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Menopausal Symptom Management With Acupuncture For Women With Breast Cancer

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Abstract

Background: Hormone therapy is often used for menopausal symptoms, yet non hormonal interventions are the focus when treating menopausal symptoms induced by chemotherapy. A significant need exists for menopausal symptom relief for women following treatment for breast cancer.

Objective: To test acupuncture for menopausal symptom relief for women following treatment for breast cancer as well as changes in ovarian hormones and quality of life.

Setting: The study was conducted through the Yale University. Data were collected in the General Clinical Research Center at Yale.

Methods/Design: Randomized, placebo-controlled, clinical trial study.

Participants: 39 women experiencing hot flashes following treatment for breast cancer were assigned to one of three groups: Specific Acupuncture (n=16), Non Specific Acupuncture (n=17), or Enhanced Usual Care (n=6).

Intervention: The experimental treatment consisted of specific acupuncture points related to menopausal symptoms. The placebo treatment in this study consisted of acupuncture at points identified as irrelevant to the symptoms of menopause. The control group received educational materials related to symptom management and healthy life activities.

Primary Outcome Measures: Hot flash frequency over time, quality of life, and ovarian hormone levels.

Results: Both acupuncture groups demonstrated a reduced average number of hot flashes; the control group did not show a reduction in hot flashes. The Specific Acupuncture group experienced an average of three hot flashes fewer per day at study end, compared to the control group. There was no significant difference in average quality of life scores across the three groups. The average difference in ovarian hormone measurements across time was not different (p=0.542).

Conclusion: All women in the study experienced reduction in hot flash frequency with greater reduction in the acupuncture groups, suggesting participants benefited from study membership. It may be that symptom monitoring by daily symptom recording impacts symptom perception in a positive way.

Background

The risks and benefits of acupuncture treatment are well documented in traditional Chinese professional literature as well as in the National Institutes of Health Consensus Statement on Acupuncture [4]. Specifically, acupuncture is identified as widely practiced in the United States; it has been shown in clinical trials to be useful in relieving dental pain, reducing nausea and vomiting associated with chemotherapy, and has been associated with pain reduction in a number of chronic conditions along with allopathic treatments.

Acupuncture is proposed as an alternative or complementary treatment for menopause symptom relief based on the theory that acupuncture induces β -endorphin release through specific points historically associated with “women’s complaints”. Additionally, endorphins are thought to be involved in producing hot flashes, thus explaining why β-endorphin release decreases vasomotor symptoms [5,6].

In previous studies, acupuncture has reduced the frequency and severity of hot flashes 30-50% [7-11]. Although acupuncture has been used for centuries for women's complaints in Traditional Chinese Medicine, the literature in western scientific journals regarding the use of acupuncture for menopausal symptom relief is sparse until recently. Wyon, et al. [7] used a clinical trial with subjects randomized to either an electroacupuncture or superficial acupuncture needle insertion, the researchers examined acupuncture’s influence on the outcome measures of vasomotor symptoms, quality of life, and urinary excretion of neuropeptides. Twenty-four women were randomized to either electroacupuncture at 2 Hz or superficial needle insertion at the same acupuncture points. Daily self report of hot flashes was used. The women rated severity of hot flashes from 1-3 (1=mild, 2=moderate, 3=severe). An investigator also rated the hot flash frequency and severity from interviews done monthly throughout the study period. The study had a one month baseline, two months of treatment and a three-month post treatment follow-up. Results indicate that hot flashes decreased by 50%, quality of life remained constant and urinary excretion of

neuropeptides decreased during treatment. A second clinical trial by Wyon et al. [12] examined acupuncture as compared to oral estradiol. They found that acupuncture reduced hot flashes by 50%. However, as one would expect, estradiol had a more profound effect in decreasing hot flashes.

Other researchers have investigated the use of acupuncture for menopausal symptom management [8-10,13,14]. Porzio et al.[8] conducted an open study of 15 patients who reported tamoxifen-related hot flashes using acupuncture on a weekly schedule for 3 months with monthly follow-up treatments. Some acupuncture points are reported but it is not clear if all patients received the same points beyond six specified points. Results were based on the Greene Menopause Index that included subscales related to anxiety, depression, somatic symptoms and vasomotor symptoms. Results indicated a significant improvement (pp

Ping, et al. [10] report clinical data on 56 women with “climacteric syndrome” although only 10 women were clearly identified as menopausal with the remaining cases classified as after hysterectomy and adnexectomy or irregular menstruation. The acupuncture points were identified. The acupuncture group (30 subjects) was compared to a Western medicine group (26) receiving estriol. Both groups showed significant improvement (p [9] conducted an open study of 22 patients who were experiencing hot flashes, disturbances in sleep and social activities. A significant decrease (pp=0.017); however, hot flash frequency (p=0.001) decreased significantly (p=0.017) in both groups. Treatment did not differentiate groups on the sleep parameter as measured by the Pittsburgh Sleep Quality Index. Vincent et al. [14] reported on a randomized clinical trial with 103 participants. The placebo acupuncture was given at non meridian sites. The hot flash score (frequency x severity) was not significantly different between groups, leading the authors to conclude that the type of acupuncture used was not more effective than the non meridian needling.

Our work began with a feasibility pilot study that included women (n=17) with naturally occurring menopause randomized to two groups to explore the effect of acupuncture on menopausal hot flashes [16]. Baseline symptoms were established by completion of daily symptom records for one month. An acupuncture treatment protocol was instituted for 3 months following baseline data collection with follow-up at 3 weeks post treatment. Results indicated a decrease in hot flash severity from the baseline month (x=1.5, 95% C.I., 0.9-2.0) to month 2 (x=1.0, 95% C.I., 0.6-1.4) to month 3 (x=0.4, 95% C.I. -1.3-2.0). This demonstrated a 33% reduction of hot flash severity (one rating point on a three point scale) for site specific acupuncture. No women in the treatment group withdrew from the pilot study, but one participant in the control group withdrew after 11 weeks to seek treatment for hot flashes. Analysis of baseline data plus anecdotal reports from participants who found one month baseline data collection to be burdensome resulted in the decision to collect baseline symptom data in amenorrheic women for one week only in the present study.

Methods

Setting

This randomized, placebo-controlled, clinical trial study was conducted through the Yale University School of Nursing. Data were collected in the National Institutes of Health funded General Clinical Research Center (GCRC) associated with Yale School of Medicine and Yale New Haven Hospital (YNHH). The study was approved by the Yale University Institutional Review Board (IRB). Interviews, acupuncture treatments, educational sessions, and laboratory test specimen collection for all study participants took place at the GCRC.

A total of 39 women experiencing hot flashes following treatment for breast cancer were recruited. All participants were English speaking, had self-identified the menopausal symptom of hot flashes following treatment for breast cancer (stage I or II), were not currently taking hormonal supplementation, herbal remedies or other non hormonal pharmacologic remedies for menopause symptoms. To ensure sufficient wash-out effect, participants were required to discontinue use of hormones, herbs, or acupuncture for at least 3 months prior to enrollment in the study. Because clinical depression effects quality of life measurements, women with diagnosed clinical depression were excluded.

Intervention

Following study protocol explanation and after obtaining written informed consent, participants enrolled in the study and were randomized to one of three groups: Specific Acupuncture, Non Specific Acupuncture, or Enhanced Usual Care. All subjects were then interviewed to obtain demographic information including information on breast cancer history and current treatment. The Kupperman Index was used to screen for menopause symptoms as well as provide baseline data [17]. The Center for Epidemiological Studies Depression (CES-D) scale was administered to screen for depression at the enrollment session [18].

Experimental Group (Specific Acupuncture) The experimental acupuncture treatment consisted of specific acupuncture body points related to the menopausal symptoms, such as hot flashes, mood changes, sleep disturbances, loss of concentration, joint pain, headache and nervousness. There were eight, 20-30 minute acupuncture treatments over the course of 12 weeks. A certified and licensed acupuncturist performed all of the treatments. Each acupuncture treatment occurred once a week for four weeks, followed by once every other week for eight weeks. The pattern is similar to the intervals used by Wyon et al.[7] and Cohen et al [19].

Placebo Group (Non Specific Acupuncture) To meet the need for an appropriate placebo group in acupuncture studies, Birch proposed the use of a non specific needling procedure, defined as shallow acupuncture needle insertion at identified acupuncture points thought to be irrelevant to the condition being treated [20]. The placebo control acupuncture treatment in this study consisted of controlled needling at acupuncture points identified in the literature as irrelevant to the symptoms associated with the menopause. Frequency and duration of visits was the same as the experimental group.

Control Group (Enhanced Usual Care) The Enhanced Usual Care control group received educational materials related to menopausal symptom management and healthy life activities at a 30-40 minute session at each intervention point. There were eight visits over 12 weeks. The eight visits occurred once a week for four weeks and then once every other week for eight weeks. Materials were prepared from published sources concerning menopause symptom management. The educational sessions were taught by either a women's health nurse practitioner or a certified nurse midwife.

Objectives

We hypothesized that participants receiving site specific acupuncture would report a decrease in the frequency of hot flashes. We also sought to explore the effect of acupuncture on other menopausal symptoms.

Outcomes

Demographic Data A Demographic Data and Follow-up Form was used to gather information on menstrual history, breast cancer diagnosis, stage and treatments, as well as basic information on diet, exercise, medication (including vitamins and nutritional supplements), and other self healing practices.

Hormone Assay. Menopausal status was monitored by assays of FSH and LH. FSH and LH were measured upon entry into the study, at the end of the treatment phase and at the end of the three month follow up phase. Based on the work of Wyon et al., LH was expected to decrease over the course of the study in the experimental acupuncture group [7].

Menopause Symptom. A daily Symptom Diary was used to gather data on the frequency of menopausal symptoms (i.e., hot flashes, mood changes, sleep disturbances, and loss of concentration). The study design included a one week baseline recording of menopausal symptoms, three months of daily symptom recording during the treatment phase and once a week recording during the follow up phase for three months following treatment. A second measure for menopausal symptom experience was the Kupperman Index which was administered by the interviewer five times over the course of the study. Use of two methods for symptom recording provided concurrent validity of the symptom experience.

Quality of Life. Quality of Life was measured using The Menopause-Specific Quality of Life Questionnaire (MENQOL), a 30-item questionnaire. The MENQOL has four domains: vasomotor, physical, psychosocial, and sexual health and a global quality of life question. Hilditch, et al. indicate high face and content validity [21]. Test-retest reliability (intraclass correlation coefficients) was 0.81 (physical), 0.79 (psychosocial), 0.70 (sexual) and 0.55 (quality of life). The vasomotor domain had a lower coefficient of 0.37. However, vasomotor symptoms were measured in the study by both daily diaries and periodic interviewer ratings (Kupperman Index), which is why the low reliability was of less concern. The MENQOL was administered upon entry into the study, at the end of the treatment phase and at the end of the three month follow up phase.

Sample Size

A pilot study provided trend data to calculate real effect size for a three group repeated measures design with change in hot flash severity as the primary variable (p=0.05) was conducted. The calculations were based on Kronenberg's study of the general population of menopausal women's hot flash severity ratings of severe (3) = 26% (n=68), moderate (2) = 22% (n=57), mild (1) =12% (n=31), and a compromise between the generous effect size of a 50% reduction in hot flashes with acupuncture treatment found by Wyon, et al. and a 30% reduction in hot flashes in the Cohen et al. feasibility pilot study [7,19,22]. Therefore, to obtain an effect size of 40% at 80% power, nine subjects per group or a total of at least 27 subjects were needed.

Randomization and Allocation

Each of the 39 participants was assigned to one of three experimental groups: Specific Acupuncture (n=16), Non Specific Acupuncture (n=17), or

Enhanced Usual Care (n=6). Randomization was done via sealed envelope technique. The Primary Investigator (PI) set-up the randomization scheme prior to anyone being enrolled in the study and the Program Director, following subject enrollment, opened the envelope and communicated group assignment to the acupuncturist or the Enhanced Usual Care nurse practitioner/certified nurse midwife performing the intervention.

Blinding

Due to the nature of acupuncture treatments and the Enhanced Usual Care group, it was not feasible to blind the practitioner or the participants. Since the acupuncturist was not blind to the type of acupuncture treatment, the specific vs. non specific intervention arms were employed to discern the unique effect of the acupuncture using body points specific to menopausal symptoms. The PI and statistician were both blinded to group assignment.

Statistical Analysis

Descriptive statistics were generated for all variables in the study. Although a repeated measures analysis of variance (ANOVA) model is often used to examine data between and among treatment groups, the symptom diary data did not provide evidence to suggest that the assumptions of normality were adequately met. The frequency data exhibit strong positive skewness. Therefore, the ANOVA model was not the best choice and other methodological strategies were investigated. Considering the possible entries for frequency are 0-3 (non-negative integers), we implemented a model that treats the data as discrete rather than continuous. A piecewise linear function was used to relate a patient's average frequency to time; this approach was chosen because of its ability to describe a wide range of (average) frequency vs. time relationships. This structure accounts for over-dispersion across the Poisson measurements of all subjects at a fixed time period and allows for the determination of the magnitude and duration of a treatment effect, if one exists [23]. Quality of life data were examined using a repeated measures ANOVA model. A p-value of

Results

It is important to note the details about drop-outs in this study. No participants in either treatment group (Specific or Non Specific acupuncture) dropped out of the study. However, 10 participants randomized to the Enhanced Usual Care group dropped-out immediately after receiving their randomization. Although the analysis plan used an intent-to-treat analytic approach, there were no baseline data for these participants.

Participant recruitment began in January 1999 and continued through December 2001, when the study was closed to new enrollment. Follow-up on participants was complete in June 2002.

Thirty-nine participants completed the study. Illustration 1 provides selected baseline demographics. As would be expected for a randomized trial, ANOVA tests reveal no significant difference in mean age upon entry across the three groups (p=0.064), as well as no significant difference in mean menopause age across the three groups (p=0.849).

As described above, a piece-wise Poisson regression model was developed to better describe the mean hot flash frequency behavior over time, the primary outcome under investigation. The results of this model are that acupuncture, whether site specific or controlled needling, reduces the average number of hot flashes over time. However, the education treatment in the Enhanced Usual Care group did not reduce hot flashes. Data from the piecewise linear regression model are summarized in Illustration 2. The data there show the expected difference in average hot flash frequency (HFF) at day 1, 7, 14, 42, and 91 of the study. For example, the first row of Illustration 2 examines expected difference in Specific Acupuncture versus Enhanced Usual Care HFF means. On Day 1 the expected difference is zero, but at day 91 this difference is three hot flashes. This means that the Specific Acupuncture group experienced an average of three hot flashes fewer per day by the end of the study, compared to the Enhanced Usual Care Group. Of note, the first time the treatment group gained an average improvement greater than one over the Enhanced Usual Care group was on Day 13, with an increased improvement of two hot flashes per day on Day 38, and three hot flashes per day on Day 65. The remainder of the illustration is interpreted this same way.

Both the Specific and Non Specific Acupuncture groups experienced a significant decrease in average hot flash frequency over the first nine weeks of treatment; at each time after this nine week period the average hot flash frequency¾for both treatment groups¾ is less than the corresponding baseline average with p<0.01. After this period the average hot flash frequency did not significantly increase or decrease for either treatment group, thus maintaining the decreased average frequency accrued in the first eight-to-nine weeks. The magnitude of the common decrease in hot flash frequency over the first nine weeks was, on average, 2.3 hot flashes. The decrease in the Non Specific Acupuncture group was not

significantly different from that of the Specific Acupuncture group. The baseline measurements for the Non Specific Acupuncture group (n=17) were significantly higher than those for the Specific Acupuncture group (n=16) by an average of two hot flashes per day.

The quality of life index, which is divided into the vasomotor, psychosocial, physical, and sexual domain, was measured for each subject at Weeks 1, 11, and 26. Illustration 3 displays the week 1 scores averaged within each group. Individual ANOVA tests performed within each domain for all three time periods did not reveal any significant difference in average quality of life score across the three groups.

Paired t-tests reveal the average difference in FSH and LH measurements across the following time intervals were not statistically significantly different from zero (p=0.542). These tests were conducted for the Specific Acupuncture group and the Non Specific Acupuncture group separately, as well across all participants. No significant mean difference was found in any case.

Conclusion

Both Specific and Non Specific Acupuncture decreased hot flash frequency in these participants, while the Enhanced Usual Care group did not exhibit a reduction. Our results indicate acupuncture holds promise for hot flash symptom frequency and severity reduction in women with a history of breast cancer. A 30% reduction in symptoms or symptom severity is clinically significant, especially in this group who are known to experience heightened menopause symptoms as a result of past or ongoing cancer treatment. We did not measure symptom distress in this study, which may be an important indicator for a future study. Of note, FSH and LH levels did not differ from baseline across the study in any group. This suggests the experimental treatment had no impact on these hormone levels.

One of the challenges in acupuncture randomized clinical trials is how to select a control group. In an attempt to explore this further, we chose to use both an enhanced usual care group with no acupuncture and a non specific acupuncture group, which did not include menopause specific sites. There were no significant differences in results between the Specific and the Non Specific Acupuncture groups. It may be that the general acupuncture points selected for our study rendered tonic effects that changed women's symptom interpretation, or that acupuncture in general produced results for the participants. In future studies, other sham acupuncture treatments might provide a better control condition by which to measure the experimental or site specific acupuncture treatment. The Enhanced Usual Care group, compromised some by the high drop-out rate, seemed to be the more "authentic" control group in this study.

Demographic characteristics of study participants were not significantly different among the three groups. Of interest, more than half of each group reported tamoxifen use and this mirrors other reports of women post primary breast cancer treatment at the time of the study. Since it is known that tamoxifen and like pharmaceuticals increase frequency and severity of hot flashes, our results support a need for continued study of alternatives for hot flash management in breast cancer survivors. Mean age of menopause in our sample was young than for women with naturally occurring menopause ($x = 51.4 \pm 4$ years), lending support to the notion that breast cancer treatment leads to premature menopause. Coupled with the use of adjuvant therapy such as tamoxifen or other hormonal therapies, it is reasonable to assume that symptoms of menopause in breast cancer survivors may last longer than in women without cancer histories. Prospective, longitudinal study of large numbers of breast cancer survivors is needed to firmly establish their menopause symptom profiles.

Quality of life scores (vasomotor, psychosocial, and sexual) were not significantly different across the study in any group. There was a significant difference in the average physical quality of life scores from Week 1 to Week 11 in the Acupuncture Specific treatment group. This indicates the acupuncture treatment had an impact on physical symptoms separate from hot flashes. More study of physical symptoms is necessary to understand the importance of this finding. However, each group exhibited a downward trend in scores from Week 1 to Week 11.

All women in the study, regardless of group assignment, experienced significant reduction in hot flash and night sweat frequency. This suggests our participants benefited from study membership, and it may be that symptom monitoring by daily symptom recording impacts symptom perception in a positive way. Others have noted the impact of symptom monitoring on atopic eczema, chronic headaches, bulimia nervosa, and urinary incontinence [24-28]. Moreover, acupuncture decreased hot flashes beyond the level found in the Enhanced Usual Care group.

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Illustrations

Illustration 1

Demographic summaries for participants according to experimental group.

	Acupuncture (Specific)	Acupuncture (Non Specific)	Enhanced Usual Care (Enhanced Usual Care)
n	16	17	6
mean age entering study	53.9	55.8	48.2
mean menopausal age	45.1 (*n* = 12)	46.6 (*n* = 15)	45.8 (*n* = 4)
percent on tamoxifen	62.5 (10/16)	58.8 (10/17)	66.7 (4/6)

Illustration 2

Piecewise linear negative binomial regression model summary for the comparison between treatment and Enhanced Usual Care groups, Specific and Non Specific Acupuncture groups, and Non Specific Acupuncture and Enhanced Usual Care groups. Illustration entries represent expected differences in average HFF for a particular day; standard errors for these estimates are included in parentheses.

	Difference in Average HFF				
	Day 1	Day 7 (Baseline)	Day 14 (End of 1st Tx week)	Day 42 (Tx frequency decreases)	Day 91 (End of study)
Specific Acupuncture vs. Enhanced Usual Care	0.03 (1.38)	-0.63 (0.78)	-1.04 (0.50)	-2.17 (0.34)	-3.00 (0.90)
Specific Acupuncture vs Non Specific Acupuncture	-1.24 (1.28)	-1.81 (0.60)	-1.71 (0.47)	-1.51 (0.29)	-1.63 (0.55)
Non Specific Acupuncture vs Enhanced Usual Care	1.23 (1.35)	1.19 (0.81)	0.68 (0.53)	-0.66 (0.35)	-1.36 (0.82)

Illustration 3

Week 1 quality of life scores averaged within each group for each of the four quality of life categories: vasomotor, psychosocial, physical, and sexual.

	Vasomotor	Psychosocial	Physical	Sexual
Acupuncture (Specific)	5.60	3.47	3.47	3.00
Acupuncture (Non Specific)	5.02	2.99	3.51	3.69
Enhanced Usual Care	5.33	3.31	2.99	3.17

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