

New studies fail to find cardiovascular risk with testosterone therapy

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Two studies scheduled for presentation at the American College of Cardiology's 64th Annual Scientific Session in San Diego failed to find a connection between testosterone therapy in men and heart problems, contradicting research that prompted the U.S. Food and Drug Administration to investigate its safety. The new studies include a meta-analysis of data from 29 studies involving more than 120,000 men and an observational study from a Wisconsin health system.

"With an aging population and more and more [men](#) needing [testosterone therapy](#), it is important to better understand its potential effect on cardiovascular health," said Pawan Patel, M.D., academic physician at Regions Hospital in St. Paul, Minnesota, and the lead investigator of the meta-analysis. "Our analysis ... gives hope that we can do more with testosterone therapy."

But this research also underscores the need for a long-term, prospective, randomized trial to truly understand whether testosterone therapy can be used without putting men at greater risk for [cardiovascular events](#) such as heart attacks, worsening of heart failure or sudden cardiac death.

The recent conflicting findings on testosterone therapy prompted Patel and his team to conduct a large systematic literature search for studies evaluating the relationship between testosterone replacement therapy and cardiovascular events among men. The meta-analysis included data from recent studies that found a link between testosterone therapy and adverse cardiovascular events.

Testosterone is a hormone that plays a key role in the development of male sexual characteristics. As a man ages, the amount of testosterone in his body gradually declines. An estimated 13 million men in the United States suffer from low testosterone, which occurs when the body fails to make enough hormones because of a problem with the testicles or pituitary gland. Testosterone therapy is widely used to help address the effects that low testosterone can have on cognition, muscle mass and strength, bone density, metabolic function and mood. Nearly one in 25 men over the age of 60 receives testosterone therapy.

In the second study, researchers at Aurora Health Care, a large community-based health care system in Wisconsin, analyzed demographic and health data from 7,245 men with [low testosterone levels](#) from 2011-2014. After obtaining data from the electronic record systems of 15 hospitals and 150 clinics, the researchers looked at the combined cardiovascular event rate of heart attack, stroke and death in men with low testosterone who received testosterone therapy and in those who did not. They found the event rate at three years was low in both the treated group at 5.5 percent and in the untreated group at 6.7 percent, suggesting a potential cardiovascular benefit of testosterone replacement therapy on initial analysis. However, after adjusting for baseline differences including age, prior heart attack or stroke, cholesterol levels, smoking status and length of follow-up, researchers found no difference in cardiovascular event rates between the two groups.

Arshad Jahangir, M.D., the study's senior author and director at the Center for Integrative Research on Cardiovascular Aging, Aurora Health Care, said there were important limitations and inconsistencies with recent studies that linked testosterone replacement therapy to cardiovascular risks, leaving the medical community and many men without clear answers.

"The reassurance we get from this analysis in the community setting is that testosterone replacement therapy in patients with low serum levels is not causing any harm, even if it is not providing much cardiovascular benefit [in this patient population]," Jahangir said. "In the absence of prospective data, I think studies like ours will help ease anxieties around this treatment and provide some information on which physicians can base their prescribing decisions."

He also emphasized that given these study results, it is important for physicians to continue to aggressively manage established [cardiovascular disease risk](#) factors in patients, as testosterone therapy may not have an impact. An analysis of the effects of testosterone therapy on metabolic parameters and bone fractures is ongoing.

These two studies come on the heels of a recent pooled analysis by researchers at Beth Israel Deaconess Medical Center in Boston, which cast further doubt on the link between testosterone therapy and cardiovascular risk and suggested a positive association between higher testosterone levels and improvements in reduction of cardiovascular risk.

As always, men should talk with their doctor about what is right for them.

Both studies were independently funded through each respective health center with no industry involvement.

The first study, "Effect Of Testosterone Therapy On Adverse Cardiovascular Events Among Men: A Meta-Analysis," will be presented on March 15 at the American College of Cardiology's 64th Annual Scientific Session in San Diego.

More information: "Effects of Testosterone Supplement Therapy on Cardiovascular Outcomes in Men with Low Testosterone" will be

presented on March 14 at 10 a.m. PT/1 p.m. ET/5 p.m. UTC. The meeting runs March 14-16.

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