High-Dose Soy Reduced Vasomotor Symptoms

Soy-containing isoflavones were associated with significant improvements in postmenopausal women.

BY BETSY BATES
Los Angeles Bureau

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, of 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 aimed at physical functioning, including energy and activities of daily life; vasomotor symptoms, including hot flashes and night sweats; psychosocial symptoms, including mood and depression; and sexual functioning.

The mean age of the women included in the interim analysis was 55. Despite the improvement in their reported menopausal symptoms, there were no changes 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).

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, Dr. Dupree said during 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.

But study investigators 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 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 the moderator of the press conference, Mary Lee Vance, M.D., professor of endocrinology and metabolism and 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." ■

Study Evaluates Sexual Function Post Hysterectomy

BY SHERRY BOSCHERT
San Francisco Bureau

RANCHO MIRAGE, CALIF. — Supracervical hysterectomy did not leave women with better sexual function or quality of life, compared with total abdominal hysterectomy in the first randomized study to evaluate these outcomes in women who have had an abdominal hysterectomy.

Renewed interest in supracervical hysterectomies in recent decades grew out of speculation that women undergoing hysterectomies might enjoy better postoperative sexual function if the cervix were left intact.

Initially, the women with supracervical hysterectomy had better sexual function; however, no differences were seen 2 years after surgery.

The study's findings confirm previous nonrandomized results from British, Danish, and Finnish studies that found no difference in function or quality of life with supracervical rather than total abdominal hysterectomy.

"I hope we can separate myth from reality in counseling patients" who are considering hysterectomy, Lee Learman, M.D., said at the annual meeting of the Society of Gynecologic Surgeons.

The study included 135 women scheduled for hysterectomies at four U.S. clinical centers to treat symptomatic uterine fibroids and/or abnormal uterine bleeding refractory to hormonal management.

At randomization, women in the supracervical hysterectomy group had higher scores on the 100-point Medical Outcomes Study sexual problems scale, with 100 representing no problems. The mean score of 69 suggested better baseline sexual function, compared with the abdominal hysterectomy group (mean score of 55).

Phone interviews 4 weeks after surgery and then every 3 months for 2 years found significant improvements in sexual problems scores in both groups within 6 months. Scores plateaued by 1 year. At 2 years, scores were similar between groups—82 in the supracervical hysterectomy group, and 80 in the abdominal hysterectomy group, said Dr. Learman of San Francisco General Hospital, and his associates.

The principal investigator for the study was Miriam Kupperman, Ph.D., also of the hospital.

The supracervical hysterectomy group reported higher orgasm frequency and quality scores at 6 months, but no differences between groups were seen at 2 years.

Both groups reported psychological benefits even before they had physically recovered from the surgery, quality of life assessments found. Health-related quality of life after hysterectomy was similar between groups. ■

Thermoablation Safe, Effective for Idiopathic Menorrhagia, Study Finds

BY DOUG BRUNK
San Diego Bureau

SAN DIEGO — Thermal balloon endometrial ablation is a safe and effective option for the treatment of women with idiopathic menorrhagia, results from a 3-year study of 330 women have shown.

"The procedure is simple, does not require additional training in operative hysterectomy, and compares favorably with other ablative techniques," Stefanos Chandakas, M.D., Ph.D., reported at an international congress of the Society of Laparoendoscopic Surgeons. "These good results, however, need to be confirmed in a randomized, controlled trial."

For the study, he and his associates used a 6-mm diameter Cavaterm Plus thermoablation system in 330 women with a mean age of 42 years.

All of the participants had experienced heavy menstrual bleeding, failed medical treatment for the condition, and otherwise would have required hysterectomy, endometrial laser ablation, or endometrial resection.

The outpatient procedures were performed from January 2001 to June 2004 at Princess Royal University Hospital and Farnborough Hospital, Orpington, England.

Contraindications included undiagnosed uterine bleeding, pregnancy or the desire to become pregnant, atypical endometrial cells, cervical length greater than 6 mm, gross uterine abnormalities that would result in an inappropriate balloon contact with the endometrium, a uterine cavity less than 4 cm or greater than 10 cm, uterine wall weakness, or ongoing infection.

No endometrial preparation was used. Each ablation lasted 10 minutes at a temperature of 78° C.

Follow-up occurred at intervals of 3, 6, 12, 24, and 36 months, for a mean of 22 months.

Nearly half of the participants (48%) were amenorrheic after 1 year, while the rates of amenorrhea were 39% and 38% after 2 and 3 years, respectively. (See chart.)

The majority of women (83%) reported a reduction in dysmenorrhea and premenstrual symptoms at 1 year, "which is a recognized and consistent finding following endometrial destructive procedures," said Dr. Chandakas of the minimal access unit in the department of obstetrics and gynecology at Princess Royal.

At 3 years, 73% of women reported a reduction in dysmenorrhea and premenstrual symptoms.

No balloons failed, and no major complications were noted.

Dr. Chandakas credited the success of the procedure in large measure to the Cavaterm Plus silicone balloon, which is formed to adapt to the uterine cavity. "The adjustable balloon length fits every uterus and protects the cervix from burns," he said.

Dr. Chandakas disclosed that he has no financial interest in Wallsten Medical, the Swiss manufacturer of Cavaterm Plus. ■

Thermal Balloon Endometrial Ablation

Follow-Up	Amenorrhea	Hypomenorrhea
6 months (n = 321)	61%	22%
12 months (n = 289)	48%	27%
18 months (n = 193)	42%	31%
24 months (n = 132)	39%	35%
36 months (n = 91)	38%	35%

Source: Dr. Chandakas