A MONASCUS PURPUREUS RICE EXTRACT REDUCES SERUM CHOLESTEROL AND TRIGLYCERIDES IN ELDERLY PATIENTS WITH PRIMARY HYPERLIPIDEMIA

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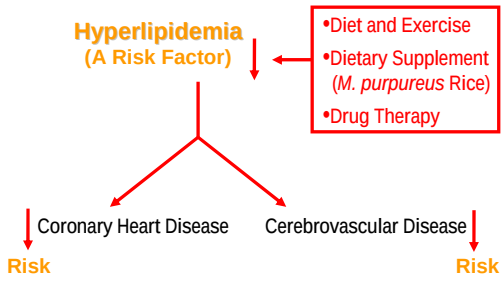
Abstract

This randomized, double-blind, placebo-controlled clinical trial evaluated the ability of a natural product, a *Monascus purpureus* Rice extract, to regulate blood lipids in elderly patients with primary hyperlipidemia. 69 patients were randomly assigned to 2 groups: a *M. purpureus* Rice preparation group (n=35) and a placebo group (n=34). After 8 weeks, the *M. purpureus* Rice preparation (1.2 g/day) significantly reduced serum total cholesterol by 26% and LDL-cholesterol by 33% (both p<0.001), whereas the control group (1.2 g/day placebo) showed 6% and 8% reductions, respectively. This *M. purpureus* Rice product, after 8 weeks, lowered serum triglycerides by 19.9% (p=0.02), while there were no significant changes in controls. Few side effects were observed during the 8-week treatment with the *M. purpureus* Rice preparation. We concluded that use of the *M. purpureus* Rice preparation is safe in elderly patients and effective in managing elevated serum cholesterol and triglycerides that influence cardiovascular health.

Introduction



红曲米 (Red Yeast Rice)

(*Monascus purpureus* Went Rice)

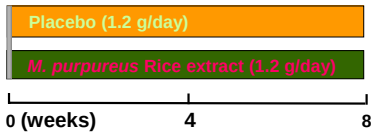
- Widely used as a food supplement in China and other Asian countries for centuries: for the preparation of fish, meat, and bean curd, and in the making of rice wine
- Used in traditional Chinese food and medicine
  - To improve blood circulation
  - To promote healthy digestive functions

M. purpureus Rice Extract Ingredients

Dietary Fiber	0.8%
Proteins	5.8%
Fatty Acids	7.9%
Including unsaturated fatty acids: ~ 6.0% (Oleic acid, Linolenic acid, Linoleic acid, other unidentified)	
Total Natural Pigments	0.3%
Trace Elements (Ca, Al, Fe, Mn, Mg, Cu, Ag)	
Total Monacolins (HMG-CoA reductase inhibitors)	11 mg/g extract

Clinical Trial Design

• Double-blind • Randomized • Placebo-controlled



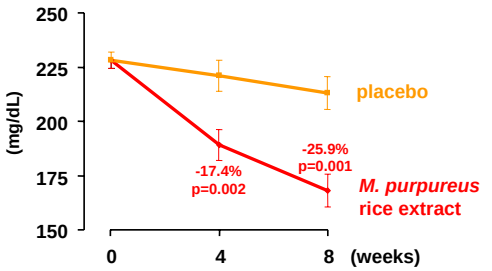
Inclusion Criteria:

- Age: 55 - 80 years
- Total cholesterol: > 200 mg/dL
- Triacylglycerols: 180 ~ 500 mg/dL

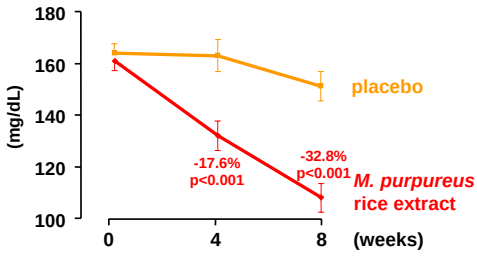
Baseline Characteristics of the Patients at Randomization

	Treatment group	Placebo group
Number of patients	35	35
Sex	22 M, 13 F	22 M, 13 F
Age (years)	62.7 ± 4.2	63.5 ± 5.0
Age range (years)	55 ~ 79	55 ~ 74
Disease history (years)	1 ~ 23	1 ~ 20
Associated with coronary heart disease (n)	5	7
Associated with hypertension (n)	13	13
Associated with cerebro-vascular diseases (n)	3	3

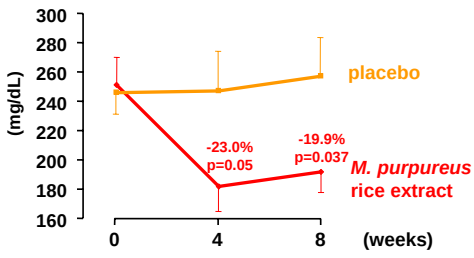
Changes in Total Cholesterol



Changes in LDL Cholesterol



Changes in Triacylglycerols



Side Effects

	M. purpureus	Placebo
• Headache	0	1 (2.9%)
• Slightly ↑ BUN (<20% greater than upper normal limit)	2 (5.9%)	2 (6.5%)
• Slightly ↑ CK (133 to 182 IU/L)	2 (5.9%)	1 (3.2%)
• No other abnormalities		

Summary

8-week *M. purpureus* rice extract treatment

↓ Total Cholesterol by 26%
↓ LDL-Cholesterol by 33%
↓ Triacylglycerols by 20%

Conclusion

- A proprietary *Monascus purpureus* rice extract is safe and highly effective in maintaining normal blood lipids.
- This study provides further support that a proprietary *M. purpureus* rice product can represent a novel and economic approach to cardiovascular health.