

Patients report long-term favorable effects of weight loss surgery in their daily lives

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A new analysis from the STAMPEDE trial shows that over the course of five years, patients who had bariatric and metabolic surgery to treat uncontrolled type 2 diabetes reported greater physical health, more



energy, less body pain, and less negative effects of diabetes in their daily lives, compared with patients who had medical therapy alone for their diabetes.

Long-term changes in psychosocial and emotional quality of life measures were not significantly different between the surgical and medical groups. The research was published in the *Annals of Surgery*.

"Chronic diseases, such as severe obesity and diabetes, can negatively affect quality of life," said Ali Aminian, M.D., director of Cleveland Clinic's Bariatric & Metabolic Institute and lead author of the study. "It is important to study the effects of different treatments on the well-being of patients in their daily lives." The Cleveland Clinic-led STAMPEDE study (Surgical Therapy and Medications Potentially Eradicate Diabetes Efficiently) was the first randomized controlled clinical trial that compared head-to-head bariatric surgery with intensive medical therapy for the treatment of type 2 diabetes in patients with poorly controlled diabetes and obesity.

The trial initially involved 150 participants, who were divided into three groups: 1) Fifty patients received intensive medical therapy only, including counseling and medications; 2) Fifty patients underwent Rouxen-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 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.

The study's initial results showed that metabolic surgery is superior to medical therapy alone for achieving weight loss and diabetes control with less reliance on anti-diabetic medications. The five-year results



showed that the benefits of metabolic surgery persist over time.

This current study looked at 104 STAMPEDE trial participants: 1) Twenty-six patients who received intensive medical therapy only; 2) Forty-one patients who underwent Roux-en-Y gastric bypass surgery and received medical therapy; 3) Thirty-seven patients who underwent sleeve gastrectomy and received medical therapy.

The 104 patients were asked to answer two generic health-related quality of life questionnaires (the RAND 36-Item Health Survey and European QoL 5-Dimensions) and a diabetes-specific questionnaire at the beginning of the trial, and then on an annual basis following enrollment. Those three questionnaires were chosen to assess how surgical or medical treatment of obesity and diabetes may affect key elements of quality of life.

The results show that over the course of five years, the 78 patients in the surgical groups had significantly better scores on physical functioning, more energy, less body pain, and improved general heath scores compared with the 26 patients in the medical therapy group. The diabetes questionnaire looked at 12 various aspects of life in patients who have type 2 diabetes, such as maintaining a diet, going on vacation, planning meals or eating out with others, and family life. Over five years, data show that diabetes has less negative impact on quality of life in the metabolic surgery groups compared with the medical therapy group.

"Patients with long duration of diabetes tend to have poor quality of life, especially when they develop microvascular complications like eye and kidney diseases," said Sangeeta Kashyap, M.D., co-investigator involved with the trial and an endocrinologist at Cleveland Clinic's Endocrinology & Metabolism Institute. "When diabetes is coupled with obesity, the impact on lower quality of life can be related to the mechanical effects



of obesity as well, which leads to poor mobility and bodily pain. Significant weight loss and insulin independence following metabolic surgery drive the improvement in general health measures and quality of life for patients with type 2 diabetes," said Dr. Kashyap.

"Our findings suggest that psychological well-being needs may require more attention in metabolic surgical patients," said Dr. Aminian. "As part of our multidisciplinary approach to weight management at Cleveland Clinic, our patients have appointments with psychologists before and after surgery. The study results highlight that we may need greater emphasis on that aspect of the treatment, such as identification of psychosocial and emotional factors before surgery that can predict outcomes of surgery, as well as continuous psychosocial support after surgery."

More long-term research is needed to continue to gather feedback directly from patients on the effects of <u>metabolic surgery</u> on their quality of life.

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