

Abstract

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Incidence of prostate cancer in hypogonadal men receiving testosterone therapy: observations from 5-year median followup of 3 registries.

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PURPOSE: Although there is no evidence that testosterone therapy increases the risk of prostate cancer, there is a paucity of long-term data. We determined whether the incidence of prostate cancer is increased in hypogonadal men receiving long-term testosterone therapy.

MATERIALS AND METHODS: In 3 parallel, prospective, ongoing, cumulative registry studies 1,023 hypogonadal men received testosterone therapy. Two study cohorts were treated by urologists (since 2004) and 1 was treated at an academic andrology center (since 1996). Patients were treated when total testosterone was 12.1 nmol/l or less (350 ng/dl) and symptoms of hypogonadism were present. Maximum followup was 17 years (1996 to 2013) and median followup was 5 years. Mean baseline patient age in the urological settings was 58 years and in the andrology setting it was 41 years. Patients received testosterone undecanoate injections in 12-week intervals. Pretreatment examination of the prostate and monitoring during treatment were performed. Prostate biopsies were performed according to EAU guidelines.

RESULTS: Numbers of positive and negative biopsies were assessed. The incidence of prostate cancer and post-prostatectomy outcomes was studied. A total of 11 patients were diagnosed with prostate cancer in the 2 urology settings at proportions of 2.3% and 1.5%, respectively. The incidence per 10,000 patient-years was 54.4 and 30.7, respectively. No prostate cancer was reported by the andrology center. **Limitations are inherent in the registry design without a control group.**

CONCLUSIONS: Testosterone therapy in hypogonadal men does not increase the risk of prostate cancer. If guidelines for testosterone therapy are properly applied, testosterone treatment is safe in hypogonadal men.

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