Symposium on Surgery For Diabetes Sparks Debate
World Congress Sought Consensus Among Specialties

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New York—Tempers flared and no consensus was reached regarding the support of new guidelines, but leading surgeons, endocrinologists and health officials struggling to find common ground on surgical approaches to treating type 2 diabetes concluded a historic meeting here with widespread agreement on the need for major clinical trials to move the field forward.

“We've heard some compelling evidence for the need for a clinical trial,” said Judith Fradken, MD, director of the Division of Diabetes, Endocrinology and Metabolic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Bethesda, Md. “We at NIDDK would be interested in working with this community to see how that might be developed.”

Even while declining to support for now any new, more aggressive guidelines on the use of bariatric procedures specifically to treat diabetes, officials of both the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) threw their support behind continued research.

“We enthusiastically endorse continued research in this area,” said Jeffrey Mechanick, MD, a member of the board of directors of the AACE. “But at the present time, we as a society are unable to endorse setting guidelines for any procedures outside the framework of research.”

Sue Kirkman, MD, vice president for clinical affairs at the ADA, said much the same, explaining, “Yes, we as an association are conservative, we are slow to change. We require high levels of evidence. I know that frustrates people. But many times what practitioners think is true doesn’t turn out to be true. Many believed that lowering glucose levels [in patients with type 2 diabetes] would result in less cardiovascular disease. Three randomized controlled trials came out showing that it did not.”

While acknowledging the need for research, the organizer of the conference told General Surgery News that new guidelines are necessary now for surgeons already offering the procedure to the growing numbers of persons with type 2 diabetes, now estimated at 24
million Americans.

“At the beginning of a field like this, where knowledge is not adequate and we have more questions than answers, the risk is that we’re going to do things we should not be doing,” said Francesco Rubino, MD, director of gastrointestinal metabolic surgery at NewYork-Presbyterian Hospital/Weill Cornell Medical Center and organizer of the First World Congress on Interventional Therapies for Type 2 Diabetes. “That is why we need today—and not tomorrow—to establish widely accepted clinical guidelines, to make sure that we promote respect of safe standards.”

The view of most nonsurgeons who attended the meeting, however, was that the evidence is insufficient at this time to serve as a rational basis for formulating new surgical guidelines aimed specifically at diabetes in people with a body mass index (BMI) under 35 kg/m$^2$, rather than at obesity in people with a BMI at least that high.

“There is suggestive early data that bariatric surgery for diabetes may be of value,” said Harold Lebovitz, MD, professor of medicine in the Division of Endocrinology and Metabolism/Diabetes at the State University of New York Health Sciences Center at Brooklyn. “But until the randomized studies are done comparing surgery to best medical care, the argument will go on between you and us.”

“It’s not us versus you; we’re all physicians seeking the best care of our patients,” replied Philip Schauer, MD, past president of the American Society for Metabolic and Bariatric Surgery and director of the Cleveland Clinic Bariatric and Metabolic Institute. “Why don’t you work with us to convince the NIH to support the randomized trials you want? We need to all work together.”

One explanation for the lack of willingness of endocrinologists to throw their weight behind new surgical guidelines may be their perception that medical care for diabetes is generally quite good.

“Nationwide, the proportion of people with diabetes achieving good control is increasing,” said the president of the ADA, John Buse, MD, chief of endocrinology at the University of North Carolina at Chapel Hill School of Medicine. “About 55% of people in the United States with diabetes have an $A_1c$ of less than 7%, and the average is 7.2%. That’s a dramatic improvement over the last decade. Part of this is because we’re making the diagnosis earlier, but even in patients on insulin and oral agents, there has been an improvement. We have entered an era with new and exciting medical therapies.”

Another cause of endocrinologists’ reluctance to embrace surgical solutions for diabetes is the potential for complications. Beyond the well-understood changes in the absorption of fat-soluble vitamins and minerals, severe cases of hyperinsulinemic hypoglycemia are now being diagnosed in a small but growing number of patients, said Allison Goldfine, MD, associate professor of medicine at Harvard Medical School and head of the section of clinical research at Joslin Diabetes Center, in Boston.

“Some of these cases develop five to 10 years after the bariatric procedure,” she noted. She knew of about 100 cases, at Joslin, Mayo Clinic and at other institutions, some of which were severe enough to require pancreatectomy. “We try desperately to avoid pancreatectomy. We don’t even know if it’s the right treatment.”
Concerns such as these, particularly regarding novel procedures described at the meeting (see New Procedures Provide Clues to Surgery’s Effect on Diabetes), provoked a word of caution from the surgeon whose paper in the Annals of Surgery (1995;222:339-350) is considered by many to have touched off the modern movement to treat diabetes with the scalpel rather than the syringe.

“Our first responsibility is the protection of the public,” said Walter J. Pories, MD, professor of surgery and deputy director of the Metabolic Institute for the Study of Diabetes and Obesity at East Carolina University in Greenville, N.C. For all the promise of bariatric surgery as a treatment for diabetes, he said, “That includes a fair assessment of both the medical and surgical options with an agreement on how to assess the patients and how to measure the benefits and risks in terms of short- and long-term outcomes. Since both the medical advances and the surgical results appear so promising and since diabetes is exploding, we owe it to our patients to find these answers as quickly as possible through fair, prospective national studies.”

Just as bariatric surgeons worked together in 2003 to establish centers of excellence, he said, so those surgeons seeking to treat diabetes need to work together to establish guidelines, conduct studies and clarify the risks and benefits.

Coming on the heels of the Diabetes Surgery Summit, held in Rome in 2007, the First World Congress drew health care luminaries from the United States and abroad, including the health secretary of Mexico, José Angel Córdova Villalobos, MD, and the New York State commissioner of health, Richard Daines, MD. Both described the enormous expense that diabetes is costing their governments, and the toll it is taking on their citizens.

Results of two recent studies drew considerable attention at the meeting. One, a retrospective cohort study, found that after a mean follow-up of 7.1 years, diabetes-attributable mortality was 92% lower among patients who had undergone gastric bypass than among a control group of severely obese patients (N Engl J Med 2007;357:753-761).

The other study, a trial of 55 obese patients randomized to either adjustable gastric banding or conventional medical treatment, found that after two years, 22 (73%) of the patients in the surgical group and four (13%) of those in the conventional therapy group had achieved remission of type 2 diabetes, with the surgical patients 5.5 times more likely to achieve remission than the medical patients (95% confidence interval, 2.2-14.0).

However, despite the results of these and other studies, the endocrinologists insisted that much longer, much larger, multicenter trials are necessary.

“You need to follow them not for two years, but for 10 and 15 years,” said Xavier Pi-Sunyer, MD, a past president of the ADA who serves as chief of the Division of Endocrinology, Diabetes and Nutrition at St. Luke’s-Roosevelt Hospital in New York City. “I don’t care about a single investigator’s case series that gives us 2,400 patients with no control groups.”

One of the most promising trials now under way, a collaboration between researchers at Columbia University, National Taiwan University and the University of Minnesota, is randomizing 150 patients with type 2 diabetes and a BMI of 30 to 35 kg/m² to either standard medical care or Roux-en-Y gastric bypass. But with enrollment only half completed, results are not expected for years.
Still, Dr. Goldfine said that the meeting showed the extraordinary level of interest that surgeons and endocrinologists share in the promise of interventional treatments for diabetes. “We came away on common ground, excited that bariatric surgery may hold unrecognized value,” she said. “We have greater clarity on the level of current information and what problems remain incompletely understood. We recognize the need to work as a team across disciplines that includes endocrinologists and surgeons to bring.”