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ORIGINAL CONTRIBUTIONS

Advanced Age as an Independent Predictor of Perioperative Risk after Laparoscopic Sleeve Gastrectomy (LSG)

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Abstract
Background While the safety of many bariatric procedures has been previously studied in older patients, we examine the effect of advancing age on medical/surgical complications in laparoscopic sleeve gastrectomy, a relatively unstudied procedure but that is trending upwards in use.
Methods Patients undergoing laparoscopic sleeve gastrectomy (LSG) and laparoscopic gastric bypass (RYGB) were extracted from the National Surgical Quality Improvement Program 2005–2012 database. Pre- and postoperative variables were analyzed using chi-square and student *t* test as appropriate to determine the comparative safety of LSG to RYGB in the elderly. Multivariate regression modeling was used to evaluate whether age is associated with adverse 30-day events following LSG.
Results Of the patients that met the inclusion criteria, 56,664 (84 %) patients underwent RYGB and 10,835 (16 %) underwent LSG. In the LSG cohort, incidence of overall complications, medical complications, and death significantly increased with increasing age ($p<0.05$). No statistically significant differences in rates of 30-day complications, return to the OR, and mortality exist between RYGB and LSG cohorts in patients older than 65 years. The age group of over 65 years independently predicted increased risk for overall and medical complications (OR, 1.748; OR, 2.027). Notably, age was not significantly associated with surgical complications in LSG.
Conclusion In this large, multi-institutional study, advanced age was significantly associated with overall and medical complications but not surgical complications in LSG. Our findings suggest that the risk conferred by advancing age in LSG is predominantly for medical morbidity and advocate for improved perioperative management of medical complications. LSG may be the preferable option to RYGB for elderly patients as neither procedure is riskier with regards to 30-day morbidity while LSG has been shown to be safer with regards to long-term reoperation and readmission risk.

Keywords Bariatric surgery · Laparoscopic sleeve gastrectomy · Age

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Introduction

Age is well recognized as a risk factor in risk stratification models for perioperative morbidity and mortality following bariatric procedures [1–5]. Laparoscopic sleeve gastrectomy (LSG), originally a component of the biliopancreatic diversion with duodenal switch procedure, is gradually gaining popularity over other bariatric procedures and, since 2012, has been indicated by the American Society for Metabolic and Bariatric Surgery as an acceptable option as a primary bariatric procedure and as a first stage procedure in high-risk patients based on the previous data reported on its efficacy and safety. While studies have reported on the relative effectiveness of LSG, little has been done regarding the comparative safety of LSG

among other laparoscopic bariatric procedures [6–13]. Since their last update of their position on LSG, the ASBMS has specifically encouraged new reports on LSG outcomes to better understand the risk/benefit profile of this surgical modality. Even fewer multi-institutional observational studies have examined the safety of LSG in the elderly population, and they are limited by their inability to isolate age as an independent predictor of early morbidity [14, 15].

In 2012, the Center for Medicare and Medicaid Services (CMS) announced that decisions regarding LSG coverage will be relegated to the regional Medicare Administrative Contractors, further suggesting the importance of evidence to refute or support perioperative safety of LSG. Thirty-five percent of patients older than 60 years of age suffer from obesity and the prevalence of obesity will surely trend upwards, increasing the volume of bariatric surgeries. For the aforementioned reasons and because the complication profiles in the elderly undergoing surgery has been a recent active area of investigation [16–19], we performed a retrospective analysis via the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) to determine the comparative safety of LSG relative to other laparoscopic bariatric procedures in the elderly and to identify whether age is independently associated with perioperative risk after LSG.

Methods

Patients

The ACS-NSQIP registry from 2005 to 2012 was retrospectively reviewed. The details of the ACS-NSQIP data collection methods have previously been described in detail and validated [20, 21]. Patients undergoing laparoscopic bariatric surgery were identified by *current procedural terminology* (CPT) codes laparoscopic Roux-en-Y gastric bypass (43644), long-limb laparoscopic Roux-en-Y gastric bypass (43645), and laparoscopic sleeve gastrectomy (43775). The entire dataset was stratified by procedure: laparoscopic gastric bypass (RYGB) and laparoscopic sleeve gastrectomy (LSG). Extracted patients were stratified into groups by their age (19–35, 35–50, 50–65, 65 and over), and all patients younger than 19 years of age and with a BMI of less than 35 kg/m^2 were excluded.

Age, race, outpatient status, and BMI were included as part of patient demographics. Clinical characteristics examined included alcohol use, smoking, steroid use, radiotherapy in the prior 90 days, chemotherapy in the prior 30 days, previous operations in the prior 30 days, and ventilator dependence. Surgical case characteristics examined included emergency case status and average operative time. Also identified were comorbidities including diabetes, dyspnea, hypertension, COPD, congestive heart failure, bleeding disorders, history of percutaneous coronary intervention (PCI), cardiac surgery, stroke, transient ischemic attack (TIA), hemiplegia, disseminated cancer, and ASA class Table 1.

Primary Outcomes

The primary outcome of interest was 30-day complication rates, categorized as surgical, medical, and overall complications. Surgical complications include superficial, deep, and organ space surgical site infections (SSIs) and wound dehiscence as classified by the NSQIP User Guide. Medical complications included pneumonia, unplanned intubation, ventilator dependence greater than 48 h, progressive renal insufficiency, acute renal failure, urinary tract infections, peripheral neurologic deficiency, intraoperative or immediate postoperative transfusion requirement, pulmonary embolism, stroke, coma, cardiac arrest, myocardial infarction, deep vein thrombosis, sepsis, septic shock, and death. Overall complication rates were defined as the total of one or more of the above events tracked by the NSQIP database. Return to the OR was defined as a return to the operating room within 30 days of the primary procedure.

Statistical Analysis

Patients were stratified into four age groups, 19–35, 35–50, 50–65, 65 and over. Patient demographics, comorbidities, and outcomes were assessed using chi-square tests for categorical variables and one-way ANOVA tests for continuous variables.

The association between complications and age in laparoscopic gastric bypass and laparoscopic sleeve gastrectomy was examined using multivariate analysis. Risk-adjustment of the regression model was performed with the aforementioned preoperative variables. Risk factors with an alpha value less than 0.2 in the bivariate analysis were included in regression model. Hosmer–Lemeshow and C-statistics calculations were performed to evaluate calibration and discrimination of the regression model [22, 23]. An alpha value of less than 0.05 was considered statistically significant for all multivariate analyses. All analyses were performed using SPSS, version 22 (Chicago, IL).

Results

Of the 2,320,920 patients captured in the NSQIP database, 67,499 patients underwent laparoscopic bariatric surgery and met inclusion criteria. About 13,999 (20.7 %) were between 19 and 35 years, 29,413 (43.6 %) were between 35 and

Table 1 Patient demographics and comorbidities

Laparoscopic sleeve gastrectomy										
		19–35 (n=2330)		35–50 (n=4889)		50–65 (n=3313)		65+ (n=303)		p value
Race*	Asian	21	0.90 %	34	0.70 %	28	0.85 %	2	0.66 %	<0.001
	Black	529	22.70 %	1126	23.03 %	518	15.64 %	20	6.60 %	
	Other	298	12.79 %	471	9.63 %	269	8.12 %	27	8.91 %	
	White	1482	63.61 %	3258	66.64 %	2498	75.40 %	254	83.83 %	
Outpatient		151	6.48 %	328	6.71 %	230	6.94 %	11	3.63 %	0.169
Male*		434	18.63 %	1123	22.97 %	813	24.54 %	99	32.67 %	<0.001
Diabetes*		237	10.17 %	984	20.13 %	1130	34.11 %	144	47.52 %	<0.001
Smoker*		332	14.25 %	518	10.60 %	233	7.03 %	10	3.30 %	<0.001
Alcohol use		3	0.13 %	5	0.10 %	7	0.21 %	0	0.00 %	0.538
Dyspnea*		279	11.97 %	640	13.09 %	581	17.54 %	71	23.43 %	<0.001
Ventilator dependent		0	0.00 %	1	0.02 %	0	0.00 %	0	0.00 %	0.749
Hypertension*		515	22.10 %	2251	46.04 %	2372	71.60 %	267	88.12 %	<0.001
Previous stroke*		5	0.21 %	17	0.35 %	35	1.06 %	7	2.31 %	<0.001
Previous cardiac surgery*		3	0.13 %	29	0.59 %	79	2.38 %	16	5.28 %	<0.001
Wound Infection		7	0.30 %	17	0.35 %	21	0.63 %	1	0.33 %	0.17
Steroid Use*		23	0.99 %	53	1.08 %	57	1.72 %	6	1.98 %	0.025
Bleeding disorder*		8	0.34 %	42	0.86 %	55	1.66 %	18	5.94 %	<0.001
Chemotherapy		0	0.00 %	1	0.02 %	1	0.03 %	0	0.00 %	0.863
Radiotherapy		0	0.00 %	1	0.02 %	0	0.00 %	0	0.00 %	0.749
Previous sepsis		9	0.39 %	10	0.20 %	3	0.09 %	0	0.00 %	0.088
ASA Class 3, 4, or 5*		1266	54.33 %	3168	64.80 %	2495	75.31 %	259	85.48 %	<0.001
Age*		29.0 (4.1)		42.0 (4.2)		55.7 (4.0)		67.5 (3.6)		<0.001
BMI*		47.7 (9.0)		46.3 (8.3)		45.2 (7.6)		44.7 (7.8)		<0.001
Total operation time*		95.8 (45.5)		98.7 (49.9)		102.5 (48.4)		104.7 (49.1)		<0.001

*Denotes significance $p<0.05$

Categorical variables expressed as N, % total

Continuous variables expressed as mean (SD)

50 years, 21,588 (32.0 %) were between 50 and 65 years, and 2499 (3.7 %) were older than 65 years. About 56,664 (84 %) patients underwent RYGB and 10,835 (16 %) underwent laparoscopic sleeve gastrectomy. Within the group that underwent laparoscopic sleeve gastrectomy, 2330 patients were between 19 and 35 years, 4889 were between 35 and 50 years, 3313 were between 50 and 65 years, and 303 were older than 65 years of age. Differences in gender, race, age, BMI, diabetes status, smoking, dyspnea, hypertension, previous stroke, previous cardiac surgery, steroid use, bleeding disorders, and ASA class were noted among the age groups.

In the LSG cohort, incidence of overall complications, medical complications, and death significantly increased with increasing age ($p<0.05$). It is interesting to note that the largest increase in overall and medical complication rate occurred between the 50–65 age group and the 65+ age group. Rate of surgical complications and reoperation did not demonstrate a similar trend ($p=0.456$ and 0.18, respectively) (Table 2). In the RYGB cohort, incidence of overall, medical, surgical complications, and mortality was significantly increased with increasing age ($p<0.001$). No statistically significant differences in rates of 30-day complications, return to the OR, and mortality exist between RYGB and LSG cohorts in patients older than 65 years (Table 3).

Multivariate regression models were constructed to assess the independent relationship between perioperative complications and advancing age in patients undergoing laparoscopic sleeve gastrectomy (Table 4). The age group of over 65 years independently predicted increased risk for overall and medical complications (OR, 1.748; OR, 2.027). Notably, age was not significantly associated with surgical complications in LSG. C-statistics and Hosmer–Lemeshow statistics have been included in Table 5 to validate discriminatory capability and calibration of the regression models that were constructed.

Table 2 Postoperative outcomes

	Laparoscopic sleeve gastrectomy (n=10,835)					Laparoscopic gastric bypass (n=56,664)				p value
	19–35	35–50	50–65	65+	p value	19–35	35–50	50–65	65+	
Surgical complications	1.20 %	1.60 %	1.40 %	1.30 %	0.456	2.00 %	2.70 %	2.90 %	2.60 %	<0.001
Medical complications	2.40 %	3.10 %	3.10 %	6.60 %	0.001	2.70 %	3.20 %	4.30 %	6.30 %	<0.001
Overall complications	3.20 %	4.00 %	4.00 %	7.30 %	0.006	4.30 %	5.30 %	6.50 %	7.80 %	<0.001
Death	0.00 %	0.10 %	0.10 %	0.70 %	0.002	0.00 %	0.10 %	0.20 %	0.50 %	<0.001
Return to OR	1.40 %	1.40 %	1.80 %	2.60 %	0.18	2.40 %	2.60 %	2.80 %	3.20 %	0.088
Total	2330	4889	3313	303	10,835	11,669	24,524	18,275	2196	56,664

Discussion

Our current work, which addresses the paucity of literature on the indications of LSG use in the elderly, investigated the perioperative risk associated with advancing age in LSG. Our multi-institutional retrospective study identified, via multivariate analysis, the 65+ age group undergoing LSG as an independent predictor of medical and overall complications, but not surgical complications.

We demonstrated a significant association between the age group 65+ and increased risk of medical and overall complications in LSG. Surgical complication, which has been previously described as a primary cause of perioperative morbidity [10], was not found to be independently associated with advanced age. The findings in our study should be interpreted in the context of its methodology. High comorbidity burden and male predominance in the elderly cohort may influence their greater predisposition to 30-day medical/overall complications and mortality [24]. Our regression analysis adjusts for these potentially confounding factors, allowing us to evaluate the independent effect of advancing age on postoperative morbidity. A matched analysis, which balances the disparate comorbidity burden and demographic profiles across age groups, may allow for a more rigorous comparison. To our knowledge, there is very little in the literature regarding matching non-binary treatment effects (four age groups). This is a technique that future research may explore. Our findings suggest that postoperative morbidity in patients over 65 years undergoing LSG is attributed to medical complications. Effort should be directed towards the perioperative management and prevention of these complications.

Table 3 Bypass vs LSG outcomes in patients older than 65 years

	Bypass (n=2196)	LSG (n=303)	p value
Surgical complications	2.60 %	1.30 %	0.19
Medical complications	6.30 %	6.60 %	0.832
Overall complications	7.80 %	7.30 %	0.748
Death	0.50 %	0.70 %	0.629
Return to OR	3.20 %	2.60 %	0.608

Another important finding of our study, which compared 56,664 RYGB patients to 10,835 LSG patients, was that no statistically significant difference in 30-day rates of complications, return to OR, or mortality existed between the two procedures. While the benefits of LSG such as increased type 2 diabetes mellitus remission, improved satiety, reduced hunger, and long-term weight loss have been described, comparatively less is known about its associated risks [25–27]. Because the use of LSG is only recently trending upwards, the ability to perform robust, retrospective analysis on LSG outcomes is limited by the number of patients. Hutter et al. reported lower risk-adjusted reoperation/intervention rates in 944 patients undergoing LSG compared to 26,684 patients undergoing RYGB [9]. Birkmeyer et al., among other studies that endorsed the safety of LSG, demonstrated a similar reduction in complication rate in 854 LSG patients relative to a larger RYGB cohort [10, 28, 29]. Our study, which evaluated the comparative safety of LSG to other laparoscopic procedures in a large national patient sample, did not find a statistically significant difference in 30-day complications, reoperations, and death between laparoscopic gastric bypass and LSG cohorts in patients older than 65 years. It is possible that our study of over 10,000 LSG patients may more powerfully elucidate the complication profile of the procedure and also demonstrate the variable influence of age on comparative safety. In short, LSG does not seem to be any riskier or safer than RYGB for the elderly. We performed a univariate comparative analysis, which does not adjust for potential confounding variables that may affect 30-day rates of complications. We argue that dissimilar comorbidity burden may not distort the conclusions of our univariate analysis, as the proportions of patients 65 and over who were ASA Class 3, 4, or 5 in either cohort were not significantly different via chi square analysis (52.6 vs. 54.3 %; p=0.130). An important future direction will be to focus on the effect of surgical modality on postoperative morbidity, independent of any

Table 4 Risk adjusted multivariate analysis: Laparoscopic sleeve gastrectomy

Age (years)	Overall complications				Surgical complications				Medical complications			
	p value	Adjusted OR	95 % CI		*p* value	Adjusted OR	95 % CI		*p* value	Adjusted OR	95 % CI	
19–35[a]												
35–50	0.213	1.196	0.902	1.584	0.143	1.403	0.892	2.208	0.401	1.148	0.832	1.583
50–65	0.744	1.054	0.767	1.45	0.569	1.163	0.692	1.955	0.927	1.017	0.709	1.46
65+	0.037	1.748	1.034	2.956	0.988	0.992	0.332	2.959	0.014	2.027	1.157	3.552

[a] Reference group

differences in patient characteristics, of which comorbidity burden is not one. Taken together, our findings suggest that age should not be a determining factor in the decision to choose between these two bariatric procedures. As more LSG procedures are performed, future retrospective studies will revisit its comparative risk.

Flum et al. assessed perioperative risk in elderly patients undergoing bariatric surgery (excluding laparoscopic procedures) via Medicare claims data and reported that the risk of early death was associated with advancing age (65+) [30]. Unlike this study, ours is not dependent on Medicare claims data and identifies and controls for multiple variables that may confound the relationship between advancing age and perioperative risk. Because of the improved safety of laparoscopic bariatric procedures over open procedures and the trending use of the laparoscopic technique in the elderly, Dorman et al. performed a similar ACS-NSQIP study that examined age in both open and laparoscopic procedures [3]. Via data from 2006–2009, Dorman et al. reported increased length of stay and death in patients over 65 years undergoing open and laparoscopic procedures and no significant change in 30-day complications. This study excluded laparoscopic sleeve gastrectomy procedures, a procedure that is trending upwards but one that CMS has yet to make a definite ruling regarding coverage. Ritz et al. reported no increased in incidence of post-LSG surgical and non-surgical complications in 164 patients above 60 years compared to 1379 patients below 40 years. Their findings advocated LSG as a potentially safer procedure compared to RYGB in the elderly [14]. To date, a consensus in the literature does not exist regarding the perioperative safety of bariatric surgery in the elderly [31–33].

We have demonstrated that advanced age is independently associated with overall and medical complications but not surgical complications. Concurrently, we identified other risk factors for 30-day overall complication, including inpatient status, hypertension, dyspnea, and operation time. The NSQIP dataset robustly captures over 50 preoperative variables of which their respective associations with 30-day morbidity can be assessed with proper risk adjustment. We argue that age should be considered in the context of the other putative risk factors when risk stratifying patients undergoing laparoscopic bariatric procedures. Three multi-institutional studies recently published predictive risk models for mortality and morbidity after bariatric surgery that incorporates age as a predictive factor [1, 2, 34]. The development of an interactive individualized risk calculator that estimates 30-day risk of complication that is based on patient demographics and comorbidities and takes into account multiple surgical modalities (i.e., bypass, banding, and sleeve gastrectomy) will be an important future direction.

This study is not without limitations. While the ACS NSQIP dataset provides a robust platform for retrospective analysis, it does not provide procedure specific outcomes such as strictures, anastomotic leaks, and marginal ulcers. Data on the quality of life years saved, which could provide insight into the efficacy of bariatric surgery in the elderly, is not available. In addition, we are unable to capture the entire the postoperative complication profile of each patient because of the 30-day follow-up limit. The method by which we stratified age groups is somewhat arbitrary and may affect the conclusions that we draw, although it has been previously used [3]. The possibility of selection bias cannot be ignored, as comorbidity burden may predispose patients to what procedure they receive. Unfortunately, the reason for choosing a particular procedure is not documented in the database.

Table 5 Hosmer–Lemeshow (HL) and C-statistics

Predictive model	HL	C
Overall complications	0.651	0.653
Medical complications	0.468	0.634
Surgical complications	0.841	0.67

Conclusion

Bariatric surgery is an acceptably safe procedure with a 30-day mortality rate of 0.7 and 0.5 % for patients over 65 years of age undergoing LSG and RYGB, respectively. In light of a paucity of literature regarding the safety of LSG in the elderly, our study performed a robust, retrospective analysis on over

10,000 patients undergoing laparoscopic sleeve gastrectomy (LSG) to determine its risk profile in the elderly. Our findings suggest that the risk conferred by advancing age in LSG is predominantly for medical morbidity and advocate for improved perioperative management of medical complications. LSG may be the preferable option to RYGB for elderly patients as neither procedure is riskier with regards to 30-day morbidity while LSG has been shown to be safer with regards to long-term reoperation risk.

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Ethical Approval De-identified patient information is freely available to all institutional members who comply with the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) Data Use Agreement. The Data Use Agreement implements the protections afforded by the Health Insurance Portability and Accountability Act of 1996 and the ACS-NSQIP Hospital Participation Agreement, and conforms to the Declaration of Helsinki.

Disclaimer The NSQIP and the hospitals participating in the NSQIP are the source of the data used herein; they have not been verified and are not responsible for the statistical validity of the data analysis, or the conclusions derived by the authors of this study.

Conflict of Interest The authors declare that they have no conflict of interest.

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