Objectives: It is to evaluate the effect of black cohosh on genital atrophy and its adverse effect in postmenopausal women. Methods: A total of 100 postmenopausal women having moderate to severe degree of climacteric symptoms were randomly allocated to receive black cohosh combined preparation (n = 50) or placebo (n = 50) daily for 12 weeks. A total of seventy eight subjects completed the study. The effect of black cohosh on vaginal atrophy was evaluated by measuring Maturation value (MV). MV was determined from vaginal smear at 0 and 12 weeks of treatment. Safety assessment included vital signs, physical examinations, adverse events, and routine laboratory parameters. Assessments were carried out at the beginning, and after 4, 8, and 12 weeks of treatment. Results: The mean (± standard deviation) MV decreased 0.18 (0.48 ± 0.33 to 0.30 ± 0.24) in the black cohosh group and 0.13 (0.44 ± 0.31 to 0.31 ± 0.22) in the placebo group. There was no statistical difference between the groups. But adverse events were observed in 7 (14%) patients in the black cohosh group and 6 (12%) patients in the placebo group, without statistical significance. No significant effects were observed on blood pressure, heart rate, body temperature, physical findings, and laboratory values. Black cohosh was well tolerated. Conclusion: Black cohosh did not exert estrogenic effects with regards to vaginal atrophy. Further studies on the long-term safety and the appropriate doses of cohosh are needed.

Key Words: Adverse effects, Cimicifuga, Genital diseases female
for decades. However, concerns about the safety and efficacy of existing hormonal replacement therapy became serious after the Women’s Health Initiative (WHI), and Women’s Health Initiative Memory Study (WHIMS) studies reported that the risk of breast cancer, cardiovascular diseases, thromboembolism, and dementia were increased by hormone replacement. As a result, a large number of menopausal women have discontinued taking hormones, and have turned to herbs, phytoestrogens, and dietary supplements instead because they worry about their reactions to hormones. These alternatives have been advertised as natural plant hormones that function like estrogen in selected tissues. Thus, they have been recognized as safer substitutes for hormones in terms of complications such as breast cancer.

Black cohosh has been most commonly used as a hormone substitute in western countries, and has been studied widely for treatment of menopausal symptoms. Black cohosh, a plant of the family of ranunculuses, is native to North America, and its root and rhizome have been used for medical treatments of conditions such as gynecological diseases over the past several hundred years. Black cohosh, which was first used by Native Americans, has been used as phytotherapy for the treatment of menopausal symptoms for 50 years in Europe. The German Commission E, which is a committee on herbal medicines in Germany, approved cohosh as a medicine for menopausal symptoms as well as premenstrual syndrome and menstrual pain. Recently, an effect of cohosh on menopausal symptoms such as febrile flushing has been proven in double-blind, placebo-controlled studies. Therefore, following existing studies on the effects of cohosh complex medication on menopausal symptoms, this study investigated the effect of cohosh on vaginal atrophy in menopausal women by observing changes in the vaginal maturation value, which is the secondary outcome variable of this study. Whether a cohosh complex medication was safe to use for menopausal women over the short term was investigated by comparing side effects and laboratory tests including liver enzymes of placebo and control groups.

Materials and Methods

The subjects were 100 menopausal women who had visited any of 3 university hospitals within 13 months, from June 2007 to July 2010. The study design was retrospective chart review.

Among the naturally menopausal women over 40 who had experienced amenorrhea for at least a year, and those with amenorrhea for at least 6 months with an follicle-stimulating hormone (FSH) blood concentration of 40 mIU/mL, women were included as subjects who had menopausal symptoms above the moderate level, with a Kupperman index score of over 20. The following cases were excluded: those with a current or past history of malignancy, bilateral ovariectomy, hysterectomy, chemotherapy, radiotherapy on the pelvis, psychiatric treatment, hormonal replacement therapy within the 3 months before taking the medication of this study, cardiovascular disease, cerebrovascular disease, hepatic dysfunction (specifically, those with 2 times the upper limit of normal values of liver enzymes), phytosensitivity reaction (a contraindication for St. John’s wort), taking other medications in other clinical trials within 30 days before starting this study, and planning to take other medications for other clinical trials during the period of this study.

Among the 100 naturally menopausal women, cohosh complex medication and a placebo were allotted randomly to groups of 50 women each. Two tablets of the placebo or two tablets of the cohosh complex medication were prescribed twice a day for groups of 50 women for 12 weeks. The placebo consisted of lactose, microcrystalline cellulose, and sodium starch glycolate. A tablet of Feramin-Q® (Dongkook

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