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Testosterone Replacement Therapy and Prostate Cancer Risk

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TOPLINE:

Testosterone replacement therapy in middle-aged and older men with hypogonadism does not increase the risk for high-grade or any prostate cancer, new data confirmed.

METHODOLOGY:

- The relationship between testosterone replacement therapy and prostate cancer risk remains unclear. Epidemiologic studies have shown inconsistent findings, and clinical trials have not examined prostate safety. As a result, guidelines generally advise against testosterone replacement therapy in men with a history of or increased risk for prostate cancer.
- The current placebo-controlled, double-blind, parallel-group randomized study included 5204 men, ages 45-80, who had two fasting testosterone concentrations < 300 ng/dL, one or more hypogonadal symptoms, and a history of cardiovascular disease or increased cardiovascular risk. Patients were randomly assigned 1:1 to receive either testosterone replacement therapy or placebo.
- The primary prostate safety endpoint was incident high-grade prostate cancer (Gleason score 4 + 3 or higher).

- Secondary endpoints included incidence of any prostate cancer, acute urinary retention, invasive procedure for benign prostatic hyperplasia, prostate biopsy, and new pharmacologic treatment for lower urinary tract symptoms.

TAKEAWAY:

- The incidence of high-grade prostate cancer did not differ significantly between groups. Over a mean follow-up of 33 months, only 0.19% (5 of 2596 participants) in the testosterone replacement therapy group and 0.12% (3 of 2602) in the placebo group were diagnosed with high-grade disease (hazard ratio [HR], 1.62; $P = .51$).
- The rate of any prostate cancer also did not differ significantly between the testosterone vs placebo groups (0.46% vs 0.42%; HR, 1.07; $P = .87$).
- The rates of acute urinary retention (0.77% vs 0.61%; HR, 1.25; $P = .50$), invasive procedures for benign prostatic hyperplasia (0.89% vs 0.46%; HR, 1.91; $P = .07$), prostate biopsy (0.62% vs 0.54%; HR, 1.13; $P = .74$), or new treatment for lower urinary tract symptoms (3.89% vs 3.34%; HR, 1.16; $P = .32$) did not differ significantly between the testosterone vs placebo groups.
- Compared with placebo, testosterone therapy did increase prostate-specific antigen (PSA) levels, but the differences were small and did not increase after 12 months.

IN PRACTICE:

In a population of middle-aged and older men with hypogonadism, "the incidences of high-grade or any prostate cancer and other prostate events were low and did not differ significantly between testosterone- and placebo-treated men," the authors concluded. "The study's findings will facilitate a more informed appraisal of the potential prostate risks of testosterone replacement therapy."

SOURCE:

This study, led by Shalender Bhasin, MB, BS, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, was published online on