

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

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**Introduction:** 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.

**Methods:** Prospective registry study of 255 men (mean age  $60.6 \pm 8.0$  years), with testosterone levels  $\leq 3.5$  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.