

INTRAMUSCULAR TESTOSTERONE UNDECANOATE FOR SUBSTITUTION IN MALE HYPOGONADISM: THE EXPERIENCE OF 13.5 YEARS

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Background: A reliable form of testosterone substitution with favourable kinetics and tolerance is important for hypogonadal men. Intramuscular injections of long-acting testosterone undecanoate (TU) offer a convenient modality.

Methods: We report data from 281 patients (134 with primary, 88 with secondary hypogonadism and 59 with late-onset ("mixed" or "metabolic" hypogonadism) aged 15 to 72 years (mean 40±13 years) receiving altogether 4913 intramuscular injections of 1000 mg of TU during a maximal treatment time of 13.5 years, overall corresponding to 1069 treatment years.

Components of the metabolic syndrome were assessed in 216 men receiving 2864 injections.

Results: Trough levels of testosterone were within the low normal range and stable throughout the observation period, indicating sufficient substitution. As expected, prostate volume increased during the first year of treatment and remained stable during follow-up. PSA showed minor fluctuations but remained stable over time. In two patients, PSA increased to 5.5 µg/L. Biopsies were performed and revealed prostatitis in both cases. No case of prostate cancer occurred. Hematocrit was significantly elevated under treatment but remained within the normal range, except for occasional measurements (maximal value 56.3%).

Waist circumference decreased from 112.0±10.3 to 96.4±9.1 cm ($p<0.001$) within a year (body composition from 30.4±5.1 to 28.6±3.8 cm ($p=0.001$)). Lipoprotein subfractions, blood pressure and fasting glucose levels improved significantly.

Conclusion: Injections of testosterone undecanoate represent a feasible, safe and well tolerated modality of androgen substitution in hypogonadal men of a wide age-range, substantiated by more than one decade of experience, facilitating a decrement of metabolic/cardiovascular risk factors.