

Hypogonadal Men with Inflammatory Bowel Diseases (M. Crohn and Colitis ulcerosa) Benefit from Long-term Treatment with Injectable Testosterone Undecanoate

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Objective: Testosterone (T) has anti-inflammatory effects. T treatment has been found to be beneficial in rheumatoid arthritis and chronic obstructive pulmonary disease. We had reported effects of two years of T treatment in a small group of hypogonadal men with Crohn's disease (Haider A et al., *Horm Mol Biol Clin Invest* 2010; 2(3): 287–292).

Methods and Design: In a prospective, cumulative, observational registry study, 71 hypogonadal men with Crohn's disease and 2 men with Colitis ulcerosa with T \leq 12 nmol/L from 2 centers in Bremerhaven, Germany and Aleppo, Syria received treatment with parenteral testosterone undecanoate on day 1, after 6 weeks and thereafter every 12 weeks for up to 75 months. 12 hypogonadal men of similar age with Crohn's disease who did not receive T served as an untreated control group. In total, 73 men received T and 12 hypogonadal men remained untreated. The Crohn's Disease Activity Index (CADI) was assessed as an indicator of the severity of the disease every 3 months. In addition, highly sensitive C-reactive protein (hsCRP) and leukocyte count as markers of inflammatory activity were measured. The Aging Males' Symptoms Scale (AMS) was used as a self-administered quality of life (QoL) questionnaire.

Results: T levels at baseline were 9.37 ± 1.08 nmol/l in the T group and 10.75 ± 0.36 in the control group. During treatment, T increased to 15.72 ± 0.53 and slightly declined in the control group. The CADI decreased from 231.3 ± 35.96 to 75.0 in the treated group and increased from 196.25 ± 7.11 to 210.0 in the control group. hsCRP (mg/dL) levels at baseline were 14.01 ± 9.18 in the T group vs 7.3 ± 0.98 in the control group. They decreased to 2.63 ± 1.91 after 72 months in the T group and increased to 13.7 in the control group. Leukocyte count decreased from 12.42 ± 2.46 to 5.97 ± 0.51 in the treated group and remained unchanged in the control group (from 11.38 ± 1.29 to 12.7). The AMS improved from 49.47 ± 8.11 in the T group to 17.33 ± 0.58 . In the control group, AMS remained unchanged from 47.17 ± 1.03 at baseline to 48 at the end of the observation period.

Conclusion: Normalization of T in hypogonadal men with Crohn's disease led to improvements of the CADI, hsCRP , a reduction of leukocytes and an improvement of QoL. The mechanism of this improvement may be through anti-inflammatory and immunosuppressive effects of testosterone, reducing chronic inflammation of the intestinal wall in Crohn's Disease.