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ORIGINAL ARTICLE

Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes

Philip R. Schauer, M.D., Sangeeta R. Kashyap, M.D., Kathy Wolski, M.P.H., Stacy A. Brethauer, M.D., John P. Kirwan, Ph.D., Claire E. Pothier, M.P.H., Susan Thomas, R.N., Beth Abood, R.N., Steven E. Nissen, M.D., and Deepak L. Bhatt, M.D., M.P.H.

N Engl J Med 2012; 366:1567-1576 | [April 26, 2012](#)

BACKGROUND

Observational studies have shown improvement in patients with type 2 diabetes mellitus after bariatric surgery.

METHODS

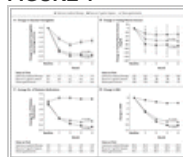
In this randomized, nonblinded, single-center trial, we evaluated the efficacy of intensive medical therapy alone versus medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy in 150 obese patients with uncontrolled type 2 diabetes. The mean (\pm SD) age of the patients was 49 \pm 8 years, and 66% were women. The average glycated hemoglobin level was 9.2 \pm 1.5%. The primary end point was the proportion of patients with a glycated hemoglobin level of 6.0% or less 12 months after treatment.

RESULTS

Of the 150 patients, 93% completed 12 months of follow-up. The proportion of patients with the primary end point was 12% (5 of 41 patients) in the medical-therapy group versus 42% (21 of 50 patients) in the gastric-bypass group ($P=0.002$) and 37% (18 of 49 patients) in the sleeve-gastrectomy group ($P=0.008$). Glycemic control improved in all three groups, with a mean glycated hemoglobin level of 7.5 \pm 1.8% in the medical-therapy group, 6.4 \pm 0.9% in the gastric-bypass group ($P<0.001$), and 6.6 \pm 1.0% in the sleeve-gastrectomy group ($P=0.003$). Weight loss was greater in the gastric-bypass group and sleeve-gastrectomy group (-29.4 ± 9.0 kg and -25.1 ± 8.5 kg, respectively) than in the medical-therapy group (-5.4 ± 8.0 kg).

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FIGURE 1



Changes in Measures of Diabetes Control from Baseline.

TABLE 1

Characteristic	Medical Therapy (n=41)	Gastric Bypass (n=50)	Sleeve Gastrectomy (n=49)
Age, mean (\pm SD)	49.2 (\pm 8.1)	49.1 (\pm 8.2)	49.3 (\pm 8.0)
Female, %	66	64	66
Duration of diabetes, mean (\pm SD), years	11.2 (\pm 6.5)	11.1 (\pm 6.6)	11.3 (\pm 6.4)
HbA1c, mean (\pm SD), %	9.2 (\pm 1.5)	9.1 (\pm 1.6)	9.3 (\pm 1.4)
Fasting glucose, mean (\pm SD), mg/dL	185 (\pm 45)	184 (\pm 46)	186 (\pm 44)
Weight, mean (\pm SD), kg	115 (\pm 25)	114 (\pm 26)	116 (\pm 24)
Weight loss at 12 months, mean (\pm SD), kg	-5.4 (\pm 8.0)	-29.4 (\pm 9.0)	-25.1 (\pm 8.5)
Proportion with HbA1c \leq 6.0% at 12 months, %	12	42	37

Characteristics of the Patients at Baseline.

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respectively, than in the medical therapy group ($P < 0.001$ for both comparisons). The use of drugs to lower glucose, lipid, and blood-pressure levels decreased significantly after both surgical procedures but increased in patients receiving medical therapy only. The index for homeostasis model assessment of insulin resistance (HOMA-IR) improved significantly after bariatric surgery. Four patients underwent reoperation. There were no deaths or life-threatening complications.

CONCLUSIONS

In obese patients with uncontrolled type 2 diabetes, 12 months of medical therapy plus bariatric surgery achieved glycemic control in significantly more patients than medical therapy alone. Further study will be necessary to assess the durability of these results. (Funded by Ethicon Endo-Surgery and others; ClinicalTrials.gov number, [NCT00432809](https://clinicaltrials.gov/ct2/show/study/NCT00432809).)

Supported by a grant (EES IIS 19900) from Ethicon Endo-Surgery, a grant (R01-DK089547) from the National Institutes of Health, and LifeScan.

Dr. Schauer reports receiving payment for board membership from Ethicon Endo-Surgery, Surgique, Barosense, RemedyMD, and Stryker, consulting fees from Ethicon Endo-Surgery, Stryker, Gore, and Carefusion, payment for expert testimony from Physicians Review of Surgery, and lecture fees from Ethicon Endo-Surgery, Allergan, Cinemed, and Quadrant Healthcare, holding a patent for a medical device to enhance weight loss in codevelopment with the Cleveland Clinic, royalties from Springer, having an equity interest in Intuitive Surgical, Barosense, Surgique, and RemedyMD, and receiving institutional grant support (to the Cleveland Clinic) from Ethicon Endo-Surgery and Bard Davol; Dr. Kashyap, receiving consulting fees from Ethicon; Dr. Brethauer, receiving consulting fees, lecture fees, and payment for board membership from Ethicon Endo-Surgery and lecture fees from Covidien; Dr. Kirwan, receiving grant support from Nestle and ScottCare; Dr. Nissen, receiving institutional grant support (to the Cleveland Clinic) from Orexigen and Vivus; and Dr. Bhatt, receiving institutional grant support (to Brigham and Women's Hospital) from Amarin, AstraZeneca, Bristol-Myers Squibb, Eisai, and Sanofi Aventis and from Medtronic and the Medicines Company (to Boston VA Research Institute) and serving as the international principal investigator for the CRESCENDO cardiovascular outcome trial of the weight-loss drug rimonabant versus placebo. The Cleveland Clinic had received a grant from Sanofi Aventis for the CRESCENDO trial. No other potential conflict of interest relevant to this article was reported.

[Disclosure forms](#) provided by the authors are available with the full text of this article at [NEJM.org](http://www.nejm.org).

This article (10.1056/NEJMoa1200225) was published on March 26, 2012, and updated on April 26, 2012, at [NEJM.org](http://www.nejm.org).

We thank Chytaine Hall for recruitment support; Craig Balog, Debbie Gladish, Betty Moore, Karen Myers, Tammy Scebbi, Diane Smith, Maura Schnauffer, Randy Scott, and Janice Bell for statistics and data-management support; Matthew Kroh, M.D., Tomasz Rogula, M.D., Bipan Chand, M.D., Derrick Cetin, M.D., Betul Hatipoglu, M.D., Mario Skugor, M.D., Adi Mehta, M.D., Leslie Heinberg, Ellen Calogeras, Wendy Kirby, and Lauren Sullivan for medical-site support; Rishi Singh, M.D., and Lisa Yerian, M.D., for technical support; and Suzanne Turner and Mary Ann Citraro for graphical support.

SOURCE INFORMATION

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