Q/ Is red-yeast rice a safe and effective alternative to statins?

EVIDENCE-BASED ANSWER

A/ Yes, but perhaps not the red-yeast rice extracts available in the United States.

In patients with known coronary artery disease and dyslipidemia (secondary prevention), therapy with red-yeast rice extract containing naturally-occurring lovastatin is associated with a 30% reduction in coronary heart disease (CHD) mortality and a 60% reduction in myocardial infarction (MI), similar to the effect of statin medications (strength of recommendation [SOR]: B, randomized controlled trials [RCTs] in China).

In patients older than 65 years with hypertension and a previous MI, the rate of adverse effects from lovastatin-containing red-yeast rice is 2.1% (SOR: B, RCT in China).

In patients with previous statin intolerance, the rates of myalgias and treatment discontinuation with lovastatin-containing red-yeast rice therapy are similar to either placebo or another statin (SOR: C, low-powered RCTs).

The US Food and Drug Administration (FDA) doesn’t allow lovastatin-containing red-yeast rice products on the US market; physicians should be aware that products purchased by patients online contain variable amounts of lovastatin.

Evidence summary

Red-yeast rice is a Chinese dietary and medicinal product of yeast (Monascus purpureus) grown on rice. It contains a wide range of biologically active compounds, including lovastatin (monacolin K). The FDA has banned the sale of red-yeast rice products with more than trace amounts of lovastatin.¹

Red-yeast rice beats placebo, similar to statins

A systematic review of 22 RCTs (N=6520), primarily conducted in China using 600 to 2400 mg red-yeast rice extract daily (lovastatin content 5-20 mg), assessed outcomes in patients with known CHD and dyslipidemia.² In one trial of 4870 patients, users of red-yeast rice had significant reductions in CHD mortality (relative risk [RR]=0.69; 95% confidence interval [CI], 0.54-0.89), incidence of MI (RR=0.39; 95% CI, 0.28-0.55), and revascularization (RR=0.67; 95% CI, 0.50-0.89) compared with placebo users.

However, when compared with statin therapy, red-yeast rice didn’t yield statistically significant differences in CHD mortality (2 trials, N=220; RR=0.26; 95% CI, 0.06-1.21), incidence of MI (1 trial, N=84; RR=0.95; 95% CI, 0.30-3.05) or revascularization (1 trial, N=84; RR=1.14; 95% CI, 0.38-3.46).

Red-yeast rice outperforms placebo in CHD and MI—but not stroke

A secondary analysis of an RCT evaluated the impact of red-yeast rice extract (600 mg twice a day) for 4.5 years on cardiovascular events and mortality in 1530 Chinese patients 60 years of age and older with hypertension and a previous MI.³ The lovastatin content of the red-yeast rice was 5 to 6.4 mg/d.

Compared with placebo, red-yeast rice was associated with a lower incidence of cardiovascular events and mortality. However, red-yeast rice did not significantly lower the rates of non-fatal stroke, non-fatal myocardial infarction, or revascularization compared with placebo.

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CHD events (RR=0.63; 95% CI, 0.36-0.83), nonfatal MI (RR=0.48; 95% CI, 0.37-0.71), and all-cause mortality (RR=0.65; 95% CI, 0.49-0.83) but not with a statistically significant difference in stroke (RR=0.63; 95% CI, 0.47-1.09) or cardiac revascularization (RR=0.68; 95% CI, 0.52-1.19).

Total adverse events in this study were similar for red-yeast rice and placebo (2.1% vs 1.2%, respectively; P>.05). They included gastrointestinal discomfort, allergic reactions, myalgias, edema, erectile dysfunction, and neuropsychological symptoms.

Red-yeast rice is similar to placebo or another statin in statin-induced myalgia

In a small community-based trial of 62 adults with dyslipidemia and a history of statin-induced myalgia, investigators randomized patients to receive either red-yeast rice extract at 1800 mg (with 3.1 mg lovastatin) or placebo twice daily for 24 weeks. Patients’ weekly self-reports of pain (on a 10-point scale) were skewed at baseline (1.4 in the red-yeast rice group vs 2.6 in the placebo group; P=.026) but similar at 12 weeks (1.4 with red-yeast rice vs 1.9 with placebo; P=.30) and 24 weeks (1.2 with red-yeast rice vs 2.0 with placebo; P=.120).

An RCT of 43 adults with dyslipidemia and history of statin intolerance compared red-yeast rice extract (2400 mg, with 10 mg lovastatin) with pravastatin (20 mg) dosed twice a day. At the end of 12 weeks, mean self-reported pain scores (on a 10-point scale) were similar (1.4 with red-yeast rice vs 1.1 with pravastatin; P=.82), as were discontinuation rates because of myalgia (5% with red-yeast rice vs 9% with pravastatin; P=.99).

**Recommendations**

A narrative review of alternative therapies for heart failure and hypercholesterolemia states that red yeast rice may be a cost-saving option for hypercholesterolemia in patients who can’t afford other medications (purchased mostly online, cost $8-$20/month for a dosage equivalent to lovastatin 20 mg/d).

A ConsumerLab review of red yeast rice products available since the FDA ban in 2011 tested products marketed in the United States and found variable amounts of lovastatin. The group determined that labeling was a poor guide to lovastatin content, which ranged from 0 to 20 mg per daily dose, and that the products may not have been standardized. The group concluded that therapeutic effects weren’t predictable.

**References**


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