Bariatric surgery dramatically outperforms standard treatment for type 2 diabetes

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In the first published study of its kind, researchers from the Catholic University/Policlinico Gemelli in Rome, Italy, and NewYork-Presbyterian/Weill Cornell Medical Center found that bariatric surgery dramatically outperforms standard medical treatment of severe type 2 diabetes.

These findings were published today in an advanced online edition of the *New England Journal of Medicine* (*NEJM*).

The study's authors report that most bariatric surgery patients were able to discontinue all diabetes medications and maintain disease remission for the two-year study period, while none of those randomly assigned to receive standard medical treatment did.

"Although bariatric surgery was initially conceived as a treatment for weight loss, it is now clear that surgery is an excellent approach for the treatment of diabetes and metabolic disease," says senior author Dr. Francesco Rubino, chief of Gastrointestinal Metabolic Surgery and director of the Metabolic and Diabetes Surgery Center at NewYork-Presbyterian/Weill Cornell and associate professor of surgery at Weill Cornell Medical College.

It is particularly challenging to treat obese patients who have type 2 diabetes, because insulin therapy and other hypoglycemic medications often cause additional weight gain. In this study, most surgery patients experienced improvements in blood sugar levels, decreased total

cholesterol and triglycerides, and improved HDL-cholesterol concentrations. This suggests that bariatric surgery for the treatment of diabetes may reduce a patient's cardiovascular risk.

"The unique ability of surgery to improve blood sugar levels and cholesterol levels as well as reduce weight makes it an ideal approach for obese patients with type 2 diabetes," says lead author Dr. Geltrude Mingrone, chief of the Division of Obesity and Metabolic Diseases and professor of medicine at Catholic University in Rome.

This was a randomized, controlled trial of patients aged 30 to 60.

This study evaluated remission of diabetes in 60 severely obese patients (those with a body mass index [BMI] greater than 35) with advanced diabetes. Patients were randomly assigned to three groups: one group underwent Roux-en-Y gastric bypass (RYGB); a second group had bilopancreatic diversion (BPD); and the third group received conventional individualized medication and rigorously monitored dietary and lifestyle modification.

None of the patients in the medical-therapy group has gone into remission since the start of the trial. By contrast, diabetes remission occurred and has been maintained in 95 percent of those who underwent BPD and 75 percent of those receiving RYGB. Remission is defined as fasting glucose of less than 100 mg and hemoglobin A1c (HbA1c) of less than 6.5 percent for at least one year.

The authors found that age, gender, preoperative BMI, duration of diabetes and weight-loss post surgery were not predictors of diabetes remission.

"These findings confirm that the effects of bariatric surgery on type 2 diabetes may be attributed to the mechanisms of surgery rather than the

consequences of weight loss," says Dr. Mingrone. "Studying the actual mechanisms by which surgery improves diabetes may help understand the disease better" she adds.

Bariatric operations throughout the world are currently used primarily according to 1991 U.S. National Institutes of Health guidelines, which limit surgery for type 2 diabetes to individuals with a BMI greater than 35 kg m□□.

"BMI is correlated with the risk of developing diabetes in the general population; in an individual, however, BMI does not tell much about the severity of diabetes, its potential to cause complications or the mechanisms of disease," says Dr. Rubino. "The study confirms that using strict cut-off BMI levels to define eligibility for surgery in patients with diabetes is medically inappropriate and that there is an urgent need to define better criteria for patient selection," he says.

Previous experimental studies by Dr. Rubino have shown that gastrointestinal bypass operations (like RYGB and BPD) activate direct, weight-independent mechanisms of diabetes control, supporting the use of surgery as a diabetes treatment, including in less obese patients. A randomized study comparing gastric bypass surgery and best medical treatment in patients with BMI 26 to 35 is currently ongoing at NewYork-Presbyterian/Weill Cornell Medical Center.

All patients in the current study were treated in Rome. Dr. Mingrone and her team of diabetes specialists were responsible for medical treatment of patients in the study. Dr. Rubino, who also holds an adjunct academic title at Catholic University in Rome, performed the laparoscopic RYGB surgeries and a team of surgeons from the Catholic University performed the BPD procedures.

The current study is part of a broader, ongoing research collaboration

between the Catholic University of Rome and Weill Cornell Medical College in New York. In March 2007, the Catholic University hosted the "Diabetes Surgery Summit" where a group of leading international scholars first recommended consideration of gastrointestinal surgery to intentionally treat type 2 diabetes ("diabetes surgery"). In the same year, NewYork-Presbyterian/Weill Cornell Medical Center established the Diabetes Surgery Center, the first academic program of its kind, as an effort to model clinical practice, education and research around the specific aim of surgically treating diabetes. The Center has since organized the first two editions of the "World Congress on Interventional Therapies for Type 2 Diabetes," which raised global awareness of diabetes surgery.

An estimated 8.3 percent of the global population has type 2 diabetes, according to World Health Organization 2010 statistics, and that number is projected to increase to 9.9 percent by 2030. As many as 23 percent of patients with morbid obesity also have type 2 diabetes. The costs associated with diabetes pose a huge burden on health care systems. Previous studies have suggested that bariatric surgery may be a cost-effective approach for obese patients with diabetes.

In spite of the potential gains, however, access to surgery for those eligible is very limited, and barriers are substantial. Less than 2 percent of eligible patients have access to bariatric/metabolic surgery in the U.S., and the figure is even lower in the rest of the world. The authors hope their study will help change the way bariatric surgery is perceived and that based on these findings, physicians will consider surgery in the treatment of diabetes.

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