

The antihyperlipidemic effect of a standardized dry extracts of amla (*Emblica officinalis*), walnut (*Juglans regia*), olive (*Olea europaea*) and red yeast rice (*Monascus purpureus*) powder: Reduction in circulatory low-density lipoprotein-cholesterol (LDL-C) and remnant cholesterol (RC) levels in patients with hypercholesterolemia

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Hyperlipidemia is associated with a higher rate of cardiovascular, cerebrovascular, and peripheral vascular disease. Conventional drugs such as statins are effective in controlling hyperlipidemia, but are associated with various side-effects, especially myalgia. Nutraceutical lipid-lowering interventions are becoming increasingly popular, particularly among patients who are intolerant or refractory to statins. Substantial preclinical and clinical evidence suggests that amla, walnut, and olive extracts and red yeast rice (RYR) powder possess significant antihyperlipidemic effects. This study aimed to evaluate the efficacy, safety, and patient's satisfaction of a combined supplementation of standardized dry extracts of amla fruit (500 mg), walnut leaves (50 mg), olive fruit (25 mg) and RYR powder (33.6 mg) (Cholesfytol NG ®) in hypercholesterolemic patients. This was a real-life setting, retrospective, observational, single-arm, non-randomized study in hypercholesterolemic patients (total cholesterol (TC) $\geq$ 200 mg/dL or lowdensity lipoprotein-cholesterol (LDL-C) $\geq$ 130 mg/dL), enrolled at 57 general practitioner (GP) surgeries in Belgium from March 2020 to January 2022. These patients received GP prescribed daily single dosage of 2 oral tablets of Cholesfytol NG ® supplementation for 2-months to overcome their hypercholesterolemia in the absence of a conventional lipid-lowering drug (LLD) (n=208) or with a LLD (n=13). At two-months follow-up, lipid profile was re-evaluated, with a questionnaire on treatment general satisfaction and willingness to pursue supplementation. After supplementation, TC fell by 15%, LDL-C by 19%, non-high-density lipoproteincholesterol (non-HDL-C) by 20% (all $p < 0.0001$), tryglycerides (TG) by 9% ($p = 0.0028$) (-18.4%, $p = 0.0042$, in patients with baseline TG > 180 mg/dL, n=58), and remnant cholesterol (RC) by 12% ($p = 0.0001$). These changes were unaffected by statin (in)tolerance status in patients who received Cholesfytol NG ® alongside statin. The supplement was well tolerated by all patients and no serious adverse events or supplement-emergent effects were reported. Most patients were satisfied with the supplementation and wanted to pursue the nutraceutical. According to this study, a combined supplementation of amla, walnut, and olive extracts and RYR powder exerts significant antihyperlipidemic effect, leading to decrease in circulatory LDL-C and RC levels in hypercholesterolemia. The supplementation bears excellent safety and rated as satisfactory and pursuable, even among patients with statin intolerance.

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