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Beth Israel Deaconess Medical Center

Study finds no causal link between testosterone replacement, prostate cancer or cardiac disease

A retrospective analysis by researchers at Beth Israel Deaconess Medical Center published in The New England Journal of Medicine found no causal relationship between testosterone replacement and prostate cancer or heart disease risk.

The comprehensive review of 72 studies, addresses the current controversy about testosterone replacement therapy and its potential health risks to men.

"We reviewed decades of research and found no compelling evidence that testosterone replacement therapy increases the incidence of prostate cancer or cardiovascular disease," said Abraham Morgentaler, MD, a urologist at BIDMC and associate clinical professor at Harvard Medical School. "Although it would be helpful to have data from long-term, large-scale studies, it must also be recognized that there already exists a substantial body of research on the effects of testosterone in men."

Low levels of testosterone affect an estimated 2 to 4 million men in the United States, a condition termed hypogonadism, and the prevalence of this condition increases with age. The symptoms include diminished libido and sense of vitality, erectile dysfunction, reduced muscle mass and bone density, depression, and anemia.

The causes of hypogonadism may be classified as primary, meaning inadequate function of the testes; secondary, inadequate pituitary stimulation of the testes; or a combination of primary and secondary causes, which is common in older men. Testosterone supplementation, in the form of injections, patches, gels and a buccal tablet, is designed to elevate a hypogonadal man’s testosterone levels into the normal physiologic range and alleviate symptoms.

"Testosterone is only for men who have symptoms of low testosterone combined with a confirmatory blood test. Testosterone therapy can be beneficial and safe for these men as long as they are appropriately monitored by their physician," says Morgentaler.

It has been known since the 1940’s that severe reductions of testosterone can cause shrinkage of metastatic prostate cancer, and therefore there has been a concern that raising testosterone levels might cause growth of any hidden prostate cancers. However, the study by Ernani L. Rhoden, M.D., and Morgentaler found no connection between higher testosterone levels and prostate cancer, nor did they find evidence that testosterone treatment causes prostate cancer.

In fact, they note that prostate cancer becomes more prevalent exactly at the time of a man’s life when testosterone levels decline. To date, prospective studies have demonstrated no difference in prostate cancer incidence among hypogonadal men using testosterone therapy compared to men in the general population.

Regarding benign prostatic hyperplasia (BPH), multiple studies have failed to demonstrate consistent exacerbation of voiding symptoms during testosterone supplementation. "The impact

of testosterone therapy on benign prostate growth appears to be mild," says Rhoden, "and rarely of clinical significance. However, testosterone therapy should be used cautiously in men with severe urinary symptoms."

Monitoring the prostate during testosterone therapy is mandatory, given the theoretical concern that testosterone treatment may stimulate the growth of an occult cancer. Before and during treatment men should undergo regular evaluation, with a digital examination of the prostate, and a blood test called prostate-specific antigen (PSA). Patients with an abnormal prostate exam or an elevated PSA should undergo a prostate biopsy before initiating testosterone replacement to exclude the possibility that cancer is present. To monitor BPH, they recommend determining a base-line voiding history at the start of treatment and assessing urinary symptoms at follow-up.

The belief that testosterone may be a risk factor in cardiovascular disease is based on the observation that more men than women have cardiovascular events and men have higher testosterone levels than women. However, Rhoden and Morgentaler write that few, if any, data support a causal relation between higher testosterone levels and heart disease.

Indeed, several studies suggest that higher testosterone levels may actually have a favorable effect on atherosclerosis and heart disease. Studies of testosterone replacement therapy have not demonstrated an increased incidence of cardiovascular disease, myocardial infarction, stroke, or angina, according to the retrospective analysis.

Rhoden and Morgentaler describe other potential risks or side effects from testosterone replacement therapy as infrequent (acne or oily skin, sleep apnea); rarely of clinical significance (fluid retention); or reversible with cessation of treatment (gynecomastia, testicular atrophy or infertility). Testosterone treatment should be used cautiously or not at all in men with advanced liver disease. Skin reactions are commonly encountered in men being treated with the patch with a low incidence observed with testosterone gel.

Beth Israel Deaconess Medical Center is a major patient care, teaching and research affiliate of Harvard Medical School, and ranks third in National Institutes of Health funding among independent hospitals nationwide. BIDMC is clinically affiliated with the Joslin Diabetes Center and is a founding member of the Dana-Farber/Harvard Cancer Center. BIDMC is the official hospital of the Boston Red Sox.

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