



HerbClip™

Mariann Garner-Wizard
Heather S Oliff, PhD

Shari Henson
Marissa Oppel-Sutter, MS

Brenda Millot, ELS
Silvia Giovanelli Ris

Executive Editor – Mark Blumenthal

Managing Editor – Lori Glenn

Consulting Editors – Dennis Awang, PhD, Francis Brinker, ND, Steven Foster

Assistant Editor – Tamarind Reaves *Production* – George Solis

File: ■ Black Cohosh (*Actaea racemosa* syn. *Cimicifuga racemosa*)

- Exercise
- Bone Mineral Density
- Coronary Heart Disease
- Menopause

HC 051051-402

Date: June 15, 2010

RE: The Surprising Effects of Intensity of Exercise and Black Cohosh on Coronary Heart Disease Risk and Bone Density

Bebenek M, Kemmler W, von Stengel S, Engelke K, Kalender WA. Effect of exercise and *Cimicifuga racemosa* (CR BNO 1055) on bone mineral density, 10-year coronary heart disease risk, and menopausal complaints: the randomized controlled Training and *Cimicifuga racemosa* Erlangen study. *Menopause*. March 18, 2010. [Epub ahead of print] doi: 10.1097/gme.0b013e3181cc4a00.

During early post-menopause, estrogen depletion causes women to have a change in body composition, menopausal symptoms, accelerated bone loss, and a change in fat distribution. Aside from hormone replacement therapy (HRT), exercise is considered an effective approach to counteracting the effects of estrogen depletion. Black cohosh (*Actaea racemosa* syn. *Cimicifuga racemosa*) is an herbal alternative to HRT. There are in vitro, in vivo, and human studies that demonstrate a positive synergistic effect of exercise and estrogen on bone. Hence the purpose of this study was to examine the effects of a high-intensity exercise regimen on bone and cardiovascular health, and to investigate whether a combination of exercise and black cohosh improves the effect of exercise alone. This study is known as the TRACE study (Training and *Cimicifuga racemosa* Erlangen).

Patients (aged 48-55 years) living in Erlangen-Nuremberg, Germany, were recruited by mail to participate in this 12-month, placebo-controlled, randomized study. Included women were 1-3 years post-menopause, were not using any medication that would affect study endpoints, had no history of stroke or cardiac events, had no secondary osteoporosis, and had no athletic history. Women (n = 128) were stratified by age, and randomized to 1 of 3 treatment groups: (1) exercise = a complex high-intensity aerobic and resistance exercise program that focused primarily on bone strength, plus placebo (n = 43), (2) exercise as described above and 40 mg/day black cohosh (CR BNO 1055; Bionorica; Neumarkt, Germany) (n = 43), and (3) wellness control = program with low training frequency and intensity (i.e., walking, balance, flexibility) that focused on well-being (n = 42). The exercise program focused on bone parameters for the first 6 weeks

and then cardiovascular parameters the second 6 weeks, in an alternating pattern for 1 year. The black cohosh dosage was as per the manufacturer's recommendation; specifically, 3 months of intake followed by 3 months abstaining from use, followed by 3 months of intake, and so forth. All participants received calcium (1,500 mg/d) and cholecalciferol (vitamin D, 500 IE/d) supplements (Opfermann; Wiehl, Germany). The primary efficacy variables were bone mineral density (lumbar spine and proximal hip) and the 10-year coronary heart disease (CHD) risk according to Wilson et al.¹ The secondary endpoints were menopausal symptoms, body composition, and aerobic capacity. Measurements were taken at baseline and 12 months.

There were 7 patients in the exercise group, 6 patients in the black cohosh/exercise group, and 12 participants in the control group who were lost to follow-up. None of the discontinuations were due to adverse events. At baseline, there was no difference between groups on any measurement. Compliance with black cohosh treatment and calcium/vitamin D supplementation was high. Exercise attendance was 65% for both groups. The groups were successfully blinded, with 77% of the patients in the black cohosh group believing that they were in the placebo group.

At the lumbar spine, bone mineral density was maintained in both exercise groups, but significantly decreased in the control group ($P < 0.001$). There was no significant difference between the exercise and the black cohosh/exercise groups in bone mineral density of the lumbar spine. There was no significant change in bone mineral density of the femoral neck of any group.

The ten-year Framingham-based risk for CHD significantly increased in the black cohosh/exercise group by $12.9\% \pm 25.1\%$ ($P = 0.018$), and increased by $16.5\% \pm 27.8\%$ in the control group ($P = 0.007$). In contrast, the exercise group had only a $2.7\% \pm 21.9\%$ increase in risk.

In both exercise groups, menopausal complaints (psychological, somato-vegetative, and urogenital domains) significantly decreased by $20.0\% \pm 23.7\%$ ($P < 0.001$) in the exercise group and $20.7\% \pm 34.1\%$ ($P = 0.003$) in the black cohosh/exercise group compared with baseline. There was no significant change in total or abdominal body fat in either group. Both exercise groups had a significant increase in aerobic capacity; there was no significant difference between groups.

Contrary to agents with selective estrogen receptor modification, black cohosh did not enhance the positive effect of exercise on bone mass density, menopausal symptoms, aerobic capacity, or lean body mass. However, the authors state that an important new finding is the knowledge that it is not necessary to exercise continuously at high loading intensities to impact bone density. The exercise intensity, duration, and frequency should have been sufficient to impact the CHD risk score. The authors state that the significant increase in the 10-year CHD risk in the black cohosh/exercise group and the control group "is alarming." They provide no explanation for this alarming finding or for the limited improvement in menopausal symptoms in the black cohosh/exercise group: no significant differences were detected "concerning modifiable factors constituting ... or corresponding with ... risk score between the groups." It should be noted that these findings are specific for women 1-3 years post-menopause. The results may differ in a different patient population.

Two weaknesses of the study not noted by the authors are: 1) The article states that all patient groups received vitamin D and calcium which per se have antiosteoporotic effects. Other published studies have found that a combination of vitamin D and calcium was able to prevent the development of osteoporosis significantly. Hence, a totally untreated group should have served as a negative control. 2) The 10-year expectation of cardiovascular diseases on the basis of the Framingham-based risk for CHD is another point of concern. Nowhere in other literature is it stated that black cohosh increases cardiovascular risk factors and this is substantiated by the finding that abdominal fat – the major risk factor for CHD – was not significantly different in each of the 3 treatment groups.

—Heather S. Oliff, PhD

Reference

¹Wilson PW, D'Agostino RB, Levy D, Belanger AM, Silbershatz H, Kannel WB. Prediction of coronary heart disease using risk factor categories. *Circulation*. 1998;97:1837-1847.

The American Botanical Council has chosen not to reprint the original article.

The American Botanical Council provides this review as an educational service. By providing this service, ABC does not warrant that the data is accurate and correct, nor does distribution of the article constitute any endorsement of the information contained or of the views of the authors.

ABC does not authorize the copying or use of the original articles. Reproduction of the reviews is allowed on a limited basis for students, colleagues, employees and/or members. Other uses and distribution require prior approval from ABC.