

# Nonobese Get Metabolic Benefits From Surgery

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GRAPEVINE, TEX. — The next frontier in obesity surgery may be its extension to people who are mildly to moderately obese—or even nonobese—so they, too, can reap the metabolic benefits.

Several studies presented at the annual meeting of the American Society for Metabolic and Bariatric Surgery called into question current National Institutes of Health (NIH) guidelines recommending bariatric surgery only for patients with a body mass index greater than 40 kg/m<sup>2</sup> or those with a BMI greater than 35 with type 2 diabetes or other obesity-related comorbidities. Those guidelines serve as the basis for insurance coverage decisions. But the new studies consistently showed marked benefits of obesity surgery in patients who don't fall within the NIH guidelines, including the potential for reversing type 2 diabetes.

"I think those guidelines need to be challenged," said Dr. Jenny J. Choi of Columbia University Medical Center, New York.

Considering that more than 30% of U.S. adults have a BMI in excess of 30, that's a high-stakes proposition.

Dr. Choi presented data from an ongoing prospective observational study that, to date, includes 66 patients who had laparoscopic adjustable gastric banding (LAGB). The patients enrolled in the study had either a BMI of 30-35 and comorbidities or a BMI of 35-40 with no comorbidities. The control group consisted of 475 LAGB patients who met the NIH bariatric surgery criteria.

At 18 months' follow-up, the NIH non-

qualifiers had an average 42% excess weight loss, the same as in the control group. Although the low-BMI cohort had fewer baseline comorbidities than did controls, those with diabetes, hypertension, gastroesophageal reflux disease, obstructive sleep apnea, hyperlipidemia, stress incontinence, or depression saw improvement in their comorbidities to an extent similar to that of the more obese controls. Indeed, only arthritis was less likely to show significant improvement in the low-BMI group than in controls, according to Dr. Choi.

The 6% complication rate in the low-BMI cohort consisted mainly of band slippage or erosion. LAGB is an attractive bariatric procedure for patients with mild to moderate obesity, because even though it results in less weight loss than does gastric bypass, it has substantially less morbidity, she explained.

Dr. Choi noted that hers is not the first study to show that LAGB has significant benefits in patients too thin to qualify for bariatric surgery under the NIH guidelines, which date back to 1991.

For example, a landmark randomized trial by Dr. Paul O'Brien and his colleagues at Monash University, Melbourne, involving 80 patients with a BMI of 30-35, showed an 87% excess weight loss at 2-years' follow-up in the LAGB group, compared with 22% in patients assigned to intensive medical management.

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The prevalence of the metabolic syndrome—38% at baseline in both study arms—dropped to 3% at 2 years in the LAGB group, versus 24% in the intensive medical management group. Significant quality-of-life improvements at 2 years were documented in all eight domains of the Short Form-36 for LAGB-treated patients but in only three domains for the nonsurgically managed group (Ann. Intern. Med. 2006;144:625-33).

Most recently, investigators at New York University reported that LAGB in 53 patients with a mean preoperative BMI of 33.1 dropped their BMI to 25.8 at 2 years' follow-up,

with a mean 70% excess weight loss. Of the 53 patients, 49 had at least one baseline obesity-related comorbid condition; substantial improvement was noted in their diabetes, hypertension, asthma, osteoarthritis, hyperlipidemia, obstructive sleep apnea, and depression (Surg. Endosc. 2009;23:1569-73).

A small, randomized Brazilian trial presented at the bariatric surgery meeting showed that two versions of laparoscopic ileal interposition and sleeve gastrectomy had similarly substantial weight-loss and metabolic benefits. Dr. Aureo L. De Paula of Albert Einstein Hospital in São Paulo reported on 38 nonobese type 2 diabetic patients with a mean baseline BMI of 28.5. They were randomized to laparoscopic surgery in

which a 170-cm segment of ileum was transposed to the proximal jejunum in conjunction with a sleeve gastrectomy, or to having the same segment of ileum interposed to the proximal duodenum.

The study hypothesis was that the latter procedure, involving both foregut and distal gut mechanisms, would show greater benefit. And although there was a trend in that direction, it did not achieve significance in this small study. Indeed, both procedures proved dramatically effective in reversing diabetes.

For example, in the group as a whole, mean HbA<sub>1c</sub> dropped from 8.5% preoperatively to 5.9% at 26 months' follow-up; 35 patients had an HbA<sub>1c</sub> below 7%. Thirty-five permanently discontinued all antidiabetic medications. Mean fasting blood glucose went from 207 mg/dL to 114 mg/dL, postprandial blood glucose fell from 250 mg/dL to 140 mg/dL, and mean BMI dropped by 5.

Session co-chair Dr. Michel Gagner of Mount Sinai Medical Center, Miami Beach, commented that this is "fairly complex" surgery, especially the version involving diversion of the second portion of the duodenum. Why not just study gastric bypass—the most widely performed bariatric operation, and one that's technically more straightforward—in nonobese patients with type 2 diabetes? he asked.

Dr. De Paula replied that he has found gastric bypass to be less effective in reversing type 2 diabetes than the laparoscopic ileal interposition he and his colleagues have developed.

Dr. De Paula disclosed that his study was partially funded by Covidien. ■

## Adjustable Gastric Banding Effective Even in Superobese

GRAPEVINE, TEX. — Proponents of other types of bariatric surgery often question whether laparoscopic adjustable gastric banding is a sufficiently potent weight loss procedure in superobese patients, but outcomes at one bariatric surgery center attest to its effectiveness.

Among 2,909 patients who underwent LAGB at New York University Medical Center in the past 7 years, substantial, and indeed nearly identical, weight loss was achieved and maintained over time across all baseline body mass index categories, Dr. George Fielding reported at the annual meeting of the American Society for Metabolic and Bariatric Surgery.

The study population as a whole had a mean 37.6% excess weight loss at 1 year in this retrospective study, increasing to a maximum of 53% at 3 years, then falling back modestly to 47% excess weight loss at 6 years, according to Dr. Fielding, codirector of the New York University Program for Surgical Weight Loss.

Patients with a baseline BMI below 40 kg/m<sup>2</sup> had a mean 49% excess weight loss at 6 years. Those with a baseline BMI

of 40-49, who comprised 61% of the total cohort, had a mean 45.9% excess weight loss. The 18% of patients with a baseline BMI of 50-59 had a mean 47.5% excess weight loss, as did the 5% with a BMI of 60 or greater.

Complications consisted of band slippage in 4.5%, port-related problems in 3.3%, band intolerance or malfunction in 1.6%, and band erosion in 0.2%.

This study did not track changes in comorbidities over time. However, the high baseline prevalence of major medical comorbidities in the study population is worth noting. After all, bariatric surgery is the only treatment for severe obesity with demonstrated long-term efficacy, and substantial improvement in obesity-related comorbidities often occurs 1-2 years after LAGB, noted Dr. Fielding, who serves as an advisor to Allergan Inc. and Ethicon Endo-Surgery Inc.

At baseline, coronary heart disease was present in 45% of the 2,909 LAGB patients, osteoarthritis in 42%, hypertension in 38%, depression in 20%, sleep apnea in 19%, and diabetes in 14%. ■

## Surgeon Volume Is Inversely Related to Adverse Event Rate

GRAPEVINE, TEX. — Even for experienced bariatric surgeons operating at recognized centers of excellence, the adverse event rate for Roux-en-Y gastric bypass declines by 10% for every additional 10 cases performed annually, Dr. Mark D. Smith said at the annual meeting of the American Society for Metabolic and Bariatric Surgery.

Dr. Smith, a bariatric surgeon in Portland, Ore., reported on 3,409 patients who underwent an initial Roux-en-Y gastric bypass with 31 surgeons at 10 centers of excellence. All of the centers were participating in the National Institute of Diabetes and Digestive and Kidney Diseases-sponsored, prospective Longitudinal Assessment of Bariatric Surgery-1 (LABS-1) study.

Fifteen of the 31 surgeons averaged fewer than 50 of the procedures per year, 9 performed 50-99 annually, and 7 did 100 or more. The primary, composite 30-day adverse event end point comprised death, venous thromboembolism, reintervention, or hospitalization for the full 30 days. It occurred in

4.0% of patients whose surgeons performed at least 50 Roux-en-Y gastric bypasses annually and 9.1% of patients of lesser-volume surgeons. After adjust-



**Surgeons with fewer than 50 cases per year conferred twice the adverse event risk as those who had more than 50.**

DR. SMITH

ment for patients' operative risk, the relative risk of adverse events was 2.2-fold greater with surgeons who averaged fewer than 50 cases per year than with those who did more.

Further analysis showed that the inverse relationship between surgeon volume and adverse outcomes was continuous, and that for every 10 cases performed annually, the risk of adverse events decreased by 10%, said Dr. Smith. ■