

# High Testosterone Tied to CHD in Elderly Men

*Increased levels of both testosterone and SHBG raised risk of ischemic events.*

BY DOUG BRUNK

FROM THE ANNUAL MEETING OF THE ENDOCRINE SOCIETY

SAN DIEGO — Elevated endogenous testosterone levels in elderly men are associated with a significantly increased risk of coronary heart disease, according to a large, multicenter study.

“These results are important given that testosterone has been associated with cardiovascular health, and we have yet to understand how it works and to what extent,” Dr. Kristen T.

Sueoka said at the meeting.

“For a disease like coronary heart disease that affects many Americans, any insight into its pathogenesis and any new identifiable and possibly modifiable risk factors can have implications for the health of our population.”

Dr. Sueoka, an internal medicine resident at the University of California, San Francisco, went on to note that while the current study focused on endogenous sex hormones, “our results may raise concern about the safety of exogenous hormone use. Indeed, our results emphasize the importance of further studies.”

She and her associates analyzed data from 697 men enrolled in the National Institutes of Health–funded Osteoporosis Fractures in Men Study (MrOS) ancillary sleep study, which targeted elderly men at six medical centers in the United States and followed them for an average of 4 years.

At baseline, the men underwent sleep studies and had hormones processed by mass spectrometry for sex hormones and chemiluminescence for sex hormone-binding

globulin (SHBG). They also filled out survey information and answered personal interviews regarding their extensive medical history, including risk factors for coronary heart disease.

Study participants were contacted every 4 months by mail to monitor for coronary heart disease events: acute coronary syndrome, revascularization (including percutaneous coronary intervention and coronary artery bypass graft surgery), ischemic heart failure, and ischemia-related mortality. Reported events were reviewed by a cardiologist.

The researchers then analyzed the relationship between coronary heart disease risk and quartile of sex hormones. For example, the quartiles of total testosterone were less than 308 ng/dL, 308-392 ng/dL, 393-495 ng/dL, and greater than 495 ng/dL.

At baseline, the mean age of the study participants was 72 years and their mean body mass index was 28 kg/m<sup>2</sup>. Their mean level of total testosterone was 414 ng/dL, the mean levels of bioavailable testosterone was 212 ng/dL, and the mean level of free testosterone was 8

ng/dL. Dr. Sueoka reported that at 4 years, 100 of the men (14%) suffered an incident coronary heart disease event. The re-

searchers observed a 29% increased risk of coronary heart disease per standard deviation increase in total serum testosterone.

The pattern was similar for bioavailable and free testos-

terone, which was statistically significant,” Dr. Sueoka said.

“We did not find a statistically significant relationship between total estradiol and coronary heart disease.”

“On the other hand, there was a statistically significant relationship looking at SHBG, with increasing of SHBG associated with a higher risk of coronary heart disease,” Dr. Sueoka said.

The study was limited by the fact that it included an older population and that there was only one measurement of sex hormone, she said.

“Higher endogenous testosterone was associated with an increased risk for coronary heart disease,” Dr. Sueoka concluded.

“This effect remained after accounting for common cardiovascular risk factors. We noted similar trends for all forms of testosterone, including bioavailable and free. We did further analyses which showed a similar trend for broader cardiovascular disease, including stroke and peripheral vascular disease,” she added. ■



**Risk of coronary heart disease increased from the lowest to highest quartiles of testosterone.**

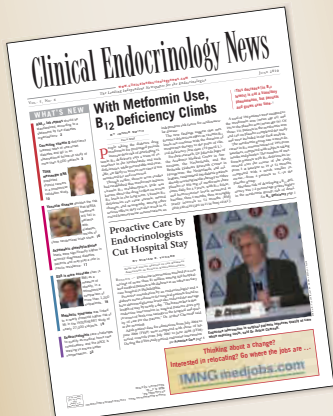
DR. SUEOKA

terone (a 22% increased risk of coronary heart disease per standard deviation increase in each hormone).

Higher levels of SHBG also were associated with increased risk of heart disease (a 31% increase per standard deviation increase). However, no significant associations between total estradiol and coronary heart disease risk were observed.

In the analysis of sex hormones by quartile, the researchers observed “an increasing risk of coronary heart disease as you move from the lowest to highest quartiles of testosterone, which was statis-

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## FDA Approves Folate-Containing Oral Contraceptive

BY TERESA LASSMAN

FROM A FOOD AND DRUG ADMINISTRATION ANNOUNCEMENT

The Food and Drug Administration on Sept. 24 approved Beyaz, a combined oral contraceptive that contains a folate.

Levomefolate calcium is a folic acid metabolite, a B vitamin “that helps produce and maintain new cells in the body,” according to an FDA announcement. Low folate levels in women of child-bearing age have been associated with neural tube defects, such as spina bifida.

Therefore, current recommendations suggest that all women of child-bearing

age take supplemental folate.

Beyaz, manufactured by Bayer Health-Care Pharmaceuticals Inc., is based on the previously approved oral contraceptive YAZ and contains the same doses of estrogen and progestin (ethinyl estradiol, 20 mcg; drospirenone, 3 mg). Beyaz also contains 0.451 mg of levomefolate calcium.

**Beyaz, which is based on the YAZ oral contraceptive, contains the same doses of estrogen and progestin, but also contains 0.451 mg of levomefolate calcium.**

Beyaz shares YAZ's approved indications: pregnancy prevention, treatment of premenstrual dysphoric disorder symptoms in women who use OCs for contraception, and treatment of moderate acne in patients aged 14 years and older who have chosen to use an oral contraceptive for birth control. Beyaz is approved for

### VITALS

**Major Finding:** Elderly men experienced a 29% increased risk of coronary heart disease per standard deviation increase in total testosterone and a 22% increased risk per standard deviation increase in bioavailable and free testosterone.

**Data Source:** Analysis of the National Institutes of Health–funded Osteoporosis Fractures in Men Study (MrOS) ancillary sleep study involving 697 men.

**Disclosures:** Dr. Sueoka has received funding from the UCSF Clinical and Translational Science Institute.

users, especially those older than age 35, should not smoke. Side effects of Beyaz are expected to be similar to those of YAZ. ■

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