肥満手術の血糖値に対する効果は時間が経過しても持続する(LBCT 416-12)

STAMPEDE：肥満手術施行患者は術後5年間インスリンを使用することなく健康的な血糖値を維持している

STAMPEDE: Patients maintain healthy blood glucose levels without the use of insulin five years after bariatric surgery

第65回American College of Cardiology年次集会で発表されたSTAMPEDEトライアルの追跡結果から、軽度から中等度の2型糖尿病患者において肥満手術の血糖コントロールに対する有益な効果は最長5年間持続し、糖尿病治療薬のみの治療法に対する優越性は時間とともに拡大する可能性があることが示された。胃バイパス手術患者の29%およびスリーブ状胃切除術患者の23%が正常血糖値を達成し維持したのに対し、薬物療法のみの患者におけるその割合は5%であった。減量は胃バイパス術およびスリーブ状胃切除術において薬物療法よりも有意に大であり、血糖コントロールの主要な促進因子であった。

Full Text

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 blood glucose levels, 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 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.

"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 medical therapy."

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 diabetes 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, gastric bypass maintained greater weight loss than sleeve gastrectomy 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 patients with a BMI of 27 to 34 is durable at least up to five years."

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Dr. Schauer is a paid consultant for Ethicon.

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