

HEALTH

Testosterone Therapy and Your Heart: New Research Finds No Increased Risk

New study finds therapy doesn't raise heart attack, stroke risks when administered properly

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A new study of testosterone therapy found no risk of major cardiovascular events, including heart attacks, but researchers reported a few cases of pulmonary embolism. PHOTO: DANIEL ACKER/BLOOMBERG

Testosterone-replacement therapy doesn't increase risks of heart attack, stroke or death from cardiovascular issues for men who are properly treated, according to a study that tested longstanding concerns of regulators and physicians.

The study, published Friday in the *New England Journal of Medicine*, did find other cardiovascular risks. The authors cautioned that the results don't apply to

everyone taking testosterone, an important caveat after prescriptions have climbed in the U.S.

The Food and Drug Administration requires manufacturers of prescription testosterone products to label the products as presenting a risk of blood clots and increasing the risk of heart attacks and strokes. A few studies and an agency advisory group concluded in 2014 the treatment may raise the risk of major cardiovascular events.

The new clinical trial of about 5,200 men was conducted by researchers at the Cleveland Clinic and funded by drugmakers led by [AbbVie](#). It found no increase in risk of major cardiovascular events for middle-aged and older men who had low levels of testosterone when they enrolled in the trial and had or were at risk for cardiovascular disease.

While the study found no risk of major cardiovascular events such as heart attacks, researchers did report a few cases of pulmonary embolism, or a blood clot affecting the lungs; atrial fibrillation, a heart-rhythm disorder; acute kidney injury; and small blood-pressure increases among men who received testosterone treatment.

Doctors and patients considering testosterone treatment should balance the risks with how symptoms—which can include reduced sex drive, sexual dysfunction and fatigue—affect quality of life, said Dr. Michael Domanski, a cardiologist and professor at the University of Maryland School of Medicine.

“What I would say to a patient is that there may be some small increase in risk in using this drug but that it can also be beneficial,” said Domanski, who wasn’t involved in the study. He was a member of the FDA advisory committee that recommended the FDA labeling requirement.

The long-term risks are unclear because trial participants received treatment for less than two years on average, Domanski said: “You’re going to have people who are going to be taking this potentially for many years.”

The results don’t apply to athletes who use high doses of anabolic steroids—synthetic versions of testosterone—to build muscle and boost performance. “We do not want this to lead to the misuse of testosterone,” said Dr. Steven Nissen, chair of the study and chief academic officer of the Cleveland Clinic’s Heart and Vascular Institute.

Prescriptions for testosterone products have grown to 8.6 million in 2022 from 6.2 million in 2015, according to the IQVIA Institute for Human Data Science. “Low T” clinics market testosterone replacement therapies widely to men on the Internet and social media, some with promises to restore energy and vitality.

Testosterone products are approved by the FDA for men with hypogonadism, conditions that cause testosterone deficiency because of genetic disorders, tumors and other specific medical conditions. Their safety and efficacy haven’t been proven for low testosterone due to aging, according to the agency.

An FDA spokesperson said that the agency generally doesn’t comment on specific studies but will review the findings of the trial, “including the

information presented in the paper once published and take regulatory action if needed.”

Not all providers give proper blood tests to determine whether patients have low testosterone and medically need the therapies, the study authors said. “We don’t know that it’s safe if you give it to someone who shows up at a ‘feel younger’ clinic and never gets his testosterone level checked,” said Dr. Michael Lincoff, the trial’s lead investigator and vice chair for research in the Department of Cardiovascular Medicine at the Cleveland Clinic.

The results remove the worry of major risks to men who qualify for treatment, said Dr. Bradley Anawalt, an endocrinologist and professor at the University of Washington School of Medicine who wasn’t involved in the study.

He said the findings about pulmonary embolism and atrial fibrillation should be studied further.

Patients should be evaluated for their risk of blood clotting before receiving testosterone therapy and their blood pressure should be monitored, said Dr. Shalender Bhasin, director of the Research Program in Men’s Health: Aging and Metabolism at Brigham and Women’s Hospital in Boston and a trial investigator.

Men in the randomized controlled trial ranged in age from 45 to 80 and had low testosterone as measured in two blood tests taken after fasting and at least one symptom of testosterone deficiency.

More than 60% of participants stopped using the prescription testosterone or placebo gel before the trial was over, though most participated in follow-ups after the treatment period. The authors said the low-adherence rate was similar in other trials of testosterone products.

A little more than half of the participants had cardiovascular disease and the others had at least three risk factors including hypertension, diabetes, or high cholesterol. Nearly half were age 65 or older, itself a cardiovascular disease risk factor, and about 79% were white.