

Incidence of prostate cancer in hypogonadal men on long-term treatment with testosterone undecanoate injections

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Introduction: There are concerns regarding the safety of testosterone treatment, particularly in elderly men.

Methods: Registry studies of 850 men with testosterone levels ≤ 12.1 nmol/L from three German centers. Patients received testosterone undecanoate for up to 60 months.

Results:

In cohort A (mean age: 60.6; Haider), PSA increased from 1.77 ± 0.96 to 1.82 ± 0.96 ng/ml ($p < 0.0001$). Prostate volume increased from 28.51 ± 11.2 to 30.23 ± 12.4 ml ($p < 0.0001$). 3/255 patients were diagnosed with prostate cancer at 18 weeks of treatment. The proportion was 1.18% with an incidence of 30.334 per 10.000 patient-years.

In cohort B (mean age: 58; 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.

All patients underwent radical prostatectomy.

In cohort C (mean age: 42; Zitzmann), PSA increased from 1.8 ± 0.5 to 1.9 ± 0.4 ($p < 0.001$). Prostate volume increased from 16.1 ± 5.2 to 19.7 ± 5.4 ml ($p < 0.001$). No patient was diagnosed with prostate cancer.

The International Prostate Symptom score (IPSS) improved from 6.73 to 2.83 ($p < 0.0001$) in cohort A and from 10.35 to 6.58 ($p < 0.0001$) in cohort B. Residual bladder volume declined from 46.61 to 19.74 and 23.82 to 17.59, resp.

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 studies, the incidence of prostate cancer does not suggest an increased risk in hypogonadal men on long-term testosterone treatment.