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Hospital Volume and Outcomes for Laparoscopic Gastric Bypass and Adjustable Gastric Banding in the Modern Era

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Abstract

Background—Over the last decade, there has been a rapid decline in adverse events after bariatric surgery. As a result, it is possible that the influence of hospital volume on outcomes has attenuated over time.

Objectives—To examine whether the relationship between hospital volume and adverse events has persisted in the era of laparoscopic surgery.

Setting—This study is based on analysis of State Inpatient Databases (SID) for 12 states from 2006 through 2011, which includes 446,127 patients.

Methods—Using hospital discharge data, we studied changes in serious complications, reoperations and mortality over time, and the impact of hospital volume on outcomes among patients undergoing laparoscopic adjustable gastric band (LAGB) and laparoscopic Roux-en-Y gastric bypass (LRYGB). Hospitals were stratified by operative volume and using multivariable logistic regression to adjust for patient characteristics and procedure-type, we examined the relationship between hospital volume and outcomes during three two-year periods: 2006–07, 2008–09 and 2010–11.

Results—The rate of reoperations and mortality were low and there were no significant differences between the highest (>125 cases/year) and lowest (<50 cases/year) volume hospitals for both LAGB and LRYGB. The volume-outcome relationship was most prominent when examining rates of adjusted odds ratios for serious complications at the lowest volume hospitals when compared to the highest volume hospitals (LAGB - 1.65 [CI: 1.18,2.30] for 2006–2007, 1.81 [CI: 1.36,2.41] for 2008–2009 and 2.08 [CI:1.40,3.09] for 2010–2011; LRYGB - 1.55 [CI: 1.23,1.95] for 2006–2007, 1.39 [CI:1.09,1.76] and 1.39 [CI:1.07,1.80] for 2010–2011.)

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Conclusion—Outcomes improved over the study period at both high and low volume hospitals. There remain significant differences in serious complications between the highest and lowest volume hospitals for both stapled and non-stapled procedures.

Introduction

Early critical appraisal of bariatric surgery focused largely on safety by evaluating short-term adverse outcomes and perioperative death. At that time, numerous studies demonstrated a strong volume-outcome relationship with high-volume hospitals experiencing shorter length of stays, lower 30-day morbidity, mortality and decreased costs.^{1–5} However, in the last decade the safety of bariatric surgery has improved remarkably. Given advances in minimally invasive technique, fellowship training, patient selection and processes of care, adverse outcomes have declined significantly and mortality is rare.^{6–9}

With improved outcomes over time, it is unclear if the volume-outcome relationship still exists for bariatric surgery. Studies demonstrating a volume-outcome effect, reported between 1991 and 2003 are considered to be dated, particularly in the era of laparoscopic surgery.^{2, 3, 10, 11} Recent evidence evaluating the volume-based referral program for bariatric surgery has raised doubts as to whether volume is still an accurate proxy for quality after bariatric surgery.^{6, 12} It is also important to re-evaluate this in light of the decrease in volume criterion from 125 cases/year to 50 cases/year for comprehensive accredited centers mandated by the American Society of Metabolic and Bariatric Surgery (ASMBS) and American College of Surgeons (ACS).¹³

In this context, we sought to determine whether the volume-outcome relationship exists in the modern era by conducting a systematic evaluation of perioperative outcomes after bariatric surgery using data from 12 states over a 6- year period. In addition to comparing the absolute effect of volume on serious complications, reoperations and mortality, we also examined the relative effect over time after stratifying hospitals based on volume.

Methods

Study Population

This study is based on analysis of State Inpatient Databases (SID) for 12 states (AZ, CA, FL, IA, MA, MD, NC, NE, NJ, NY, WA, and WI) from 2006 through 2011, which included 446,127 patients. Data were obtained from Healthcare Cost and Utilization Project (HCUP) sponsored by the Agency for Healthcare Research and Quality. The SID encompass about 90% of all U.S. community hospital discharges and contains a core set of clinical and nonclinical information on all patients, regardless of payer, including persons covered by Medicare, Medicaid, private insurance, and the uninsured.

We identified all patients undergoing laparoscopic adjustable gastric band surgery (LAGB) and laparoscopic Roux-en-Y gastric bypass (LRYGB) using specific ICD-9-CM procedure codes (44.95 and 44.38, respectively) as well as a confirmatory diagnosis code for morbid obesity (ICD-9-CM codes 278.0, 278.00, 278.01, and V77.8) and DRG code for weight loss

surgery (DRG 288 through October 1, 2007 and MS-DRG code 619–621 after October 1, 2007). We excluded patients with stomach or intestinal cancer or who underwent emergent or open procedures. Hospitals were stratified into three groups based on volume to reflect the decrease in the volume criterion by the AMSBS and ACS: <50 cases/year, 50–125 cases/year and > 125 cases/year.

Outcome Variables

Outcomes of interest included: 1) serious complications, defined as any complication with length of stay ≥ 5 days; 2) reoperations and 3) in-hospital mortality. Serious complications included splenic injury, hemorrhage, anastomotic leaks and wound complications requiring reoperation, as well as respiratory tract, cardiac, neurological, thromboembolic or genitourinary tract complications, or multi-system organ failure (defined by Santry et al).¹⁴ Reoperations for surgical complications included splenic injury, hemorrhage, anastomotic leaks and wound complications and involved either reopening of surgical site, re-closure of dehiscence, management of post-operative shock/hemorrhage, retrieval of retained foreign body, re-operation for management of deep surgical site infection, repair of an organ injury or laceration, management of wound complication, and management of stoma complication that occurred during admission or re-admission after a bariatric surgical procedure. Reoperations excluded cholecystectomy and endoscopy.

Analysis

The goal of this analysis was to assess the relationship between hospital volume and patient outcomes after LAGB and LRYGB. For our main analyses we created logistic regression models for each outcome (serious complication, reoperation, and mortality) separately. In these models, the outcome was the dependent variable and hospital volume was an independent variable. We also included patient characteristics to adjust for any differences between high and low volume hospitals, including comorbidities and procedure-type. Patient characteristics included age, race, sex, type of insurance (Medicare and non-Medicare), and Elixhauser comorbidities.¹⁵ The output from these models was an odds ratio that represents the risk of each adverse outcome for each hospital volume category.

To assess whether these relationships changed over time, we constructed separate models for three distinct time periods: 2006–07, 2008–09 and 2010–11. To account for clustering of patients within hospitals, we used robust standard errors. For all statistical tests, p-values are two-tailed and alpha was set at 0.05. We used STATA 12.0 (College Station, TX) for all statistical analyses.

Results

Patient characteristics are presented in Table 1 and are stratified by hospital volume and by year for both LAGB and LRYGB. During the study period, the majority of LAGB cases were performed at the lowest volume hospitals (<50 cases/year), while the majority of LRYGB cases were performed at the highest volume hospitals (>125 cases/year).

Laparoscopic Adjustable Gastric Band

There were no significant differences in rates of reoperations and mortality between the highest (>125 cases/year) and lowest (<50 cases/year) volume hospitals after LAGB over the study period. Although the rate of serious complications decreased at both high and low volume hospitals from 2006 to 2011 (1.08% to 0.72% and 1.87% to 1.59%, respectively) (Table 2a), the rate of serious complications was significantly higher among the lowest volume hospitals when compared to highest volume hospitals during each time period (1.87 vs. 1.08 for 2006–2007, 1.60 vs. 0.74 for 2008–2009 and 1.59 vs. 0.72 for 2010–2011, $p<0.05$) (Figure 1a). The volume-outcome relationship was strongest for serious complications, as the adjusted odds ratio for the lowest volume hospitals compared to the highest volume hospitals was 1.65 [CI: 1.18,2.30] for 2006–2007, 1.81 [CI: 1.36,2.41] for 2008–2009 and 2.08 [CI: 1.40,3.09] for 2010–2011.

Laparoscopic Roux-en-Y Gastric Bypass

Similarly, there were no significant differences in rates of reoperations and mortality between the highest (>125 cases/year) and lowest (<50 cases/year) volume hospitals after LRYGB over the study period. Serious complication rates decreased at both the highest and lowest volume hospitals between 2006 and 2011 (1.50% to 1.19% and 2.32% to 1.61%, respectively) (Table 2a). However, the rate of serious complications was significantly higher among the lowest volume hospitals when compared to highest volume hospitals during each time period (2.32 vs. 1.50 for 2006–2007, 1.49 vs. 1.14 for 2008–2009 and 1.61 vs. 1.19 for 2010–2011, $p<0.05$) (Figure 1b). The volume-outcome relationship was also strongest for serious complications as the adjusted odds ratio for the lowest volume hospitals compared to the highest volume hospitals was 1.55 [CI: 1.23,1.95] for 2006–2007, 1.39 [CI: 1.09,1.76] for 2008–2009 and 1.39 [CI: 1.07,1.80] for 2010–2011.

Discussion

Bariatric surgery has demonstrated unprecedented improvements in safety since its inception over 20 years ago. In this study, we found that adverse events declined at both high and low volume hospitals over the study period and mortality was a rare event. However, relative differences between high and low volume hospitals persist for serious complications even in the most recent time period. Moreover, this volume-outcome relationship is consistent for both stapled (LRYGB) and non-stapled (LAGB) bariatric procedures.

Prior studies evaluating the effect of volume on outcomes after bariatric surgery demonstrated a strong relationship between low volume hospitals and high rates adverse events when compared to high volume hospitals.^{1–3, 5, 16, 17} In a study that examined patients only undergoing gastric bypass at academic hospitals, Nguyen *et al.*, observed that high volume hospitals were associated with a shorter length of stay, lower morbidity and mortality, and decreased costs. The volume-outcome relationship was more pronounced for patients older than 55 years, for whom in-hospital mortality was 3-fold higher at low volume hospitals.⁴ Similarly, Flum *et al.*, found that the mortality rate was 1.6 times higher for Medicare patients of surgeons with less than the median surgical volume of bariatric procedures after adjusting for age, sex and comorbidity index.¹¹ Likewise, when evaluating

statewide databases, Birkmeyer, Hollenbeak and Weller found that rates of serious complications and mortality were inversely associated with hospital and surgeon procedure volume.^{1, 3, 17}

There is good reason to believe that many of these prior studies are no longer relevant. First, bariatric surgery has evolved over the past decade and both procedure type and technique have changed significantly.^{8, 10} Today, the majority of bariatric operations are performed laparoscopically because of the proven benefits of lowered complication rates, hospital length of stay and recovery time.^{18–22} As a result, conclusions made in prior studies are likely dated and may not be applicable to current practices and policies.

Thus far, the only study to evaluate volume and outcomes after bariatric surgery in the era of laparoscopy was that by Jafari *et al.*, who demonstrated higher rates of mortality (OR 2.5, [CI 1.3–4.8], $p < 0.01$) and serious morbidity (OR 1.2, [CI 1.1–1.4], $p < 0.01$) at low volume centers (<50 cases/year) performing stapled cases.¹⁰ Our findings are consistent with respect to the volume-outcome relationship for serious complications as we demonstrate higher rates of complications at the lowest volume centers when compared to the highest volume centers. Moreover, we demonstrate that this relationship is true over three separate time periods and for both stapled and non-stapled cases.

It is also important to note that the relationship between surgical volume and mortality for high-risk procedures has been attributed ability to effectively rescue patient from complications.^{23, 24} Historically, bariatric surgery has been considered a high-risk procedure and patients within this population often have multiple comorbidities rendering them least likely to tolerate complications. Much like Jafari *et al.*, our study demonstrates that mortality is exceedingly low in the modern era (<1%), which is a vast improvement to the rates published prior to 2006. However, in contrast to Jafari *et al.*, we demonstrated that there is no significant volume-outcome effect on mortality. This may be explained by the fact that our study includes an additional year of data (2010–2011) and that our analysis was stratified by year, which accounts for low volume hospitals that may have become high volume hospital in a subsequent year.

Reduction in mortality is likely due to a decrease in the number of open bariatric procedures, as well as hospital-wide implementation of a multidisciplinary approach to treating obesity coupled with specific process measures and improved patient selection. Finally, minimally invasive and bariatric surgery fellowship training has decreased the learning curve for technically challenging procedures such as laparoscopic gastric bypass. Surgical outcomes from post-fellowship surgeons are comparable to their experienced mentors as well as published outcomes in the literature, thus validating the need for such training in bariatric surgery.^{25–27}

There are several limitations to the data presented in this study. First, although claims data may not be a reliable representation of clinical data. This data is similar to previously published studies evaluating volume and outcome after bariatric surgery.^{28–30} Our study is also limited to hospital volume and not surgeon volume specifically. Surgeon volume and associated skill has been shown to have a direct correlation to patient outcomes after

bariatric surgery.^{2, 5, 17, 31} Nevertheless, hospital-wide processes such as surgical safety checklists are independent of a surgeon's technique or skill, and account for differences in perioperative morbidity and mortality.³²

Our study was also limited to perioperative safety, which included short-term outcomes such as complications, reoperations and in-hospital mortality. Long-term outcomes including weight-loss, comorbidity resolution and patient satisfaction could not be assessed. Furthermore, data on long-term outcomes can be difficult to obtain if patient follow-up is poor and these findings may be less attributable to surgeon or hospital volume when compared to short-term perioperative complications.

Given that the volume-outcome effect persists in the era of laparoscopic surgery, it is important to address this data in the context of bariatric surgery accreditation, which has evolved since the American Society of Metabolic and Bariatric Surgery (ASMBS) established the Center of Excellence (COE) designation in 2004. The COE criteria, which were established by expert opinion and clinical consensus included implementation of specific hospital structure and process elements, a minimum hospital volume requirement (>125 cases/year), and a mandate to submit data to the ACS (American College of Surgeons) or ASMBS sponsored Surgical Review Corporation (SRC) clinical registry.^{33, 34} Although widely credited for improving bariatric surgery outcomes, the most rigorous studies on the effect of the referral process for Medicare patients fail to demonstrate differences between COE and non-COE centers.^{6, 35} The diminished effect was best demonstrated by Dimick and Birkmeyer *et al.*, and thus put into question the merits of COE criteria, such as hospital volume. Dimick *et al.*, also demonstrates that risk-adjusted morbidity is better than hospital volume at predicting future performance with bariatric surgery.¹² Nevertheless, volume is just one aspect of accreditation and our data supports its use as a proxy for quality at the present time, given its effect on serious complications. However, given the low mortality rates after laparoscopic bariatric surgery, the effect of hospital volume on mortality appears to be diminished.

In 2012, the ASMBS and the ACS initiated the Metabolic Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) and has changed the volume requirement for comprehensive accreditation to 50 stapled cases.¹³ This reflects the current notion of overall improvements in safety after bariatric surgery and is supported by our study. As with the volume-outcome effect, certain process measures, systems of care and infrastructure directed at improving bariatric care may also need periodic re-evaluation before consideration as a requirement for accreditation.

Conclusions

Significant improvements in the safety of bariatric surgery have occurred in the last decade as both high and low volume hospitals have experienced a decrease in adverse events over time. However, the inverse relationship between hospital volume and surgical quality still exists, as the highest volume hospitals experience less serious complications than lowest volume hospitals for both stapled and non-stapled procedures. However, the effect of

hospital volume on mortality is diminished and may no longer serve as an accurate measure of quality.

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Figure 1a:

Figure 1b:

Figure 1.

Figure 1a: Serious complications after LAGB among highest (> 125 cases/year) and lowest (<50 cases/year) volume hospitals over the study period (2006–2011).

Figure 1b: Serious complications after LRYGB among highest (> 125 cases/year) and lowest (<50 cases/year) volume hospitals over the study period (2006–2011).

Table 1

Patient Characteristics

Characteristics of patients undergoing bariatric surgery from 2006–2011, stratified by hospital volume and procedure type. Values represent percentage (%) unless otherwise specified.

	Time period (year)									
	2006–2007			2008–2009			2010–2011			
	Hospital volume									
LAGB	< 50	50–125	> 125	< 50	50–125	> 125	< 50	50–125	> 125	> 125
n	41,139	9,623	9,884	44,064	20,465	18,454	50,026	15,057	7,736	7,736
%	67.8	15.9	16.3	53.1	24.7	22.2	68.7	20.7	10.6	10.6
Mean Case Volume	17	75	259	19	84	257	17	79	235	235
Age (years)	43.2	44.3*	43.4	44.5*	45	45	45.1	45.2	45.3	45.3
Female	80.94*	78.75*	77.36	78.4*	77.85*	76.19	77.55*	77.97*	74.35	74.35
White	72.94*	74.62*	68.99	69.31*	72.44	72.21	67.63*	65.51*	71.69	71.69
Hypertension	50.71	49.62	49.62	54.81*	52.73	52.9	55.39*	52.15	51.69	51.69
Diabetes	26.89*	25.15	23.62	30.46*	30.05*	27.69	31.02*	29.65*	26.01	26.01
Chronic pulmonary disease	17.4	18.12*	16.95	16.8	18.11*	17.28	18.29*	17.91*	16.49	16.49
Liver disease	9.3*	9.21*	4.79	10.02*	10.75*	6.07	11.45	7.56*	11.09	11.09
Congestive heart failure	0.12	0.19	0.12	0.97	1.19*	0.91	1.27*	0.95	0.89	0.89
Renal failure	0.55	0.58	0.58	0.86	1*	0.74	1.33*	1.06	0.94	0.94
Coagulopathy	0.29	0.22	0.22	0.32	0.38	0.31	0.47	0.27	0.37	0.37
Peripheral vascular disease	0.41	0.37	0.33	0.4	0.34	0.4	0.49	0.54	0.37	0.37
LRYGB										
n	11,471	20,743	36,986	16,862	21,350	46,375	12,894	18,993	44,005	44,005
%	16.6	30.0	53.4	19.9	25.2	54.8	17.0	25.0	58.0	58.0
Mean Case Volume	25	85	295	26	86	330	25	88	332	332
Age (years)	43.3	43.2*	43.5	44.7	44.6	44.7	45.5*	45.1	44.9	44.9
Female	79.61	80.7	80.39	76.83*	78.45	78.17	75.56*	77.74	77.97	77.97

	Time period (year)											
	2006–2007					2008–2009					2010–2011	
	Hospital volume											
White	75.27 *	70.43 *	73.08	73.33 *	69.87 *	70.66	70.23 *	70.65 *	65.93			
Hypertension	49.95 *	48.98 *	51.65	51.55 *	54.37	54.5	51.54 *	55.16	54.74			
Diabetes	24.79 *	25.65 *	26.94	29.3	29.75	30.05	28.32 *	30.95	30.43			
Chronic pulmonary disease	16.31 *	17.54	17.57	16.98	17.75	17.36	17.13	18.59 *	17.76			
Liver disease	6.31 *	7.99 *	9.33	5.91 *	7.62 *	11.23	7.83 *	8.96 *	11.72			
Congestive heart failure	0.11	0.13	0.12	0.93	1.16 *	0.98	1.17	1.25	1.11			
Renal failure	0.52	0.55	0.57	0.71	1.02 *	0.87	1.31	1.22	1.21			
Coagulopathy	0.26	0.26	0.28	0.31	0.44	0.3	0.36	0.52	0.37			
Peripheral vascular disease	0.81	0.35	0.28	0.43	0.36	0.39	0.59	0.56	0.46			

* Indicates significant difference (p<0.05)

Table 2a

LAGB Adjusted rates and Odds Ratios

Adjusted rates and odds ratios of adverse events after LAGB, stratified by hospital volume and by time period.

	2006–2007				2008–2009				2010–2011			
	Unadjusted Rate (%)	Adjusted Rate (%)	OR (95% CI)	p-value	Unadjusted Rate (%)	Adjusted Rate (%)	OR (95% CI)	p-value	Unadjusted Rate (%)	Adjusted Rate (%)	OR (95% CI)	p-value
<i>Serious complications</i>												
Hosp Vol < 50	1.87	1.88	1.65 (1.18,2.30)	0.0032	1.60	1.58	1.81 (1.36,2.41)	<.0001	1.59	1.57	2.08 (1.40,3.09)	0.0003
Hosp Vol -50–125	1.27	1.32	1.01 (0.66,1.55)	0.9546	1.24	1.27	1.27 (0.94,1.73)	0.1196	0.82	0.86	1.16 (0.76,1.76)	0.4879
Hosp Vol > 125	1.08	1.00	1	Ref	0.74	0.77		Ref	0.72	0.79		Ref
<i>Reoperations</i>												
Hosp Vol < 50	0.74	0.74	1.44 (1.01,2.05)	0.0422	0.67	0.66	1.58 (1.12,2.25)	0.0099	0.57	0.56	1.04 (0.67,1.63)	0.8556
Hosp Vol-50–125	0.53	0.53	1.05 (0.63,1.76)	0.8383	0.61	0.62	1.23 (0.84,1.81)	0.2926	0.37	0.40	0.78 (0.46,1.33)	0.3618
Hosp Vol > 125	0.45	0.44	1	Ref	0.35	0.37		Ref	0.49	0.50		Ref
<i>In-hospital mortality</i>												
Hosp Vol < 50	0.06	0.07	240 (0.65,8.81)	0.1875	0.07	0.08	1.72 (0.74,4.02)	0.2081	0.05	0.06	NA	NA
Hosp Vol-50–125	0.04	0.05	1.63 (0.31,8.51)	0.562	0.01	0.02	0.34 (0.09,1.32)	0.1183	0.03	0.03	NA	NA
Hosp Vol > 125	0.02	0.01		Ref	0.03	0.03		Ref	0.00	0.00		Ref

Table 2b

LRYGB Adjusted rates and Odds Ratios

Adjusted rates and odds ratios of adverse events after LRYGB, stratified by hospital volume and by time period.

	2006-2007				2008-2009				2010-2011			
	Unadjusted Rate (%)	Adjusted Rate (%)	OR (95% CI)	p-value	Unadjusted Rate (%)	Adjusted Rate (%)	OR (95% CI)	p-value	Unadjusted Rate (%)	Adjusted Rate (%)	OR (95% CI)	p-value
Serious complications												
Hosp Vol < 50	2.32	2.24	1.55 (1.23,1.95)	0.0002	1.49	1.46	1.39 (1.09,1.76)	0.0080	1.61	1.51	1.39 (1.07,1.80)	0.0144
Hosp Vol 50-125	1.83	1.85	1.24 (1.00,1.54)	0.0472	1.71	1.71	1.30 (1.05,1.61)	0.0147	1.63	1.62	1.20 (0.96,1.50)	0.1109
Hosp Vol > 125	1.50	1.51	1	Ref	1.14	1.16		Ref	1.19	1.23		Ref
Reoperations												
Hosp Vol < 50	0.79	0.77	1.27 (0.95,1.72)	0.1112	0.52	0.52	1.13 (0.82,1.56)	0.4411	0.60	0.58	1.19 (0.88,1.61)	0.2694
Hosp Vol 50-125	0.69	0.70	1.08 (0.83,1.39)	0.5637	0.62	0.62	1.12 (0.83,1.51)	0.4712	0.61	0.61	1.12 (0.84,1.48)	0.4432
Hosp Vol > 125	0.69	0.69	1	Ref	0.61	0.61		Ref	0.48	0.49		Ref
In-hospital Mortality												
Hosp Vol < 50	0.035	0.034	0.95 (0.31,2.91)	0.9342	0.065	0.065	1.39 (0.61,3.15)	0.4298	0.054	0.051	1.13 (0.43,2.97)	0.8111
Hosp Vol 50-125	0.063	0.074	1.67 (0.73,3.81)	0.223	0.038	0.045	0.71 (0.29,1.73)	0.4505	0.037	0.044	0.79 (0.31,2.02)	0.6181
Hosp Vol > 125	0.038	0.047		Ref	0.041	0.049		Ref	0.043	0.052		Ref