A randomized trial of high-dose compared with low-dose omega-3 fatty acids in severe IgA nephropathy.

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Tested was the hypothesis that high-dose omega (omega)-3 fatty acids will be more effective than low-dose omega-3 fatty acids in preserving renal function in patients with severe IgA nephropathy in a randomized, open-label, parallel-group clinical trial. Patients were assigned to receive either high-dose fatty acids (EPA 3.76 g and DHA 2.94 g) or low-dose fatty acids (EPA 1.88 g and DHA 1.47 g), both given daily in a highly purified ethyl ester concentrate (Omacor). Patients were treated for a minimum of 2 yr in the absence of a treatment failure or until study closure (January 2000). Seventy-three patients were enrolled in the trial with two ranges of elevated serum creatinine (SC): 63 patients (86%) with a range of 1.5 to 2.9 mg/dl and 10 patients (14%) with a range of 3.0 to 4.9 mg/dl. The primary end point, within-patient rates of change in SC (2-yr minimum), showed an annualized median increase in SC of 0.08 mg/dl per yr in the low-dose group and 0.10 mg/dl per yr in the high-dose group (P: = 0.51). Patients in the lower entry SC range had lower SC slopes (P: = 0.02) and less end-stage renal disease (ESRD) (P: < 0.001) compared with those in the higher entry SC range. No patient died, and 18 patients developed ESRD: 10 in the low-dose group and 8 in the high-dose group (P: = 0.56). SC slopes were significantly lower, and survival free of ESRD was significantly higher (both, P: = 0.04) in the 63 Omacor-treated patients compared with the 22 placebo-treated patients from our previously reported clinical trial in which both groups had a similar level of renal impairment. Patient compliance was excellent, and no serious adverse events were noted. Low-dose and high-dose omega-3 fatty acids were similar in slowing the rate of renal function loss in high-risk patients with IgA nephropathy, particularly those with moderately advanced disease.