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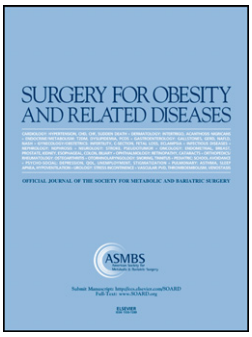

The IDF Position Statement on Bariatric Surgery for Type 2 Diabetes: Implications for Patients, Physicians and Surgeons

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Editorial

The IDF Position Statement on Bariatric Surgery for Type 2 Diabetes: Implications for Patients, Physicians and Surgeons

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F. Rubino:

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Drs Schauer and Rubino were both members of the expert panel for the IDF consensus meeting

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The International Diabetes Federation (IDF) Position Statement on bariatric surgery co-published in this month's issue of *Surgery for Obesity and Related Diseases (SOARD*) and other obesity, endocrine and diabetes journals is a major step forward in global recognition of metabolic surgery as specific treatment of diabetes, not just obesity. Surgeons, internists, diabetologists, primary care physicians and other health care providers who manage patients with diabetes should carefully read this document as it provides very important, practical, evidenced based recommendations on how to best utilize surgery for treating type 2 diabetes mellitus (T2DM). It is the most comprehensive position statement or guideline yet published.

What is the International Diabetes Federation?

The IDF www.idf.org , founded in 1950, is an umbrella organization of over 200 national diabetes associations in over 160 countries.. with the mission to promote diabetes care, prevention and a cure worldwide. The Federation's activities aim to influence policy, increase public awareness and provide education for people with diabetes and their healthcare providers. The IDF is associated with the Department of Public Information of the United Nations and has official relations with the World Health Organization (WHO) and the Pan American Health Organization (PAHO). Developing position statements and guidelines on various aspects of diabetes management, such as the one published this month in SOARD, is in line with the IDF's mission to educate health care providers and patients regarding advances in treatment.

How did this Position Statement come about?

Although observations that bariatric operations can dramatically improve diabetes can be traced back to the 1950's, not much attention was given to this rather remarkable finding until the late 1980's when investigators such as Pories et al. reported reproducible results in large series of

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patients.[1] Over the next 2 decades multiple studies reported very powerful treatment effects of bariatric procedures with remission rates of diabetes as high as 80% for gastric bypass, 50% for restrictive operations (banding, vertical banded gastroplasty), and even >95% for biliopancreatic diversion. Yet, diabetes specialists seemed to be either unimpressed or skeptical perhaps due to the fact that most of the studies were published almost exclusively in the surgical literature and were not prospective, randomized, controlled trials. Throughout the 1990's and the first decade of the new millennium, none of the major diabetes scientific professional societies, mentioned any role for bariatric surgery in their diabetes guidelines. Recent investigations on the mechanism of action of gastrointestinal procedures and the knowledge that the anti-diabetic effects of certain operations are at least in part independent of weight loss have advanced the hypothesis that bariatric operations may be considered as a specific treatment for diabetes and sparked the interest of physicians and scientists for the emerging field of metabolic surgery [2]. In 2007, for the first time in history, a diverse panel of more than 50 international experts, representing many medical specialties including diabetology, surgery, gastroenterology, and cardiology, met in Rome, Italy to develop the first consensus statements regarding the role of gastrointestinal surgery to treat T2DM. This conference, known as the Diabetes Surgery Summit (DSS), resulted in the first published recommendations on the use and study of diabetes surgery.[3] Shortly thereafter in 2009, the ADA, became the first major national diabetes organization to recognize the role of surgery for treating diabetes, especially in patients with severe obesity (BMI > 35 kg/m^2)[4]. The ADA statement on bariatric surgery, however, was relatively brief, comprising only 2 pages of a 200-page annual diabetes guideline. In order to provide a more comprehensive and global perspective on the role of bariatric surgery for diabetes, the IDF set out to create the detailed position statement now published in *SOARD*.

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How was the IDF Consensus Panel Organized?

The IDF initiative was coordinated by the IDF Task Force on Epidemiology and Prevention, chaired by Professors Paul Zimmet (Australia) and George Alberti (UK).. The consensus panel was convened by four internationally recognized experts (Paul Zimmet, MD, George Alberti MD, John Dixon, MD and Francesco Rubino, MD) in diabetes, obesity and surgery and included 20 leading experts representing diabetology (10), internal medicine (3), pediatrics (1) and metabolic surgery (6), from all continents of the world. The consensus panel reviewed key studies from the literature (> 100) regarding outcomes of medical and surgical management of T2DM.[4] The panel met for a 2-day conference at the IDF headquarters in Belgium in December, 2010 to discuss, debate and ultimately develop evidence-based consensus on key issues related to metabolic surgery for diabetes treatment. Some of the discussion topics included the link between obesity and diabetes, relative outcomes of medical vs. surgery treatment, relative risks of surgery, nutritional management after surgery, cost-effectiveness of surgery, access to surgical treatment, requirements for bariatric centers, surgery for adolescents, and novel surgical procedures. The discussions were quite lively, respectful, and frankly interesting as panelist shared knowledge that is uncommonly shared among physicians and surgeons from traditionally distinct disciplines. The goals of such discussions were: to develop practical recommendations for practicing physicians and national organizations, to identify barriers to surgical access, suggest policy changes to ensure equitable access to surgery when indicated and identify priorities for research.

Following the meeting in Brussels, the consensus recommendations of the expert panel were included in a document that underwent further review and approval by the executive board of the

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IDF, ultimately generating an official Position Statement from the organization. This statement was publicly presented in a dedicated session during the recent 2nd World Congress on Interventional Therapies for Type 2 Diabetes (New York City, March 28, 2011)

The Key points of the Position Statement

The IDF expert panel reviewed data related to both conventional, standard bariatric operations as well as novel interventional procedures. For severely obese (BMI >35 kg/m^2) diabetic patients the following standard procedures were considered in the clinical recommendations of the IDF statement: gastric banding, sleeve gastrectomy, gastric bypass, biliopancreatic diversion and duodenal switch. There was general agreement that while novel surgical procedures (i.e. Duodenal Jejunal Bypass and Ileal Interposition) and GI device interventions (i.e. endoluminal procedures and electrophysiologic interventions) represent interesting and promising approaches for the treatment of diabetes and obesity, their clinical use should still be considered investigational. Since very few comparative studies have been conducted comparing surgical procedures head to head, the expert panel did not make specific recommendations on specific procedures and called for RCT studies as an important research priority.

In agreement with the DSS and ADA position statements/guidelines the IDF document states that "Bariatric surgery is an appropriate treatment for people with type 2 diabetes and severe obesity (BMI equal to or greater than 35 kg/m^2)." The IDF statement goes one step further by pronouncing that surgery "should be prioritized for severely obese patients (BMI > 35 kg/m^2) with T2DM" as opposed to suggesting that it is merely "an option". This prioritization for surgery (i.e. surgery should be an accepted option) stems from the fact that severely obese

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patients are often refractory to conventional therapy with insulin and oral agents due to severe insulin resistance.

The IDF statement agrees with the DSS recommendation that " under some circumstances people with a BMI 30-35 kg/m^2 should be considered for surgery". Such circumstances include HbA1c greater than 7.5% despite fully optimized conventional therapy, especially if weight is increasing, or in the presence of other weight responsive co-morbidities not achieving targets on conventional therapies (i.e. blood pressure, dyslipidemia and obstructive sleep apnea). .

For Asian and some other ethnicities of increased risk, BMI action points for surgery may be lower (eg. 27. 5kg/m^2 to 32.5 kg/m^2) according to the IDF statement..

The IDF statement encourages a wiser use of BMI in the selection of surgical candidates, recognizing the limitations of this parameter and its variability with age, gender and ethnicity.

The IDF statement also recommends that surgery should be integrated as a treatment option in the algorithm of diabetes management, along with lifestyle modifications and pharmacologic therapy . This is a real and practical step forward since none of the professional diabetes organizations such as ADA, AACE, or EASD has yet incorporated surgery into their standard treatment algorithms.

The IDF position statement also recommends that diabetes-specific parameters be systematically measured in order to obtain a proper preoperative characterization of the disease as well as reliable and reproducible measures of postoperative outcomes. In addition to anthropometric measures, diabetes measures should include HbA1c, fasting glucose and insulin, retinopathy status, test for microalbuminuria, lipid profile, documentation of medications, as well as fasting C-peptide and auto-antibody (e.g. anti-GAD) where available.

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Why is the IDF statement a "game changer" in bariatric/metabolic surgery?

The formal recognition of surgery as a valuable option for diabetes by an authoritative organization such as the IDF will hopefully influence national diabetes societies and thousands of physicians worldwide.

In fact, the IDF Position Statement places the role of bariatric interventions, for the first time, into a public health, clinical and socio-economic perspective. This will predictably increase awareness of diabetes surgery among the medical community and the public at large.

The IDF recommendations have both conceptual and practical ramifications. First, they emphasize that a surgical approach should be considered earlier in the treatment of type 2 diabetes and no longer be seen as a last resort. Furthermore, the distinction between conditions of eligibility for surgery vs. conditions when surgery is recommended allows a rational approach to prioritize access to surgical treatment until further data allow the identification of more reliable predictors of risk/benefit profile, especially in patients with lower BMI levels.

An important merit of the IDF position statement is the introduction of clinical considerations for patient selection recognizing the relevance of disease stage and cardiovascular (CV) risk rather than BMI alone. In particular, the IDF document suggests that bariatric surgery may be a reasonable option for patients who are not achieving recommended treatment targets with medical therapy, especially where there are other obesity related co-morbidities that increase CV risk. This is an important element of novelty that introduce more clinically meaningful criteria

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for patients selection, whereas so far indication for bariatric surgery has been based on rigid and absolute BMI cutoffs, an approach that has almost no equivalent in other field of surgery.

For the first time, the IDF statement recognizes that BMI action points for surgery should be lower for certain ethnicities. Previous guidelines based on strict BMI cutoffs did not recognize the significant differences in BMI-associated health risk among ethnic groups, creating a potential barrier for equitable access to surgery,

The recognition that the surgical approach to diabetes should be recommended and prioritized in certain circumstances (i.e. BMI >35kg/m^2, uncontrolled hyperglycemia, weight gain and substantial CV risk) is a fundamental shift from previous guidelines that considered the above circumstances as a condition of simple eligibility for bariatric surgery. This is not a semantic difference and will hopefully increase access to surgery from the current <2% of eligible patients to a more "physiologic" figure, as appropriate for a treatment option that is both life-saving and cost-effective. With most insurance carriers and national health systems already covering bariatric surgery for patients with BMI greater than 35 kg/m^2, the IDF Position Statement can have an immediate impact and ensure that more patients will be able to benefit from bariatric/metabolic surgery.

Barriers to surgical access are not limited to lack of insurance coverage. Lack of awareness, the stigma and discrimination against obesity, misperceptions regarding the safety of bariatric surgery are still very pervasive in the medical community and among the public at large. Hopefully, the IDF statement will help develop the field in a more rational and less "emotional" way.

The recommendation that surgery should be considered early in the management of diabetes and,

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even more, the call for a formal inclusion of surgery in the algorithm of diabetes management have practical implications for endocrinologists, family physicians and health care providers involved in the management of diabetic patients. As of today referral for bariatric surgery is rarely the result of counseling with primary care physicians or diabetes specialists; when this happens, it is usually in response to specific requests from patients who are often self-referred or self informed.

Physicians and endocrinologists, with individual exceptions, do not usually consider surgery as an option for a patient that is seeking medical attention for T2DM, regardless of their BMI level. Plainly, measuring BMI as a criterion to decide which treatment strategy to pursue is not a standard practice in most medical offices.

The IDF position statement implies that diabetes specialists and family physicians recognize surgery as one of the legitimate options in the armamentarium of therapies forT2DM. Patients from now on should be informed and appropriately counseled about surgical treatment of diabetes. The inclusion of interventional therapies in the algorithm of diabetes management will allow physicians to escalate treatment according to disease stage and severity.

How should surgeons respond to the IDF statement?

The IDF Statement is a much needed guide for surgical treatment of diabetes. First, based on the evidence available, the document appears to be reasonable and fair, neither overstating or understating, the current role of surgery. It is comprehensive and should be applicable to diverse international environments. As any position statement, it is based on available evidence and will

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evolve as new data become available. Therefore, in our opinion, surgeons should adopt this position statement and follow it without overreaching its boundaries. For example, in this phase surgeons should recognize the experimental nature of a surgical approach to diabetes in non-obese patients (BMI <30 kg/m^2) and pursue rigorous clinical trials in this patient population. Likewise, if an obese patient with T2DM is well controlled with conventional medical treatment (HbA1c < 7.0%), then there currently is insufficient evidence to recommend surgery to treat diabetes, given the inherent risks. Secondly, surgeons should not only follow the IDF recommendations but should share them and use them to educate primary care physicians, internists, endocrinologists as well as patients about the current role of surgery for treating T2DM. Most importantly, surgeons should share the IDF document with the decision makers of third party payers both public and private. We cannot forget that still many health insurance polices will not cover bariatric surgery regardless of BMI or diabetes status.

The concept of "diabetes surgery" is often mistakenly defined as novel procedures to treat diabetes in patients with low BMI levels (as opposed to bariatric surgery intended as conventional operations performed in patients with BMI >35 kg/m^2).

In fact, "diabetes surgery" should not be considered merely as a treatment of diabetes in non-obese patients or as a set of novel, yet experimental interventions. For instance, gastric cancer surgery is not defined by what surgical procedure is used (i.e. the same operations may be used for benign gastric conditions), but by the disease that one intends to treat. Likewise, when the goal of surgical treatment is to improve diabetes and not only causing weight loss, the term diabetes surgery defines the approach more properly than bariatric surgery. Hence, using a conventional procedure (i.e. RYGB) to treat diabetes in patients with BMI greater than 40 kg/m^2

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is, by all means, "diabetes surgery". Surgeons who want to practice metabolic and diabetes surgery should recognize the need to develop specific clinical expertise, understand the disease process, appreciate the distinct mechanisms of action of various surgical procedures and make appropriate adjustments in the preoperative evaluation of patients as well as in their postoperative management. Appropriate outcome measures cannot be limited to a quantification of excess weight loss but require measurement of diabetes-specific outcomes. The IDF statement provides guidance in this sense and indicates a number of standard measures to test and report.

What's Next?

It usually takes many years, sometimes decades, before new, effective treatments become widely adopted. We surgeons should not forget that diabetes has been the quintessential "medical disease" managed with shots and pills for nearly a century since the discovery of insulin (by Nobel laureate surgeons, Banting and Best) in 1920. Radical changes in treatment strategies take time for acceptance. The IDF position statement on surgical treatment for type 2 diabetes is an important step toward implementation of surgery in standard of care practice and will hopefully guide regional organizations and policy makers in establishing appropriate national policies to ensure equitable access to surgery when indicated. Further research is necessary to advance diabetes surgery and define more precise criteria for surgical indications and the exact role of specific surgical procedures. In defense of those who believe that the evidence to support surgery is soft, it is true that few RCT's comparing surgery to conventional treatment have been conducted. However, based on current trial listings on clinicaltrials.gov, in the next 2-3 years a

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half dozen RCT's should come to publication. These results should provide us with a better understanding of relative effectiveness of surgery compared to medical treatment and which procedure may be best for different patient conditions. In the mean time we should foster investigation and let science be the driver. Encouragingly, other diabetes organizations such as the Endocrine Society, AACE, and EASD, Diabetes UK are contemplating guidelines for diabetes surgery. This means every one is thinking about diabetes surgery. And that's a good thing. We will let the data do the talking.

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