

# Gastric Bypass Beat Medical Care for Moderate Obesity

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LAS VEGAS — Laparoscopic gastric band bypass produced significantly better outcomes for weight loss, health, and quality of life without sacrificing safety in a randomized, controlled trial comparing surgery with medical treatment for mild to moderate obesity.

At 2 years of follow-up, surgical patients had lost more excess weight (68%) than patients given individualized medical care (17%), Paul E. O'Brien, M.D., reported at the annual meeting of the North American Association for the Study of Obesity.

The trial included 80 patients, mean age 41 years, of whom 40 were randomized to surgery and 40 to medical care. At the outset, 38% of each group had metabolic syndrome. At 2 years' follow-up, all surgical patients except one were free of metabolic syndrome, whereas 24% of the medical patients still met criteria for the constellation of disorders.

Medical and surgical patients alike lost 45% of their excess weight in the first 6 months of the study. Over time, however, the medical patients began to gain weight, while the surgical patients continued to lose; they were still shedding pounds at the end of 2 years.

Despite the disparity in results, Dr. O'Brien characterized the medical group's average loss of 17% of their excess weight over 2 years as "still quite a reasonable outcome for this group of patients."

The surgical patients reported better quality-of-life outcomes on the SF-36 questionnaire. They showed significant improvement in all eight subscales, whereas the medical patients did so in only three: physical functioning, vitality, and mental health.

The medical treatment was primarily a very-low-calorie diet, with counseling, exercise, and a behavioral therapy program. Although orlistat (Xenical) was prescribed, Dr. O'Brien minimized its role, characterizing compliance as "touchy."

"We feel it's time that health administrators, insurers, physicians, and surgeons recognize the effectiveness of bariatric surgery for this most common and most lethal of our health problems," said Dr. O'Brien, a surgeon at Monash University in Victoria, Australia, where the study was conducted.

The investigators found no difference in adverse events between the medical and surgical patients. Eight medical patients could not tolerate orlistat or another medication prescribed as part of their regimen, Dr. O'Brien said.

No major surgical complications occurred, but one surgical patient had a transient port infection, and four had to have their bands adjusted because of posterior prolapse. Four medical patients and one surgical patient underwent cholecystectomy for acute cholecystitis.

Participants had to agree to accept randomization before entering the trial; Dr. O'Brien said none were allowed to choose between medical and surgical care. Nonetheless, one man in the surgical group backed out on the eve of surgery, and five medical patients withdrew during the study.

In each case, Dr. O'Brien said the patient's last clinical measures were carried forward in the intent-to-treat analysis presented at the meeting, which was cosponsored by the American Diabetes Association.

None of the patients met U.S. National Institutes of Health criteria for gastric bypass surgery, which specify that the surgery can be considered in motivated patients with severe obesity (body mass index greater than 40 kg/m<sup>2</sup>) or in patients with a BMI greater than 35 and high-risk comorbid conditions. The average BMI of the study patients was 33, with a range of 30-35.

A randomized trial would not have been ethical had the patients been more obese, Dr. O'Brien pointed out.

"Ethically, I couldn't look someone in the eye with a BMI of 36 and say medical therapy might just work as well as surgery," he said, "whereas 30-35 is a gray zone in our thinking."

In an interview, Dr. O'Brien predicted that the laparoscopic gastric band procedure would be standard for patients with mild to moderate obesity in 5-10 years. First, he said, advocates must balance the costs of surgery against the costs of continuing to treat diabetes and the other conditions that make up metabolic syndrome.

The investigators did not build an economic analysis into this trial, but Dr. O'Brien said they have begun doing such studies. "It frightens administrators to think everybody is going to need to have surgery," he said. "I think that might be cost effective, though." ■

## Hospitals' Low Bariatric Surgery Volume Predicts Worse Patient Outcomes

LAS VEGAS — Adverse outcomes are significantly more common in hospitals that perform fewer than 50 bariatric surgeries annually, Edward H. Livingston, M.D., said at the annual meeting of the North American Association for the Study of Obesity.

"There is a very, very steep drop-off [in adverse outcomes] above 50 cases per hospital per year," said Dr. Livingston, chair of the Division of Gastrointestinal/Endocrine Surgery at the University of Texas, Dallas.

He presented data from the 2001 National Inpatient Survey (NIS), which included 10,672 cases. Adverse outcomes fell from roughly 15% of bariatric cases in low-volume hospitals to about 5% in hospitals performing 50-75 and 75-100 bariatric surgeries per year.

In higher-volume hospitals, adverse outcomes continued to decline but at a much less dramatic rate, Dr. Livingston said.

He calculated 656 adverse outcomes (6.1%) and 36 deaths (0.3%) in the NIS sample. He described this as "about the range for most serious complications of bariatric surgery."

The study used three proxy criteria to identify complications in the database: death during surgery, discharge to a long-term care facility, and a length of stay twice the median length of stay (7 days or more, based on a median of 3 days). Dr. Livingston said he chose these criteria because he had found in a previous study that many obviously adverse outcomes of

bariatric surgery were not coded as complications.

He also reported that the procedure-volume relationship remained statistically significant after he corrected for age and sex, two known risk factors in bariatric surgery. The overall odds ratio of procedure volume being a risk factor for adverse outcomes was 0.98, he said. Being male produced the highest odds ratio (1.59) followed by age (1.04).

The study overcame two challenges, Dr. Livingston said at the meeting, cosponsored by the American Diabetes Association. First, it needed a large administrative database that would also reflect the full range of bariatric surgeries performed. The NIS data are drawn from hospital (both academic medical center and non-academic) admissions in 29 states.

"Most series outcomes come from individuals, in university practices, with a high technical degree of expertise," he said. "We tried to look at the community at large."

Second, although volume-outcome relationships are common in technically complex operations, Dr. Livingston said they are difficult to calculate in low-mortality procedures. To that end, he focused on adverse outcomes, as well as mortality.

"Clearly, we can demonstrate a volume-outcome relationship for low-mortality procedures if adverse outcomes are used in addition to mortality to find the effect," he said. ■

# Calcium Loss Documented After Roux-en-Y Gastric Bypass

LAS VEGAS — Calcium absorption decreases about a third after Roux-en-Y gastric bypass surgery, placing patients in jeopardy of clinically significant bone loss, Claudia Riedt said at the annual meeting of the North American Association for the Study of Obesity.

A prospective study of 19 severely obese women found that average total calcium absorption was 137 mg per day in 17 patients who were examined 6 months after surgery. "This is about 40% below the estimated total amount of calcium required per day to maintain health and balance," said Ms. Riedt, a doctoral candidate in nutritional sciences at Rutgers University, New Brunswick, N.J.

The investigators undertook the study because osteopenia had been seen in pa-

tients after Roux-en-Y gastric bypass. Although the procedure is believed to result in less malabsorption than other bypass procedures, Ms. Riedt and her colleagues theorized that inadequate calcium absorption was a factor along with decreased food intake and weight loss.

The women recruited for the study had a mean age of 45. They entered with an average body mass index (BMI) of 54 kg/m<sup>2</sup>, an average weight of 143 kg, and an average energy intake of 2,466 kcal per day. They consumed a mean of 1,123 mg of calcium, of which they absorbed 37%: a total of 425 mg of calcium per day.

By 6 months, the women had lost 104 kg on average and had a mean BMI of 39. Their energy intake had decreased to 840 kcal per day, and their calcium intake had

dropped to 829 mg per day, Ms. Riedt said. Not only were they consuming less calcium, but the true fraction of calcium absorption had decreased by nearly 34%, becoming only 25% of their calcium intake.

The researchers also observed changes in bone turnover markers that are typical with weight loss and suggest that calcium was being mobilized from bone.

Estradiol and parathyroid hormone levels correlated with the rate of calcium absorption. Vitamin D levels were relatively low and did not change during the study or predict calcium absorption, Ms. Riedt said.

Two women in the study followed recommendations that patients consume at least 1 g of calcium in daily supplements after the procedure. They increased their

total intake by about 1200 mg to 2400 mg and 2600 mg of calcium, respectively. As a result, the average amount of calcium absorbed by all 19 women reached 223 mg per day—closer to but still under the nutritional goal of 240 mg per day.

"Nutritional interventions must compensate for drastically reduced calcium absorption," Ms. Riedt said at the meeting, cosponsored by the American Diabetes Association. She recommended 1,500 mg per day above dietary intake but acknowledged that compliance can be a problem, especially in the first few months after the procedure.

"All the women were always encouraged to take extra calcium. Whether they did was another matter," she said in an interview. ■