Long-term treatment of middle-aged to elderly hypogonadal men with testosterone undecanoate does not indicate an increased risk of prostate cancer

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Introduction: There are still concerns regarding the safety of testosterone treatment, particularly in elderly men. This study investigated whether men receiving long-term treatment with testosterone were exposed to a higher risk of prostate cancer.

Methods: Registry studies of 516 hypogonadal men from two urology offices in Germany. They received parenteral testosterone undecanoate for up to 60 months.

Results:
Prostate: In cohort A (Haider), PSA increased from 1.77 to 1.82 ng/ml ($p<0.0001$). Prostate volume increased from 28.51 to 30.23 ml ($p<0.0001$). 3/255 patients were diagnosed with prostate cancer following elevated PSA (> 4 ng/mL) at 18 weeks of treatment. The proportion was 1.18% with an incidence of 30.334 per 10.000 patient years.
In cohort B (Yassin), PSA increased from 0.86 to 1.41 ng/ml ($p<0.0001$). Prostate volume increased from 27.9 to 34.79 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.
For comparison: in the PLCO trial with a 7-year follow-up, the proportion of prostate cancer was 7.35% with an incidence of 116 per 10.000 patient years [1], in the ERSPC trial with a 11-year follow-up, 9.6% and 96.6, resp. [2].
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 incidence of prostate cancer does not suggest an increased risk of prostate cancer in hypogonadal men on long-term testosterone treatment. Parameters related to BPH/LUTS suggest an improvement of clinical symptoms.