Recombinant Methionyl Human Leptin Therapy in Replacement Doses Improves Insulin Resistance and Metabolic Profile in Patients with Lipoatrophy and Metabolic Syndrome Induced by the Highly Active Antiretroviral Therapy FREE

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Abstract

Context: Highly active antiretroviral therapy (HAART) for HIV-1 infection has been associated with a metabolic syndrome characterized by insulin resistance, hyperlipidemia, and redistribution of body fat (lipodystrophy). A subset of patients with predominant lipoatrophy has low levels of the adipocyte-secreted hormone leptin.

Objective: The objective of the study was to assess whether administration of recombinant methionyl human leptin (r-metHuLeptin) improves insulin resistance and other metabolic abnormalities in HIV+ leptin-deficient subjects with HAART-induced lipoatrophy.

Design, Setting, Patients, and Intervention: We conducted a randomized, placebo-controlled, double-blinded, crossover study from 2002 to 2004 in seven HIV+ men with HAART-induced lipoatrophy, serum leptin level less than 3 ng/ml, and fasting triglyceride level greater than 300 mg/dl, who were administered placebo for 2 months before or after administration of r-metHuLeptin at physiological doses for an additional 2 months.

Main Outcome Measures: Insulin resistance, lipid levels, inflammatory markers, body composition, and HIV control were measured.

Results: Compared with placebo, r-metHuLeptin therapy improved fasting insulin levels, insulin resistance (as expressed by the homeostasis model assessment index and an insulin suppression test), and high-density lipoprotein. Body weight and fat mass decreased on r-metHuLeptin, mainly due to a decrease in truncal fat but not peripheral fat or lean body mass. r-metHuLeptin was well tolerated, and HIV control was not adversely affected.

Conclusions: r-metHuLeptin replacement at physiological doses in HIV+ leptin-deficient patients with HAART-induced lipoatrophy improves insulin resistance, high-density lipoprotein, and truncal fat mass. Future larger and more long-term studies in HAART-induced lipoatrophy, including patients with more severe metabolic abnormalities, are warranted to evaluate the physiological and potentially therapeutic role of r-metHuLeptin for this condition and to fully clarify the underlying mechanisms of action.

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