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Bariatric surgery + medical therapy: Effective Tx for T2DM?

Short-term studies have indicated “Yes,” but does a long-term randomized controlled trial give it a thumbs up?

PRACTICE CHANGER

Consider bariatric surgery with medical therapy as a treatment option for adults with uncontrolled type 2 diabetes and a body mass index ≥ 27 kg/m².¹

STRENGTH OF RECOMMENDATION

B: Based on a nonblinded, single-center, randomized controlled trial.

Schauer PR, Bhatt DL, Kirwan JP, et al; STAMPEDE Investigators. Bariatric surgery versus intensive medical therapy for diabetes—5-year outcomes. *N Engl J Med*. 2017;376:641-651.

ILLUSTRATIVE CASE

A 46-year-old woman presents with a body mass index (BMI) of 28 kg/m², a 4-year history of type 2 diabetes mellitus (T2DM), and a glycated hemoglobin (HgbA1c) of 9.8%. The patient is currently being treated with intensive medical therapy (IMT), including metformin 2000 mg/d, sitagliptin 100 mg/d, and insulin glargine 12 units/d, with minimal change in HgbA1c. Should you recommend bariatric surgery as an option for the treatment of diabetes?

One in 11 Americans has diabetes and at least 95% of those have type 2.^{2,3} The treatment of T2DM is generally multimodal in order to target the various mechanisms that cause hyperglycemia. Treatment strategies may include lifestyle modifications, decreasing insulin resistance, increasing secretion of insulin, insulin replacement, and targeting incretin-hormonal pathways.

The American Diabetes Association (ADA) currently recommends diet, exercise, and behavioral modifications as first-line therapy for the management of diabetes,² but these by themselves are often inadequate. In addition to various pharmacotherapeutic strategies for other populations with T2DM (see the PURL, “How do these 3 diabetes agents compare in reducing mortality?” page 99), the ADA recommends bariatric surgery for the treatment of patients with T2DM, a BMI ≥ 35 kg/m², and uncontrolled hyperglycemia.^{2,4} However, this recommendation from the ADA supporting bariatric surgery is based only on short-term studies.

For example, one single-center nonblinded randomized controlled trial (RCT) involving 60 patients with a BMI ≥ 35 kg/m² found reductions in HgbA1C levels from the average baseline of 8.65 \pm 1.45% to 7.7 \pm 0.6% in the IMT group and to 6.4 \pm 1.4% in the gastric-bypass group at 2 years.⁵ In another study, a randomized double-blind trial involving 60 moderately obese patients (BMI, 25-35 kg/m²), gastric bypass had better outcomes than sleeve gastrectomy, with 93% of patients in the gastric bypass group achieving remission of T2DM vs 47% of patients in the sleeve gastrectomy group ($P=.02$) over a 12-month period.⁶

The current study sought to examine the long-term outcomes of IMT alone vs bariatric surgery with IMT for the treatment of T2DM in patients who are overweight or obese.¹

TABLE 1

Secondary outcomes at the end of 5 years¹

Secondary outcome	IMT	Gastric bypass	Gastric bypass vs IMT	Sleeve gastrectomy	Sleeve gastrectomy vs IMT
Body weight (% change from baseline)	-5%	-23%	<i>P</i> <.003	-19%	<i>P</i> <.003
HDL cholesterol (% change from baseline)	7%	32%	<i>P</i> <.012	30%	<i>P</i> <.016
Triglycerides (% change from baseline)	-8.3%	-40%	<i>P</i> <.03	-29%	<i>P</i> <.04
Insulin use at study end	40%	12%	<i>P</i> <.05	11%	<i>P</i> <.05
% of patients taking no medication for T2DM at study end	2%	45%	<i>P</i> <.05	25%	<i>P</i> <.05

HDL, high-density lipoprotein; IMT, intensive medical therapy; T2DM, type 2 diabetes mellitus.

STUDY SUMMARY

5-year follow-up shows surgery + intensive medical therapy works

This study by Schauer et al was a 5-year follow-up of a nonblinded, single-center RCT comparing IMT alone to IMT with Roux-en-Y gastric bypass or sleeve gastrectomy in 150 patients with T2DM.¹ Patients were included if they were 20 to 60 years of age, had a BMI of 27 to 43 kg/m², and had an HgbA1C >7%. Patients with previous bariatric surgery, complex abdominal surgery, or uncontrolled medical or psychiatric disorders were excluded.

Each patient was randomly placed in a 1:1:1 fashion into 3 groups: IMT only, IMT and gastric bypass, or IMT and sleeve gastrectomy. All patients underwent IMT as defined by the ADA. The primary outcome was the number of patients with an HgbA1c ≤6%. Secondary outcomes included weight loss, glucose control, lipid levels, blood pressure, medication use, renal function, adverse effects, ophthalmologic outcomes, and quality of life.

Of the 150 patients, 1 died during the follow-up period leaving 149; 134 completed the 5-year follow-up; 8 patients in the IMT group and 1 patient in the sleeve gastrectomy group never initiated assigned treatment; an additional 6 patients were lost to follow-up.

One patient from the IMT group and 1 patient from the sleeve gastrectomy group crossed over to the gastric bypass group.

Results. More patients in the bariatric surgery and sleeve gastrectomy groups achieved an HgbA1c of ≤6% compared with the IMT group (14 of 49 gastric bypass patients vs 2 of 38 IMT patients; *P*=.01; 11 of 47 sleeve gastrectomy patients vs 2 of 38 IMT patients; *P*=.03). Compared with those in the IMT group, the patients in the bariatric surgery and sleeve gastrectomy groups showed greater reductions from baseline in body weight and triglyceride levels, and greater increases from baseline in high-density lipoprotein (HDL) cholesterol levels; they also required less diabetic medication for glycemic control (see TABLE 1¹). However, when data were imputed for the intention-to-treat analysis, *P*-values were *P*=0.08 for gastric bypass and *P*=0.17 for sleeve gastrectomy compared with the IMT group for lowering HgbA1c.

WHAT'S NEW?

Adding surgery has big benefits with minimal adverse effects

Prior studies that evaluated the effect of gastric bypass surgery on diabetes were observational or had a shorter follow-up duration. This study demonstrates bariatric

surgery plus IMT has long-term benefits with minimal adverse events compared with IMT alone.^{1,5} Additionally, this study supports recommendations for bariatric surgery as treatment for T2DM for patients with a BMI ≥ 27 kg/m², which is below the starting BMI (35 kg/m²) recommended by the ADA.^{1,4}

CAVEATS

Surgery is not without risks

The risk for surgical complications, such as gastrointestinal bleeding, severe hypoglycemia requiring intervention, and ketoacidosis, in this patient population is significant.¹ Complications can include gastrointestinal leak, stroke, and infection.¹ Additionally, long-term complications from bariatric surgery are emerging and include choledocholithiasis, intestinal obstruction, and esophageal pathology.⁷ Extensive patient counseling regarding the possible complications is necessary to ensure that patients make an informed decision regarding surgery.

This study utilized surrogate markers (A1c, lipid levels, and body weight) as disease-oriented outcome measures. Patient-oriented outcomes, such as morbidity and mortality, were not explored in this study.

Due to the small sample size of the study, it is unclear if the outcomes of the 2 surgery groups were significantly different. Patients who received gastric bypass surgery had more weight loss and used less diabetes medication at the end of follow-up compared with the patients who received sleeve gastrectomy. More information is needed to determine which gastric surgery is preferable for the treatment of T2DM while minimizing

adverse effects. However, both of the procedures had outcomes superior to that with IMT, and selection of a particular type of surgery should be a joint decision between the patient and provider.

CHALLENGES TO IMPLEMENTATION

Access and cost may be barriers

The major barriers to implementation are access to, and the cost of, bariatric surgery. **JFP**

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> This study supports recommendations for bariatric surgery as treatment for T2DM for patients with a body mass index ≥ 27 kg/m², which is below the starting BMI recommended by the ADA.

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