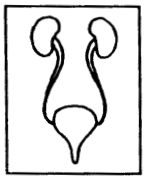

DR. JERRY B. EMTAGE
M.B. B.S. (HONS) F.R.C.S (C)
DIPLOMAT OF THE AMERICAN BOARD OF UROLOGY
"CHELFORD", GEORGE WASHINGTON HOUSE
BUSH HILL, ST. MICHAEL

Red Yeast Extract Reduces Major Coronary Events in Large, Randomized Clinical Trial CME/CE

News Author: Michael O'Riordan

June 16, 2008 — A large, randomized clinical trial with the partially purified extract of Chinese red yeast rice has shown that the extract, known as **Xuezhikang** (XZK), reduced the risk of major coronary events by almost 50% as well as reduced the risk of cardiovascular and total mortality, in patients with a previous myocardial infarction (MI) [1].

"Results showed that treatment of this study population with XZK produced profound changes in both lipoprotein lipids and the number of recurrent coronary events," writes lead investigator **Dr Zongliang Lu** (Peking Union Medical College, Beijing, China) in the June 15, 2008 issue of the *American Journal of Cardiology*. "The decrease in these events found in the present study appears to exceed those reported with statin monotherapy in a similar trial of Western patients enrolled in the **Cholesterol and Recurrent Events** and other statin trials."

Extracts of red yeast rice have been widely used in China for therapy in patients with circulatory and digestive disorders for centuries, and preparations of red yeast rice have been shown to lower plasma lipoprotein levels. **Lovastatin**, the first statin approved in the United States, occurs naturally in certain forms of red yeast rice that are made when the rice is cultivated with the mold *Monascus purpureus*. Interestingly, XZK also gives Peking duck and spare ribs their distinctive bright color.

In this study, known as the **Chinese Coronary Secondary Prevention Study**, investigators sought to determine the long-term efficacy of XZK on the reduction of recurrent cardiovascular events in Chinese patients with average low-density lipoprotein (LDL)-cholesterol levels. The multicenter, randomized, double-blind study was conducted in 4870 patients, aged 18 to 70 years, over a five-year period at more than 60

hospitals in the People's Republic of China. All patients had total-cholesterol levels between 170 and 250 mg/dL and triglyceride levels ≤ 400 mg/dL.

Patients in the treatment arm received 300-mg capsules of XZK. After an average follow-up of 4.5 years, the primary end point, a composite of nonfatal MI and death from coronary heart disease, was 10.4% in the placebo group and 5.7% in the XZK-treated group, a relative risk reduction of 45%. Treatment with XZK also decreased cardiovascular and total mortality, reduced the need for revascularization, and significantly lowered total- and LDL-cholesterol levels. Cancer risk was also significantly reduced with the red yeast extract.

Changes in plasma lipids in patients treated with XZK for 3.5 years

Lipid measures (mg/dL)	XZK, baseline	XZK, on therapy	p
Total cholesterol	207	180	< 0.001
LDL cholesterol	129	103	< 0.001
HDL cholesterol	46	48	< 0.001
Non-HDL cholesterol	161	130	< 0.0001
Triglycerides	164	140	< 0.001

Events according to treatment arm

Event	Placebo, n = 2441 (%)	XZK, n = 2429 (%)	Relative risk reduction (95% CI)
Nonfatal MI	4.9	1.9	0.38 (0.27 - 0.54)
Coronary disease mortality	5.5	3.8	0.69 (0.52 - 0.88)
Fatal MI	1.2	0.8	0.67 (0.38 - 1.20)
Fatal stroke	0.5	0.5	0.91 (0.42 - 1.99)
Coronary revascularization	4.2	2.8	0.64 (0.47 - 0.86)
Cardiovascular mortality	6.1	4.3	0.70 (0.54 - 0.89)
Cancer mortality	1.2	0.5	0.44 (0.23 - 0.84)
Total mortality	7.7	5.2	0.67 (0.52 - 0.82)

The authors point out that the XZK capsules contain a combination of lovastatin, lovastatin hydroxyl acid, ergosterol, and other components. They note that while the lovastatin component is quantitatively predominant, it is "unlikely to account solely for the favorable plasma lipid lowering and rather striking cardiovascular benefit found." The issue, they note, deserves further study, and various components of XZK will need to be

adequately isolated and analyzed for consistency, stability, and other pharmacologic properties.

"Future use of this product," they conclude, "will depend on the separation, identification, characterization, and development of a carefully formulated preparation of red yeast rice."

Last August, the US Food and Drug Administration (**FDA)** warned physicians and consumers to steer clear of several cholesterol-lowering supplements that contain what the FDA terms "unauthorized" lovastatin. As previously reported by **heart*wire*** , FDA testing revealed that several brands of nonprescription "red yeast rice extract" supplements contained lovastatin, a regulated prescription drug. In the MedWatch safety alert, the FDA told consumers to "avoid using" the products because they "may contain an unauthorized drug that could be harmful to their health." The FDA has also recently turned away Merck's attempt to sell lovastatin over the counter.