

## Low Adverse Event Rate for Bariatric Surgery; Several Comorbidities Associated with Poor Outcome

Flum D, Belle S, King W, et al. Perioperative safety in the longitudinal assessment of bariatric surgery. *N Engl J Med* 2009;361:445–54.

### Study Overview

**Objective.** To determine the risk of bariatric surgery.

**Design.** Multicenter, prospective cohort study conducted by the Longitudinal Assessment of Bariatric Surgery (LABS) consortium.

**Setting and participants.** 4776 patients  $\geq$  18 years old undergoing a first-time bariatric surgery procedure. 33 surgeons performed all of the procedures at 10 clinical sites. Certified data collectors evaluated patients prior to surgery with a history, chart review, and physical exam, and they measured weight, height and blood pressure. Patients self-reported comorbid conditions.

**Main outcome measures.** A composite of serious adverse events within 30 days of surgery, including death, venous thromboembolism, reintervention, or lack of discharge from the hospital.

**Main results.** The mean age of patients was 44.5 years (SD, 11.5), and 79% were female. The mean body mass index (BMI) was 46.5. More than one-half of patients had comorbid medical conditions, with hypertension (55.1%), obstructive sleep apnea (48.9%), diabetes (33.2%), and asthma (23.1%) as the most common. Surgeons performed Roux-en-Y gastric bypass on most patients (71.4%), of which 87.2% were laparoscopic. Laparoscopic adjustable gastric banding comprised another 25.1%. The small number of additional procedures included sleeve gastrectomy and biliopancreatic diversion with or without duodenal switch. Patients undergoing open Roux-en-Y gastric bypass had higher BMI and more comorbid conditions of a greater severity than other patients. Patients undergoing laparoscopic adjustable gastric banding were the healthiest of the groups. The primary endpoint occurred in 4.1% of patients—7.8% of those undergoing open Roux-en-Y bypass, 4.8% with laparoscopic Roux-en-Y bypass, and 1% of those with gastric banding. 15 patients (0.3%) died after surgery, and all deaths were among those receiving Roux-en-Y bypass. 6 died after receiving the laparoscopic Roux-en-Y (0.2% of patients receiving this sur-

gery) and 9 after open (2.1%). In adjusted results controlling for age, sex, baseline BMI, and the presence of comorbid conditions, patients receiving open Roux-en-Y were 5.8 times more likely to experience the composite outcome than those receiving gastric banding. Patients receiving laparoscopic Roux-en-Y were 4.8 times more likely to experience the composite outcome. No difference in the 2 types of Roux-en-Y procedures was evident for the composite outcome (1.21 [95% confidence interval {CI}, 0.71–2.04]). Extremes of BMI, an inability to walk 200 feet prior to surgery, and a history of venous thromboembolism and obstructive sleep apnea were also related to an increased risk for adverse events. The predicted probability for an adverse event for a patient with a history of venous thromboembolism, sleep apnea, and a BMI of 70 kg/m<sup>2</sup> was 10%.

**Conclusion.** Bariatric surgery is generally safe when performed in medical centers that received specialized training in bariatric surgery. 4.1% of patients experienced a significant adverse event (only 0.3% died). More data are needed on bariatric surgery performed in community hospitals.

### Commentary

Recently published research has documented substantial benefits of bariatric surgery. The Swedish Obese Subjects study has followed 4047 patients prospectively for a mean of 10.9 years [1]. These patients include subjects who elected to receive bariatric surgery as part of an intervention study and matched controls who elected to receive conventional, nonsurgical treatment. Gastric bypass patients lost a mean of 25% of initial weight, and gastric banding patients lost a mean of 14% by the end of this follow-up period. Bariatric surgery patients also had complete resolution of hypertension, hypertriglyceridemia, hyperuricemia, diabetes, and low HDL cholesterol at a significantly higher rate than control subjects [2].

Mortality rates appear to decline after bariatric surgery as well. Adjusted mortality in the Swedish study was 29% lower for bariatric surgery patients than for the control group [1]. Bariatric surgery patients experienced a 40% reduction in adjusted mortality in a U.S. retrospective cohort

study of 7925 bariatric surgery patients and 7925 matched controls taken from driver's license records [3].

Despite this apparent good news, bariatric surgery still appears to be associated with a high risk of death, especially in some populations. A study of 16,155 Medicare patients from 1997 to 2002 found a death rate of 2%, 2.8%, and 4.6% at 1 month, 3 months, and 1 year [4]. Patients older than age 75 years had a 5 times higher rate of death at 90 days than those under 75 after adjustment for sex and comorbidities. The rate of death was 1.6 times higher if the surgeon performing surgery conducted less than the median number of surgeries, after adjustment for age, sex, and comorbidities. Researchers used Medicare claims data for this study and could not clearly associate the cause of death with bariatric surgery.

Hospitalizations after bariatric surgery also rise. One study of 60,077 who received Roux-en-Y gastric bypass from 1995 to 2004 in California found a doubling of the hospitalization rate in the year after bariatric surgery compared to the year prior to surgery (19.3% vs. 7.9%) [5]. The increased admission rate persisted for 3 years after surgery. Reasons for admission were thought to be procedure-related, and hospitalizations were increased among those with more comorbidities.

Flum et al undertook this large prospective study to explore the risks of bariatric surgery with enough power to detect small associations between patient characteristics and outcomes. The overall adverse event rate was low at 4.1%, with only 0.3% of patients dying in the 30-day postoperative period. Need for endoscopy and repeat abdominal surgery comprised the great majority of adverse events. Roux-en-Y bypass, performed open or laparoscopically, was associated with more adverse events as were extremes of BMI, immobility, a history of venous thromboembolism, and obstructive sleep apnea. Prior research has documented a higher adverse event rate among patients with baseline obstructive sleep apnea [6] as well as among patients with higher baseline BMI and pre-existing risk for venous thromboembolism [7,8]. Age was not a predictor of adverse outcomes as has been shown in prior studies [7,8]; however, more than half of patients in this study were in their 30s or 40s. Older patients in this study also had lower BMIs at baseline than younger patients, perhaps showing some selection of healthier patients at older ages. Hypertension and male sex also were not associated with adverse events despite evidence for these associations in prior research [7,8].

This study achieved successful enrollment and included almost all patients who were screened and deemed eligible to participate. Of the screened patients who could have surgery completed prior to the end of enrollment, exclusions were limited to 36 surgeries during which anesthesia cancelled the case and 257 patients who were not receiving

their first bariatric surgery. The analytic methods used also were strong and appropriately accounted for clustering of outcomes by surgeon and clinical site through generalized linear mixed models.

Several limitations were apparent. First, the study had no control group. Rates of adverse events could not be compared to similar patients who did not have surgery or who were having another abdominal surgery. As a result, we don't know if the low rate of adverse events is different than what might be expected to occur even without surgery or with other abdominal surgeries. Some of the outcomes in this study are only applicable to a postsurgical environment; therefore, an adequate control group should include patients undergoing another elective abdominal surgery, such as elective cholecystectomy. Second, researchers only report adverse events up to 30 days after the surgery. Other adverse events related to the surgery could have developed after 30 days, leading to an underestimation of adverse events. Third, researchers relied on patient self-report of comorbidities rather than a potentially more objective data source. Systematic bias could result from self-report. Yet, researchers screened patients prospectively, and bias should not result unless patients who reported fewer comorbidities were somehow more motivated for the surgery and as a result experienced better outcomes. Such an occurrence seems unlikely. Fourth, researchers failed to report data on the number of surgeries performed by each surgeon. Prior data have shown a higher rate of adverse events for surgeons performing lower volumes of bariatric surgery [4]. This study could have provided additional information on this issue at the higher end of patient volume since all of the surgeons in this study were certified by the Longitudinal Assessment of Bariatric Surgery (LABS) consortium and were likely high-volume.

The LABS certification process clearly included a cadre of high-volume, experienced bariatric surgeons to perform surgeries for this study. The relatively low adverse event rate with exceedingly low death rate may not be representative of bariatric surgery patients across the U.S. More research should be done in community settings with the same prospective study design that can characterize the specific risks associated with surgery in these settings.

This study reports a higher rate of complications for patients undergoing Roux-en-Y gastric bypass when compared with adjustable gastric banding. As the authors state, this comparison is not entirely legitimate because Roux-en-Y is, by design, more invasive than gastric banding and will result in higher reoperation rates. Roux-en-Y also is associated with more weight loss. An understanding of the risks of this more invasive procedure should not be considered without a clear representation of the benefits of additional weight loss.

**Applications for Clinical Practice**

Bariatric surgery has a relatively low adverse event rate at 30 days if performed by a specially trained cadre of bariatric surgeons. Clinicians should have a thorough discussion of the risks and benefits of bariatric surgery with their patients and should clearly explain that patients with obstructive sleep apnea, immobility, extremely high BMI, and history of venous thromboembolism are at particularly high risk. Roux-en-Y gastric bypass is also associated with higher risks than adjustable gastric banding, but these risks should be considered within the context of potentially improved weight loss results with Roux-en-Y. More prospective research on bariatric surgery is needed in community settings.

—Review by Jason P. Block, MD, MPH

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