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FILE: ■ Flaxseed (*Linum usitatissimum*)
■ Blood Lipids
■ Menopause, Menopausal Symptoms

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RE: Effects of Flaxseed Intake in Healthy Menopausal Women

Dodin S, Lemay A, Jacques H, Légaré F, Forest JC, Mâsse B. The effects of flaxseed dietary supplement on lipid profile, bone mineral density, and symptoms in menopausal women: a randomized, double-blind, wheat germ placebo-controlled clinical trial. *J Clin Endocrinol Metab.* 2005;90(3):1390–1397.

Since the recent finding from the Women's Health Initiative that hormone replacement therapy is associated with an increased risk of cardiovascular disease and breast cancer, menopausal women have been opting for nonmedicinal alternatives to alleviate their menopausal symptoms. Flaxseed (*Linum usitatissimum*) is one such alternative, and it has gained popularity as a dietary supplement. Flaxseed is the richest known source of lignans, one of the three major classes of phytoestrogens, and is also a rich source of α -linolenic acid (ALA) and soluble and insoluble fibers. Despite the increasing popularity of flaxseed as a dietary supplement, no large randomized clinical trials of its effects on estrogen deficiency in healthy menopausal women have been published. The objective of this study was to evaluate the effects of flaxseed consumption on the lipid profile, bone mineral density (BMD), and symptoms of healthy menopausal women.

Between January 2000 and May 2001, 199 French Canadian menopausal women were randomly assigned to receive 40 g of either flaxseed ($n = 101$) or wheat germ as placebo ($n = 98$) daily for 12 months. Half of the daily amount of flaxseed and wheat germ was provided as 2 slices of bread, and the other half was provided as ground grains that were added to cereal, juice, or yogurt. Baseline and follow-up assessments were conducted at the St. François d'Assise Hospital's clinical unit in Canada. Menopausal symptoms (hot flashes and night sweats) were evaluated at baseline and at 12 months by using the Menopause-Specific Quality of Life questionnaire. BMD was measured by dual-energy X-ray absorptiometry at baseline and at 6 and 12 months. Serum concentrations of triglycerides and total, high-density-lipoprotein, and low-density-lipoprotein cholesterol were measured at baseline and at 3, 6, and 12 months. Body weight, body mass index, and blood pressure were also evaluated.

Eighty-five subjects in the flaxseed group and 94 subjects in the placebo group completed the study, and compliance was determined to be "very good." The main reason for subject dropout in both groups was digestive problems. At 12 months, within-group scores for hot flushes and night sweats were significantly lower than those at baseline after flaxseed and placebo treatments ($P < 0.0001$ for both); however, the differences between groups were not significant. Within-group changes in lumbar BMD from baseline to 12 months were significant ($P < 0.0001$) in both treatment groups; within-group changes in femoral neck BMD were not significant. No significant differences in lumbar or femoral neck BMD were observed between treatment groups. The differences in total cholesterol (-0.20 ± 0.51 mmol/L; $P = 0.012$) and high-density-lipoprotein cholesterol (-0.08 ± 0.24 mmol/L; $P = 0.031$) between treatment groups were significant. Serum low-density-lipoprotein cholesterol and triglycerides were not significantly different between groups at 12 months. Body weight, body mass index, and blood pressure all decreased with flaxseed consumption; however, the differences between treatment groups were not clinically significant in healthy menopausal women.

The results indicate that the incorporation of flaxseed into the diet for 12 months had "favorable, but limited, effects" on blood lipid concentrations but no significant effects on BMD or menopausal symptoms in healthy menopausal women. Although the decrease in total cholesterol with flaxseed consumption was statistically significant, the magnitude of the reduction (5.3%) may have been too small to be clinically significant. However, the beneficial effects on the lipid profile and the slight decreases in body weight, body mass index, and blood pressure may reduce the incidence of lipid abnormalities and cardiovascular disease risk. The failure to improve these symptoms with flaxseed may have been due to a "ceiling effect" in that observing a distinct effect of flaxseed was not possible because of the good baseline characteristics of the subjects. The authors suggest that additional studies be conducted to determine the effects of the major components of flaxseed on nontraditional markers of lipoprotein metabolism, hemostasis (stoppage or sluggishness of blood flow), and inflammation.

One important note to make is that except for the digestive complaints, there were no apparent negative health effects from consuming flaxseed as part of the subjects' diets. Also, this study was not designed to investigate the effect of flaxseed on women who experience significant symptoms of estrogen deficiency, therefore it is difficult to extrapolate the study's results to women who are not healthy and/or do not have a balanced diet.

—*Brenda Milot, ELS*

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