

## Testosterone gel fails to boost Viagra's effects

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Study found no added benefit to men being treated for erectile dysfunction.

(HealthDay)—Men who have erectile dysfunction and low testosterone may get no extra benefit from adding the hormone to their Viagra prescription, a new study suggests.

The first-choice treatments for <u>erectile dysfunction</u> are drugs called PDE5 inhibitors, which include sildenafil (Viagra), vardenafil (<u>Levitra</u>) and tadalafil (Cialis). They work by helping the smooth muscles of the penis to relax, which increases <u>blood flow</u>.

When men with erectile dysfunction also have <u>low testosterone levels</u>, doctors often prescribe <u>testosterone</u> gel along with a PDE5 inhibitor. But now a new clinical trial of 140 men with erectile dysfunction and low levels of testosterone puts that treatment combination into question.

"We had expected to see some added benefit from testosterone," said



lead researcher Dr. Matthew Spitzer, an endocrinology fellow at Boston University School of Medicine. "But that's not what we observed."

Researchers found that, over 14 weeks, men who were randomly assigned to take Viagra plus testosterone gel did no better than those given the drug plus a hormone-free placebo gel.

Overall, men in both groups responded to the drug, Spitzer said.

On average, the men's score on a standard set of erectile dysfunction questions increased by about 8 points—moving them up to the "mild" erectile dysfunction category. And there was no substantial difference between men who used the testosterone gel and those who used the placebo.

The findings, which appear in the Nov. 20 issue of the journal <u>Annals of Internal Medicine</u>, surprised the researchers.

The results are good news for men with erectile dysfunction and low testosterone, Spitzer said. "This suggests sildenafil alone works extremely well for them," he said.

Another expert said the study could have <u>clinical implications</u>.

The findings are "likely to change the routine use of testosterone in these men," said Dr. Alvin Matsumoto, a professor at the University of Washington School of Medicine, in Seattle, who was not involved in the study.

But that doesn't mean testosterone is of no use to any man with erectile dysfunction, said Matsumoto, an endocrinologist who studies the effects of testosterone throughout the body.



There are men who are diagnosed with hypogonadism, a deficiency in testosterone. That's based on more than the level of testosterone in a man's blood, which, Matsumoto said, should be measured more than once, since a "low" will often turn out to be normal on a second test. The diagnosis is also based on possible signs and symptoms—not just erectile dysfunction, but also problems like low bone mass, waning muscle, fatigue and depression.

The men in this study, whose ages ranged from 40 to 70, were assessed only for erectile dysfunction and not other symptoms, Spitzer said. So it's not clear whether the findings would apply to men with hypogonadism.

"If you have low testosterone, but [erectile dysfunction] is the only thing that's going on, it's reasonable to try sildenafil alone," Matsumoto said.

Another question, Matsumoto said, is whether adding testosterone therapy can help some men with low testosterone who fail to get a good result from Viagra or other erectile dysfunction drugs.

All of the men in this study first went through a few weeks on Viagra alone. If they failed to respond to the drug, the researchers upped their dose, to a maximum of 100 milligrams a day. Spitzer's team then randomly assigned 70 men to use the testosterone gel every day for 14 weeks; the other half of the group used the placebo gel.

In the end, men in both groups essentially maintained the improvement they'd had when they were on Viagra only.

Matsumoto said that speaks to the benefit of "optimizing" a man's Viagra dose, and giving the drug some time to work.

But, he added, if a man still sees no erectile dysfunction improvement,



and his testosterone level remains low, "my sense is that he should consider trying testosterone."

It's controversial whether low testosterone is a medical condition that needs treatment. Companies that make testosterone products—which can cost a few hundred dollars a month—have been criticized for trying to promote normal male aging as a disease. And testosterone gels can have side effects: acne, prostate enlargement (which can cause urinary problems) and an increased prostate cancer risk are a few, according to the Endocrine Society.

But clinical hypogonadism is real, doctors say, and testosterone replacement is an approved treatment.

"If you're already on testosterone and have found benefit, it's reasonable to continue," Spitzer said. Men who have concerns, he added, should talk to their doctor—and not just abandon the therapy because of these findings.

The study was funded by the U.S. National Institute of Child Health and Human Development. Auxilium Pharmaceuticals provided the testosterone gel, and Pfizer supplied the <u>Viagra</u>.

**More information:** Learn more about erectile dysfunction from the U.S. National Institute of Diabetes and Digestive and Kidney Diseases.

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