

Bariatric/Metabolic Surgery for Diabetes: Incorporating a Powerful Treatment into Standard Care

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Type 2 diabetes (T2D) is one of the major clinical consequences of obesity and confers much of the risk for morbidity and mortality. The past three decades have seen an alarming increase in the prevalence of T2D, as well as expansion to previously unaffected populations such as adolescents and people living outside North America and Europe. Unfortunately, treatment for the majority of patients with diabetes remains suboptimal despite advances in basic and clinical research and steady gains in drug development. Notably, one of the key observations from recent clinical studies is the dramatic impact of surgical procedures such as gastric bypass and sleeve gastrectomy to remedy diabetes. In fact there is now ample evidence from randomized clinical trials (RCTs) that the effects of surgery on glucose regulation far outstrip what can be accomplished with aggressive medical therapy. However, at present there is not a generalized approach to incorporate surgery into standards of care for diabetes.

In September 2015, a group of clinicians and scientists with expertise in bariatric/metabolic surgery met in London for the second Diabetes Surgery Summit (DSS-II). This conference provided a forum to review current evidence and develop consensus around a set of conclusions and key questions to guide more effective use of surgery to treat diabetes. The full report of the expert panel is published in *Diabetes Care* (1), and the major conclusions of the conference are published in the *Executive Summary* (see Table 1). Given the accumulation of high-quality studies focused on metabolic surgery in recent years, this summary is timely and provides a useful platform supporting more widespread application of these highly effective procedures in patients with obesity and with T2D (2). Moreover, the development of this document also identified key gaps in knowledge that should be given priority in future research.

Perhaps the most fundamental conclusion from the DSS-II is that decisions on which patients are considered for surgery should be free from body mass index (BMI) criteria. The classification of obesity based solely on BMI does not reflect the differential susceptibility of patients to obesity-related pathology and so does not allow precision in predicting who will benefit from surgery. The role of visceral adiposity to cause insulin resistance in mild or moderate obesity and the identification of people with “metabolically healthy” obesity are well-established cases in point. In the studies so far reported, subjects across the spectrum of BMI had comparable improvement or resolution of diabetes following gastric bypass or sleeve gastrectomy. While subjects with BMI of 30 to 35 kg/m² are

under-represented in the current database of studies, based on available information there is no reason to think this group will be less responsive than people with a BMI >35 kg/m². In light of current evidence, yoking surgical eligibility of patients with diabetes to classes of obesity based on BMI is arbitrary and outdated.

While expanding the criteria for metabolic surgery in patients with diabetes to considerations beyond BMI seems obvious at this point, the conclusions of the DSS-II are vague with regard to patient selection. This uncertainty is common to other expert guidelines for diabetes care (3), in which surgery is listed as an option but not specifically incorporated into treatment algorithms. Which patients should be prioritized for metabolic surgery is a question that is difficult to answer given the current evidence. The progressive nature of T2D seems to be present in at least some patients who have surgery since mean remission rates wane over time, and good predictors as to which patients will have the greatest and most lasting effects of surgery are lacking. While an argument can be made to use bariatric procedures primarily for patients with poorly controlled diabetes—due to severity of disease, difficulty with medical compliance, or confounding comorbidities—it is possible that a surgical approach would ultimately be the most efficacious in persons with early, mild disease in whom remissions might be more permanent; patients with early diabetes might also be the group that would have the largest reduction of end-organ complications of diabetes. These are important questions for further investigation. On a population basis, economic analyses could provide important guidance as to the role of surgery in the diabetes care path; evidence in this area is emerging but still lags the studies demonstrating efficacy. Based on current evidence it seems incontrovertible that many more patients with diabetes could benefit from gastric bypass or sleeve gastrectomy than are receiving surgery. However, which patients are the most appropriate candidates and how to maximize the impact of present surgical capacity remain unknowns that limit optimal practice.

Another important limitation is the health care resources available for diabetes care. There is a dramatic undersupply of clinicians expert in diabetes care to address a disease that reaches prevalence rates of 10% and greater in many parts of the world. This shortage in personnel includes surgeons expert in metabolic surgery. In addition to shortages in experienced providers, it is clear that disparities in access to other essentials of diabetes care—diagnostic and testing supplies, medications, healthful foods—also prevent many patients from reaching the level of treatment that is possible. Access to

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TABLE 1 Executive summary

- T2D is associated with complex metabolic dysfunctions, leading to increased morbidity, mortality, and cost. Although population-based efforts through lifestyle interventions are essential to prevent obesity and diabetes, people who develop this disease should have access to all effective treatment options.
- Given its role in metabolic regulation, the gastrointestinal (GI) tract constitutes a clinically and biologically meaningful target for the management of T2D.
- A substantial body of evidence has accumulated, including numerous, albeit mostly short/mid-term RCTs, demonstrating that metabolic surgery—defined here as the use of GI surgery with the intent to treat T2D and obesity—can achieve excellent control of hyperglycemia and reduce cardiovascular risk factors.
- Although additional studies are needed to further demonstrate long-term benefits, there is now sufficient clinical and mechanistic evidence to support inclusion of metabolic surgery among antidiabetes interventions for people with T2D and obesity.
- Complementary criteria to the sole use of BMI, the traditional criterion used to select candidates for bariatric surgery, need to be developed to achieve a better patient selection algorithm for metabolic surgery.
- Metabolic surgery should be a *recommended* option to treat T2D in appropriate surgical candidates with class III obesity (BMI ≥ 40 kg/m²), regardless of the level of glycemic control or complexity of glucose-lowering regimens, as well as in patients with class II obesity (BMI 35.0–39.9 kg/m²) with inadequately controlled hyperglycemia despite lifestyle and optimal medical therapy.
- Metabolic surgery should also be *considered* to be an option to treat T2D in patients with class I obesity (BMI 30.0–34.9 kg/m²) and inadequately controlled hyperglycemia despite optimal medical treatment by either oral or injectable medications (including insulin).
- All BMI thresholds should be reconsidered depending on the ancestry of the patient. For example, for patients of Asian descent, the BMI values above should be reduced by 2.5 kg/m².
- Metabolic surgery should be performed in high-volume centers with multidisciplinary teams that understand and are experienced in the management of diabetes and GI surgery.
- Ongoing and long-term monitoring of micronutrient status, nutritional supplementation, and support must be provided to patients after surgery, according to guidelines for postoperative management of bariatric/metabolic surgery by national and international professional societies.
- Metabolic surgery is a potentially cost-effective treatment option in obese patients with T2D. The clinical community should work together with health care regulators to recognize metabolic surgery as an appropriate intervention for T2D in people with obesity and to introduce appropriate reimbursement policies.

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surgery must be considered among these barriers, with inconstant and variable reimbursement for metabolic surgery by health care insurers and other payers a recurrent problem.

The issue of safety is a concern often voiced when greater use of surgery is proposed. The perioperative and short-term complications of surgery have steadily declined with the use of laparoscopic techniques and the concentration of procedures in high-volume centers with multidisciplinary teams expert in metabolic surgery (4). In these centers of excellence, short-term morbidity and mortality are comparable with other common abdominal surgeries such as cholecystectomy and colectomy. Progress in identifying and treating long-term complications is not as refined, although understanding of the surgical and nutritional problems that can emerge after gastric bypass is improving (5-7). What is important is that patients with diabetes treated with metabolic surgery be managed in a chronic care model similar to those receiving medical treatment of diabetes, with regular evaluation and monitoring even of patients who have remissions or other favorable outcomes. By designating metabolic surgery as a highly effective but not curative or final therapy, the need for long-term follow-up can be reinforced and ingrained into practice.

The conclusions of the DSS-II panel provide firm footing on which to advance metabolic surgery into routine treatment of patients with diabetes. While knowledge gaps exist, it is important that surgery be an option for appropriate patients. At present this group should include patients with obesity with persistently uncontrolled hyperglycemia and not be limited by BMI criteria. The presence of other comorbidities that are amenable to bariatric surgery, such as degenerative joint disease, cardiorespiratory problems, and nonalcoholic fatty liver disease, would add impetus to send a patient with diabetes for surgery. Health policy and resource allocation directed at optimizing diabetes care should include support for surgery along with medical and behavioral approaches. **O**

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