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Concomitant use of policosanol and antiplatelet drugs in older patients

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Introduction: Policosanol is a cholesterol-lowering drug with antiplatelet action. Policosanol effects have been investigated in clinical trials and post-marketing surveillance, its efficacy and safety are demonstrated. Policosanol has resulted very safely, even when administered to special populations with high consumption of concomitant drugs, without demonstration of drug-related Adverse Events (AE). Accordingly, the potential risk of Drug-Drug Interaction (DDI) with policosanol appears to be low. DDI generally comes from pharmacokinetic or/and pharmacodynamic actions. Experimental data show that DDI with policosanol derived from pharmacokinetic interactions is not very probable. Nevertheless, DDI based on pharmacological interactions needs to be investigated. Antiplatelet drugs are widely used in middle-aged and geriatric populations mainly to prevent recurrent coronary or cerebrovascular events. Experimental and small clinical studies have shown that policosanol enhances the antiplatelet effects of aspirin in an additive manner. Hence, the interest to study putative DDI between policosanol and antiplatelet drugs in a population sensitive to drug-related effects, as the elderly, is supported.

Objective: The objective of the present analysis as a part of a prevention study, we investigated whether policosanol administered to older individuals taking antiplatelet drugs supposes concern regarding a potential risk for adverse drug-drug interactions.

Methods: We randomized 1470 elderly patients at high coronary risk to policosanol 5 mg/day or placebo for 3 years. For this analysis, the records of all patients (334) taking antiplatelet drugs were included. The analysis was by intention-to-treat.

Results: After one year, policosanol decreased significantly Low-Density Lipoprotein-Cholesterol (LDL-C) (21.0%), total cholesterol (16.9%) and triglycerides (19.6%), while raised High-Density Lipoprotein-Cholesterol (HDL-C) (6.2%). Policosanol effects were maintained, even improved, during the follow-up. At study completion policosanol lowered LDL-C (34.3 %), total cholesterol (23.9%), triglycerides (22.2%) and raised HDL-C (14.5%). Sixty patients (41 placebo, 19 policosanol, $p < 0.01$) withdrew from the study, 33 (23 placebo, 10 policosanol) ($p < 0.01$) due to some adverse event, all serious. Policosanol did not impair safety indicators and did not increase any adverse event with respect to placebo.

Conclusions: The policosanol can be administered to older patients taking antiplatelet drugs without risk of relevant adverse drug-drug interactions.

Biography

Julio Cesar Fernandez Travieso is a Senior Investigator in Clinical Trials Unit, National Centre for Scientific Research, Havana, Cuba. He has completed his BSc in Pharmaceutical Sciences from Havana University, Cuba in 1996. He was awarded with PhD in Pharmaceutical Sciences in 2003. He has published more than 130 publications and presented more than 100 papers in various scientific events. His research interest mainly focuses on clinical trials phase I-IV of different natural products: Policosanol, Abexol, Prevenox and Palmex.

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