POEMs

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Intensive Lifestyle Intervention Fails to Improve Patient-Oriented Outcomes in Persons with Obesity and Diabetes

Clinical Question

Does an intensive lifestyle intervention focused on weight loss and exercise improve outcomes in patients with diabetes mellitus?

Bottom Line

This large, well-designed trial failed to find a statistically significant improvement in patient-oriented outcomes in patients with diabetes, despite a fairly intensive life-style intervention and long-term follow-up. (Level of Evidence = 1b)

Synopsis

There is relatively little high-quality clinical trial evidence to support recommendations for weight loss and exercise in patients with type 2 diabetes. In this study, 5,145 adults, 45 to 75 years of age, with type 2 diabetes and a body mass index of at least 25 kg per m² were randomized to receive an intensive lifestyle intervention (weekly visits providing group and individual counseling regarding calorie-reducing diet and exercise, with a goal of 7% weight loss and at least 175 minutes of exercise per week), or support and education (three group sessions per year in years 1 to 4, and one session per year after that). At the beginning of the study, all participants had an A1C level of 11% or less, blood pressure lower than 160/100 mm Hg, a triglyceride level less than 600 mg

per dL (6.77 mmol per L), an established relationship with their primary care physician, and clearance to exercise. The mean age of participants was 59 years, 40% were men, and 37% were of a nonwhite race or ethnicity. Their average body mass index was 36 kg per m², and the average weight was 101 kg (222 lb). Groups were balanced at the start of the study, outcomes were adjudicated by persons masked to group assignment (patients and their physicians were not masked), and patients were followed for a median of 9.6 years.

At one year, patients in the intervention group had greater weight loss (about 8 kg [18 lb]), greater reduction in waist circumference (7 cm [2.8 in]), greater reduction in A1C level (0.6%), and an increase in fitness level (as measured in metabolic units). These differences diminished over time as the control group gradually showed improvement in these parameters and the intervention group showed evidence of backsliding. There were no differences in key clinical outcomes, including allcause mortality (0.73% intervention vs. 0.86% control) and a composite primary outcome of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for angina (1.83% intervention vs. 1.92% control). Most of the individual outcomes had relative risks of less than 1.0, but none were statistically significant. The study was adequately powered to detect an 18% relative reduction in the primary outcome if one existed. Patients in the intervention group did have lower rates of statin, antihypertensive, and insulin use at the end of the study than those in the control group.

Study design: Randomized controlled trial (single-blinded)

Funding source: Government

Allocation: Uncertain

Setting: Population-based

Reference: Wing RR, Bolin P, Brancati FL, et al.; Look AHEAD Research Group. Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. N Engl J Med. 2013;369(2):145-154.

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