Erectile Function in 478 Hypogonadal Men with Moderate to Severe ED with and without Testosterone Therapy for up to 10 Years

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Introduction and Objectives

Long-term data for treatment of erectile dysfunction (ED) are scarce. We investigated effects of testosterone therapy (TTh) in a registry study in a urological office setting in comparison to an untreated hypogonadal control group.

Methods

478 men with testosterone ≤350 ng/dL and hypogonadal symptoms had moderate to severe ED according to IIEF-ED (≥1, maximum score: 30). 246 received testosterone undecanoate injections (TU) 1000 mg/12 weeks following an initial 6-week interval (T-group). 232 men opted against TTh and served as controls (CTRL).

10-year data are presented.

Changes over time between groups were compared by a mixed effects model for repeated measures with a random effect for intercept and fixed effects for time, group and their interaction, and adjusted for age, weight, waist circumference, blood pressure, fasting glucose, lipids and quality of life to account for baseline differences between groups.

Results

Total group mean age was 61 ± 7 years (T-group: 58 ± 8, CTRL: 64 ± 5). 34% of men in the T-group and 44% in CTRL had type 2 diabetes at baseline (p<0.05). 91.1% of men in the T-group and 77% in CTRL had hypertension at baseline (p<0.0005).

In the T group, IIEF-ED increased from 15.2 ± 3.7 to 25.7 ± 2.2 at 10 years (p<0.0001) with a change from baseline by 11.5 points. The improvement was statistically significant for the first nine years. In CTRL, IIEF-ED decreased from 18.2 ± 3.7 to 10.0 ± 4.3 at 10 years (p<0.0001) with a change from baseline by 8.2 points. The decrease was statistically significant for the first nine years. The estimated adjusted difference between groups at 10 years was 19.7 (p<0.0001).

Use of PDE5 inhibitors at baseline was 25.2% in the T-group and 22.4% in CTRL (non-significant). Baseline weight was 102.9 ± 17 kg in the T-group and 95.7 ± 13 kg in CTRL (p<0.0001). Only 9.3% of patients in the T-group and 8.6% in CTRL had normal weight at baseline. Men in the T-group lost 18.6 ± 9.1% of their baseline weight at 10 years (p<0.0001) while men in CTRL gained 2.2 ± 4.6% (p<0.0001). The estimated adjusted difference between groups at 10 years was 19.4% (p<0.0001).

Medication adherence to TTh was 100% as all injections were applied in the office and documented.

Conclusions

TTh in hypogonadal men improves erectile function over a long period of time. It deteriorates in untreated hypogonadal men. These results may in part be mediated by changes in body weight.

Baseline and 10-year data are presented for IIEF-ED, Weight (kg) and Aging Males' Symptoms Scale (AMS).