Testing testosterone: Trial finds no link to hardening of the arteries

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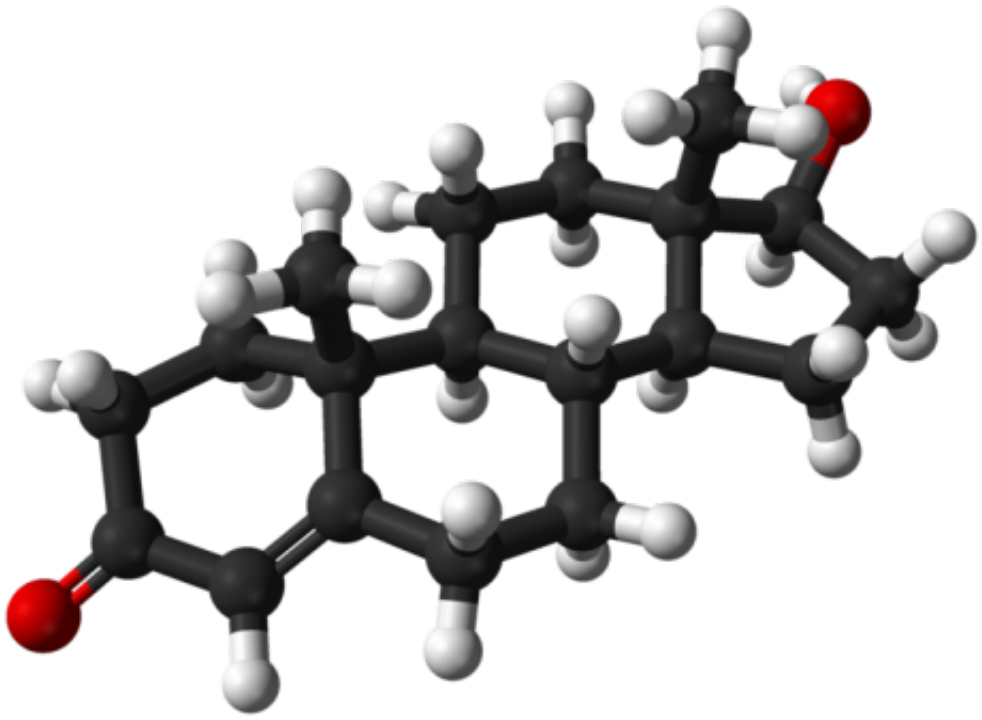

Ball-and-stick model of the testosterone molecule, $C_{19}H_{28}O_2$, as found in the crystal structure of testosterone monohydrate. Credit: Ben Mills/Wikipedia

Testosterone sales have grown rapidly over the last decade, but few studies have examined the long-term effects of taking testosterone on cardiovascular health and other important outcomes. This week, investigators from Brigham and Women's Hospital (BWH) report the

results of the Testosterone's Effects on Atherosclerosis Progression in Aging Men (TEAAM) trial in the *Journal of the American Medical Association* (*JAMA*). The three-year study finds that testosterone administration had no effect on the progression of hardening of the arteries in older men with low to low normal testosterone levels and did not significantly improve sexual function or health-related quality of life.

"The results of this trial suggest that testosterone should not be used indiscriminately by men," said corresponding author Shalender Bhasin, MD, director of BWH's Research Program in Men's Health: Aging and Metabolism and director of the Boston Claude D. Pepper Older Americans Independence Center at BWH. "We find that men with low and low normal testosterone are unlikely to derive benefits in terms of sexual function or quality of life, two reasons why men may seek testosterone therapy. And although we find that testosterone did not affect the rate of hardening of the arteries, we need long-term data from large trials to determine testosterone's effects on other major cardiovascular events."

Testosterone, a hormone primarily secreted by the testicles, plays a key role not only in male reproductive tissues but also in muscle growth, bone mass and body hair. As men get older, their testosterone levels naturally decline - on average by 1 percent a year after age 40. Previous studies that have aimed to examine rates of cardiovascular events in men taking testosterone have reported conflicting results but have raised concerns that testosterone therapy might increase a person's risk of a heart attack or stroke. Atherosclerosis, or the buildup of plaque in the arteries, is a critical risk factor for such cardiovascular events.

In the three-year, double-blind TEAAM trial, the research team enrolled more than 300 men over the age of 60 with total testosterone levels between 100-400 ng/dL (low to low normal range) and measured two indicators of atherosclerosis: calcium deposits in the arteries of the heart

(coronary artery calcification) and the thickness of inner lining of the carotid arteries that supply blood to the brain (common carotid artery intima-media thickness). To measure secondary outcomes of sexual function and health-related quality of life, the research team had participants also completed a 15-item questionnaire. Participants applied a testosterone or placebo gel daily for three years.

"Our study has important implications for clinical practice, and for older men who are seeking testosterone therapy," said Bhasin. "Many men, as they get older, experience a decline in testosterone and in sexual function and vitality. But our study finds that taking testosterone, when levels are in the low to low normal range, may not improve sexual function or quality of life."

The TEAAM trial was designed to examine atherosclerosis progression and not cardiovascular events—further studies will be needed to determine the cardiovascular safety of testosterone use in older men. The research team also notes that comparing patients using statins to those who are not could be another important direction for future studies.

More information: *JAMA*, doi:10.1001/jama.2015.8881

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