

## Improvement of Lipid Pattern, Insulin Resistance, and Blood Pressure in 300 Hypogonadal Men Treated with Testosterone Undecanoate Injections up to 6 Years: an Update from a Registry Study

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**Introduction:** Very few long-term studies on testosterone replacement therapy (TRT) allow investigating the sustainability of its effects. Our registry study follows unselected hypogonadal patients presenting to a urological office since 2004. We have published 5-year data on effects on components of the metabolic syndrome (Traish A et al., Int J Clin Pract, accepted September 08, 2013). Here we report for the first time data of a 6-year follow-up.

**Methods:** Cumulative, prospective, registry study of 300 men (mean age:  $57.7 \pm 6.8$  years) with testosterone levels below 12.1 nmol/L. All men received parenteral testosterone undecanoate 1000 mg/12 weeks following an initial 6-week interval. 88 men were treated six years, 148 five, 189 four, 213 three, 252 two, and 287 one year. The changing numbers do not reflect drop-out rates but are a result of the design. Between 5 and 6 years follow-up only two patients were lost to follow-up suggesting an excellent treatment adherence.

**Results:** Total cholesterol (mg/dl) decreased from  $279.72 \pm 40.85$  to  $189.61 \pm 8.93$ . This decrease was statistically significant during the first two years ( $p < 0.0001$ ). Model-adjusted mean change from baseline was  $-91.55 \pm 2.11$  mg/dl. HDL (mg/dl) increased slightly from  $56.47 \pm 17.85$  to  $61.06 \pm 18.06$ . Mean change from baseline was  $+9.97 \pm 0.37$  mg/dl. LDL (mg/dl) decreased from  $163.22 \pm 40.87$  to  $126.02 \pm 33.4$ . Mean change from baseline was  $-24.81 \pm 1.51$  mg/dl. Triglycerides (mg/dl) decreased from  $272.94 \pm 50.8$  to  $188 \pm 8.3$ . Mean change from baseline was  $-84.87 \pm 2.51$  mg/dl. The ratio of total cholesterol:HDL decreased from  $5.37 \pm 1.56$  to  $3.39 \pm 1.03$ . All changes in lipids were statistically significant during the first two years ( $p < 0.0001$ ) and remained stable thereafter.

Fasting glucose (mg/dl) decreased from  $102.93 \pm 13.55$  to  $95.98 \pm 2.38$ . This reached statistical significance during the first two years. HbA1c (%) decreased from  $6.94 \pm 1.48$  to  $6.05 \pm 0.59$ . Mean change from baseline was  $-1.47 \pm 0.08\%$ . This was statistically significant during the first 5 years.

Systolic blood pressure (mmHg) decreased from  $153.06 \pm 17.37$  to  $137.07 \pm 9.19$ , diastolic blood pressure from  $92.58 \pm 11.22$  to  $78.59 \pm 6.61$ . Mean reductions were  $-17.85 \pm 0.58$  and  $-14.88 \pm 1.54$  mmHg, respectively. Changes in blood pressure were statistically significant during the first two years and remained stable thereafter.

**Conclusions:** TRT produced improvement of metabolic syndrome components. In contrast to anthropometric parameters, most changes were statistically significant during the first two treatment years suggesting effects independent of decreases in weight and waist circumference which occurred during the full observation period. Long-term TRT results in sustainable reduction of cardiometabolic risk factors in hypogonadal men.