



## Benefits of a Long-Term Therapy with Policosanol on Hypercholesterolemic Elder Patients: A Controlled Study

Julio C. Fernández-Travieso

National Centre for Scientific Research, Havana, Cuba

### Abstract:

**Objectives:** Investigate whether policosanol administered for 3 years was able to reduce the incidence of vascular serious adverse events (SAE) in older hypercholesterolemic patients.

**Methods:** We randomized 1470 old patients of both sexes with type II hypercholesterolemia, between 60 to 85 years old with  $\leq 1$  non-lipid coronary risk factors. They were treated with policosanol or placebo, for 3 years. The incidence of vascular SAE occurred during the study was considered as a primary efficacy variable, while the total of SAE (vascular and non-vascular), mortality, and the changes on lipid profile were considered secondary efficacy variables. Analysis was done by Intention-to-treat.

**Results:** The frequency of vascular SAE was lower in the policosanol group (15 events) compared with placebo (49 events). The amount of cardiovascular SAE compared to placebo (33 events) was significantly lower in the policosanol group (7 events). Also, there were 12 cerebrovascular SAE (1.6 %) in the placebo and 5 (0.7 %) in the policosanol group. There were 109 patients who experienced SAE: 83 (11.3 %) in placebo and 26 (3.5 %) in policosanol group ( $p < 0.0001$ ). Twenty-three (23) deaths occurred up to study completion: 19 in the group of placebo patients (2.6 %), and 4 in the policosanol group (0.5 %). At study completion, the changes induced by policosanol in LDL-C, total cholesterol, triglycerides and HDL-C with respect to baseline were -30 %, -22 %, -20 % and +15 %, respectively.



**Conclusions:** The group treated with policosanol reported a significant lower amount of vascular SAE and mortality, relevant positive changes on serum lipid profile and lower frequency of total AE. These findings support the recommendation of policosanol use as treatment in primary or secondary prevention program for older patients at cardiovascular risk.

### Biography:

JULIO CÉSAR FERNÁNDEZ 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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