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Testosterone Replacement in Hypogonadal Men With Type 2 Diabetes and/or Metabolic Syndrome (the TIMES2 Study)

T. Hugh Jones, MD, FRCP^{1,2,4}, Stefan Arver, MD³, Hermann M. Behre, MD⁴, Jacques Buvat, MD⁵, Eric Meuleman, MD⁶, Ignacio Moncada, MD⁷, Antonio Martin Morales, MD⁸, Maurizio Volterrani, MD, FCCP⁹, Ann Yellowlees, CSTAT¹⁰, Julian D. Howell, MB, BS, FRCS, MFPM¹¹, Kevin S. Channer, MD, FRCP¹² and TIMES2 Investigators

 Author Affiliations

↵Corresponding author: T. Hugh Jones, hugh.jones@nhs.net.

Abstract

OBJECTIVE This study evaluated the effects of testosterone replacement therapy (TRT) on insulin resistance, cardiovascular risk factors, and symptoms in hypogonadal men with type 2 diabetes and/or metabolic syndrome (MetS).

RESEARCH DESIGN AND METHODS The efficacy, safety, and tolerability of a novel transdermal 2% testosterone gel was evaluated over 12 months in 220 hypogonadal men with type 2 diabetes and/or MetS in a multicenter, prospective, randomized, double-blind, placebo-controlled study. The primary outcome was mean change from baseline in homeostasis model assessment of insulin resistance (HOMA-IR). Secondary outcomes were measures of body composition, glycemic control, lipids, and sexual function. Efficacy results focused primarily on months 0–6 (phase 1; no changes in medication allowed). Medication changes were allowed in phase 2 (months 6–12).

RESULTS TRT reduced HOMA-IR in the overall population by 15.2% at 6 months ($P = 0.018$) and 16.4% at 12 months ($P = 0.006$). In type 2 diabetic patients, glycemic control was significantly better in the TRT group than the placebo group at month 9 (HbA_{1c}: treatment difference, -0.446% ; $P = 0.035$). Improvements in total and LDL cholesterol, lipoprotein a (Lpa), body composition, libido, and sexual function occurred in selected patient groups. There were no significant differences between groups in the frequencies of adverse events (AEs) or serious AEs. The majority of AEs (>95%) were mild or moderate.

CONCLUSIONS Over a 6-month period, transdermal TRT was associated with beneficial effects on insulin resistance, total and LDL-cholesterol, Lpa, and sexual health in hypogonadal men with type 2 diabetes and/or MetS.

Footnotes