Medical Xpress

Testosterone therapy might increase heart attack risk

January 29 2014, by Kathleen Doheny, Healthday Reporter

Researchers say risk doubles after treatment starts for men under 65 with heart problems and all men over 65.

(HealthDay)—Testosterone therapy—widely advertised as a way to help men improve a low sex drive and reclaim diminished energy—might raise the risk of heart attack, according to new research.

The increased risk was found in men younger than 65 with a history of heart disease, and in older men even if they didn't have a history of the disease. In both groups, heart attack risk doubled in the 90 days after the men began testosterone therapy, said researcher William Finkle, CEO of Consolidated Research, in Los Angeles.

"It was more or less the same increase in risk," Finkle said.

Testosterone therapy typically is given in gel, patch or injection form,

and is widely promoted in television advertisements about "low T." Although the treatment risk to men over 65 has been documented in previous research, Finkle said, the new study is believed to be the first to look at men under 65.

The study, published online Jan. 29 in the journal *PLoS One*, was conducted by a research team that included experts from Consolidated Research, the U.S. National Cancer Institute and the University of California, Los Angeles.

It was triggered by a 2010 report in the *New England Journal of Medicine*, Finkle said. In that study, a clinical trial of testosterone gel in men over 65 was halted early after an increase in heart attacks and other heart problems occurred in the group using the testosterone supplements.

Finkle's team used data from Truven Health Analytics, which gathers nationwide information on patient care. The researchers looked at the medical records of nearly 56,000 men who had been prescribed testosterone therapy—more than 48,000 of whom were under age 65.

"We identified the [timing of the] first prescription and followed them for 90 days," Finkle said. The risk for heart attack doubled in that 90-day period for men over 65 and those under 65 with a history of heart disease, the researchers found.

When they continued to follow the men for another 90 days, the researchers said, the risk declined to the level it was at the study's start for men who did not refill their initial prescription.

Even though the two-fold increase in risk in younger men was seen only in those with a history of heart disease, Finkle said he's uncertain of the therapy's safety in younger, healthy men.

"We don't have enough evidence to say testosterone supplements in men under age 65 without heart disease are safe," he said.

Although the researchers found an association between testosterone therapy and increased risk of heart attack, the study did not prove a cause-and-effect relationship.

The study authors also did not examine the explanation for the link, but Finkle said it could be tied to the effect of testosterone in blood.

"The theory is that testosterone most likely promotes clotting," he said. In older men who tend to have thinner vessels, that clotting could cause problems, he said.

The supplements might also increase men's circulating estrogen, the researchers said. Estrogen therapy has been linked to an increase in heart troubles in both men and women.

AbbVie and Actavis, the makers of testosterone therapies, did not respond to requests for comment on the study.

But one expert not involved in the research expressed skepticism, citing flaws in the study design.

"Based on the best available data, testosterone replacement still appears to be safe ... for properly selected patients," said Dr. Ryan Terlecki, director of the Men's Health Clinic at the Wake Forest Baptist Medical Center.

Among the flaws in the study, Terlecki said, was the use of information obtained from medical claims data, which makes it uncertain which men actually used the testosterone.

"This is important since compliance can be poor, especially with topical formulations," he said. Terlecki reported that he previously worked as a consultant for Auxilium, which makes testosterone therapy.

The researchers did not have information on why the testosterone therapy was prescribed, so it could have been prescribed inappropriately, Terlecki said. He also cited other data that has linked low testosterone—not testosterone therapy—to an increased risk of heart disease.

Men who are discussing testosterone therapy with their doctors "should add the risk of heart attack to the discussion of the risks and benefits of testosterone," Finkle said.

Terlecki said men who have a lack of energy should first see their doctor and ask about screening for depression and other conditions—such as thyroid disease or B12 deficiency—that could also be the cause.

Testosterone therapy is marketed so successfully that the independent medicine website Drugs.com reported that sales of Androgel exceeded sales of Viagra in 2013, according to UCLA researchers.

More information: To learn more about low testosterone, visit the Urology Care Foundation.

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