Abstract

Hypercholesterolemia is a major coronary risk factor. The main goal of dyslipidemia control is to lower elevated LDL-C levels. Policosanol is a cholesterol-lowering drug purified from sugar cane wax with a therapeutic range from 5 to 20 mg/d, which significantly reduces LDL-C levels. Atorvastatin is an HMGCoA reductase inhibitor, which across its dose range (10 - 80 mg/d) shows significantly greater lipid-lowering effects than previously available statins. This study was undertaken to compare the efficacy, safety and tolerability of policosanol and atorvastatin in patients with type II hypercholesterolemia. This randomized, single-blinded, parallel group study was conducted in patients of both sexes with type II hypercholesterolemia. After 5 weeks on cholesterol lowering diet, 175 patients showing LDL-C values ≥ 3.4 mmol/L were randomized to policosanol or atorvastatin 10-mg tablets once daily with the evening meal for 8 weeks. Assessment of lipid profile, safety indicators and adverse events (AE) was done. After 8 weeks, policosanol 10 mg/d significantly (p < 0.000 001 vs baseline) lowered LDL-C (27.0 %), TC (19.6 %), LDL-C/high-density lipoprotein cholesterol (HDL-C) (30.1 %) and TC/ HDL-C (23.9 %) ratios, as well as (p < 0.000 01) TG (12.4 %). In turn, atorvastatin 10 mg/d decreased (p < 0.000 001 vs baseline) LDL-C (35.2 %), TC (26.2 %), LDL-C/HDL-C (34.5 %), TC/HDL-C (25.9 %) and (p < 0.000 1) TG (10.2 %). Atorvastatin was more effective than policosanol (p < 0.001) to reduce LDL-C and TC (p< 0.0001) Policosanol, but not atorvastatin, significantly increased HDL-C by 10.4 % (p < 0.000 1). At the interim check-up performed at week 4, the changes induced by both drugs on lipid profile were yet significant, the effects of atorvastatin being similar to those achieved at week 8, while policosanol increased the effects with treatment duration. Both policosanol and atorvastatin were safe and well tolerated. Atorvastatin significantly increased (p < 0.01) CPK and ALAT levels respect to baseline, while policosanol decreased (p < 0.01) such values. Policosanol, but not atorvastatin, decreased systolic pressure (p < 0.01) compared with baseline, but individual values remained within normal ranges. Six patients withdrew from the study due to AE, all from atorvastatin group, reported 12 AE during the study. Seventeen patients reported some AE during the study: three policosanol and 14 atorvastatin patients (p < 0.01) who reported a total of 4 and 23 AE, respectively. Atorvastatin (10 mg/d) for 8 weeks was more effective than similar doses of policosanol to reduce LDL-C and TC in patients with type II hypercholesterolemia, but similarly effective to reduce TG and both LDL-C/HDL-C and TC/ HDL-C ratios. Policosanol, however, but not atorvastatin, was effective to increase HDL-C levels. Policosanol was better tolerated than atorvastatin as indicated blood biochemistry safety indicators and AE report.
Keywords
Policosanol, atorvastatin, type II hypercholesterolemia, cholesterol-lowering drugs.