

Cardiovascular Health Update: Red Yeast Rice

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The fermentation of rice with *Monascus purpureus*, or other related molds, results in red yeast rice (RYR). This fermentation process enriches the rice with numerous compounds, including monacolins, which can help control cholesterol levels. RYR has a long history of medicinal and culinary use and is now one of the leading dietary supplements for lowering cholesterol. Around 13 monacolins, arising from different fermentation conditions, have been identified so far in RYR, with monacolin K receiving the most attention because of its structural similarity to lovastatin. Monacolins have lipid-lowering effects by acting as mild antagonists of HMG CoA reductase, the rate-limiting enzyme in cholesterol synthesis.¹

Studies have shown that daily consumption of RYR lowers plasma levels of LDL cholesterol by 15-25% within six to eight weeks, with proportionate reductions in total cholesterol, apolipoprotein-B, and high-sensitivity C-reactive protein.² There is also evidence that RYR may improve arterial stiffness and endothelial function, thereby potentially helping to prevent cardiovascular events.³

Concern about the safety of RYR occurred following reports of citrinin toxicity in animal models. In these studies, animals fed citrinin (a mycotoxin that can be a by-product of the fermentation process) for long periods, developed nephrotoxicity and cancer. No citrinin-related adverse events have been recorded in humans, but findings from these preclinical studies led to the European Food Safety Agency limiting the highest amount of citrinin considered permissible in RYR products to 0.2 µg/kg per day.⁴ RYR extract formulations have not been linked to liver injury or elevated serum enzymes in prospective controlled trials, but isolated case reports of hepatotoxicity have been reported in the literature, mainly in patients who had similar adverse reactions to lovastatin.⁵

Several meta-analyses support the safety and efficacy of RYR in people with mild to moderate hypercholesterolemia.^{6,7,8} A recent meta-analysis published in 2022 examined evidence from 15 high quality randomized controlled trials. In addition to corroborating conclusions from previous systematic reviews, it found that RYR lowers levels of triglyceride-rich lipoproteins, which are strongly associated with cardiovascular disease risk. Triglyceride-rich lipoproteins are precursors of the most atherogenic small, dense LDL-C particles that have decreased affinity for LDL-C receptors, increased arterial entry and retention, and greater susceptibility to oxidation.⁹ This meta-analysis confirmed that the safety and tolerability profile of RYR is similar to that of statins, although studies have shown that RYR causes less muscle fatigue,¹⁰ fewer gastrointestinal side effects, and less frequent elevation of transaminase levels than statin drugs.¹¹

Even though the mechanism of action and metabolism of monacolin K is identical to lovastatin, RYR is well tolerated. Daily ingestion of 3-10mg monacolin K is associated with minimal risk. Myalgias, when they do happen, are mild, and seen in patients who were previously severely intolerant of statins.¹² In a head-to-head comparison with pravastatin, RYR was found to be well tolerated, and able to achieve a comparable reduction of LDL-C in a sample of participants who were intolerant of statins other than pravastatin.¹³ Furthermore, in the treatment of patients with statin intolerance, adding RYR to the non-statin drug ezetimibe increased the number

of patients who reached the target of LDL-C reduction, without increasing adverse reactions.^{14,15}

In addition to modifying lifestyle factors, for example, improvements to diet and exercise, along with using botanical medicines such as berberine and plant sterols, that address cardiovascular health through different mechanisms, clinicians might consider RYR for the management of mild to moderate hypercholesterolemia in low-risk patients, especially those with severe intolerance of statins and other LDL-lowering therapeutics.

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