

Study finds that testosterone therapy is not linked with blood clot disorders in veins

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Lead author Jacques Baillargeon is a professor of epidemiology in the department of preventive medicine and community health. Credit: University of Texas Medical Branch

A new study from The University of Texas Medical Branch at Galveston of more than 30,000 commercially insured men is the first large comparative analysis to show that there is no link between testosterone therapy and blood clots in veins. The study found that middle-aged and older men who receive testosterone therapy are not at increased risk of this illness. The findings are detailed in *Mayo Clinic Proceedings*.

Venous thromboembolism is a disease where [blood clots](#) form in the veins and cause blockages. The most common forms of VTE are [deep vein thrombosis](#), which occurs often in the legs and pulmonary embolism, which is a clot in the lungs. VTE is the third most common cardiovascular illness, after heart attack and stroke.

"In 2014, the Federal Drug Administration required manufacturers to add a warning about potential risks of VTE to the label of all approved testosterone products," said Jacques Baillargeon, professor of epidemiology in the department of preventive medicine and community health and lead author of the study. "The warning, however, is based primarily on post-marketing drug surveillance and case reports. To date, there have been no published comparative, large-scale studies examining the association of testosterone therapy and the risk of VTE."

As a result of this conflicting evidence and the broad media attention it has received, there are many [men](#) with medically confirmed low testosterone who are afraid to receive testosterone therapy and there may be physicians who are reluctant to prescribe testosterone therapy based on this conflicting information.

The case-control study included 30,572 men 40 years and older who were enrolled in one of the nation's largest commercial insurance programs between Jan. 1, 2007 and Dec. 31, 2012. Cases were defined as men who had a primary diagnosis of VTE and received an anticoagulant drug or an intravascular vena cava filter in the 60 days

following their diagnoses. Cases were matched with three control subjects on age, geographic region, diagnosis of low testosterone and diagnosis of any underlying pro-clotting condition.

The researchers found that having a prescription for testosterone therapy was not associated with an increased risk of VTE. In addition, none of the specific routes of administration examined—topical creams, transdermal patches or intramuscular injections—were associated with an increased risk. There were no differences between men who received the therapy 15, 30 or 60 days before being diagnosed with VTE.

"It is important to acknowledge, for a man who has medically-diagnosed low testosterone, that there are clear risks to not receiving testosterone therapy, including osteoporosis, sexual dysfunction, increased amounts of fat tissue, decreased lean muscle mass, possible metabolic syndrome and cardiovascular disease," said Baillargeon. "It's also important to note that further research needs to be conducted to rigorously assess the long-term risks of [testosterone therapy](#)."

These findings may help to inform the benefit-risk assessment for men with testosterone deficiency considering treatment.

Provided by University of Texas Medical Branch at Galveston

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