Bioidentical Progesterone Cream for Menopause-Related Vasomotor Symptoms: Is it Effective?

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OBJECTIVE: To evaluate the efficacy of bioidentical progesterone cream in the treatment of menopause-related vasomotor symptoms.

DATA SOURCES: A systematic search (from time of inception to September 2012) of PubMed, EMBASE, *International Pharmaceutical Abstracts*, *International Journal of Pharmaceutical Compounding*, Cochrane, and CINAHL was conducted using the terms progesterone, vasomotor symptoms, night sweats, hot flash or flush, and randomized controlled trials (RCTs). Hand-searching of citations from relevant articles was also performed.

STUDY SELECTION AND DATA EXTRACTION: Articles selected for inclusion described RCTs evaluating the use of bioidentical progesterone cream for the treatment of menopause-related vasomotor symptoms. Studies included were placebo controlled and participants were postmenopausal women experiencing vasomotor symptoms.

DATA SYNTHESIS: Searching identified 3 published RCTs. Only one study, which used a bioidentical progesterone cream specifically compounded for the trial, found that the bioidentical progesterone was more effective than placebo in relieving menopause-related vasomotor symptoms. The 2 studies using manufactured bioidentical progesterone creams found that the creams were no more effective than placebo. Vaginal bleeding and headaches were the most commonly reported adverse effects in the studies.

CONCLUSIONS: Available evidence from RCTs does not support the efficacy of bioidentical progesterone cream for the management of menopause-related vasomotor symptoms. Adverse effects appear to be mild and self-limiting.

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Request

Is bioidentical progesterone cream an effective treatment for menopause-related vasomotor symptoms?

Response

BACKGROUND

Several patients in a family medicine clinic presented to their physicians requesting prescriptions for bioidentical progesterone cream for their menopause-related vasomotor symptoms (VMS). The cream had been recommended by a compounding pharmacist. Before prescribing this cream the physicians asked their pharmacist team member to review the evidence for the use of bioidentical progesterone cream for VMS.

The incidence of VMS (hot flashes and night sweats) in menopausal women has been estimated at 60-80%.[1] These symptoms can significantly affect a woman's quality of life and many women will seek relief with medications.[1] The most effective treatment for VMS is conventional hormone therapy (CHT), which consists of estrogen and/or progestin.[1] When the results of the Women's Health Initiative (WHI) trial were published, the use of CHT became associated with several health risks.[2] Following this, health care practitioners and women sought treatments with similar efficacy to CHT, but with safer adverse effect profiles. One of the alternatives to CHT is hormone therapy using bioidentical estrogen and progesterone hormones rather than synthetic or nonhuman estrogens and progestins. The term *bioidentical hormones* (BHs) is used widely in the medical and public communities. However, there is much controversy and confusion surrounding the term. For example, the Food and Drug Administration

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(FDA) considers BHs to be a marketing rather than a medical term.[3] A commentary by Bhavnani and Stanczyk concludes that use of the term BH is inappropriate and misleading.[4] A review of the literature identified over 55 ways of defining BHs.[5] Thus, there is no universal acceptance of this term or its definition. For the purposes of this article, BHs are defined as "chemical substances that are identical in molecular structure to human hormones."[5] Using this definition, some examples of BHs are progesterone, estrone, estradiol, and estriol, which are administered using commercially manufactured products or are compounded into preparations.

Interest in BHs has surged, due in part to endorsement by celebrities, promotion by compounding pharmacies, and the view that they are safer than CHT.[6,7] However, data on actual use are limited. The authors of one paper stated that they prefer to use BHs in their family practice.[8] Another study reported that, following the publication of the WHI, 10.5% of primary care physicians and 18.2% of obstetricians/gynecologists (OB/GYNs) used more bioidentical estrogen or progestogen, while 15.5% of primary care physicians and 7.8% of OB/GYNs reported using fewer BHs.[9] A survey of women reported that approximately 3% of respondents switched to BHs after discontinuing CHT.[10] Two other surveys of women reported use of BHs ranging from 7% to 20%.[11,12]

In CHT, estrogen is used for its beneficial effect on menopausal symptoms, while progestin is added to inhibit estrogen-induced endometrial stimulation.[13] This mimics the role of progesterone in menstruating women, where progesterone converts the estrogen-induced proliferating endometrium into a secretory endometrium, thus reducing the proliferation and protecting against unopposed endometrial stimulation.[14] However, there is evidence that progestin alone (as oral progesterone, oral medroxyprogesterone acetate, or injectable depomedroxyprogesterone) is effective for menopause-related VMS.[15-20] Although synthetic progestins traditionally have been used in CHT, they have been associated with adverse effects including bloating, weight gain, and various metabolic changes.[14] These unwanted effects led to an interest in using bioidentical progesterone to protect the endometrium while minimizing adverse effects.[14] Because orally administered bioidentical progesterone undergoes rapid metabolism in the gut and liver, proponents of BH therapy often recommend the transdermal administration of progesterone in a cream base to bypass this inactivation.[14] Creams containing bioidentical progesterone are available commercially but can also be compounded to meet the needs of specific patients. Data from randomized controlled trials (RCTs) examining the efficacy of bioidentical progesterone cream for VMS are presented below.

LITERATURE REVIEW

Four RCTs were identified that examined the use of bioidentical progesterone cream for menopausal symptoms.[21-24] The Stephenson study was dropped from further review as, based on the data provided, it was not possible to discern the effects of the bioidentical progesterone cream specifically on VMS alone.[23] The remaining 3 studies[21,22,24] are reviewed here. Each study was critically assessed using Cochrane Collaboration's risk of bias method.[25]

In 1999 Leonetti et al. published the results of a 12-month RCT comparing bioidentical progesterone cream (n = 43) to placebo (n = 47) in women within 5 years of menopause, with serum follicle-stimulating hormone (FSH) levels greater than 40 mIU/mL, and who had not taken any hormonal therapy 12 months prior to the beginning of the study.[21] Thirty women in the treatment group and 27 women in the placebo group had VMS at baseline. Participants applied one quarter of a teaspoon of either progesterone cream (20 mg progesterone in tocopherol cream) or placebo (tocopherol cream) daily, rotating between upper arms, breasts, or thighs. At the end of each week, participants recorded whether their hot flashes remained the same, improved, or had stopped. Absorption of progesterone was not verified by measuring serum levels. After 4 months, 5 of 27 (19%) in the placebo group versus 25 of 30 (83%) in the treatment group reported improvement or complete resolution of vasomotor symptoms ($p < 0.001$). Two women (1 in each group) developed rashes. In the progesterone group there were 8 reports of vaginal spotting ($p < 0.01$). Of the 8, one biopsy showed a proliferative endometrium, while the other 7 had insufficient tissue for a biopsy. In all 8 cases, the spotting resolved in 1-2 days. The investigators concluded that the use of bioidentical progesterone cream resulted in a significant improvement in vasomotor symptoms, compared to placebo. The risk of bias assessment concluded that the study clearly described randomization, sequence generation, and blinding. However, rating of changes to vasomotor symptoms was done using patient self-report, as opposed to using a validated tool. The progesterone product was compounded specifically for the study, with few details provided.

An RCT of 3 months' duration, published by Wren et al. in 2003,[24] recruited women aged 45-70 years who had been postmenopausal for at least 6 months, had FSH levels greater than 30 mIU/mL, had at least 1 hot flash per day, and discontinued any medications used for hot flashes 8 weeks prior to study enrollment. Women were randomly assigned to bioidentical progesterone cream (ProFeme; Lawley Pharmaceuticals) 32 mg/day (n = 38) or placebo cream (n = 42). ProFeme is an oil-in-water cream containing progesterone BP, dl-alpha-tocopherol, almond oil, macadamia oil, emulsifiers, and preservatives. The placebo

was the same cream without the progesterone. Seventy-two women completed the study. Reasons for drop-out included bleeding (n = 2), return of hot flushes (n = 3), difficulty in getting to clinic visits (n = 1), and nonadherence (n = 2). It was not specified to which group these women were randomized. No other adverse effects were mentioned. Although decreases in scores measuring VMS (using the Greene Climacteric Scale and the Menopause-Specific Quality of Life questionnaire) were noted, the change from baseline was not statistically significant in either group. There was a significant (p = 0.000) increase (from 0.11 to 0.31 ng/mL) in serum progesterone levels after 12 weeks, a level suggested by the authors as insufficient to induce a secretory change in the endometrium. Authors concluded that the use of bioidentical progesterone cream did not result in changes to VMS. Risk of bias assessment noted that reporting of sequence generation, allocation concealment, and blinding was unclear, meaning that the study did not provide sufficient data to permit a judgment. As no sample size calculation was reported, it is possible that the study may have been underpowered to detect a difference between the 2 groups.

The third study, an RCT of 6 months' duration published by Benster et al. in 2009,[22] enrolled women between the ages of 40 and 60 who were experiencing moderate to severe climacteric symptoms, had not had menses for 1 year or more, had FSH levels greater than 30 mIU/mL, and had not received hormone therapy in the previous 8 weeks. Women were randomly assigned to different doses of bioidentical progesterone cream, supplied as Progestelle (provided by Natural Medicine Company): 5 mg/day (n = 46), 20 mg/day (n = 44), 40 mg/day (n = 43), 60 mg/day (n = 45), or placebo (n = 43). One measure (0.7 mL) of cream was applied once daily to the forearm. No details regarding the composition of the cream or placebo were provided. Using the Greene Climacteric Scale, a decrease in the weekly incidence of hot flushes and night sweats was reported in all 5 groups, including the placebo group. Although there was no significant difference in results among the groups, there was a trend to greater improvements at higher progesterone doses. Headaches were reported in all groups: 60 mg (11%), 40 mg (7%), 20 mg (11%), 5 mg (4%), and placebo (2%). Bleeding, described as spotting or light, was reported in all groups: 60 mg (20%), 40 mg (9%), 20 mg (16%), 5 mg (13%), and placebo (11%). The authors suggested that this high incidence could be reflective of atrophic vaginitis in the study participants who were postmenopausal and had mostly refused hormone therapy. Additionally, there was no thickening of endometrial tissue, and histology was mainly atrophic or inadequate for diagnosis. Mean serum progesterone levels after 6 months were 0.82, 0.28, 0.35, and 0.22 ng/mL for women in the 60-, 40-, 20-, and 5-mg groups, respectively. These differences, as compared to placebo, were all significant (p < 0.001). However, the authors stated that these levels were low and were consistent with results from other studies. The investigators concluded that progesterone cream was not more effective than placebo for relief of menopausal symptoms. Although the study appeared to be well done, risk of bias assessment was rated as unclear for randomization, allocation concealment, and blinding, primarily due to insufficient data being provided for a judgment to be made. No sample size calculation was provided, so there may not have been enough participants enrolled to detect any differences between groups.

Discussion

The efficacy of bioidentical progesterone cream for menopause-related VMS has been compared to placebo in at least 3 RCTs. To examine efficacy of treatment for VMS, the FDA recommends that the mean change in symptoms from baseline be measured at 4 and 12 weeks.[26] All 3 studies included in this review were of sufficient duration according to FDA guidelines; however, only 121 showed a positive result.

All 3 studies used topical preparations in daily doses ranging from 5 to 60 mg, with the 1 positive study[21] using a daily dose of 20 mg. The other 2 studies[22,24] included some participants who used daily doses of 20 mg or higher, yet neither study showed a positive effect of topical bioidentical progesterone on hot flashes. Ingredients in the cream base used to deliver progesterone were different in each study. It is known that the topical absorption of progesterone is influenced by a number of factors, including the type of base used to deliver it through the skin, the site of application, and the surface area to which the cream is applied.[27] Two[22,24] of the 3 studies evaluated the absorption of progesterone by measuring serum progesterone levels, although authors commented that serum levels may not adequately reflect the levels of progesterone in tissues.[22] Unfortunately, the study that detected a reduction in hot flashes did not measure how much progesterone was absorbed from the product. It is possible that the base that was used in that product allowed better absorption of progesterone than those used in the studies that did not show a reduction in hot flashes and did show low levels of progesterone absorption. However, without serum levels, this is speculation.

Interestingly, the 2 studies[22,24] that used manufactured products showed no benefit over placebo, while the cream specially compounded for the other study[21] was effective. If one wanted to recommend the use of bioidentical progesterone cream for VMS based on the results of the Leonetti et al. trial, then, ideally, the same product should be used. However, the exact composition of the contents of the cream was not discernable from the study report; therefore, it would not be possible to compound an identical product.

The FDA recommends assessing hot flash severity using a 3-category scale (mild, moderate, and severe).[3] None of the studies used this scale. Results from the study that reported statistically significant positive effects on VMS[21] were based on patient self-report, with no details on how these changes were assessed, which may bring into question the validity of the results. The 2 trials[22,24] reporting negative results used validated tools[28,29] to measure outcomes. This is important, as use of validated tools in clinical trials helps to minimize measurement bias and improve confidence in the results.[30,31]

Occurrence of vaginal bleeding in women using bioidentical progesterone cream appeared to be highest in the study by Benster et al.,[22] but the authors noted that the bleeding tended to occur in the first 3 months, was light, and resolved on the same day. This was also true of the Leonetti et al. study,[21] where 8 subjects using bioidentical progesterone cream reported vaginal spotting that lasted only 1-2 days. Two subjects withdrew from the Wren et al.[24] study because of vaginal bleeding, but it was not clear whether they were from the progesterone or placebo group. Both Leonetti et al.[21] and Benster et al.[22] conducted biopsies and reported little effect on the endometrium, as noted earlier. These results suggest that the levels of progesterone that were absorbed were insufficient to have an effect on the endometrium. However, another study[32] reported that progesterone administered in a cream base for 28 days inhibited estrogen-induced endometrial proliferation. Headache was commonly reported in the Benster et al. study,[22] although the authors stated that the headaches were considered to be only possibly related to therapy.

Summary

This evidence-based, critically appraised review of randomized controlled trials found only one study that reported bioidentical progesterone cream to be more effective than placebo in reducing menopause-related VMS. Although this study had a low risk of bias, the use of a compounded product not readily available to the consumer and of self-reporting to assess changes in symptom occurrence is a limitation to the generalizability of the results. Bioidentical progesterone cream appeared to be well tolerated, with headache and bleeding (of short duration) being the most commonly reported adverse effects. Overall, the data from the RCTs presented in this review do not support the use of bioidentical progesterone cream for relief of menopause-related VMS. Although evidence may exist from other types of studies and/or anecdotal reports, RCTs are recognized as higher level evidence and thus were used in answering this question. Additional well-designed, adequately powered RCTs using bioidentical progesterone preparations (with details of their formula) for at least 12 weeks in duration and use of validated tools to measure outcomes are needed to substantiate the few positive results that have been reported in RCTs to date.

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EXTRACTO

La Crema de Progesterona Bioidéntica Para los Síntomas Vasomotores Relacionados a la Menopausia: Será efectiva?

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OBJETIVO: Evaluar la eficacia de la crema de progesterona bioidéntica en el tratamiento de los síntomas vasomotores relacionados a la menopausia.

FUENTES DE INFORMACIÓN: Se llevó a cabo una búsqueda sistemática (desde el inicio a septiembre de 2012) en Pubmed, EMBASE, *Abstractos Farmacéuticos Internacionales*, *International Journal of Pharmaceutical Compounding*, Cochrane y CINAHL usando los términos progesterona, síntomas vasomotores, sudores nocturnos, sofocones, y estudios aleatorios controlados (RCTs). Además, se llevaron a cabo búsquedas a mano de citas de artículos relevantes.

SELECCIÓN DEL ESTUDIO Y EXTRACCIÓN DE LOS DATOS: Los artículos seleccionados para ser incluidos describían RCT que evaluaron el uso de la crema de progesterona bioidéntica en el tratamiento de los síntomas vasomotores relacionados a la menopausia. Para ser incluidos, los estudios debían ser controlados con placebo y tener participantes en la posmenopausia y que experimentaran síntomas vasomotores.

SÍNTESIS DE LOS DATOS: La búsqueda identificó 3 RCT publicados. Solo un estudio, el cual usó una crema de progesterona bioidéntica específicamente formulada para el estudio, encontró que la progesterona bioidéntica fue más efectiva que el placebo en aliviar los síntomas vasomotores relacionados a la menopausia. Dos estudios, en los cuales se usaron cremas de progesterona bioidéntica manufacturadas, encontraron que las cremas no fueron más efectivas que el placebo. Sangrado vaginal y dolor de cabeza fueron los efectos adversos más comúnmente informados en los estudios.

CONCLUSIONES: La evidencia disponible obtenida de los RCT no sustenta la eficacia de la crema de progesterona bioidéntica en el manejo de los síntomas vasomotores relacionados a la menopausia. Los efectos adversos parecen ser leves y auto limitados.

Traducido por Rafaela Mena

RÉSUMÉ

Crèmes de Progestérone Bio-Identiques pour le Traitement des Symptômes Vasomoteurs de la Ménopause: Efficaces?

AM Whelan, TM Jurgens, M Trinacty

Ann Pharmacother 2013;47:112-6.

OBJECTIF: Évaluer l'efficacité des crèmes de progestérone bio-identiques pour le traitement des symptômes vasomoteurs de la ménopause.

PROVENANCE DES DONNÉES: Une recherche (jusqu'à septembre 2012) des banques informatisées Pubmed, EMBASE, *International Pharmaceutique Résumé*, *International Journal of Pharmaceutical Compounding*, Cochrane, et CINAHL a été effectuée en utilisant les termes: progestérone, symptômes vasomoteurs, sueurs nocturnes, bouffées de chaleurs et essais cliniques aléatoires. La bibliographie des articles sélectionnés a été revue dans le but d'identifier des publications supplémentaires.

SÉLECTION DES DONNÉES: Les publications ont été sélectionnées si elles décrivaient un essai clinique aléatoire comparant un crème de progestérone bio-identique à un placébo pour le traitement des symptômes vasomoteurs de la ménopause. Toutes les participantes devaient être ménopausées et présenter des symptômes vasomoteurs.

RÉSUMÉ: Seules 3 études correspondaient aux critères d'inclusion. L'une de ces études démontra qu'une crème bio-identique spécialement fabriquée pour l'étude était plus efficace qu'un placébo pour soulager les symptômes vasomoteurs de la ménopause. Deux études, utilisant cette fois-ci 2 produits ouvrés différents, démontrèrent que ces crèmes n'étaient pas plus efficaces qu'un placébo. Des saignements vaginaux et des maux de tête étaient les effets secondaires les plus fréquemment rapportés dans ces études.

CONCLUSIONS: Les données actuellement disponibles ne permettent pas de conclure à l'efficacité des crèmes de progestérone bio-identiques pour le soulagement des symptômes vasomoteurs de la ménopause. Les effets secondaires semblent de faible intensité et se résolvant d'eux-mêmes.

Traduit par Suzanne Laplante