the positive effects of magnetic energy have been reported in many studies. As a result of the current randomised, controlled clinical study of patients with pain in the upper extremity region or trunk, the biogel treatment was determined to have made a statistically significant improvement in both the VAS scores and the NHP-P scores. In addition, there was no statistically significant change in the MAP values.

Limitations

A limitation of this study could be said to be that only patients with acute pain were included. An investigation of the effect of biogel on patients with chronic pain could be supportive of the current study. Another limitation was that the effect of biogel was only investigated on pain in the upper extremity and/or trunk. It can be recommended that further studies are planned to evaluate the efficacy of biogel on acute and chronic pain in more specific regions with larger and different patient groups.

CONCLUSIONS

The results of this study demonstrated that biogel can be accepted as a complementary medicine method in the treatment of acute pain in the upper extremity and/or trunk. As a result of the burden of acute and chronic pain and the associated suffering, there are great costs to society. These types of complementary medicine applications focussed on pain treatment can reduce the disease burden and can probably reduce costs. It can be predicted that these types of biogels will become more widely used in the future due to the ease-of use, rapid effect, and reduction in costs of public services. The optimal treatment for acute pain is a function of the desire of an individual to choose between the side-effects of treatment and pain control. The results of this study suggest that T&CM applications with no side-effects should be supported in addition to evidence-based medicine.

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