National Surgical Quality Improvement Program Analysis of Bariatric Operations: Modifiable Risk Factors Contribute to Bariatric Surgical Adverse Outcomes

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BACKGROUND: The increase in obesity coupled with greater acceptance of the field of bariatric surgery has resulted in a substantial rise in the number of weight-loss operations. Because obese individuals are at high risk for surgical complications, concern about the safety of bariatric procedures exists. Earlier investigations of the clinical features associated with surgical complications have produced conflicting results. We sought to identify risk factors for surgical complications in a large, nationally representative population of US veterans.

STUDY DESIGN: We analyzed data on bariatric procedures performed at 12 Veterans' Affairs medical centers approved to perform weight-loss operations between 1998 and 2004. Detailed pre-, intra-, and postoperative information and longterm mortality data were prospectively collected using the National Surgical Quality Improvement Program methodology. We used multivariable logistic regression to identify clinical features associated with postoperative complications.

RESULTS: Among 575 bariatric patients assessed between 1998 and 2004, 74% were men with a mean age of 51 years. Thirty-day mortality was 1.4%. Overall complication rate was 19.7%. Of those with complications, one-half were of considerable clinical importance, as they were associated with prolonged length of stay. Clinical features that were predictive of adverse events in our multivariable analyses were superobesity, weight > 350 pounds, and smoking. A more than 20 pack-year history of smoking was also associated with difficulty in weaning from a ventilator postoperatively.

CONCLUSIONS: We identified smoking and superobesity as preoperative risk factors associated with postoperative complications. Future studies should examine the effect of preoperative weight loss and smoking cessation on bariatric procedure outcomes. (J Am Coll Surg 2006;203:625–633.
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Bariatric operation remain the only proven mechanism for inducing both sustained and profound weight loss for morbidly obese individuals.[1] The Veterans' Affairs (VA) system has the highest reported rate of morbid obesity of any health care system, with 6% of female and 3.3% of male veterans with body mass indices (BMI; calculated as kg/m^2) exceeding 40.[2] The high prevalence of obesity coupled with a dramatic increase in the number of weight-loss operations in the private sector spurred an increase in the number of bariatric procedures within the VA. The VA bariatric population differs from the private sector in several important ways:

1. The veteran population is 95% men. All earlier series reporting bariatric operation outcomes contain a preponderance of women. Male gender has been associated with a higher risk of adverse outcomes,[3,4] such that the acceptable

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Abbreviations and Acronyms

BIRLS = Beneficiary Identification Records Locator Subsystem
BMI = body mass index
NSQIP = National Surgical Quality Improvement Program
VA = Veterans' Affairs

standards for morbidity and mortality for a male population undergoing these procedures is unknown.

2. Users of the Veteran's health care system are typically of lower socioeconomic background—another category of individuals with known higher risk for unfavorable outcomes after surgical interventions.[5-7]
3. The veteran population is older than the private sector population. Advanced age has been associated with greater risk of adverse events in bariatric populations,[3,8,9] although other reports have found no increased complications in the elderly undergoing these procedures.[10,11]
4. The VA collects detailed quality-of-care data for major surgical procedures performed in VA medical centers.[12] Before October 1, 2004, selected patients were assessed using established criteria for the National Surgical Quality Improvement Program (NSQIP) program.[12] After this date, all VA bariatric surgical procedures have been entered into the NSQIP database.

Previous reports of complication and death rates for bariatric operations were from single institutions without systematic reporting or followup of their patients, or were from large administrative databases that contain limited information and were subject to coding inconsistencies. The NSQIP prospectively reports patient risk factor and outcomes information that is collected by trained nurses using a standardized protocol. Clinical information contained in the NSQIP database is more reliable than that found in administrative databases, yet the advantage of administrative database analysis, ie, assessment of clinical outcomes from multiple centers free of any potential reporting bias, is retained. Given these advantages, the American College of Surgeons has adopted the NSQIP methodology for outcomes assessment of operations performed in private hospitals.

To establish the rates of morbidity and mortality from bariatric procedures in the VA, and to identify risk factors associated with adverse outcomes, we analyzed the NSQIP database for bariatric operations performed in the VA from the years 1998 to 2004.

METHODS

Bariatric patients were identified in the NSQIP database using an algorithm of Current Procedural Terminology and ICD-9 codes (Table 1). These same codes have been used to characterize bariatric surgical procedures since 1995. To ensure the reliability of this case-finding strategy, the medical centers with the largest volumes were asked to verify that cases identified by this coding strategy were indeed bariatric cases. They were also asked to identify any known bariatric procedures that were missed by this coding approach. We found that the algorithm identified bariatric cases with a sensitivity of 99.2% and specificity of 99.9%. Finally, because the VA had not included preoperative body weight or height in the NSQIP before 2004, surgical service personnel at each medical center provided these for each patient. Complications have standardized definitions and are entered into the database by the nurse reviewers.[12,13]

Mortality is entered into the NSQIP database in a variety of ways. The NSQIP nurse follows each patient for postoperative mortality and morbidity for 30 days after the operation. Veterans who receive benefits from the VA (ie, compensation, pension, education, or burial benefits) have a file in the Beneficiary Identification Records Locator Subsystem (BIRLS).[14] BIRLS will reflect a patient's death if they are receiving benefits that must be terminated when they die. The NSQIP database is merged with BIRLS semiannually, allowing us to capture longterm mortality information for NSQIP patients.

Thirty-day mortality was defined as the patient dying from any cause within 30 days of the bariatric procedure. Any death occurring from any cause after 30 days was defined as a late mortality. Complications as defined by NSQIP have been described previously.[12] Tobacco smokers were classified by whether or not they had smoked within the past year and also by having a greater than 20 pack-year history of smoking or not.

A subset of the NSQIP database was created that only included deidentified patient level information for bariatric surgical patients. This was maintained and analyzed using the Statistical Analysis Software package (SAS Institute). Statistical comparisons for continuous data were made with *t*-tests. Chi-square analysis and the Fisher's exact test were used for categorical data. Graphical analysis was performed using the SigmaPlot (SPSS Inc) graphing program. There were not enough deaths to model pre-

Table 1. CPT-4 Procedure Codes Used to Identify Bariatric Operations in the National Surgical Quality Improvement Program Database

CPT-4 codes	Description
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity, vertical banded gastroplasty
43843	Other than vertical banded gastroplasty
43846	Gastric restrictive procedure, with gastric bypass, for morbid obesity; with short limb (< 100 cm) Roux-en-Y gastroenterostomy
43847	With small intestine reconstruction to limit absorption
43848	Revision of gastric restrictive procedure for morbid obesity (separate procedure)
43659*	Gastrectomy, total; with Roux-en-Y reconstruction
43621*	Gastrectomy, partial, distal; with Roux-en-Y reconstruction
43633*	Unlisted laparoscopy procedure, stomach (this code added in 2000)

*Codes also considered related to bariatric procedures when used in conjunction with ICD-9 278.01 (morbid obesity) as the primary diagnosis.
CPT, Current Procedural Terminology.

operative risk factors as predictors for perioperative death. We used multivariable logistic regression to assess the association between preoperative demographic and clinical variables with other adverse outcomes. One of the outcomes (dependent variable) of interest for these analyses was presence of any postoperative complications from the bariatric operation. All preoperative demographic and clinical variables that were notably associated with the rate of adverse events on bivariate analysis ($p < 0.20$) were included in our multivariable model that was run with stepwise elimination.

Other exploratory analyses were also performed with multivariable logistic regression using smoking status (current smoker or history of heavy smoking) as the independent variable of interest and respiratory complications as dependent variables (failure to wean within 48 hours of operation, reintubation, or development of pneumonia). Superobesity was defined as BMI $\geq$ 50.

RESULTS

We identified 575 assessed patients in the NSQIP database of a total of 675 bariatric surgical procedures performed for the years 1998 to 2004. These procedures were performed in 12 VA medical centers that contributed between 8 and 119 patients to the series. Demographic and clinical information for this cohort are provided in Table 2. Our population consisted of 74% men with a mean age of 51 years, of whom nearly 42% were superobese (BMI $\geq$ 50). Mean weight was 336 pounds (range 190 to 565 pounds). Mean BMI was 49.6 (range 30.3 to 102.6). Of those undergoing an operation, 6 had BMI ranging from 30.3 to 34.9 and 42 had BMI between 35.0 and 35.9, the remainder had BMI exceeding 40.0. The most common comorbid condition was diabetes, with 37% of patients taking oral hypoglycemic agents or requiring insulin treatment. Dyspnea was present in 22% of patients and nearly 17% had smoked within the past year.

Median time to complete the operation was 3.3 hours (range 1.2 to 11.2 hours). Procedure durations fell by an hour over the years we assessed. In 1998, median operating room time was 4.0 hours. By 2004, this had fallen to 3.0 hours. Complications as defined by NSQIP occurred in 19.7% of patients. Of all operations performed, 9.7% were associated with prolonged hospitalization defined as two times the median length of stay for the procedure performed. For open Roux-en-Y gastric bypass, median length of stay was 6 days and for laparoscopic procedures it was 4 days. There were eight deaths resulting in a 30-day mortality rate of 1.4%. There were another six deaths that occurred between 30 and 90 days, another three between 90 days and 1 year postoperatively, and one that occurred within 2 years of operation. Overall longterm mortality was 3.1%, with a median followup of 33 months. There were 14 (2.4%) revision procedures. The complication rate for primary operations was 19.6% and for revisions it was 21.4% (p = NS, chi-square). Consequently, revision procedures were combined with first time procedures in all subsequent analysis.

Table 3 lists the complications that occurred in the cohort we examined. The most frequent NSQIP complication was superficial wound infection. The next most common NSQIP complication was failure to wean from the ventilator, followed by urinary tract infection, reintubation, and wound dehiscence. Eight patients died within 30 days of their bariatric procedure. Complications associated with patient mortality were cardiac

Table 2. Demographic and Preoperative Factors for the Population Studied

Demographic and preoperative factors	All patients
n	575
Male	74
Mean weight ± SD (lb)	336 ± 61
Mean BMI ± SD*	49.6 ± 8.0
Superobese†	41.7
Mean age ± SD (y)	51.1 ± 8.1
Age ≥ 65 y	4.4
Hispanic	1.9
African American	8.5
Caucasian	66.0
CHF	2.1
COPD	9.0
TIA	0.7
Diabetes	37.0
Renal insufficiency	1.2
Dyspnea with exertion	20.3
Dyspnea at rest	2.2
Functional status: partial or full dependence	3.1
Smoked within past 1 y	16.7
ASA2	13.2
ASA3	82.1
ASA4	4.7

Values are percentages except where otherwise indicated.
*Calculated as kg/m^2.
†Superobesity is defined as BMI ≥ 50.
ASA, American Society of Anesthesiologists; BMI, body mass index; CHF, congestive heart failure; TIA, transient ischemic attack.

arrest, postoperative renal failure, failure to wean from the ventilator, sepsis, pneumonia, urinary tract infection, and pulmonary embolism.

Bivariate analysis of the preoperative patient characteristics failed to demonstrate a relationship (ie, $p \leq 0.2$) between postoperative complications and the following: age, history of congestive heart failure, history of cerebrovascular accident with neurologic deficit, history of transient ischemic attack, impaired sensorium, diabetes of any type, dyspnea at rest, alcohol abuse, partially dependent functional status, recent chemotherapy for malignancy, steroid use, history of chronic obstructive pulmonary disease, recent dialysis, elevated alkaline phosphatase, elevated bilirubin, elevated blood urea nitrogen, elevated creatinine, elevated or abnormally low hematocrit, abnormal preoperative sodium, and low white blood count. The remaining clinical features were entered into a stepwise elimination logistic regression model. The following variables were eliminated during the regression procedure: gender, history of cerebrovascular event without neurologic deficit, hemiplegia, dyspnea on exertion, bleeding disorder, preoperative wound infection, elevated partial thromboplastin time, elevated SGOT, and elevated WBC. Only a history of smoking in the past year (odds ratio = 1.68; 95% CI, 1.00−2.80; $p = 0.0481$) and superobesity (odds ratio = 1.96; 1.29−2.98; $p = 0.0016$) remained statistically significant predictors for postoperative complications. Odds ratio for weight > 350 pounds was 1.92 (96% CI, 1.26−2.91) when it was entered into the regression equation instead of superobesity.

Graphic analysis of age, BMI, and body weight are presented in Figure 1. Distribution for age for those with complications was the same as for patients without complications. Complication−BMI histogram is shifted to the right consistent with our observation that BMI > 50 is associated with a higher complication rate. Body weights > 350 pounds were associated with complications. Complication rate for those > 350 pounds was 27%, compared with a complication rate of 16% for those ≤ 350 pounds ($p = 0.0017$). Male gender was not associated with a higher risk of complications. Men had a complication rate of 21%, compared with a complication rate of 16% for women ($p = 0.1623$). Although substance abuse is common in the VA population, only two patients provided a history of drinking more than two drinks per day within the 2 weeks before undergoing their bariatric operation. Only one of these experienced postoperative complications. Pneumonia developed in that patient, who remained on a ventilator for a prolonged period of time but eventually recovered.

The impact of smoking on failure to wean from the ventilator within 48 hours of the procedure is shown in Figure 2. The column on the left represents results for patients who had not smoked tobacco within the year before their bariatric operation and who had a lifetime history of smoking that was less than 20 pack-years. For these individuals, 1.8% could not be weaned off the ventilator within 48 hours of their operation. This cohort had a total complication rate of 18.8%. The middle column represents patients who had not smoked for at least 1 year before their weight-loss operation, but had a lifetime smoking history exceeding 20 pack-years; 5.8% of these individuals could not be weaned off the ventilator within 48 hours of their operation ($p = 0.0085$; compared with those not currently smoking with a less than 20 pack-year lifetime smoking history) and had an overall complication rate of 15.1%. The column on the

Table 3. Number of Patients with Bariatric Surgical Complications as Defined by National Surgical Quality Improvement Program

Complication	NSQIP complication	Complication rate	Mortality (30-d)*	Death rate†
Cardiac arrest	9	1.6	3	33.3
MI	3	0.5	0	0.0
Coma > 24 h	2	0.3	1	50.0
Stroke	0	0.0	0	0.0
Peripheral nerve injury	1	0.2	0	0.0
Bleeding requiring > 4 U PRBC within 72 h of operation	4	0.7	1	25.0
DVT	4	0.7	0	0.0
Sepsis	11	1.9	2	18.2
Failure to wean from ventilator > 48 h postoperatively	17	3.0	2	11.8
Pneumonia	10	1.7	2	20.0
Pulmonary embolism	3	0.5	2	66.7
Reintubation	13	2.3	0	0.0
Postoperative renal failure	6	1.0	3	50.0
Postoperative renal insufficiency	7	1.2	1	14.3
UTI	16	2.8	2	12.5
Wound dehiscence	12	2.1	1	8.3
Superficial wound infection	53	9.2	1	1.9
Deep wound infection	10	1.7	0	0.0

*No. of patients who died within 30 d of operation.
†Death rate refers to mortality associated with the presence of each listed complication. Some patients had multiple complications and some who died had several complications, such that the totals in each column do not reflect actual morbidity or mortality rates.
DVT, deep vein thrombosis; NSQIP, National Surgical Quality Improvement Program; PRBC, packed red blood cells; UTI, urinary tract infection.

right shows an 11.1% failure-to-wean rate ($p < 0.0001$; compared with those not currently smoking with a less than 20 pack-year lifetime smoking history) and overall complication rate of 26.7%. Having a greater than 20 pack-year history of smoking was notably associated with failure to wean off the ventilator within 48 hours of operation (odds ratio = 5.16; 95% CI, 1.92−13.84), but not with the need for reintubation or development of pneumonia.

Table 4 presents results for open and laparoscopic procedures. The length of stay for laparoscopic procedures was 2 days less than for open procedures. Patients undergoing laparoscopic operations had slightly lower BMI and markedly lower overall complication rate. There were no deaths or superficial wound infections in the laparoscopic group.

DISCUSSION

This series is unique because it is the first to report NSQIP results for bariatric operations. It is also novel in that every earlier report of bariatric surgical outcomes assessed patient cohorts that were composed mostly of women. Male gender has been consistently identified as a risk factor for adverse outcomes after these procedures.[3,4,9] The VA's mostly male population, as such, is inherently high-risk. Despite the risk, we found a 30-day mortality of 1.4%.

Both the short and longterm mortality we observed compared favorably with other series.[3,9,15,16] Although some bariatric procedure mortality analyses report perioperative death rates of < 1%,[17-20] series of high-risk patients operated on in university referral centers report mortality rates of approximately 1.5%.[3,15] The highest reported 30-day mortality was from Washington State and was associated with surgeon inexperience.[16] We had previously examined mortality in male and female patients in one large case series and found that the combined short and longterm mortality associated with bariatric procedures was 3.0% for men and 0.8% for women,[17] nearly identical to what we found in the VA NSQIP analysis. We[17] and others[4] had found male gender to be a mortality risk factor. Given that no other earlier reported bariatric procedure series had a preponderance of men, the expected mortality rate is not known for a mostly male cohort. Thirty-day mortality rate of 1.4% should serve as a benchmark for the VA nationally.

We observed a total death rate of 3.1% over 2 years

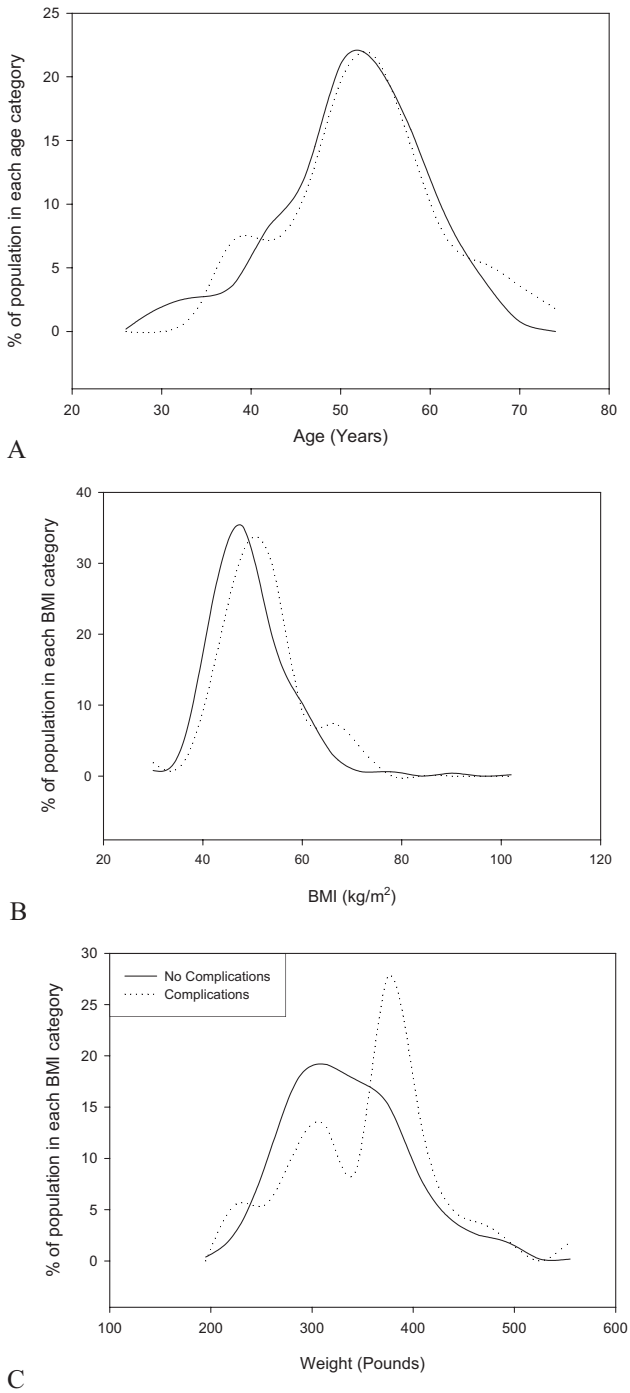

Figure 1. The impact of age, body mass index (BMI), and body weight on complication rates.

postoperation. This also compares favorably with other similar datasets. Most bariatric operation series lack complete followup for operated patients, ranging from 70% to 80%. One exception was a 9-year study conducted in North Carolina that, through the extensive efforts of the investigators, achieved a > 95% followup. Overall death rate for gastric bypass patients was 9% in 9 years, translated to an annualized postoperative mortality rate of 1% per year.[21] Because of the linkage of the BIRLS to NSQIP, we have very reliable mortality information that is entered into NSQIP irrespective of where or how the veteran died. We found an overall death rate of 3.1% in 2 years, such that the annualized mortality rate was 1.5%.

For bariatric procedures, we found the postoperative complication rate to be 19.7%. With time, adverse event rates have been falling in the VA. When NSQIP results were first reported, general surgical complication rates were 17.4%[13] and have now fallen to the 7% to 13% range.[22] What the acceptable complication rate for bariatric operations should be is unknown. There is no standard classification scheme for them, resulting in extreme variability in reported complication rates. Complications also vary in their clinical importance, with some being relatively minor and others causing extreme disability. Excessive length of stay has been used as a marker for the occurrence of clinically important complications.[17] The 10% unanticipated prolonged hospitalization rate for bariatric operations in US hospitals compares favorably with the 9.7% rate found in the current series.

Our series occurred during a time of considerable evolution for the field of bariatric surgery. It was during this time period that this treatment modality gained acceptance, such that surgeons who had been performing these operations could do more of them. Younger surgeons were receiving more formalized training in bariatric procedures than had occurred in the past. Improvements in technique were manifested by a reduction in operating room time by 1 hour between 1998 and 2004. In 2004, the median operating room time was 3.00 hours, seemingly higher than that reported in other series. This might be because of the greater technical difficulty inherent in a population of large male patients. Alternatively, the seemingly longer surgical times could be related to difference in definitions of start and stop times. Operation duration is typically defined as starting with an incision and stopping when the incision is closed. For the VA NSQIP, the start time is when an incision is made. Stop times are defined as the "time when instrument and sponge counts are completed and verified as correct; all postoperative radiologic studies to be done in the operating room are completed; all dress-

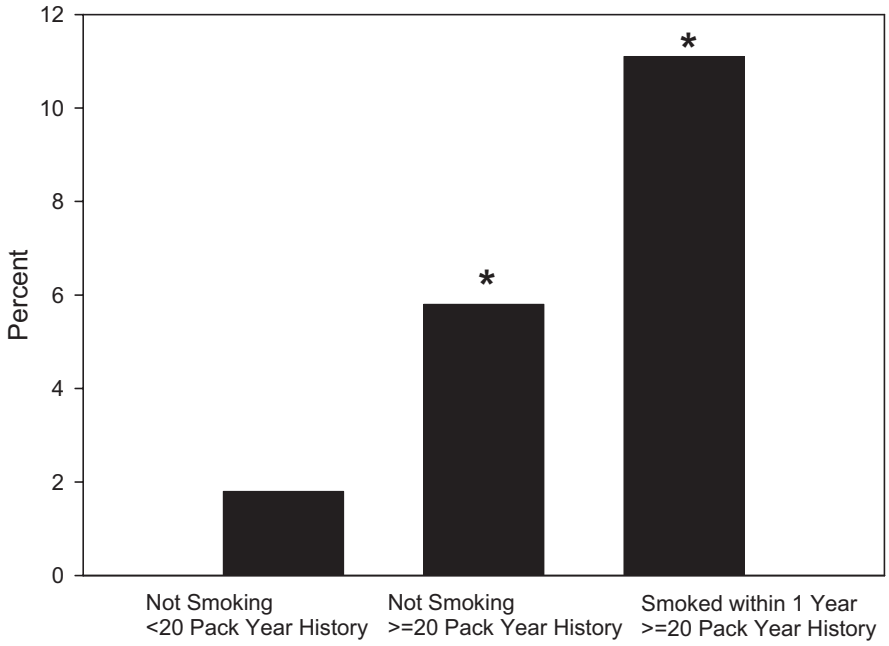

Figure 2. Effect of current and a history of heavy smoking on bariatric operation outcomes. *$p < 0.01$ relative to patients not currently smoking with a less than 20 pack-year history of smoking.

ings and drains are secured; and the physicians and surgeons have completed all procedure-related activities on the patient." These added definitions for the procedure stop time can result in the VA operating room times appearing longer than those reported in other series where definitions might differ.

Our analysis of VA NSQIP bariatric operations identified two important risk factors for adverse outcomes from these procedures: smoking and superobesity. Smoking was an independent risk factor for complications and those who do not currently smoke but have a history of heavy smoking were also found to have increased respiratory complications. These patients would potentially benefit from preoperative respiratory conditioning to maximize pulmonary function. Superobesity was the most important risk factor for perioperative complications. Although patients undergoing bariatric procedures invariably have a history of failed dieting, preoperative weight loss can improve patient safety for these procedures. Aggressive medical therapies, such as very-low−calorie diets, are transiently effective for morbidly obese patients. The major limitation of medical obesity treatments for these patients is generally unsustainable weight loss rather than an inability to lose weight at all. Given these circumstances, preoperative weight loss can prove to be a reasonable approach to reduce adverse outcomes for superobese bariatric surgical patients.

Unlike earlier studies, we did not find male gender to be a risk factor for bariatric surgical complications. Because the majority of patients were men, there was a reduced likelihood for finding male gender as an important factor. It is not known if male gender per se is a risk factor, or that men are, on average, larger than women, and that size is the more important predictor of adverse outcomes. Like many others,[3,9,15,23] our study found that size as measured by BMI or body weight was associated with a higher complication rate. BMI and weight distribution for men and women were nearly identical in the VA (data not shown), suggesting that women of similar size to men will experience similar complication rates. Our study suggests that larger-sized patients have a higher risk for complications. Male gender risk might be a proxy for larger size and higher risk.

All of the VA centers could be classified as low-volume bariatric operation centers. Clinical outcomes are thought to be better for high-risk procedures when performed in high volumes by physicians.[24] Earlier studies of bariatric operations volume-outcomes analysis have had findings similar to those for other technically complex procedures. In academic medical centers, the morbidity and mortality were lower at facilities performing more than

Table 4. Analysis of Open and Laparoscopic Procedures

	Open	Laparoscopic	p Value
n	502	73	
Mean age ± SD (y)	51.3 ± 8.1	50.0 ± 8.1	0.217
Mean BMI* ± SD	49.9 ± 8.4	47.4 ± 7.0	0.013†
Mean body weight ± SD (lb)	338 ± 60	326 ± 65	0.119
Male	75	67	0.182
Superobese	43	30	0.081
Smokers %	16	21	0.345
Superficial wound infection	11	0	< 0.0001‡
Deep wound infection	1	0	0.580‡
Wound dehiscence	2	0	0.193‡
Failure to wean from ventilator	3	0	0.096‡
Reintubation	3	0	0.168‡
Return to OR	7	8	0.65
Pneumonia	2	1	0.377
Any complication	22	3	< 0.0001‡
Deaths	2	0	0.277‡

Values are percentages except where otherwise indicated.
Comparisons of continuous variables were made by *t*-tests and categorical variables by chi-square.
*Calculated as kg/m^2.
†Unequal variances, used ANOVA.
‡Fisher's exact test.
BMI, body mass index; OR, operating room.

100 bariatric procedures annually, compared with those with less than 50.[19] An analysis emphasizing surgeon bariatric operation case load revealed more favorable outcomes for surgeons performing more than 200 procedures per year. High-volume hospitals where operations were performed by high-volume surgeons had the best results. High-volume surgeons operating at low-volume facilities had a higher risk of adverse events.[20] Volume has not been an important predictor of outcomes in the VA system for intermediate risk procedures.[25] This might be because many VA surgeons also perform operations in affiliated university medical centers and the surgeon's true case volume might be higher than reported in VA databases. All bariatric surgeons included in the present analysis had either substantial experience with these operations or had received specialized training in bariatric procedures. Outcomes reported in this series are well within norms for bariatric procedures and might reflect results for high-volume surgeons. Facility volumes have been shown to have an independent effect on outcomes.[20] Our findings differ, although the number of centers in our analysis was small and none reached the threshold for high-volume consideration.

Bivariate analysis demonstrated that there was a lower adverse event rate for laparoscopic procedures. BMI for patients undergoing laparoscopic operations was less than that for patients operated on with an open technique. No patient undergoing a laparoscopic operation suffered from superficial wound infection, but 11% of patients undergoing open procedures did. Earlier randomized controlled trials comparing open with laparoscopic gastric bypass suggested that the laparoscopic operation might be superior because of fewer adverse events and short hospitalizations.[26,27] Our findings are consistent with these studies, given that laparoscopic patients had a shorter median length of stay and prevented superficial wound infections.

Author Contributions

Study conception and design: Livingston
Acquisition of data: Schifftner, Henderson
Analysis and interpretation of data: Livingston, Arterburn, Schifftner, Henderson, DePalma
Drafting of manuscript: Livingston, Arterburn, Schifftner
Critical revision: Livingston, Arterburn, Schifftner, Henderson, DePalma

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