

Testosterone therapy does not increase heart attack risk, study shows

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Testosterone prescriptions for older men in the United States have increased more than three-fold over the past decade. Recent studies linking testosterone use with increased risk of heart attack and stroke have caused widespread concern among patients and their families. A new U.S.-based study of more than 25,000 older men shows that testosterone therapy does not increase men's risk for heart attack.

The study, conducted by researchers at the University of Texas Medical Branch at Galveston, examined 25,420 Medicare beneficiaries 66 years or older treated with [testosterone](#) for up to eight years. It appears in the July 2 issue of the *Annals of Pharmacotherapy*.

"Our investigation was motivated by a growing concern, in the U.S. and internationally, that [testosterone therapy](#) increases men's risk for cardiovascular disease, specifically [heart attack](#) and stroke," said Jacques Baillargeon, UTMB associate professor of epidemiology in the Department of Preventive Medicine and Community Health and lead author of the study. "This concern has increased in the last few years based on the results of a clinical trial and two observational studies," he said. "It is important to note, however, that there is a large body of evidence that is consistent with our finding of no increased risk of heart attack associated with testosterone use."

In recent years, the testosterone therapy market has grown to \$1.6 billion annually as men seek to supplement low testosterone counts with products that may increase muscle tone and sex drive. Previous safety

investigations presented conflicting findings. A few of these studies suggest testosterone is linked with increased risk of heart attack, although some critics have questioned the quality of these data. Doctors, researchers and government agencies all agree that more research into this issue is necessary.

The Food and Drug Administration decided June 20 to expand labeling on testosterone products to include a general warning about the risk of blood clots in veins. The FDA and European Medicines Agency are also further examining the safety of these products. This newest FDA warning comes shortly after the announcement that several testosterone treatment manufacturers, including Abbott Laboratories, AbbVie Inc., Eli Lilly and Company, Pfizer and Actavis, are facing a consolidated multidistrict litigation in Federal Court based on claims that they hid the risks of using testosterone treatments.

This new UTMB study evaluated enrollment and claims Medicare data for a clinically and socioeconomically diverse national sample treated with testosterone from 1997-2005. Men of the same age, race, Medicaid eligibility, and health status who did not receive testosterone therapy were used as a control group for comparison.

The analyses show that testosterone therapy was not associated with an increased risk of heart attack. Further, testosterone users with a higher probability of cardiovascular problems had a lower rate of heart attacks in comparison to equivalent patients who did not receive testosterone therapy.

"This is a rigorous analysis of a large number of patients," said Baillargeon. "Our findings did not show an increased risk of heart attack associated with testosterone use in [older men](#)," he said. "However, large-scale, randomized clinical trials will provide more definitive evidence regarding these risks in the coming years."

Provided by University of Texas Medical Branch at Galveston

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