



ASMBS

American Society for Metabolic & Bariatric Surgery

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GROWING CONSENSUS FOR ‘DIABETES SURGERY’

International Task Force Endorses Diabetes Surgery for Morbidly Obese Patients, Strongly Calls for Research into Use of Surgery in Non-Obese to Stem Diabetes Epidemic

GAINESVILLE, FL – November 23, 2009 – With a diabetes and obesity epidemic spiraling out of control and a growing amount of research on the topic, an international group of 50 scientific and medical experts joined the chorus of medical societies endorsing diabetes surgery to treat type 2 diabetes in morbidly obese patients, but went further in saying the surgery may also be appropriate to treat diabetes in the mildly to moderately obese population.

The first international Diabetes Surgery Summit published its findings and recommendations on diabetes surgery today in the online edition of *Annals of Surgery*. Diabetes surgery encompasses conventional bariatric or metabolic surgery including gastric bypass, gastric banding and biliopancreatic diversion (BPD).

Twenty-two medical and scientific organizations including the American Society for Metabolic and Bariatric Surgery (ASMBS), The Obesity Society and the American Diabetes Association (ADA) endorsed the summit held at Catholic University of Rome, Italy and at time of publication six professional societies including the ASMBS, have endorsed the recommendations.

“With surgery, we're not only treating diabetes. In many cases, we are putting it into remission,” said John Baker, MD, president of ASMBS. “However, surgery is not for everyone, and these recommendations help better define which operations work for which patients and where we still don't have the evidence to draw a conclusion.”

In its position statement, the Diabetes Surgery Summit says "surgery should be considered for the treatment of type 2 diabetes" in patients with a body mass index (BMI) of 35 kg/m² or more "who are inadequately controlled by lifestyle and medical therapy." People with a BMI of 35 kg/m² or more are typically at least 75 to 80 pounds overweight and have medical condition known as morbid obesity.

The statement also went on to say that diabetes surgery may also be appropriate for treatment of people with mild to moderate obesity (BMI 30-35 kg/m²), which goes beyond parameters established by the National Institutes of Health (NIH) for bariatric surgery in 1991. In its recommendations, the NIH limited bariatric surgery to people with a BMI of 35 kg/m² or more and an obesity-related condition or a BMI of 40 kg/m² or more with or without an obesity-related condition. Almost 20 years later, these parameters are still adhered to by most insurance companies in determining coverage of the surgery.

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"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," said Phillip R. Schauer, MD, one of the authors of the position statement and Professor of Surgery at the Cleveland Clinic Lerner College of Medicine and Director of the Cleveland Clinic Bariatric and Metabolic Institute. "The evidence isn't there yet to say surgery should be performed on non-obese patients with diabetes, but there is new evidence to suggest that certain procedures can work for people with lower BMIs, with low rates of complications and mortality in the short- to mid-term."

In addition to the ASMBS, Diabetes United Kingdom, International Association for the Study of Obesity, International Federation for the Surgery of Obesity and Metabolic Diseases, the Brazilian Society for Bariatric and Metabolic Surgery, and The Obesity Society have each endorsed the diabetes surgery position statements. Other groups and societies are expected to follow suit.

According to the ASMBS, about 220,000 bariatric or metabolic procedures were performed last year in the U.S. The ADA reports 23.6 million children and adults or 7.8 percent of the U.S. population have diabetes and another 57 million have pre-diabetes. The World Health Organization estimates that 220 million people worldwide have diabetes with 90 percent affected by type 2 diabetes.

Earlier this year, the ADA issued its own widely followed annual recommendations on diabetes treatments, where it bolstered its section on bariatric surgery saying "bariatric surgery should be considered for adults with BMI ≥ 35 and type 2 diabetes" and that "rates of morbidity and mortality directly related to the surgery have been reduced considerably in recent years" with 30-day mortality rates similar to those of laparoscopic gallbladder surgery. The ADA fell short of a general recommendation on surgery for those with a BMI of less than 35, but did support the use of surgery in these patients if done under a research protocol.

The Diabetes Surgery Summit position statement said novel and emerging surgical techniques including sleeve gastrectomy, duodenal-jejunal bypass operations and endoluminal sleeves show promising results for the treatment of diabetes, but should only be used in Institutional Review Board (IRB)-approved and registered trials.

"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," lead author Dr. Francesco Rubino, director of the gastrointestinal metabolic surgery program at New York-Presbyterian Hospital/Weill Cornell Medical Center and associate professor of surgery at Weill Cornell Medical College.

The group also called for more research on the non-morbidly obese population in the form of randomized controlled clinical trials and the development of standards for measuring clinical and physiological outcomes of diabetes surgery to further improve the quality of medical evidence and help in clinical decision-making.

A 2009 study published in the *American Journal of Medicine* found that 86.6 percent of patients improved or resolved their Type 2 diabetes after bariatric surgery. In 2008, a *Journal of the American Medical Association (JAMA)* study found that 73 percent of gastric band patients resolved their Type 2 diabetes after surgery and a 2004 *JAMA* study showed diabetes resolved in 76.8 percent of patients.

One of the first studies demonstrating the effect of bariatric surgery on Type 2 diabetes appeared 15 years ago in the *Annals of Surgery*, the same journal that published today's findings. Walter Pories, MD, a bariatric surgeon at East Carolina University in Greenville, N.C. and other researchers, in a paper entitled, "Who Would Have Thought It?...", reported that gastric bypass patients not only experienced significant weight loss, but that 83 percent of the patients with diabetes had normal blood sugar control after 14 years.

About the Diabetes Surgery Summit

From March 29 - 31, 2007, an international multidisciplinary group of experts representing endocrinologists, gastroenterologists, diabetologists, surgeons, epidemiologists, clinical trial design experts and basic-science investigators gathered in Rome to review the scientific evidence regarding the safety and efficacy of gastrointestinal surgery to treat Type 2 diabetes and to develop the Diabetes Surgery Summit Position Statement. In total, approximately 400 people from 27 countries on 6 continents participated. Fifty voting delegates weighed the evidence and developed the position statement subsequent to the summit. The Diabetes Surgery Summit was supported by grants from Covidien, Ethicon Endo-Surgery, 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.

About ASMBS

The ASMBS is the largest organization for bariatric surgeons in the world. It is a non-profit organization that works to advance the art and science of bariatric surgery and is committed to educating medical professionals and the lay public about bariatric surgery as an option for the treatment of morbid obesity, as well as the associated risks and benefits. It encourages its members to investigate and discover new advances in bariatric surgery, while maintaining a steady exchange of experiences and ideas that may lead to improved surgical outcomes for morbidly obese patients. For more information about the ASMBS, visit www.asmb.org. To view the Consensus please visit

http://www.asmb.org/Newsite07/resources/DSS_Consensus%20Annals_Final.pdf