

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

Conclusion: Normalisation 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.