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Research Article

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Using Farabloc to Decrease Hot Flashes in Postmenopausal Women: A Randomized Controlled Study

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ABSTRACT

Objective: To investigate whether Farabloc used as a bottom bed sheet fabric decreases the number of moderate to severe hot flashes in postmenopausal women.

Methods: A prospective, randomized, crossover, double-blind study was conducted on postmenopausal women. After a two-week washout period, participants slept on either Farabloc or placebo fabric for two weeks in a randomized order. After another two-week washout period, participants were crossed over and slept on the opposite fabric for 2 weeks. The primary outcome was the number of hot flashes of moderate to severe rating as perceived by the participants.

Results: From February 2014 through June 2015, 33 women were enrolled; 8 failed to complete the study. The average number of moderate to severe hot flashes experienced by the 25 participants during the 2 weeks on placebo was 36.8 ± 16.5, compared with 29.8 ± 18.3 on Farabloc (P=0.008). The mean overall reduction in moderate to severe hot flashes between placebo and Farabloc use during the 2 weeks was -7.04 ± 12.2. Various participant characteristics including age, duration and perceived severity had no correlation with the effect of Farabloc on hot flashes. There were no reported side effects from Farabloc use.

Conclusion: The use of Farabloc fabric at night significantly reduced the frequency of hot flashes in postmenopausal women, suggesting that Farabloc may be considered as a safe alternative non-medicinal treatment option or adjunct for the alleviation of hot flashes.

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Farabloc; Non-hormonal treatment; Hot flashes; Randomized trial

Introduction

The transition to menopause is retrospectively diagnosed after twelve months of amenorrhea not associated with a pathological cause [1]. It is a physiologically complex process that occurs at the average age of 51 years. With menopause, there is a dramatic reduction in ovarian hormone secretion that is associated with mood and cognitive changes, sexual dysfunction, urinary incontinence, and most commonly, vasomotor dysfunction [2]. Vasomotor symptoms are commonly manifested as spontaneous sensations of warmth ("hot flush"), which can produce peripheral vasodilation and perspiration ("hot flash") [2]. These undesirable symptoms affect around 70% of women within three months of menopause and continue to impact 20% of these individuals for up to 15 years [3]. The median duration of hot flashes reported by women to be moderate to severe was 10.2 years [1].

Hormonal replacement therapy (HRT), such as estrogen with or without the combination of progesterone, has been proven to be the most effective treatment for menopausal symptoms [4]. However, two large randomized controlled trials by the Women's Health Initiative also showed increased risks of stroke and venous thromboembolic events with the usage of HRT. Possibly as a result of these findings, there has been a dramatic increase in the use of complementary and alternative medicine for menopausal symptoms [5-10]. Popular alternative herbal remedies include black cohosh, soy extract and red clover isoflavones

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[7-9]. Others have utilized energy-modulating modalities such as acupuncture and magnets [10,11]. which supposedly alter bioelectric fields around the body to help decrease vasomotor symptoms [12]. However, there has been inconsistent evidence for their effectiveness [2,9]. Our study examined the effect of blocking high frequency electromagnetic fields (EMF) on the frequency of significant vasomotor symptoms. We tested Farabloc (devised by Frieder Kempe, 1978), a fabric shield consisting of a woven nylon and stainless steel with iron, nickel, and chromium that effectively blocks high-frequency EMF between 1 to 10,000 MHz [13,14,16]. Several studies have documented the ability of Farabloc to decrease undesirable symptoms experienced in fibromyalgia, phantom limb pain, and muscle soreness [13-16]. To our knowledge, the use of Farabloc as an alternative treatment for hot flashes has not been previously studied. Our objective with this study was to test our hypothesis that the use of Farabloc as a bottom bed sheet fabric decreases the number of moderate to severe hot flashes in postmenopausal women.

Materials and Methods

Study design and oversight

This prospective, randomized, double-blind crossover study evaluated the effectiveness of Farabloc versus placebo fabric in reducing hot flashes at night. All Farabloc and placebo fabrics used in this study were provided by the Farabloc Development Corporation (Coquitlam, British Columbia, Canada). The study was approved by the Clinical Research Ethics Board at the University of British Columbia (H13-03228), was registered at www.clinicaltrials.gov (NCT02006238), and was conducted without assistance or payment from any source. The Farabloc Development Corporation provided the Farabloc and placebo fabrics for the trial, assigned randomized codes to them, and kept them unknown to researchers and participants throughout the study. The codes were revealed after the completion of data collection. Otherwise, they had no role in the design of the study, the collection, monitoring, analysis, and interpretation of the data, or the writing of the report. The manuscript was written without the assistance of anyone who is not an author.

Participants

Postmenopausal women were recruited from Vancouver and the Lower Mainland in British Columbia, Canada, between February 1, 2014 and June 31, 2015 from radio commercials and poster ads. They were eligible to participate if they: (1) had greater than 12 months of amenorrhea or had undergone surgical or treatment-induced menopause, and (2) experienced on average more than two hot flashes per night. Any previous use of hormonal replacement therapy or alternative medicine was discontinued during the initial washout period and for the duration of the study. Participants were not eligible if they had one or more of the following: other medical conditions associated with night sweats, medications known to be associated with night sweats, an average of less than two nocturnal hot flashes per night, allergies to metals, history of unstable mental status, or an inability to safely discontinue hormonal replacement therapy or herbal supplements for the duration of the study. All participants provided written informed consent.

Study protocol and randomization

The Farabloc fabric contained 13% metal content and 87% nylon, and the placebo was 100% nylon. The two types of fabric were indistinguishable by sight or touch. Fabrics were identifiable only by randomized codes that were assigned by the manufacturer. Each participant was assigned a sealed envelope that contained either the Farabloc or the placebo fabrics in random order. At any time, only one type of fabric was distributed to the participants to prevent error. Participants were instructed to sleep on the 85 cm x 155 cm fabric that was placed underneath the top layer of their mattress sheet. Having the fabric below rather than above the participants increases the likelihood of the patient being in contact with the fabric throughout the night. Fabrics were permitted to be washed if soiled. The duration of the study was 8 weeks. In the first washout period (weeks 1 and 2), all participants recorded their baseline hot flash symptoms without any intervention. During this time, participants stopped all their pharmacologic and non-pharmacologic treatments of hot flashes. No supplementary treatment of hot flashes was allowed for the entire duration of the study. For the next 2 weeks (weeks 3 to 4), participants received the first randomized fabric A. There was another washout period (weeks 5 and 6) before the trial of the second randomized fabric B (weeks 7 and 8). The order of fabric usage (Farabloc or placebo) was randomized

(Figure 1). Participants were required to attend an initial screening interview prior to being recruited into the study. After the initial interview, there were four additional visits every two weeks where the hot flash diaries were collected and the assigned fabrics were distributed (Figure 1).

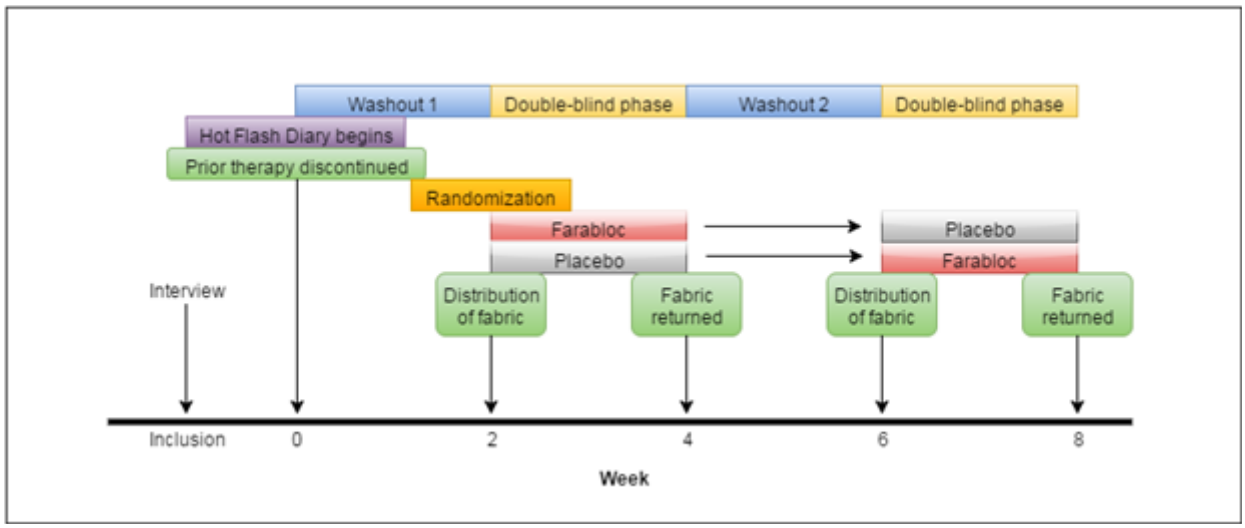

Figure 1. Randomized, Double-blind, Crossover Design of the Study. The study included 2-week treatment phases (week 2 to 4 and week 6 to 8) which were both preceded by 2-week washout phases. Participants were interviewed at inclusion. All prior hot flash therapies were discontinued before the first washout period. Due to the strict distribution and return policy, participants had access to only one fabric at any time during the study.

Outcome measures and definitions

Enrolled participants used the Hot Flash Diary, which conforms to FDA and EMEA guidelines, to characterize the quantity and severity of hot flashes [17]. Subjects record the number of hot flashes experienced for each of the three severity categories by recollection. Participants were instructed to record their symptoms as soon as possible to prevent memory recall errors. In this diary, frequency was measured as the number of hot flashes the participant experienced while lying in bed for the purpose of sleep, excluding daytime naps. Severity was evaluated by the participant based on the disturbance of the symptoms on quality of life. A "mild" rating was waking up to damp clothes but without disturbance to sleep at night. A "moderate" rating was some disturbance to sleep without the need for cooling intervention at night. A "severe" rating was the sensation of intense heat with sweating causing significant disturbance to sleep with the need for cooling intervention at night. Some examples of cooling interventions included using a fan or removing layers of clothing. The primary outcome was the sum of "moderate" and "severe" ratings, as this composite number would best show Farabloc's effects on functional disturbance compared to placebo. These diaries were submitted biweekly.

Statistical analysis

The mean number of moderate to severe hot flashes recorded during Farabloc and placebo fabric use was compared using the two-tailed paired t test. A P value of less than 0.05 was considered to be statistically significant. Correlation analysis of participant characteristics with the efficacy of Farabloc in hot flash reduction was measured by calculating the R^2 value from the Pearson correlation coefficient. For clinical significance, we estimated that the use of Farabloc should decrease the average number of hot flashes by 20%. A sample size of 69 was estimated to be required for 80% power, given α=0.05.

Results

Recruitment and follow-up was conducted between February 1, 2014 and June 31, 2015. Of 37 women who were screened, 33 were enrolled in the study due to exclusionary criteria. Eight participants discontinued the study due to unexpected family issues, sickness, or dropout. The remaining 25 women completed the study. Their mean age was 58.1 ± 7.1 years. The mean overall subjective hot flash severity level was high, 7.5 ± 1.8 out of a maximum value of 10. The average duration of hot flashes prior to starting the study was 8.6 ± 8.3 years (Table 1).

Table 1. Characteristics of the 25 Participants Included in Analyses

Characteristics of the 25 Participants Included in Analyses	
Age (years)	58.1 ± 7.1
Hot Flash Severity (max.10)	7.5 ± 1.8
Duration of Hot Flashes (years)	8.6 ± 8.3
% Using Prior Therapeutic Agents	28% (7/25)

Other therapeutic agents were used by 28% of participants (7/25) prior to the study. Two were using

hormonal agents and five were using alternative non-prescribed agents such as black cohosh and red clover. All diaries were fully completed as instructed and there were no missing data. The average number of moderate to severe hot flashes experienced during the 2 weeks on placebo was 36.8 ± 16.5, compared with 29.8 ± 18.3 on Farabloc, and this difference was significant (Figure 2, P=0.008). The mean overall difference between placebo and Farabloc use during the 2 weeks was 7.04 ± 12.2 fewer hot flashes experienced on Farabloc than placebo, a relative reduction of 19%. Other participant characteristics including age, duration and severity scale ratings had no correlation with the effect of Farabloc on hot flashes (Table 1) and (Figure 3). With the exception of one participant who reported mild discomfort of sleeping on an extra layer of fabric, participants did not report any negative physical or psychological effects.

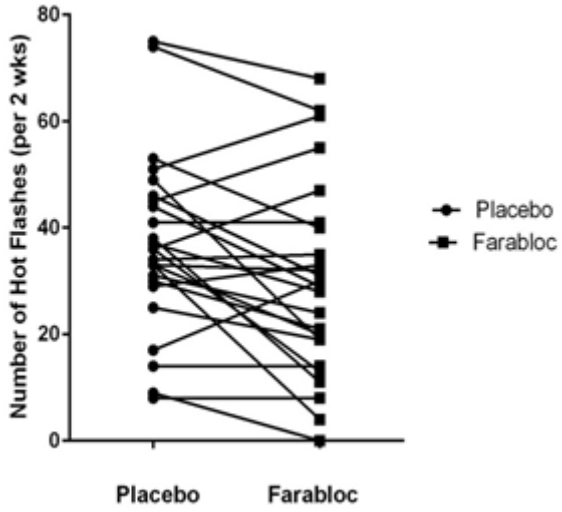

Figure 2. Comparing Mean Number of Nocturnal Hot Flashes in Placebo vs Farabloc

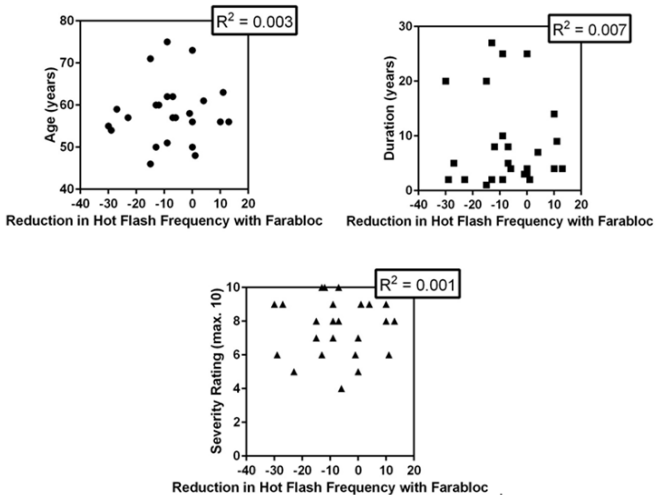

Figure 3. Correlation between Participant Characteristics and Effect of Farabloc Correlation analysis of age, duration in years of hot flashes since menopause, and subjective severity rating scale showed no relation to the efficacy of Farabloc in hot flash reduction. Created using GraphPad Prism 6.

Discussion

Using a randomized, double-blind crossover design, our study showed that the use of Farabloc material could reduce nocturnal hot flashes by 19% over a two-week period compared with placebo in post-menopausal women who had frequent nocturnal hot flashes. Its onset appears to be rapid as evidenced by a reduction of severe symptoms within 2 weeks. In addition, the treatment was safe with no participants reporting any side effects. These results, however, raise more questions not only about the mechanism of its action but also if greater efficacy can be achieved if used with other methods to decrease the frequency and intensity of hot flashes.

Farabloc was developed to block high frequency EMF by principles similar to a Faraday Cage. In other clinical situations, Farabloc has demonstrated efficacy in placebo-controlled studies for pain-related conditions. Bach and Clement showed that patients with fibromyalgia experienced significantly less muscle pain after sleeping in a Farabloc gown [13]. While small studies have shown the effectiveness of Farabloc metal-threaded socks as pain management for phantom limb sensation, larger RCTs did not demonstrate the same significance [14,15]. The use of Farabloc fabric wrapped around the thigh after exposure to eccentric exercises in untrained human participants led to significantly reduced pain and strength loss in delayed-onset quadriceps muscle soreness, with evidence of decreased serum biochemical markers of muscle damage [16]. In all of these cases, the mechanism of Farabloc remains unclear. Similarly, our findings are difficult to explain as vasomotor dysfunction in menopause is poorly understood. The current understanding is that reduced estrogen levels lead to decreased endorphin concentration in the hypothalamus, which in turn increases the release of certain neurotransmitters that lowers the set point in the thermoregulatory nucleus leading to an inappropriate heat loss process [1,2]. The positive finding from this study suggests that the alteration of EMF exposure in some way may have an effect on the biological mechanism of hot flashes. A recent critical review has estimated that 53% of menopausal women use at least one type of complementary and alternative medicine (CAM), as it is perceived to be safer than HRT and allows for more personal control over one's health care [18,19]. A longitudinal analysis of CAM use in symptomatic women revealed vitamins and minerals to be the most commonly used treatment (68.79%),

followed by herbal medicines (26.80%), and massage therapy (25.26%) [18]. In terms of efficacy, combined results from double-blind, randomized, placebo-controlled trials showed that soy extract isoflavones and red clover isoflavones reduce the number of daily hot flashes by 1.15 (95% CI -2.33 to 0.03) and 0.44 (-1.47 to 0.58) respectively, while SSRI (selective serotonin reuptake inhibitor) and SNRI (selective noradrenergic reuptake inhibitor) antidepressants were shown to reduce daily hot flashes by 1.13 (-1.70 to -0.57) [20]. In comparison, transdermal estrogen was the most effective therapy by reducing the number of daily hot flashes by 3.2 (-5.1 to -1.5) [4]. Comparatively, in this study, Farabloc use reduced the average number of hot flashes by 7.04 over a 2-week period, or a reduction in daily hot flashes by 0.50 (-1.37 to 0.37). Of note, the former data from antidepressants and hormone replacement therapies measured the number of daytime hot flashes as the primary outcome, whereas our study investigated the number of nocturnal hot flashes. Since our results do not take into account hot flashes experienced in the daytime, the absolute effect of Farabloc could potentially be underestimated. Several factors limit the generalizability of our findings. First, despite the positive findings, the sample size was small and larger studies may be needed to confirm these observations. Although the original sample size estimate was 69, due to funding the final study sample size was limited to 25. Second, the duration of treatment was short, and it is unknown whether Farabloc may also have long term efficacy to reduce hot flashes. Third, other factors that contribute to the severity and frequency of vasomotor dysfunction may not have been considered, such as the participant's general health status, body mass index, and lifestyle factors [1,2]. Fourth, participants in this study may be more affected by vasomotor symptoms than the general menopausal population, thus potentially limiting the generalizability of these results. Fifth, our study relied on subjective reporting, which can be affected by memory recall issues or personal characteristics such as the participant's mood. Crawford et al. found that women with milder vasomotor symptoms are more likely to underreport retrospectively recalled symptoms, whereas participants with higher symptom awareness were more likely to over report [21]. Further research would need to measure the outcome of hot flashes in a more objective way, such as measuring skin temperature or sternal skin conductance monitoring, for example. Finally, our study involved an intervention taking place in participants' homes. Therefore, proper adherence to protocol is not guaranteed. Overall, our study found that the use of Farabloc fabric at night safely and significantly reduced the frequency of hot flashes in postmenopausal women, suggesting that Farabloc may be considered as an alternative non-medicinal treatment option or adjunct for the alleviation of hot flashes.

Conclusion

The use of Farabloc fabric at night significantly reduced the frequency of hot flashes in postmenopausal women, suggesting that Farabloc may be considered as a safe alternative non-medicinal treatment option or adjunct for the alleviation of hot flashes.

Acknowledgement

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