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Comparison of Two Effective Methods in Postmenopausal Hot Flash Therapy: Acupuncture versus Hormone Therapy

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Abstract

Background: Postmenopausal hot flash is a common disease amongst women with high prevalence of 75%. Hormone Replacement Therapy (HRT) is a well-known relief of symptoms which has disadvantages such as side effects and contraindication for certain types of hormone related diseases and breast or Estrogen related cancers. One of the alternatives is acupuncture which is an East Asian and more specifically Chinese method. In this study hormone therapy and acupuncture effectiveness have been compared in postmenopausal hot flash treatment. **Materials and Methods:** This study is aimed to initially diagnose vasomotor symptoms such as elevated body temperature, palpitation, headache and perspiration. Afterwards, assessment and finally comparing the efficacy of two methods for each symptom treatment have been carried out. In this clinical trial study, 20 climacteric female samples participated. Two study and control groups have been formed and each method efficacy has been evaluated on each of four major vasomotor symptoms. **Results:** For all postmenopausal vasomotor symptoms, acupuncture and HRT had similar notably high relief of symptoms effectively; namely in hot flash 90% and 85%, in palpitation 65% and 70%, in perspiration 77.77% and 81.25%, and in headache 50% and 81.3%, respectively. Although in all fields except hot flashes, HRT had slightly better success. **Conclusion:** This survey pointed out that acupuncture is as effective as hormone therapy in relief of symptoms hot flash for postmenopausal women. Further researches are needed to assess the clear side effects of acupuncture method. [GMJ.2015;4(2):83-89]

Keywords: Acupuncture; Hormone Replacement Therapy; Hot Flashes; Iran; Menopause

Introduction

Menopause is generally indicated in women of the age 50 introducing differences in their menstruation pattern until it finally stops which is due to decrease of ovarian hormones (Estrogen and Progesterone) secretion [1]. In other words, simultaneous

absence of menstruation and Follicular Secretion Hormone (FSH) of upper than 40 mUnit/lit is an indication of menopause [2]. Across Iran, mean age of menopause has been reported 50.4 years [3]. While, another research in Tehran, capital of Iran, confirmed that mean age of menopause was 47.71 [4]. A common symptom among perimenopausal and

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postmenopausal women is sense of intense warmth in the areas of face, neck and chest which is known as hot flash [5]. The prevalence of flashes are different regarding to study population as it was diagnosed in 70% of climacteric Europeans and North Americans [6, 7] but only in nearly 34% of Iranians [8] and 5-18% of South East Asians [9, 10]. Hot flash is normally accompanied by other Vasomotor Symptoms (VMS) such as perspiration, palpitation and headache [11]. Hot flash and other vasomotor symptoms reduce women quality of life notably and force them to use medical or physical symptom relief methods [6, 12]. One of the most applicable methods is Hormone Replacement Therapy (HRT) in which either Estrogens (for women with uterus) or progestins and Estrogens together (for women without uterus) are used for treatment [13, 14]. Although this method proved to be aiding in many cases, it has some application restrictions and side effects. The most well-known side effects are risk of breast and endometrial cancers and heart attack. Also, contraindications are for breast or Estrogen-related cancers, undiagnosed vaginal bleeding, endometrial hyperplasia, blood clotting disorder, hypertension, liver disease and hypersensitivity to active or excipient compounds used in HRT [15, 16]. In order to avoid the side effects or in cases of restriction, many other methods can be applied but there are many uncertainties for a firm replacement [17, 18]. One of indirect approaches is the use of antidepressants recently approved by FDA. Another way is to alleviate hot flash and VMS is botanical and soy medical products. But this may show adverse effects or in some cases less efficacy than placebo [19]. One eastern method that nowadays has drawn much global attention is acupuncture. Major applied subdivisions of acupuncture for hot flash and VMS treatment are Traditional Chinese Method (TCM) [20], moxibustion [21], Electro-acupuncture [22] and sham acupuncture [23]. Many surveys have been carried out to find whether this treatment is efficient [24-26] and suitable for replacement with HRT [11, 27]). One of the most recent Scandinavian researches showed no statistical significant difference between control (advice on self-care)

and study group (advice on self-care plus 12 weeks of acupuncture); however, slight advantage of acupuncture was reported [28].

This study aims to compare HRT and acupuncture efficacy for treatment of hot flash and VMS in Tehran, capital of Iran.

Materials and Methods

In this clinical trial study, 20 climacteric women referring to "Boali" hospital gynecology clinic have been randomly chosen as study population. Two parallel arms with 10 members (not matched by baseline characteristics, i.e. weight, drug history, etc.) have been defined; one study arm and one control arm. The control arm has been provided with hormone therapy medicine that was 0.625mg oral Estrogen (AboReihan, Iran) along with 2.5mg Medroxy Progesterone Acetate (AboReihan, Iran) for 12 weeks. On the other hand, the study arm has been treated with TCM acupuncture method by Que Chi (internal energy) control which was focused on ear. 2 to 3 main points along with 1 to 2 additional points have been chosen. Needles were in place for 40 minutes, no stimulation carried out by any means. Sessions took place twice a week for 5 weeks [29].

For hot flash and other vasomotor symptoms, four indicators have been chosen: count of flashes, palpitation, perspiration and headache. Initially, each symptom has been diagnosed in both groups. In the next step, treatments have been applied to control and study groups and after 12 weeks data acquisition has been performed by a blinded specialist to evaluate the efficacy of each method. Data were collected in each arm for four main VMS domains. In each domain, classification was done on percentile ranking basis by physical examination of each patient so that each participant must be a member in one of 4 groups in each domain; these groups include:

- 1- 100%: complete relief of symptoms
- 2- 75%: remarkable relief of symptoms
- 3- 50%: slight relief of symptoms
- 4-25%: unremarkable relief of symptoms

The study was approved in the ethical committee of Azad University and written informed consent to participate in the study. This study

is also registered in IRCT (Iranian Registry of Clinical Trials). This trial is registered under RCT ID: IRCT2014110719842N1.

Finally, two arms have been compared statistically with Chi-square test by SPSS V.13 software. AP value less than 0.05 was considered significant.

Results

The mean age of subjects was 50.6 ± 2.5 . All women were married.

1. Control Arm

1.1. Count of Flashes

All 10 members of control arm had flashes, which HRT healed 6 (60%) completely, 3 (30%) remarkably and 1 (10%) unremarkably (Table 1.)

1.2. Palpitation

Five participants in control arm had palpitation difficulties, which 2 (40%) had complete, 1 (20%) had remarkable, 1 had slight and 1 had unremarkable relief of symptoms.

1.3. Perspiration

Eight out of 10 members of control arm had perspiration problems, which 5 (62.5%) of them had complete, 1 (12.5%) remarkable, 1 slight and 1 unremarkable relief of symptoms.

1.4. Headache

6 females in control group had headache, 3 (50%) healed completely, 2 (33.3%) remarkably and 1 (16.7%) medially.

2. Study Arm

2.1. Count of Flashes

All 10 members of study arm had hot flash, which 6 (60%) had complete and 4 (40%) had remarkable alleviation.

2.2. Palpitation

In this domain, 5 out of 10 participants had palpitation, which 1 (20%) person showed complete relief of symptoms, 2 (40%) showed remarkable relief of symptoms, 1 showed slight relief of symptoms and 1 showed unremarkable relief of symptoms (Table 1).

2.3. Perspiration

This domain had 9 members, which 4 (44.4%) of them completely, 3 (33.3%) of them remarkably 1 (11.1%) medially and 1 unremarkably healed.

2.4. Headache

This domain had 4 members; 1 (25%) healed completely, 1 medially and 2 (50%) unremarkably.

Discussion

Count of Flashes

This was the only domain which acupuncture efficacy showed higher average percentage. However, for complete relief of symptoms, power of both methods was the same (6 out of 10 patients) but remarkable relief of symptoms was more in acupuncture method. This could be due to the highest efficacy of acupuncture in treatment of elevated body temperature cases. It should be noted that in this domain, both methods had their highest efficacy that might be as a result of placebo effect because all patients referring to the clinic highly focused on finding a treatment for their hot flash.

Palpitation

In this domain, HRT had more 100 % success rate (2 of 5 against 1 of 5) and average efficacy. This result may be caused by the difference in nature of two methods as acupuncture affects neural network but HRT directly transfers its effect to the blood; thus, longer time may have been needed for acupuncture treatment comparing HRT. Such a point needs further research consideration.

Perspiration

For perspiration, HRT showed better full success (5 of 8 against 4 of 9) but worse remarkable relief of symptoms (1 of 8 against 3 of 9). The average efficacy was higher for HRT but the slight difference should be due to larger numbers of symptomatic patients in control group.

Headache

In this domain, severe size difference of control and study groups (6 against 4) caused the greatest difference between efficacy average of HRT and acupuncture in all domains. Moreover, complete and remarkable relief of symptom rates was higher in control arm (3 against 1 and 2 against none, respectively).

Table1. Relief of VMS Symptoms in Control and Study Arms

Group	Symptom	Control arm (HRT)		Study arm (Acupuncture)		P value
		N	%	N	%	
Hot flash	Complete relief of symptoms	6	60	6	60	> 0.05
	remarkable relief of symptoms	3	30	4	40	
	slight relief of symptoms	0	0	0	0	
	unremarkable relief of symptoms	1	10	0	0	
	Count of symptomatic patients in field	10	100	10	100	
Palpitation	Complete relief of symptoms	2	40	1	20	> 0.05
	remarkable relief of symptoms	1	20	2	40	
	slight relief of symptoms	1	20	1	20	
	unremarkable relief of symptoms	1	20	1	20	
	Count of symptomatic patients in field	5	100	5	100	
Perspiration	Complete relief of symptoms	5	62.5	4	44.5	> 0.05
	remarkable relief of symptoms	1	12.5	3	33.3	
	slight relief of symptoms	1	12.5	1	11.1	
	unremarkable relief of symptoms	1	12.5	1	11.1	
	Count of symptomatic patients in field	8	100	9	100	
Headache	Complete relief of symptoms	3	50	1	25	> 0.05
	remarkable relief of symptoms	2	33.3	0	0	
	slight relief of symptoms	1	16.7	1	25	
	unremarkable relief of symptoms	0	0	2	50	
	Count of symptomatic patients in field	6	100	4	100	

In this survey, HRT treatment had better efficacy for 3 of 4 VMS domains (palpitation, perspiration and headache) which confirms the findings of two systematic reviews by Cho and Lee [26, 27]. In these two reviews, 19 and 17 electronic databases have been reviewed, respectively. In Cho review, eleven studies which included 764 individual cases were systematically reviewed. The methodological quality of trials varied substantially. Six trials compared acupuncture treatment to sham or placebo acupuncture. Only one study using a non-penetrating placebo needle found a significant difference in the severity outcomes of hot flashes between groups (mean difference,

0.48; 95% CI, 0.05-0.91). Five studies reported a reduced frequency of hot flashes within groups; however, none found a significant difference between groups. An analysis of the outcomes of these trials comparing acupuncture with hormone therapy or oryzanol for reducing vasomotor symptoms showed that acupuncture was superior. Three RCTs reported minimal acupuncture-related adverse events. Cho finally concluded that there is no evidence from RCTs that acupuncture is an effective treatment in comparison to sham acupuncture for reducing menopausal hot flashes. Some studies have shown that acupuncture therapies are better than hormone therapy for reducing vasomotor symptoms. However,

the number of RCTs compared to a non-penetrating placebo control needle or hormone therapy was too small and the methodological quality of some RCTs was poor. Further evaluation of the effects of acupuncture on vasomotor menopausal symptoms based on a well-controlled placebo trial is therefore warranted. This is exactly in line with our study. In Lee study, totally six RCTs could be included. Four RCTs compared the effects of acupuncture with penetrating sham acupuncture on non-acupuncture points. All of these trials failed to show specific effects on menopausal hot flash frequency, severity or index. One RCT found no effects of acupuncture on hot flash frequency and severity compared with penetrating sham acupuncture on acupuncture points that are not relevant for the treatment of hot flashes. The remaining RCT tested acupuncture against non-penetrating acupuncture on non-acupuncture points. Its results suggested favorable effects of acupuncture on menopausal hot flash severity. However, this study was too small to generate reliable findings. Lee concluded that Sham-controlled RCTs fail to show specific effects of acupuncture for control of menopausal hot flashes. More rigorous research seems warranted. Our findings showed exactly same points and confirmed these findings.

The only domain which acupuncture had better efficacy was hot flash which is in line with findings of Borud et al [25, 28]. First, Borud and his team in 2009 found that hot flash frequency decreased by 5.8 per 24 hours in acupuncture group (n = 134) and 3.7 per 24 hours in the control group (n = 133), a difference of 2.1 ($P < 0.001$). Hot flash intensity decreased by 3.2 units in the acupuncture group and 1.8 units in the control group, a difference of 1.4 ($P < 0.001$). The acupuncture group experienced statistically significant improvements in vasomotor, sleep and somatic symptoms dimensions of Women's Health Questionnaire compared to the control group. Urine calcitonin gene-related peptide excretion remained unchanged from baseline to week 12. In this study, they concluded that acupuncture plus self-care can contribute to a clinically rel-

evant reduction in hot flashes and increased health-related quality of life in postmenopausal women which confirms our findings.

Borud and his team in 2010 found that from baseline to 6 months, the mean reduction in hot flash frequency per 24 hours was 5.3 in acupuncture group and 5.0 in control group, an insignificant difference of 0.3. In 12th months, the mean reduction in hot flash frequency was 6.0 in acupuncture group and 5.8 in control group, an insignificant difference of 0.2. Differences in quality-of-life scores were not statistically significant in 6th and 12th months. They concluded that statistically significant differences between study groups found in 12th weeks were no longer present in 6th and 12th months. Acupuncture can contribute to a more rapid reduction in vasomotor symptoms and increase in health-related quality of life in postmenopausal women but probably has no long-term effects. Our study did not assess the effects of time but in terms of method effectiveness, these two studies are in line.

Conclusion

As mentioned previously, acupuncture compared to HRT did not shown statistically meaningful difference in relief of vasomotor symptoms. This may occur due to two main reasons:

- I) Extended treatment period required for acupuncture comparing to HRT
- II) Unequal symptomatic patients in each domain in each arm

Both these assumptions are subject to further investigation and research. However, excluding theories from facts in this survey, HRT had exiguous efficacy advantage over acupuncture. Thus, substitution of HRT by acupuncture shall come to aid in case of hormone contraindication and breast cancer. However, general replacement of HRT with acupuncture demands additional trials.

Conflicts of Interest

None declared.

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