

## **PRESS RELEASE ABSTRACTS (EMBARGOED 0001H UK time WEDS 28 MAY)**

### **TESTOSTERONE (4 ABSTRACTS):**

T5:PO.013

#### **Anthropometric parameters in 46 hypogonadal men with obesity grade III improve upon long-term treatment with testosterone undecanoate injections: observational data from two registry studies**

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**Introduction** There is a robust inverse association between testosterone and obesity. Only few testosterone replacement therapy (TRT) studies in hypogonadal men focus on effects on anthropometry.

**Methods** From two cumulative, prospective, registry studies of 561 hypogonadal men, 46 men with obesity grade III were selected. All men received parenteral testosterone undecanoate 1000 mg/12 weeks for up to 6 years.

**Results** At the end of the observation period, mean weight (kg) decreased from  $129.02 \pm 5.67$  to  $103.33 \pm 4.17$ . This decrease was statistically significant vs baseline ( $p < 0.0001$ ) and each year compared to previous year ( $p < 0.0001$ ). Mean change from baseline was  $-27.15 \pm 0.74$  kg.

Percent change from baseline was  $-2.77 \pm 1.77\%$  after one year,  $-7.26 \pm 3.04\%$  after two,  $-10.85 \pm 3.26\%$  after three,  $-13.88 \pm 3.16\%$  after four,  $-17.43 \pm 3.09\%$  after five, and  $-20.99 \pm 3.16\%$  after six years.

Waist circumference (cm) decreased from  $118.41 \pm 5.69$  to  $106.48 \pm 4.91$ . This decrease was statistically significant vs baseline ( $p < 0.0001$ ) and each year compared to previous year ( $p < 0.0001$ ) with the exception of year 6 which had a p-value of 0.0132 vs year 5. The mean change from baseline was  $12.44 \pm 0.36$  cm.

Body mass index (BMI; kg/m<sup>2</sup>) decreased from  $41.93 \pm 1.5$  to  $33.62 \pm 1.58$ . The mean change from baseline was  $8.79 \pm 0.23$  kg/m<sup>2</sup>. There were no drop-outs.

**Conclusion** All changes were progressive and remained statistically significant each year compared to previous year for the full observation period. TRT seems to be an effective approach to achieve sustained weight loss in excessively obese hypogonadal men. Patients with a BMI  $\geq 40$  are candidates for metabolic surgery. In hypogonadal men, TRT may provide a non-invasive alternative.

T5:PO.014

#### **Metabolic parameters in 46 hypogonadal men with obesity grade III improve upon long-term treatment with testosterone undecanoate injections: observational data from two registry studies**

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**Introduction:** There are inverse associations between testosterone and all components of the metabolic syndrome.

**Methods:** From two cumulative, prospective, registry studies of 561 hypogonadal men, 46 men with obesity grade III were selected. All men received parenteral testosterone undecanoate 1000 mg/12 weeks for up to 6 years. 46 men were followed for two years, 43 for three years, 37 for four years, 34 for five years, and 24 for six years. Declining numbers are result of the registry design.

**Results:** The mean age was  $60.28 \pm 5.39$  (min 43; max 69).

Mean fasting glucose (mg/dl) decreased from  $115.48 \pm 23.85$  to  $96.54 \pm 2.9$  ( $p < 0.0001$ ). Mean change from baseline was  $-18.48 \pm 2.96$  mg/dl. HbA1c (%) decreased from  $7.57 \pm 1.38$  to  $6.08 \pm 0.5$ . Mean change from baseline was  $-1.61 \pm 0.13\%$ .

Total cholesterol (mg/dl) decreased from  $306.76 \pm 43.03$  to  $192.23 \pm 9.17$  ( $p < 0.0001$ ). LDL (mg/dl) decreased from  $190.57 \pm 36.6$  to  $136.24 \pm 28.07$  ( $p < 0.0001$ ). Triglycerides (mg/dl) decreased from  $326.87 \pm 60.21$  to  $194.4 \pm 12.59$  ( $p < 0.0001$ ). HDL (mg/dl) increased from  $62.76 \pm 18.7$  to  $72.55 \pm 13.34$  ( $p < 0.0001$ ). The ratio of total cholesterol : HDL declined from  $5.47 \pm 2.57$  to  $2.75 \pm 0.59$  ( $p < 0.0001$ ).

Systolic blood pressure (mmHg) decreased from  $161.04 \pm 14.3$  to  $142.05 \pm 9.57$ , diastolic blood pressure from  $97.07 \pm 10.91$  to  $80.89 \pm 6.76$ .

Liver enzymes AST and ALT (U/L) decreased from  $42.39 \pm 17.84$  to  $20.33 \pm 1.9$  and from  $43.52 \pm 20.68$  to  $20.43 \pm 2.75$ , respectively ( $p < 0.0001$  for both), suggesting reductions in liver fat content. C-reactive protein (CRP, mg/L) declined from  $3.96 \pm 4.31$  to  $0.57 \pm 0.59$  ( $p < 0.0001$ ).

**Conclusion:** Testosterone replacement therapy in excessively obese hypogonadal men resulted in significant and sustained improvements in all features of the metabolic syndrome, consistent with the changes in anthropometry observed in the same cohort.

T5:PO.015

### **Comparable weight loss in hypogonadal men with obesity grades II and III under long-term treatment with testosterone undecanoate injections: observational data from two registry studies**

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**Introduction:** In a bi-directional relationship, testosterone deficiency may cause obesity, and obesity may cause hypogonadism. In epidemiological studies, an up to 52% prevalence of hypogonadism in obese men has been reported.

**Methods:** From two registry studies of hypogonadal men, 131 men with obesity grade II (Group A) and 46 men with obesity grade III (Group B) were selected. All men were treated with three-monthly testosterone undecanoate injections for up to 6 years.

**Results:** Mean weight (kg) decreased from  $117.02 \pm 6.99$  to  $96.78 \pm 7.47$  in Group A and  $129.02 \pm 5.67$  to  $103.33 \pm 4.17$  in Group B. Mean change from baseline was  $-20.67 \pm 0.51$  and  $-27.15 \pm 0.74$  kg, resp. In both groups, the decrease was statistically significant vs baseline and each year compared to previous year ( $p < 0.0001$ ).

Percent change from baseline at the end of the observation time was  $-17.03 \pm 5.02\%$  in Group A and  $-20.99 \pm 3.16\%$  in Group B. Waist circumference (cm) decreased from  $114.23 \pm 7.51$  to  $102.52 \pm 6.5$  in Group A and from  $118.41 \pm 5.69$  to  $106.48 \pm 4.91$  in Group B. This decrease was statistically significant vs baseline and each year compared to previous year in both groups. The mean change from baseline was  $12.29 \pm 0.33$  cm in Group A and  $12.44 \pm 0.36$  cm in Group B.

Body mass index (BMI; kg/m<sup>2</sup>) decreased from  $37.39 \pm 1.46$  to  $31.05 \pm 2.02$  in Group A and from  $41.93 \pm 1.5$  to  $33.62 \pm 1.58$  in Group B. The mean change from baseline was  $6.58 \pm 0.16$  and  $8.79 \pm 0.23$  kg/m<sup>2</sup>, respectively.

No patient gained weight.

**Conclusion:** Testosterone replacement therapy in hypogonadal men with obesity grade II and III resulted in meaningful and sustained weight loss.

T5:PO.016

### **156 hypogonadal men with obesity and type 2 diabetes achieve weight loss and improved glycaemic control upon treatment with testosterone undecanoate up to 6 years: A subgroup analysis from two observational registry studies**

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**Introduction:** Obesity is a major risk factor for type 2 diabetes (T2D). In men, both diseases have a high prevalence of testosterone deficiency.

**Methods:** Cumulative, prospective, observational registry studies of 561 hypogonadal men from two urological centers. Obese men with T2D were selected for subgroup analysis. Patients received testosterone injections for up to six years. All men were treated for their T2D by their family physicians.

**Results:** 156 men (mean age  $61.2 \pm 6.2$  years) met our criteria.

Weight (kg) decreased from  $113.56 \pm 11.53$  to  $97.18 \pm 9.04$  ( $p < 0.0001$ ). Mean change from baseline was  $-17.49 \pm 0.58$  kg. Mean per cent weight loss (%) was  $15.04 \pm 0.48$ .

Waist circumference (cm) declined from  $114 \pm 8.69$  to  $102.52 \pm 7.93$  ( $p < 0.0001$ ). Mean change from baseline was  $-11.56 \pm 0.34$  cm.

BMI (kg/m<sup>2</sup>) decreased from  $36.31 \pm 3.51$  to  $31.19 \pm 2.6$  ( $p < 0.0001$ ). Mean change from baseline was  $-5.59 \pm 0.18$  kg/m<sup>2</sup>.

Fasting glucose (mg/dl) decreased from  $128.37 \pm 31.63$  to  $101.55 \pm 17.02$  ( $p < 0.0001$ ). Mean change from baseline was  $-27.14 \pm 2.48$  mg/dl.

HbA1c decreased from  $8.08 \pm 0.9$  to  $6.14 \pm 0.71\%$  ( $p < 0.0001$  vs. baseline, significant for the first 5 years vs. previous year and approaching significance from year 6 to year 5 at  $p = 0.0635$ ). The mean change from baseline was  $-1.93 \pm 0.06\%$ .

At baseline, 25 (16%) of all patients had HbA1c  $\leq$  7.0% and 12 (7.7%) HbA1c  $\leq$  6.5%. At the end of the observation, 128 (82.05%) had reached HbA1c target of  $\leq$  7.0% and 106 (67.95%) HbA1c target of  $\leq$  6.5%.

**Conclusion:** Correcting hypogonadism with testosterone undecanoate injections in obese hypogonadal men with T2D resulted in sustained improvements in weight, waist circumference, and glycaemic control over the full 6 years of the study.

### Obesity trends in Himalayan Mountain Villages between 1995 and 2013: Role in Diabetes?

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**Introduction:** This study was conducted to assess the trends in prevalence of overweight and obesity among adults in Himalayan mountain villages.

**Methods:** Two independent population based were conducted in 1995 and 2013 in Gilgit Baltistan region of Pakistan in random samples of men and women aged 18 years and older. The total number of participants with complete height and weight measurements was 4,674. WHO cut-offs were used to define overweight, obesity (BMI, 25–29, and 30).

**Results:** Overall, during the study period, obesity increased from 2.3% in 1995 to 12.5% in 2013. Prevalence of overweight increased from 11.5% in 1995 to 27.1% in 2013. Of the 1,077 participants examined in 2013, 69 (6.4%) had type 2 diabetes and 82 (7.6%) were pre-diabetics. Statistically significant ( $p < 0.05$ ) correlates for type 2 diabetes were elevated waist circumference (Adjusted Odds ratio (AOR)=4.06; 95% CI 2.16, 7.64), age (AOR = 1.03; 95% CI 1.021, 1.054), and elevated waist circumference (Adjusted Odds ratio AOR = 2.17; 95% CI 1.16, 4.06). Significant correlates for pre-diabetes included obesity (AOR = 15.96; 95% CI 7.77, 32.78) and age (AOR = 1.02; 95% CI 1.01, 1.05).

**Conclusion:** Overweight and obesity is rapidly growing public health burden in the rural population of Pakistan. Overall obesity and central obesity were significant correlates for type 2 diabetes and pre-diabetes in the high mountain study population

T2:RS1.3

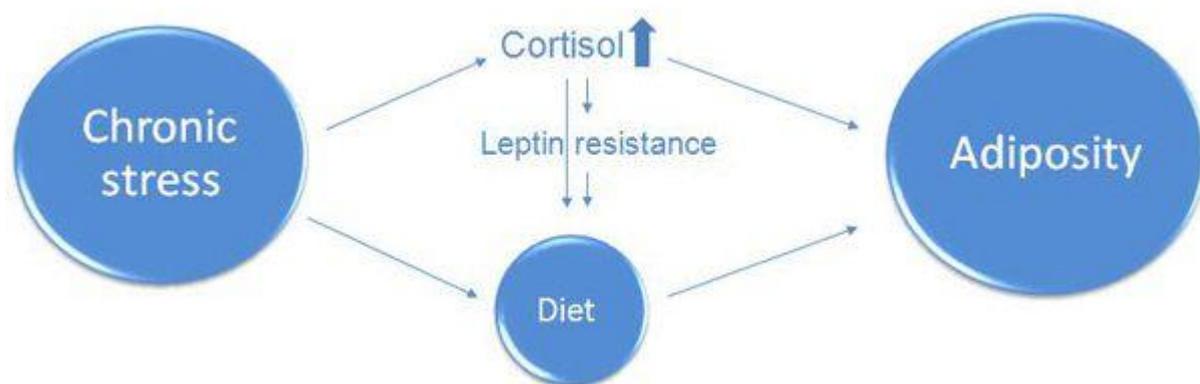
### Children's stress influences their diet and adiposity: Role of cortisol and leptin

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**Introduction:** Psychosocial stress and adiposity are important public health threats that have been mutually associated but underlying behavioral and hormonal factors still need to be revealed. We aim to study the longitudinal effect of children's stress on diet and adiposity and to test the role of the hormones cortisol and leptin. The stress hormone cortisol might directly influence adiposity or might deteriorate dietary intake and food reward through leptin resistance (see figure).

**Methods:** In 312 Belgian children (5–12 y) of the ChiBS study, the two-year longitudinal stress-diet-adiposity relation was examined. Stress data (negative events, problem behavior, negative emotions), food consumption, psychological eating behavior and adiposity (BMI, fat% by BodPod, waist) were measured. At baseline, also salivary cortisol levels (4 samples/day) and fasting serum leptin were determined. Mplus cross-lagged analyses tested the longitudinal stress-diet-adiposity relations. Multilevel time modeling examined the relation of cortisol with diet and leptin.



**Results:** Children with a high stress score reported more sweet food consumption, emotional eating, external eating and restrained eating. Stress increased adiposity only in children with high sweet food consumption and cortisol. High cortisol was associated with an unhealthy diet especially with the sweet foods. High cortisol was also associated with higher leptin levels in girls.

**Conclusion:** The associations of cortisol with leptin and diet support the theory of cortisol-induced comfort food preference. Indeed, children's stress deteriorates their diet which stimulates adiposity. This creates a perspective for multi-factorial obesity prevention, targeting stress (coping skills) and lifestyle factors (stress-induced eating) in parallel.

T2:OS1.1

### **Mediterranean diet, overweight and body composition in children from eight European countries: Cross-sectional and prospective results from the IDEFICS study**

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**Introduction:** The role of a Mediterranean-like dietary pattern in childhood obesity prevention is unclear. Therefore, we investigated its popularity among European children and the association with overweight and obesity.

**Methods:** Weight, height, waist circumference, and skinfolds were measured at baseline (n = 16,220) and after two years (n = 9,114) in children from eight European countries, recruited during the IDEFICS study. Diet was evaluated by a parental food frequency questionnaire (FFQ, 43 foods) and by a single 24h dietary recall. The Mediterranean diet score (MDS) was calculated based on food frequencies (FFQ) and associated with various overweight and obesity indicators both cross-sectionally and prospectively. An alternative score based on food quantities was calculated from recall data.

**Results:** High MDS were inversely associated with overweight including obesity (OR = 0.85, 95% CI: 0.77; 0.94) and percent fat mass ( $\beta = -0.22$ , 95% CI:  $-0.43$ ;  $-0.01$ ) independently of age, sex, socioeconomic status and country. High MDS at baseline inversely predicted high changes in BMI (OR = 0.87, 95% CI: 0.78; 0.98), waist circumference (OR = 0.87, 95% CI: 0.77; 0.98) and waist-to-height ratio (OR = 0.88, 95% CI: 0.79; 0.99). The classification of countries based on adherence levels differed when calculating the score from food frequencies or quantities. In Italy and Sweden differences between weekdays and weekend days were shown.

**Conclusion:** The promotion of a Mediterranean dietary pattern should be part of EU obesity prevention strategies and should be particularly intense in those countries where low levels of adherence are detected.