

# Large Database Defines Bariatric Surgery Trends

BY BRUCE JANCIN

GRAPEVINE, TEX. — First data from the landmark Bariatric Outcomes Longitudinal Database show that two types of surgery—Roux-en-Y gastric bypass and gastric banding—account for 93% of all primary bariatric procedures performed at U.S. centers of excellence.

Among 57,918 bariatric surgery patients enrolled during the first 16 months of BOLD, 53.5% had a gastric bypass and 39.2% had a gastric banding procedure. Rounding out the top four most frequently performed primary operations were sleeve gastrectomy (2.3%) and biliopancreatic diversion/duodenal switch (1%), Dr. Eric J. DeMaria said at the annual meeting of the American Society for Metabolic and Bariatric Surgery.

All-cause mortality at 90 days in this huge series was just 0.112%, a result that underscores the high quality of out-

comes achieved in ASMBS-designated centers of excellence, said Dr. DeMaria, professor of surgery at Duke University, Durham, N.C.

BOLD, the world's largest prospective clinical database for bariatric surgery, is enrolling about 2,700 patients per month.

The baseline BOLD data presented by Dr. DeMaria provide a close-up of contemporary bariatric surgery as conducted at 371 ASMBS-approved centers with 639 ASMBS-approved surgeons. Another 105 centers are provisionally approved.

Although it's far too early to draw conclusions about the relative effectiveness of the various procedures in maintaining weight loss, Dr. DeMaria presented data on key demographics and short-term outcomes. Some of the findings are as follows:

► The patients' average age was 46.6, and 79% were women. A total of 78% were white, 10% black, and 6% Hispanic.

► Mean preoperative body mass index was 46.5 kg/m<sup>2</sup>. A total of 53% of patients had a BMI of 40-49, and 17% had a BMI of 35-39.

► Roux-en-Y gastric bypass was per-



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formed laparoscopically in 89% of cases, as were 3% of sleeve gastrectomies and two-thirds of biliopancreatic diversion/duodenal switches.

► Vertical gastric banding accounted for less than 1% of all gastric banding procedures in BOLD.

► Most patients received two forms of venous thromboembolism prophylaxis in-hospital, but 7% had none.

► Duration of surgery averaged 91 minutes, with 129 minutes of anesthesia, 41 mL of blood loss, and a 2.5-day length of hospital stay.

► Adverse events occurred prior to discharge in 3.6% of cases.

► With a maximum follow-up of 16 months, the percentage of patients experiencing one or more adverse events varied by procedure: gastric banding, 4%; sleeve gastrectomy, 10%; gastric bypass, 14%; and biliopancreatic diversion/duodenal switch, 25%.

The ambitious quality improvement project is "believed to be a model for other specialties," Dr. DeMaria said.

He disclosed that he serves as unpaid chair of the research advisory committee of the Surgical Review Corp., a nonprofit company formed to run BOLD. ■

## Complication Rate for Bariatric Surgery 4.1%

BY MARY ANN MOON

The most common bariatric surgeries carry low rates of adverse perioperative outcomes when performed by experienced surgeons in established centers, according to a recent report.

In a prospective, multicenter, observational study, 30-day mortality was 0.3% and the rate of major complications was 4.1%, which are comparable to rates for other major operations. Those rates are considered low for bariatric surgery, because most patients are extremely obese and have multiple comorbid conditions, said Dr. David R. Flum of the University of Washington, Seattle, and his associates in the Longitudinal Assessment of Bariatric Surgery (LABS) study (N. Engl. J. Med. 2009;361:445-54).

The investigators evaluated 4,776 consecutive patients who underwent first-time bariatric surgery in 2005-2007, which was performed by 33 surgeons certified by the LABS consortium.

The most common procedure was Roux-en-Y gastric bypass (71% of patients), which was performed laparoscopically in 87% of cases and as an open procedure in 13%. Another 25% of the patients underwent laparoscopic adjustable gastric banding, and the remaining 4% had other bariatric procedures.

The primary outcome of the study was a composite end point of death, deep vein thrombosis, venous thromboembolism, reoperation, or failure to be discharged

within 30 days. That occurred in 1% of the patients undergoing laparoscopic adjustable gastric banding, 4.8% with Roux-en-Y gastric bypass, and 7.8% with open Roux-en-Y gastric bypass.

Patients who had a history of thrombotic disorders, had poor functional status, or had sleep apnea were at increased risk of poor outcomes.

"Regardless of the type of procedure, the predicted probability of



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DR. FLUM

the composite end point was lowest among patients who did not have a history of deep vein thrombosis or venous thromboembolism or of obstructive sleep apnea, and who were in the middle range of the spectrum of body mass index for the cohort," Dr. Flum and his colleagues said.

The researchers added that the study focused on perioperative adverse events. Another study that has just completed recruitment (LABS-2) will assess the long-term effects of bariatric surgery on health conditions, quality of life, health care costs, and psychosocial issues.

Dr. Flum said he has received grants from Sanofi-Aventis and Covidien AG and served as an expert witness on cases involving adverse events after bariatric surgery. ■

## Abnormal Glucose Tolerance Tests May Be Seen After Gastric Bypass

BY BRUCE JANCIN

GRAPEVINE, TEX. — Gastric bypass surgery's status as the gold-standard weight-loss procedure has come under question by new evidence that many recipients develop late, often-unrecognized glucose abnormalities contributing to significant weight regain.

"The gastric bypass has been the procedure of choice, especially for sweet eaters. I think it's time to reconsider. I actually believe that vertical sleeve gastrectomy and duodenal switches that are not severely malabsorptive will be the best operations in the future," Dr. Mitchell S. Roslin said at the annual meeting of the American Society for Metabolic and Bariatric Surgery.

After weight loss induced by gastric bypass, patients have an enhanced insulin response. A substantial subgroup of these patients develop rapid emptying of their surgically created pouch, with resultant reactive hypoglycemia that contributes to grazing and other maladaptive eating behaviors, hypothesized Dr. Roslin of Lenox Hill Hospital, New York.

This hypothesis arose from conversations with large numbers of post-gastric bypass patients contemplating revisional bariatric surgery because of troubling weight regain.

"They were essentially saying that 1 or 2 hours after eating they were ravenously hungry. Many complained of being light-headed. The symptoms sounded to me a lot like hypoglycemia," he recalled.

To test his hypothesis, he gave a 100-g oral glucose tolerance test to 63 patients coming to the obesity surgery clinic for routine follow-up a mean of 4 years after Roux-en-Y gastric bypass. Their mean age was 48.5 years, 81% were women, and one-third of the patients had diabetes preoperatively. Their mean preoperative weight was 138 kg. They had a maximum 55% excess weight loss, but had regained an average of 12 kg.

Fully 49 of the 63 patients (78%) had an ab-

normal glucose tolerance test. Six had hyperglycemia as defined by any postchallenge blood glucose value greater than 200 mg/dL, with none below 80 mg/dL. Significantly, all but one of these six patients had normal fasting blood glucose. "That means we need to be very careful what we call surgical cure or control of diabetes," he observed.

Another 35 patients had reactive hypoglycemia, defined as a blood glucose value below 60 mg/dL or a decrease of at least 100 mg/dL between hours 1 and 2, with no value greater than 200 mg/dL. Another eight patients had both reactive hypoglycemia and hyperglycemia. Thus, more than two-thirds of the study group had evidence of hypoglycemia. These patients displayed a rapid postchallenge upsurge in blood glucose correlating with a rising insulin level, then a rapid decline in glucose in the second hour.

A normal maximum-to-minimum glucose ratio on the 100-g test is 1.5-2:1. However, 22 patients in this study had ratios greater than 3:1, and 7 had ratios greater than 4:1.

Dr. Harvey J. Sugerman, whose studies in the late 1990s are widely credited as enthroning gastric bypass as the gold-standard bariatric surgery procedure, rose from the audience to tell Dr. Roslin, "I think your hypothesis may be very valid. I see a lot of rapid emptying." A nonsurgical solution to these problems, he added, is simply to have affected patients drink half a glass of orange juice 30 minutes after they eat.

"It levels off their insulin and glucose levels. It takes away the unpleasant symptoms of dumping and also that ravenous hunger," said Dr. Sugerman of Sanibel, Fla., who is editor-in-chief of Surgery for Obesity and Related Diseases, the official journal of the American Society for Metabolic and Bariatric Surgery.

Dr. Roslin said that he has potential conflicts of interest resulting from relationships with Covidien AG, C.R. Bard Inc., ValenTx Inc., Scientific Intake Ltd., and VentralFix Inc. ■