Bariatric Surgery Improves Glycemic Control

Reviewed by Michael Pignone, MD, MPH

STUDY

Dixon JB, Obrien PE, Playfair J, Chapman L, Schachter LM, Skinner S, Proietto J, Bailey M, Anderson M: Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *JAMA* 299:316-323, 2008

SUMMARY

Design. A randomized controlled trial comparing a conventional lifestyle change intervention to conventional management plus laparoscopic adjustable gastric banding for the outcomes of "diabetes regression," defined as fasting glucose < 126 mg/dl and hemoglobin A1c (A1C) < 6.2% while using no glucose-controlling medications.

Subjects. Sixty patients with a BMI of 30–40 kg/m^2 and recently (within 2 years) diagnosed diabetes.

Methods. Eligible participants were 20–60 years of age, had type 2 diabetes diagnosed within 2 years, and had no evidence of impaired renal function or diabetic retinopathy. Potential participants completed a 3-month run-in period that included efforts to optimize their diabetes treatment. Those completing the run-in period were randomized, and no attempt was made to blind patients or providers to their intervention status. Those assigned to conventional therapy had access to a team of providers and were seen at least every 6 weeks. They were counseled to follow a low-fat, low-glycemic-index diet and to engage in moderate physical activity. Those in the intervention group received similar conventional treatment, underwent laparoscopic placement of the adjustable gastric band, and had visits every 4–6 weeks. The main outcome of regression of diabetes was assessed after 2 years; secondary measures included A1C, weight, and lipid levels.

Results. Of the 60 enrolled patients, 55 completed 2-year follow-up. Participants in the surgical intervention group were more likely to achieve diabetes remission than those in the conventional treatment control arm (73 vs. 13%, relative risk 5.5, 95% CI 2.2, 14.0). Weight loss was also greater in the surgical group (20.7 vs. 1.7% for the conventional treatment group). Remission was well correlated with weight loss ($R^2 = 0.46$). Four patients in the surgical arm had important adverse events (one post-surgical wound infection treated with intravenous antibiotics; two cases of gastric pouch enlargement requiring re-operation; and one patient who had "persistent eating difficulties" and required band removal).

Conclusions. Obese adults with recent onset of diabetes who were assigned to receive laparoscopic gastric banding plus conventional therapy were more likely to achieve diabetes remission than those assigned to conventional treatment alone.

COMMENTARY

Dixon and colleagues are to be commended for conducting a randomized trial to help us better understand the efficacy of laparoscopic gastric banding as a means of helping patients reduce their weight and improve remission of diabetes. They found that laparoscopic surgery plus conventional treatment was substantially more effective than conventional treatment alone throughout 2 years of follow-up. The combined intervention produced greater weight loss and greatly increased the likelihood of "diabetes remission." Adverse events were relatively uncommon, and other secondary outcomes, including presence of metabolic syndrome and the use of antihypertensive medications, were also improved. These results suggest that laparoscopic gastric banding may offer important benefits for obese patients with newly diagnosed diabetes.

These promising results should be viewed in the context of some important limitations. First, this trial was small, with only 60 total participants. Because the trial produced large effects, the small size did not affect its ability to determine efficacy. The limited number of participants, however, raises questions about the generalizability of the findings. Participants were volunteers and were required to complete a run-in phase before randomization. Enrolled patients had BMIs between 30 and 40 kg/m^2, so we cannot be sure that those with lesser or greater degrees of overweight or obesity would derive similar benefits, nor can we determine whether the effects would be the same for patients with "pre-diabetes" or longer standing duration of disease. Perhaps more importantly, the surgical team had extensive experience with the laparascopic gastric banding and had low

rates of complications and no surgical deaths. Ensuring safe surgical outcomes is necessary if such procedures are to be considered for patients such as those enrolled in this trial.

Randomization produced relatively equal groups with respect to important co-morbid conditions, and there were relatively few participants lost to follow-up. Intention-to-treat analyses were appropriately conducted, and we can have good confidence that the results obtained did not suffer from measurement error.

The results of this trial help confirm anecdotal and observational data suggesting improvements in many metabolic parameters after bariatric surgery. It will be important to replicate this trial among a larger, more diverse set of centers and patients to test its generalizability. If these results are replicated, more focused attention will need to be paid to helping patients consider this option when examining potentially effective therapies for obesity-related illnesses.

Michael Pignone, MD, MPH, is an associate professor of medicine at the University of North Carolina Department of Medicine in Chapel Hill and an associate editor of Clinical Diabetes.