Perioperative Safety in the Longitudinal Assessment of Bariatric Surgery

The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium

ABSTRACT

BACKGROUND

To improve decision making in the treatment of extreme obesity, the risks of bariatric surgical procedures require further characterization.

METHODS

We performed a prospective, multicenter, observational study of 30-day outcomes in consecutive patients undergoing bariatric surgical procedures at 10 clinical sites in the United States from 2005 through 2007. A composite end point of 30-day major adverse outcomes (including death; venous thromboembolism; percutaneous, endoscopic, or operative reintervention; and failure to be discharged from the hospital) was evaluated among patients undergoing first-time bariatric surgery.

RESULTS

There were 4776 patients who had a first-time bariatric procedure (mean age, 44.5 years; 21.1% men; 10.9% nonwhite; median body-mass index [the weight in kilograms divided by the square of the height in meters], 46.5). More than half had at least two coexisting conditions. A Roux-en-Y gastric bypass was performed in 3412 patients (with 87.2% of the procedures performed laparoscopically), and laparoscopic adjustable gastric banding was performed in 1198 patients; 166 patients underwent other procedures and were not included in the analysis. The 30-day rate of death among patients who underwent a Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding was 0.3%; a total of 4.3% of patients had at least one major adverse outcome. A history of deep-vein thrombosis or pulmonary embolus, a diagnosis of obstructive sleep apnea, and impaired functional status were each independently associated with an increased risk of the composite end point. Extreme values of body-mass index were significantly associated with an increased risk of the composite end point, whereas age, sex, race, ethnic group, and other coexisting conditions were not.

CONCLUSIONS

The overall risk of death and other adverse outcomes after bariatric surgery was low and varied considerably according to patient characteristics. In helping patients make appropriate choices, short-term safety should be considered in conjunction with both the long-term effects of bariatric surgery and the risks associated with being extremely obese. (ClinicalTrials.gov number, NCT00433810.)

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Determining the incidence of infrequent adverse outcomes and the factors associated with them requires large prospective cohorts with standardized presurgical evaluation and complete assessment of outcomes. The Longitudinal Assessment of Bariatric Surgery (LABS) consortium conducted a prospective, multicenter, observational cohort study (LABS-1)[7] that used a standardized assessment in consecutive patients undergoing bariatric surgery. This report presents the incidence of, and factors associated with, 30-day safety outcomes in patients from this cohort who underwent an initial bariatric surgical procedure.

METHODS

PATIENTS

The study included consecutive patients 18 years of age or older who underwent bariatric surgical procedures from March 11, 2005, through December 31, 2007, performed by 33 LABS-certified surgeons (see the Appendix for a list of centers and the data coordinating center). The study protocol and consent form were approved by the institutional review board at each institution.[7] Surgeons were certified to participate in the LABS-1 study, but bariatric surgical accreditation did not exist when the LABS-1 study began.

By December 31, 2007, a total of 5648 patients had been invited to participate in the study, and 4776 had undergone primary operations. Roux-en-Y gastric bypass was performed either laparoscopically or through an "open" approach; laparoscopic adjustable gastric banding was considered separately. Procedures that started laparoscopically and were converted to open surgery were considered to be open. Procedures that comprised less than 3% of all procedures (biliopancreatic diversion with or without a duodenal switch, sleeve gastrectomy, vertical banded gastroplasty, and open adjustable gastric banding) were excluded from the outcome analyses.

COLLECTION OF DATA

Details of the preoperative, operative, and postoperative data-collection forms and definitions have been reported previously.[7] The preoperative evaluation was completed by means of an in-person interview, physical examination, and chart review, all of which were conducted by LABS-certified data collectors. Standardized protocols and instruments were used to measure weight, height, and blood pressure within 30 days before surgery. Coexisting conditions were self-reported, and severity was based on the associated use of health care resources (e.g., patients were asked if they had sleep apnea and, if so, whether they used a continuous positive airway pressure machine). The primary outcome was a composite end point of any of the following occurring within 30 days after surgery: death; deep-vein thrombosis or venous thromboembolism; reintervention with the use of percutaneous, endoscopic, or operative techniques; or failure to be discharged from the hospital within 30 days after surgery. We did not consider readmission per se as an adverse event, owing to the variable severity of problems that led to readmission. We did not collect information on insurance status, and research funds were not used to pay for procedures.

STATISTICAL ANALYSIS

Enrollment of patients was dictated by the number of procedures performed by participating surgeons. Before enrollment began, we calculated the number of patients that would be needed for the study to have a power of 90% to detect a doubling in the risk that selected outcome events would occur with various incidences, given the prevalence of several putative risk factors.

Characteristics of the patients who underwent

the two bariatric procedures were compared with the use of Pearson's chi-square test for categorical variables and the Kruskal–Wallis test for continuous variables. The incidence of 30-day adverse outcomes was compared among the procedures with the use of Pearson's chi-square test. Generalized linear mixed-effect models were used to evaluate predictors of the composite end point, with the log odds of events modeled as a linear function of baseline covariates. Correlation among patients of the same surgeon was accounted for by the inclusion of different random intercepts for sites and for surgeons within site. Linear and quadratic effects of body-mass index on the composite end point were considered, since the unadjusted analysis showed a quadratic relationship.

For multivariable models, a stepwise variable selection was performed, starting with all the variables from univariate models that had a P value of less than 0.25 as potential predictors. Variables were eliminated from the multivariable model if the P value was greater than 0.10, and the process was continued. After the inclusion of main effects that had a P value of less than 0.10, variables that had been considered previously were again included in models to determine whether further adjustment changed the P value of those effects. The final model included only main effects that had a P value of less than 0.10, at which point two-way interactions among all the main effects were evaluated. Predicted probabilities of the composite end point were calculated on the basis of the multivariable model. All P values reported are two-sided.

RESULTS

PATIENTS

Of 4776 patients undergoing first-time or "primary" bariatric procedures, the mean (±SD) age was 44.5±11.5 years (Table 1). The median body-mass index (the weight in kilograms divided by the square of the height in meters) was 46.5; 21.1% of the patients were men. The most common procedure was Roux-en-Y gastric bypass, which was performed in 3412 of the patients (71.4%); 87.2% of these procedures were performed laparoscopically and 12.8% with an open surgical technique. A total of 1198 patients (25.1%) underwent laparoscopic adjustable gastric banding; 166 patients (3.5%) underwent other bariatric procedures (Fig. 1).

Coexisting conditions were common (see Table 1 in the Supplementary Appendix, available with the full text of this article at NEJM.org): 82.1%

of the patients had at least one condition, 53.9% had two or more, and 26.5% had three or more. The most common coexisting conditions were hypertension (55.1%), obstructive sleep apnea (48.9%), diabetes (33.2%), and asthma (23.1%). Other relatively less frequent coexisting conditions included ischemic heart disease (4.4%), venous edema with ulcerations (4.0%), a history of deep-vein thrombosis or venous thromboembolism (3.5%), dependence on supplemental oxygen (3.5%), congestive heart failure (2.2%), an inability to walk 61 m (approximately 200 ft) (1.8%), and pulmonary hypertension (1.2%). Preoperative medications that were used by patients included antidepressants (39.9%), statins (26.6%), beta-blockers (17.9%), and narcotics (16.1%).

Patients undergoing open Roux-en-Y gastric bypass, as compared with those undergoing laparoscopic Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding, had a higher median body-mass index (50.9 for open Roux-en-Y gastric bypass, 46.9 for laparoscopic Roux-en-Y gastric bypass, and 44.1 for laparoscopic adjustable gastric banding) and more coexisting conditions (P<0.001 for all comparisons). Patients undergoing open Roux-en-Y gastric bypass generally had the most severe coexisting issues (e.g., insulin-dependent diabetes and an inability to walk at least 61 m, necessitating assistive devices); patients undergoing either laparoscopic Roux-en-Y gastric bypass or open Roux-en-Y gastric bypass had more coexisting conditions than those undergoing laparoscopic adjustable gastric banding (Table 1 in the Supplementary Appendix).

PRIMARY OUTCOME

For the analyses of outcomes, we excluded the 166 patients who underwent operations that are performed relatively rarely, since the putative risks are quite disparate and the frequencies are too small for meaningful analyses (Table 2). Within 30 days after surgery, 0.3% of the patients had died: none of the 1198 patients who had undergone laparoscopic adjustable gastric banding, 0.2% of the 2975 patients who had undergone laparoscopic Roux-en-Y gastric bypass, and 2.1% of the 437 patients who had undergone open Roux-en-Y gastric bypass.

The composite end point of death, deep-vein thrombosis or venous thromboembolism, reintervention, or failure to be discharged by 30 days after surgery occurred in 4.1% of patients: 1.0% of patients who had undergone laparoscopic ad-

Table 1. Characteristics of the Patients.*

Characteristic	Total (N=4776)†	Laparoscopic Adjustable Gastric Banding (N=1198)	Laparoscopic Roux-en-Y Gastric Bypass (N=2975)	Open Roux-en-Y Gastric Bypass (N=437)	Sleeve Gastrectomy (N=117)	Biliopancreatic Diversion with or without a Duodenal Switch (N=47)	P Value‡
Age							
Mean — yr	44.5±11.5	46.0±12.5	43.6±11.0	45.9±10.7	46.3±13.6	43.9±10.7	<0.001
Age group — no. (%)							<0.001
<30 yr	513 (10.7)	133 (11.1)	321 (10.8)	37 (8.5)	18 (15.4)	4 (8.5)	
30 to <40 yr	1196 (25.0)	244 (20.4)	826 (27.8)	92 (21.1)	18 (15.4)	16 (34.0)	
40 to <50 yr	1380 (28.9)	337 (28.1)	868 (29.2)	134 (30.7)	28 (23.9)	13 (27.7)	
50 to <60 yr	1200 (25.1)	300 (25.0)	728 (24.5)	128 (29.3)	34 (29.1)	8 (17.0)	
60 to <65 yr	318 (6.7)	93 (7.8)	172 (5.8)	36 (8.2)	12 (10.3)	5 (10.6)	
≥65 yr	169 (3.5)	91 (7.6)	60 (2.0)	10 (2.3)	7 (6.0)	1 (2.1)	
Body-mass index§							
Median	46.5	44.1	46.9	50.9	56.2	48.9	<0.001
Interquartile range	42.1–52.4	40.5–49.0	42.7–52.3	44.7–60.0	44.4–62.5	43.2–53.1	
Index group — no. (%)							<0.001
<40	640 (13.4)	262 (21.9)	332 (11.2)	30 (6.9)	10 (8.5)	6 (12.8)	
40 to <50	2518 (52.7)	674 (56.3)	1613 (54.2)	175 (40.0)	34 (29.1)	21 (44.7)	
50 to <60	1188 (24.9)	205 (17.1)	810 (27.2)	123 (28.1)	31 (26.5)	18 (38.3)	
≥60	430 (9.0)	57 (4.8)	220 (7.4)	109 (24.9)	42 (35.9)	2 (4.3)	
Male sex — no. (%)	1009 (21.1)	277 (23.1)	534 (17.9)	140 (32.0)	42 (35.9)	16 (34.0)	<0.001
Race or ethnic group — no./total no. (%)¶							
Nonwhite	516/4730 (10.9)	130/1184 (11.0)	338/2943 (11.5)	31/437 (7.1)	14/117 (12.0)	3/47 (6.4)	0.07
Hispanic	293/4774 (6.1)	66/1197 (5.5)	196/2974 (6.6)	16/437 (3.7)	13/117 (11.1)	2/47 (4.3)	0.02
Smoker within previous year — no./total no. (%)	679/4775 (14.2)	124/1198 (10.4)	458/2975 (15.4)	79/436 (18.1)	14/117 (12.0)	4/47 (8.5)	<0.001

* Plus–minus values are means ±SD.
† One patient underwent a vertical banded gastroplasty, and one underwent an adjustable gastric banding.
‡ P values are for the comparison between treatment groups. Values were calculated with the use of the chi-square test for categorical variables and the Kruskal–Wallis test for continuous variables.
§ The body-mass index is the weight in kilograms divided by the square of the height in meters.
¶ Race or ethnic group was self-reported.

justable gastric banding, 4.8% of those who had undergone laparoscopic Roux-en-Y gastric bypass, and 7.8% of those who had undergone open Roux-en-Y gastric bypass (Table 2). Patients in the open Roux-en-Y-group whose surgery was started as laparoscopic and was converted to open had a lower incidence of the composite end point than patients whose surgery began as open (3.9% vs. 8.3%). The most commonly occurring components of the end point were abdominal reoperation (2.6%) and endoscopic intervention (1.1%). Although the protocol for reporting adverse outcomes included only those events that necessitated reintervention, we collected information on intraoperative events. There was one unplanned splenectomy during a gastric bypass, and three patients underwent a concurrent blood-vessel repair or ligation to control bleeding. Data about the management of postoperative bleeding without reintervention were not collected.

Several characteristics of the patients and the procedure types were associated with the composite end point in unadjusted analyses (Table 2 in the Supplementary Appendix). Owing to interrelationships among several of those variables, after adjustment, only the type of procedure (open and laparoscopic Roux-en-Y gastric bypass, as compared with laparoscopic adjustable gastric banding), extremes of body-mass index, an inability to walk 200 ft, a history of deep-vein thrombosis or venous thromboembolism, and a history of obstructive sleep apnea were significantly associated with the composite end point. After adjustment for specific patient characteristics, the risk of the composite end point with laparoscopic Roux-en-Y gastric bypass, as compared with laparoscopic adjustable gastric banding, was increased by a factor of 4.8; the risk of the composite end point with open Roux-en-Y gastric bypass, as compared with laparoscopic adjustable gastric banding, was increased by a factor of 5.8. After adjustment, there was no significant difference in the odds of the composite end point with open Roux-en-Y gastric bypass, as compared with laparoscopic Roux-en-Y gastric bypass, regardless of whether surgeries in which the laparoscopic approach was converted to the open approach were included (odds ratio for the inclusion of converted approaches, 1.21; 95% confidence interval [CI], 0.71 to 2.04; odds ratio for the exclusion of converted approaches, 1.38; 95% CI, 0.77 to 2.49).

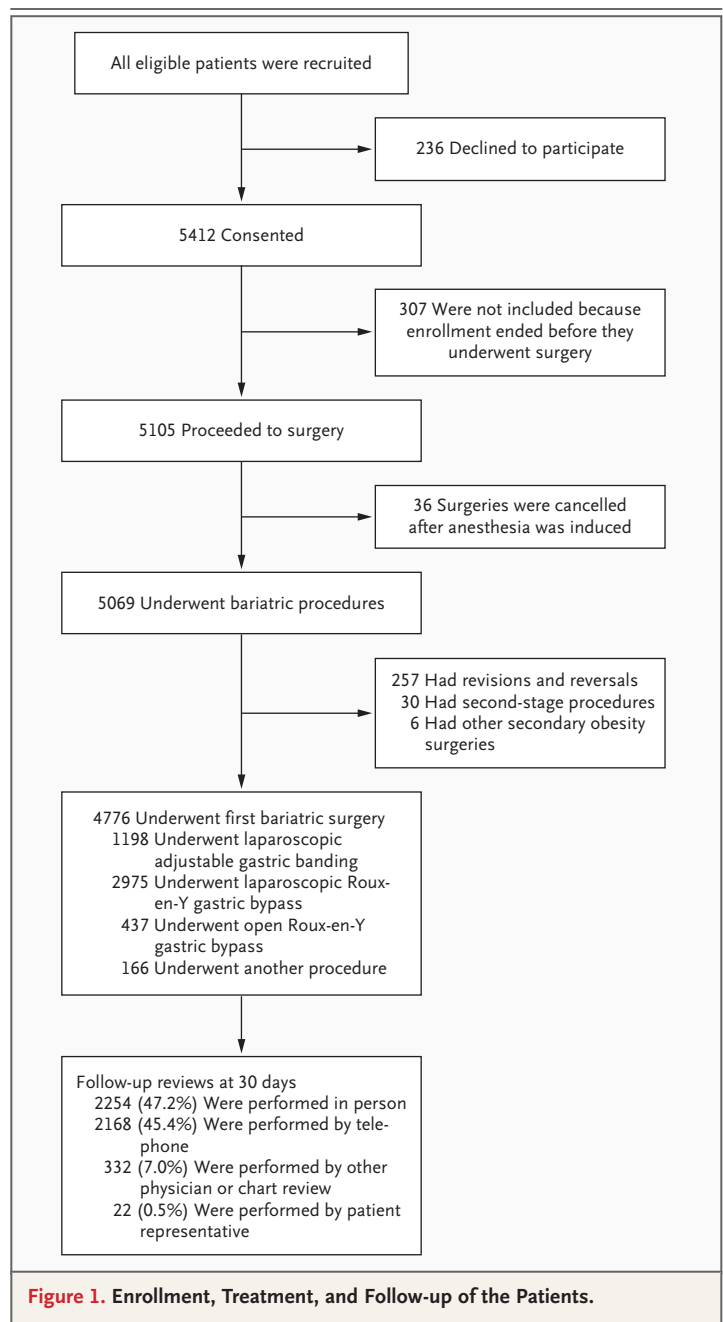Regardless of the type of procedure, the pre-

Figure 1. Enrollment, Treatment, and Follow-up of the Patients.

dicted probability of 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. The estimated percentage of patients with the composite end point ranged from approximately 3% among patients who did not have a history of obstructive sleep

Table 2. Adverse Outcomes within 30 Days after Surgery, According to Surgical Procedure.

Outcome	Total (N=4610)*	Laparoscopic Adjustable Gastric Banding (N=1198)	Laparoscopic Roux-en-Y Gastric Bypass (N=2975)	Open Roux-en-Y Gastric Bypass (N=437)	P Value†
		number (percent)			
Death	15 (0.3)	0	6 (0.2)	9 (2.1)	<0.001
Deep-vein thrombosis or venous thromboembolism	20 (0.4)	3 (0.3)	12 (0.4)	5 (1.1)	0.05
Tracheal reintubation	20 (0.4)	2 (0.2)	12 (0.4)	6 (1.4)	0.004
Endoscopy	51 (1.1)	1 (0.1)	45 (1.5)	5 (1.1)	<0.001
Operation					
Tracheostomy	11 (0.2)	0	6 (0.2)	5 (1.1)	0.001
Placement of percutaneous drain	16 (0.3)	0	13 (0.4)	3 (0.7)	0.48
Abdominal operation	118 (2.6)	9 (0.8)	94 (3.2)	15 (3.4)	<0.001
Failure to be discharged by day 30	17 (0.4)	0	13 (0.4)	4 (0.9)	0.02
Composite end point‡	189 (4.1)	12 (1.0)	143 (4.8)	34 (7.8)	<0.0001

* The total excludes 166 procedures, including 117 sleeve gastrectomies, 47 biliopancreatic diversions with or without a duodenal switch, 1 vertical banded gastroplasty, and 1 open adjustable gastric banding.
† P values are for the comparison between treatment groups. Values were calculated with the use of the chi-square test.
‡ This end point is a composite of death; deep-vein thrombosis or venous thromboembolism; reintervention with the use of a percutaneous, endoscopic, or operative technique; or failure to be discharged from the hospital within 30 days after surgery.

apnea or venous thromboembolism and had a body-mass index in the 50s to more than 10% among patients who had a history of deep-vein thrombosis or venous thromboembolism and of obstructive sleep apnea and a body-mass index of 70 (Fig. 2). Despite higher point estimates for the predicted probability of the composite end point among patients with a body-mass index of less than 53 (the value at which the predicted probability of the composite end point was lowest), the confidence intervals for those estimates are wide; only 13.5% of procedures and 12.2% of events occurred in patients who had a body-mass index of less than 40.

DISCUSSION

In this study, we report major perisurgical adverse outcomes in a recent cohort of patients undergoing the most common bariatric surgical procedures performed by experienced surgeons in established U.S. centers. Despite multiple coexisting conditions in this severely obese population, the overall 30-day mortality (0.3%) and the rate of major adverse outcomes were low. Specific presurgical health conditions and extreme obesity were associated with an increased number of adverse outcomes within 30 days after surgery. These higher-risk charac-

teristics were generally more common among patients undergoing gastric bypass than among those undergoing adjustable banding, but the patients who underwent gastric bypass had a higher risk of adverse events, even after we accounted for these characteristics, and the patients who underwent more invasive procedures also had a higher risk of events.

Characteristics of the patients (e.g., male sex, coexisting medical conditions, and a higher body-mass index), of the operation (i.e., degree of invasiveness), of the surgeon, and of the site have been thought to increase the risk of adverse outcomes. Our study provides standardized, prospective data on a cohort from multiple centers that is large enough to evaluate potential factors associated with safety outcomes. Understanding the factors that underlie risk is imperative for developing risk-stratification models that can be used for comparing the outcomes among hospitals and surgeons and for providing the best advice to patients. The complex interplay of factors associated with adverse outcomes represents a challenge in determining a predictive model for risk in bariatric surgery. At least one scoring system of risk that was created from a single-site retrospective cohort has been proposed[8] and has been validated in an alternative cohort[9]; the variables used in
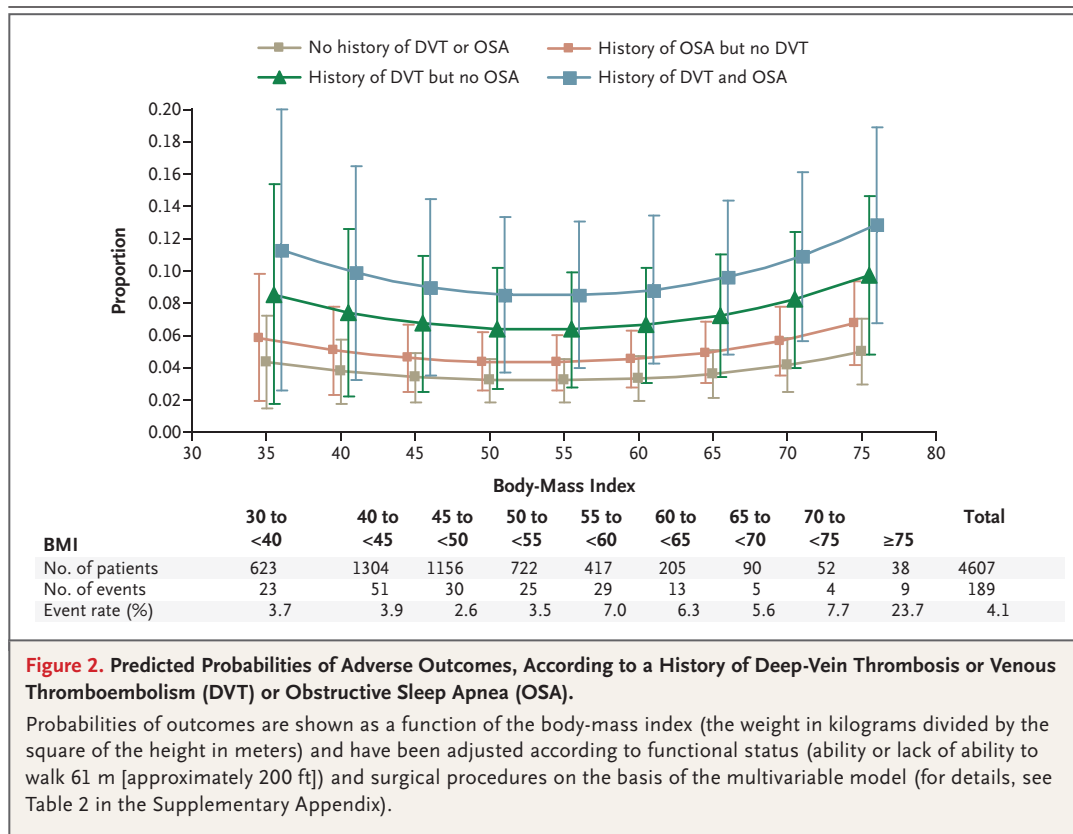
BMI	30 to <40	40 to <45	45 to <50	50 to <55	55 to <60	60 to <65	65 to <70	70 to <75	≥75	Total
No. of patients	623	1304	1156	722	417	205	90	52	38	4607
No. of events	23	51	30	25	29	13	5	4	9	189
Event rate (%)	3.7	3.9	2.6	3.5	7.0	6.3	5.6	7.7	23.7	4.1

Figure 2. Predicted Probabilities of Adverse Outcomes, According to a History of Deep-Vein Thrombosis or Venous Thromboembolism (DVT) or Obstructive Sleep Apnea (OSA).

Probabilities of outcomes are shown as a function of the body-mass index (the weight in kilograms divided by the square of the height in meters) and have been adjusted according to functional status (ability or lack of ability to walk 61 m [approximately 200 ft]) and surgical procedures on the basis of the multivariable model (for details, see Table 2 in the Supplementary Appendix).

the scoring included age, body-mass index, sex, presence or absence of hypertension, and risk or no risk of venous thromboembolism. Of these factors, only body-mass index and a history of venous thromboembolism were independently associated with the composite end point in our study.

Although a higher body-mass index has been shown to increase the risk of an adverse outcome after bypass procedures,[5] our study showed that the body-mass index had a quadratic relationship to the predicted probability of the composite end point. The lowest predicted risk was found at a body-mass index of 53. The risk of the composite end point among patients with a body-mass index of 75 was 61% higher than the risk among those with a body-mass index of 53 (odds ratio, 1.61; 95% CI, 1.04 to 2.48). The predicted risk of the composite end point among patients with a body-mass index of less than 53 was also higher than the risk among those with a body-mass index of 53, but the odds ratio did not differ significantly for any body-mass index below 53.

Although blacks have been reported to lose less weight than whites after bariatric surgery,[10-12]

disparity in the safety outcome has not been rigorously evaluated. Safety outcomes may turn out to be independent of weight-loss outcomes. The experience at the centers in our study may be unique, and perhaps previous studies that showed differences in outcomes according to race did not adequately control for the relationship between race and other factors. Furthermore, the statistical power to disentangle race from other confounding factors may be inadequate in our study, since only 10.9% of the patients were nonwhite. Although older age has been associated in many studies[6,13,14] with an increased likelihood of adverse outcomes, age was not significantly associated with outcome in our study. This finding may be explained in part either by the relatively small number of older patients (more than half the patients were in their 30s or 40s) or by a preferential selection of relatively healthy patients. In our study, older patients had, on average, a lower body-mass index than younger patients.[15] A recent single-surgeon report of 1000 Roux-en-Y gastric bypass procedures showed that obstructive sleep apnea conferred a risk of perioperative death that

was increased by a factor of three.[16] Whether an established diagnosis of obstructive sleep apnea is a marker of other factors that are predictive of an adverse outcome (perhaps because there is an increased use of screening for obstructive sleep apnea among patients at high risk) or whether obstructive sleep apnea itself truly confers an increased risk of the composite end point has not been determined. A history of deep-vein thrombosis or venous thromboembolism is a well-known risk factor for subsequent episodes of deep-vein thrombosis or venous thromboembolism.

The type of procedure was associated with a difference in the risk of the composite end point. Patients who underwent either an open Roux-en-Y gastric bypass or a laparoscopic Roux-en-Y gastric bypass had a much higher risk of the composite end point than those who underwent laparoscopic adjustable gastric banding. There were no significant differences in the composite end point between those who underwent an open Roux-en-Y gastric bypass and those who underwent a laparoscopic Roux-en-Y gastric bypass after adjustment for patient and center characteristics. Patients who underwent an open Roux-en-Y gastric bypass after an attempted laparoscopic bypass had a similar rate of the composite end point as those who underwent a completed laparoscopic Roux-en-Y gastric bypass.

When a choice must be made among different bariatric procedures, short-term safety may not be the only relevant factor. Laparoscopic adjustable gastric banding and laparoscopic Roux-en-Y gastric bypass have different effects on weight and obesity-related conditions. In most patients, Roux-en-Y gastric bypass affects glycemic control even before weight loss occurs,[17] whereas the effects of laparoscopic adjustable gastric banding are dependent on weight loss.[1,18] Data concerning the effectiveness of the procedures and the durability of their effects are critical.[19,20] Although our study was designed to evaluate short-term safety events, LABS-2 (ClinicalTrials.gov number 00465829), a long-term, prospective cohort evaluation that has just finished recruitment, is designed to assess the effect of these operations on health conditions, quality of life, health economic issues, diet and exercise behavior, and other psychosocial issues.

Our study had several limitations, which have been noted previously[17] and are summarized here. Whether our findings would be replicated in the general community is unknown. Recent data from administrative databases have shown that in-hospital outcomes after bypass surgery have improved since the 1990s.[21,22] Owing to Center of Excellence programs and formal training programs, we anticipate that the low rates of perioperative death and adverse outcomes seen in LABS centers will be achievable elsewhere. Since our study was large, multicenter, and prospective, some of the subgroups of patients were large; however, the limited size of other patient subgroups may have resulted in a type II error that did not identify a difference in safety among groups. Although we found expected differences in the rates of safety events among procedures on the basis of the degree of invasiveness, between-procedure comparisons on the basis of a common safety metric may not be appropriate. Some adverse outcomes are expected to occur only in the case of certain procedures (e.g., leaks of gastrointestinal anastomoses are a risk in Roux-en-Y gastric bypass but not in laparoscopic adjustable gastric banding), so a common metric that includes reoperation is biased against procedures with anastomoses. An additional limitation was that the preoperative existence and severity of conditions was determined by patients' self-report. Finally, although the case volume of a particular center or surgeon is worthwhile to document in evaluating outcomes, we could not determine the case volume at the centers, because at some centers not all surgeons participated in the LABS consortium, and surgeons in the LABS consortium were certified by the consortium to participate at various times during the year. Thus, the actual surgical volume for that year may not have been captured. The multivariable analysis was adjusted for center but not explicitly for center volume.

Obesity remains a major cause of illness and death, and bariatric surgery appears to be the only intervention that consistently results in substantial, sustained weight loss. The safety of such surgery is an important consideration, and our study shows that the incidence of death and adverse events within 30 days after bariatric surgery is low but is varied among different risk groups. These short-term risks should be considered in the context of the long-term health effects of surgically induced weight loss on coexisting health conditions, the long-term risks of the bariatric surgery itself, the competing risk of death from extreme obesity, and the relative benefits of the rate and durability of weight loss.

APPENDIX

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