Hospital Complication Rates With Bariatric Surgery in Michigan

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Context  Despite the growing popularity of bariatric surgery, there remain concerns about perioperative safety and variation in outcomes across hospitals.

Objective  To assess complication rates of different bariatric procedures and variability in rates of serious complications across hospitals and according to procedure volume and center of excellence (COE) status.

Design, Setting, and Patients  Involving 25 hospitals and 62 surgeons statewide, the Michigan Bariatric Surgery Collaborative (MBSC) administers an externally audited, prospective clinical registry. We evaluated short-term morbidity in 15,275 Michigan patients undergoing 1 of 3 common bariatric procedures between 2006 and 2009. We used multilevel regression models to assess variation in risk-adjusted complication rates across hospitals and the effects of procedure volume and COE designation (by the American College of Surgeons or American Society for Metabolic and Bariatric Surgery) status.

Main Outcome Measure  Complications occurring within 30 days of surgery.

Results  Overall, 7.3% of patients experienced perioperative complications, most of which were wound problems and other minor complications. Serious complications were most common after gastric bypass (3.6%; 95% confidence interval [CI], 3.2%-4.0%), followed by sleeve gastrectomy (2.2%; 95% CI, 1.2%-3.2%), and laparoscopic adjustable gastric band (0.9%; 95% CI, 0.6%-1.1%) procedures (P < .001). Mortality occurred in 0.04% (95% CI, 0.001%-0.13%) of laparoscopic adjustable gastric band, 0 sleeve gastrectomy, and 0.14% (95% CI, 0.08%-0.25%) of the gastric bypass patients. After adjustment for patient characteristics and procedure mix, rates of serious complications varied from 1.6% (95% CI, 1.3-2.0) to 3.5% (95% CI, 2.4-5.0) (risk difference, 1.9; 95% CI, 0.08-3.7) across hospitals. Average annual procedure volume was inversely associated with rates of serious complications at both the hospital level (< 150 cases, 4.1%; 95% CI, 3.0%-5.1%; 150-299 cases, 2.7%; 95% CI, 2.2-3.2; and ≥ 300 cases, 2.3%; 95% CI, 2.0%-2.6%; P = .003) and surgeon level (< 100 cases, 3.8%; 95% CI, 3.2%-4.5%; 100-249 cases, 2.4%; 95% CI, 2.1%-2.8%; ≥ 250 cases, 1.9%; 95% CI, 1.4%-2.3%; P = .001). Adjusted rates of serious complications were similar in COE and non-COE hospitals (COE, 2.7%; 95% CI, 2.5%-3.1%; non-COE, 2.0%; 95% CI, 1.5%-2.4%; P = .41).

Conclusions  The frequency of serious complications among patients undergoing bariatric surgery in Michigan was relatively low. Rates of serious complications are inversely associated with hospital and surgeon procedure volume, but unrelated to COE accreditation by professional organizations.
Whether COE accreditation helps patients and payers identify safer hospitals for bariatric surgery remains a matter of debate. Hospital procedure volume, a core component of accreditation, has been linked to perioperative mortality with bariatric surgery. However, many of these studies are outdated. As bariatric surgery has been more commonplace and mortality has declined, previous hospital volume benchmarks (125 per year for COEs) may be less important now than in the past. To date, only 1 published study has directly compared the outcomes of bariatric surgery at COE and non-COE hospitals, noting higher mortality and equivalent morbidity at the former. Because this study was based on administrative data, however, its reliability in capturing hospital complication rates is questionable. It also included data from only 1 year, 2005, when COE programs were just beginning to be implemented.

In this context, we studied perioperative outcomes at 25 hospitals participating in the Michigan Bariatric Surgery Collaborative (MBSC), a payer-funded quality improvement program that administers a prospective, externally audited clinical outcomes registry. In addition to comparing complication rates by procedure and among hospitals, we examined relationships between procedure volume, COE accreditation, and hospital safety.

**METHODS**

**Study Sample**

This study is based on analysis of data from the MBSC. As described in greater detail elsewhere, the MBSC is a regional consortium of hospitals and surgeons performing bariatric surgery in Michigan. Participation in the MBSC is voluntary and any hospital that performs a minimum of 25 bariatric procedures per year is eligible to participate. The MBSC now enrolls approximately 6000 patients per year from 25 hospitals in its clinical registry. Participating hospitals submit data for all of their bariatric surgery patients including those undergoing gastric bypass, laparoscopic gastric banding, biliopancreatic diversion with or without duodenal switch, and sleeve gastrectomy procedures. Procedures done on an outpatient basis are included in the MBSC registry and are subject to the same data collection requirements.

In the MBSC, data for the clinical registry is collected via medical record review for each patient at the end of the 30-day perioperative period. Information collected includes demographic variables, preoperative clinical characteristics and conditions, as well as perioperative process of care and outcomes. Patient readmissions to other hospitals are captured if it is recorded in the medical records of the hospital performing the bariatric surgery. The medical record reviews are performed by centrally trained nurse data abstractors using a standardized and validated instrument. Each participating hospital is visited annually by the project data quality coordinator to verify the accuracy and completeness of its MBSC clinical registry data. The collection of data for the purposes of participation in the MBSC has been approved by the institutional review boards of all member sites.

For this study, we identified all patients undergoing bariatric surgery between June 2006 and September 2009, which includes 15 275 patients from 25 hospitals. We excluded patients undergoing revisional surgery from this analysis because of the heterogeneity of the patient population and surgical procedures as well as inherently higher rates of complications for patients undergoing revisional surgery. We also excluded patients undergoing duodenal switch (n = 245) for confidentiality reasons since most of these procedures were performed by 1 surgeon in the state. We combined patients undergoing open and laparoscopic gastric bypass procedures as there was no difference in the rates of major complications with the 2 procedures following adjustment for patient case mix and because open gastric bypass is now performed so rarely (<5% of patients during the study period).

**Outcomes**

Data were collected on 12 different types of bariatric surgery–related complications. Complications were grouped according to severity as non–life-threatening, potentially life-threatening, or life-threatening complications associated with residual and permanent disability or death. Potentially life-threatening complications included abdominal abscess (requiring percutaneous drainage or reoperation), bowel obstruction (requiring reoperation), leak (requiring percutaneous drainage or reoperation), bleeding (requiring transfusion >4 units, endoscopy, reoperation, or splenectomy), respiratory failure (requiring 2-7 days intubation), renal failure (requiring dialysis while patient is hospitalized during the perioperative period), wound infection/dehiscence (requiring reoperation), and venous thromboembolism (deep vein thrombosis or pulmonary embolism). Complications resulting in permanent disability included myocardial infarction or cardiac arrest, renal failure requiring long-term dialysis, respiratory failure requiring more than 7 days of intubation, or tracheostomy. The MBSC end points committee grades the severity of any perioperative complications not falling unambiguously into one of these categories. Our primary outcome measure for this study was the occurrence of a serious complication defined as potentially life threatening or resulting in death or disability.

**Independent Variables**

Data on patient characteristics include patient demographics, weight and medical history, and weight-related and other comorbidities listed in Table 1. In general, MBSC comorbidity definitions include clinical documentation of the condition, its treatment, or both in the medical record. Lung disease includes asthma, other obstructive/restrictive lung disease, and home oxygen use. Cardiovascular disease includes coronary artery disease, heart rhythm disorder, congestive heart failure, or peripheral vascular disease. Patients with nonalcoholic fatty liver, clinical or subclinical cir-
rhosis, or liver transplant are considered to have liver disorders.

Annual hospital and surgeon volume categories (Table 2) were determined using a combination of generally accepted volume cut points and empirical derivation based on the distribution of patients, hospitals, and surgeons. Sites were deemed centers of excellence if they were designated as such by the American College of Surgeons or the American Society of Metabolic and Bariatric Surgeons at any point during our study period. Two sites held Blue Cross and Blue Shield Centers of Distinction status, which has similar criteria to the other COE accreditation programs in addition to COE accreditation from the American College of Surgeons or American Society of Metabolic and Bariatric Surgeons.

**Statistical Analyses**

Pearson χ² test for categorical variables and the Kruskal-Wallis test for continuous variables were used to compare patient characteristics and rates of 30-day complications among patients undergoing the different types of bariatric procedures. Multilevel mixed-effects logistic regression models were used to evaluate risk factors for serious complications, with the log (odds) of the outcome modeled as a linear function of baseline covariates. The final models included all patient risk factors that were significant in multivariate analyses (age, body mass index [calculated as weight in kilograms divided by height in meters squared], male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions) and procedure type (laparoscopic adjustable gastric band, sleeve gastrectomy, or gastric bypass) as fixed effects, and hospital identifier as a random effect to adjust for clustering of patients within hospitals.

Because hospital and surgeon complication rates can vary due to chance alone, we adjusted our estimates for reliability. This technique adjusts hospital and surgeon outcomes for random variation, ensuring that performance is not overestimated or underestimated due to statistical noise. Empirical Bayes methods shrink the observed complication rate at each hospital or for each surgeon toward the overall average, depending on its reliability. Reliability is measured on a scale of 0 (completely unreliable) to 1 (perfectly reliable) and is largely a function of sample size. For this analysis, we used the random effects from the mixed-effects models to calculate risk- and reliability-adjusted complication rates for each hospital. For this calculation, we add the overall average log (odds) of serious complications to the random effect (since the mean is 0 by definition) and then take the inverse log of this sum. All reported P values are 2-sided, and P<.05 was considered statistically significant. All statistical analyses were performed using Stata version 10.1 (StataCorp, College Station, Texas).

### RESULTS

#### Patient Characteristics

There were significant differences across the procedure types with regard to all potential risk factors for complications, including demographics, medical history, and obesity-related comorbidity (Table 1). In general, patients receiving laparoscopic adjustable gastric bands were lower risk than patients receiving gastric bypass or sleeve gastrectomy. Specifically, patients receiving laparoscopic adjustable gastric bands had significantly lower body mass index at baseline and lower rates of associated comorbid conditions. The predicted risk of serious complications based on a logistic regression model including significant multivariable risk factors for serious complications, with the log (odds) of the outcome modeled as a linear function of baseline covariates. The final models included all patient risk factors that were significant in multivariate analyses (age, body mass index [calculated as weight in kilograms divided by height in meters squared], male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions) and procedure type (laparoscopic adjustable gastric band, sleeve gastrectomy, or gastric bypass) as fixed effects, and hospital identifier as a random effect to adjust for clustering of patients within hospitals.

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<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (N=15 275)</th>
<th>Laparoscopic Adjustable Gastric Band (n=5380)</th>
<th>Sleeve Gastrectomy (n=854)</th>
<th>Gastric Bypass (n=9041)</th>
<th>P Value&lt;sup&gt;a&lt;/sup&gt;</th>
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<td>Demographics</td>
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<td>Predicted risk of serious complications&lt;sup&gt;c&lt;/sup&gt;</td>
<td>2.7</td>
<td>2.4</td>
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<sup>a</sup>Abbreviations: BMI, body mass index; IQR, interquartile range.

<sup>b</sup>P values for medians calculated using a nonparametric k-sample test on the equality of medians and P values for categorical variables calculated using χ² tests.

<sup>c</sup>BMI was calculated as weight in kilograms divided by height in meters squared.

<sup>d</sup>Based on a multivariate logistic regression model including all significant patient risk factors for serious complications (age, body mass index, male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions).
late predictors (age, body mass index, male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions) was 2.4% for laparoscopic adjustable gastric band, 3.0% for sleeve gastrectomy, and 2.8% for gastric bypass.

Incidence of Specific Complications

Overall, 7.3% (95% confidence interval [CI], 6.9%-7.7%) of patients experienced 1 or more perioperative complications. Rates of potentially life-threatening complications (Table 3) were highest for patients undergoing gastric bypass (3.1%; 95% CI, 2.8%-3.5%), followed by sleeve gastrectomy (2.2%; 95% CI, 1.3%-3.5%), and laparoscopic adjustable gastric band (0.78%; 95% CI, 0.56%-1.1%) procedures (P < .001). Fatal complications occurred in 2 patients receiving laparoscopic adjustable gastric band (0.04%; 95% CI, 0.01%-0.13%), 0 patients receiving sleeve gastrectomy, and 13 patients receiving gastric bypass (0.14%; 95% CI, 0.08%-0.25%). Complications that were not fatal but that resulted in permanent disability occurred in 2 patients receiving laparoscopic adjustable gastric band (0.04%; 95% CI, 0.01%-0.13%) and 30 patients receiving gastric bypass (0.33%; 95% CI, 0.22%-0.47%).

Complications at the surgical site occurred in 5.9% of patients (95% CI, 5.6%-6.3%) and were highest in patients undergoing gastric bypass (8.7%; 95% CI, 8.1%-9.3%), followed by patients receiving sleeve gastrectomy (3.6%; 95% CI, 2.5%-5.1%), and laparoscopic adjustable gastric band (1.7%; 1.4%-2.1%). Infection was the most frequent type of complication (3.2%; 95% CI, 2.9%-3.5%) and was most common among patients undergoing gastric bypass (4.4%; 95% CI, 4.0%-4.8%) and sleeve gastrectomy (2.5%; 95% CI, 1.5%-3.7%) procedures (Table 3). The subcategory of medical complications (including venous thromboembolism, cardiac, renal failure, and respiratory) occurred in 1.5% of patients overall (95% CI, 1.1%-1.7%), with the incidence varying from 0.5% (95% CI, 3.2%-1.3%) in patients with laparoscopic adjustable gastric band to 2.1% (95% CI, 1.8%-2.4%) in patients who received gastric bypass.

Rates of reoperation ranged from 0.59% (95% CI, 0.19%-1.4%) for sleeve gastrectomy to 2.5% (95% CI, 2.2%-2.8%) for gastric bypass procedures (Table 3). Transfers to other medical facilities (0.14%; 95% CI, 0.09%-0.22%) occurred infrequently. Hospital readmission and emergency department visits occurred in 4% (95% CI, 3.7%-4.3%) and 6.8% (95% CI, 0.4%-7.2%) of patients overall, respectively. Rates of both readmission and emergency department visits were lowest in patients who received laparoscopic adjustable gastric band and highest in those receiving gastric bypass. Median hospital length of stay (days) was 1 (range, 0-96), 2 (range, 0-63), and 2 (range, 0-148) for patients receiving laparoscopic adjustable gastric band, sleeve gastrectomy, and gastric bypass, respectively.

Variation in Serious Complication Rates

Risk- and reliability-adjusted rates of serious complications varied from 1.6% (95% CI, 1.3%-2.0%) to 3.5% (95% CI, 1.8%-2.4%).
2.4%-5.0%) by hospital (Figure). Rates were significantly lower than the state-wide average for 3 hospitals. The majority of hospitals (68%) had serious complication rates between 2% and 3%.

Risk of serious complications was inversely associated with average annual bariatric procedure volume (Table 2). For surgeon volume, rates in the low-, medium-, and high-volume categories were 3.8% (95% CI, 3.2%-4.5%), 2.4% (95% CI, 2.1%-2.8%), and 1.9% (95% CI, 1.4%-2.3%), respectively (P for trend=.001). For hospital volume, adjusted rates of serious complications were 4.1% (95% CI, 3.0%-5.1%), 2.7% (95% CI, 2.2%-3.2%), and 2.3% (95% CI, 2.0%-2.6%) in low-, medium-, and high-volume hospitals, respectively (P for trend<.001). Serious complication rates were about twice as high (4.0%; 95% CI,
2.8%-5.3%) for low-volume surgeons at low-volume hospitals than for high-volume surgeons at high-volume hospitals (1.9%; 95% CI, 1.4%-2.3%). Overall, rates of serious complications were similar among patients undergoing surgery at a COE (2.7%; 95% CI, 2.5%-3.1%) than for patients undergoing surgery at non-COE hospitals (2.0%; 95% CI, 1.5%-2.4%). After adjustment for patient case and procedure mix, there remained no significant difference in rates of serious complications at COE and non-COE hospitals (adjusted odds ratio [OR], 1.27; 95% CI, 0.72-2.25; \( P = .41 \)). There also was no significant difference (adjusted OR, 1.34; 95% CI, 0.88-2.05; \( P = .18 \)) in rates of serious complications in the COE hospitals compared with the non-COE hospitals within hospital procedure volume categories.

In our multivariate models, including patient risk and procedure mix reduced variation in serious complication rates across centers by 22% (Table 4). Individually adding surgeon volume, hospital procedure volume, and COE status to this model reduced variation in serious complication rates across centers by 75%, 59%, and 25%, respectively.

**COMMENT**

In this study, we report major perioperative adverse outcomes in a large cohort of bariatric surgery patients. Our results provide information about the perioperative risks of the various types of bariatric procedures in general practice. Overall, 7% of patients experienced perioperative complications. The majority of complications were nonlife-threatening with minor wound problems being the most frequent type of complication. Approximately 2.5% of patients had more serious complications with mortality occurring in 0.12% of patients. Complication rates were highest for patients undergoing gastric bypass, followed by sleeve gastrectomy, and laparoscopic adjustable gastric band procedures.

Our study also suggests that the outcomes of bariatric surgery reported from select academic centers are achievable more broadly. Rates of serious complications were similar across providers with rates between 2% and 3% for the majority of hospitals and surgeons. The results of our study are similar to those recently reported by a select group of high-volume bariatric programs participating in the National Institutes of Health–funded Longitudinal Assessment of Bariatric Surgery (LABS) Consortium.\(^9\) Despite similar patient populations, the overall rate of death and major complications are higher in LABS than those reported in our study. Higher complication rates reported in LABS may be attributable to the time periods studied, which included patients undergoing surgery between 2005 and 2007 in LABS and between 2006 and 2009 in Michigan.

Similar to many high-risk surgical procedures, procedure volume has been shown to be an important predictor of adverse outcomes in bariatric surgery.\(^1,8,13,14\) The results of our study are similar to what others have found regarding the magnitude of the procedure volume effect on morbidity with bariatric surgery. For example, a study based on discharge claims data from the state of Florida (1999-2003) found approximate 2-fold differences in adjusted rates of serious complications comparing the lowest to the highest volume strata for both hospitals and surgeons.\(^7\) A limitation of studies based on discharge claims databases is their ability to reliably capture nonfatal complications. Most of these prior volume outcome analyses in bariatric surgery are also quite dated with the most recent cohort including patients from 2005.\(^8\)

Our results support those recently reported by Livingston\(^6\) that COE accreditation is not associated with lower rates of bariatric complications. The prior study used 2005 National Inpatient Survey data to compare morbidity and mortality rates among 19,363 bariatric surgery patients at 24 COE and 229 non-COE centers. Mortality rates were higher at COE centers (0.17%) than non-COE centers (0.09%) and morbidity rates were close to identical (6.3% COE vs 6.4% non-COE). ORs adjusted for procedure volume, patient

<table>
<thead>
<tr>
<th>Table 4. Results of Model Fitting</th>
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<td><strong>Level</strong></td>
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<td>Covariance parameter</td>
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<td>Reduction in between center variability, %</td>
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\(^a\)Based on a multivariate logistic regression model including all significant patient risk factors for serious complications (age, body mass index [calculated as weight in kilograms divided by height in meters squared], male sex, mobility limitations, prior history of venous thromboembolism, and total number of comorbid conditions) and procedure type (laparoscopic adjustable gastric band, sleeve gastrectomy, or gastric bypass).

\(^b\)Akaike information criterion is defined as minus twice log likelihood plus 2 degrees of freedom.
risk, and teaching status were 1.76 (P = .71) and 1.00 (P = .97) for mortality and morbidity, respectively. The study by Livingston differed from ours in that it was based on claims data that captured only in-hospital complications and also included data from only 1 year (2005) when COE programs were just beginning to be implemented.15-17

There are a number of reasons why COE accreditation by professional organizations or payers might not necessarily identify safer hospitals with bariatric surgery. First, although COE applications often ask hospitals for rates of specific outcomes (eg, postoperative venous thromboembolism), such outcomes data are generally not audited for accuracy or completeness and are often loosely defined. Second, aside from minimum case loads, most requirements for bariatric COE accreditation, including the availability of specific protocols and resources for managing morbidly obese patients, are easily met by most hospitals with bariatric programs and likely have little bearing on surgical complication rates. Finally, given the highly competitive marketplace for bariatric surgery, COE accreditation programs may be attracting hospitals motivated as much by marketing advantage as by the desire to demonstrate and improve their quality.

This study has numerous limitations. First, because all but 8 of the 25 hospitals were COE-accredited by the end of the study period, we had suboptimal statistical power for detecting differences in risk between COE and non-COE hospitals. Based on an alpha level of .05, our study had only 70% power to detect a relative risk reduction of 25% or more associated with COE accreditation.

Second, we counted as COEs any hospital that had received that designation by the end of the study period. In sensitivity analysis, however, we assessed the outcomes of patients according to whether their hospitals were COEs at the time of their procedures. As in our main analysis, there was no significant difference in rates of serious complications between COE and non-COE hospitals (adjusted OR, 1.15; 95% CI, 0.92-1.43; P = .22).

When considering undergoing bariatric surgery, patients should weigh the risks and benefits of the various treatment options. Although we cannot yet report on the relative effectiveness of different bariatric procedures, prior studies suggest that weight loss is greater with procedures that combine both restrictive and malabsorptive elements than in purely restrictive procedures such as the laparoscopic adjustable gastric band.18-24 In the future, our study will be able to provide information regarding the relative effectiveness of these different procedures with regard to weight loss, weight-related comorbidity resolution, late complications, quality of life, patient satisfaction, and health care resource utilization.

Our study findings may not be generalizable outside of the state of Michigan. These results reflect the outcomes among bariatric surgery centers that participate in a statewide collaborative quality improvement initiative. The extent to which this program, still in its first few years of existence, explains the relatively low rates of serious complications among bariatric hospitals and surgeons in the state is unknown. However, these efforts go beyond data feedback, requiring the active participation of bariatric surgeons in quality improvement initiatives and mandatory attendance at collaborative meetings held 3 times each year. For this reason, we believe that the results reported in this study represent the outcomes of bariatric surgery that are possible, but not necessarily those that are typical in community settings.

In conclusion, the frequency of serious complications among patients after bariatric surgery in Michigan is low. Rates of serious complications are inversely associated with hospital and surgeon procedure volume but not COE status. These data may serve as useful safety performance benchmarks for hospitals performing bariatric surgery. We hope that they might also inform the debate about the effectiveness of various approaches to ensuring high-quality care for bariatric surgery patients.

REFERENCES

Author Contributions: Dr N. Birkmeyer had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: N. Birkmeyer, Dimick, Hawasli, English, Genaw, Finks, Carline, J. Birkmeyer.
Acquisition of data: N. Birkmeyer, J. Birkmeyer.
Analysis and interpretation of data: N. Birkmeyer, Dimick.
Drafting of the manuscript: N. Birkmeyer, Dimick, J. Birkmeyer.
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