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

**HC 041453-505**

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**RE: Black Cohosh Reduces the Size of Uterine Fibroids in Menopausal Women**

Xi S, Liske E, Wang S, et al. Effect of isopropanolic *Cimicifuga racemosa* extract on uterine fibroids in comparison with tibolone among patients of a recent randomized, double blind, parallel-controlled study in Chinese women with menopausal symptoms. *Evid Based Complement Alternat Med.* 2014;2014:717686. doi: 10.1155/2014/717686.

Uterine fibroids (also called myomas) are the most common benign tumors in women. The use of hormone replacement therapy (HRT) to ameliorate menopausal symptoms in women with uterine fibroids is controversial because there is some evidence that estrogens can increase the growth of uterine fibroids. The drug tibolone (a hormone-like medication) and isopropanolic black cohosh (*Actaea racemosa* syn. *Cimicifuga racemosa*) root extract (iCR) are used to treat menopausal symptoms. The purpose of this randomized, double-blind, parallel-controlled study was to compare the effect of tibolone and iCR treatment on uterine fibroid size in women treated for menopausal complaints.

This study constitutes a subgroup analysis of a previously published report on 244 patients.<sup>1</sup> The present study included only the women in the original trial who had uterine fibroids (n = 62, aged 41-60 years). Study participants were recruited from 5 hospitals in China. The patients were treated with 40 mg/day iCR (n = 34, Remifemin®; Schaper & Brümmer GmbH; Salzgitter-Ringelheim, Germany) or 2.5 mg/day tibolone (n = 28, Zizhu Pharm; Beijing, China) for 12 weeks. At baseline, 4 weeks, and 12 weeks of treatment, the patients underwent transvaginal ultrasonography to measure the myoma. If the patient had multiple myomas, the largest one was used for the analysis.

At baseline, there was no significant difference between groups. The median volume of the largest myoma at study end decreased in the iCR group (P = 0.085). The volume was decreased in 24 (70.1%) women of the iCR group with a volume reduction of 30.3%. In comparison, a decrease was observed in only 10 (35.7%) women of the tibolone group; the difference between groups was significant (P = 0.016). Similarly, the mean diameter and the geometric mean diameter of the myomas significantly decreased with iCR treatment (P = 0.006 and P = 0.006, respectively), but not with tibolone treatment (P = 0.819 and P = 0.778, respectively); again, the difference between the

groups was significant ( $P = 0.021$  and  $P = 0.016$ , respectively). For the tibolone group, no statistical difference from baseline was observed for these parameters.

In over one-half (53.6%) of the women treated with tibolone, fibroid volume increased by an average of 4.7% (equivalent to 21% per year). However, these findings are in agreement with 2 other studies assessing the natural change in fibroid volume over time. The authors conclude that 2.5 mg/day tibolone for 12 weeks does not interfere with the natural course of uterine fibroids but caution that regular reexaminations should be conducted.

The authors conclude that while both groups had a significant improvement in menopause symptoms,<sup>1</sup> iCR decreased uterine fibroid size and tibolone did not. They state, "iCR seems to be the better choice in alleviating menopausal symptoms in women with uterine fibroid ... as it provides adequate relief from menopausal symptoms and avoids increase in uterine fibroid size, which is usually a cause of concern for the patient." The study is limited by the small population size and the short duration of the study. Women using therapeutics to ameliorate complaints associated with menopause typically take a treatment for more than 12 weeks. Therefore, the effect of iCR on uterine fibroids needs to be evaluated in trials of longer duration. With respect to the known non-hormone-like/non-estrogenic effects of this herbal extract, similar results are also expected.<sup>2</sup>

—Heather S. Oliff, PhD

#### Reference

<sup>1</sup>Bai W, Henneicke-von Zepelin H-H, Wang S, et al. Efficacy and tolerability of a medicinal product containing an isopropanolic black cohosh extract in Chinese women with menopausal symptoms: a randomized, double blind, parallel-controlled study versus tibolone. *Maturitas*. 2007;58(1):31-41.

<sup>2</sup>Liske E, Hänggi W, Henneicke-von Zepelin H-H, Boblitz N, Wüstenberg P, Rahlfs VW. Physiological investigation of a unique extract of black cohosh (*Cimicifugae racemosae rhizoma*): a 6-month clinical study demonstrates no systemic estrogenic effect. *J Womens Health Gend Based Med*. 2002;11(2):163-174.

Referenced article can be found at <http://www.hindawi.com/journals/ecam/2014/717686/>.

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