

Evidence Based Practice Critically Appraised Topic

Red Yeast Rice and Cholesterol Management

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Clinical Scenario

A 43 year old female presents to the clinic for her annual physical. Lab reports show elevated total cholesterol at 228 mg/dl and an elevated LDL at 140 mg/dl. Trial period of simvastatin and lovastatin led to the development of myalgias. Family history: positive for coronary artery disease. Results indicate uncontrolled hyperlipidemia and intolerance to statins.

Clinical Question

Among statin-intolerant adult patients with hyperlipidemia, are red yeast rice supplements as effective in lowering or treating elevated cholesterol levels?

Articles:

Becker, D.J., Gordon, R.Y., Halbert, S.C. ... Rader, D.J. (2009). Red yeast rice for dyslipidemia in statin-intolerant patients. *Annals of Internal Medicine*, 150, 830-839.

Lin, Z.L., Liu, J.P., Zhang, A.L. ... Visconte, D. (2011). Chinese herbal medicine for hypercholesterolemia. *Cochrane Database of Systematic Reviews*, Issue 7, Art.No.: CD008305. doi: 10.1002/14651858.CD008305.pub2.

Summary and Appraisal of Key Evidence

Study 1 Becker et al., (2009) conducted a randomized, double blinded, placebo control trial to assess the effectiveness and tolerability of red yeast rice to treat dyslipidemia in patients who cannot tolerate statin therapy providing a Level 1, Grade A level of evidence. The study included sixty-two participants that were suffering from dyslipidemia and had discontinued statin therapy due to myalgias. All participants were also enrolled in a twelve week therapeutic lifestyle change program. Eligible participants were 21 to 80 years of age with a known hypercholesterolemia and had discontinued at least one statin due to myalgias and had relief when the medication was stopped.

The randomly assigned patients were given three 600 mg capsules of red yeast rice or three placebo capsules twice daily for 24 weeks. All patients participated in a therapeutic lifestyle change program for 12 weeks and were then encouraged to continue education gained independently while adhering to the red yeast rice regimen. The primary outcome was

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monitoring the LDL (low density lipoprotein) level at baseline, at 12 weeks and again at 24 weeks. Other measured outcomes included total cholesterol, HDL (high density lipoprotein), triglyceride levels and weight.

Study 2 Lin et.al. (2011) conducted randomized control trials (RTC's) investigating Chinese herbal medicines with placebo, no treatment, and pharmacological or non-pharmacologic treatment options in hypercholesterolemia participants providing Level 1, Grade A level of evidence. They independently assessed and extracted data on methods, participants, interventions and outcomes that consisted of participants with documented hypercholesterolemia, side effects observed and adherence to therapy. The types of participants included adults age 18 or older of any ethnic origin that had hypercholesterolemia. Hypercholesterolemia was defined as an elevated total blood cholesterol or LDL cholesterol with normal or low levels of HDL levels.

Twenty-two randomized trials were included. The mean duration was 2.3 ± 1.3 months. Five different herbal medicines were evaluated with red yeast rice (xuezhikang) being the most commonly used herbal therapy. There were no serious adverse events that occurred. In two trials, a significant effect on total cholesterol was observed with the use of xuezhikang or red yeast rice. The main outcomes measured included any cardiovascular events including fatal and nonfatal myocardial infarctions, angina, stroke, peripheral artery disease and sudden death as well as serum cholesterol levels (total cholesterol, LDL and HDL levels).

Results

The results of the studies indicate that the use of red yeast rice in patients intolerant to statins that are suffering from hypercholesterolemia may be effective in lowering serum cholesterol levels. However, both studies had several limitations of which included a small sample size and the short duration of study. Further research is recommended at this time. The short duration of the study does not allow the determination of long term adverse effects of the red yeast rice therapy. In study 1, there is also the concomitant therapeutic lifestyle change program that may have yielded improved cholesterol results.

Clinical Bottom Line

According to these two studies, the use of red yeast rice can be recommended as a treatment option for patients intolerant to statins however further research is necessary to determine the true effectiveness. These studies are relevant to practice today because there is a 57% recurrence rate of myalgias in patients that are trialing a second statin therapy after a failed first statin. As hyperlipidemia is becoming more of a public health crisis for our society and is highly related to ischemic heart disease practitioners are going to need alternative therapy options. There must be a way to ascertain the safety and efficacy of alternative therapy options for treatment.

Implications for Practice

I would recommend the use of red yeast rice in patients intolerant to statin therapy however I would highly encourage and guide these patients to find a therapeutic lifestyle program to assist as well. I would follow the same lab monitoring parameters that are currently in place for statin therapy to assure that the use of red yeast rice was effective in reducing the risk of heart disease for my patients without leading to any adverse complications. Although these studies did not

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address co-morbid conditions, I would be very cautious in prescribing red yeast rice to those with cardiac risk equivalents or those at high risk of devastating heart disease. More research on this topic would be extremely beneficial.