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Review article

Traditional acupuncture for menopausal hot flashes: A systematic review and *meta*-analysis of randomized controlled trials

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ABSTRACT

Introduction: This study was conducted to evaluate the efficacy of traditional acupuncture (TA) for treatment of hot flashes (HFs) in *peri*-menopausal and post-menopausal women based on a systematic review of randomized controlled trials (RCTs).

Methods: The following international electronic databases: PubMed, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), China National Knowledge Infrastructure (CNKI), and four Korean medical databases were searched for randomized controlled trials (KISS; Korean-studies Information Service System, Korean Traditional Knowledge Portal, NDSL; National Discovery for Science Leaders, KiSTi; Korean Institute of Science and Technology Information, OASIS; Oriental Medicine Advanced Searching Integrated System). The Cochrane Collaboration's risk of bias was used for quality assessment. The efficacy outcomes were frequency and severity of HFs and quality of life were analyzed using the mean differences in the random effects model. The RevMan 5.3 program was used for *meta*-analysis.

Results: Eleven RCTs were included in this systematic review, and nine were included in the *meta*-analysis. Traditional acupuncture (TA) showed statistically significant improvement relative to sham acupuncture (SA) in HF severity without heterogeneity. However, HF frequency and quality of life (QOL) did not differ between TA and SA. Nevertheless, TA showed significant improvement of HF frequency and severity, and QOL when compared to the control (wait list or no treatment).

Conclusion: The evidence suggested that TA can improve HF in menopausal women and could be a potential treatment for menopausal women.

1. Introduction

Menopause is the permanent cessation of menstrual periods that naturally occurs in women. [1]. The entire early post-menopause lasts approximately 5 to 8 years, and studies of hormonal changes have shown that most notable vasomotor symptoms are most likely to occur in the first 2 years during early post-menopause [2]. Hot flashes, also known as hot flushes (HFs), are subjective sensations of heat in the face, neck, or chest. HFs are a common manifestation of vasomotor, menopausal, or climacteric symptoms. HFs are a form of flushing caused by reduced levels of estradiol that may be due to changes in temperature regulation by the hypothalamus. Almost a third of women report symptoms lasting up to 5 years after natural menopause, and HFs may persist for up to 15 years in 20% or more of all women [3]. Moreover, almost two-thirds of postmenopausal women experience HFs, and 10% to 20% find them very distressing [4].

Acupuncture is the insertion of needles into the skin and underlying tissues at particular sites, known as acupuncture points, for therapeutic purposes. In accordance with Korean Medicine, a theory of menopausal symptoms is predominantly related to a decline in kidney qi, especially kidney yin, kidney yang deficiency, or a combination of both, which is often diagnosed with concomitant syndromes associated with deficiencies in other organs [5]. However, the term kidney used in traditional medicine including Korean medicine, Chinese medicine and Japanese Kampo medicine, is different from that of the Western medicine, and it is often described as an organ in which the kidney store the essential substance of the human body to maintain balance in order to age well and live long. Preliminary data suggest that acupuncture may

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reduce vasomotor symptoms (VMS) by inhibiting the impact of the hypothalamic-pituitary-adrenal (HPA) axis on the hypothalamic-pituitary-ovarian (HPO) axis and by increasing the release of endogenous opioids, potentially influencing the functioning of the hypothalamic thermoregulatory center [6,7].

Acupuncture is a widely accepted and frequently recommended treatment method for menopausal HFs in Korean medical centers. However, systematic reviews have shown the effectiveness of acupuncture to be controversial. One systematic review found that acupuncture showed no specific effects on HFs in menopausal women [8], and another systematic review [9] and a recent *meta*-analysis [10] concluded that acupuncture reduced HF more than no intervention, but not greater than the effect of sham acupuncture. All forms of acupuncture treatments such as traditional acupuncture, electro-acupuncture, laser acupuncture, acupressure, moxibustion and acupoint catgut embedding were included in these reviews [9,10], and acupuncture with or without electrical stimulation were included in one systematic review [8].

Thus it is thought to be necessary to summarize randomized controlled trials (RCTs) with clearly defined patient and intervention for systematic review. To date, RCTs with diverse types of patients and intervention have been included for systematic review: Patients with HF caused by natural menopause and by medical menopause such as breast cancer were both included in a systematic review. And for the acupuncture treatment, not only the classical acupuncture which is defined as needling to acupoints of main meridians with skin penetration and no other stimulation that de-qi, but also other stimulation methods such as electric acupuncture, auricular acupressure were included in a previous review. Therefore, this systematic review was conducted to reorganize the PICO process of RCTs to assess evidence from RCTs for or against the effectiveness of traditional acupuncture as a treatment option for menopausal HFs.

2. Methods

2.1. Literature search

Databases were searched from their inception through December 20, 2016. The literature search was performed on December 21, 2016 by two investigators (Nam EY and Park JY), who are Korean medical doctors. A systematic literature search was performed using the following databases: PubMed, EMBASE, CENTRAL (The Cochrane Library), China Academic Journal Network Publishing Database, Korean-studies Information Service System, Korean Traditional Knowledge Portal, NDSL (National Discovery for Science Leaders), Korean Institute of Science and Technology Information and Oriental Medicine Advanced Searching Integrated System. The following keywords were searched: (“Acupuncture” OR “Acupressure” OR “Acupoint” OR “Meridian”) AND (“Menopause”) AND (“Hot flashes” OR “Hot flushes”) AND (“randomized controlled trial” OR “RCT”) (In English). (“针” OR “针刺” OR “刺法” OR “留针” OR “經穴” OR “經絡”) AND (“绝经” OR "更年" OR “围绝经期”) AND (“潮热” OR “烘熱”) AND (“随机” OR “對照”) (In Chinese). (“침” OR “자침” OR “경혈” OR “경락”) AND (“갱년기” OR “폐경” OR “난소부전”) AND (“안면홍조”) AND (“randomized controlled trial” OR “RCT”) (In Korean).

2.2. Study selection

Study selection was performed independently by two investigators (Nam EY and Park JY). Duplicate studies were excluded using Microsoft Excel by comparing the title, author, and year published. Inappropriate studies were excluded by examining the title and abstract. When articles contained insufficient information to make a decision regarding eligibility, Nam EY attempted to contact authors of the original reports to obtain further details.

2.3. Criteria for considering studies for this review

2.3.1. Types of studies

Randomized controlled trials (RCTs) of acupuncture for HFs in menopausal women were considered. Non-RCT studies including quasi-RCT, case studies, and experimental studies were excluded.

2.3.2. Types of participants

The patients selected were diagnosed with *peri*-menopausal or post-menopausal state with HFs. Studies of women with menopause induced by radiation or chemotherapy or women with breast cancer were excluded.

2.3.3. Types of intervention

The interventions selected involved traditional acupuncture with classic meridian points. Other forms of acupuncture treatments (electro-acupuncture, laser acupuncture, auricular acupuncture, scalp acupuncture, acupressure, acupuncture point catgut embedding, seven-star needle, etc.) were excluded. Studies that assessed the combined treatment effects of acupuncture with prescribed herbal remedies were excluded. However, if an acupuncturist decides it is necessary, additional other treatment modalities (infrared irradiation, moxibustion, manual stimulation (de qi), electrical stimulation of acupuncture at some acupuncture points, etc.) this could be added to traditional acupuncture.

2.3.4. Types of control

No restrictions were placed on the types of control. Placebo-controlled (sham acupuncture, non-acupuncture points), wait list, no treatment (usual care, self care advice, and wait list) were included.

2.3.5. Types of outcome measurements

The outcome measure was set to the frequency and severity of HFs at the end of treatment (EOT) as the primary outcome. HF frequency was defined as the number of HFs per day. The severity of HFs was measured by the Visual Analogue Scale (VAS) score, or graded from 1 to 3 or from 1 to 4, after which it was calculated by multiplying the HF frequency and severity on a daily basis. Quality of life (QOL) evaluated with any validated QOL instruments (the Menopause Rating Scale (MRS) [11], the Menopause-Specific Quality of Life questionnaire (MENQOL) [12], the Women’s Health Questionnaire (WHQ) [13], the Greene Climacteric Scale [14], etc.) was as the secondary outcome. A lower score of each scale indicated a high level of QOL and lower level of menopausal symptoms.

2.4. Data extraction

Data extraction was performed independently by two investigators (Nam EY and Park JY) and discrepancies were resolved through discussion. Data from the articles were extracted using a predefined data extraction form including sample size, age range, intervention, treatment duration, and outcome.

2.5. Risk of bias assessment

Risk of bias (ROB) assessment was independently performed by two reviewers (Nam EY and Park JY) using the Cochrane Handbook for