

## Final stampede results: Glycemic benefits of bariatric surgery persist over time

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In the final, five-year follow-up report from the influential STAMPEDE trial, Cleveland Clinic research shows that bariatric surgery's beneficial effects on blood glucose control in mild and moderately obese patients with type 2 diabetes may persist for up to five years, with the advantage over diabetes medications-only approach widening over time.

The five-year follow-up also reported that:

- Over 88 percent of gastric bypass and sleeve gastrectomy patients maintained healthy blood glucose levels without the use of insulin.
- 29 percent of gastric bypass patients and 23 percent of sleeve gastrectomy patients achieved and maintained normal <u>blood</u> <u>glucose levels</u>, compared to just 5 percent of those on medication alone.
- Weight loss was significantly greater with gastric bypass and sleeve gastrectomy than with medications and was the primary driver for glucose control.
- The effects of both surgical procedures to normalize glucose levels did however diminish overtime and some late complications were noted with surgery.

"Our findings show continued durability of glycemic control after metabolic surgery, as well as persistent weight loss, reduction in diabetes and cardiovascular medications at five years," said Philip Schauer, M.D., lead author and Cleveland Clinic bariatric surgeon, who presented the



results today at ACC.16, the American College of Cardiology's 65th Annual Scientific Session.

"The superior benefits of surgery to attain diabetes treatment goals must be carefully balanced with the long-term risks associated with surgery for individual patients," said Sangeeta Kashyap, M.D., co-investigator involved with the trial and an endocrinologist at Cleveland Clinic's Endocrinology & Metabolism Institute.

According to the CDC, 29 million people in the United States (9.3 percent) have diabetes. More than 70,000 persons die annually due to complications associated with diabetes, according to the American Diabetes Association. Approximately 50 percent of patients currently treated for type 2 diabetes with medications are not meeting standard targets of glycemic control and thus are at risk for developing complications of diabetes.

"Left unchecked, diabetes can lead to kidney failure, blindness, and limb amputation," said Dr. Kashyap. "At the five-year mark, bariatric surgery's metabolic effect persists and is more effective at treating type 2 diabetes in moderate and severely obese patients when compared to <u>medical therapy</u>."

The STAMPEDE (Surgical Therapy And Medications Potentially Eradicate Diabetes Efficiently) trial is the largest randomized trial with one of the longest follow-ups comparing medical therapy with bariatric surgery.

The trial initially involved 150 overweight patients with poorly controlled diabetes. The patients were divided into three groups: 1) Fifty patients received intensive medical therapy only, including counseling and medications; 2) Fifty patients underwent Roux-en-Y gastric bypass surgery and received medical therapy; 3) Fifty patients underwent sleeve



gastrectomy and received medical therapy.

Effectiveness was gauged by the percentage of patients who achieved blood sugar control, defined in this study as hemoglobin HbA1c level of less than or equal to 6.0 percent - a more aggressive target than the American Diabetes Association's guidelines. HbA1c is a standard laboratory test that reflects average blood sugar over three months.

Findings from the five-year follow-up confirm those from the one-year and three-year reports and include the following:

- Rates of achieving and maintaining an HbA1c level of 6.0 percent or less at five years were significantly higher with gastric bypass (29 percent) and sleeve gastrectomy (23 percent) than with intensive medical therapy alone (5 percent).
- Weight loss was significantly greater with gastric bypass and sleeve gastrectomy than with medical therapy.
- Use of cardiovascular and glucose-lowering medications, including insulin, at five years was significantly reduced from baseline in both surgical groups, and was significantly lower in the surgical groups than in the medical therapy group. Over 88 percent of surgically treated patients maintained glycemic control without use of insulin.

The five-year analysis also yielded several new insights, including the following:

- In the two surgical groups, achieving the primary end point of an HBA1c less than or equal to ? 6.0 percent was predicted both by a reduction in body mass index (BMI) and a duration of <u>diabetes</u> of less than eight years.
- There were no late major complications of surgery except for one reoperation (a successful laparoscopic conversion of sleeve



gastrectomy to gastric bypass for recurrent gastric fistula) four years after randomization.

- Significant and durable improvements in bodily pain and general health were demonstrated using a validated quality-of-life instrument in both surgical groups relative to the medical group.
- Several biomarkers associated with heightened cardiovascular risk were reduced in the surgical arms, but there were no beneficial effects on retinopathy or nephropathy seen at 5 years.

"Some advantages of gastric bypass over sleeve gastrectomy have emerged during follow-up," Dr. Schauer said. "At five years, <u>gastric</u> <u>bypass</u> maintained greater weight loss than sleeve gastrecomy while requiring fewer medications."

He also notes that the final STAMPEDE results might help expand the population of patients in whom bariatric surgery may be considered for improving glycemic control.

"Most clinical guidelines and insurance policies for bariatric surgery limit access to patients with a BMI of 35 or above," Dr. Schauer added. "Our five-year results demonstrate that glycemic improvement in <u>patients</u> with a BMI of 27 to 34 is durable at least up to five years."

Provided by Cleveland Clinic

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