Efficacy and safety of niacin/laropiprant therapy in familial hypercholesterolemic patients with coronary artery disease

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Background: Cardiovascular disease is the principal cause of premature mortality and morbidity in Europe. Patients with familial hypercholesterolemia are at particularly increased risk and, despite lipid-lowering therapy, continue to experience cardiovascular events. Currently, for these patients a new treatment option is represented by extended-release niacin/laropiprant (ERN/LRPN).

Material and Methods: We followed-up for 16 weeks a group of 23 familial hypercholesterolemic patients (mean age 61±7 years, 74% male) with chronic coronary artery disease and ERN/LRPN added on top of maximally tolerated lipid-lowering therapy. ERN/LRPN was administered at the dose of 1 gr/day for the first 4 weeks and then at 2 gr/day for the remaining period. Clinical examination and blood sampling (including lipid profile, renal and hepatic function) were performed at baseline, after 4 weeks, at the end of follow-up, and in the case of eventual clinical manifestations.

Results: During follow-up, 14 patients discontinued therapy due to side effects (headache, asthenia, and gastrointestinal disorders in 4 patients, muscle aches and CK increase in 3 patients, eruptive skin rash in 2 patients, onset of diabetes mellitus in 2 patients, dizziness associated with inability to drive in 1 patient, acute hepatitis in 1 patient and palpitations in 1 patient) and 2 patients voluntarily interrupted the therapy. In the remaining 7 patients, an improvement in lipid profile was observed (total cholesterol -14%, HDL cholesterol +7%, LDL cholesterol -16%, Triglycerides -53%, Apolipoprotein A1 +8%, Apolipoprotein B -21%, Apolipoprotein E -31%) in the absence of substantial changes in other laboratory analyses (with the exception of a non-significant increase in uric acid). Intolerable skin flushing was not observed in any patient. In addition, among patients who did report flushing, a reduction in the incidence of the episodes was observed after the first month of therapy.

Conclusions: In our population, ERN/LRPN therapy improved lipid profile but was poorly tolerated in the majority of patients (61%). In this latter group, we recorded an unexpectedly high incidence of both common (less than 1 in 10 patients) and uncommon (less than 1 in 100 patients) side effects.

Key words: familial hypercholesterolemia, extended-release niacin, laropiprant, chronic coronary artery disease.