

## Side Effect Profile of Long-Term Treatment of Elderly Hypogonadal Men with Testosterone Undecanoate

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**Introduction and Objectives:** Testosterone therapy for hypogonadal men has been used for decades. However, there are still concerns regarding the safety of this treatment, particularly in elderly men. We assessed incidence of prostate cancer and other safety parameters during long-term testosterone treatment.

**Methods:** Cumulative registry study of 255 men (mean age  $60.6 \pm 8.0$  years), with testosterone levels between  $\leq 3.5$  ng/ml. They received parenteral testosterone undecanoate 1000 mg at day 1, week 6 and every 12 weeks thereafter for up to 66 months.

**Results:** After 60 months the following changes were observed:

Erythropoiesis: haemoglobin increased from  $14.44 \pm 0.72$  to  $14.99 \pm 0.45$  g/dl ( $p < 0.0001$  vs baseline). Haematocrit increased from  $43.22 \pm 2.84$  to  $48.78 \pm 1.7\%$  ( $p < 0.0001$  vs baseline). Four patients had haematocrit levels  $> 52\%$  which resolved without intervention.

Prostate: PSA increased from  $1.77 \pm 0.96$  to  $1.82 \pm 0.96$  ng/ml ( $p < 0.0001$  vs baseline) with a plateau after 24 months. Prostate volume increased from  $28.51 \pm 11.2$  to  $30.23 \pm 12.4$  ml ( $p < 0.0001$  vs baseline). 3/255 patients were diagnosed with prostate cancer following elevated PSA ( $< 4$  ng/mL) at 18 weeks of treatment. Tumour grade was T2 in all three and Gleason score 3+3 in two and 3+2 in one patient, resp. They all underwent radical prostatectomy. The proportion was 1.18% with an incidence of 30.334 per 10.000 patient years. 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]. – The International Prostate Symptom score (IPSS) improved from  $6.73 \pm 4.21$  to  $2.83 \pm 1.25$  ( $p < 0.0001$ ).

Liver enzymes: aspartate transaminase (AST) decreased from  $43.05 \pm 17.29$  to  $20.16 \pm 3.21$  U/L ( $p < 0.0001$  vs baseline) reaching a plateau after 24 months, alanine transaminase (ALT) from  $43.89 \pm 18.11$  to  $20.54 \pm 3.92$  U/L ( $p < 0.0001$  vs baseline) with a plateau after 36 months.

**Conclusions:** The incidence of 3/255 patients with prostate cancer does not suggest an increased risk of prostate cancer in elderly men on long-term testosterone treatment. Long-term treatment with testosterone undecanoate with monitoring according to the guidelines is acceptably safe.