

# Bariatric Surgery + Medical Therapy: Effective Tx for T2DM?

Short-term studies have indicated “Yes.” But does a long-term randomized controlled trial give this combination a thumbs up?

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## PRACTICE CHANGER

Consider bariatric surgery with medical therapy as an option for adults with uncontrolled type 2 diabetes and a BMI  $\geq 27$ .<sup>1</sup>

## STRENGTH OF RECOMMENDATION

**B:** Based on a nonblinded, single-center, randomized controlled trial (RCT).

A 46-year-old woman presents with a BMI of 28, a 4-year history of type 2 diabetes mellitus (T2DM), and an A1C 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 U/d, with minimal change in A1C. Should you recommend bariatric surgery?

One in 11 Americans has diabetes, and at least 95% of those have T2DM.<sup>2,3</sup> The treatment of T2DM is generally multimodal to target the various mechanisms that cause hyperglycemia. Strategies may include making lifestyle modifications, decreasing insulin resistance, increasing insulin secretion, replacing insulin, and targeting incretin-hormonal pathways.

The American Diabetes Association (ADA) recommends diet, exercise, and behavioral modifications as firstline therapy for diabetes management, but these methods are often inadequate.<sup>2</sup> In addition to various pharmacotherapeutic strategies for some populations with T2DM, the ADA recommends bariatric surgery for those with a BMI  $\geq 35$  and uncontrolled hyperglycemia.<sup>2,4</sup>

However, this recommendation is based only on short-term studies. For example, in a single-center, nonblinded RCT of 60 patients with a BMI  $\geq 35$ , the average baseline A1C levels of  $8.65 \pm 1.45\%$  were re-

duced 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.<sup>5</sup> In another study, a randomized double-blind trial involving 60 moderately obese patients (BMI, 25-35), gastric bypass yielded better outcomes than sleeve gastrectomy: 93% of patients in the former group and 47% of those in the latter group achieved remission of T2DM over a 12-month period.<sup>6</sup>

The current study by Schauer et al examined the long-term outcomes of IMT alone vs bariatric surgery with IMT for the treatment of T2DM in patients who are overweight or obese.<sup>1</sup>

## STUDY SUMMARY

### 5-year follow-up: surgery + IMT works

This study 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.<sup>1</sup> Patients were included if they were ages 20 to 60, had a BMI of 27 to 43, and had an A1C  $> 7\%$ . Patients with a history of bariatric surgery, complex abdominal surgery, or uncontrolled medical or psychiatric disorders were excluded.

Patients were randomly placed in a 1:1:1 fashion into 3 groups: IMT (as defined by the ADA) only, IMT and gastric bypass, or IMT and sleeve gastrectomy. The primary outcome was the number of patients with an A1C  $\leq 6\%$ . 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. Of these, 134 completed the 5-year follow-up. Eight patients in the IMT group and 1 patient in the sleeve gastrectomy group never initiated assigned treatment, and 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.

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**TABLE**  
**Secondary Outcomes After 5 Years**

Secondary outcome	IMT	Gastric bypass	Gastric bypass vs IMT	Sleeve gastrectomy	Sleeve gastrectomy vs IMT
Body weight*	-5%	-23%	$P < .003$	-19%	$P < .003$
HDL cholesterol*	7%	32%	$P < .012$	30%	$P < .016$
Triglycerides*	-8.3%	-40%	$P < .03$	-29%	$P < .04$
Insulin use at study end†	40%	12%	$P < .05$	11%	$P < .05$
No T2DM medication use at study end†	2%	45%	$P < .05$	25%	$P < .05$

\* Percent change from baseline.

† Percent of patients.

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

Source: Schauer et al. *N Engl J Med*. 2017.<sup>1</sup>

**Results.** More patients in the bariatric surgery and sleeve gastrectomy groups achieved an A1C of  $\leq 6\%$  than in the IMT group (14 of 49 gastric bypass patients, 11 of 47 sleeve gastrectomy patients, and 2 of 38 IMT patients). Compared with those in the IMT group, the patients in the 2 surgery groups showed greater reductions from baseline in body weight and triglyceride levels and greater increases from baseline in HDL cholesterol levels; they also required less antidiabetes medication for glycemic control (see Table).<sup>1</sup>

## WHAT'S NEW?

### Big benefits, minimal adverse effects

Prior studies evaluating the effect of gastric bypass surgery on diabetes were observational or had a shorter follow-up duration. This study demonstrates that bariatric surgery plus IMT has long-term benefits with minimal adverse events, compared with IMT alone.<sup>1,5</sup> Additionally, this study supports recommendations for bariatric surgery as treatment for T2DM in patients with a BMI  $\geq 27$ , which is below the starting BMI (35) recommended by the ADA.<sup>1,4</sup>

## CAVEATS

### Surgery is not without risks

The risk for surgical complications—eg, gastrointestinal bleeding, severe hypoglycemia requiring intervention, and ketoacidosis—in this patient population is significant.<sup>1</sup> Other potential complications include gastrointestinal leak, stroke, and infection.<sup>1</sup> Addition-

ally, long-term complications from bariatric surgery are emerging and include choledocholithiasis, intestinal obstruction, and esophageal pathology.<sup>7</sup> Extensive patient counseling 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 underwent gastric bypass surgery had more weight loss and used less diabetes medication at the end of follow-up, compared with patients who underwent 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 those of 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 cost of, bariatric surgery. **CR**

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