

Prostate cancer incidence in hypogonadal men on long-term treatment with testosterone undecanoate injections

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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; Haider), 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; Yassin), 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; Zitzmann), 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). In our registry studies, the incidence of prostate cancer does not suggest an increased risk in hypogonadal men on long-term testosterone treatment.