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Bergamot polyphenolic fraction enhances rosuvastatin-induced effect on LDL-cholesterol, LOX-1 expression and protein kinase B phosphorylation in patients with hyperlipidemia.

Gliozzi M(1), Walker R, Muscoli S, Vitale C, Gratteri S, Carresi C, Musolino V, Russo V, Janda E, Ragusa S, Aloe A, Palma E, Muscoli C, Romeo F, Mollace V.

Author information:

(1)Research Centre for Food Safety & Health (IRC-FSH), University "Magna Graecia", Catanzaro, Italy.

**BACKGROUND:** Statins are the most commonly prescribed drugs to reduce cardiometabolic risk. Besides the well-known efficacy of such compounds in both preventing and treating cardiometabolic disorders, some patients experience statin-induced side effects. We hypothesize that the use of natural bergamot-derived polyphenols may allow patients undergoing statin treatment to reduce effective doses while achieving target lipid values. The aim of the present study is to investigate the occurrence of an enhanced effect of bergamot-derived polyphenolic fraction (BPF) on rosuvastatin-induced hypolipidemic and vasoprotective response in patients with mixed hyperlipidemia.

**METHODS:** A prospective, open-label, parallel group, placebo-controlled study on 77 patients with elevated serum LDL-C and triglycerides was designed. Patients were randomly assigned to a control group receiving placebo (n=15), two groups receiving orally administered rosuvastatin (10 and 20mg/daily for 30 days; n=16 for each group), a group receiving BPF alone orally (1000 mg/daily for 30 days; n=15) and a group receiving BPF (1000 mg/daily given orally) plus rosuvastatin (10mg/daily for 30 days; n=15).

**RESULTS:** Both doses of rosuvastatin and BPF reduced total cholesterol, LDL-C, the LDL-C/HDL-C ratio and urinary mevalonate in hyperlipidemic patients, compared to control group. The cholesterol lowering effect was accompanied by reductions of malondialdehyde, oxyLDL receptor LOX-1 and phosphoPKB, which are all biomarkers of oxidative vascular damage, in peripheral polymorphonuclear cells.

**CONCLUSIONS:** Addition of BPF to rosuvastatin significantly enhanced rosuvastatin-induced effect on serum lipemic profile compared to rosuvastatin alone. This lipid-lowering effect was associated with significant reductions of biomarkers used for detecting oxidative vascular damage, suggesting a multi-action enhanced potential for BPF in patients on statin therapy.

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