

## ORIGINAL ARTICLE

# Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 5-Year Outcomes

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## ABSTRACT

**BACKGROUND**

Long-term results from randomized, controlled trials that compare medical therapy with surgical therapy in patients with type 2 diabetes are limited.

**METHODS**

We assessed outcomes 5 years after 150 patients who had type 2 diabetes and a body-mass index (BMI; the weight in kilograms divided by the square of the height in meters) of 27 to 43 were randomly assigned to receive intensive medical therapy alone or intensive medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy. The primary outcome was a glycosylated hemoglobin level of 6.0% or less with or without the use of diabetes medications.

**RESULTS**

Of the 150 patients who underwent randomization, 1 patient died during the 5-year follow-up period; 134 of the remaining 149 patients (90%) completed 5 years of follow-up. At baseline, the mean ( $\pm$ SD) age of the 134 patients was 49 $\pm$ 8 years, 66% were women, the mean glycosylated hemoglobin level was 9.2 $\pm$ 1.5%, and the mean BMI was 37 $\pm$ 3.5. At 5 years, the criterion for the primary end point was met by 2 of 38 patients (5%) who received medical therapy alone, as compared with 14 of 49 patients (29%) who underwent gastric bypass (unadjusted  $P=0.01$ , adjusted  $P=0.03$ ,  $P=0.08$  in the intention-to-treat analysis) and 11 of 47 patients (23%) who underwent sleeve gastrectomy (unadjusted  $P=0.03$ , adjusted  $P=0.07$ ,  $P=0.17$  in the intention-to-treat analysis). Patients who underwent surgical procedures had a greater mean percentage reduction from baseline in glycosylated hemoglobin level than did patients who received medical therapy alone (2.1% vs. 0.3%,  $P=0.003$ ). At 5 years, changes from baseline observed in the gastric-bypass and sleeve-gastrectomy groups were superior to the changes seen in the medical-therapy group with respect to body weight (–23%, –19%, and –5% in the gastric-bypass, sleeve-gastrectomy, and medical-therapy groups, respectively), triglyceride level (–40%, –29%, and –8%), high-density lipoprotein cholesterol level (32%, 30%, and 7%), use of insulin (–35%, –34%, and –13%), and quality-of-life measures (general health score increases of 17, 16, and 0.3; scores on the RAND 36-Item Health Survey ranged from 0 to 100, with higher scores indicating better health) ( $P<0.05$  for all comparisons). No major late surgical complications were reported except for one reoperation.

**CONCLUSIONS**

Five-year outcome data showed that, among patients with type 2 diabetes and a BMI of 27 to 43, bariatric surgery plus intensive medical therapy was more effective than intensive medical therapy alone in decreasing, or in some cases resolving, hyperglycemia. (Funded by Ethicon Endo-Surgery and others; STAMPEDE ClinicalTrials.gov number, NCT00432809.)

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The contributions of the authors and committee members in the Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) trial are listed in the Supplementary Appendix, available at NEJM.org.

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