

# The Medical Letter®

## On Drugs and Therapeutics

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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.<sup>1</sup>

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).<sup>2</sup>

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  $\geq 65$  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  $\geq 65$  years old, and 1.40 for younger men with a history of heart disease.<sup>3</sup>

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).<sup>4</sup>

1. FDA Drug Safety Communication January 31, 2014: FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products. Available at [www.fda.gov/drugs/drugsafety/ucm383904.htm](http://www.fda.gov/drugs/drugsafety/ucm383904.htm). Accessed February 24, 2014.

2. R Vigen et al. Association of testosterone therapy with mortality, myocardial infarction, and stroke in men with low testosterone levels. *JAMA* 2013; 310:1829.
3. WD Finkle et al. Increased risk of non-fatal myocardial infarction following testosterone therapy prescription in men. *PLoS One* 2014; 9:e85805.
4. L Xu et al. Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials. *BMC Med* 2013; 11:108.

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