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Mary Ann Liebert,

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Physiological investigation of a unique extract of black cohosh (Cimicifugae racemosae rhizoma): a 6-month clinical study demonstrates no systemic estrogenic effect.

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Abstract

OBJECTIVE: This study sought to confirm the efficacy and safety of the currently recognized dose of Cimicifugae racemosae rhizoma (40 mg/day) and to evaluate a higher dose and its associated physiological effects.

METHODS: We conducted a controlled, randomized, double-blinded parallel group study of perimenopausal and postmenopausal women treated with two different doses (39 mg and 127.3 mg) of a unique C. racemosa preparation over a 24-week period. Efficacy and tolerability were determined by the Kupperman Menopause Index, Self-Rating Depression Scale (SDS), a global assessment of tolerability, adverse events, routine hematology, and biochemical tests. To determine if the unique C. racemosa preparation exerts its effect through an estrogen-identical mode of action, we investigated vaginal cytology and gynecologically relevant hormones.

RESULTS: Both perimenopausal and postmenopausal patients tolerated the treatment well, and menopausal symptoms decreased regardless of dose (responder rate 70% and 72%, respectively). The lack of change in vaginal cytology measures indicates a nonestrogenic effect of the tested extract in this critical organ. Likewise, the lack of significant changes in the levels of gynecologically relevant hormones does not indicate an overall estrogenic effect.

CONCLUSIONS: The higher dose did not exert a significantly greater effect on any end point. Thus, the currently recognized standard dose of the isopropanolic aqueous C. racemosa extract should be preferred over the higher dose. Despite the absence of a placebo group, this study suggests that C. racemosa extract is associated with improvement in menopause symptoms without evidence of estrogenlike effects.

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