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Can Technical Factors Explain the Volume-Outcome Relationship in Gastric Bypass Surgery?

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Abstract

Background—The existence of a relationship between surgeon volume and patient outcome has been demonstrated for different complex surgical operations. This relationship has also been confirmed for patients undergoing Roux-en-Y gastric bypass (RYGB) in the Longitudinal

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Assessment of Bariatric Surgery (LABS) study. Despite multiple studies demonstrating volume-outcome relationships, fewer studies investigate the causes of this relationship.

Objective—The purpose of the present study is to understand possible explanations for the volume-outcome relationship in LABS.

Setting—Multiple Clinical Centers – University and Private Practice, United States.

Methods—LABS includes a 10-center, prospective study examining 30-day outcomes following bariatric surgery. The relationship between surgeon annual RYGB volume and incidence of a composite endpoint (CE) has been published previously. Technical aspects of RYGB surgery were compared between high and low volume surgeons. The previously published model was adjusted for select technical factors.

Results—High volume surgeons (>100 RYGBs/year) were more likely to perform a linear stapled gastrojejunostomy, use fibrin sealant and place a drain at the gastrojejunostomy compared to low volume surgeons (<25 RYGBs/year), and less likely to perform an intraoperative leak test. After adjusting for the newly identified technical factors, the relative risk of CE was 0.93 per 10 RYGB/year increase in volume, compared to 0.90 for clinical risk adjustment alone.

Conclusion—High volume surgeons exhibited certain differences in technique when compared to low volume surgeons. After adjusting for these differences, the strength of the volume-outcome relationship previously found was reduced only slightly, suggesting that other factors are also involved.

Keywords

Bariatric surgery; RYGB; volume-outcome relationship

Introduction

The prevalence of bariatric surgery has seen a dramatic increase over the last decade^(1,2), with up to 220,000 operations being performed in North America in 2008. Reasons that may explain this increase include the high and increasing prevalence of morbid obesity^(3,4), the demonstrated effect of bariatric surgery on achieving sustained weight loss⁽⁵⁾ and improved survival^(6,7), and the improved safety record of modern bariatric surgery⁽⁸⁾.

Roux-en-Y gastric bypass (RYGB) remains the most frequently performed operation for treatment of morbid obesity⁽²⁾, representing 51% of the bariatric procedures performed in the USA and Canada in 2008. Laparoscopic adjustable gastric banding (LAGB) is nearly as prevalent, representing 44% of operations performed in 2008, with the remainder made up of sleeve gastrectomy, biliopancreatic diversion and duodenal switch. Although RYGB offers durable long term weight loss in multiple case series⁽⁹⁾, it is complex surgery. Reported mortality rates of 0.4% remain higher than that of LAGB at less than 0.1%⁽⁸⁾. Furthermore, major complications such as anastomotic leak and pulmonary embolism are reported in 0.6 to 4.4% of patients⁽¹⁰⁾.

With many complex operations, it is possible to demonstrate a relationship between surgeon or hospital volume and patient complication rates^(11–17). This volume outcome relationship has been previously demonstrated for RYGB^(18–20), and has recently been confirmed in the prospective risk adjusted cohort of the Longitudinal Assessment of Bariatric Surgery (LABS)-1⁽²¹⁾ which is based on clinical rather than administrative data.

Although the concept of a volume outcome relationship for complex operations is well described, there are fewer studies attempting to explain this relationship. Differences in

patient characteristics affecting surgical risk may be one factor confounding this relationship⁽²²⁾. In the LABS-1 cohort risk adjustment was performed according to previously identified clinical risk factors⁽²¹⁾. However, clinical risk adjustment did not eliminate the volume-outcome relationship. Hospital clinical support services⁽²³⁾, surgeon credentialing⁽²⁴⁾, and surgical technical factors⁽¹¹⁾ have also been shown to influence the volume outcome relationship in different surgical settings. In Smith et al.⁽²¹⁾, neither hospital clinical support, nor surgeon credentialing was specifically addressed, however all participating hospitals were bariatric centers of excellence, and all included surgeons underwent a credentialing process prior to participating in LABS. We have been unable to identify any studies exploring how surgical technical factors affect the volume outcome relationship after RYGB.

The Longitudinal Assessment of Bariatric Surgery (LABS) is a 10-center consortium funded by the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) in the National Institute of Health (NIH) that conducts observational cohort studies of bariatric surgical outcomes. These involve prospective, standardized and comprehensive collection of clinical data, and include several related protocols. LABS-1 comprised 30-day outcome data on consecutive patients, 18 years or older, undergoing an initial bariatric procedure. All participants consented to LABS data collection and Institutional Review Board approval was obtained at all participating centers.

The purpose of the present study is to explore possible explanations for the volume outcome relationship in LABS. In particular we sought to determine whether high volume surgeons exhibit systematic differences in technique when compared to low volume surgeons, and if so whether correcting for these differences changes the volume outcome relationship. Importantly, this study does not seek to address the relationship between technical factors and the composite endpoint outside of the volume outcome relationship.

Methods

LABS-1 procedures were conducted by 34 LABS certified surgeons at: University of Pittsburgh Medical Center (Pennsylvania), New York- Presbyterian Hospital [Columbia and Weill-Cornell Medical Centers] (New York), East Carolina Medical Center (North Carolina), the MeritCare Health Systems through the Neuropsychiatric Research Institute (North Dakota), Sacramento Bariatric (California), University of Washington Medical Center or Virginia Mason Medical Center (Washington), and Oregon Health and Sciences University or Legacy Good Samaritan Hospital (Oregon). The LABS-1 inclusion criteria and data collection has previously been described in detail⁽²⁵⁾. Results demonstrating a continuous relationship between surgeon annual volume of RYGB surgery and patient 30-day outcomes have been reported previously⁽²¹⁾.

For the present study inclusion criteria, adjustment and outcomes were standardized with those previously reported by LABS to allow for comparison^(8,21). Specifically, all patients at least 18-years-old undergoing RYGB as an initial bariatric procedure between March 2005 and December 2007 were included. Risk adjustment for clinical factors was performed according to the patient's body mass index (BMI), history of obstructive sleep apnea, history of deep venous thrombosis, ability to walk 200ft and surgical approach (open versus laparoscopic). Method of gastrojejunostomy was initially recorded as a binary response to whether each of three methods (hand sewing, linear stapling or circular stapling) was used in constructing the anastomosis. This was recoded to reflect the general use of these clinical terms by surgeons. In other words linear stapled with or without hand sewn is treated as predominantly linear stapled, circular stapled with or without hand sewn is classified as predominantly circular stapled, hand sewn with no staples is classified as predominantly

hand sewn. The primary endpoint was a composite event (CE) defined as occurrence of any one of the following events within 30-days of surgery: death, venous thrombosis, pulmonary embolism, re-operation, non-discharge at 30-days⁽⁸⁾.

Statistical Analysis

Surgeon volume for a surgeon within LABS was computed as the ratio of the number of procedures performed by the surgeon within LABS and the time between the first and last procedure within LABS expressed as procedures per year. Two surgeons each with fewer than 10 surgeries were excluded from the analysis. For analyzing the relationship between technical factors and surgeon volume, the volume was categorized as 0–24, 25–49, 50–99, and 100+ cases per year. Duration of procedure across surgeon volume categories was compared using Kruskal-Wallis test, while the frequencies of categorical variables, e.g. method of gastrojejunostomy, were compared using the Jonckheere-Terpstra trend test. Incidence of CEs by technical factors is reported using frequencies and percentages, and also by relative risks and 95% confidence intervals. Multivariable log-linear regression model with CE as outcome, accounting for correlation among patients within the same site and surgeon as random effects, was employed to assess how adjustment for technical factors and other patient characteristics impact the volume-outcome relationship. The results are reported as adjusted relative risks and 95% confidence intervals.

Results

LABS-1 included 3412 initial RYGB operations performed by 33 surgeons. Two surgeons performed only one RYGB operation each and were excluded from the analysis, leaving a total of 3410 RYGB operations performed by 31 surgeons. Fifteen surgeons performed an average of 49 or fewer RYGB operations per year in LABS, 9 averaged 50 to 99 and 7 averaged 100 or more.

The variation in intra operative techniques by surgeon volume category is shown in Table 1. When compared to surgeons performing fewer than 25 RYGB cases per year (low volume), those performing at least 100 RYGB cases per year (high volume) were more likely to construct the gastrojejunostomy using a linear stapled technique, more likely to use sealant at the gastrojejunostomy and more likely to place a drain. High volume surgeons were less likely to mechanically test their gastrojejunal anastomosis intraoperatively, and less likely to have a resident or fellow present during the surgery.

Table 2 shows the relationship between surgical technical factors and CE rate. Aside from surgeon volume, only performance of a circular stapled gastrojejunostomy, performance of a concurrent procedure and longer duration of surgery were associated with a higher rate of CE rate in univariate analysis.

In the multiple regression model assessing the association of surgical technical factors on the volume-outcome relationship (Model 2), we included all covariates that were significantly associated with CE in a previous analysis⁽²¹⁾ plus technical factors associated with CE with $p < 0.20$ in univariate analysis. Results are presented in Table 3. To see how the volume-outcome relationship changed with the adjustment of technical factors, we tabulated the results from the Smith et al. model⁽²¹⁾ under the heading of Model 1 in Table 3. The Smith et al. model shows that in the absence of intra-operative factors, the relative risk of CE (95% CI) for each 10 case/year increase in surgeon's annual volume is 0.90 (0.85–0.95). When intra-operative factors were added as covariates (Model 2), in addition to the patient characteristics BMI, history of deep vein thrombosis, history of obstructive sleep apnea, and inability to walk 200ft, method of gastrojejunostomy, duration of procedure, and surgeon annual volume are statistically significantly associated with the CE. Although the relative

risk is attenuated slightly (0.93 per 10 cases/year; 95% CI 0.88–0.98), the intra- operative factors that LABS included in its dataset failed to account for most of the variation due to the surgeon volume. Thus, even when technical factors are accounted for, an increase in surgeon volume by 10 cases per year is still expected to reduce the risk of CE by 7%.

Discussion

In this study we demonstrate that high volume surgeons in LABS were more likely to construct a linear stapled gastrojejunostomy, use sealant and place a drain, and less likely to mechanically test their gastrojejunostomy compared to low volume surgeons. Despite adjusting for these technical differences between high and low volume surgeons in LABS we found the relationship between surgeon RYGB volume and CE rate was not eliminated. The relationship between surgeon and volume and patient outcomes is difficult to evaluate. Possible confounding factors include the effects of patient risk, hospital volume, hospital characteristics, surgeon training and experience, learning curves, and procedure specificity. Even accounting for these differences, the mechanism by which surgeon volume affects patient outcomes is unclear and since there are so many factors that make up care delivery, simple evaluations of single process metrics have limited value. The previously published study from the LABS consortium explored the relationship between surgeon annual volume of RYGB and CE rate following this procedure⁽²¹⁾. In that study, patient risk was adjusted for using clinical risk factors found to be significant for CE, namely BMI, history of obstructive sleep apnea, history of deep venous thrombosis, ability to walk 200ft and surgical approach (open versus laparoscopic).

Hospital volume has also been shown to influence complication rate following RYGB surgery independent of surgeon volume⁽¹⁸⁾. Although not demonstrated for bariatric surgery, hospital clinical characteristics including staffing levels, availability of specialist services, and experience with similar clinical procedures have been shown to affect volume outcome relationship in different settings^(23,26–28). In LABS we were not able to examine the influence of hospital volume, or specific hospital characteristics, however all participating centers are certified as ‘centers of excellence’ by one of two certification programs^(29,30). These programs mandate safe minimum standards for infrastructure, clinical support and minimum hospital annual volume requirements.

Surgeon training and experience has also been demonstrated to affect patient outcomes^(31,32). In addition, procedure specificity, or the effect of performing similar procedures varies in different settings^(28,33). Our previous report described the statistically non-significant association between surgeon self-reported lifetime experience and surgeon annual volume of laparoscopic adjustable gastric band surgery and found that adjustment for self-reported lifetime experience did not affect the volume outcome relationship for RYGB⁽²¹⁾. LABS required participating surgeons to hold board certification or equivalent in general surgery, but did not require subspecialty bariatric fellowship training, and to have experience performing at least 25 bariatric operations prior to inclusion in LABS. This baseline experience requirement may have eliminated any further effect of self-reported surgeon experience on patient outcome.

Despite substantial research addressing volume outcome relationships, few studies have explored the effect of surgical technical factors. A study from 2008 examined surgical blood loss in patients undergoing radical cystectomy before and after the introduction of a vascular stapling device⁽³⁴⁾. They found that blood loss was decreased after introducing the vascular stapler in patients of both high and low volume surgeons, although the improvement was greater for low volume surgeons. Mean operating time was only reduced for the low volume surgeons.

A multi-center study using the Surveillance, Epidemiology and End Results (SEER) database examining the influence in hospital volume on mortality in patients undergoing cystectomy looked at issues such as epidural anesthesia, invasive monitoring and blood transfusions⁽³⁵⁾. Here the authors found that adjusting for peri-operative processes had a modest effect on reducing the impact of hospital volume on perioperative mortality (OR 1.39 reduced from 1.46).

Another multi-center study from Germany examined a prospective registry of open abdominal aortic aneurysm repairs in 131 hospitals⁽¹¹⁾. This study examined a number of pre-operative and intraoperative variables and found the patient age, length of procedure, suprarenal aortic clamping and aneurysm diameter were independently associated with perioperative mortality using stepwise regression analysis. When adjusting for these predictors, hospital volume treated as a continuous variable was not predictive of mortality.

One of the major strength of the present study is the use of a multi-center prospective clinical database in which data were recorded regarding multiple intra-operative details. The large numbers of patients and surgeons involved also contribute to the power of this study.

Possible limitations of this study include the use of a composite endpoint, and the number and choice of intra-operative variables examined. Although the use of a composite endpoint to improve statistical power has been criticized previously⁽³⁶⁾, the CE has already been reported in LABS publications^(8,21). In particular, the previously reported relationship between volume and CE⁽²¹⁾ is precisely what this manuscript attempts to explain. Regarding the choice of intra-operative variables, all intra-operative technical data considered by expert surgeons to be potentially relevant to outcome were included in the dataset and included in this analysis. Furthermore, this analysis included only 32 bariatric surgeons at 10 centers within the United States which may limit the variability needed to identify technical factors that could explain the volume outcome relationship for RYGB. Because all sites became accredited as centers of excellence by one of the two programs at the time, the results are not likely to be generalizable to all bariatric surgeons.

The findings of this study should be considered when developing strategies to reduce the volume outcome relationship for RYGB but should not be interpreted as a cause and effect relationship. While differences were found between the intra-operative clinical practice of high- and low-volume surgeons, adjusting for these differences did not eliminate the volume-outcome relationship and we did not test the potential impact of lower volume surgeons adopting more of these 'high volume surgeon' techniques.

Patient care is a highly complex activity that incorporates patient selection, preoperative preparation, nursing and anesthetic care in addition to the controlled surgical environment. Further research is still required to determine whether different surgeon specific technical factors, or other unrelated factors explain the volume-outcome relationship for RYGB.

Conclusion

In conclusion, although high- and low-volume RYGB surgeons differ in preferred method of gastrojejunal anastomosis, testing of the anastomosis, and use of sealant or drains, adjusting for these factors does not eliminate the volume outcome relationship.

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Table 1

Distribution of technical factors by surgeon volume

Technical factors	Overall	By LABS Surgeon Volume (Cases per year in LABS)				p-value*
		< 25 (n = 352)	25 to < 50 (n = 461)	50 to < 100 (n = 1219)	100 (n = 1378)	
Trainee present (n, %)	2335 (68.5)	237 (67.3)	437 (94.8)	803 (65.9)	858 (62.3)	<0.001
Anastomosis tested (n, %)	2839 (83.4)	311 (88.6)	458 (99.6)	1026 (84.2)	1011 (75.8)	<0.001
By Air (n, %)	388 (11.4)	102 (29.1)	16 (3.5)	186 (15.3)	84 (6.1)	<0.001
By Endoscopy (n, %)	1439 (42.3)	151 (43.0)	157 (34.1)	453 (37.2)	678 (49.2)	<0.001
By Methylene Blue (n, %)	1204 (35.4)	64 (18.2)	296 (64.4)	551 (45.2)	293 (21.3)	<0.001
Method of GJ**						<0.001
Predominantly Hand Sewn (n, %)	839 (24.7)	105 (30.0)	180 (39.4)	552 (45.4)	2 (0.2)	
Predominantly Linear Stapled (n, %)	1305 (38.4)	56 (16.0)	43 (9.4)	404 (33.3)	802 (58.2)	
Predominantly Circular Stapled (n, %)	1255 (36.9)	189 (54.0)	234 (51.2)	259 (21.3)	573 (41.6)	
GJ sealed (n, %)	1990 (58.6)	104 (29.6)	319 (69.8)	732 (60.4)	835 (60.6)	<0.001
Drain placed at GJ (n, %)	671 (19.7)	46 (13.1)	13 (2.8)	281 (23.1)	331 (24.0)	<0.001
Concurrent Procedure performed (n, %)	1744 (51.1)	210 (59.7)	191 (41.4)	631 (51.8)	712 (51.7)	0.72
DVT prophylaxis administered or ordered (n, %)	3392 (99.5)	350 (99.7)	460 (99.8)	1206 (99.9)	1376 (99.9)	0.26
Duration of procedure (minutes) (incision to skin closure) [median (25 th , 75 th)]	135 (108, 168)	160 (130, 190)	150 (120, 174)	140 (113, 175)	121 (100, 150)	<0.001

GJ gastrojejunostomy, DVT deep venous thrombosis, n number

* p-values from trend test for discrete variables and from Kruskal-Wallis test for continuous variables

** Method of gastrojejunostomy is coded to reflect the general use of these clinical terms by surgeons. Linear stapled with or without hand sewn is treated as predominantly linear stapled, circular stapled with or without hand sewn is classified as predominantly circular stapled, hand sewn with no staples is classified as predominantly hand sewn.

Table 2

Composite event rates by technical factors

Characteristics	Category	n	CE (%)	Relative Risk (95% CI)	P- value*
Overall		3410	177 (5.2)		
Trainee Present	No Yes	1075 2335	45(4.2) 132(5.7)	Ref 1.25 (0.79, 1.99)	0.33
Anastomosis tested	No Yes	567 2839	15(2.6) 162(5.7)	Ref 2.08 (0.99, 4.38)	0.054
Method of GJ**	Predominantly Hand Sewn Predominantly Linear Stapled Predominantly Circular Stapled	839 1305 1255	46(5.5) 36(2.8) 95(7.6)	1.65 (0.82, 3.32) Ref 2.56 (1.35, 4.85)	0.161 0.004
GJ sealed	No Yes	1407 1990	82(5.8) 95(4.8)	Ref 0.86 (0.54, 1.37)	0.518
Drain placed at GJ	No Yes	2739 671	152(5.5) 25(3.7)	Ref 0.90 (0.53, 1.54)	0.707
Concurrent Procedure performed	No Yes	1666 1744	71(4.3) 106(6.1)	Ref 1.49 (1.08, 2.05)	0.015
DVT prophylaxis administered or ordered	No Yes	17 3392	0(0.0) 177(5.2)	NA*** NA***	NA***
Duration of procedure (per 20 minutes)				1.13 (1.08, 1.18)	<0.001
Surgeon's LABS volume (per 10 cases/year)				0.89 (0.86, 0.93)	<0.001

CE composite endpoint, CI confidence interval, GJ gastrojejunostomy, NA not available, n number, Ref reference value.

* p-values are from generalized linear mixed model adjusted for random effects of surgeon within site and surgeon.

** Method of gastrojejunostomy is coded to reflect the general use of these clinical terms by surgeons. Linear stapled with or without hand sewn is treated as predominantly linear stapled, circular stapled with or without hand sewn is classified as predominantly circular stapled, hand sewn with no staples is classified as predominantly hand sewn.

*** A relative risk could not be computed since there was no event in the reference group.

Table 3

Multiple regression analysis (generalized linear mixed model) of composite events and surgeon volume in relation to technical factors and patient characteristics.

	Model 1 (Smith et al., 2010)		Model 2^b	
Characteristics	Relative Risk (95% CI)	p-value	Relative Risk (95% CI)	p-value
Technical factors				
Trainee Present (vs. absent)				
Anastomosis tested (Yes vs. No)			1.43 (0.74, 2.76)	0.288
Method of GJ [*]				0.006
Pred. Circular Stapled vs. Pred. Linear Stapled Pred. Hand-Sewn vs. Pred. Linear Stapled			1.64 (0.95, 2.85) 2.17 (1.35, 3.50)	0.077 0.002
GJ sealed (Yes vs. No)				
Drain placed at GJ (Yes vs. No)				
Concurrent Procedure performed (Yes vs. No)			1.27 (0.92, 1.76)	0.14
Duration of procedure (per 20 minutes)			1.10 (1.04, 1.17)	<0.001
Surgeon's LABS volume (per 10 cases/year)	0.90 (0.85, 0.95)	<0.001	0.93 (0.88, 0.98)	0.011
Patient Characteristics				
Body mass index (BMI), Kg/m ²	NA ^a	linear, 0.293 Quadratic, 0.005	NA ^a	linear, 0.17 Quadratic, 0.006
History of DVT (Yes vs. No)	2.06 (1.18, 3.60)	0.011	1.94 (1.11, 3.40)	0.021
History of OSA (Yes vs. No)	1.43 (1.04, 1.98)	0.029	1.35 (0.98, 1.86)	0.069
Inability to walk 200 feet (Yes vs. No)	2.13 (1.12, 4.06)	0.022	2.04 (1.07, 3.87)	0.029

CI confidence interval, GJ gastrojejunostomy, DVT deep venous thrombosis, OSA obstructive sleep apnea.

^aSince BMI has both linear and quadratic terms in the model, the relative risk is not a constant (depends on BMI levels). For example, in Model 1 an increase in BMI from 50 Kg/m² to 70 Kg/m² would increase the risk of composite event by 15%, whereas an increase of same magnitude in BMI from 55 Kg/m² to 75 Kg/m² increases the risk by 37%.

^bModel 2 included all variables from Smith et al. 2010 plus the technical factors which were significantly or near significantly ($p < 0.20$) associated with the composite event (Table 2).

^{*} Method of gastrojejunostomy is coded to reflect the general use of these clinical terms by surgeons. Linear stapled with or without hand sewn is treated as predominantly linear stapled, circular stapled with or without hand sewn is classified as predominantly circular stapled, hand sewn with no staples is classified as predominantly hand sewn.