Improvement of metabolic syndrome in 300 hypogonadal men treated with testosterone undecanoate injections: observational 6-year-data from a registry study

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**Background:** 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. Here we report data of a 6-year follow-up.

**Methods:** Cumulative, prospective, registry study of 300 men (mean age: 57.7±6.8 years) with testosterone levels ≤12.1 nmol/L. All men received parenteral testosterone undecanoate 1000 mg/12 weeks following an initial 6-week-interval.

**Results:** Total cholesterol (mg/dl) decreased from 279.72±40.85 to 189.61±8.93 (p<0.0001). Model-adjusted mean change from baseline was -91.55±2.11 mg/dl.

HDL (mg/dl) increased slightly from  $56.47\pm17.85$  to  $61.06\pm18.06$  (p<0.0001). Mean change from baseline was  $+9.97\pm0.37$  mg/dl.

LDL (mg/dl) decreased from 163.22 $\pm$ 40.87 to 126.02 $\pm$ 33.4 (p<0.0001). Mean change from baseline was -24.81 $\pm$ 1.51 mg/dl.

Triglycerides (mg/dl) decreased from 272.94±50.8 to 188±8.3 (p<0.0001). Mean change from baseline was -84.87±2.51 mg/dl.

The ratio of total cholesterol:HDL decreased from  $5.37\pm1.56$  to  $3.39\pm1.03$  (p<0.0001).

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  $102.93\pm13.55$  to  $95.98\pm2.38$  (p<0.0001), HbA<sub>1c</sub> from  $6.94\pm1.48$  to  $6.05\pm0.59\%$  (p<0.0001). Mean change from baseline was -1.47 $\pm0.08\%$ .

Systolic blood pressure (BP; mmHg) decreased from 153.06±17.37 to 137.07±9.19, diastolic BP from 92.58±11.22 to 78.59±6.61. Mean reductions were -17.85±0.58 and -14.88±1.54 mmHg, respectively. Changes in BP were statistically significant during the first two years (p<0.0001) and remained stable thereafter.

Changes over time compared to baseline in total cholesterol, LDL, triglycerides, fasting glucose, HbA<sub>1c</sub> and BP were significantly correlated with changes in waist circumference and weight. Changes in HDL were correlated to changes in testosterone.

**Conclusions:** TRT produced improvement of all elements of the metabolic syndrome. Long-term TRT results in sustainable reduction of cardiometabolic risk factors in hypogonadal men.