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Effect of niacin on lipid and lipoprotein levels and glycemic control in patients with diabetes and peripheral arterial disease: the ADMIT study: A randomized trial. Arterial Disease Multiple Intervention Trial.

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Abstract

CONTEXT: Although niacin increases low levels of high-density lipoprotein cholesterol (HDL-C), which frequently accompany diabetes, current guidelines do not recommend use of niacin in patients with diabetes because of concerns about adverse effects on glycemic control; however, this is based on limited clinical data.

OBJECTIVE: To determine the efficacy and safety of lipid-modifying dosages of niacin in patients with diabetes.

DESIGN AND SETTING: Prospective, randomized placebo-controlled clinical trial conducted in 6 clinical centers from August 1993 to December 1995.

PARTICIPANTS: A total of 468 participants, including 125 with diabetes, who had diagnosed peripheral arterial disease.

INTERVENTIONS: After an active run-in period, participants were randomly assigned to receive niacin (crystalline nicotinic acid), 3000 mg/d or maximum tolerated dosage (n = 64 with diabetes; n = 173 without diabetes), or placebo (n = 61 with diabetes; n = 170 without diabetes) for up to 60 weeks (12-week active run-in and 48-week double-blind).

MAIN OUTCOME MEASURES: Plasma lipoprotein, glucose, hemoglobin A(1c) (HbA(1c)), alanine aminotransferase, and uric acid levels; hypoglycemic drug use; compliance; and adverse events, in patients with diabetes vs without who were receiving niacin vs placebo.

RESULTS: Niacin use significantly increased HDL-C by 29% and 29% and decreased triglycerides by 23% and 28% and low-density lipoprotein cholesterol (LDL-C) by 8% and 9%, respectively, in participants with and without diabetes (P<.001 for niacin vs placebo for all). Corresponding changes in participants receiving placebo were increases of 0% and 2% in HDL-C and increases of 7% and 0% in triglycerides, and increases of 1% and 1% in LDL-C. Glucose levels were modestly increased by niacin (8.7 and 6.3 mg/dL [0.4 and 0.3 mmol/L]; P =.04 and P<.001) in participants with and without diabetes, respectively. Levels of HbA(1c) were unchanged from baseline to follow-up in participants with diabetes treated with niacin. In

participants with diabetes treated with placebo, HbA(1c) decreased by 0.3% (P =.04 for difference). There were no significant differences in niacin discontinuation, niacin dosage, or hypoglycemic therapy in participants with diabetes assigned to niacin vs placebo.

CONCLUSIONS: Our study suggests that lipid-modifying dosages of niacin can be safely used in patients with diabetes and that niacin therapy may be considered as an alternative to statin drugs or fibrates for patients with diabetes in whom these agents are not tolerated or fail to sufficiently correct hypertriglyceridemia or low HDL-C levels. JAMA. 2000;284:1263-1270

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