Soy Protein Lowered Blood Pressure in Chinese Trial

BY BRUCE JANCIN
Denver Bureau

VANCOUVER, B.C. — Increased intake of soybean protein may provide an important means of preventing and treating hypertension, Jiang He, M.D., declared at a meeting sponsored by the International Academy of Cardiology.

He presented results from a multicenter, double-blind, randomized, controlled trial of soybean protein in 302 Chinese adults with prehypertension or stage 1 hypertension. Participants in the 12-week trial ate cookies containing either 40 g/day of isolated soybean protein or 40 g of complex carbohydrates from wheat. The cookies were identical in taste and appearance. Most subjects ate them in lieu of their usual breakfast.

Baseline mean blood pressure was 135/85 mm Hg. The main study finding was a highly significant net blood pressure reduction of 4.3 mm Hg for systolic and 2.8 mm Hg for diastolic in the soy group, compared with the control group.

This effect was larger than was found in studies of currently recommended lifestyle modifications, with the single notable exception of the National Heart, Lung, and Blood Institute–sponsored Dietary Approaches to Stop Hypertension (DASH) diet, noted Dr. He of Tulane University, New Orleans.

The blood pressure reduction was greater in subjects with stage 1 hypertension than in those who were prehypertensive. Indeed, stage 1 hypertensives experienced a net reduction of 7.9/5.3 mm Hg in response to soybean protein supplementation. The 2.4/1.3 mm Hg reduction in prehypertensive subjects didn't achieve statistical significance; however, the study wasn't powered for subgroup analysis, he said.

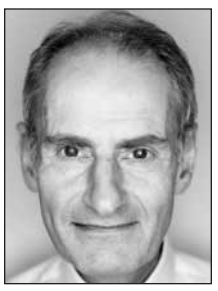
Session cochair Martha L. Daviglus, M.D., of Northwestern University, Chicago, noted that the observational International Study on Macronutrients and Blood Pressure, in which she was an investigator, found an association between greater consumption of vegetable protein—but not animal protein—and lower blood pressure. This raises the question of whether the blood pressure–lowering effect documented in Dr. He's study is unique to soy protein or might be achievable with a diet enriched with mixed vegetable protein.

The daily portion of soy cookies contained 76 mg of total isoflavones (45 mg genistein and 27 mg daidzein). The study was funded by Tulane; the National Heart, Lung, and Blood Institute; and the Ministry of Science and Technology, People's Republic of China. ■

Diet Lowered LDL by 30%

NEW YORK — Diet can work almost as well as a statin for cutting a patient's level of LDL cholesterol.

Patients who stuck with a highly structured diet rich in plant sterols, soy protein, viscous fibers, and almonds maintained their serum LDL-cholesterol level at 30% below their baseline level for a year, a decrease that was similar to the average 33% drop seen in patients treated with 20 mg of lovastatin daily, David J.A. Jenkins, M.D., reported at an international symposium on triglycerides and HDL cholesterol.



'Using cholesterol-lowering foods bridges the … gap between a generally good diet and statin therapy.'

DR. JENKINS

"Using cholesterol-lowering foods bridges the therapeutic gap between a generally good diet and statin therapy," said Dr. Jenkins, a professor in the department of nutritional sciences at the University of Toronto.

The special diet also dropped the average starting serum level of C-reactive protein by about 30%, compared with an average 35% with lovastatin. The year-long study began with a total of 66 patients with LDL-cholesterol levels of at least 158 mg/dL at baseline who had not taken statins for 2 weeks prior to the study and were otherwise healthy; 58 completed the study.

The diet was built on a foundation of the American Heart Association's step II diet, which is recommended by the National Cholesterol Education Program. Patients randomized to statin treatment also ate the step II diet, as did a control group who received no other intervention beyond the step II diet.

The group assigned to the special diet also ate the following lipid-lowering foods: plant sterols, 1 g/1,000 kcal of diet, consumed as a plant sterol–enriched margarine; viscous fiber, 9.8 g/1,000 kcal of diet, which came from oats, barley, and psyllium; soy protein, 21.4 g/1,000 kcal of diet, in the form of soy milk and meat analogs made from soy; and whole almonds, 14 g/1,000 kcal of diet.

After a year, the control patients had an average 8% reduction in their LDL-cholesterol level, compared with baseline, and no change in their C-reactive protein level, said Dr. Jenkins at the symposium, sponsored by the Giovanni Lorenzini Foundation. A detailed assessment of a subgroup of the participants showed that compliance with the prescribed lipid-lowering diet was the major factor linked to substantial reductions in LDL-cholesterol levels, Dr. Jenkins said.

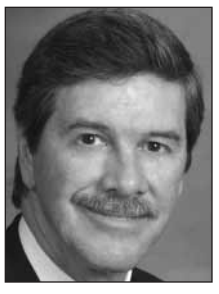
—Mitchel L. Zoler

Fibrate/Statin Called Safer Combo Therapy

BY MITCHEL L. ZOLER
Philadelphia Bureau

NEW YORK — The combination of fenofibrate and a statin appears to be safer than gemfibrozil and a statin, according to an analysis of adverse event reports to the Food and Drug Administration.

From January 1998 through March 2002, the FDA received 0.6 reports of rhabdomyolysis for the combination of fenofibrate plus any statin except cerivastatin per every million prescriptions written for this drug combination, Peter H. Jones, M.D., said at an international symposium on triglycerides and HDL.



Fenofibrate is metabolized by a different set of enzymes, so it has little impact on statin metabolism.

DR. JONES

During the same period, the FDA received 8.6 reports of rhabdomyolysis for the combination of gemfibrozil plus any statin except cerivastatin per every million prescriptions written for this combination, a rate that is more than 14 times higher than for fenofibrate plus a statin, said Dr. Jones, codirector of the lipid metabolism and atherosclerosis clinic at Baylor College of Medicine, Houston.

Recent reports from other research groups provide an explanation for this observation. Treatment with gemfibrozil appears to boost the maximum concentration and the area under the curve for any concurrently administered statin, an effect that's not seen with fenofibrate, he said.

This effect appears to occur because statins and gemfibrozil are metabolized by the same liver enzymes. In contrast, fenofibrate is metabolized by a different set of liver enzymes and hence has little impact on statin metabolism, said Dr. Jones at the symposium, sponsored by the Giovanni Lorenzini Medical Foundation.

Adverse report analysis by Dr. Jones and his collaborator excluded cerivastatin because treatment with that statin was associated with an unusually high number of cases of rhabdomyolysis.

The study found that the FDA received two reports of rhabdomyolysis in patients treated with fenofibrate plus a statin other than cerivastatin out of more than 3.4 million prescriptions for the drug combination written during the 4-year study period. In comparison, 57 reports of rhabdomyolysis were submitted to the FDA regarding patients treated with gemfibrozil plus any statin but cerivastatin out of more than 6.6 million prescriptions written for this combination.

Dr. Jones receives research support from Pfizer Inc., which markets gemfibrozil (Lopid), and from Abbott Laboratories, which markets fenofibrate (Tricor). He is also a consultant to Abbott. He does not have a relationship with the companies that market the two other brand formulations of fenofibrate (Antava and Lofibra).

Based on the results of several studies, the combination of a statin and a fibrate (either gemfibrozil or fenofibrate) appears to be very effective for normalizing serum lipid levels in patients with diabetes, metabolic syndrome, or atherogenic dyslipidemia, which features a high level of serum triglycerides and a low level of HDL cholesterol. ■

High-Quality Carbs May Reduce C-Reactive Protein

WASHINGTON — A high-quality carbohydrate diet is associated with reduced levels of C-reactive protein, Emily B. Levitan reported at conference on cardiovascular disease epidemiology and prevention sponsored by the American Heart Association.

The finding, from the Women's Health Study, suggests that diets characterized by a high intake of soluble fiber and a low glycemic index appear to reduce inflammation, and therefore might reduce the risk of cardiovascular disease and type 2 diabetes. Previous smaller studies have linked dietary carbohydrates with inflammation, as measured by a high-sensitivity C-reactive protein (hsCRP) level, said Ms. Levitan, a medical student at Harvard Medical School, Boston.

The first large, cross-sectional study examining both fiber intake and dietary glycemic burden involved 15,033 of the Women's Health Study participants who filled out food frequency questionnaires, provided a baseline blood sample, and were not users of postmenopausal hormones. They were divided into quintiles for each of five measurements of carbohydrate quality: glycemic index (the degree to which an average gram of carbohydrate increases blood glucose, compared with white bread); glycemic load (a measure of both glycemic index and carbohydrate quantity); total fiber consumed; insoluble fiber intake; and soluble fiber intake.

After adjustment for age, body mass index, smoking, and various other medical and dietary factors, geometric mean plasma concentration of hsCRP was significantly associated with dietary glycemic index. Soluble fiber intake was inversely related to hsCRP.

There was no linear relationship between hsCRP level and either dietary glycemic load or insoluble fiber intake. The relationship with total fiber consumed was also significant, largely because of the influence of soluble fiber, she said.

—Miriam E. Tucker