

Side effect profile of long-term treatment of hypogonadal men with testosterone undecanoate

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Maximum 300 words

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 252 men (mean age 60.6 ± 8.0 years), with testosterone levels between ≤ 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 ± 0.72 to 14.99 ± 0.45 g/dl ($p < 0.0001$ vs baseline). Haematocrit increased from 43.18 ± 2.83 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 1.76 ± 0.96 to 1.82 ± 0.96 ng/ml ($p < 0.0001$ vs baseline) with a plateau after 24 months. 3/255 patients were diagnosed with prostate cancer following elevated PSA 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 and were excluded from the analysis. Prostate volume increased from 28.3 ± 11.12 to 30.23 ± 12.4 ml ($p < 0.0001$ vs baseline). The International Prostate Symptom score (IPSS) improved from 6.7 ± 4.22 to 2.83 ± 1.25 . This was statistically significant vs baseline ($p < 0.0001$) and the decrease remained statistically significant compared to the previous year over the first 48 months.
Liver enzymes: aspartate transaminase (AST) decreased from 43.34 ± 17.31 to 20.16 ± 3.21 U/L, alanine transaminase (ALT) from 44.04 ± 18.16 to 20.54 ± 3.92 U/L ($p < 0.0001$ vs baseline with a plateau after 24 months).

Conclusions: The incidence of 3/255 patients with prostate cancer is similar to that in screening programmes. Long-term treatment with testosterone undecanoate with monitoring according to the guidelines is acceptably safe.