



1 December 2016

## The BMJ Press Release

### Increased risk of blood clots soon after starting testosterone treatment

*Risk peaks rapidly in first six months and declines gradually thereafter*

Starting testosterone treatment is associated with an increased risk of serious blood clots (known as venous thromboembolism or VTE) that peaks within six months and declines gradually thereafter, concludes a study in **The BMJ** today.

Although the increased risks are temporary, and still relatively low in absolute terms, the researchers warn that failure to investigate the timing and duration of testosterone use in previous studies could have masked this association.

Over the first decade of this century there has been a striking increase in testosterone prescribing in men, mainly for sexual dysfunction and/or decreased energy.

Studies have reported contradictory results on an association between testosterone use and the risk of VTE, but failure to investigate the timing and duration of use may explain the conflicting findings.

In June 2014, the US Food and Drug Administration and Health Canada required a warning about the risk of VTE to be displayed on all approved testosterone products.

So an international team of researchers set out to determine the risk of VTE associated with use of testosterone treatment in men, focusing particularly on the timing of the risk.

The study involved data from 19,215 patients with confirmed VTE and 909,530 age-matched controls from over 2.2 million men registered with the UK Clinical Practice Research Database between January 2001 and May 2013.

Three mutually exclusive testosterone exposure groups were identified: current treatment, recent (but not current) treatment, and no treatment in the previous two years. Current treatment was subdivided into duration of more or less than six months.

VTE was defined as comprising deep vein thrombosis (leg clot) and pulmonary embolism (lung clot).

After taking account of potentially influential factors, the researchers estimated rates of VTE in association with current testosterone treatment compared with no treatment.

In the first six months of testosterone treatment, they found a 63% increased risk of VTE among current testosterone users, corresponding to 10 additional VTEs above the base rate of 15.8 per 10,000 person years. The risk declined substantially after more than six months' treatment and after treatment stopped.

This is an observational study so no firm conclusions can be drawn about cause and effect, say the authors. And they stress that the increased risks are temporary, and still relatively low in absolute terms.

Nevertheless, they say their study suggests "a transient increase in the risk of venous thromboembolism that peaks during the first three to six months and declines gradually thereafter." And they add that failure to investigate the timing of venous thromboembolisms in relation to the duration of testosterone use "could result in masking of an existing transient association."

“Future research is needed to confirm this temporal increase in the risk of venous thromboembolism and to investigate the risk in first time testosterone users and confirm the absence of risk with long term use,” they conclude

[Ends]

### **Note to Editors**

Research: Testosterone treatment and risk of venous thromboembolism: population based case-control study

<http://www.bmj.com/cgi/doi/10.1136/bmj.i5968>

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