Mediterranean Diet Plus Nuts Lowers CV Risk

BY MARY ANN MOON
Contributing Writer

An ad libitum Mediterranean-style diet, supplemented with a daily serving of mixed nuts, appears to decrease the prevalence of metabolic syndrome in older people at high risk for cardiovascular disease, according to Spanish researchers.

In a 1-year study, the diet also lowered the prevalences of hypertriglyceridemia and hypertension, two chief components of the metabolic syndrome. Those beneficial effects were achieved by dietary changes alone; the study subjects did not lose weight or increase their physical activity, said Dr. Jordi Salas-Salvadó of the University of Rovira I Virgili, Reus, Spain, and his associates in the PREDIMED study.

Traditionally, diets recommended to improve health are low in fat and calories, and "generally are not palatable," the researchers said. The study's results "show that a non-energy–restricted traditional Mediterranean diet enriched with nuts, which is high in fat … and palatable, is a useful tool in managing the metabolic syndrome."

The PREDIMED (Prevención con Dieta Mediterránea) study is an ongoing multicenter clinical trial involving approximately 9,000 older patients (aged 55-80 years) who are at high risk for cardiovascular disease but as yet show no sign of it.

A subgroup of 1,224 patients was assessed for the report. They were randomly assigned to follow a Mediterranean-style diet supplemented with mixed nuts (primarily walnuts, hazelnuts, and almonds), a Mediterranean-style diet supplemented with virgin olive oil, or a control group.

A total of 61% of the subjects met the criteria for metabolic syndrome, and nearly 45% had type 2 diabetes, the investigators reported.

After 1 year, the rates of elevated triglycerides, high blood pressure, and abdominal obesity were significantly decreased with both dietary interventions, but were not in the control group. Those reductions were more pronounced in the group that followed the Mediterranean-style diet supplemented with nuts.

The overall prevalence of the metabolic syndrome decreased by 14% in the diet-plus-nuts arm of the trial, and by 7% in the diet-plus–olive-oil arm, compared with a 2% reduction in the control group.

"The novelty of our findings is that a positive effect on the metabolic syndrome was achieved by diet alone, in the absence of weight loss or increased energy expenditure in physical activity," Dr. Salas-Salvado and his associates said (Arch. Intern. Med. 2008;168:2449-58).

Longer follow-up in the study, which is designed to continue for another 3 years, may provide stronger evidence of the cardiovascular benefits of the Mediterranean diet, the investigators added.

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Heart benefits were more pronounced when nuts were included in the diet.

Dr. Salas-Salvadó is a nonpaid member of the Scientific Advisory Council of the International Nut Council. ■

Orlistat Not Helpful in Teens With Metabolic Syndrome

BY JANE SALODOF MACNEIL
Southwest Bureau

PHOENIX — Orlistat produced modest weight loss in extremely obese adolescents but failed to reverse comorbidities associated with metabolic syndrome in a randomized, placebo-controlled trial conducted by the National Institutes of Health.

Teenagers treated with orlistat (Xenical) lost more weight than did those on placebo after 6 months of treatment, but measures of blood pressure, cholesterol, insulin resistance, and fat-soluble vitamins were not significantly different—except for triglycerides, which were lower in the placebo group ($P = .05$).

"Orlistat really cannot be routinely recommended for treatment of obese-adolescents for comorbid conditions associated with obesity," Dr. Jack A. Yanovski, the principal investigator, concluded during his presentation of the data at the annual scientific meeting of the Obesity Society.

Dr. Yanovski, head of the unit on growth and obesity within the National Institute of Child Health and Human Development, noted that orlistat gained approval for use in obese 12- to 16-year-olds in 2003 after a large randomized trial sponsored by Hoffmann-La Roche Inc. showed a modest but statistically significant reduction in body mass index (BMI) for this population. Only a quarter of participants met metabolic syndrome criteria, however, and changes in lipids, glucose, blood pressure, and insulin resistance were not significant.

Roche contributed orlistat and placebo for the current study, which enrolled 200 overweight black and white teenagers, all of whom had at least one comorbidity associated with metabolic syndrome. The group was evenly randomized: 100 participants to the full adult dose of 120 mg of orlistat three times per day and 100 teens to placebo. All were given a low-calorie diet.

The population was about 65% female and 61% black with an average age of about 14.6 years and average BMI of 41.7 kg/m^2. Nearly half the participants met criteria for metabolic syndrome. The two arms of the study were well balanced, with 87 teens on orlistat and 84 on placebo completing the study.

The orlistat group lost significantly more weight: –2.9 kg. vs. –0.6 kg for the placebo group. The orlistat group also had a significantly greater reduction in BMI (–1.72 vs. –0.70) and in fat mass (–3.9 kg. vs. –1.4 kg).

Blacks lost significantly less weight on orlistat than did whites, but orlistat was just as efficacious when weight gain in the black placebo group was taken into account. For blacks, the difference between weight loss on orlistat and weight gain on placebo was 2.5 kg. Whites lost whether they were on orlistat or placebo, but they lost more on orlistat with a similar difference of 2.2 kg.

Liver enzymes were significantly and unexpectedly higher with orlistat, he reported. Gastrointestinal side effects also were more common, but described as short in duration and well tolerated.

Although the trial was blinded, Dr. Yanovski reported most participants in the orlistat arm guessed correctly that they were on the study medication—possibly as a result of the GI side effects associated with orlistat. ■

Sibutramine Kept Off Weight For 2 Years, Then Gains Resumed

BY JANE SALODOF MACNEIL
Senior Editor

PHOENIX — Sibutramine helped people who had lost substantial amounts of weight maintain much of their weight loss for 2 years in a multicenter, double-blind, randomized trial. By 3 years, however, they had regained about as much as a control group on placebo.

In all, 466 participants started the maintenance study after losing an average of 30 kg in nonpharmacologic weight-loss programs. Although they all had begun to put the pounds back on before entering the trial, they had to have maintained at least half of their peak weight loss for 6 months to be eligible.

"The placebo group steadily gained weight throughout the study. The sibutramine group gained less weight," Dr. James W. Anderson, the principal investigator, reported in an analysis at the annual meeting of The Obesity Society.

Indeed, the net weight gain for the two groups was significantly less with sibutramine (Meridia) for the first 2 years—0.6% vs. 3.1% at 6 months, 2.8% vs. 5.6% at 1 year, and 7.1% vs. 9.8% at 24 months. At 3 years, the sibutramine group still had less net weight gain (9.6% vs. 11.7%), but the difference was no longer statistically significant, and both groups appeared to plateau with no difference from 30 to 48 months.

Dr. Anderson, professor emeritus of medicine and clinical nutrition at the University of Kentucky, Lexington, has been medical director of the HMR Weight Loss Program at the university for 22 years. He said he proposed the study to address the common problem of weight rebound after weight loss and designed the trial to run for 60 months.

Abbott Laboratories became the study sponsor after acquiring sibutramine and decided to curtail follow-up at 36 months, Dr. Anderson said. He emphasized that he has not received any financial support from Abbott for more than 5 years.

The trial randomized 236 subjects to receive 15 mg of sibutramine per day and 230 to placebo at 26 sites. Of these,

'The placebo group steadily gained weight. … The sibutramine group gained less weight.'

DR. ANDERSON

150 placebo patients and 144 sibutramine patients completed 36 months.

The baseline population was about 48 years old on average. More than 90% were white, and three-fourths were women. The participants weighed about 91 kg with a mean body mass index slightly over 32 kg/m^2. All went to a behavior-modification class once a week for the first 12 months, and then once a month until they left the study.

With data on 289 participants, Dr. Anderson estimated that they would have maintained 10.4 kg of weight loss at 5 years—or 35.1% of their initial weight loss before entering the trial.

Blood pressure and pulse rate were significantly higher with sibutramine, said Dr. Anderson, but total adverse events were not. "Sibutramine may be a useful adjunct in selected patients," he concluded. ■