High-Dose Soy Improves Vasomotor Symptoms

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San Diego — High doses of soy containing isoflavones were associated with significant improvements in energy, vasomotor symptoms, and psychosocial functioning among postmenopausal women, according to an interim analysis of data from a randomized, placebo-controlled study.

Among the first 35 subjects to complete a 3-month study, the 18 receiving active soy had a 40% reduction in psychosocial symptoms, a 36% reduction in vasomotor symptoms, and a 30% reduction in physical complaints, compared with those receiving placebo.

The study ultimately will enroll 100 healthy women who have not taken hormone therapy for the 6 months prior to enrollment, Kendall Dupree, M.D., said at the annual meeting of the Endocrine Society.

"At this point, we're pretty happy about the results. We think that soy may show an improvement in quality of life in women who have postmenopausal symptoms," said Dr. Dupree, who works in the division of endocrinology and metabolism at Johns Hopkins University in Baltimore.

The primary outcome of the study is to determine whether high doses of a carefully studied formulation of a product containing the isoflavonoids genistein and daidzein can produce a quantified impact on quality of life in postmenopausal women.

Results were calculated using the Menopause-Specific Quality of Life questionnaire at baseline, 6 weeks, and 3 months.

Within the survey are questions that specifically address physical functioning, including energy and activities of daily life. There also are questions about vasomotor symptoms, including hot flashes and night sweats, as well as questions about psychosocial symptoms, including mood and depression, and sexual functioning.

The mean age of the women who participated in the interim analysis was 55. Despite the improvement in their reported menopausal symptoms, there were no changes noted in their serum sex hormones.

Previous studies of soy and postmenopausal symptoms have been largely unconvincing, with a systematic review identifying few well-designed trials that show a significant impact on hot flashes or other symptoms (Obstet. Gynecol. 2004;104:824-36).

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However, many previous trials have used relatively low doses of phytoestrogens, often 50 mg/day to about 85 mg/day. The dose in this study was 160 mg/day.

The preparation was dehydrated and did not use alcohol extraction during processing, according to Dr. Dupree who also spoke at a press conference at the meeting.

"Alcohol extraction removes the proteins, which in combination with isoflavones seem to be important," she said.

A commercial product (Revival Soy, manufactured by Physicians Laboratories Inc., of Kernersville, N.C.) was used in the study.

However, study investigators pointed out that they also conducted an independent analysis to ensure that the dosages listed on the label were actually contained in the product.

Physicians Laboratories also helped to fund the study, which was done in conjunction with the National Center for Complementary and Alternative Medicine within the National Institutes of Health.

"I think this is really hot stuff," said Mary Lee Vance, M.D., who served as moderator of the press conference and who is a professor of endocrinology and metabolism and is associate director of the General Clinical Research Center at the University of Virginia in Charlottesville.

"Other studies have not shown that soy is very beneficial." ■