





Consensus from Diabetes Organizations Worldwide: Metabolic Surgery Recognized as a Standard Treatment Option for Type 2 Diabetes

A Special Issue of Diabetes Care Reports First-Ever Clinical Guidelines for When to Recommend or Consider Metabolic Surgery as Treatment for People with Diabetes

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ALEXANDRIA, Va., May 24, 2016 /PRNewswire-USNewswire/ -- Metabolic, or weight-loss, surgery quickly and dramatically improves blood glucose control. Until now, however, it has not been included in clinical practice guidelines as a treatment option for people with diabetes. In a Joint Statement endorsed by 45 international professional organizations, diabetes clinicians and researchers are urging that metabolic surgery be recommended or considered as a treatment option for certain categories of people with diabetes, including people who are mildly obese and fail to respond to conventional treatment. The Statement and Clinical Guidelines will be published in the June 2016 issue of <u>Diabetes Care</u>, which will be available in print and online on May 24, 2016.

"Given the rapid developments in the field, it is important to focus on this topic for those who care for individuals with diabetes. These new Guidelines, based on the results of multiple clinical studies, validate that metabolic surgery is indicated for certain people with diabetes and can yield significantly improved outcomes," said *Diabetes Care* Editor in Chief William T. Cefalu, MD, adding that it is the first time guidelines recommend surgery as a treatment option specifically for diabetes.

The special *Diabetes Care* issue includes a Commentary, authored by Drs. Cefalu, Francesco Rubino and David E. Cummings, along with 10 research reports and the Consensus Statement endorsed by the American Diabetes Association.

The new Guidelines emerged from the Second Diabetes Surgery Summit (DSS-II), an international consensus conference held September 28–30, 2015, in London, and jointly organized with the American Diabetes Association (ADA), International Diabetes Federation (IDF), Diabetes UK (DUK), Chinese Diabetes Society (CDS), and Diabetes India (DI). The goal of the Summit was to develop global guidelines to inform clinicians and policy makers about the benefits and limitations of metabolic surgery for type 2 diabetes.

In the report, metabolic surgery is defined as the use of gastrointestinal operations, originally designed to induce weight loss ("bariatric surgery"), with the primary intent to treat type 2 diabetes and obesity. These procedures remove parts of the stomach or reroute the small intestine. Many people who undergo metabolic surgery experience major improvements in glycemia, as well as a reduction in cardiovascular risk factors, making it a highly effective treatment for type 2 diabetes and a highly effective means of diabetes prevention.

"Despite continuing advances in diabetes pharmacotherapy, fewer than half of adults with type 2 diabetes mellitus (T2D) attain therapeutic goals designed to reduce long-term risks of complications, especially for glycemic control, and lifestyle interventions are disappointing in the long term," wrote the Guideline authors in the commentary. Metabolic surgery, on the other hand, has been shown to "improve glucose homeostasis more effectively than any known pharmaceutical or behavioral approach," they wrote. Despite such evidence, to date, metabolic surgery had not been included in clinical guidelines for diabetes care as a recommended intervention.

According to the new Guidelines, metabolic surgery should be recommended to treat type 2 diabetes in patients with Class III obesity (BMI greater than or equal to 40 kg/m²), as well as in those with Class II obesity (BMI between 35 and 39.9 kg/m²) when hyperglycemia is inadequately controlled by lifestyle and medical therapy. It should also be considered for

patients with type 2 diabetes who have a BMI between 30 and 34.9 kg/m² if hyperglycemia is inadequately controlled, the authors agreed. The Consensus Statement also recognizes that BMI thresholds in Asian patients, who develop type 2 diabetes at lower BMI than other populations, should be lowered 2.5 kg/m² for each of these categories.

These conclusions are based on a large body of evidence including 11 randomized clinical trials showing that in most cases surgery can either reduce blood sugar levels below diabetic thresholds ("diabetes remission") or maintain adequate glycemic control despite major reduction in medication usage. While relapse of hyperglycemia may occur in up to 50% of patients with initial remission, most patients maintain substantial improvement of A1C long term, the authors noted.

"Surgery represents a radical departure from conventional approaches to diabetes. The new Guidelines effectively introduce, both conceptually and practically, one of the biggest changes for diabetes care in modern times," said Dr. Francesco Rubino, a Professor of Metabolic and Bariatric Surgery at King's College London in the UK, co-director of the DSS-II and the first author of the report. "This change is supported by documented clinical efficacy and by the evidence of an important role of the gut in metabolic regulation, which makes it an appropriate target for anti-diabetes interventions," he added.

Economic studies also show that metabolic surgery is cost-effective. The authors of the new Guidelines recommend that health care regulators introduce appropriate reimbursement policies for metabolic surgery for people with type 2 diabetes.

Although metabolic surgery is similarly safe compared to commonly performed operations such as gallbladder surgery, there are still risks of complications and long-term nutritional deficiencies, which require lifelong vitamin/nutritional supplementation and rigorous long-term follow up by a multidisciplinary team with appropriate expertise. The report also identifies current gaps in knowledge and indicates priorities for research. In particular, long-

term studies looking at cardiovascular endpoints and other diabetes complications in less obese people and adolescents are necessary to better refine the role of surgery in management algorithms.

Ten articles in the special issue include a report on the status of the pandemic of diabetes and metabolic surgery issues; the role of the gut in glucose homeostasis; the mechanisms of diabetes improvement following bariatric surgery; clinical outcomes of bariatric surgery; ethnic considerations for metabolic surgery; barriers to appropriate utilization of surgery; and reports on the potential for using weight-loss surgery as a treatment for youth with type 2 diabetes, obese patients with type 1 diabetes and those with only mild obesity.

The full articles, consensus statement and commentary will be published online at http://care.diabetesjournals.org/content/current on May 24, 2016.

About the American Diabetes Association

The American Diabetes Association is leading the fight to Stop Diabetes® and its deadly consequences and is fighting for those affected by diabetes. The Association funds research to prevent, cure, and manage diabetes; delivers services to hundreds of communities; provides objective and credible information; and gives voice to those denied their rights because of diabetes. Founded in 1940, the Association's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. For more information, please call the American Diabetes Association at 1-800-DIABETES (1-800-342-2383) or visit diabetes.org. Information from both of these sources is available in English and Spanish.

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