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Source: JAMA and Archives Journals

Date: November 21, 2006

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## Testosterone Replacement Therapy Appears Safe For Prostate

Preliminary research suggests that testosterone replacement therapy for men with low testosterone levels appears to have little effect on the prostate gland, contrary to some reports that this therapy may be harmful, according to a study in the November 15 issue of JAMA, a theme issue on men's health.

Leonard S. Marks, M.D., of the Urological Sciences Research Foundation and University of California, Los Angeles, presented the findings of the study today at a JAMA media briefing on men's health in New York.

Testosterone replacement therapy (TRT) in aging men is a widespread, growing practice. According to pharmaceutical industry estimates, more than 1.8 million prescriptions for testosterone products were written in the United States in 2002, a 30 percent increase over the previous year and a 170 percent increase over the previous 5 years. In 2005, a total of 2.3 million prescriptions were written for these products. Serum levels of testosterone decline with age, and many aging men with low levels of the hormone may experience depression, sexual dysfunction, diminished lean body mass, muscle volume and strength, and reduced bone mineral density, according to background information in the article. Such changes, in association with low testosterone levels, have been called "male menopause."

Aspects of the syndrome may be improved with TRT, and most testosterone prescriptions are currently written for men older than 45 years, a demographic in which prostate disease is most common. Between 2 and 4 million men, nearly all in this "prostatic age group," may be candidates for treatment, the authors write. In men with advanced prostate cancer, testosterone administration often worsens the disease. Thus, when aging men receive supplemental testosterone, a primary concern is prostate safety. Even in men with no sign of prostate cancer, the possibility of stimulating growth in subclinical disease exists. Instances of prostate cancer in men receiving testosterone supplementation have been reported. When TRT is prescribed, careful monitoring for prostate disease is considered mandatory. But there is little information regarding the effects of TRT on prostate tissue in men.

Dr. Marks and colleagues conducted a randomized controlled trial to assess the effects of TRT on prostate tissue of 44 men, age 44 to 78 years, with low serum testosterone levels. The study was conducted between February 2003 and November 2004. Participants were randomly assigned to receive by injection 150 mg of replacement testosterone or matching placebo every 2 weeks for 6 months. Of the 44 men randomized, 40 had prostate biopsies performed both at baseline and at the end of the study and were included in the final analysis (TRT, n = 21; placebo, n = 19).

Testosterone replacement therapy increased serum testosterone levels to the mid-

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When prostate cancer returns, doctors usually recommend hormonal therapy. This can help with pain and can help reduce symptoms from the spread of the disease to the bones and other organs. Hormonal therapy will not remain effective indefinitely. When it fails, doctors shift to palliative care. Chemotherapy, usually a drug called Novantrone (mitoxantrone), at this stage of disease can help reduce pain. Recently, drugs called taxanes, especially Taxotere (docetaxel), have shown to provide a modest increase in survival.

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normal range with no significant change in serum testosterone levels in matched, placebo-treated men. In prostate tissue, TRT increased median (midpoint) androgen (male sex hormone) concentrations only slightly compared with baseline levels or between the 2 groups. No treatment-related change was observed in prostate histology, tissue biomarkers, gene expression, or cancer incidence or severity. Treatment-related changes in prostate volume, serum prostate-specific antigen, voiding symptoms, and urinary flow were slight.

"... under the conditions herein, including the biopsy to detect cancer performed pretreatment, a degree of prostate safety is defined for men undergoing TRT," the authors write. "The prostate risks to men undergoing TRT may not be as great as once believed, especially if the results of the pretreatment biopsy are negative. However, establishment of prostate safety for large populations of older men undergoing longer duration of TRT requires further study," the researchers conclude.

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