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Article *in* Journal of alternative and complementary medicine (New York, N.Y.) · November 2011

DOI: 10.1089/acm.2010.0635 · Source: PubMed

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THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 17, Number 12, 2011, pp. 1133–1140

DOI: 10.1089/acm.2010.0635

Local Thermal Therapy Effects on Menopausal Symptoms and Bone Mineral Density

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Abstract

Objectives: The aim of this study was to evaluate the effects of local thermal therapy with far-infrared rays (FIR) on menopausal symptoms and bone mineral density (BMD) in postmenopausal women.
Subjects and methods: A prospective randomized, controlled trial was conducted in female volunteers from communities in Northern Taiwan. The intervention group ($n = 22$) received local thermal therapy with the help of FIR from an FIR emitter, for approximately 20 minutes per day, twice a week, for 20 sessions. They received the therapy on their backs while lying in a supine position. The control group ($n = 21$) received no treatment. The primary outcome was the change in the Perceived Perimenopausal Disturbances Scale, designed for the measurement of menopause-related symptoms (MRS) before and after completion of treatment in a 10-week period. Secondary outcome parameters included serum levels of estradiol (E2) with osteocalcin (OC), and calcaneal BMD by quantitative ultrasound.
Results: After 10 weeks of intervention, MRS determined by the scale decreased in mean total scores and mean scores for vasomotor, musculoskeletal, urologic, reproductive, and psychologic domains ($p < 0.05$), except for reproductive (sexuality-related) symptoms. In the control group, mean total scores and scores of each domain had no significant difference between baseline and follow-up examination after 10 weeks. There was no significant difference between the quantitative ultrasound parameters in the calcaneus, serum E2, and OC levels either at the baseline or in the changes from the baseline between the intervention and control groups of women ($p > 0.05$).
Conclusions: Local thermal therapy with FIR results in a significant reduction of MRS in postmenopausal women. Serum E2, OC levels, and calcaneal BMD showed no significant changes between the two groups. These results suggest that FIR local thermal therapy may be a potential alternative for the management of postmenopausal symptoms.

Introduction

The controversy regarding the adverse effects and potential risks of hormone replacement therapy from Women's Health Initiative[1] and the Million Women Study[2] has led to an increased interest in nonhormonal therapies for managing climacteric symptoms in postmenopausal women. Among the many approaches of complementary and alternative medicine (CAM) used during menopause, acupuncture has gained much attention partly due to it being a relatively safe treatment modality.[3] Although evidence from previous randomized controlled trials showed inconsistent effectiveness in reducing menopausal hot flashes,[3] acupuncture therapies have improved menopause-related symptoms in recent large-scale studies.[4,5] Acupuncture treatments need to be performed by specialized practitioners, which is not suitable for those who need long-term management.[6] Moxibustion, an alternative to acupuncture, has been shown to be effective in reducing both the frequency and severity of menopausal hot flashes.[7] Moxibustion does not require penetration of the skin and can be self-treating. In clinical practice, it is advised that moxibustion be conducted by appropriately trained specialists because of the risk of skin injuries induced by moxa burning.[7,8] It has been demonstrated that moxibustion

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with a traditional moxa stick produces its potent therapeutic effects by thermal action, primarily emitting long-wavelength infrared radiation.[8,9] In an attempt to search for nonhormonal strategies in the health care of postmenopausal women, a prospective study was conducted to examine the effect of local thermal stimulation by a far-infrared (FIR) emitter.

FIR radiation emits a characteristic wavelength between 5.6 and 1000 μm that can be perceived as heat by thermoreceptors of the skin.[10] FIR radiation promotes microvascular blood flow and angiogenesis in animal models.[11,12] Repeated thermal therapy by FIR saunas has been effective in managing cardiovascular disease, relieving chronic pain, and treating chronic fatigue syndrome.[13–15] Acupoint stimulation with FIR therapy is more effective than heat pads in decreasing both stress and fatigue levels in patients undergoing hemodialysis treatment.[16] Enhanced autonomic nervous system activity was detected in the FIR group of patients, suggesting that mechanisms other than local thermal effect might result from the treatment.[16]

According to the theory of Traditional Chinese Medicine (TCM), the human body is regulated by a network called meridians, through which *Qi* runs. *Qi* is classified as *Yin* and *Yang*. *Yin* represents the Cold, Slow, and passive aspect of *Qi*, whereas *Yang* represents the Hot, Excited, and more active aspect of *Qi*. According to this theory, menopause-related symptoms are mainly caused by a decline in Kidney essence, leading to a *Yin/Yang* imbalance. The treatment principle in managing these syndromes is to reinforce the Kidney essence and balance the *Yin/Yang*.[17,18] This can be achieved by acupuncture, moxibustion, medicated hot compress, herb medications, and other interventions.[19]

The objectives of the present study were to evaluate the effectiveness of using FIR in managing the health-related problems of postmenopausal women by applying local thermal treatment on the meridians. The primary measure outcome was the change in the Perceived Perimenopausal Disturbances Scale designed for the measurement of menopause-related symptoms (MRS), and the secondary outcome was the impact on bone mineral density (BMD).

Subjects and Methods

Study subjects

All study procedures were approved by the committee at the National Taipei College of Nursing. A total of 53 female volunteers were recruited in a health maintenance program for postmenopausal women from communities in Northern Taiwan. Women were asked to report any symptoms that they may have experienced in the past 6 months. They were also counseled on exercise, diet/weight, calcium intake, and smoking cessation. The coordinator assessed the eligibility criteria and obtained written informed consent. Postmenopausal status was defined as at least 12 months of spontaneous amenorrhea. Serum follicle-stimulating hormone and estradiol levels were measured to confirm postmenopausal status. All participants also met the following criteria: (1) they had not used any hormone therapy for at least 6 months; (2) they were fully conscious; and (3) they were able to communicate verbally. Exclusion criteria included (1) dermatological disorders; (2) disturbances of temperature sensation, such as thermanesthesia; (3) prior history of oophorectomy or hysterectomy; (4) prior cancer and/or tumor histories; and (5) current use of drugs or CAM that may contradict or interfere with measured outcomes. After the completion of baseline evaluation, participants were assigned by register code entry on computer to either the intervention or the control group. The assessors (Shu-Ju Liu and Ying Chang) were not blinded to the assignment of participants. The researcher (Li-Wei Chien) who was not involved in the intervention procedure collected and analyzed the data.

Interventions

Local thermal therapy with far-infrared rays (Bio-Warm™, Chislehurst, Kent, UK) was used for this study. The electrified ceramic plates of this emitter generate electromagnetic waves with wavelengths in the range of 3–25 μm (peak between 5 and 6 μm). This device was composed of a heating pad (45 cm in width and 60 cm in length), a temperature sensor, and a heat controller. The temperature of the pad was set at 40°C constantly during the treatment. Participants took a supine position on the bed in a quiet and warm room. Thermal therapy was performed for 20 minutes twice a week for a total of 20 sessions. The bladder channel (BL) and the *du* vessels (DV) are meridians located along the spine containing many accessible tonification acupoints used both in acupuncture and moxibustion. Treatment was given at these points from the cervical spine to the sacrum.

Participants who were allocated to the control group did not receive any intervention. At the end of the study, those with no intervention in the control group were offered the same intervention procedure if they wanted. Outcome measures including MRS evaluation, BMD, and biochemical measurement were performed at the initial evaluation and at the end of the study period of 10 weeks in both groups.

Outcome Measures

Menopause-related symptoms

The pPrimary outcome measurement was MRS, evaluated by measuring with the Perceived Perimenopausal Disturbances Scale. The scale was designed to measure subjective perimenopausal and postmenopausal symptoms, and has been published in previous studies on menopausal health management.[20,21] Thirty-eight (38) items with five main categories of symptoms were measured, namely, vasomotor (9 items), musculoskeletal (2 items), urologic (5 items), reproductive (9 items), and psychologic symptoms (14 items). Each item was given a score of 1–4, where a higher score indicated greater discomfort for perimenopausal symptoms and a stronger influence on daily life. A lower score indicated less discomfort and slight or zero influence on daily life. This scale had a Cronbach α of 0.95.

Bone mineral density measurements

Bone density was assessed using a quantitative ultrasound (QUS). BUA (broadband ultrasound attenuation, a QUS parameter) was measured in the left calcaneus after application of gel to the heel using a McCue Cuba Mark II machine (McCue Ultrasonics, London, UK). The mean of two left heel measurements, obtained with repositioning, was used. The coefficient of variation was 3.5%. The BUA output is expressed both as an absolute value (db/MHz) and, with reference to the embedded normative data, as a *T*-score.

Biochemical measurements

Serum samples were collected after a 10–14-hour fast. To minimize variability due to diurnal variation, subjects were instructed to report between 6:00 AM and 10:00 AM for all visits. The plasma was separated by centrifugation and stored at −70°C until assayed. Serum estradiol (E2) concentration was measured by using a commercially available RIA kit (Diagnostic Systems Laboratories, TX). The detection limit of the assay was 5 pg/mL. The intra- and interassay variations ranged from 4% to 8%. Serum osteocalcin (OC) was determined by an automated Roche electrochemiluminescence system (Elecsys 2010, Roche Diagnostics, IN). Coefficient of variation was 5.5%. Serum assay was performed at the end of the study period in a single batch.

Assessment of adverse events

Trial safety was evaluated based on all adverse events reported during this study. Participants were told to report adverse events regardless of whether they believed them to be linked to the FIR treatment.

Statistical analysis

All statistical analyses were based on per-protocol population except for the baseline comparisons between groups, which were based on intent-to-treat population. Normal distributed continuous variables were expressed as mean ± standard deviation, and tested with two independent-sample t tests; Non-normal distributed continuous variables were expressed as median (interquartile range), and tested with nonparametric Mann-Whitney U test. In case of mean score of MRS at baseline and post-treatment within group, if the scores were normal-distributed at baseline and post-treatment, paired t test was performed; nonparametric Wilcoxon signed rank test was performed in all other cases. Categorical data including marital status, education level, and vocation were presented as numbers (percent). The association between categorical data and group was tested by χ^2 test except for education level because of the small count in some cells. Pearson correlation coefficients were determined to assess the correlations between continuous variables. Analyses were performed with the SPSS 15.0 software package (SPSS Inc., Chicago, IL). All statistical assessments were two-sided, with statistical significance set at 0.05.

Results

Participant flow

Fifty-three (53) women were assessed for eligibility, excluding 6 due to unsuitability to the study criteria (Fig. 1). Of the 47 eligible participants, 43 completed the study. One (1) subject in the intervention group did not complete the treatment sessions, and 3 subjects in the control group dropped out due to missed follow-up measurements. No adverse events were reported regarding the FIR thermal therapy during the study period.

Demographic data

Baseline characteristics of patients belonging to intervention and control groups were compared. There was no significant difference in the age, height, weight, material status, education level, and vocation between the two groups ($p > 0.05$, Table 1).

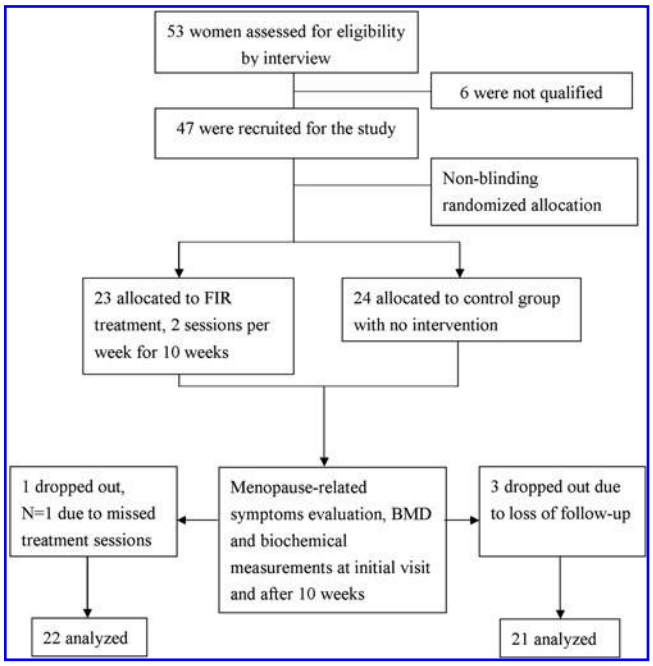

FIG. 1. Flow chart displaying distribution of study cohort. FIR, far-infrared emitter; BMD, bone mineral density.

Outcomes

Menopause-related symptoms

The mean scores of MRS for the two groups were compared (Table 2). There were no significant differences in the six domains of symptoms at baseline between the two groups ($p > 0.05$). After 10 weeks of intervention, the differences arising between pre- and post-treatment scores were compared as well as the change from baseline scores between the two groups. Change ratio of mean scores, defined as (score at 10th week – baseline score)/baseline score, decreased significantly after 10 weeks of intervention for each domain, except for reproductive (sexuality-related) symptoms. Mean scores for vasomotor symptoms were decreased more in the intervention group than in the control group (-0.14 ± 0.17 versus -0.03 ± 0.15, $p = 0.037$), and similar results were obtained in musculoskeletal symptoms [-0.25 (-0.33, 0.00) versus 0.00 (0.00, 0.00), $p = 0.006$], urologic symptoms (-0.06 ± 0.19 versus 0.07 ± 0.23, $p = 0.046$), psychologic symptoms (-0.11 ± 0.13 versus -0.01 ± 0.14, $p = 0.019$), and total symptoms (-0.12 ± 0.11 versus 0.04 ± 0.14, $p = 0.002$).

Bone mineral density and biochemical measurements

The result of BMD and biochemical measurements is shown in Table 3. T score, BUA, serum E2, and OC at baseline, and the change from baseline, were not significantly different between the two groups ($p > 0.05$). The level of serum E2 significantly decreased after 10 weeks of intervention in both the intervention and control groups ($p < 0.05$ for both). Figure 2 shows the result of correlation analysis. There was no significant correlation between BMD and the biomarkers ($p > 0.05$ for all; Table 4).

Table 1. Baseline Characteristics of Participants

Item	*Intervention* (n = 23)	*Control* (n = 24)	p-*Value*
Age at randomization, year[a]	57.89 (55.47, 62.35)	57.69 (55.23, 60.93)	0.809
Age at menopause, year[a]	51.00 (50.00, 52.25)	50.00 (48.00, 51.00)	0.050
Height, cm[b]	156.61 ± 4.38	156.60 ± 7.11	0.996
Weight, kg[a]	57.00 (54.75, 63.50)	63.00 (57.00, 71.00)	0.123
Marital status[c]			0.243
Single[d]	8 (36.4%)	5 (20.8%)	
Married[e]	14 (63.6%)	19 (79.2%)	
Education level[f]			0.073
Elementary	7 (31.8%)	15 (62.5%)	
Middle	13 (59.1%)	6 (25.0%)	
College and above	2 (9.1%)	3 (12.5%)	
Vocation[c]			0.887
Housewife	6 (27.3%)	7 (29.2%)	
Employed	16 (72.7%)	17 (70.8%)	

[a]Data were presented as medium (interquartile range), and compared by Mann-Whitney *U* test.
[b]Data were presented as mean ± standard deviation, and compared by two-sample *t* test.
[c]Data were presented as number (%), and compared by χ^2 test.
[d]Including widowed and separated.
[e]Including cohabiting.
[f]Data were presented as number (%), and compared by Fisher's exact test.

Discussion

The efficacy of FIR local thermal therapy in reducing postmenopausal symptoms was explored based on the theory of TCM. Significant improvements in the vasomotor, musculoskeletal, urologic, and psychologic domains of MRS were found in the treatment group of women after 10 weeks of intervention compared to those with no treatment. The strength of the present study is the prospective development of a design to test the feasibility of using an FIR emitter to deliver a moxibustion-like effect. The impact on the MRS was detected by using a specific questionnaire for measuring subjective menopausal symptoms. Biochemical factors and qualitative ultrasound parameters regarding the BMD changes in postmenopausal women were also examined before and after the treatment.

Table 2. Menopause-Related Symptoms at Baseline and Change from Baseline in Total Scores

	Total score		
	Intervention (n = 22)	*Control* (n = 21)	p-*Value*
Vasomotor symptoms			
Baseline[a]	13.41 ± 3.55	12.81 ± 3.47	0.579
Change from baseline[a]	−0.14 ± 0.17*	−0.03 ± 0.15	0.037**
Musculoskeletal symptoms			
Baseline[b]	4.00 (3.00, 5.00)	4.00 (3.00, 4.00)	0.464
Change from baseline[b]	−0.25 (−0.33, 0.00)*	0.00 (0.00, 0.00)	0.006**
Urologic symptoms			
Baseline[a]	8.45 ± 1.79	8.19 ± 2.27	0.674
Change from baseline[a]	−0.06 ± 0.19	0.07 ± 0.23	0.046**
Reproductive symptoms			
Baseline[a]	11.91 ± 3.07	12.05 ± 2.78	0.878
Change from baseline[a]	−0.10 ± 0.14	0.12 ± 0.35	0.093
Psychologic symptoms			
Baseline[b]	19.50 (17.00, 25.00)	21.00 (18.00, 23.00)	0.659
Change from baseline[a]	−0.11 ± 0.13*	−0.01 ± 0.14	0.019**
Total			
Baseline[a]	59.55 ± 13.12	58.19 ± 10.42	0.710
Change from baseline[a]	−0.12 ± 0.11*	0.04 ± 0.14	0.002**

Change from baseline was defined as (score at 10th week − baseline score)/baseline score.
[a]Data were presented as mean ± standard deviation, and the difference between the two groups was compared by two-sample *t* test.
[b]Data were presented as median (interquartile range), and the difference between the two groups was compared by Mann-Whitney *U* test.
*$p < 0.05$, statistical significance between pre- and postmeasurement using paired *t* test or Wilcoxon signed-rank test.
**$p < 0.05$, statistical significance between the two groups using two-sample *t* test or Mann-Whitney *U* test.

Table 3. Menopause-Related Symptoms at Baseline and Change from Baseline in Mean Scores

Domains	*Mean scores*		p-*Value*
	Intervention (n = *22*)	*Control* (n = *21*)	
Vasomotor symptoms			
Baseline[a]	1.49 ± 0.39	1.42 ± 0.39	0.579
Change from baseline[a]	−0.14 ± 0.17*	−0.03 ± 0.15	0.037**
Musculoskeletal symptoms			
Baseline[b]	2.00 (1.50, 2.50)	2.00 (1.50, 2.00)	0.464
Change from baseline[b]	−0.25 (−0.33, 0.00)*	0.00 (0.00, 0.00)	0.006**
Urologic symptoms			
Baseline[a]	1.69 ± 0.36	1.64 ± 0.45	0.674
Change from baseline[a]	−0.06 ± 0.19	0.07 ± 0.23	0.046**
Reproductive symptoms			
Baseline[a]	1.49 ± 0.38	1.51 ± 0.35	0.878
Change from baseline[a]	−0.10 ± 0.14	0.12 ± 0.35	0.093
Psychologic symptoms			
Baseline[b]	1.39 (1.21, 1.79)	1.50 (1.29, 1.64)	0.659
Change from baseline[a]	−0.11 ± 0.13*	−0.01 ± 0.14	0.019**
Total			
Baseline[a]	1.57 ± 0.35	1.53 ± 0.27	0.710
Change from baseline[a]	−0.12 ± 0.11*	0.04 ± 0.14	0.002**

Change from baseline was defined as (score at 10th week – baseline score)/baseline score.
[a]Data were presented as mean ± standard deviation, and the difference between the two groups was compared by two-sample *t* test.
[b]Data were presented as median (interquartile range), and the difference between the two groups was compared by Mann-Whitney *U* test.
*$p < 0.05$, statistical significance between pre- and postmeasurement using paired *t* test or Wilcoxon signed-rank test.
**$p < 0.05$, statistical significance between the two groups using two-sample *t* test or Mann-Whitney *U* test.

The concept of a meridian system has been considered an essential theoretical basis for acupuncture and moxibustion therapy; however, no clear evidence-based data regarding anatomical and physiologic nature of meridians have been found.[22] The sensory phenomenon of propagated sensation along meridians provides a possible explanation for the nature of acupuncture points.[23] Polymodal receptors are thought to play an important role because they can be activated by both thermal (moxibustion) and mechanical (acupuncture) stimuli.[23] The authors proposed that FIR local thermal stimulation on the meridian might follow the principle of acupuncture–moxibustion to exert its therapeutic effect.

Although controversies underlying the mechanisms of vasomotor symptoms in postmenopausal women still exist, the general consensus is that they are caused by thermoregulatory dysfunction.[24,25] The regulation of thermoregulatory function is very complex, generally believed to involve three main components: the brain, the internal body cavity, and the peripheral vasculature.[25] Dysregulation at one or more of these sites may result in impaired core–body temperature regulation that presents as exaggerated heat-loss responses. Acupuncture–moxibustion treatment may alter neuromodulators such as serotonin and β-endorphin to stabilize the thermoregulatory center in the brain in order to control vasomotor symptoms.[26,27] It was speculated that FIR thermal therapy may also have a local effect on peripheral circulation in the tissue and muscle. Based on the theory of moxibustion, Takayama and colleagues demonstrated that local thermal stimulation, with a heat transfer control device at the skin of the paraumbilical region, could increase blood flow in the superior mesentery artery 20 minutes after stimulation in healthy subjects.[28] They suggested that heat stimulation in the umbilicus area simultaneously stimulated multiple acupoints related to the intestine.[28] It has been shown that by stimulating somatic afferent fibers in the skin and related neurons at the spinal cord level, acupuncture may modulate the central circulatory system to increase parasympathetic cholinergic activity and induce the subsequent hemodynamic changes in internal organs.[29] These responses are mediated by the autonomic nervous system and, therefore, are expected to be reflected in heart rate variability changes.[30,31] An increase in autonomic nervous system activity has been demonstrated in previous studies of FIR stimulation.[16] It is possible that through these mechanisms, local thermal therapy may help postmenopausal women adapt to different neurochemical levels in thermoregulation.[25,32] In a similar way, FIR therapy might work through different physiologic pathways to have an effect on musculoskeletal, urologic, and psychologic symptoms in postmenopausal women.

Local thermal treatment on the BL and DV meridian regions simultaneously stimulates multiple acupoints related to the kidney tonifying effect. In particular, *Dazhu* (BL 11), *Ganshu* (BL 18), *PiShu* (BL-20), *Shenshu* (BL 23), and *Zhishi* (BL 52) have been used in previous trials of acupuncture treatment for menopausal women under the TCM diagnosis of Kidney Deficiency.[4,17,18] For example, BL 23 is an acupoint on the BL, located inferior and lateral to the spinous process of the second lumbar spine, used frequently in the management of menopausal hot flashes and osteoporosis.[4,17,18,33,34] Acupuncture at BL 23 has been shown to be effective in promoting bone formation, improving bone architecture, and reversing osteoporosis in the mice model.[33,34] These effects were suggested in relation to some degree of enhancement in the secretion of sex hormone and declining bone turnover by decreased OC levels.[33,34] There has been no report

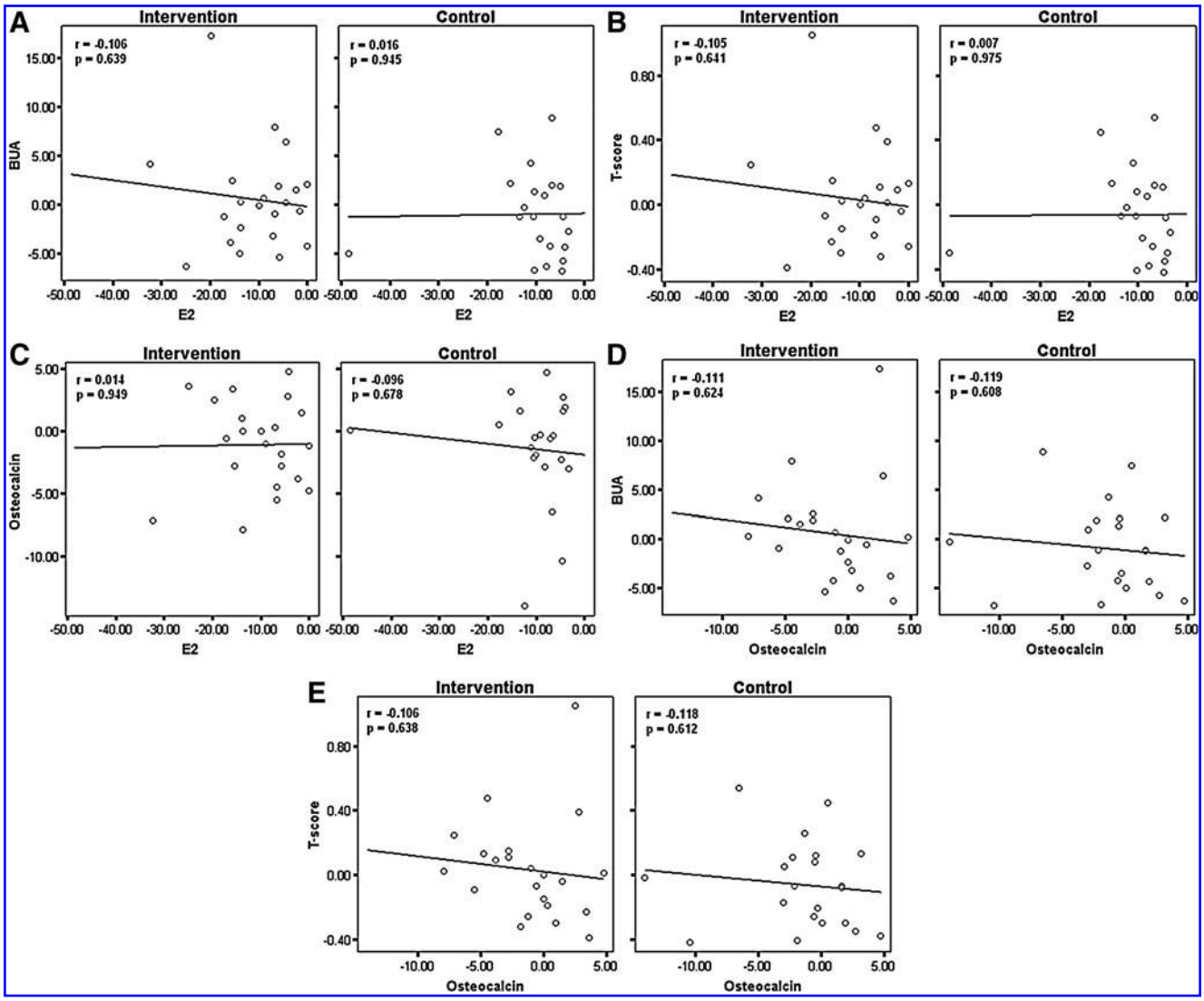

FIG. 2. Correlation analysis between **(A)** broadband ultrasound attenuation (BUA) and estradiol (E2); **(B)** *T*-score and E2; **(C)** osteocalcin and E2; **(D)** BUA and osteocalcin; and **(E)** *T*-score and osteocalcin for intervention and control groups ($p > 0.05$ for all).

Table 4. Biomarkers at Baseline and Change from Baseline

Items	*Intervention* (n = 22)	*Control* (n = 21)	p-*Value*
BUA			
Baseline[a]	64.96 ± 12.08	61.24 ± 13.69	0.351
Change from baseline[b]	0.03 (−3.41, 2.15)	−1.20 (−4.70, 1.94)	0.350
T score			
Baseline[a]	−1.49 ± 0.73	−1.71 ± 0.83	0.353
Change from baseline[b]	0.01 (−0.20, 0.14)	−0.07 (−0.30, 0.12)	0.349
Serum E2			
Baseline[a]	14.70 (7.96, 17.13)	11.30 (6.99, 16.75)	0.473
Change from baseline[b]	−8.03 (−15.58, −4.39)*	−8.24 (−11.74, −4.79)*	0.932
Serum osteocalcin			
Baseline[a]	19.20 ± 6.81	21.16 ± 8.31	0.401
Change from baseline[b]	−0.80 (−3.98, 1.75)	−0.50 (−2.60, 1.60)	0.971

[a]Data were presented as mean ± standard deviation, and compared by two-sample *t* test.
[b]Data were presented as medium (interquartile range), and compared by Mann-Whitney *U* test.
BUA, broadband ultrasound attenuation; *T* score, *T* score of BUA; E2, estradiol.
*$p < 0.05$, statistical significance between pre- and postmeasurement using Wilcoxon signed-rank test.

in the English literature regarding the effect of acupuncture–moxibustion treatment for reducing BMD loss. Several studies in Chinese literature claim that acupuncture–moxibustion treatment might increase BMD in postmenopausal women by enhancing sex hormones and biochemical indexes to delay bone loss.[35,36] The present results did not show a beneficial effect of meridian thermal stimulation on calcaneal bone density within a short-term period of 10 weeks. Further studies at different anatomical sites using different instrumentation with a longer period of time might be needed to examine the effect of acupuncture–moxibustion treatment of BMD in postmenopausal women. Decreased serum E2 levels were observed in both groups of women during the period of 10 weeks because they were advised not to take any hormone-containing medication or food. This observation may explain why no improvement was found in the reproductive (sexuality-related) symptoms after FIR treatment.

The authors have not applied TCM diagnostic categories to study the effect of FIR meridian thermal stimulation. It is recognized that participants who anticipate treatment and/or placebo effects may encounter changes in their climacteric symptoms. Because there is still no consensus on the best way to conduct controlled studies in acupuncture or moxibustion trials,[7,17] potential bias should be noted in the interpretation of these data. Nevertheless, the authors made efforts to limit the interaction between practitioner and participants by standardizing the procedure of intervention and outcome measurements. Methodological weaknesses of this study include unblinded assessments, a smaller sample size, and lack of concealed randomization. The physiologic effect of FIR therapy on meridian and nonmeridian acupoints should be assessed in greater detail by either biophysical or biochemical approaches. Further studies with larger samples, possibly including placebo controls and TCM-driven interventions, are still needed to confirm the local thermal effect on postmenopausal women.

Conclusions

This study demonstrated that FIR local thermal therapy resulted in a significant improvement in MRS in postmenopausal women. Thermal therapy had no effect on serum E2 or OC levels, and dose-related calcaneal BMD changes were not detected. FIR local thermal therapy may be a potential alternative for the management of menopausal symptoms in women who are unable to or do not want to receive hormone replacement therapy.

Acknowledgments

We would like to thank Prof. I.L. Tsao (National Taipei College of Nursing, Taiwan) for her kindly assistance in providing the Perceived Perimenopausal Disturbances Scale. We received no funding in this study.

Disclosure Statement

No competing financial interests exist.

References

1. Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: Principal results from the Women's Health Initiative randomized controlled trial. JAMA 2002;288:321–333.
2. Million Women Study Collaborators. Breast cancer and hormone-replacement therapy in the million women study. Lancet 2003;362:419–427.
3. Cho SH, Whang WW. Acupuncture for vasomotor menopausal symptoms: A systematic review. Menopause 2009;16:1065–1073.
4. Borud EK, Alraek T, White A, et al. The Acupuncture on Hot Flushes Among Menopausal Women (ACUFLASH) study, a randomized controlled trial. Menopause 2009;16:484–493.
5. Kim KH, Kang KW, Kim DI, et al. Effects of acupuncture on hot flashes in perimenopausal and postmenopausal women: A multicenter randomized clinical trial. Menopause 2010;17:269–280.
6. Borud EK, Alraek T, White A, Grimsgaard S. The Acupuncture on Hot Flashes Among Menopausal Women study: Observational follow-up results at 6 and 12 months. Menopause 2010;17:262–268.
7. Park JE, Lee MS, Jung S, et al. Moxibustion for treating menopausal hot flashes: A randomized clinical trial. Menopause 2009;16:660–665.
8. Shen X, Ding G, Wei J, et al. An infrared radiation study of the biophysical characteristics of traditional moxibustion. Complement Ther Med 2006;14:213–219.
9. Pach D, Brinkhaus B, Willich SN. Moxa sticks: Thermal properties and possible implications for clinical trials. Complement Ther Med 2009;17:243–246.
10. Toyokawa H, Matsui Y, Uhara J. Promotive effects of far-infrared ray on full-thickness skin wound healing in rats. Exp Biol Med 2003;228:724–729.
11. Ikeda Y, Biro S, Kamogawa Y, et al. Repeated sauna therapy increases arterial endothelial nitric oxide synthase expression and nitric oxide production in cardiomyopathic hamsters. Circ J 2005;69:722–729.
12. Yu SY, Chiu JH, Yang SD, et al. Biological effect of far-infrared therapy on increasing skin microcirculation in rats. Photodermatol Photoimmunol Photomed 2006;22:78–86.
13. Beever R. Far-infrared saunas for treatment of cardiovascular risk factors: Summary of published evidence. Can Fam Physician 2009;55:691–696.
14. Masuda A, Koga Y, Hattanmura M, et al. The effects of repeated thermal therapy for patients with chronic pain. Psychother Psychosom 2005;74:288–294.
15. Masuda A, Kihara T, Fukudome T, et al. The effects of repeated thermal therapy for two patients with chronic fatigue syndrome. J Psychosom Res 2005;58:383–387.
16. Su LH, Wu KD, Lee LS, et al. Effects of far infrared acupoint stimulation on autonomic activity and quality of life in hemodialysis patients. Am J Chin Med 2009;37:215–226.
17. Avis NE, Legault C, Coeytaux RR, et al. A randomized, controlled pilot study of acupuncture treatment for menopausal hot flashes. Menopause 2008;15:1070–1078.
18. Borud EK, Alræk T, White A, Grimsgaard S. The acupuncture treatment for postmenopausal hot flushes (Acuflash) study: Traditional Chinese medicine diagnoses and acupuncture points used, and their relation to the treatment response. Acupunct Med 2009;27:101–108.
19. Povolny B. Acupuncture and traditional Chinese medicine: An overview. Tech Reg Anesth Pain Manag 2007;11:141–147.
20. Tsao LI, Su MC, Hsiao PJ, et al. The longitudinal effects of a perimenopausal health education intervention on the midlife women in Taiwan. Maturitas 2007;57:296–305.

21. Tsao LI, Huang KE. Effectiveness of a perimenopausal health education intervention for mid-life women in northern Taiwan (#MS03-21-LW). Patient Educ Couns 2004;54: 321–328.
22. Park J, Linde K, Manheimer E, et al. The status and future of acupuncture clinical research. J Altern Complement Med 2008;14:871–881.
23. Kawakita K, Shinbara H, Imai K, et al. How do acupuncture and moxibustion act? Focusing on the progress in Japanese acupuncture research. J Pharmacol Sci 2006;100:443–459.
24. Freedman RR. Hot flashes: Behavioral treatments, mechanisms, and relation to sleep. Am J Med 2005;118:124–130.
25. Deecher DC, Dorries K. Understanding the pathophysiology of vasomotor symptoms (hot flushes and night sweats) that occur in perimenopause, menopause, and postmenopause life stages. Arch Womens Ment Health 2007;10:247–257.
26. Wyon Y, Lindgren R, Lundeberg T, Hammar M. Effects of acupuncture on climacteric vasomotor symptoms, quality of life, and urinary excretion of neuropeptides among postmenopausal women. Menopause 1995;2:3–12.
27. Yano T, Kato B, Fukuda F, et al. Alterations in the function of cerebral dopaminergic and serotonergic systems following electroacupuncture and moxibustion applications: Possible correlates with their antistress and psychosomatic actions. Neurochem Res 2004;29:283–293.
28. Takayama S, Seki T, Watanabe M, et al. Changes of blood flow volume in the superior mesenteric artery and brachial artery with abdominal thermal stimulation. Evid Based Complement Alternat Med 2011;2011:214089.
29. Uchida S, Hotta H. Acupuncture affects regional blood flow in various organs. Evid Based Complement Alternat Med 2008;5:145–151.
30. Low DA, Davis SL, Keller DM, et al. Cutaneous and hemodynamic responses during hot flashes in symptomatic postmenopausal women. Menopause 2008;15:290–295.
31. Hoikkala H, Haapalahti P, Viitasalo M, et al. Association between vasomotor hot flashes and heart rate variability in recently postmenopausal women. Menopause 2010;17:315–320.
32. Romanovsky AA. Thermoregulation: Some concepts have changed. Functional architecture of the thermoregulatory system. Am J Physiol Regul Integr Comp Physiol 2007;292: R37–R46.
33. Zhang W, Kanehara M, Ishida T, et al. Preventive and therapeutic effects of acupuncture on bone mass in osteopenic ovariectomized rats. Am J Chin Med 2004;32:427–443.
34. Feng Y, Lin H, Zhang Y, et al. Electroacupuncture promotes insulin-like growth factors system in ovariectomized osteoporosis rats. Am J Chin Med 2008;36:889–897.
35. Zhang X, Peng Y, Yu J, et al. Changes in histomorphometric and mechanical properties of femurs induced by acupuncture at the Shenshu point in the SAMP6 mouse model of senile osteoporosis. Gerontology 2009;55:322–332.
36. Zhao LH, Nong ZN, Zhong X, et al. Effects of warm needle moxibustion on bone mass density and biochemical indexes of bone metabolism in patients of postmenopausal osteoporosis [in Chinese]. Zhongguo Zhen Jiu 2008;28:897–900.

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