

Long-term treatment with testosterone undecanoate injections does not increase prostate cancer incidence in hypogonadal men

ID: 123940 Password: 297442

Ahmad Haider¹, Michael Zitzmann², Aksam A. Yassin^{3,4}

¹Private Urology Practice, Bremerhaven, Germany, ²Department of Reproductive Medicine, Andrology and Clinical Andrology, University of Muenster, Muenster, Germany, ³Institute for Urology and Andrology, Norderstedt, Germany, ⁴Dresden International University, Dresden, Germany

Background: Concerns regarding the safety of testosterone treatment, particularly regarding prostate cancer in elderly men, still hamper the use of testosterone in hypogonadal men.

Methods: Registry studies of 942 men with testosterone levels ≤ 12.1 nmol/L from three German centers. Patients received testosterone undecanoate for up to 16 years.

Results: In cohort A (mean age: 57.70 ± 6.76 years; Bremerhaven), PSA increased from 1.77 ± 0.97 to 2.0 ± 1.01 ng/ml ($p=0.0021$). Prostate volume increased from 28.34 ± 10.79 to 30.72 ± 14.28 ml ($p<0.0001$). 5/300 patients were diagnosed with prostate cancer. The proportion was 1.7% with an incidence of 39.4 per 10,000 patient-years.

In cohort B (mean age: 59.53 ± 8.35 years; Norderstedt), PSA increased from 0.86 ± 0.57 to 1.38 ± 0.49 ng/ml ($p<0.0001$). Prostate volume increased from 27.9 ± 8.15 to 36.98 ± 7.22 ml ($p<0.0001$). 6/261 patients were diagnosed with prostate cancer. The proportion was 2.3% with an incidence of 54.5 per 10,000 patient-years.

One patient in cohort B was treated with external beam radiation, all other patients underwent radical prostatectomy.

In cohort C (mean age: 42.6 ± 13.4 years; Muenster), PSA increased from 1.6 ± 0.4 to 1.9 ± 0.4 ($p<0.001$). Prostate volume increased from 16.9 ± 5.1 to 19.9 ± 5.3 ml ($p<0.001$). No patient was diagnosed with prostate cancer.

Conclusions: The PLCO trial reported an incidence of 116 per 10,000 patient-years (Andriole, NEJM 360(13):1310-9), the ERSPC trial 96.6 (Schröder, NEJM 366(11):981-90). Although these screening trials cannot be directly compared to our registries of hypogonadal men receiving testosterone replacement therapy, the incidence of prostate cancer in our registry studies does not suggest an increased risk in hypogonadal men on long-term testosterone treatment.