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Effect of fish oil on ventricular tachyarrhythmia and death in patients with implantable cardioverter defibrillators: the Study on Omega-3 Fatty Acids and Ventricular Arrhythmia (SOFA) randomized trial.

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Abstract

CONTEXT: Very-long-chain n-3 polyunsaturated fatty acids (omega-3 PUFAs) from fish are thought to reduce risk of sudden death, possibly by reducing susceptibility to cardiac arrhythmia. **OBJECTIVE:** To study the effect of supplemental fish oil vs placebo on ventricular tachyarrhythmia or death. **DESIGN, SETTING, AND PATIENTS:** The Study on Omega-3 Fatty acids and ventricular Arrhythmia (SOFA) was a randomized, parallel, placebo-controlled, double-blind trial conducted at 26 cardiology clinics across Europe. A total of 546 patients with implantable cardioverter-defibrillators (ICDs) and prior documented malignant ventricular tachycardia (VT) or ventricular fibrillation (VF) were enrolled between October 2001 and August 2004. Patients were randomly assigned to receive 2 g/d of fish oil (n = 273) or placebo (n = 273) for a median period of 356 days (range, 14-379 days). **MAIN OUTCOME MEASURE:** Appropriate ICD intervention for VT or VF, or all-cause death. **RESULTS:** The primary end point occurred in 81 (30%) patients taking fish oil vs 90 (33%) patients taking placebo (hazard ratio [HR], 0.86; 95% confidence interval [CI], 0.64-1.16; P = .33). In prespecified subgroup analyses, the HR was 0.91 (95% CI, 0.66-1.26) for fish oil vs placebo in the 411 patients who had experienced VT in the year before the study, and 0.76 (95% CI, 0.52-1.11) for 332 patients with prior myocardial infarctions. **CONCLUSION:** Our findings do not indicate evidence of a strong protective effect of intake of omega-3 PUFAs from fish oil against ventricular arrhythmia in patients with ICDs. **TRIAL REGISTRATION:** clinicaltrials.gov Identifier: NCT00110838.

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