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Diabetes Surgery Summit Consensus Lays Foundation for New Field of Medicine

Consensus Statement Recognizes the Legitimacy of Surgery as a Dedicated Treatment for Type 2 Diabetes in Carefully Selected Patients

NEW YORK (Nov. 23, 2009) — A first-of-its-kind consensus statement on diabetes surgery is published online today in the *Annals of Surgery*. The report illustrates the findings of the first international consensus conference — Diabetes Surgery Summit (DSS) — where an international group of more than 50 scientific and medical experts agreed on a set of evidence-based guidelines and definitions that are meant to guide the use and study of gastrointestinal surgery to treat type 2 diabetes. The document is considered to be the foundation of diabetes surgery as a medical discipline of its own.

The Diabetes Surgery Summit was held at the Catholic University of Rome, Italy, under the auspices of 22 international medical and scientific organizations, notably including the American Diabetes Association, the American Society for Metabolic and Bariatric Surgery, Diabetes United Kingdom, The Obesity Society and the European Association for the Study of Diabetes. A draft of the DSS consensus statement was critically reviewed by official representatives of these organizations during the recent 1st World Congress on Interventional Therapies for Type 2 Diabetes, held in New York City and organized by NewYork-Presbyterian Hospital/Weill Cornell Medical Center.

At present, bariatric surgery is only available as a treatment for severe obesity, defined as having a body mass index (BMI) of 35 kg/m² or more, according to National Institutes of Health (NIH) guidelines established in 1991. The DSS consensus statement

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acknowledges that the cutoff is arbitrary and not supported by scientific evidence, and recognizes the need to use more appropriate criteria for surgery in patients with diabetes.

“With an emphasis on caution and patient safety, the DSS position statement boldly advances a revolutionary concept: the legitimacy of gastrointestinal surgery as a dedicated treatment for type 2 diabetes in carefully selected patients,” explains lead author Dr. Francesco Rubino, director of the gastrointestinal metabolic surgery program at NewYork-Presbyterian Hospital/Weill Cornell Medical College and associate professor of surgery at Weill Cornell Medical College. “The recommendations from the Diabetes Surgery Summit are an opportunity to improve access to surgical options supported by sound evidence, while also preventing harm from inappropriate use of unproven procedures.”

The article in the *Annals of Surgery*, co-authored by the DSS organizers on behalf of 50 voting delegates, summarizes the mounting body of evidence showing that bariatric surgery effectively reverses type 2 diabetes in a high proportion of morbidly obese patients, sometimes within weeks or even days, well before these patients have lost a significant amount of body weight.

Dr. Rubino’s experimental studies demonstrated that gastric bypass surgery can improve type 2 diabetes through direct anti-diabetic mechanisms and not solely as a result of weight loss, a finding that has been corroborated by other researchers with both experimental and human investigations. Based on these data, the 50 international delegates of the Rome summit achieved strong consensus that certain intestinal bypass operations engage anti-diabetes mechanisms beyond those related to reduced food intake and body weight.

“This and the remarkable clinical efficacy of gastrointestinal surgery justify considering it as a specific diabetes intervention, rather than viewing diabetes remission merely as a collateral effect of weight-loss surgery,” says Dr. David E. Cummings, a leading endocrinologist at the Diabetes & Obesity Center of Excellence of the University of Washington in Seattle and senior author of the consensus document. “That understanding may also usher in a new era of drug discovery and development based on the identification of the metabolic pathways and mechanisms that drive the disease.”

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“The diabetes surgery consensus statement, together with the combined American Diabetes Association/European Association for the Study of Obesity guidelines for treating diabetes published in January 2009, are major steps forward toward leading diabetes experts in recognizing the important role that surgery may play in the treatment of diabetes,” says Dr. Philip R. Schauer of the Bariatric and Metabolic Institute, Lerner College of Medicine, Cleveland Clinic, another co-author of the report.

The NIH has already responded to the document’s call for research, issuing several recent Requests for Applications for projects focusing on the effects of gastrointestinal surgery on diabetes, including in patients with a BMI as low as 30 kg/m² (i.e., with only mild obesity).

“That’s in line with the recommendations of the Rome summit,” says co-author Dr. Lee M. Kaplan of the Boston Obesity and Nutrition Research Center, Harvard Medical School, Massachusetts General Hospital. “Understanding the mechanisms of action of surgery on diabetes is a unique opportunity to advance the treatment of the disease.”

“In the United States, type 2 diabetes is a leading cause of death and the number-one cause of blindness, kidney failure and amputation,” Dr. Cummings says. “It is also alarmingly on the rise worldwide, creating an increasing economic burden on both developed and developing countries. Given the global epidemic growth of diabetes and the relevance of ethnic and socio-economic aspects for diabetes surgery, geographical criteria were considered in the selection of delegates to ensure appropriate representation of regional issues.”

“Prevention will always be the best strategy to approach the global epidemic of diabetes,” says Dr. Rubino. “But gastrointestinal surgery promises to be an important addition to the armamentarium of available treatments, and its study may also allow us to understand the disease mechanism in depth. We can only prevent what we truly understand.”

The BMI Debate

In its position statement, the Diabetes Surgery Summit states: “Surgery should be considered for the treatment of type 2 diabetes” in patients with a BMI of 35 or more “who are inadequately controlled by lifestyle and medical therapy.” The statement goes

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on to state that diabetes surgery may also be appropriate for treatment of people with type 2 diabetes and merely mild-to-moderate obesity (BMI 30-35). This goes beyond parameters established by the NIH for bariatric surgery in 1991, which reserved bariatric surgery for people with a BMI of 35 or more with an obesity-related condition, or a BMI of 40 or more with or without any obesity-related condition. These parameters are still adhered to by most insurance companies in determining coverage of the surgery.

“The science of diabetes, obesity and surgery has significantly advanced since 1991, and the evidence suggests that a precise BMI cut-off of 35 is not a good predictor of whether or not surgery will induce diabetes remission or improvement,” Dr. Schauer says.

Dr. Rubino explains that BMI is an inadequate measure as a stand-alone criterion for patient selection:

“Once a patient has full-blown diabetes, BMI can’t accurately predict that patient’s cardiovascular risk, much less who will and won’t be likely to benefit from surgery. It simply doesn’t make sense to offer the surgical option to a patient with a BMI of 35 and deny it to one with a BMI of 34, especially if the latter patient has more severe diabetes. The health risks associated with a BMI of 35 may vary, too, with gender, race and ethnicity, compounding its inadequacy as a parameter for patient selection. High up on our research agenda is the search for new eligibility criteria that should be based on diabetes-specific metrics, and include patient’s history, metabolic profile and disease severity.”

A Multidisciplinary Effort

The DSS consensus document emphasizes the importance of multidisciplinary approaches to guide the development of the discipline of diabetes surgery from the outset. A specific recommendation of the Diabetes Surgery Summit called for the establishment of a multidisciplinary, international taskforce that includes endocrinologists, surgeons, clinical and basic investigators and bioethicists, among others. The International Diabetes Surgery Taskforce has been established as a nonprofit organization that will cooperate with existing professional societies, government agencies and patient advocacy groups in order to expand and disseminate evidence-based knowledge of diabetes surgery.

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In recognition of the importance of the new recommendations, several respected medical and surgical associations have already endorsed the DSS position statement. These organizations include The Obesity Society, Diabetes United Kingdom, the International Association for the Study of Obesity, the American Association for Bariatric and Metabolic Surgery, the International Federation for the Surgery of Obesity and Metabolic Diseases, and the Brazilian Society for Bariatric and Metabolic Surgery. Other groups and societies are expected to follow suit.

For more information, call (866) NYP-NEWS.

Diabetes Surgery Summit

On March 29 to 31, 2007, an international, multidisciplinary group of experts representing endocrinologists, gastroenterologists, diabetologists, surgeons, epidemiologists, clinical-trial design experts, and basic science investigators gathered at the Catholic University in Rome, Italy, to review the scientific evidence regarding the safety and efficacy of bariatric surgery to treat type 2 diabetes and to develop a diabetes surgery summit position statement. Approximately 400 people from 27 countries on 6 continents participated. Fifty voting delegates weighed the evidence and developed the position statement during and subsequent to the summit. Dr. Rubino conceived the idea of the DSS. Drs. Rubino, Kaplan, Schauer, and Cummings served as co-directors of the DSS and equally participated in the planning and execution of the conference. They have co-authored the report for the Annals of Surgery on behalf of the 50 voting DSS delegates. The Diabetes Surgery Summit was supported by generous grants from Covidien, Ethicon, Allergan, Storz, GI Dynamics, Roche, Amylin, and Power Medical Interventions. The sponsors had no role in any aspect of the conference organization, the selection of voting delegates, or the generation of consensus statements. They have not influenced the analysis of the findings, the preparation of the manuscript, or its content.

The International Diabetes Surgery Taskforce (IDSTF)

The IDSTF was created as a nonprofit organization of 20 members, representing diverse expertise in diabetes, obesity, surgery, gastroenterology, and clinical-trials development. The taskforce promotes DSS recommendations, collaborating with professional societies to expand and disseminate evidence-based knowledge of diabetes surgery.

NewYork-Presbyterian Hospital/Weill Cornell Medical Center

NewYork-Presbyterian Hospital/Weill Cornell Medical Center, located in New York City, is one of the leading academic medical centers in the world, comprising the teaching hospital NewYork-Presbyterian and Weill Cornell Medical College, the medical school of Cornell University. NewYork-Presbyterian/Weill Cornell provides state-of-the-art inpatient, ambulatory and preventive care in all areas of medicine, and is committed to excellence in patient care, education, research and community service. Weill Cornell

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physician-scientists have been responsible for many medical advances — including the development of the Pap test for cervical cancer; the synthesis of penicillin; the first successful embryo-biopsy pregnancy and birth in the U.S.; the first clinical trial for gene therapy for Parkinson’s disease; the first indication of bone marrow’s critical role in tumor growth; and, most recently, the world’s first successful use of deep brain stimulation to treat a minimally conscious brain-injured patient. NewYork-Presbyterian Hospital also comprises NewYork-Presbyterian Hospital/Columbia University Medical Center, NewYork-Presbyterian Morgan Stanley Children’s Hospital, NewYork-Presbyterian Hospital/Westchester Division and NewYork-Presbyterian Hospital/The Allen Hospital. NewYork-Presbyterian is the #1 hospital in the New York metropolitan area and is consistently ranked among the best academic medical institutions in the nation, according to U.S.News & World Report. Weill Cornell Medical College is the first U.S. medical college to offer a medical degree overseas and maintains a strong global presence in Austria, Brazil, Haiti, Tanzania, Turkey and Qatar. For more information, visit www.nyp.org and www.med.cornell.edu.

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