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ORIGINAL ARTICLE

Efficacy of Farabloc as an analgesic in primary fibromyalgia

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Abstract The goal of our study was to determine the efficacy of Farabloc, an electromagnetic shielding fabric compared to placebo fabric when worn as a nightgown, as an analgesic in patients hospitalized with fibromyalgia. In a rheumatologic and rehabilitation hospital, we performed a phase 1, single-blind study of patients using Farabloc (F) or placebo (P) gowns for 8 h per night during the 20-day hospitalization and a phase 2, single-blind crossover study of patients using both F and P gowns randomly and alternatively switching after 10 of 21 days hospitalization (phase 1: 42 F, mean age 49.02 years, 35 female, 7 male; 84 P, mean age 48.08 years, 72 female, 12 males; phase 2: 25 F/P, P/F, or P/P, mean age 44.0 years, 24 female, 1 male). The study involved randomly selected and blinded use of hospital gown 8 h per night of either F or P fabric. The main outcome measures were changes from admission or midpoint to discharge in quantity of pain (QN), quality of pain (QL), and paracetamol use (PU). In phase 1, all three variables significantly favored F over P when using paired *t* test, two sample *t* test, Mann–Whitney, and analysis of covariance tests. QN was reduced (F=−2.03∓0.99*, P=0.59∓0.71). QL was reduced (F=−10.64∓5.69*, P=−2.54∓3.40). PU was reduced (F=10.69∓6.68*, P=26.12∓9.37). In phase 2, comparing midpoint to discharge levels in the three variables again favored P/F over F/P and P/P (>0.001): QN (P/F +16.00∓8.35* F/P −13.27∓11.40), QL (P/F +8.71∓4.75* F/P −6.55∓5.59), and PU (F −9.29∓4.39* P −18.00∓5.27) (*p=<0.001). Patients with fibromyalgia had less pain after sleeping in a gown made of Farabloc than with a placebo fabric. This suggests that Farabloc, an electromagnetic shielding fabric, has analgesic properties in fibromyalgia. Reduced pain observation is consistent with previous studies in phantom limb pain and delayed onset muscle pain. Limitations of this study include single blind design, small sample size, and in phase 2, a lack of washout period and a F/F group.

Keywords Analgesic · Electromagnetic shield · Farabloc · Fibromyalgia

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Introduction

Fibromyalgia is characterized by diffuse, persistent, and unexplained muscle pain associated with generalized allodynia and hyperalgesia in a minimum of 11 of 18 defined anatomical points as specified by the American College of Rheumatology [1]. Central sensitization of nociceptive neurons in the dorsal horn due to activation of *N*-methyl-*d*-aspartic acid receptors and disinhibition of pain due to deficient function of the descending inhibitory system are possible pathogenic factors for allodynia and hyperalgesia [2]. Desmeules et al. [3] using quantitative sensory testing found that fibromyalgic subjects showed significantly altered cold and heat thresholds and tolerance to cold pain was radically significantly decreased in 85 patients with fibromyalgia compared to controls. Bagis et al. [4] found patients with fibromyalgia had higher levels of malondialdehyde than controls, which is consistent with

lipid peroxidation secondary to excess free radicals. This may suggest that fibromyalgia is associated with oxidative stress. Chronic pain in fibromyalgia can produce ongoing emotional and physical stress that may induce sleep disturbance causing fatigue and cognitive disorders [5]. Therapeutic interventions including drugs, physical therapy, and cognitive behavior therapy have not been universally curative [6–10]. The prevalence of this disorder is reported to be 3 to 5% of the population with a significant female predominance [11].

Farabloc fabric is woven with fibers of extremely fine steel and nylon. The fabric has an appearance similar to linen. It can be tailored like any conventional fabric and is washable. Farabloc has a significant shielding effect on high frequency (HF) electromagnetic fields (EMF). HF EMF greater than 1 MHz such as radio waves are completely blocked by double layers of Farabloc fabric [12].

Farabloc fabric when wrapped around the post amputation stump was found to have a favorable effect on phantom limb pain (PLP) by the inventor, Frieder Kempe. A controlled double blind study on phantom limb pain confirmed this impression [13]. A single-blind crossover study in untrained subjects on delayed onset muscle soreness (DOMS) demonstrated significantly reduced pain, strength loss, and serum inflammatory markers when double wrapping the thigh post exercise was compared to placebo fabric [12]. These research studies have not determined the mechanism by which Farabloc reduced phantom limb pain or delayed onset muscle soreness. Incomplete effectiveness of standard therapies in primary fibromyalgia stimulated the study of the efficacy of Farabloc on the modification of pain in this debilitating syndrome. Two phases were undertaken. Phase 1 involved 126 patients using either a placebo or Farabloc gown at night while phase 2 studied 25 patients in a crossover design to determine whether Farabloc had analgesic properties in patients with fibromyalgia.

Phase 1

Method

One hundred twenty-six patients (106 women and 20 men) hospitalized over a 4-year period completed participation in a study to evaluate the therapeutic effects of Farabloc.

Inclusion required that patients have all 18 tender points present not just 11 as required by the American College of Rheumatology criteria for Primary Fibromyalgia. Exclusion criteria were recent severe trauma, infection, neoplastic disease, history of unstable mental status, and abnormal laboratory testing, which included elevation in the ESR, CRP, or abnormal hemoglobin levels. Subject consent and ethical approval meet the standards set by the Klinik Auerbach, Akutklinik für Innere Medizin und Rheumatologie. Subjects were randomly assigned to wear a coded hospital gown from a pool (36 placebos and 18 Farabloc) at night during sleep for approximately 8 h. Suits were washed after use and recycled into the next pool. A notary kept code until the conclusion of all data collection.

The study was a single blind, placebo-controlled evaluation of the efficacy of Farabloc vs placebo garments worn for 20 days during hospitalization. The patients were assigned by random code to wear either a Farabloc or placebo garment on admission to hospital. All medications were discontinued on hospitalization with the exception of paracetamol. The use of paracetamol was administered only on patient demand during hospitalization and monitored to establish total drug use during the 20 days in hospital. Physical therapy and counseling were provided for all patients in both the Farabloc and placebo groups equally during hospitalization.

Quantity of pain, quality of pain, and total paracetamol dosage were the outcome variables studied on admission and again on discharge 20 days later. The subjective quantity of the pain experienced by each patient who personally marked a visual analogue scale (VAS) of 10 cm (0 meaning no pain and 10 meaning severe pain). Quality of pain was determined by the physician examiner applying approximately 4 kg of topical local pressure to 18 tender points, 9 on each side of the body. Patient response to each of the 18 points was evaluated on a five-point scale (no pain = 0, slight pain = 1, moderate pain = 2, severe pain = 3, and unbearable pain = 4). Total quality of pain was the sum of all 18 points ranked from 0 through 4 at the time of admission and after 20 days of exposure to either the placebo or Farabloc garment. Total drug use was determined by calculating the total dosage of paracetamol requested by each patient during the hospitalization for both the Farabloc and placebo group.

Statistical evaluation

All three variables, quantity of pain, quality of pain, and total drug use were compared using the difference of values at hospital admission and discharge between the Farabloc and placebo groups by using the paired *t* tests, two sample *t* tests, analysis of covariance, and Mann–Whitney tests. Significance was set at 0.005.

Results

At the conclusion of the study, 84 patients wore a placebo gown and 42 patients wore a Farabloc gown for their hospitalization of 20 days. The two groups were not significantly different with respect to age or sex.

Characteristics of the subjects are shown below

	Farabloc	Placebo
Number of patients	42	84
Age (years)	49.02	48.08
Female	35	72
Male	7	12
Symptoms (years)	11.40	10.03

The changes from admission to discharge were assessed in each group separately. Paired *t* tests show statistically significant changes in quantity of pain, quality of pain, and total paracetamol use. This result was repeated when evaluation of changes was assessed by two-sample *t* test. The same results were obtained using the Mann–Whitney test to compare medians rather than means. Analysis of covariance using change in quantity of pain as the outcome variable, with group as the main effect and age and sex as covariates confirmed the significant group effect and lack of effect due to the covariates. The same results were obtained for changes in quality of pain.

Quantity of pain

The difference in pain on admission and discharge

	For the placebo group (n=84)		For the Farabloc group (n=42)		
	Mean	Standard deviation	Mean	Standard deviation	*P*-value
Admission	7.41	0.52	7.41	0.49	0.99
Discharge	6.83	0.59	5.39	0.99	>0.001
Difference	−0.59	0.71	−2.03	0.99	>0.001

Quality of pain

The difference of tenderness on admission and discharge

	For the placebo group (n=84)		For the Farabloc group (n=42)		
	Mean	Standard deviation	Mean	Standard deviation	*P*-value
Admission	49.40	4.02	48.86	3.71	0.46
Discharge	46.87	3.43	38.21	6.17	>0.001
Difference	−2.54	3.40	−10.64	5.69	>0.001

Total paracetamol use

This was established by totaling the dosage of paracetamol used on demand by subjects during their 20 days of hospitalization.

For the placebo group (n=84)		For the Farabloc group (n=42)		
Mean	Standard deviation	Mean	Standard deviation	*P*-value
26.12	9.37	10.69	6.68	<0.001

95% confidence intervals

	Farabloc	Placebo
Change in quantity of pain	2.03±0.30 (1.73, 2.33)	0.59±0.15 (0.44, 0.74)
Change in quality of pain	10.64±1.72 (8.92, 12.36)	2.54±0.73 (1.81, 3.27)
Total paracetamol use	10.69±1.17 (9.52, 11.86)	26.12±1.64 (24.48, 27.76)

Side effects

Side effects occurred equally in both experimental groups. Fourteen patients using the placebo gown noted slight scratching and itching. One subject noted occasional sense of heat. Fourteen patients using the Farabloc gown also noted scratching and itching while five subjects also noted a sense of heat. All completed the study. Nine placebo subjects and four Farabloc users failed to complete the testing and were excluded from the study. Reasons for withdrawal in four patients using a Farabloc gown were itching and scratching in two subjects, slight erythema in one. The fourth withdrew with no reason given. Nine patients using the placebo gown withdrew mainly due to scratching and itching. Anxiety was noted twice in this group, slight redness and burning to skin once and warmth once.

Phase 2

Method

Subjects

Twenty-five patients, 24 female and one male with a mean age of 44 years were hospitalized for 21 days average after meeting the diagnostic criteria of primary fibromyalgia. The inclusion and exclusion criteria were identical to phase 1 disease. Each patient was given physical therapy and counseling in an identical manner. Before admission, patients used antidepressants, analgesics, muscle relaxants, sleep medication, and herbal medication. There were no significant differences in drug use by the P or F patients at the outset. All drug therapy was ceased on admission with the exception of paracetamol. Hospital staff provided this drug on demand and the total drug use monitored.

Intervention

Gowns were divided into two groups. Because of the logistics, only 18 Farabloc gowns were available. Group 1 consisted of 25 placebo gowns (P) and group 2 had 18 Farabloc gowns (F) and seven placebo gowns (P). Each gown was coded and randomly selected to produce a blinded order. A notary kept codes until the conclusion of the study. All gowns were changed according to the blinded order at the midpoint of the hospitalization. This lead to three distinct groups for statistical comparison:

	n
1. F/P	11
2. P/P	7
3. P/F	7

Variables

Each patient was assessed on admission, at midpoint, and at discharge for quantity of pain, quality of pain, and drug use. The methods of evaluation were identical to phase 1.

Statistical method

Logistical constraints on the availability of Farabloc gowns made the inclusion of a fourth group, F/F not possible. As hospitalization for fibromyalgia was limited to 21 days, no washout period in this crossover design was feasible. For these reasons, the change from midpoint to final discharge was computed for each subject in the three groups: F/P, P/P, and P/F. One sample *t* tests, two sample *t* tests, and the Mann–Whitney test were used to compare the change in tenderness, pain, and drug use from midpoint to discharge. Significance was set a $p=0.005$.

Results

Twenty-four subjects were female and one male. Mean age was 44±7.6 years. Mean hospitalization was 21.1±1.3 days.

n	11	7	7
Group	F/P Mean∓SD	P/P Mean∓SD	P/F Mean∓SD
Change from midpoint to discharge			
Quantity of pain	−13.27∓11.40; $p>0.001$	−4.43∓5.80	+16.00∓8.35
Quality of pain	−6.55∓5.59; $p>0.001$	−0.29∓2.56	+8.71∓4.75
Paracetamol use	−18.00∓5.27; $p>0.001$	−16.00∓5.10	−9.29∓4.39

Plus sign (+) signifies relative reduced pain or drug use
Minus sign (−) signifies relative increased pain

Group F/P and group P/F are of prime interest. One sample *t* tests confirm the mean changes in quantity and quality of pain are significantly different from zero in the negative direction for group F/P and positive for group P/F ($p<0.001$). That is, subjects taken off the Farabloc worsen and subjects put on the Farabloc improve. Group P/P, as expected, is somewhere between the mean levels for group F/P and group P/F.

Two sample *t* tests confirm that the change in quality and quantity of pain are significantly better with Farabloc ($p<0.001$). All subjects had a higher drug use at discharge as compared to midpoint but in group P/F the increase was significantly less.

To assess the order effect, the change scores of group F/P were compared with the change scores of group P/F but the sign on the changes was reversed for group P/F. Comparing the median of group F/P to the "negative" median of group P/F using the Mann–Whitney test shows no significant difference for the quantity and quality of pain. That is, while using the Farabloc garment, quality and quantity of pain were reduced by the same amount whether it was before or after the placebo garment. No one withdrew from the study because of side effects although subjects reported itchiness with both the Farabloc and placebo gowns in equal numbers. Results from this study lend support to the hypothesis that Farabloc reduces quantity and quality of pain and paracetamol use among primary fibromyalgia patients.

Discussion

All three variables evaluated in the two phases of this study were significantly reduced in those subjects who wore the Farabloc garments at night. This was the only intervention that was different between the Farabloc and placebo groups. The observed reduction in the quantity of pain, quality of pain, and total drug use in the Farabloc users implies some alteration in somatic pain perception. Limitations of this study include single blind design, small sample size and in phase 2, a lack of washout period and a F/F group, plus intra- and interexaminer and patient variability in evaluation of tenderness.

Side effects in both groups were similar with four F and nine P patients withdrawing. The frequency of heat, itchiness, and scratching were more prevalent in the F group. In our experience, a heat sensation is often noted in the subject using Farabloc and may not represent a side effect.

As the etiology and pathology of primary fibromyalgia are yet unknown, it is difficult to understand how Farabloc

acts to reduce pain [14]. Perturbation of the pain mechanism in fibromyalgia with the use of Farabloc is associated with reduced pain awareness and paracetamol use. It cannot be determined whether changing the electromagnetic field (EMF) environment has a similar effect to an analgesic drug. This current study does not explain the mechanism by which a shield to high frequency (HF) EMF has an effect on pain, nor does the observations of pain reduction in PLP provides a clue. The DOMS study demonstrated reduction of pain and strength loss, but even more importantly, a decrease in the blood markers for inflammation and cell destruction. Reductions of creatine phosphokinase and myoglobin suggest less permeability of the muscle membrane. Less malondialdehyde is consistent with less lipid peroxidation of the cell membrane. Reduced leukocytes and neutrophils suggest a possible antiinflammatory action. It should be noted that Bagis et al. [4] found increased malondialdehyde in patients with fibromyalgia while the DOMS study showed reduced malondialdehyde with the use of Farabloc. The use of a fabric made of a fine steel alloy and nylon was designed to shield the body from EMF. Farabloc shields HF EMF such as radio waves completely but does not shield low frequency (LF) EMF as created by the common electrical appliances [12]. Is there evidence that perturbations of EMF produce biological effects?

Electrobiological effects in humans is being investigated at an increasing frequency. One of the earliest applications of EMF investigated the effects on bone healing. This concept is now well established in orthopedic practice. Controlled weight bearing and LF EMF both promote bone repair. Weight bearing introduces mechanical strain to bone which creates strain generated potential signals based on the time varying electrical field, $E(t)$. This $E(t)$ is directly induced with LF EMF devices stimulating ionic transfer across cell membranes in bone caniculi [15].

In the past two decades, the concept of electroporation has become well established. Short high voltage pulsed electrostimulation of cellular tissue increases the permeability of the cell membrane. This method can enhance chemotherapy drug delivery to targeted tissues of the body with reduced dosage and side effects. Research and practice includes the use of electroporation in gene delivery [16, 17].

Research studies on LF EMF exposure to human lymphocytes showed a reduction in cell membrane fluidity and an increase in superoxide dismutase. This suggests that as the cell membrane is exposed to the EMF spectrum there is a variable influence on permeability [18]. That is to say LF may reduce permeability, and as the frequency increases so does the permeability. As the energy content of the radiation spectrum moves in parallel to the frequency, does permeability vary in a similar manner? Low energy of LF EMF appears to reduce permeability while higher energy of HF EMF increases permeability [19]. The extreme cell membrane destruction is obvious in ionizing radiation.

Conclusions

This study on fibromyalgia supports an analgesic effect by the use of Farabloc fabric when compared to placebo fabric. These positive results in pain reduction in fibromyalgia by the use of an externally applied electromagnetic shielding fabric are unexplained but may have an important clinical application for patients afflicted by this disorder. Further study of Farabloc on a larger sample of fibromyalgic patients is indicated.

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