Fish Oil Fails to Cut Arrhythmias in SOFA Trial

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STOCKHOLM — Fish-oil supplements did not significantly reduce the incidence of life-threatening ventricular arrhythmias in high-risk patients in a large, double-blind, randomized European trial, Ingeborg A. Brouwer, Ph.D., said at the annual congress of the European Society of Cardiology.

Results of the Study on Omega-3 Fatty Acids and Ventricular Arrhythmia (SOFA) were disappointing in view of the great need for broad new approaches to reducing the risk of sudden arrhythmic death in the general population.

Implantable cardioverter defibrillators (ICDs) are highly effective but serve a relatively small number of the highest-risk patients; the great majority of sudden deaths occur in individuals who will never be candidates for such devices. The published literature had held out the promise that increased intake of fish oil might be an easy, safe, and effective means of reducing risk in the general population, explained Dr. Brouwer of the Wageningen (the Netherlands) Center for Food Sciences.

SOFA did not completely shut the door on fish oil as an antiarrhythmic agent, however. In a subgroup analysis confined to participants with prior MI, there was a strong, albeit nonsignificant, trend toward a beneficial effect worthy of further investigation, she added.

SOFA was a 26-center double-blind trial involving 546 ICD wearers in eight European countries who were randomized to 2 g/day of fish oil or placebo for 1 year. Patients with ICDs were chosen for the study because the device memory provides detailed information on all arrhythmic episodes.

After 1 year of follow-up, the rate of the combined end point of all-cause mortality or life-threatening ventricular arrhythmia was 33% in the control group and 30% in the fish-oil group, a nonsignificant difference. The difference between the two groups in time to a first life-threatening arrhythmic episode was also nonsignificant.

However, in the 342 patients with a history of MI, the rate of the composite end point was 35% with placebo and 28% in the fish-oil group—not a statistically significant difference, but encouraging, Dr. Brouwer continued.

SOFA was the second negative randomized trial of fish oil in ICD patients in recent months. Earlier, investigators at Oregon Health and Science University, Portland, reported on 200 patients with an ICD who were randomized to 1.8 g/day of fish oil or placebo in a double-blind, multicenter trial. During 2 years of follow-up, 65% of patients in the fish-oil group experienced one or more appropriate ICD firings to terminate a life-threatening ventricular arrhythmia, a rate not significantly different from the 59% figure among controls (JAMA 2005;293:2884-91).

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Discussant Luigi Tavazzi, M.D., said there is another randomized trial of fish oil in patients with ICDs, this one not yet published but strongly positive. The one consistent finding in all of these studies is that fish oil is safe. Much larger than all three studies put together, however, is the ongoing Italian Group for the Study of Cardiac Insufficiency Survival (GISSI)–HF study, in which more than 7,000 patients with chronic heart failure have been randomized to fish oil or placebo, and those eligible for statin therapy have been randomized to 10 mg/day of rosiglitazone or placebo. Follow-up is planned for 3 years, with results anticipated in late 2007.

GISSI–HF was undertaken because of the provocative results of the earlier GISSI–Prevention trial. In this landmark study, more than 11,300 patients were randomized to daily fish oil and/or vitamin E beginning not more than 3 months after an MI. Vitamin E was found to have no benefit. However, during 3.5 years of follow-up, fish oil was associated with a 30% reduction in risk of cardiovascular death and a 44% reduction in sudden death (Lancet 1999;354:447-55).

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Pages 60a—60b