Three cohorts´ study in terms of incidence of prostate cancer in hypogonadal patients on long-term treatment with testosterone undecanoate injections

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Objectives: To investigate safety in terms of prostate cancer incidence in patients under testosterone treatment.

Methods: Observational registry studies of 850 hypogonadal men with testosterone levels ≤ 12.1 nmol/L from 3 centers in Germany. All patients received parenteral testosterone undecanoate 1000 mg for up to 60 months.

Results:
Prostate: In cohort A (Haider: 255 pat., mean age: 60.6 years) 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 following elevated PSA (> 4 ng/mL) at 18 weeks of treatment. Proportion was 1.18% with an incidence of 30.334 per 10.000 patient years. International Prostate Symptom score (IPSS) improved from 6.73 to 2.83 ($p<0.0001$). Postvoiding volume declined from 46.61 to 19.74 ml

In cohort B (Yassin: 261 pat. mean age: 58 years), 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. Proportion was 2.3% with an incidence of 54.5 per 10.000 patient years. International Prostate Symptom score (IPSS) improved from 10.35 to 6.58 ($p<0.0001$). Postvoiding volume declined from 23.82 to 17.59 ml.

In cohort C (Zitzmann: 334 pat., mean age: 42 years), 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 CaP.

Conclusions: Data suggest that testosterone treatment does not increase the risk of prostate cancer in hypogonadal patients on long-term testosterone treatment. Prostate safety parameters related to BPH/LUTS surprisingly suggest an improvement of clinical symptoms.

1878 Zeichen
erlaubt: max. 1800

References:
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[2] Schröder F et al. New Engl J Med 366(11): 981-990 (2012)