

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

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**Introduction & Objectives:** To investigate the treatment safety profile with regard to prostate health parameter including prostate cancer incidence in patients under testosterone treatment therapy (TRT)

**Materials & Methods:** Observational registry studies of 850 hypogonadal men with testosterone levels  $\leq 12.1$  nmol/L from three centers in Germany. All patients received parenteral testosterone undecanoate 1000 mg for up to 60 months.

### Results:

In cohort A (Haider: 255 pat., mean age: 60.6 years) PSA increased from  $1.77 \pm 0.96$  to  $1.82 \pm 0.96$  ng/ml ( $p < 0.0001$ ). Prostate volume increased from  $28.51 \pm 11.2$  to  $30.23 \pm 12.4$  ml ( $p < 0.0001$ ). 3/255 patients were diagnosed with prostate cancer following elevated PSA ( $> 4$  ng/mL) at 18 weeks of treatment. The proportion was 1.18% with an incidence of 30.334 per 10.000 patient years. The International Prostate Symptom score (IPSS) improved from 6.73 to 2.83 ( $p < 0.0001$ ). Residual bladder volume declined from 46.61 to 19.74 ml.

In cohort B (Yassin: 261 pat. mean age: 58 years), PSA increased from  $0.86 \pm 0.57$  to  $1.38 \pm 0.49$  ng/ml ( $p < 0.0001$ ). Prostate volume increased from  $27.9 \pm 8.15$  to  $36.98 \pm 7.22$  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. The International Prostate Symptom score (IPSS) improved from 10.35 to 6.58 ( $p < 0.0001$ ). Post-voiding residual volume declined from 23.82 to 17.59 ml.

In cohort C (Zitzmann: 334 pat., mean age: 42 years), PSA increased from  $1.8 \pm 0.5$  to  $1.9 \pm 0.4$  ( $p < 0.001$ ). Prostate volume increased from  $16.1 \pm 5.2$  to  $19.7 \pm 5.4$  ml ( $p < 0.001$ ). No patient was diagnosed with prostate cancer.

**Conclusion:** 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.