Bariatric Surgery Plus Intensive Medical Therapy Is Better Than Medical Therapy Alone for Diabetes

Clinical Question
In adults with uncontrolled type 2 diabetes mellitus, how does bariatric surgery plus intensive medical therapy compare with intensive medical therapy alone?

Bottom Line
Bariatric surgery in conjunction with intensive medical therapy results in significantly enhanced glycemic control at three years compared with medical therapy alone, as well as better weight control, less use of glucose-lowering medications, and improved quality of life. (Level of Evidence = 1b)

Synopsis
Between March 2007 and January 2011, 150 adults with uncontrolled type 2 diabetes were randomized to receive intensive medical therapy, Roux-en-Y gastric-bypass plus intensive medical therapy, or sleeve gastrectomy plus intensive medical therapy. In this trial, patients 20 to 60 years of age with a body mass index (BMI) between 27 and 43 kg per m$^2$ and an A1C level greater than 7.0% were eligible for the trial. The primary outcome was an A1C level less than or equal to 6.0% with or without the use of medications. Secondary outcomes included weight loss, the use of glucose-lowering medications, and quality-of-life scores. At baseline, 68% of the patients were women, 74% were white, and the average age was 48 years. The average BMI was 36 kg per m$^2$ ± 3.5 kg per m$^2$, and the average A1C level was 9.3% ± 1.5%. Of the 150 patients enrolled, nine withdrew and four were lost to follow-up, leaving 137 to be evaluated at the three-year mark.

After 36 months, 5% of the intensive medical therapy patients met the A1C target, compared with 38% of the Roux-en-Y patients and 24% of the sleeve gastrectomy patients. These differences were statistically significant, with a number needed to treat of 5 for sleeve gastrectomy and 3 for Roux-en-Y. Relapse was most common with medical therapy alone and least likely with Roux-en-Y (80% vs. 50% vs. 24%); the difference between Roux-en-Y and medical therapy was statistically significant. At three years, patients in both surgical groups had a reduced need for glucose-lowering medications, as well as reductions in BMI, body weight, and waist circumference, compared with the medical therapy alone group. Five of eight mental and physical quality-of-life measures were also significantly improved in the two surgical groups. Results may be limited by the small sample size, which prevents the ability to detect differences in incidence of diabetes complications, including stroke and myocardial infarction.

Study design: Randomized controlled trial (nonblinded)
Funding source: Industry plus government
Allocation: Uncertain
Setting: Outpatient (specialty)

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