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Original article

Concomitant removal of gastric band and sleeve gastrectomy: analysis of outcomes and complications from the ACS-NSQIP database

Elie P. Ramly, M.D., Ramzi S. Alami, M.D., F.A.C.S., Hani Tamim, Ph.D., Rami Kantar, M.D., Elias Elias, M.D. M.P.H., Bassem Y. Safadi, M.D., F.A.C.S.*

Department of Surgery, American University of Beirut Medical Center, Lebanon, Beirut

Abstract

Background: Conversion of adjustable gastric band to laparoscopic sleeve gastrectomy (LSG) is feasible, but multiple reports have indicated higher morbidity and staple line leak rates when this is performed as a single-stage procedure. The objective of this study is to compare the safety profile and outcomes of LSG with concomitant gastric band removal (LSG/GBR) versus LSG using the American College of Surgeons' National Surgical Quality Improvement Program (ACS-NSQIP).

Methods: Using the ACS-NSQIP database (2010−2012), LSG cases were identified using Current Procedural Terminology (CPT) code 43775 and concomitant LSG/LGBR using CPT code 43775 + (43772 or 43774). Baseline patient characteristics and perioperative variables including postoperative mortality and morbidity rates were retrieved. The primary endpoint was sepsis within 30 days. Bivariate and multivariate analyses were carried out.

Results: During the study period, 11,189 (96.9%) patients had LSG and 357 (3.1%) had LSG/GBR for a total of 11,546 patients. On bivariate analyses, the rate of sepsis was higher after LSG/GBR (1.68% versus .58%; $P = .022$), and the mean operative time was longer (124.6 ± 52.3 versus 98.6 ± 49.0 min; $P < .001$). There was no statistically significant difference in the rate of postoperative mortality (.28% versus .08 %; $P = .27$) or that of other outcomes such as return to the operating room, wound infection, or venous thromboembolism. After multivariate analysis, the odds of developing postoperative sepsis remained significantly higher for patients undergoing LSG/GBR compared with LSG alone (odds ratio [OR] 3.32; confidence interval [CI] 1.41–7.84; $P = .006$).

Conclusion: LSG/GBR can be performed with low morbidity and mortality. However, this procedure carries a higher rate of postoperative sepsis. (Surg Obes Relat Dis 2016;12:984–990.)

Keywords: Sleeve gastrectomy; Revisional surgery; Adjustable gastric banding; National Surgical Quality Improvement Program; Sepsis

Laparoscopic gastric banding remains one the most popular techniques used in bariatric surgery worldwide, despite a decline in recent years. Although effective in achieving weight loss in selected patients, it is associated with failure rates as high as 50% [1–4]. Failure of gastric banding can be classified as technical (e.g., slippage or erosion), or failure to achieve or maintain target weight loss or resolution of co-morbidities. Although most of these situations warrant surgical revision, the procedure of choice remains a subject of debate. Laparoscopic Roux-en-Y gastric bypass has an established role in the revision of failed gastric bands, with acceptable morbidity and long-term weight reduction [5] even when performed as a single-step procedure [6,7]. Laparoscopic sleeve gastrectomy (LSG) has the advantage of preserving gastrointestinal continuity and minimizing nutritional and mineral

*Correspondence: Bassem Safadi, M.D., F.A.C.S., Department of Surgery, American University of Beirut Medical Center, Beirut, Lebanon. E-mail: bs21@aub.edu.lb

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deficiencies, but carries the major disadvantage of a higher leak rate [8]. Most of the available literature is from single institutional experiences, with variable leak rates as high as 33% [9–12]. Recent data from the German Bariatric Surgery Registry confirmed worse outcomes for LSG with concomitant gastric band removal (LSG/GBR) [13]. Using the 2010−2012 National Surgical Quality Improvement Program (NSQIP) database, the Cleveland Clinic group examined the 30-day composite adverse event rate of LSG versus LSG/GBR and found comparable tolerability in both groups [14]. They chose Current Procedural Terminology (CPT) codes 43772 and 43773 to identify cases of GBR, although code 43773 denotes gastric band removal and replacement. We examined the same data within the same period of time using CPT codes 43775 for LSG and CPT codes 43772 and 43774 for GBR. We chose postoperative sepsis as the primary outcome measure as a surrogate marker for staple line leak, because staple line leak is not recorded as an outcome in NSQIP. Mortality, overall morbidity, length of hospital stay, and operative times were studied as secondary outcomes.

Methods

ACS-NSQIP data

Data was obtained from the American College of Surgeons' National Surgical Quality Improvement Program (ACS-NSQIP) database, a prospective outcomes registry designed to provide feedback to participating hospitals about 30-day risk-adjusted surgical mortality and morbidity. The ACS-NSQIP data collection methodology has been previously described and repeatedly validated [15,16]: trained surgical clinical reviewers obtain data for patients on admission from the medical chart, operative log, anesthesia record, interviews with the surgical attending, and telephone interviews with patients. Data quality is ensured through comprehensive training of the nurse reviewers, an interrater reliability audit of participating sites, regular conference calls, and an annual meeting. A detailed description of the ACS-NSQIP database can be found on its website (http://www.acsnsqip.org). In accordance with the American University of Beirut's guidelines (which follow the US Code of Federal Regulations for the Protection of Human Subjects), institutional review board approval was not needed or sought for this analysis because the data were collected as part of a quality assurance activity.

Patient population

National ACS-NSQIP data was obtained for the years 2010 to 2012, and queried with the CPT code for LSG: 43775 (laparoscopy, surgical, gastric restrictive procedure); longitudinal gastrectomy (i.e., sleeve gastrectomy), which was introduced in January 2010. Patients who underwent LSG were identified and constituted the total patient sample. Cases involving a concomitant removal of gastric band were identified if they included any of the CPT codes for LGBR: 43772 (laparoscopy, surgical, gastric restrictive procedure: removal of adjustable gastric band component only) or 43774 (laparoscopy, surgical, gastric restrictive procedure: removal of adjustable gastric band and subcutaneous port components).

Outcomes

ACS-NSQIP does not collect procedure-specific outcome variables. Hence, postoperative sepsis was chosen as the primary outcome, as a surrogate marker for leak. Mortality, as well as overall and specific morbidity were the secondary outcomes. Demographic characteristics, preoperative co-morbidities, and laboratory values as well as intraoperative surgical variables were retrieved, along with 30-day postoperative mortality and morbidity data.

Statistical analysis

Descriptive statistics for the distribution of patient characteristics including demographic, preoperative, and intraoperative characteristics were performed and reported as means and standard deviations (SD) for continuous variables, and percentages for categorical variables. Statistical comparisons between the 2 groups of patients were made using χ^2 test for categorical variables and Student t test for continuous variables. Variables potentially associated ($P < .20$) with the outcome in bivariate analysis were included in the initial multivariable models; variable selection for the final models was performed in a forward stepwise fashion. Logistic regression was used to assess the odds of developing each of the postoperative outcomes. The significance level (α) was set at $<.05$, all P values were 2-sided, and models were calculated with 95% confidence intervals (CI). All analyses were carried out using Statistical Analysis System, version 9.1 (IBM, Armonk, NY).

Results

A total of 11,546 patients underwent LSG with or without GBR during the study period. The mean age was 44.4 years (SD 11.4), and 22.7% of all patients were men. Of those, 11,189 (97%) patients had LSG and 357 (3%) had LSG/GBR. Tables 1 and 2 compare baseline demographic characteristics, co-morbidities, preoperative laboratory values, and intraoperative parameters between the 2 groups. On bivariate analysis, LSG patients were more likely to be men (23% versus 12%; $P < .001$) with a higher body mass index (BMI) (mean 45.5 [SD 8.6] versus 39.6 [7.8] kg/m^2; $P < .001$). They were more likely to have a higher American Society of Anesthesiologists (ASA) classification, and had a higher prevalence of diabetes (23.3% versus

Table 1
Baseline patient characteristics

Variable	All (%) (n = 11,546)	LSG/GBR (n = 357)	LSG (n = 11,189)	*P* value
Sex				
Male	23.0	22.7	23.0	<.001
Age (years)				
(Mean, SD)	44.1 ± 10.9	44.4 ± 11.4	44.1 ± 11.2	.131
<50	61.9	65.8	65.9	.228
50–65	33.9	30.9	30.9	
>65	4.2	3.2	3.2	
Race				
White	73.9	69.8	69.6	.216
Black	17.1	19.7	19.8	
Other	9.0	10.5	10.6	
Weight (kg) (Mean, SD)	279.4 ± 64.2	237.4 ± 52.4	279.4 ± 63.3	<.001
Height (cm) (Mean, SD)	65.5 ± 3.80	64.6 ± 3.1	65.5 ± 3.8	.001
BMI (kg/cm^2)				
(Mean, SD)	39.6 ± 7.8	45.5 ± 8.8	45.5 ± 8.63	<.001
<40	53.8	26.0	25.1	<.001
40–45	23.5	29.4	29.6	
45–50	11.2	20.3	20.6	
Tobacco use in the past year	10.0	8.7	10.0	.413
Diabetes on oral drugs or insulin	23.0	12.6	23.3	<.001
Hypertension requiring medication	49.8	38.4	50.2	<.001
Systemic sepsis in the previous 48 hours	.2	.6	.2	.175
Steroid use for chronic condition	1.3	1.1	1.3	.772
Operation within the previous 30 days	.1	.0	.1	.519
Functional status				
Independent	99.7	99.6	99.5	
Partially dependent	.3	.4	.4	
Dependent	.0	.1	.1	
ASA class				
I–II	49.3	34.4	34.0	<.001
III	50.7	63.4	63.8	
IV–V	.0	2.1	2.2	
Mean total operative time (min)	100.5 ± 50.1	124.6 ± 52.3	98.6 ± 49.0	<.001
Emergency case	.3	1.1	.3	.003
Infected surgical wound class	.1	.6	.1	.001

ASA = American Society of Anesthesia; BMI = body mass index; LSG = laparoscopic sleeve gastrectomy; LSG/GBR = concomitant laparoscopic sleeve gastrectomy with gastric band removal; SD = standard deviation.

12.6%; $P < .001$) or hypertension requiring medication (50% versus 38%; $P < .001$). They had a higher prevalence of elevated preoperative serum creatinine (>1.2 mg/dL), and white blood cell count (>11,000 cells per μL). Patients undergoing primary LSG also had shorter operative times (98.6 ± 49.0 versus 124.6 ± 52.3 min; $P < .001$). Conversely, patients undergoing LSG/GBR were more likely to have infected wound class status preoperatively and to undergo emergency surgery.

On bivariate analysis, the rate of sepsis was higher after LSG/GBR (1.68% versus .58%; $P = .022$). There was no statistically significant difference in the rate of postoperative mortality (.28% versus .08%; $P = .269$) or that of other outcomes such as return to the operating room, wound infection, or venous thromboembolism. After multivariate analysis, the odds of developing postoperative sepsis remained significantly higher for patients undergoing LSG/GBR compared with LSG alone (OR 3.81; CI 1.59–9.15). (Table 3).

Discussion

Our analysis of 30-day postoperative outcomes of 11,546 patients from the ACS-NSQIP database suggests that concomitant removal of a gastric band and conversion to sleeve gastrectomy is a well-tolerated and feasible procedure. The overall 30-day mortality (.28%) and morbidity rates (3.08%) are lower than what have been reported in the Longitudinal Assessment of Bariatric Surgery (LABS) study on revisional bariatric surgery (.4% and 15.1%) [17]. Although lower than previously reported in the literature, the odds of postoperative sepsis were higher in patients undergoing a single-step revisional procedure compared with primary LSG. However, this is somewhat expected and does not refute the finding that a one-step procedure can be performed. Our findings complement previously published data using the NSQIP database [18]. Fernando Santos et al. reported higher sepsis rates (1.54% versus .33%; $P = .004$) in patients undergoing LSG/GBR

Table 2
System-specific patient variables

Variable	All (%) (n = 11,546)	LSG/GBR (n = 357)	LSG (n = 11,189)	*P* value
Cardiovascular				
Dyspnea at rest or with moderate exertion	8.7	14.1	14.2	.002
Congestive heart failure in the previous 30 days	.0	.2	.2	.413
Angina in the previous 30 days	.0	.1	.1	.536
Myocardial infarction in the previous 6 months	0	.1	.1	.801
Previous percutaneous coronary intervention	1.1	.8	.8	.541
Previous cardiac surgery	.0	.5	.5	.176
History of peripheral vascular disease	.0	.1	.1	.636
Rest pain or gangrene	.0	.02	.02	.801
Respiratory				
Current pneumonia		.0		
History of severe COPD	.8	1.2	1.2	.522
Ventilator dependence in last 48 hours	.0	.02	.02	.801
Renal				
Acute renal failure	.0	.04	.04	.689
Presently on dialysis	.0	.3	.3	.290
Other				
Open wound (with or without infection)	.28	.44	.45	.640
Preoperative laboratory studies				
Serum sodium ≤135 mmol/L	5.0	7.0	7.0	.150
Serum sodium >145 mmol/L	.8	.5	.4	.279
BUN >40 g/dL	.6	1.1	1.1	.417
Serum creatinine >1.2 mg/dL	1.5	4.6	4.7	.008
Mean serum albumin, g/L (SD)	4.0 ± .3	4.0 ± .4	4.0 ± .4	.053
Total bilirubin >1.0 mg/dL	3.5	4.8	4.8	.371
SGPT >40 U/L				
Alkaline phosphatase >125 U/L	2.0	3.9	4.0	.147
WBC count >11,000 cells per μL	4.5	7.9	8.0	.022

BUN = blood urea nitrogen; COPD = chronic obstructive pulmonary disease; LSG = laparoscopic sleeve gastrectomy; LSG/GBR = concomitant laparoscopic sleeve gastrectomy with gastric band removal; SD = standard deviation; SGPT = serum glutamic-pyruvic transaminase; WBC = white blood cell.

versus LSG using NSQIP data from 2010 to 2011 [18]. The authors used the same CPT codes used in our study (43775 versus 43775 and [43772 or 43774]), but the total number of patients included in that time frame was lower (LSG: n = 4831 and LSG/GBR: n = 130). Conversely, Aminian et al. recently published an article on the same topic using the same 2010–2012 ACS-NSQIP data, yet found no statistically significant differences in postoperative sepsis on bivariate analysis, and the authors therefore did not go on to perform any risk adjustment [14]. However, in defining their LSG/GBR patient population, the authors had included CPT code 43773, which refers to "Removal *and placement* of adjustable gastric band component only," while omitting CPT code 43774: "Removal of adjustable gastric band and subcutaneous port components." In our study, we attempt to provide a more accurate definition of the concomitant LSG/GBR group, with the added value of multivariate risk adjustment, revealing the single-step LSG/GBR procedure as an independent predictor of postoperative sepsis (Table 3).

Postoperative sepsis was chosen as a surrogate marker for staple line leak—the dreaded complication of LSG/GBR—as ACS-NSQIP collected variables for the study period did not include bariatric-specific complications. Although providing a clinically useful indicator of the morbidity associated with each of the procedures, the observed rate of postoperative sepsis likely captures some patients who had other causes of infection not accounted for by our multivariate model.

Our study has limitations. First, our retrospective design does not allow for a detailed analysis of the circumstances of each case, including band-related complications such as erosion, as well as technical details of the revisional procedure. Newer bariatric-specific databases will potentially allow for more targeted investigations. Second, in addition to the risk-adjustment models, stratified analyses could potentially allow for the identification of specific subpopulations at a particular risk for staple line leak when undergoing LSG/GBR. Third, no follow-up data was available beyond 30 postoperative days, including long-term weight loss and resolution of co-morbidities. Finally, our study design is limited by the data collection and deidentification scheme of the ACS-NSQIP database itself, which does not allow for the linking of patients to their previous admissions or procedures. Therefore, it would not have been possible to capture patients who had gastric bands removed in past admissions.

Table 3
Multivariate analyses: risk-adjusted increase in postoperative mortality and morbidity of LSG/GBR versus LSG

Variable	LSG/GBR	LSG	OR_{crude}	CI	*P* value	$OR_{adjusted}$	CI	*P* value
Sepsis	1.68	.58	2.93	1.26–6.80	.022	3.32	1.41–7.84	.006
Mortality	.28	.08	3.49	.44–27.62	.270	6.60	.75–58.31	.090
Morbidity	3.08	1.91	1.63	.88–3.02	.118	1.87	.99–3.51	.050
Cardiac	.28	.11	2.62	.34–20.18	.335	4.57	.56–36.91	.154
Respiratory	.56	.65	.86	.21–3.51	.999	.87	.21–3.59	.849
Urinary tract infection	.56	.23	2.42	.57–10.23	.214	5.33	1.18–24.06	.029
Surgical site infection	1.12	.68	1.66	.60–4.55	.315	1.78	.64–4.96	.269
VTE	.56	.55	1.011	.25–4.15	.999	1.139	.27–4.75	.858
Return to operating room	2.24	1.58	1.426	.70–2.92	.285	1.332	.65–2.74	.437
Bleeding	.56	1.04	.54	.13–2.18	.590	.577	.14–2.35	.443

CI = confidence interval; LSG = laparoscopic sleeve gastrectomy; LSG/GBR = concomitant laparoscopic sleeve gastrectomy with gastric band removal; $OR_{adjusted}$ = adjusted odds ratio; OR_{crude} = crude odds ratio; VTE = venous thromboembolism.

Conclusion

LSG/GBR can be performed with low morbidity and mortality. However, this procedure carries a higher rate of postoperative sepsis, albeit lower than that reported in the literature. As large bariatric-targeted registries evolve, a more appropriate comparison of single-step versus staged revisional procedures should involve risk adjustment for specific technical variables, as well as analysis of procedure-specific complication rates.

Disclosures

No competing financial interests exist for any author.

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