Omega-3 Supplement Fails to Cut Post-MI Events

BY MITCHEL L. ZOLER

ORLANDO — Daily treatment of recent myocardial infarction patients with an omega-3 fatty acid supplement for 1 year failed to show a beneficial effect on the rate of sudden cardiac death or other adverse cardiovascular events in a controlled trial of about 3,800 patients.

One reason why the fish oil–derived supplement did not have benefit may be that most patients were on optimal medical therapy, including aspirin, clopidogrel, a statin, a beta-blocker, and an ACE inhibitor, Dr. Jochen Senges said at the annual meeting of the American College of Cardiology. "There is almost nothing you can do on top of this—the event rates were so unexpectedly low," said Dr. Senges, a professor at the Stiftung Institute for Cardiac Infarction Research in Ludwighafen, Germany.

Despite the lack of benefit from an omega-3 fatty acid supplement in this large study, some experts said it is premature to change existing American Heart Association guidelines that call for a high level of oily fish consumption in people without documented coronary heart disease, and a high level of either oily fish consumption or a daily omega-3 fatty acid supplement in patients with documented coronary heart disease (Circulation 2006;114:82-96). "I don't think we'd change the recommendations at this point" said William S. Harris, Ph.D., director of the cardiovascular health research center at the University of South Dakota in Sioux Falls, and a member of the AHA nutrition committee that made the 2006 fish oil recommendations.

He noted that the treatment studied by Dr. Senges lasted for just 1 year. "Two other major studies [of an omega-3 fatty acid supplement], GISSI-HF [Lancet 2008;372:1223-30] and JELIS [Lancet 2007;369:1090-8] showed the benefits accrue after the first year. I'd be willing to reconsider [the AHA recommendations] if a 3- to 5-year study showed the same thing" as Dr. Senges' current study, Dr. Harris said in an interview.

"I was a little surprised at the results [from Dr. Senges' study], but it is certainly possible that there are no additional effects of omega-3 fatty acid supplements on cardiovascular risk in patients with cardiovascular disease who are optimally treated," said Emily B. Levitan, Sc.D., a cardiovascular epidemiologist at Beth Israel Deaconess Medical Center in Boston. The results from his study "are important, and help dispel the idea that omega-3 fatty acids are a panacea."

The Randomized Trial of Omega-3 Fatty Acids on Top of Modern Therapy After Acute Myocardial Infarction (OMEGA) trial enrolled patients within 3-14 days after a myocardial infarction at 104 centers in Germany during October 2003–June 2007. In addition to their usual post-MI treatment, patients were randomized to receive 1 g daily of omega-3 fatty acids or placebo. The patients' average age was 64, and about three-quarters were men.

Patients received a prescription formulation of omega-3 fatty acids (Zodin) marketed by the Norwegian company Pronova. The same formulation is licensed for U.S. sale as Lovaza (previously called Omacor) by GlaxoSmithKline. The study was funded in part by Pronova, and Dr. Senges reported receiving compensation as a speaker for Pronova.

After a year of treatment, the rate of sudden cardiac death, the study's primary end point, was an identical 1.5% in the two treatment arms, each with about 1,900 patients. The results also showed no significant differences between the active-treatment and control groups for other clinical measures, including total mortality, repeat MI, and stroke. The patients receiving omega-3 fatty acid did show a significant reduction in their serum level of triglycerides, a known benefit of omega-3 supplementation.

The unexpectedly low incidence of sudden cardiac death in the study cut its power for detecting a between-group difference from the planned 80% to 50%. Despite this, Dr. Senges was skeptical as to whether a larger or longer study with greater power would have eventually produced a difference between the omega-3 and control groups because the events curves "were almost superimposable," he said. ■