



ISSN: 2644-2957

DOI: 10.33552/OJCAM.2021.06.000642

Online Journal of
Complementary & Alternative Medicine

Iris Publishers

Mini review

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Red Yeast Rice: Lipid Lowering Properties and Safety Considerations

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Received Date: May 23, 2021

Published Date: June 16, 2021

Abstract

Red yeast rice is a traditional Chinese culinary and medicinal herbal ingredient. The use of red yeast rice dates as far back as the reign of the Tang Dynasty (approximately 800 ad). Over the past several centuries, red yeast rice has been used to improve the digestive process, lower cholesterol, and enhance blood circulation. Over the past few years, red yeast rice has been proffered as an alternative to statin therapy for patients with dyslipidemia. The safety and side-effect profile of red yeast rice product use is not well established.

Keywords: Red Yeast Rice; Statin; Dyslipidemia; Safety

Red Yeast Rice for Cholesterol Therapy: Safety Considerations

Red yeast rice is produced by fermenting cooked rice kernels with *Monascus purpureus*. *Monascus purpureus*' pigmentation properties are capable of changing the color of the rice to red. Several chemical constituents have been isolated from red yeast rice, including organic acids, sterols, flavonoids, monacolins, and polysaccharides [1]. Moreover, the pharmacological extracts of red yeast rice may actively work against cancer, osteoporosis, diabetes, hyperlipidemia, atherosclerotic disease, hypertension, and fatigue [1].

Under the right fermentation processes and the strains of rice utilized, 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibiting monacolins are produced as metabolites [2]. Similar to traditional statins, monacolins inhibit HMG-CoA, which is the limiting factor for hepatic mediated cholesterol synthesis [3]. Of particular interest is the production of monacolin K. Monacolin K is structurally identical to lovastatin and is abundant in red yeast

[4,5]. Monacolin K inhibits HMG-CoA activity, resulting in reduction of endogenous cholesterol synthesis and reduced blood cholesterol levels [6].

Statin have long been the mainstay of lipid-lowering therapy, but the adverse side-effect profile has encouraged the use of alternatives. The structure of red yeast rice mirrors that of traditional statins, which has propelled red yeast rice to a leading role in complementary lipid therapy [3]. Several studies and meta-analysis have well substantiated the efficacy of red rice yeast as a lipid-lowering agent [1-9].

Although the lipid-lowering properties of red yeast rice have demonstrated great promise, there are many safety issues to be considered, including the variability of monacolin K content from product to product, presence of citrinin, drug-drug interactions, and serious side-effects.

The United States Food and Drug Administration (FDA) has labeled red yeast rice as an unapproved drug as the compound may



contain a variable, significant amount of monacolin K [3,4]. The concentration of monacolin K in commercial red yeast products often vary greatly from manufacturer to manufacturer [1,2,4,6,8-10]. The FDA has warned companies that marketing red yeast rice products that contain more than a trace of monacolin K are breaking the law [4]. Of note, the amount of monacolin-K found in products is rarely, if ever, disclosed. Therefore, the impact on blood cholesterol levels across individuals and studies can be difficult to discern [6].

Of all the chemical constituents isolated from red yeast rice, citrinin is of particular concern [1]. Citrinin is produced by fungi, including *Monascus purpureus*. If the culturing process of monacolin K is flawed, citrinin can form. Citrinin is a polyketide secondary metabolite. Citrinin is a mycotoxin that has been known to affect the liver metabolic processes as well as to cause damage to the kidneys [1,4,7]. Further, citrinin has been linked to genetic abnormalities [4]. An analysis of red yeast rice conducted in 2011 found 4 of 11 commercial red yeast preparations were found to contain citrinin [4].

As monacolin-k mirrors statin drugs, careful prescribing practices must be maintained, as there are many potential drug-drug interactions. When red yeast rice is ingested with concomitant ingestion of CYP3A4 inhibitors (clarithromycin, erythromycin, HIV protease inhibitors, ketoconazole, itraconazole, nefazodone, and telithromycin), serious side effects may occur secondary to CYP3A4 potentiation. Musculoskeletal deleterious effects are particularly prevalent [11]. Ingestion of red yeast rice has been linked to liver damage when taken with Imuran, Cyclosporin, Cimetidine, Diclofenac, Lipid, Sporanox, Rosiglitazone, Valproic Acid, Statins, and Methotrexate. Concomitant ingestion of red yeast rice and anticoagulants can increase bleeding risks [12].

The ingestion of red yeast rice has been associated with many concerning side effects, including myopathies, rhabdomyolysis, liver dysfunction, gastrointestinal distress, peripheral neuropathy, erectile dysfunction, and cutaneous reactions [1-3,6,9,13]. Gerards MC, et al. [2], conducted a systemic review of twenty randomized control trials involving 6663 patients. The most commonly reported adverse effects were kidney injury, liver injury, and myopathies.

Complementary medicine, including the inclusion of herbal remedies are widely utilized for a wide variety of health concerns. Red yeast rice has gained notable popularity over the past few years, especially for the treatment of dyslipidemia. However, prior to advocating the use of red yeast rice for individuals with dyslipidemia, careful consideration of risks and benefit should be carried out by both non-traditional and traditional health care providers.

Acknowledgement

No.

Conflict of Interest

Authors declare no conflict of interest.

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