

Effects of long-term testosterone therapy on prostate, urinary and sexual parameters in 300 hypogonadal men treated for up to 6 years

A Haider¹, G Doros², A Traish³

¹ Private Urology Practice, Bremerhaven, Germany

² Boston University School of Public Health, Department of Epidemiology and Statistics, Boston, MA, USA

³ Boston University School of Medicine, Departments of Biochemistry and Urology, Boston, MA, USA

Introduction & Objectives:

There are still concerns regarding safety of testosterone replacement therapy (TRT) for the prostate. We investigated whether long-term TRT with injectable testosterone undecanoate (TU) affected parameters related to prostate, urinary and sexual function.

Materials and methods:

Prospective, longitudinal, registry study of 300 patients (mean age 57.7 ± 6.76 years), with testosterone levels ≤ 3.5 ng/mL (12 nmol/L) receiving parenteral TU 1000 mg at baseline, after 6 weeks and thereafter every 12 weeks for up to 72 months (6 years). Prostate volume and residual voiding volume were measured by ultrasound at every or every other visit. IPSS, IIEF-EF and AMS questionnaires were filled in at every visit and blood samples taken to measure PSA. Because prostatic diseases are closely associated with the metabolic syndrome, we also assessed anthropometric and metabolic parameters.

Results:

Testosterone increased from 9.86 ± 1.34 nmol/L to trough levels of 16 to 17 nmol/L for the observation period. Prostate volume increased from 28.34 ± 10.79 to 30.72 ± 14.28 ml ($p < 0.0001$ vs baseline). PSA increased from 1.77 ± 0.97 to 2.0 ± 1.01 ng/ml ($p = 0.0021$ vs baseline). 5/300 patients were diagnosed with prostate cancer (PCa) following elevated PSA (> 4 ng/mL). Tumor stage was pT2a in 4 and pT1b in 1 man, Gleason score 3+3 in 4 and 3+2 in 1 patient, resp. All men underwent radical prostatectomy. The proportion was 1.7% with an incidence of 39.4 per 10,000 patient years. The International Prostate Symptom Score (IPSS) decreased from 6.57 ± 4.21 to 2.58 ± 1.32 ($p < 0.0001$). The residual voiding volume decreased from 46.78 ± 23.58 to 15.85 ± 5.32 ml ($p < 0.0001$). The International Index of Erectile Function – Erectile Function Domain (IIEF-EF, maximum score: 30) increased from 20.01 ± 5.06 to 26.11 ± 3.33 ($p < 0.0001$) with a plateau at 36 months. The Aging Males' Symptoms scale (AMS) as a measure of quality of life improved from 53.43 ± 10.21 to 17.41 ± 2.36 ($p < 0.0001$). Weight dropped progressively by 16.8 ± 0.41 kg, and waist circumference (WC) by 8.94 ± 0.24 . Similarly, improvements in lipid pattern, blood pressure, and glucose homeostasis were observed.

Conclusion:

The incidence of PCa did not suggest an increased risk of PCa in hypogonadal men on long-term TRT. Long-term treatment with TU did not negatively affect voiding function as measured by IPSS, or residual voiding volume. Erectile function was markedly and sustainably improved. Part of these effects may be a result of parallel reduction in body weight and visceral fat, measured by WC, and other elements of the metabolic syndrome.