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ORIGINAL ARTICLE

Testosterone replacement therapy improves the health-related quality of life of men diagnosed with late-onset hypogonadism

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KEYWORDS

Testosterone;
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Erectile dysfunction;
Depression;
Obesity

ABBREVIATIONS

AMS, Aging Males' Symptoms (scale);
ED, erectile dysfunction;
HRQoL, health-related quality of life;

Abstract ***Objectives:*** To test the hypothesis that testosterone replacement therapy (TRT) improves the long-term health-related quality of life (HRQoL) of men with late-onset hypogonadism (LOH), as studies have shown that sub-physiological testosterone levels have a negative impact on psychological (e.g. mood, vitality, libido and sexual interest) and physical features (e.g. erectile function and physical strength), all of which contribute to a sense of well-being.

Patients and methods: In all, 261 patients (mean age 58 years) diagnosed with LOH were treated with long-acting intramuscular testosterone undecanoate (TU) for up to 5 years. Health quality indicators including the International Prostate Symptom Score (IPSS), the five-item version of the International Index of Erectile Function (IIEF-5), the Aging Males' Symptoms (AMS) scale, and the percentage of patients reporting joint and muscle pain were measured at baseline and at each visit. The means were then plotted over time in parallel with mean total testosterone (TT) levels.

Results: Both the mean IPSS and AMS scores fell significantly within the first 3 months and the mean IIEF-5 score and TT levels increased within the first 3 months.

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IIEF-5, five-item version of the International Index of Erectile Function;
LOH, late-onset hypogonadism;
TRT, testosterone replacement therapy;
TT, total testosterone;
TU, testosterone undecanoate

All four parameters continued to improve over the course of the trial. The percentage of patients reporting both joint and muscle pain decreased during TRT.

Conclusions: This prospective, observational and longitudinal analysis shows a clear improvement in both psychological and physical characteristics as physiological testosterone levels are reached and maintained contributing to an improvement in the HRQoL in men with diagnosed LOH.

Introduction

Late-onset hypogonadism (LOH), as defined by a serum total testosterone (TT) level of ⩽12 nmol/L, is diagnosed when declining testosterone concentrations in the ageing male cause unwanted symptoms such as erectile dysfunction (ED), obesity, lack of physical strength, and depressed mood [1–4]. It is thought that almost 40% of men aged >45 years are hypogonadal to some degree [5].

Numerous studies have shown that testosterone levels are closely associated with both erectile function and obesity [6–8]. In fact, the presence of visceral obesity can predict ED [9] and weight loss improves erectile function and testosterone levels [10,11]. Increasing evidence shows that testosterone can reduce both total and visceral body fat [12–16], and is an effective treatment for ED, as measured by the International Index of Erectile Function (IIEF) questionnaire [17–19].

Testosterone also maintains psychological features such as mood, vitality, libido and sexual interest, which contribute greatly to an overall sense of well-being and health-related quality of life (HRQoL). Consequently, in men with LOH there is an increase in symptoms such as dysphoria, low vigour and vitality, diminished libido and orgasm, irritability, poor cognitive function, and increased risk of depression [20–23]. Associations have also been reported between both ED and depression [24], and obesity and depression where obese patients at baseline were at an increased risk of depression at follow-up [25]. Evidence that testosterone can effectively treat symptoms of depression comes from a randomised, placebo-controlled phase III trial in which 184 men with hypogonadism and metabolic syndrome were treated with testosterone undecanoate (TU) for 30 weeks. At the end of the trial period TU was found to have significantly improved depressive symptoms as measured by the Beck Depression Inventory (BDI-IA) [26].

In men undergoing androgen-deprivation therapy for prostate cancer, mood disturbances, anxiety, fatigue, and lack of drive are observed [27]. In a cohort of elderly hypogonadal men in the European Ageing Male Study, low testosterone levels were found to be associated with ED, low sexual desire, poor morning erections, fatigue, and depression [28]. Thus, low testosterone-associated sexual dysfunction has a major impact on HRQoL and emotional well-being [29–31].

Hypogonadal men undergoing testosterone replacement therapy (TRT) show improved parameters of well-being, bone density, muscle mass, physical strength, sexual function, and libido [32]. In a study of men undergoing treatment with TU, there was an increase in libido, vigour and vitality, sleep quality, a reduction in waist circumference, and a decrease in severity of ED [33]. Therefore, TRT in hypogonadal men may be a valuable tool to restore a physiological balance and achieve sexual pleasure as a component of well-being.

We hypothesised that TRT would improve both psychological and physical features that contribute to the long-term HRQoL in men with LOH.

Patients and methods

From November 2004, 261 patients (mean age 58 years) diagnosed with LOH were treated with long-acting TU (Nebido®, Bayer Pharma, Berlin, Germany) in a prospective observational and longitudinal registry study. All patients gave their written informed consent to be included in the study, which was conducted according to ethical guidelines as formulated by the German 'Ärztekammer' (the German Medical Association) for observational studies and followed the principles outlined in the Helsinki Declaration of 1975, as revised in 1983. Men with a TT concentration of ⩽3.5 ng/mL (12 nmol/L) and documented symptoms of ED (Sexual Health Inventory for Men (SHIM) score of ⩽21) met the inclusion criteria. Men received i.m. injections of 1000 mg TU at day 1 (≈3 weeks after diagnosis), week 6 and every 3 months thereafter. Patients were entered into a cumulative registry database once they had received treatment for at least 1 year and followed for up to 5 years. The average treatment period was 4.25 years.

Assessment of outcome

To assess the effect of long-term TU treatment, health quality indicators including the IPSS, the five-item version of the IIEF (IIEF-5), the Aging Males' Symptoms (AMS) scale, and the percentage of patients reporting