Effects of Policosanol 20 versus 40 mg/day in the treatment of patients with type II hypercholesterolemia: a 6-month double-blind study.

Policosanol is a well defined mixture of higher aliphatic primary alcohols isolated from sugar cane wax with cholesterol-lowering effects proven for a dose range from 5-20 mg/day in patients with type II hypercholesterolemia and dyslipidemia associated with noninsulin dependent diabetes mellitus. This randomized, double-blind study investigated the cholesterol-lowering efficacy and tolerability of policosanol 20 mg/day compared with 40 mg/day. Changes in low-density lipoprotein (LDL)-cholesterol levels were predefined as the primary efficacy endpoint. Patients with type II hypercholesterolemia were enrolled in the study and instructed to continue a step I cholesterol-lowering diet for 6 weeks and those eligible to be included (89) were randomly allocated to receive under double-blind conditions placebo (n = 30), policosanol 20 mg/day (n = 29) or 40 mg/day (n = 30). After 24 weeks, policosanol at 20 and 40 mg/day significantly ($p < 0.00001$) lowered LDL-cholesterol by 27.4% and 28.1%, total cholesterol ($p < 0.00001$) by 15.6% and 17.3%, and the LDL-cholesterol/high-density lipoprotein (HDL)-cholesterol ratio by 37.2% and 36.5%, respectively The ratio of total cholesterol/HDL-cholesterol was lowered by 27.1% and 27.5%, while HDL-cholesterol levels increased ($p < 0.001$) by 17.6% and 17.0%, respectively. Compared with baseline, policosanol 20 mg/day lowered triglycerides ($p < 0.05$) by 12.7%, while they were lowered ($p < 0.01$) by 15.6% at a dose of policosanol 40 mg/day All the above-mentioned significant differences were also different from placebo and no significant changes occurred in any lipid profile parameters in the placebo group. Based on the mean values of LDL-cholesterol levels at study completion, the mean percent reductions from baseline were 27.4% and 28.1% for the 20 and 40 mg/day groups, respectively. Thus, the effects of both policosanol doses on the main efficacy variable were practically identical. Consistent with the data obtained for LDL-cholesterol, both doses were similarly effective in changing all the other lipid profile parameters. No unexpected adverse effects were observed and there were no significant between-group differences regarding safety indicator values or reported adverse effects. In conclusion, although the tolerability profile remains excellent, according to the present results policosanol at a dose of 40 mg/day does not offer significant additional cholesterol-lowering efficacy over the 20 mg/day dose.

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