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IN BRIEF

Testosterone and Cardiovascular Risk

Prompted by the recent publication of 2 retrospective studies, the FDA has announced that it is investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products.1

The first study examined the records of 8709 men with low testosterone levels (<300 ng/dL) who underwent coronary angiography between 2005 and 2011; 1223 of these men started testosterone therapy after a median of 531 days following coronary angiography. Three years after coronary angiography, the Kaplan-Meier estimated cumulative percentages of men who died or had a myocardial infarction (MI) or ischemic stroke were 26% of those treated with testosterone and 20% of those who were not treated with the hormone, a hazard ratio of 1.29 (95% CI 1.04-1.58; P=0.02).2

The second study compared the rate of nonfatal MI during the 90 days after filling a prescription with the rate in the prior year in 56,000 men given a prescription for testosterone and in 167,000 given a phosphodiesterase type 5 inhibitor (sildenafil [Viagra] or tadalafil [Cialis]). In the testosterone group as a whole, the post/pre-prescription rate ratio was 1.36, but in men ≥65 years old it was 2.19 and in younger men with a history of heart disease it was 2.90. In men who received a prescription for sildenafil or tadalafil, the rate ratio was 1.08 for all ages, 1.15 for those ≥65 years old, and 1.40 for younger men with a history of heart disease.3

A recent meta-analysis of randomized, placebo-controlled trials of testosterone therapy also found an increased risk of cardiovascular-related events in men treated with the hormone (odds ratio [OR] 1.54; 95% CI 1.09-2.18); an analysis by funding source found that the risk was greater in trials not funded by the pharmaceutical industry (OR 2.06 vs. 0.89).4

