11 years of data add to the evidence for using testosterone therapy to treat obesity

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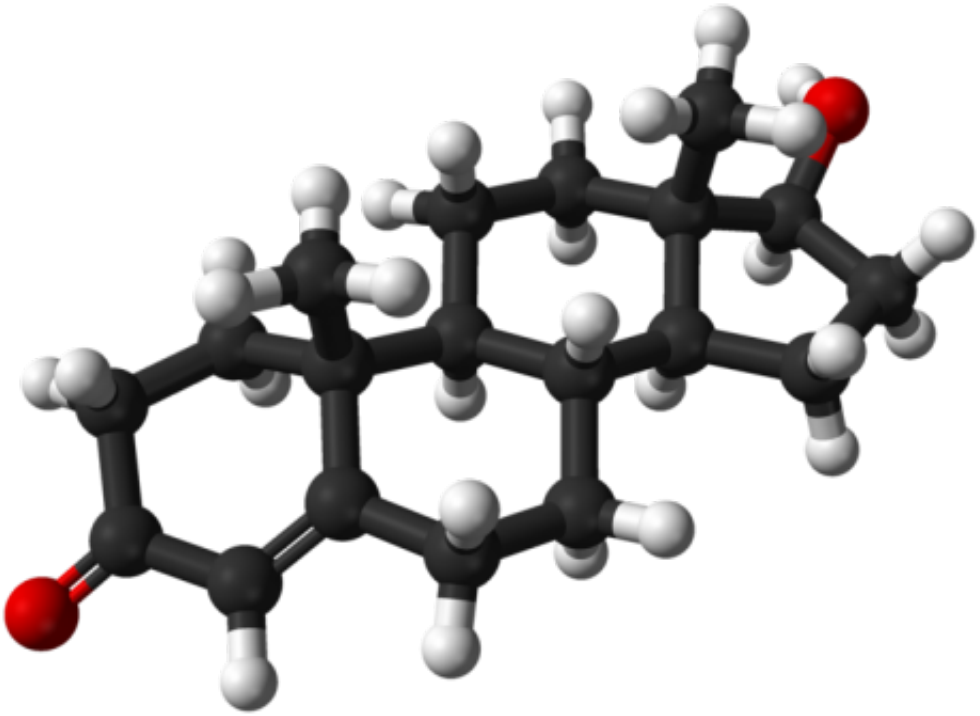

Ball-and-stick model of the testosterone molecule, $C_{19}H_{28}O_2$, as found in the crystal structure of testosterone monohydrate. Credit: Ben Mills/Wikipedia

New research covering 11 years of data presented at this year's European and International Congress on Obesity (ECOICO 2020) show that, in obese men suffering from hypogonadism (low testosterone), treatment with testosterone injections lowers their weight and improves a wide

range of other metabolic parameters. The research has been led by Dr. Farid Saad, Consultant, Medical Affairs Andrology, Bayer AG, Berlin, Germany, and Gulf Medical University School of Medicine, Ajman, UAE, and colleagues.

Across the last decade, Dr. Saad's team has presented multiple pieces of research on the effects of testosterone at other congresses, including previous years of the European Congress on Obesity. In these latest updates, they provide the newest data on the long-term benefits, and also suggest testosterone therapy (TTh) could be an effective alternative to bariatric (obesity) surgery.

The researchers collected data from a German registry of men in 2004 from a urological practice based in Bremerhaven. The men all had functional hypogonadism (low testosterone without a known organic cause), and 471 of 773 men (61%) had obesity. Of these men with obesity, 276 men received TTh with testosterone undecanoate (TU) (a 1000 mg injection in the clinic every 3 months) for up to 11 years (T-group). The other 195 men opted against TTh and served as controls (CTRL). Since injections were administered in the doctor's office and documented, there was a 100% adherence to testosterone therapy. No patients dropped out of the study.

Changes over time between groups were compared and adjusted for age, weight, waist circumference, fasting glucose, blood pressure, blood fats and quality of life to account for baseline differences between the two groups. The mean follow-up period was 8.8 years for the T-group and 8.4 years for controls, and the average age 60.6 years in the T-group and 63.5 years in the control group.

After 11 years of data collection in the registry (covering the period 2004-19 with all patients having at least 11 years of data) weight (kg) decreased by a mean of 23kg in the T group (from 114kg to 89kg before

adjustment, and to 87 kg after adjustment for baseline age, waist circumference, weight, fasting glucose, systolic and diastolic blood pressure, total cholesterol, HDL, LDL, triglycerides and the quality of life scale AMS). Conversely, mean weight increased by 6kg in the control group. In percentage terms, the results were similar—with the T-group losing an average of 20% bodyweight, whereas controls increased by 6%.

Waist circumference decreased by a mean 13cm in those receiving testosterone therapy, and increased by 7cm in the control group. Body mass index (BMI) fell by 7.6 points in the T-group (from 36.8 to 28.8 before adjustment, and to 27.9 after adjustment), while it increased by 2 points in the controls. Measurements of visceral fat (internal fat held centrally and surrounding organs, and thought to cause increased health risks) were also lower in the T-group. The so-called visceral adiposity index (VAI) decreased by 2.7 points in the T-group and increased by 3.1 in the control groups.

There was also a significant mortality difference between groups: 21 patients (7.6%) died in the T-group and 63 (32.3%) in the control group. More than a quarter of men (28%) in the control group had a heart attack, and 53 (27.2%) a stroke. There were no major cardiovascular events in the T-group. All the deaths in the T-group were related to traffic and sport accidents and post-surgical infections.

A total of 156 men (56.6%) in the T-group and 124 controls (63.6%) had type 2 diabetes at baseline (defined as glycated haemoglobin [HbA1c] of 6.5% or higher). A further 43 patients (22.1%) developed T2D during the study, meaning almost all (85%) of control patients had T2D after 11 years of follow-up. No additional patients in the T-group developed type 2 diabetes.

Dr. Saad says: "Long-term testosterone therapy in hypogonadal men

resulted in profound and sustained in weight loss which may have contributed to reductions in mortality and cardiovascular events. Untreated men with hypogonadism gained weight."

In other research presented at this ECOICO 2020 congress, the researchers looked specifically at men in the registry with obesity class III, the highest obesity category making them most eligible for obesity (bariatric) surgery. A total of 76 of the 773 men (9.8%) were in this category. Of these, 59 men received testosterone therapy as defined above, while the other 17 men opted against this and served as controls. Similar to the results for the whole registry, weight decreased by a mean 30kg in the T group and increased by 5kg in controls. BMI decreased by 10.0 points in the T group and increased by 3.0 points in controls.

Dr. Saad says: "Long-term testosterone therapy in men with hypogonadism and the most severe level of obesity resulted in profound and sustained weight loss in a magnitude comparable to that achieved with metabolic (obesity) surgery. Side effects and complications may be in favour of testosterone therapy. We believe testosterone therapy should be discussed with patients as an alternative to surgery and should be considered for male patients who cannot undergo surgery."

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