Flaxseed Bars Found Ineffective for Hot Flashes

VITALS

Major Finding: Mean hot flash scores decreased by 4.9 units (about 33%) in the flaxseed arm, and by 3.5 (about 29%) in the placebo arm, a nonsignificant difference.

Data Source: A trial of 178 postmenopausal women randomized to flaxseed bars or placebo bars for 6 weeks.

Disclosures: This study was funded by the National Cancer Institute. Dr. Pruthi reported having nothing to disclose.

BY RICHARD HYER

FROM THE ANNUAL MEETING OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

CHICAGO – Eating bars rich in flaxseed failed to reduce hot flashes for postmenopausal women in a randomized, placebo-controlled, phase III trial conducted by the North Central Cancer Treatment Group.

Mean hot flash scores fell comparably in both arms of the study, which enrolled breast cancer patients and women who never had the disease. Instead of relief from this troubling symptom, many participants reported GI distress.

"Our findings do not support the use of 410 mg of flaxseed lignans for the reduction of hot flashes. The gastrointestinal side effects seen in both groups were more likely due to the fiber content in the flaxseed and the placebo bars," said Dr. Sandhya Pruthi of the Mayo Clinic in Rochester, Minn. She presented the results at the meeting.

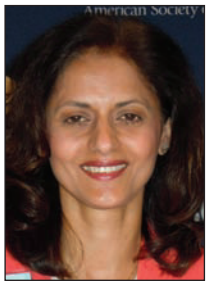
"Because hot flashes can negatively impact quality of life for many women, there is increasing interest in the use of complementary therapies such as flaxseed," Dr. Pruthi

said, laying out the rationale for the trial.

Flaxseed is an annual plant, rich in lignans, which are a major class of phytoestrogens, she said. It is thought to have a weak estrogenlike effect, as well as estrogen antagonist effect.

In 2005, a pilot study was conducted in 30 women. They were given 400 mg of ground flaxseed, and investigators reported a 57% reduction in hot flash scores and a 50% reduction in hot flash frequency. This led to the current trial, said Dr. Pruthi.

To be eligible, women with or without a history of breast cancer had to have more than 28 hot flashes per week. In all, 188 women were enrolled and 178 were randomized (88 to flaxseed bars containing 410 mg of lignans and fiber, and 90 to placebo bars containing protein and fiber, but no flaxseed, soy, or lignans). For 6 weeks, the participants were to eat one bar per day. The primary end point was a change from baseline in hot flash scores at week 6.



Although the results were disappointing, the trial does not leave women without remedies for hot flashes.

DR. PRUTHI

Of the entire group, 91 had a history of breast cancer but were without active disease. This group included women who were being treated with an aromatase inhibitor or tamoxifen.

Mean hot flash scores decreased by 4.9 units (33%) in the flaxseed arm, and 3.5 (29%) in the placebo arm ($P = .29$). "There was no significant difference in the reduction of hot flash scores between the two arms," said Dr. Pruthi.

No statistically significant toxicity differences were experienced between study arms, but both groups reported substantial abdominal distention, gas, diarrhea, and nausea.

Although the results were disappointing, the trial does not leave women without remedies for hot flashes. Dr. Pruthi noted that venlafaxine and gabapentin were effective, and had been studied in randomized, placebo-controlled trials. "However, there are side effects with those drugs. Patients need to balance between treating their symptoms and managing their side effects, which is why we need to do more studies in other complementary therapies," she said. ■

Denosumab Not Cost Effective in Some Cancers

FROM THE ANNUAL MEETING OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY

CHICAGO – Denosumab, a drug newly approved for prevention of skeletal-related adverse events in cancer patients with bone metastases from solid tumors, is not cost effective when compared with zoledronic acid in patients with breast or prostate cancers, according to a pair of pharmacoeconomic analyses.

A review of data from a key phase III trial in 2,046 patients with metastatic breast cancer found the cost per quality-adjusted life-year (QALY) gained with denosumab (Xgeva) was $643,726 when compared with zoledronic acid (Zometa), John A. Carter and his coinvestigators reported in a poster at the meeting.

This ratio is far higher than the $50,000 to $100,000 that is considered to be good value for a medical intervention, they said.

A related study in castration-resistant prostate cancer metastatic to the bone found even more substantial cost differentials. The resultant cost per QALY for denosumab would be about $1.25 million in this setting, reported Sonya H. Snedecor, Ph.D., and her coauthors in a separate poster.

In both studies, investigators attributed the high cost per QALY to the higher drug acquisition cost of denosumab combined with limited added prevention of skeletal-related events (SREs) and a lack of overall survival or disease progression benefits for denosumab vs. zoledronic acid. "What we found [in the prostate cancer study] is that there were very little gains in quality-adjusted life-years with the use of denosumab – very, very minuscule, about five per thousandths of a year," Marc Botteman of Pharmerit North America, said in an interview.

Novartis, the maker of zoledronic acid, sponsored both studies. Mr. Carter and Dr. Snedecor disclosed consultant or advisory roles with Novartis. One of their coauthors was a Novartis employee with stock ownership.

–Richard Hyer