

Long-term treatment with testosterone undecanoate (TU) in hypogonadal men with cardiovascular diseases (CVD): observational data from a registry study

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Background: Hypogonadism is associated with cardiometabolic risk. Several studies suggest that hypogonadism increases the risk of all-cause and cardiovascular mortality. While some short-term studies have been performed in men with CVD, there are no data on long-term effects of testosterone replacement therapy (TRT) in men with CVD.

Methods: In a prospective, cumulative, observational registry study from a single urologist's office, 300 men with testosterone ≤ 12.1 nmol/L received TU injections for up to 6 years. In this subgroup analysis, 68 men with a previous diagnosis of coronary artery disease (CAD; n=40) and/or a history of myocardial infarction (MI; n=40) were analyzed.

Results: Mean age was 60.76 ± 4.94 years. 68 men were included for 2 years, 59 for 3 years, 54 for 4 years, 44 for 5 years, and 28 for 6 years. Declining numbers reflect the nature of the registry (patients are included after receiving 1 year of TRT) but not drop-out rates.

Weight (kg) decreased from 115.07 ± 13.71 to 92.5 ± 9.64 . Waist circumference (cm) decreased from 112.07 ± 7.97 to 99.89 ± 6.86 . BMI decreased from 37.27 ± 4.45 to 30.14 ± 3.21 ($p < 0.0001$ for all). Mean weight loss was $17.05 \pm 0.57\%$.

Mean fasting glucose decreased from 108.74 ± 17.08 to 96.0 ± 1.92 mg/dl, HbA1c from 7.81 ± 1.17 to $6.2 \pm 0.62\%$ ($p < 0.0001$ for both).

Total cholesterol decreased from 304.66 ± 34.09 to 189.32 ± 9.68 , LDL from 184.28 ± 37.51 to 134 ± 27.91 , triglycerides from 308.38 ± 56.3 to 187.71 ± 8.67 ($p < 0.0001$ for all), and HDL increased slightly. The total cholesterol:HDL ratio declined from 5.16 ± 1.55 to 3.15 ± 0.87 ($p < 0.0001$).

Systolic BP decreased from 167.82 ± 11.01 to 142.36 ± 10.62 , diastolic BP from 102.28 ± 8.23 to 81.25 ± 8.07 mmHg ($p < 0.0001$ for both). Pulse pressure declined from 65.54 ± 5.24 to 61.11 ± 4.66 ($p < 0.0001$).

Quality of life, measured by the Aging Males' Symptoms scale (AMS) improved from 56.25 ± 10.09 to 17.11 ± 0.31 .

The minimum number of injections was 9, maximum 26. In no patient TRT was discontinued or interrupted. There were no major cardiovascular events during the observation time.

Conclusion: Correcting hypogonadism by TRT in hypogonadal men with CVD resulted in significant and sustained improvements of cardiometabolic risk factors. TRT in hypogonadal men with CVD was well tolerated. The adherence to TRT was excellent.