Niacin, Psyllium Fiber May Augment Statins

BY MITCHEL L. ZOLER
Philadelphia Bureau

NEW ORLEANS — Pairing niacin or psyllium fiber with a statin can enhance the regimen's ability to reduce a patient's cardiovascular risk factors, according to the results of two independent, controlled studies reported at the annual scientific sessions of the American Heart Association.

In one study of 167 patients, adding 1 g/day of niacin to an existing statin regimen boosted serum HDL-cholesterol levels, reduced triglyceride levels, and slowed the progression of atherosclerosis as measured by carotid intima-media thickness. In the second, 67-patient study, adding a daily dose of psyllium fiber to a standard statin dose cut serum LDL-cholesterol levels as much as did doubling the statin dose.

Niacin is the most effective agent available for treating patients with low levels of HDL cholesterol, said Allen J. Taylor, M.D., director of cardiovascular research at Walter Reed Army Medical Center in Washington. The newest revision of the National Cholesterol Education Program's guidelines flags HDL-cholesterol levels as low if they are at or below 40 mg/dL in men and 50 mg/dL in women, but the guidelines do not call for using any drug to treat low HDL cholesterol.

The study enrolled men and women aged over 30 years with known coronary disease who were already prescribed a statin drug. Patients had to have a serum LDL-cholesterol level of less than 130 mg/dL, and an HDL-cholesterol level of less than 45 mg/dL. They continued their existing statin regimen, and were randomized to 1 g of niacin or placebo daily. The niacin dosage started at 500 mg/day for the first 30 days before being boosted to the maintenance dose; treatment was for 1 year. To minimize problems with flushing, a common effect of niacin, the medication was taken at night along with the patient's usual daily dose of aspirin.

All patients had their common-carotid intima-media thickness measured by ultrasound at baseline, and were reassessed after 1 year. The study's primary end point was the change in intima-media thickness.

The average patient age was 67 years, and at baseline the mean serum HDL-cholesterol level was about 40 mg/dL, the mean LDL-cholesterol level was about 90 mg/dL, and the mean triglycerides level was about 170 mg/dL.

After 12 months, the 78 patients remaining in the niacin group (out of 87 randomized) had an average HDL-cholesterol level of 47 mg/dL and an average serum triglycerides level of 134 mg/dL, both statistically significant changes from baseline. In contrast, the 71 patients in the placebo group (out of 80 who started) had no statistically significant change in their levels of HDL cholesterol and triglycerides, said Dr. Taylor. Serum levels of LDL cholesterol showed no significant change in either treatment group.

The average carotid intima-media thickness increased in both groups. In the niacin-treated patients, it thickened by an average of 0.014 mm, not a statistically significant change from baseline. But in the placebo group, it thickened by an average of 0.044 mm, a statistically significant increase from baseline.

Niacin was well tolerated. Fewer patients withdrew because of adverse drug effects in the niacin group than in the placebo group.

"The first step for managing low levels of HDL cholesterol is to counsel a patient on the need for increased exercise, weight loss, and smoking cessation," said Philip Greenland, M.D., chairman of the department of preventive medicine at Northwestern University, Chicago. "The role of drug therapy in raising HDL cholesterol remains poorly defined, even with these new data."

The niacin study was an investigator-initiated project that received an unrestricted research grant from Kos Pharmaceuticals, which markets a formulation of niacin. Dr. Taylor has no financial relationship with Kos.

The second study assessed psyllium fiber treatment as an adjunct to statin therapy and enrolled patients who were on statin treatment because of coronary disease risk factors. All patients were withdrawn from statins during a 4-week run-in, and then randomized to three treatment groups: 10 mg/day simvastatin, 20 mg/day simvastatin, or 10 mg simvastatin plus 3.6 g soluble fiber per day. The fiber was consumed as 6 g of Metamucil psyllium fiber t.i.d. At the end of the run-in period, serum levels of LDL cholesterol averaged about 173 mg/dL.

Niacin is the most effective agent available for treating patients with low levels of HDL cholesterol.

DR. TAYLOR

After 8 weeks, serum levels of LDL cholesterol had dropped by an average of 55 mg/dL in the 23 patients on 10 mg/day of simvastatin, and by an average of 63 mg/dL among the 22 patients on 20 mg/day simvastatin daily, as well as the 22 patients who received 10 mg/day simvastatin plus the fiber supplement, reported Abel E. Moreyra, M.D., professor of medicine at Robert Wood Johnson Medical School in New Brunswick, N.J. The difference in the magnitude of the drop in LDL cholesterol between the 10-mg simvastatin group and the two comparator groups was statistically significant.

Thus, treatment with 3.6 g/day soluble fiber had the same incremental impact on lowering LDL cholesterol as did doubling a patient's dosage of simvastatin from 10 mg/day to 20 mg/day, said Dr. Moreyra. In addition, the psyllium fiber dosage used was very well tolerated. This study received no commercial funding. ■

New Nomogram Calculates Exercise Capacity in Women

BY MITCHEL L. ZOLER
Philadelphia Bureau

NEW ORLEANS — Finally, there is a nomogram for women that calculates their exercise capacity as a percentage of normal for age.

Until now, the only nomogram available for assessing exercise capacity as the percentage of normal for age was based on observations in men. But gender is one of the key factors that defines normal exercise capacity, which means that exercise capacity in women has been erroneously assessed, Martha Gulati, M.D., said at the annual scientific sessions of the American Heart Association. The exercise-capacity nomogram for men is currently recommended for use in both sexes in the joint guidelines of the American College of Cardiology and American Heart Association.

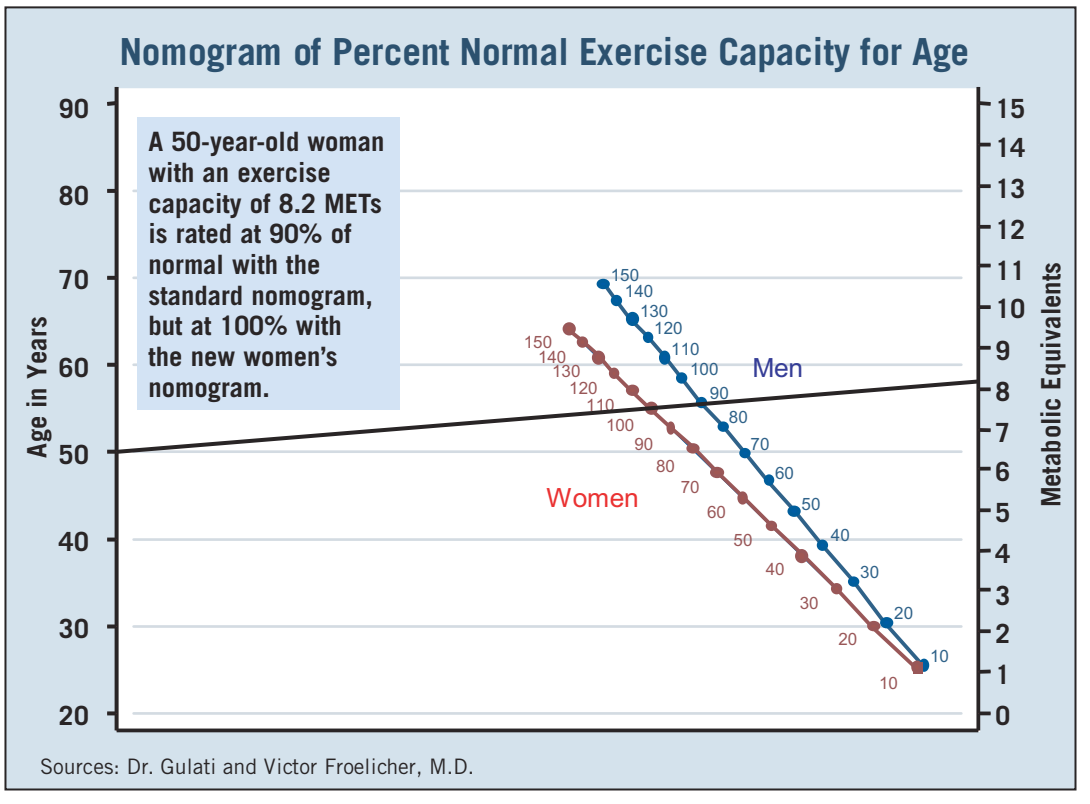
Although these two equations differ by just a small multiplicative factor (a difference of 0.02 metabolic equivalents [METs]), when this difference is multiplied by age, it creates a substantial difference. For example, a 50-year-old woman will have a normal exercise capacity 1.0 METs less than what is calculated for a man—a major difference, given that normal exercise capacity for a 50-year-old woman is 8.2 METs, said Dr. Gulati, a cardiologist at Rush University Medical Center in Chicago. (See box.)

One MET equals the amount of oxygen a person consumes while at rest.

This difference means that when women were held to the male standard for exercise capacity, they were expected to have a greater capacity than they should have. As a result, an excess of women were diagnosed with impaired exercise capacity, Dr. Gulati said.

The new nomogram was derived from exercise data collected from 5,721 women from the Chicago area who were asymptomatic for coronary disease, older than 35 years, and participants in the St. James Women Take Heart Project.

The women's nomogram was then validated using another set of exercise test results that had been collected from 4,471 women with coronary disease symptoms who participated in the Economics of Noninvasive Diagnosis study.



Sources: Dr. Gulati and Victor Froelicher, M.D.

Follow-up survival data were collected for both groups of women for an average period of about 5 years. Survival data from the asymptomatic women showed that those whose exercise capacity was less than 85% of normal for age were twice as likely to die from cardiac causes as women with an exercise capacity of 85% or greater. Follow-up of the symptomatic women showed that baseline exercise capacity of less than 85% of normal was linked with a 2.4-fold increased risk of death from cardiac causes, Dr. Gulati reported.

Pages 18a—18d