Abstract

BACKGROUND: Red yeast rice is an herbal supplement that decreases low-density lipoprotein (LDL) cholesterol level.

OBJECTIVE: To evaluate the effectiveness and tolerability of red yeast rice and therapeutic lifestyle change to treat dyslipidemia in patients who cannot tolerate statin therapy.

DESIGN: Randomized, controlled trial.

SETTING: Community-based cardiology practice.

PATIENTS: 62 patients with dyslipidemia and history of discontinuation of statin therapy due to myalgias.

INTERVENTION: Patients were assigned by random allocation software to receive red yeast rice, 1800 mg (31 patients), or placebo (31 patients) twice daily for 24 weeks. All patients were concomitantly enrolled in a 12-week therapeutic lifestyle change program.

MEASUREMENTS: Primary outcome was LDL cholesterol level, measured at baseline, week 12, and week 24. Secondary outcomes included total cholesterol, high-density lipoprotein (HDL) cholesterol, triglyceride, liver enzyme, and creatinine phosphokinase (CPK) levels; weight; and Brief Pain Inventory score.

RESULTS: In the red yeast rice group, LDL
cholesterol decreased by 1.11 mmol/L (43 mg/dL) from baseline at week 12 and by 0.90 mmol/L (35 mg/dL) at week 24. In the placebo group, LDL cholesterol decreased by 0.28 mmol/L (11 mg/dL) at week 12 and by 0.39 mmol/L (15 mg/dL) at week 24. Low-density lipoprotein cholesterol level was significantly lower in the red yeast rice group than in the placebo group at both weeks 12 (P < 0.001) and 24 (P = 0.011). Significant treatment effects were also observed for total cholesterol level at weeks 12 (P < 0.001) and 24 (P = 0.016). Levels of HDL cholesterol, triglyceride, liver enzyme, or CPK; weight loss; and pain severity scores did not significantly differ between groups at either week 12 or week 24.

**LIMITATION:** The study was small, was single-site, was of short duration, and focused on laboratory measures.

**CONCLUSION:** Red yeast rice and therapeutic lifestyle change decrease LDL cholesterol level without increasing CPK or pain levels and may be a treatment option for dyslipidemic patients who cannot tolerate statin therapy.