EDITORIAL

Searching for effective, nonhormonal treatments for vasomotor symptoms: is there a needle in the haystack?

Hot flashes and night sweats—also known as vasomotor symptoms (VMS)—are considered the hallmark of the menopausal transition. The prevalence rate of these symptoms has been reported to be between 60% and 85% in women during this period, although 10% to 20% of women may remained bothered by VMS in their late postmenopausal years. Vasomotor complaints of moderate to severe intensity have been shown to exert a negative impact on quality of life and overall functioning and linked to disrupted sleep, fatigue, lethargy, inability to concentrate, increased tension/irritability, anxiety, and depressive symptoms. Therefore, the benefits of a safe, efficacious, and well-tolerated therapy for menopause-related VMS could extend beyond the immediate symptomatic relief.

For decades, estrogen-based, menopausal hormone therapies (MHT) have been the treatment of choice to alleviate VMS in perimenopausal and postmenopausal women, with their supporters highlighting the broader scope of positive effects of MHT use on sexual function, bone density, cardiovascular protection, and even mood and cognition. MHT still remains a viable option for the management of VMS, but in reality, its acceptability has declined considerably during the past few years, given the wide publicity of the results from the Women’s Health Initiative (WHI).

Although some physicians expressed their skepticism about the WHI findings, they had a significant, adverse impact on many physicians’ and patients’ perception of the long-term safety and benefits of MHT. Consequently, many health professionals and their patients became more cautious or reluctant to initiate hormone therapies or to stay on MHT for longer periods of time; others started seeking nonhormonal strategies to improve menopause-related physical and psychological discomforts.

Among nonhormonal strategies for VMS, some psychotropic medications have demonstrated efficacy in randomized, controlled trials, but these agents face similar challenges with respect to patients’ acceptability because of the potential stigma associated with their use and risks of unwanted adverse events such as weight gain and sexual dysfunction. Thus, the search for nonhormonal, nonprescription treatments for VMS—at least among most Western-based societies—continues to be primarily focused on botanical agents and soy products. The overall impression, however, is that these agents have shown limited benefits when properly compared with placebo and are not risk-free in terms of adverse events.

The use of acupuncture for the treatment of menopause-related VMS is not a novel concept; this therapy has been the focus of various studies, and its use is taught in acupuncture schools in the United States, Japan, and China. In addition, supporters often claim a physiological explanation for the benefits of acupuncture for VMS, arguing that acupuncture exerts an effect on β-endorphins and neurotransmitters such as norepinephrine and 5-hydroxytryptamine that would subsequently impact hypothalamic thermoregulatory centers and promote amelioration of VMS.

Nonetheless, the putative efficacy of acupuncture for VMS has been questioned by some, particularly in light of methodological challenges such as the diversity of theoretical frameworks and understanding of acupuncture, the severity or bothersomeness of VMS in studied populations, and the lack of adequate control groups (eg, acupuncture-naïve participants, sham acupuncture). The use of so-called “sham interventions” in acupuncture trials has been a particular point of controversy because such denomination has been used in different scenarios—no skin penetration, superficial needling of the true acupuncture points, or even needles being inserted outside true acupuncture points.

In this issue of Menopause, Borud and colleagues from Norway present us with results of a trial applying Traditional Chinese Medicine (TCM) acupuncture for the management of moderate to severe VMS—the ACUFLASH study. The ACUFLASH study design was quite innovative as a multicenter, pragmatic, randomized, controlled trial that included two parallel arms, one that offered advice on self-care and the other with TCM acupuncture (6-10 sessions), in addition to advice on self-care. A comprehensive assessment of study participants included serial measures of VMS, sleep, somatic symptoms, mood, and overall quality of life, in addition to urine excretion of calcitonin gene–related peptide. Urine calcitonin gene–related peptide has been pointed out as a biomarker of the effects of acupuncture for VMS and was here used (unsuccessfully) as an attempt to establish a biological parallel with clinical improvement. Study participants were quite symptomatic (experiencing on average seven hot flashes/24 h), and the therapists (well-trained TCM acupuncturists) were free to individualize the treatment offered within the protocol proposed (eg, by defining the number of sessions needed and points for needle manipulation). The use of TCM acupuncture in addition to advice on self-care resulted in greater reduction of VMS per day as well as additional benefits for sleep and somatic complaints.
On the one hand, the ACUFLASH study could be seen as a closer approach to the “real world” use of TCM acupuncture in clinical settings. On the other hand, the generalization of its findings should be taken into account with caution, particularly in the North American population. After all, acupuncture still has a much greater acceptability as a “mainstream” intervention in Norway than in the United States or Canada, with lifetime use being reported by one quarter of Norwegians. Nonetheless, in the post-WHI era, any well-designed attempt to explore nonhormonal strategies for the management of VMS in postmenopausal women should be welcomed. The results by Borud et al may facilitate a broader utilization of acupuncture as a treatment strategy for symptomatic postmenopausal women—a subgroup that could perhaps benefit from other properties of this intervention (eg, analgesia and mood enhancing effects) with fewer adverse events and unwanted risks of most therapies used to date.

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