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Analysis rejects linkage between testosterone therapy, cardiovascular risk

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Summary: Fears of a link between testosterone replacement therapy and cardiovascular risk are misplaced, according to a review. The therapy has come under widespread scrutiny in recent months, including by a federal Food and Drug Administration (FDA) panel convened last fall.

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FULL STORY

Fears of a link between testosterone replacement therapy and cardiovascular risk are misplaced, according to a review published in this month's *Mayo Clinic Proceedings*. The therapy has come under widespread scrutiny in recent months, including by a federal Food and Drug Administration (FDA) panel convened last fall.

"There's no good evidence that we could find that testosterone therapy increases cardiovascular risk," says lead author Abraham Morgentaler, MD, of Director of Men's Health Boston and a urologist on staff at Beth Israel Deaconess Medical Center. "That's not to say it's perfectly safe. But we cannot find evidence and the headlines that jumped out on recent retrospective studies appear to be too strong."

Importantly, and under-recognized among physicians, Morgentaler adds, "review of the literature clearly reveals a strong relationship between higher serum testosterone concentrations ... as being beneficial for reduction in cardiovascular disease and cardiovascular risk factors."

Testosterone is a hormone that, during puberty, helps build a man's muscles, deepens his voice and increases the size of his reproductive organs. As adults, men rely on the hormone to keep muscles and bones strong and to maintain an interest in sex.

Testosterone levels generally begin a gradual decline after the age of 30, a drop that may be accompanied by a decrease in sex drive. In recent years, the use of testosterone replacement therapy has increased substantially, aided in part by "patient-friendly formulations" such as topical gels that are widely advertised on television.

Such advertisements, combined with two recent studies raising questions about cardiovascular risk associated with the treatment, were the backdrop to an FDA advisory panel on testosterone therapy convened in September 2014. The panel voted 20-1 in favor of conducting a large-scale study to assess cardiovascular risk associated with testosterone therapy; the panel also voted in favor of a change in labeling requirements restricting the indications for use of testosterone.

"Testosterone has been presented as if there were a debate about whether it is good or evil," says Morgentaler. "Rather, it is a long-accepted medical treatment for a medical condition recognized for centuries. Our intention was to cut through the confusion of loudly expressed opinions on non-scientific issues -- such as pharmaceutical advertising, anti-aging claims, and the importance of sexuality in older men -- to provide the most comprehensive review to date of the literature on testosterone and cardiovascular risk."

The article by Morgentaler and colleagues in the fields of urology, endocrinology, family medicine and steroid research identified only four published scientific journal articles since 1940 that suggest increased cardiovascular risks with testosterone prescriptions. Two of those four articles, which generated substantial media coverage over the last 15 months, had "serious methodological limitations; one placebo-controlled trial with few major adverse cardiac events and one meta-analysis that included questionable studies and [cardiovascular] events."

In contrast, Morgentaler and his co-authors cite dozens of studies examining the relationship between testosterone and heart-related issues, including coronary artery disease, ischemic stroke, cholesterol levels, angina and heart failure. They found that many of those studies identify a positive correlation between "low testosterone levels and increased mortality ... as well as atherosclerosis, incident coronary artery disease and the severity of coronary artery disease."

Two observational studies have shown that men with low testosterone levels who did not receive testosterone replacement therapy died at double the rate of similar men who did receive testosterone. A small number of randomized controlled studies have even shown that men with known heart disease (specifically angina or congestive heart failure) were able to function better when they received testosterone compared with a placebo. Numerous studies have shown that risk factors for cardiovascular disease -- such as waist circumference, obesity, and fat mass -- all improve with testosterone therapy.

Additional studies have shown benefits of testosterone therapy, including increased sex drive, energy and bone mineral density. The authors also describe "promising new data" that suggest testosterone therapy improves insulin sensitivity, reduces blood glucose and hemoglobin A1C levels in men with Type 2 diabetes or obesity.

Yet public attention appears to have been focused on the four studies that "have undergone serious criticism in the scientific literature. The FDA itself has provided commentary on these studies, concluding that none provide compelling evidence of increased cardiovascular risk."

The testosterone story "has been turned upside-down," says Morgentaler, "by trumpeting studies providing remarkably weak evidence of risk, and ignoring a substantial literature with reassuring or beneficial results."

Morgentaler and his colleagues write "public health may be harmed not only by inadequate appreciation of an actual risk but also by the failure to offer beneficial treatment for a medical condition because of false claims of risk concerns."

Story Source:

Materials provided by **Beth Israel Deaconess Medical Center.** *Note: Content may be edited for style and length.*

Journal Reference:

1. Abraham Morgentaler, Martin Miner, Monica Caliber, Andre Guay, Mohit Khera, Abdulmaged Traish. **TEMPORARY REMOVAL: Testosterone Therapy and Cardiovascular Risk: Advances and Controversies.** *Mayo Clinic Proceedings*, 2014; DOI: 10.1016/j.mayocp.2014.10.011

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