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Hospital Variation in Perioperative Complications for Laparoscopic Sleeve Gastrectomy in Michigan

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Structured Abstract

Background—Laparoscopic sleeve gastrectomy has recently surpassed gastric bypass and laparoscopic adjustable gastric banding as the most common weight-loss procedure. Previously, substantial concerns existed regarding variation in perioperative safety with bariatric surgery. This study aimed to assess rates of perioperative complications for laparoscopic sleeve gastrectomy across hospitals and in relation to procedure volume.

Study Design—We analyzed 8,693 patients who underwent laparoscopic sleeve gastrectomy from 2013 through 2014 across 40 hospitals in the Michigan Bariatric Surgery Collaborative. Mixed-effects logistic regression was used to assess hospital variation in risk- and reliability-adjusted rates of overall and serious 30-day complications and their relationship with hospital annual stapling procedure volume (gastric bypass and sleeve gastrectomy).

Results—Overall, 5.4% of patients experienced perioperative complications. Adjusted rates of overall complications varied three-fold across hospitals, ranging from 3.6% (95% CI, 1.9–6.8%) to 11.0% (95% CI, 7.7–15.5%). Serious complications occurred in just 1.2% of patients and varied minimally. In this analysis, hospital volume was not associated with overall or serious complications. The 1 hospital with significantly lower overall complication rates was high-volume (125 procedures/year); however, of the 4 hospitals with significantly higher complication rates, 3 were medium-volume (50–124 procedures/year) and 1 was high-volume. The remaining hospitals were not significantly different than the cohort mean.

Conclusions—Serious complications among patients undergoing laparoscopic sleeve gastrectomy were relatively infrequent. Rates of overall complications varied widely across

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Michigan hospitals enrolled in a quality collaborative, although this variation was unrelated to volume standards required for accreditation as a comprehensive bariatric surgery center.

Introduction

In recent years, laparoscopic sleeve gastrectomy has quickly become the most commonly performed weight-loss procedure.^{1, 2} Adjustable gastric banding has become notably less popular over the past decade, and gastric bypass has increasingly surrendered market share to sleeve gastrectomy.¹ Previously, significant concerns existed regarding hospital variation in perioperative safety for bariatric surgery.^{3, 4} Several national organizations subsequently produced accreditation standards for bariatric surgery centers, requiring minimum volume criteria among other structural measures as a response to these concerns about bariatric surgical quality.^{3, 5, 6} Specifically, the 2014 patient standards for the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program require that institutions perform a minimum of 50 stapling procedures (gastric bypass or sleeve gastrectomy) annually to attain accreditation as a comprehensive bariatric surgery center.⁶

The extent to which hospital complication rates vary for sleeve gastrectomy is unclear. Prior evidence primarily reports variation in outcomes for gastric bypass, a highly complex operation.³ Many believe that sleeve gastrectomy is a less technically complex procedure; whether postoperative outcomes vary to the same degree is unknown. Moreover, existing literature indicating that high-volume providers tend to have better surgical outcomes has been mainly limited to gastric bypass.^{3, 7-9} The extent to which hospital-level variation in perioperative outcomes is due to volume is similarly unknown for sleeve gastrectomy. Understanding the role of volume criteria in predicting outcomes for sleeve gastrectomy could better inform accreditation bodies for ensuring the safety of patients who undergo bariatric surgery.

To better characterize perioperative safety with the most common type of bariatric surgery, we studied patients who underwent laparoscopic sleeve gastrectomy across 40 hospitals in the Michigan Bariatric Surgery Collaborative from 2013 through 2014. We examined variation in 30-day complication rates across hospitals and evaluated their relationship with hospital procedure volume.

Methods

Data Sources and Study Population

This study analyzed patient data from the Michigan Bariatric Surgery Collaborative (MBSC), a statewide payer-funded consortium of hospitals and surgeons providing bariatric surgical care.^{10, 11} As described in greater detail elsewhere, participating hospitals submit data to a clinical registry for all patients who undergo a bariatric procedure at their institution.³ Regardless of their clinical performance, to participate in the MBSC data collection process centers are required to perform a minimum of 25 bariatric procedures per year. The MBSC consisted of 38 hospitals in 2014. Procedures include sleeve gastrectomy, Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, and biliopancreatic diversion with or without duodenal switch. Data collected includes patient demographic and

preoperative clinical information, perioperative and intraoperative outcomes for inpatient and outpatient procedures, and in-hospital records for up to 30 days after surgery.

Patient medical records are reviewed by nurse abstractors who are centrally trained using a standardized and validated instrument. Each participating hospital is reviewed annually by the project data quality coordinator to verify the accuracy and completeness of its clinical registry data for the MBSC.³

This study included all adult patients who underwent laparoscopic sleeve gastrectomy from January 2013 through December 2014 in the MBSC (n=8,693 patients at 40 hospitals).

Outcomes

Data were collected on 10 different types of bariatric surgery-related complications occurring within 30 days of the operation (short-term complications). Complications are grouped according to severity in the MBSC: non-life-threatening, potentially life-threatening, and life-threatening associated with residual and permanent disability or death. The primary outcome measure for this study was the occurrence of any perioperative complication within 30 days of the operation (“overall” short-term complications). The secondary outcome was the occurrence of a serious complication, defined as potentially life-threatening or one that resulted in residual and permanent disability or death, within 30 days of the operation.

Non-life-threatening complications included surgical site infection treated with antibiotics or wound opening only; stricture requiring dilation only; ulcer; bleeding requiring transfusion 4 units or endoscopy; pneumonia requiring treatment with antibiotics only; hospital-acquired infections (urinary tract infection or *Clostridium difficile* colitis); or other complication determined by the MBSC Endpoints Committee to be of low severity. Potentially life-threatening complications included abdominal abscess requiring percutaneous drainage or reoperation; bowel obstruction requiring reoperation; stricture requiring reoperation; leak requiring percutaneous drainage, reoperation, endoscopic intervention, or conservative management; bleeding requiring transfusion >4 units, reoperation, or splenectomy; surgical site infection or dehiscence requiring reoperation; respiratory failure requiring 2–7 days of intubation; renal failure requiring in-hospital dialysis; venous thromboembolism; or other complication determined by the Endpoints Committee to be of medium severity. Life-threatening complications associated with residual disability included myocardial infarction or cardiac arrest; respiratory failure requiring >7 days of intubation or tracheostomy; renal failure requiring long-term dialysis; death; or other complication determined by the Endpoints Committee to be of high severity.

Independent Variables

The primary exposure variable was the individual hospital where a patient received an operation, identified through the MBSC registry. Patient characteristics, including demographics and comorbidities, were used as covariates in the logistic regression model that determined complication rates for individual hospitals. Patient demographic data included age, gender, race, income level, insurance type, body mass index, smoking history,

and mobility limitations. Comorbid conditions included lung disease, cardiovascular disease, diabetes, gastroesophageal reflux, peptic ulcer disease, diabetes, liver disease, musculoskeletal disease, and psychiatric disease. Comorbidity status was obtained from the MBSC registry and was defined by documentation of that condition or its treatment in the medical record.

To explore the degree to which hospital variation in complication rates correlated with procedure volume, we compared overall complication rates with mean annual stapling volume at each hospital. Annual stapling volume was defined as the mean number of gastric bypass plus sleeve gastrectomy procedures performed per year at a given hospital. Biliopancreatic diversions comprised less than 1% of procedures during the study period and were excluded from the volume count. Volume cutoffs were determined partly based on the volume criteria established by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), which specifies an annual minimum of 50 stapling procedures to qualify as a comprehensive bariatric surgery center.⁶ The remaining hospitals were divided evenly to produce 3 groups of hospitals based on annual stapling volume: less than 50 procedures per year (7 hospitals), 50 to 124 procedures per year (17 hospitals), and 125 or more procedures per year (16 hospitals).

Statistical Analysis

For each hospital, we generated risk- and reliability-adjusted rates of overall and serious short-term complications. This process was first performed for overall complications and then repeated for serious complications. Multilevel mixed-effects logistic regression was used to evaluate risk factors for postoperative complications, with log-odds of overall complications modeled as a linear function of baseline covariates. This model was tested using potential predictors of postoperative complications, such as patient demographics and comorbidities as listed above, and procedure year. Using backward stepwise selection methods, the final mixed-effects logistic regression model included the following risk factors that were significant ($P < 0.05$) in multivariate analysis as fixed effects: history of hyperlipidemia, musculoskeletal disorder, total number of comorbid conditions, and procedure year. The hospital identifier was incorporated as a random effect to account for clustering of patients within hospitals.

The random effects of individual hospitals were used to generate reliability-adjusted estimates using these risk-adjusted complication rates. Reliability adjustment employs empirical Bayesian methods to account for random variation of patients' outcomes within hospitals.^{3, 12} This technique is useful for hospitals with small numbers of cases whose crude outcome measures may be skewed due to statistical "noise" (i.e. with small sample sizes, it is difficult to tell whether extremely high or low complication rates are due to chance or due to true differences in surgical quality).¹³ Reliability adjustment works by shrinking the point estimate for complication rate back toward the average complication rate for the entire cohort, with the degree of shrinkage proportional to each hospital's reliability measure.^{12, 13} This method aims to produce a truer measure of hospital complication rates that allows for more valid comparisons of surgical quality for laparoscopic sleeve gastrectomy across hospitals in the MBSC.

Using these risk- and reliability-adjusted estimates, hospitals were grouped into quartiles of adjusted overall short-term complications after laparoscopic sleeve gastrectomy in order to compare patient characteristics at these hospitals. The middle 2 quartiles were combined for purposes of presenting the data; statistical differences did not change when 4 groups were used instead of the 3 groups presented here. Characteristics of patients who underwent laparoscopic sleeve gastrectomy were compared using Pearson chi-squared test for categorical variables and one-way analysis of variance for continuous variables. Descriptive statistics were used to characterize the overall incidence of specific postoperative complications.

Hospitals were then re-grouped into categories of mean annual stapling volume— <50, 50–124, and ≥125 stapling procedures per year—in accordance with MBSAQIP volume criteria, as described above. Hospital complication rates were compared across these categories of hospital stapling volume using adjusted odds ratios.

Statistical analyses were performed using STATA version 11.2 (Stata Corp, College Station, Texas). All hypotheses were tested using a two-sided approach with a significance level of 0.05.

Results

Patient Characteristics

Patients were distributed equally across hospital quartiles of overall complication rates (Table 1). Across hospital quartiles there were several statistically significant differences in patient characteristics, including demographics and medical history. Liver disease was more common among patients at hospitals with high complication rates; however, the remaining differences were not clinically meaningful. The observed differences in patient characteristics did not reveal any systematic relationship with hospital quartiles of overall complication rates.

Incidence of Specific Complications

Overall, 5.4% (95% confidence interval [CI], 5.0–5.9%) of patients who underwent laparoscopic sleeve gastrectomy experienced at least 1 perioperative complication (Table 2). A majority of these were non-life-threatening complications, which occurred in 3.7% of patients (95% CI, 3.3–4.2%). Potentially life-threatening complications occurred in 1.5% of patients (95% CI, 1.3–1.8%). Non-fatal complications that were considered life-threatening and associated with permanent disability occurred in 0.06% of patients (95% CI, 0.02–0.13%). During the study period, the overall 30-day mortality rate after laparoscopic sleeve gastrectomy was 0.10% (95% CI, 0.05–0.20%).

The most common short-term surgical complication was bleeding requiring transfusion of 4 units (1.4% of patients; 95% CI, 1.1–1.6%). Superficial wound infection not requiring reoperation was a complication for 1.0% of patients (95% CI, 0.8–1.2%). Postoperative leak, stricture, small bowel obstruction, or ulcer occurred in less than 1% of patients (Table 2). The most common medical complication was urinary tract infection (0.67% of patients; 95%

CI, 0.51–0.86%). Less than 1% of patients experienced other medical complications within 30 days following laparoscopic sleeve gastrectomy.

Emergency department visits and hospital readmission occurred in 8.0% (95% CI, 7.4–8.6%) and 3.6% (95% CI, 3.2–4.0%) of patients, respectively. Reoperation and transfers to other medical facilities were uncommon following laparoscopic sleeve gastrectomy (Table 2).

Hospital Variation in Overall Complication Rates

Adjusted rates of overall complications varied three-fold across hospitals in the MBSC, ranging from 3.6% (95% CI, 1.9–6.8%) to 11.0% (95% CI, 7.7–15.5%) of patients. One hospital had an overall complication rate that was significantly lower than the cohort mean, while 4 hospitals had complication rates that were significantly higher (Figure 1). The remaining hospitals did not differ significantly from the cohort mean. Serious complications occurred in just 1.2% of patients and varied minimally across hospitals (data not shown).

Relationship between Overall Complications and Hospital Volume

In this analysis, hospital annual stapling volume did not correlate with adjusted rates of overall complications. The 1 hospital with significantly lower overall complication rates was high-volume (125 procedures per year); however, of the 4 hospitals with significantly higher complication rates, 1 was high-volume and 3 were medium-volume (50–124 procedures per year). Low-volume hospitals (<50 procedures per year) were scattered with medium- and high-volume hospitals regarding their adjusted overall complication rates (Figure 1).

When hospitals were re-grouped into categories of mean annual stapling volume, adjusted rates of overall complications did not statistically differ across hospital volume categories, although point estimates suggested a counterintuitive volume-outcomes relationship (Table 3). The odds of having any postoperative complication when operated on at high-volume or medium-volume hospitals were not significantly different than when operated on at low-volume hospitals (adjusted odds ratio for high-volume to low-volume hospitals, 1.53 [95% CI, 0.71–3.28] and for medium-volume to low-volume hospitals, 1.94 [95% CI, 0.89–4.23]).

Discussion

This analysis demonstrates significant variation in hospital rates of overall short-term complications among patients who underwent laparoscopic sleeve gastrectomy in the Michigan Bariatric Surgery Collaborative. In total, 5.4% of patients experienced perioperative complications, with overall complication rates varying three-fold across individual hospitals. Most complications were non-life-threatening such as minor wound complications and bleeding requiring transfusion of 4 units. Serious complications after sleeve gastrectomy were relatively infrequent for hospitals in Michigan. Additionally, the variation observed in adjusted rates of overall complications was unrelated to volume standards set by accreditation bodies for comprehensive bariatric surgery centers.

These results reflect an updated assessment of hospital variation in perioperative safety with bariatric surgery in the sleeve gastrectomy era. Prior studies that evaluated safety outcomes following bariatric surgery largely focused on gastric bypass, the gold standard and previously the most common bariatric procedure.^{3, 7–9} Gastric bypass is a highly complex operation that requires a sophisticated level of technical skill in order to achieve optimal outcomes.¹⁴ Existing evidence shows that higher procedure volumes are associated with improved clinical outcomes for this technically challenging operation.^{7–9} On the other hand, sleeve gastrectomy—which has gained an increasingly larger share of the bariatric surgery market in recent years^{1, 2}—may be a less complex procedure to perform. Nonetheless, similar to earlier literature that describes variation in hospital complication rates primarily for gastric bypass,³ this study highlights persistent variation in outcomes for laparoscopic sleeve gastrectomy, currently the most common bariatric operation. Our findings differ from prior surgical volume-outcomes literature by demonstrating that variations in complication rates for sleeve gastrectomy did not correlate with hospital procedure volume. While the relative importance of volume for predicting outcomes with bariatric surgery has been questioned in prior studies,^{15, 16} this investigation calls attention to present-day concerns regarding surgical quality with the popular sleeve gastrectomy.

Despite the persistent variation in hospital complication rates observed in this study, these results demonstrate that, in general, bariatric surgery has become safer in recent years. As expected with increasing experience, bariatric surgery providers have demonstrated improved outcomes over time.^{16, 17} Additionally, sleeve gastrectomy has shown improved safety when compared to gastric bypass.^{18–20} In this context, rates of overall and serious complications following sleeve gastrectomy in this study were lower than those observed in prior exemplar studies of bariatric surgery complications. Carlin et al.¹⁸ studied MBSC data as recent as 2011, finding that overall and serious complication rates were 6.3% and 2.4%, respectively. Using MBSC data from 2006 to 2009 on patients who primarily underwent gastric bypass, Birkmeyer et al.³ reported that 7.3% of patients experienced perioperative complications, with serious complications occurring in 2% to 3% of patients. Similarly, from 2005 to 2007 several high-volume bariatric centers that participate in the federally-funded Longitudinal Assessment of Bariatric Surgery (LABS) Consortium reported serious complication rates as high as 4%.²¹ The rarity of serious complications and lower rates of overall complications in this study emphasize the improvements in perioperative safety with bariatric surgery in the sleeve gastrectomy era.

This study has several limitations. First, these findings may not be generalizable for patients or hospitals outside the state of Michigan. Nonetheless, our patient population is similar to those reported by centers participating in LABS across the country,²¹ and our results are comparable with clinical trials conducted nationally and internationally.^{20, 22, 23} Some may further question the generalizability of these results because they reflect outcomes of bariatric surgery centers that participate in a statewide quality improvement initiative. Although this may partly explain why complication rates observed in this study were notably lower than in previous trials,²⁰ overall complications still varied three-fold across hospitals that actively participate in this quality collaborative, demonstrating ongoing opportunities for improvement. It is feasible that variations in complication rates after sleeve gastrectomy may be even more pronounced across various types of academic, community,

and private practice bariatric surgical centers. Lastly, although this study comprehensively described variation in short-term complications, we cannot draw conclusions about the long-term effectiveness of sleeve gastrectomy performed at these hospitals. However, perioperative safety with bariatric surgery has been a major issue for insurers and patient advocacy groups,^{3, 5} and this study addresses these safety concerns with an up-to-date perspective.

The observed variation in hospital complication rates with laparoscopic sleeve gastrectomy is an important finding as bariatric surgery becomes a more accepted treatment for obesity and related comorbidities. Although the overall safety of bariatric surgery has improved over time, this study revealed that certain institutions provide substantially safer care for patients who undergo sleeve gastrectomy, even among hospitals that are actively engaged in quality improvement organizations. The complications that occurred most frequently in this study—wound infection and hemorrhage—suggest that variation in complication rates may be more related to intraoperative, rather than perioperative, events for this procedure. However, the mechanisms underlying this variation in care are not known from this analysis. Future investigations could aim to understand the relative importance of specific operative technique, surgical skill, or other structural measures and processes of care on hospital complications following laparoscopic sleeve gastrectomy. Additionally, the learning curve has yet to be characterized for surgeons and institutions performing laparoscopic sleeve gastrectomy in order to better understand the relationship between operator experience and postoperative outcomes for this emerging procedure. The findings in this study shed light on potential high-yield areas for future research and quality improvement initiatives given the current scope of bariatric surgical practice.

In conclusion, bariatric surgery has demonstrated marked improvements in perioperative safety during the sleeve gastrectomy era. Relatively low rates of serious complications were observed after laparoscopic sleeve gastrectomy at hospitals in Michigan; however, wide variation persists for rates of overall complications. Hospital complications were unrelated to volume standards required for accreditation as a comprehensive bariatric surgery center. This study can be used to guide future research that informs payers, providers, and accreditation bodies on best practices for high-quality bariatric surgery.

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Abbreviations

CI	confidence interval
LABS	Longitudinal Assessment of Bariatric Surgery
MBSAQIP	Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program

MBSC

Michigan Bariatric Surgery Collaborative

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Figure 1. Adjusted rates of 30-day complications after laparoscopic sleeve gastrectomy, according to hospital in the Michigan Bariatric Surgery Collaborative
Rates of overall 30-day complications were risk- and reliability-adjusted; the horizontal line indicates the overall proportion of patients that experienced at least 1 perioperative complication (5.4%). Volume designation refers to a hospital's mean annual stapling volume (gastric bypass and sleeve gastrectomy).

Table 1

Hospital and patient characteristics according to hospital quartile of adjusted rates of overall complications.

	Hospital Quartile of Overall Complication Rates			
Hospital Characteristic	Low	Medium	High	
No. hospitals	10	20	10	
No. patients	2,289	4,203	2,201	
Annual stapling volume, median (IQR)*	102 (65–278)	96 (43–190)	117 (74–220)	
Patient Characteristic	% of patients, unless otherwise specified			P-value [‡]
Demographics				
Age, mean years (SD)	46 (12)	47 (12)	47 (12)	<0.001
Gender, % female	79	78	77	0.263
Race, % white	58	66	67	<0.001
Private insurance, %	75	74	67	<0.001
Preoperative body mass index (kg/m ²), mean (SD)	46.9 (8.4)	47.4 (8.7)	47.2 (8.6)	0.061
Comorbidities				
Lung disease	24	27	26	0.098
Cardiovascular disease	53	56	57	0.005
Hypertension	50	54	55	0.002
Hyperlipidemia	48	50	47	0.027
Diabetes	29	33	34	0.001
Gastroesophageal reflux	57	45	51	<0.001
Peptic ulcer disease	5	2	5	<0.001
Cholelithiasis	26	28	32	<0.001
Liver disease	5	7	17	<0.001
Kidney failure	0.4	0.3	0.6	0.218
Urinary incontinence	27	21	10	<0.001
Prior venous thromboembolism	4	4	5	0.217
Obstructive sleep apnea	43	47	43	0.004
Musculoskeletal disorder	76	75	67	<0.001
Psychiatric disorder	55	56	53	0.048
History of abdominal hernia repair	2	2	3	<0.001
Tobacco smoking	44	41	47	<0.001
Mobility limitations	6	7	6	0.506
Total comorbidities, mean (SD)	4.5 (2.1)	4.5 (2.1)	4.5 (2.2)	0.992
Concurrent hiatal hernia repair	30	37	27	<0.001
Postoperative Results				
Predicted risk of any complication (%) [‡]	4.1	5.3	8.2	<0.001
30-day mortality (%)	0.0	0.1	0.3	0.012

Hospital Characteristic	Hospital Quartile of Overall Complication Rates			
	Low	Medium	High	
Healthcare Utilization				
Length of hospital stay, mean no. days (SD)	1.9 (1.2)	1.9 (1.7)	2.0 (1.6)	0.035
Emergency department visits	6.8	7.8	9.5	0.003
Readmissions	2.7	3.5	4.8	0.001
Reoperations	0.6	1.1	1.0	0.142
Transfers	0.1	0.2	0.2	0.590

* Annual stapling volume: mean number of gastric bypass and sleeve gastrectomy procedures performed per year at a given hospital.

[†] Risk- and reliability-adjusted rates of any complication within 30 days after surgery were adjusted for patient risk factors that were statistically significant in multivariate analysis (history of hyperlipidemia, musculoskeletal disorder, and total number of comorbid conditions) and procedure year.

[‡] P-values were derived from Pearson chi-squared test for categorical variables and one-way analysis of variance for continuous variables across the 3 hospital categories of overall complication rates.

Table 2

Incidence of specific postoperative complications within 30 days after laparoscopic sleeve gastrectomy, 2013–2014 (n=8,693 patients).

Outcome	% of patients (95% CI)
Severity of complication	
Any complication	5.4 (5.0–5.9)
Non-life-threatening	3.7 (3.3–4.2)
Potentially life-threatening	1.5 (1.3–1.8)
Permanently disabling (non-fatal)	0.06 (0.02–0.13)
Death	0.10 (0.05–0.20)
Surgical complications	
Leak	0.46 (0.33–0.63)
Stricture	0.28 (0.18–0.41)
Small bowel obstruction	0.06 (0.02–0.13)
Ulcer	0.05 (0.01–0.12)
Hemorrhage (requiring transfusion)	1.6 (1.3–1.8)
Transfusion 4 units	1.4 (1.1–1.6)
Transfusion >4 units	0.18 (0.11–0.30)
Infections	
Abdominal abscess	0.36 (0.24–0.51)
Wound complication	1.1 (0.9–1.3)
Medical complications	
Venous thromboembolism	0.28 (0.18–0.41)
Cardiac event	0.05 (0.01–0.12)
Renal failure	0.08 (0.03–0.17)
Respiratory (pneumonia or intubation >48 hours)	0.55 (0.41–0.73)
Urinary tract infection	0.67 (0.51–0.86)
<i>Clostridium difficile</i> infection	0.16 (0.09–0.27)
Healthcare Utilization	
ED visit	8.0 (7.4–8.6)
Readmission	3.6 (3.2–4.0)
Reoperation	0.95 (0.76–1.2)
Transfer	0.16 (0.09–0.27)

Table 3

Rates of overall 30-day postoperative complications following laparoscopic sleeve gastrectomy and their association with hospital average annual stapling volume, 2013–2014.

Measure of overall complications	Hospital Annual Stapling Volume		
	Low 7 hospitals, n=214 <50 cases/year	Medium 17 hospitals, n=2,083 50–124 cases/year	High 16 hospitals, n=6,396 125 cases/year
Observed rate of overall complications (%)	2.3	5.7	5.1
Unadjusted odds ratio (95% CI)	Ref	2.02 (0.93 – 4.37)	1.62 (0.75 – 3.48)
Adjusted odds ratio (95% CI)*	Ref	1.94 (0.89 – 4.23)	1.53 (0.71 – 3.28)

* Odds ratios for overall 30-day complications (according to category of hospital volume) were adjusted for patient risk factors that were statistically significant in multivariate analysis (history of hyperlipidemia, musculoskeletal disorder, and total number of comorbid conditions) and procedure year.