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First Report from the American College of Surgeons -- Bariatric Surgery Center Network: Laparoscopic Sleeve Gastrectomy has Morbidity and Effectiveness Positioned Between the Band and the Bypass

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Abstract

Objective—To assess the safety and effectiveness of the laparoscopic sleeve gastrectomy (LSG) as compared to the Laparoscopic Adjustable Gastric Band(LAGB), the Laparoscopic Roux-en-Y Gastric Bypass(LRYGB) and the Open Roux-en-Y Gastric Bypass(ORYGB) for the treatment of obesity and obesity-related diseases.

Summary of Background Data—LSG is a newer procedure being done with increasing frequency. However, limited data are currently available comparing LSG to the other established procedures. We present the first prospective, multi-institutional, nationwide, clinically-rich, bariatric-specific data comparing sleeve gastrectomy to the adjustable gastric band and the gastric bypass.

Methods—This is the initial report analyzing data from the American College of Surgeons – Bariatric Surgery Center Network accreditation program, and its prospective, longitudinal, data collection system based on standardized definitions and collected by trained data reviewers. Univariate and multivariate analyses compare 30-day, 6-month, and one-year outcomes including morbidity and mortality, readmissions and reoperations as well as reduction in body mass index (BMI) and weight-related comorbidities.

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Results—109 hospitals submitted data for 28,616 patients, from 7/2007 to 9/2010. The LSG has higher risk-adjusted morbidity, readmission and reoperation/intervention rates compared to the LAGB, but lower reoperation/intervention rates compared to the LRYGB and ORYGB. There were no differences in mortality. Reduction in BMI and most of the weight-related comorbidities following the LSG also lies between those of the LAGB and the LRYGB/ORYGB.

Conclusion—LSG has morbidity and effectiveness positioned between the LAGB and the LRYGB/ORYGB for data up to one year. As obesity is a lifelong disease, longer term comparative effectiveness data are most critical, and are yet to be determined.

Introduction

Laparoscopic sleeve gastrectomy is a newer procedure being performed with increasing frequency for the treatment of obesity and obesity related diseases. The sleeve gastrectomy, also known as the "vertical gastrectomy", involves excision of the lateral aspect of the stomach, leaving a much reduced, lesser-curve based, tubular stomach. Initially performed as part of a biliopancreatic diversion with duodenal switch,[1] it was subsequently performed laparoscopically[2], and then promoted as the initial part of staged procedure for the super obese.[3,4,5,6] The sleeve gastrectomy is now most commonly used as a stand-alone operation performed laparoscopically. [7] Laparoscopic sleeve gastrectomy received a CPT code in 2010 (43775), and is an approved procedure by both the American Society for Metabolic and Bariatric Surgery (ASMBS) and the American College of Surgeons (ACS) with regards to consideration for accreditation status.[8,9,10] It is not currently reimbursed by Centers for Medicare and Medicaid Services (CMS)[11], although some insurers are now beginning to provide coverage. More data are becoming available with regards to its safety and effectiveness. We present the first multi-institutional, nationwide, clinically-rich, bariatric-specific data comparing the sleeve gastrectomy to the established treatments for obesity and obesity related disease: the adjustable gastric band and the gastric bypass.

This is the first report from the American College of Surgeons – Bariatric Surgery Center Network (ACS-BSCN) Accreditation Program. On February 12, 2005 the American College of Surgeons Board of Regents decided to build on its experience and success with accreditation programs for trauma and cancer care as a means to improve the access to high quality surgical care. Bariatric surgery was chosen as the next field for accreditation, because of the significant concerns at that time for the quality and safety of bariatric procedures being performed. [12-15] The ACS-BSCN Accreditation Program was developed in May of 2005, and incorporated many aspects of the evidence based recommendations from the Betsy Lehman Center Expert Panel on Weight Loss Surgery.[16-22] A data collection system was developed, and data collection began in July 2007. The American Society for Bariatric Surgery/Surgery Review Corporation developed a similar program and data collection program during this time frame as well.

On November 25, 2005, CMS released a coverage memorandum proposing that that it would *no longer* cover bariatric surgical procedures.[23] After public comment, and additional data were reviewed ,[24] CMS reversed the non-coverage proposal on February 21, 2006.[11] The National Coverage Determination for bariatric surgery stated that CMS would reimburse bariatric procedures "only when performed at facilities that are : (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center; or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence." [11] The sleeve gastrectomy was specifically stated to be a non-covered procedure at the time of that determination. This manuscript compares the short term safety and effectiveness of the sleeve gastrectomy to the adjustable gastric band and the Roux-en-Y gastric bypass, to help inform better patient care and coverage decisions by policy makers.

Methods

This is a prospective, multi-institutional, observational study of up to one-year outcomes comparing the laparoscopic sleeve gastrectomy (LSG) to the laparoscopic adjustable gastric band (LAGB) and the laparoscopic Roux-en-Y gastric bypass (LRYGB) performed at ACS-BSCN accredited facilities.

ACS-BSCN Accreditation Program

The ACS-BSCN accredits facilities in the United States that have undergone an independent, voluntary and rigorous peer evaluation in accordance with nationally recognized bariatric surgical standards.[9] Hospitals are accredited as Level I, Level II, Level II New or Outpatient facilities, depending on hospital surgical volume and resources. Level I hospitals must perform over 125 cases per year, and demonstrate sufficient resources to care for the most challenging and complex patients. They are accredited to care for patients with all levels of obesity, ages, comorbidities and are accredited to perform elective revisional surgery. Level II hospitals have lower volume requirements – 25 cases per year—and are accredited for the care of less complex obese patients. Level II centers may not perform elective revisional operations, or any elective primary procedure on high-risk patients. High-risk patients are defined as follows: non-ambulatory patients, patients over 60 years old, adolescents under the age of 18, high Body Mass Index (BMI) patients (male patients may not have a BMI $\geq$55 and female patients may not have a BMI $\geq$60), patients who have organ failure, an organ transplant, or are a candidate for a transplant, and patients with significant cardiac or pulmonary comorbid conditions. Level II New status was developed to facilitate the integration of newer programs, and features an expedited approval timeline. Outpatient status is for facilities that focus on outpatient surgery only, mostly adjustable gastric bands.

ACS-BSCN Data Collection System

Documentation of outcomes for all bariatric procedures performed is required for accredited hospitals. Results are monitored, and are further scrutinized every three years during the reaccreditation process. A data collection system was developed to monitor bariatric-specific, longitudinal data on all patients undergoing weight loss surgical procedures. Data points include variables for risk-adjustment, for the assessment of morbidity and mortality of the procedures, as well as variables to track clinical effectiveness including reduction of weight, and weight-related comorbidities. The system was designed to work either in conjunction with the American College of Surgeons – National Surgical Quality Improvement Program (ACS-NSQIP) or as a stand-alone system for those not participating in the ACS-NSQIP. Data collection variables are the same for all levels of the program: Level I, Level II and Level II new and Outpatient Centers. Standardized definitions for preoperative, intraoperative and postoperative variables were developed. Definitions from the ACS-NSQIP were used when applicable. Bariatric-specific data definitions used in published studies, in the NIH sponsored Longitudinal Assessment of Bariatric Surgery Study (LABS)[25] and from the Ali-Wolfe classification system [26] were considered in the development of the bariatric specific variables. Data elements were developed by the ACS-BSCN Advisory committee and it's Data Subcommittee, with input and comments by the Betsy Lehman Expert Panel on Weight Loss Surgery, the SAGES Bariatric Liaison Group and the SAGES Outcomes Committee. Data are collected by Surgical Clinical Reviewers (SCRs) who are centrally trained in the specifics of the program, and in the definitions for the data elements. Data from inpatient and outpatient medical records and hospital and office systems are assessed. Patients outside of those included in the 30-day ACS-NSQIP sample are not contacted directly by SCRs. SCRs are supported by national nurse reviewers, online documentation, and monthly conference calls. Surgeons or those who provide direct

clinical care do not submit the data. Data integrity is assessed as part of the site visit reaccreditation process. Patients are followed longitudinally once they have a weight loss operation, and data includes baseline variables, as well as outcomes at 30-days, 6-months, one-year and yearly thereafter. This is the initial report from the ACS-BSCN Data Collection System.

Study Sample

All cases entered into the ACS-BSCN Data Collection system from its inception in July 2007 until September 1, 2010, were considered for this analysis. Cases from all levels of hospitals were included (i.e. Level I, Level II, Level II New, and Outpatient). Analyses for this study were limited to four primary surgical procedures: LSG, LAGB, LRYGB, and open Roux-en-Y gastric bypass (ORYGB). CPT codes were used to define the procedures, when appropriate. For LRYGB these include CPT 43644 and 43645, for ORYGB these include 43846 and 43847, and for LAGB the CPT code is 43770. For LSG, the CPT code 43775 was used after it went into effect on January 1, 2010. Prior to that, a specific question was included in the data collection system to identify LSG from other potential procedures: "Was the case a sleeve gastrectomy? Yes/No". Revisional procedures, biliopancreatic diversions with duodenal switch, "mini-loop" gastric bypass, and other bariatric procedures were excluded. Cases with missing operative dates or nonsensical data were excluded from analysis.

Variables and Timeframes

Data time points for collection include outcomes at 30-days, 6-months, one-year and yearly thereafter. Time intervals for data collection are continuous, so as not to exclude important information in this observational study. Data must be assessed within 150 days of the operation for the 30-day outcomes (30 days after the ACS-NSQIP lock date). Data for the 6 month time point extend from POD #31 to 9 months postoperatively, one-year outcomes from 9 months to 18 months postoperatively, two-year outcomes from 18 months to 30 months, and yearly thereafter. However, postoperative weights and complications can be assessed throughout each time interval, and have a corresponding date associated with them to allow more accurate analyses. Workflow reminders are constantly available to the SCRs on the Bariatric Data Workstation, helping to improve longer term follow-up.

Outcomes

Objective data such as readmissions, reoperations and postoperative interventions (endoscopy, percutaneous drain placement, etc) are captured and used to identify postoperative occurrences. Suspected primary reason for the event is then determined by the SCR from a list of defined potential bariatric surgical complications.

Statistical Analyses

Univariate analyses were performed using Chi square tests for categorical data, and ANOVAs or t-tests for continuous data. Multivariate logistic regression models with LSG as the referent were used for risk-adjustment modeling. A p-value <0.05 was considered significant. SAS version 9.2 was used.

Results

109 hospitals submitted data on 28,616 patients, from 7/2007 to 9/2010, which were included for this analysis. 22,365 cases from Level I hospitals, 2,661 from Level II hospitals and 3,590 cases from Outpatient centers. 944 cases were LSG, 12,193 were LAGBs, 14,491 were LRYGB, and 988 were ORYGB. As shown in Figure 1, the numbers of LSGs has risen

consistently over time, with LSGs making up 7.8% of primary bariatric operations collected at accredited centers over the most recent time period of January 1, 2010 to September 1, 2010. As the LSG has been introduced, the percentage of LRYGB has decreased from 62% of primary bariatric procedures performed to 44%, while the percentage of LAGB has risen form 32% to 46%. Based on this data at accredited centers, the LAGB now surpasses the LRYGB as the most common surgical procedure performed: 46% vs. 44%.

Patient Characteristics

Patient characteristics are shown in Table I, according to procedure type. Patients undergoing LSG have a higher percentage of super obesity (BMI>50) at 30.2%, nearly double that of LAGB (16.42%), and higher than LRYGB (25.95%). LSG also has the lowest percentage in the 40-50 BMI range, compared to the other procedures. This perhaps reflects the current teachings for the use of LSG for the super-obese as a potential staged procedure, or for the lower BMI patients. Compared to patients undergoing LAGB, patients undergoing LSG in general are heavier, with a higher percentage of *all* obesity related diseases and other comorbid conditions, except for smoking status. Compared to LRYGB, LSG has a lower percentage of diabetics, GERD, gallstones, smokers, dialysis but comparable percentages of patients in most other characteristics. There are a higher percentage of patients with COPD and male patients in the LSG group.

LSG patients also have the highest percentage of patients who have had previous operations at 8.26%, even higher than for 3.24% for ORYGB, reflecting another potential relative indication for a sleeve gastrectomy (or potentially a specific way to get approved coverage for this procedure).

Postoperative Occurrences

Overall 30-day mortality for this combined cohort of primary bariatric procedures was 0.12%. The rate of postoperative occurrences following LSG, lies between those for the LAGB, which has lower rates, and the LRYGB, which has higher rates, for all aggregated outcomes: mortality, morbidity, readmission, and reoperation rates, though not all comparisons are statistically significant. (Table II) Statistically significant findings are that the LSG has higher 30-morbidity, readmission and reoperation/intervention rates compared to the band, and lower reoperation/intervention rate compared to the bypass.

Conversion rate, determined by the percentage of cases that were started laparoscopically and then converted to open, was 0.96% for the LSG. This is more than the LAGB rate of 0.25%, but less than the LRYGB rate of 1.4% ($p<0.001$). The only aggregated outcome where the sleeve is not positioned between the band and the bypass is the mean length of stay which is highest for LSG.

Compared to the LAGB, the LSG has statistically higher rates for peripheral nerve injury, pulmonary embolism, pneumonia, unplanned intubation, renal insufficiency, urinary tract infection, organ space infection, and sepsis. (Table 2) Compared to the LRYGB, the LSG has higher rates of organ space infection, renal insufficiency, and sepsis but lower rates of ventilator dependence.

Bariatric specific postoperative occurrences requiring readmission, reoperation or an intervention within 30-days are listed in Table III. Compared to the LAGB, LSG has a higher rate of anastomotic/staple line leaks, fluid/electrolyte/nutrition problems, strictures, infection/fevers, pulmonary embolism, bleeding and events not otherwise specified. Compared to LRYGB, LSG has a comparable rate of nearly all postoperative bariatric specific occurrences requiring readmission, reoperation or an intervention, except for a lower rate of stricture, intestinal obstruction, and anastomotic ulcer.

Risk adjusted outcomes

Risk adjusted modeling for mortality shows no significant differences between the procedures. (Table IV) The statistically significant increased mortality of ORYGB is no longer significant when the sicker patients having ORYGB are taken into consideration. The remainder of the statistically significant findings from the univariate outcomes retains their significance after risk adjustment. In general, risk adjusted results continue to show LSG postoperative outcomes positioned between the LAGB and the LRYGB: the LSG has significantly higher rates or risk-adjusted morbidity, readmission and reoperation/intervention rates compared to the LAGB, and significantly lower rates of risk-adjusted reoperation/intervention rates compared to the LRYGB.

Reductions in Weight

Absolute reduction in BMI by procedure type is shown in Figure 2. For LSG patients, the average reduction in BMI is 3.36 kg/m^2 at 30 days, 8.75 kg/m^2 at 6-months and 11.87 kg/m^2 one-year. In comparison, the LAGB has a BMI reduction of 2.45, 5.02 and 7.05 kg/m^2 at 30-day, 6-months and one-year, and the LRYGB has a BMI reduction of 3.76, 10.82 and 15.34 kg/m^2 at 30 days, 6 months and one-year. Therefore, the absolute reduction in BMI following the LSG is less than the weight loss following the LRYGB/ORYGB but greater than the weight loss after the LAGB. (Figure 2) These findings are statistically significant at the 6-month and one-year intervals studied, however the impact of these findings is limited by the small number of LSG cases with data available at the one-year interval: only 52 cases currently have data available at one-year, despite a follow-up rate of 70.2%.

Reduction in Weight-related Comorbidities

In addition to changes in weight, five weight-related comorbidities are tracked over time as a metric for clinical effectiveness of these procedures. These include: diabetes, hypertension, hyperlipidemia, obstructive sleep apnea, and gastroesophageal reflux disease (GERD). The reductions in comorbidities over time for each procedure and for each comorbidity are shown in the five graphs in Figure 3. For patients who are diabetic at baseline, 55% have their diabetes resolve or improve one year after the LSG, compared to 44% for the LAGB and 83% for the LRYGB. For patients who are hypertensive at baseline, 68% have their hypertension resolve or improve one year after the LSG, compared to 44% for the LAGB and 79% for the LRYGB. For patients who have hyperlipidemia at baseline, 35% have their hyperlipidemia resolve one year after the LSG, compared to 33% for the LAGB and 66% for the LRYGB. For patients who have obstructive sleep apnea at baseline, 62% have their obstructive sleep apnea resolve one year after the LSG, compared to 38% for the LAGB and 66% for the LRYGB. For patients who have GERD at baseline, 50% have their GERD resolve one year after the LSG, compared to 64% for the LAGB and 70% for the LRYGB. Overall, the clinical effectiveness for the LSG is positioned between the band and the bypass for diabetes, hypertension, sleep apnea, and hyperlipidemia. However, LSG appears less effective than both the band and the bypass for GERD. Again, statistical significance as shown on the graphs in Figure 3 is limited by the small number of patients with the disease who had a LSG with one year follow-up, despite follow-up rates exceeding 70%: 22 for DM, 38 for HTN, 17 for hyperlipidemia, 26 for OSA, and 22 for GERD. These small numbers limits the power of the current data set to identify significance, or to draw any substantive conclusions from these early observations.

Percent Followed-up

Percent follow-up for weight is quite good – 70.2% at one year for LSG, and similar rates for the LAGB (74.3%) LRYGB (70.7%) and ORYGB (62.7%). Similar rates of follow-up are identified for the weight-related comorbidities (Figure 3).

Discussion

In this initial study from the ACS-BSCN Accreditation Program, we report findings comparing the sleeve gastrectomy to the adjustable gastric band and gastric bypass. We show that the laparoscopic sleeve gastrectomy appears to be a safe and effective procedure for the treatment of obesity and obesity related comorbidities, using data from accredited facilities. 30-day complication rates, and reduction in weight and weight-related illnesses for up to one-year for the LSG seem to fall between the LAGB (which has relatively fewer short term complications, but less reduction in weight and weight-related diseases), and the LRYGB (which seems to have relatively more complications, and to be more effective). Though many of these results achieve statistical significance, interpretation of the longer term results are limited by the number of LSG cases with one-year data currently available.

Patient characteristics

As the LSG is a newer procedure, the types of patients undergoing LSG currently has to be interpreted in light of the current approval and reimbursement policies for this procedure. CMS and many insurers do not currently reimburse for this procedure. Those insurers who do, frequently cover only on a case by case basis, often requiring a specific reason as to why the surgeon chooses this procedure for that particular patient, as compared to a band or a bypass. Furthermore, current teaching at conferences and meetings, and in some publications, recommend the LSG as a staged procedure in the super-obese, and as a stand-alone procedure in the lower BMI patient. These factors likely lead to a selection bias which is reflected in the patient characteristics of the patients in our cohort who undergo a LSG as compared to a band or a bypass: a higher percentage of super-obese patients, fewer patients in the BMI 40-50 range, and patients with a higher rate of previous operations. Compared to the LAGB, the LSG patients are heavier and have a higher rate of all documented obesity related diseases and other comorbid conditions, except for smoking status. These findings could certainly be skewed by the relative indication for the sleeve in the super-obese. Compared to LRYGB patients, LSG patients have mostly comparable comorbidities, though they have a lower percentage of diabetic patients. The effectiveness of the LRYGB in the treatment of diabetes has been clearly documented, however similar evidence for the LSG is not yet as convincing.

As more data becomes available, further analyses of cohorts stratified by patient characteristics and procedure type will be possible, and may help determine which patients might benefit from which procedure.

Complications following LSG

Analysis of this data set shows that the mortality rate of the LSG (0.11% at 30 days, 0.21% at one year) is positioned between the LAGB (0.05% and 0.08%) and the LRYGB (0.14% and 0.34%), however these results are not statistically significant on either univariate or risk-adjusted analyses. Mortality is thankfully a rare event following bariatric surgery.

30-day morbidity rate for LSG (5.61%) is statistically higher than the LAGB rate (1.44%), however this is comparable to the LRYGB rate (5.91%). Similarly, 30-day readmission rate for the LSG (5.4%) is statistically higher than for the LAGB (1.71%), but comparable to the LRYGB (6.47%). Reoperation/intervention rates for the LSG (2.97%) are positioned between the LAGB (0.92%) and the LRYGB (5.02%), which is significant on both univariate and multivariate analyses. Overall, complication rates following the LSG seem to be positioned between those for the LAGB (which has lower 30 day morbidity, readmission and reoperation/intervention rates) and the LRYGB (which has higher reoperation rates).

Clinical Effectiveness of LSG

Reductions in weight and weight-related diseases including diabetes, hypertension, hypercholesterolemia, obstructive sleep apnea and GERD are evident in the graphical representation of the data at up to one year for all procedures. Though the graphs are compelling, and some of the results are statistically significant, please interpret this information with caution, given the limited number of LSG cases with data available at the one-year interval for each patient who had that particular obesity related disease at baseline. More data will be necessary to make more compelling conclusions about the relative reductions in comorbidities over time.

Comparisons to other large national or regional observational studies

At this time, published results about the LSG from other large national or regional observational studies of bariatric surgery in the United States are limited. The Michigan Bariatric Surgery Collaborative included results from 854 LSG procedures in its data tables, showing similar findings to this study, with LSG done in a high percentage of the super-obese, and with nearly all complication rates positioned between the band and the bypass.[27] Comparative statistical analyses were not presented. Similarly, the ASMBS BOLD data collection system includes data on 1,256 sleeve gastrectomies in their data tables, and also show complication rates for LSG (10.84%) positioned between the LRYGB (14.87%) and the LAGB (4.62%).[28] The Longitudinal Assessment of Bariatric Surgery Study (LABS) has not included LSG so far in its published results.[25] These studies have yet to publish comparative analyses of LSG, or its impact on weight reduction, and reductions in comorbidities, compared to the other established procedures.

Long term follow-up

As obesity is a lifelong disease, the critical information for the comparative effectiveness of these procedures will be determined by longer term follow-up -- beyond one year and more importantly at five years or longer. Short term safety and efficacy should alone not be the deciding factor with regard to procedure selection. Weight regain, weight-related comorbidity recidivism, longer term nutritional issues or procedure related complications, and need for revisional procedures or explantations of adjustable gastric bands are more likely to be evident over these longer time intervals. Specifically, longer term assessment of the sleeve gastrectomy is critical, as gastric pouch enlargement over time may limit its ultimate effectiveness. Analysis of this dataset shows follow-up documentation at one year of 70% for BMI in the LSG group, and similar findings in the LRYGB (71%) and LAGB (74%). Efforts to improve the documentation of longer term outcomes are underway. As the cohort of patients from this study will be continued to be followed over time, and additional patients are continuously enrolled and studied, long-term and updated information from this ongoing data collection system could help elucidate the durability of the relative effectiveness of these procedures. Low rates of longer term follow-up could limit the validity of future analyses, and the ability of this data system to collect meaningful 5 or 10-year data for research use remains in question.

Overall, bariatric surgery is quite safe for most patients, with a 30-day mortality rate of 0.12%, despite the significant, multiple comorbid illnesses associated with obesity. These results are a dramatic improvement compared to reports on selected high risk patients published in 2004-2006 and reported extensively by the media and upon which CMS were basing its non-coverage proposal: mortality rates of 1.9%, 2.0% and 3.2%.[12,13,14] Our findings with regards to the overall safety of bariatric procedures are consistent with other contemporary observational studies for bariatric surgery in the United States which include all consecutive patients at participating or accredited hospitals, including the Michigan Bariatric Surgery Collaborative (mortality = 0.10%)[27], the NIH funded Longitudinal

Assessment of Bariatric Surgery studies (mortality= 0.3%)[25] and BOLD data from the American Society of Metabolic and Bariatric Surgery/Surgical Review Corporation Centers of Excellence (mortality = 0.089%, all cause 30-day). [28]

Limitations

There are several limitations to this study and study design—First of all, it is an observational study and selection bias by surgeons or patients as to which procedure to perform on which patients cannot be completely controlled. Though the results are risk-adjusted, and do rely on clinically-rich data as opposed to administrative data, only the variables listed were considered. The ability of these variables to stratify patients and control for other potential known or unknown confounders remains limited.

Bias can also be inherent in the evaluation of any novel technique, limiting the interpretation and generalizability of the findings. The initial adopters may have more comfort or experience with bariatric operations, which might not be the same for subsequent adopters. Furthermore, as surgeons undergo a learning curve for this procedure, and as the procedure is further studied and refined with regards to technique, results may improve over time, as they have for LRYGB.

Generalizability is also limited by the fact that we report only data from accredited centers. This is not a representative sample of bariatric procedures in the United States, and is not population based. The data set is skewed as it contains a high percentage of high-volume, academic medical centers. The ACS-BSCN does include data from Level II hospitals that have lower volume requirements, however Level II hospitals performed only 9.3% of the cases. Irrespective of volume of procedures performed, there also may be an inherent difference in the type of facility that seeks accreditation, as compared to one that does not.

Any observational study has limitations from how the data is actually collected. In the ACS-BSCN, data is collected by a "third party", surgical clinical reviewer (SCR) who is not directly involved in patient care. One reviewer is trained per site, though others may be trained if volume necessitates it. Though this likely increases the objectivity of the data, the SCRs are employed by the facility or practice. Although a voluntary program, CMS and other insurers do mandate accreditation in order for the facility and providers to be eligible for reimbursement, potentially setting up a conflict. We and others think that a third party data reviewer may help to minimize this potential effect, but acknowledge that a potential conflict might not be eliminated.[18,22]

Follow-up beyond in-hospital or 30-days remains a challenge. Other large data bases are yet to publish results beyond this early time interval. Our follow-up at one year is 70% for BMI in the LSG group, and those lost to follow-up may not be appropriately represented by those who do follow-up. Obtaining long term follow-up remains the Achilles' heel for any observational study, and has been a major challenge for the major ongoing observational studies.

The data presented is limited to a cohort of patients who all had a surgical procedure for weight loss. Using this data, the effectiveness of these procedures cannot be directly compared to alternative treatments for obesity including diet, exercise and behavior modifications, medications, or other interventions to promote weight loss or to treat weight-related diseases. Data from such potential comparative cohorts are not captured. Similarly, information on a similar cohort of patients *not* receiving any treatment for their obesity or obesity related diseases is not captured, and so direct comparisons to such groups are not possible with this dataset.

In conclusion, data from the ACS- BSCN accredited hospitals show that the laparoscopic sleeve gastrectomy appears to be a safe and effective procedure for the treatment of obesity and obesity related comorbidities. At one year, complication rates and reduction in weight and weight-related illnesses for the LSG seem to fall between the LAGB (which has relatively fewer short term complications, but less reduction in weight and weight-related diseases), and the LRYGB (which seems to have relatively more complications, and to be more effective). As obesity is a lifelong disease, longer term comparative effectiveness of these procedures at 5 years, 10 years and beyond, are most critical, and are yet to be determined.

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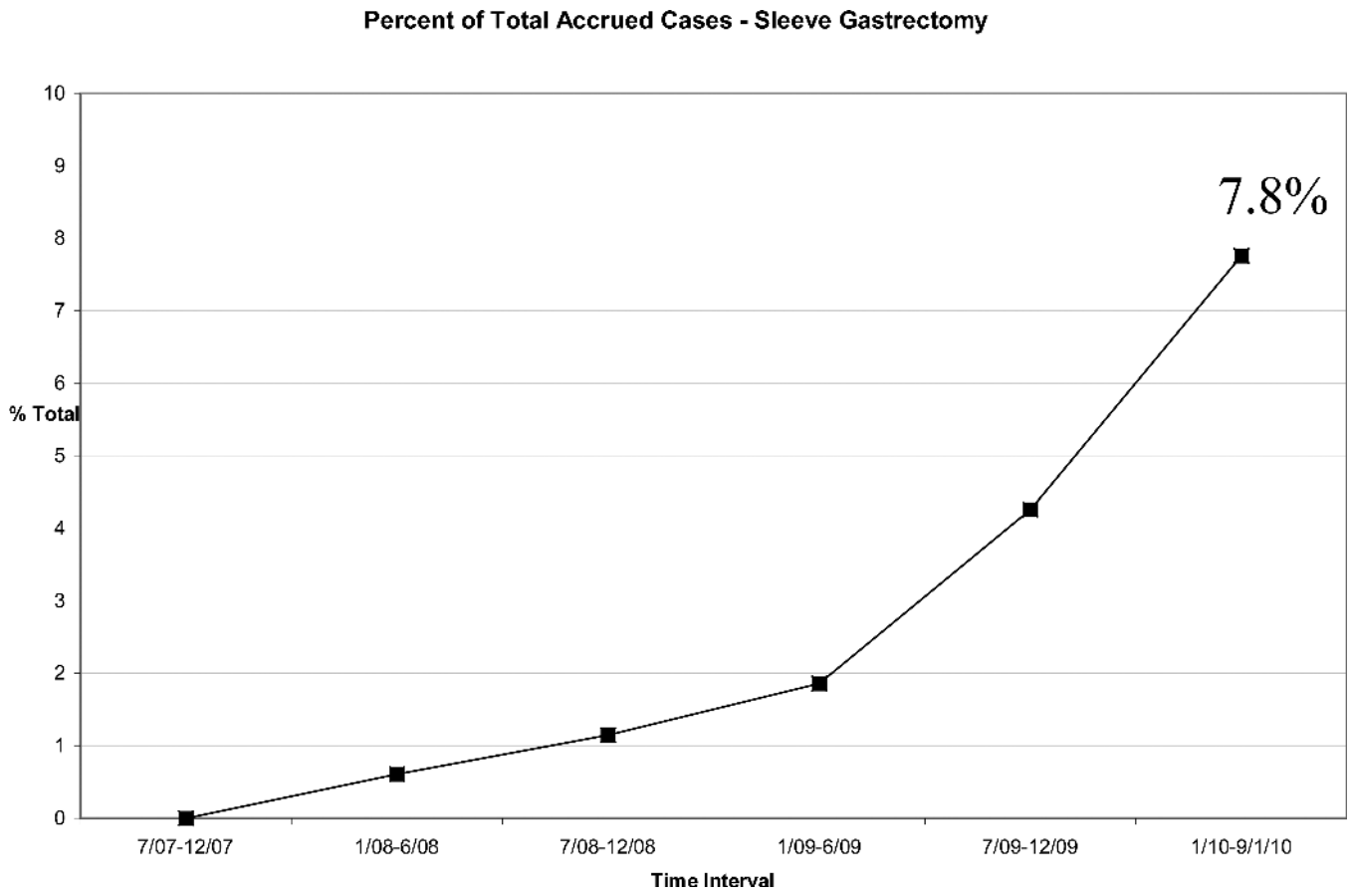
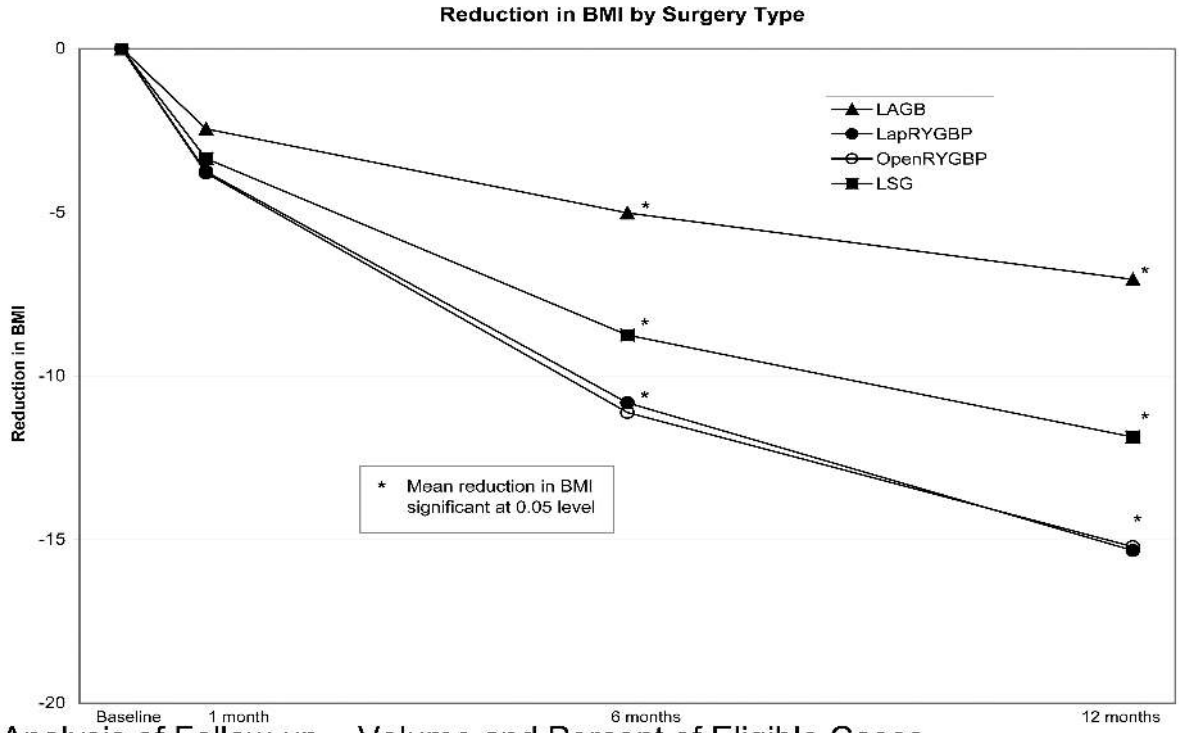


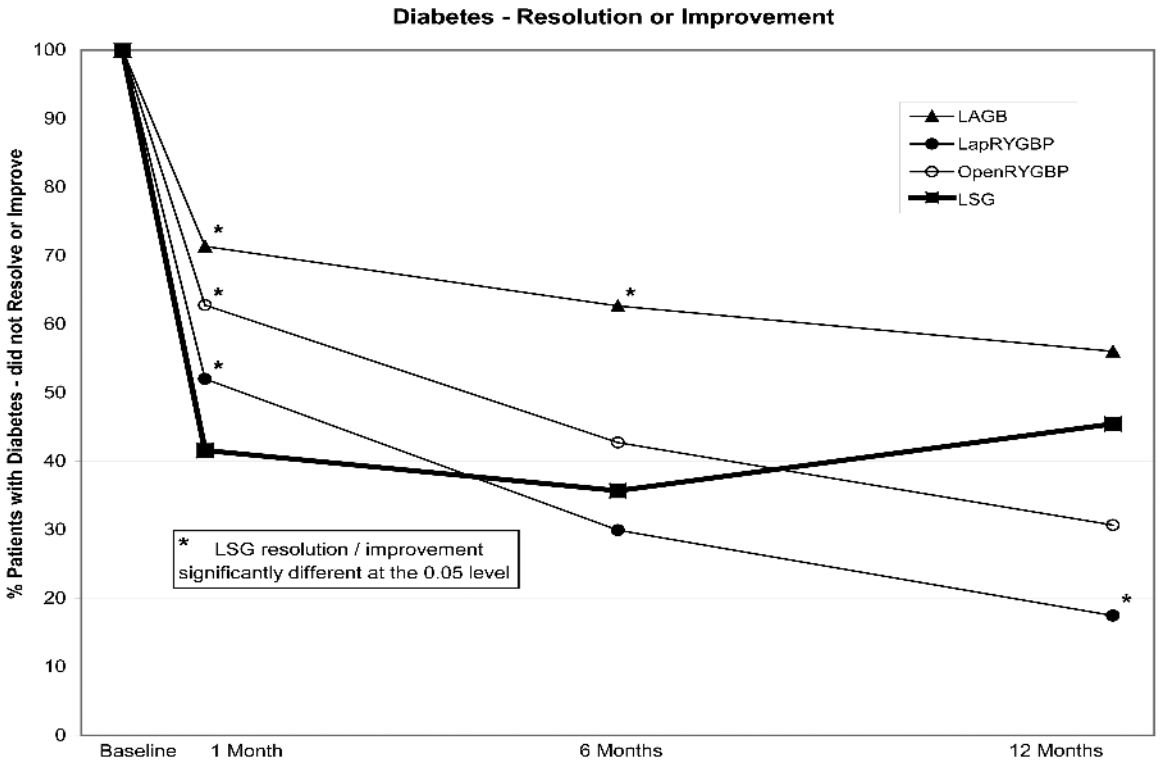
Figure 1.
Increasing incidence of Sleeve Gastrectomy.



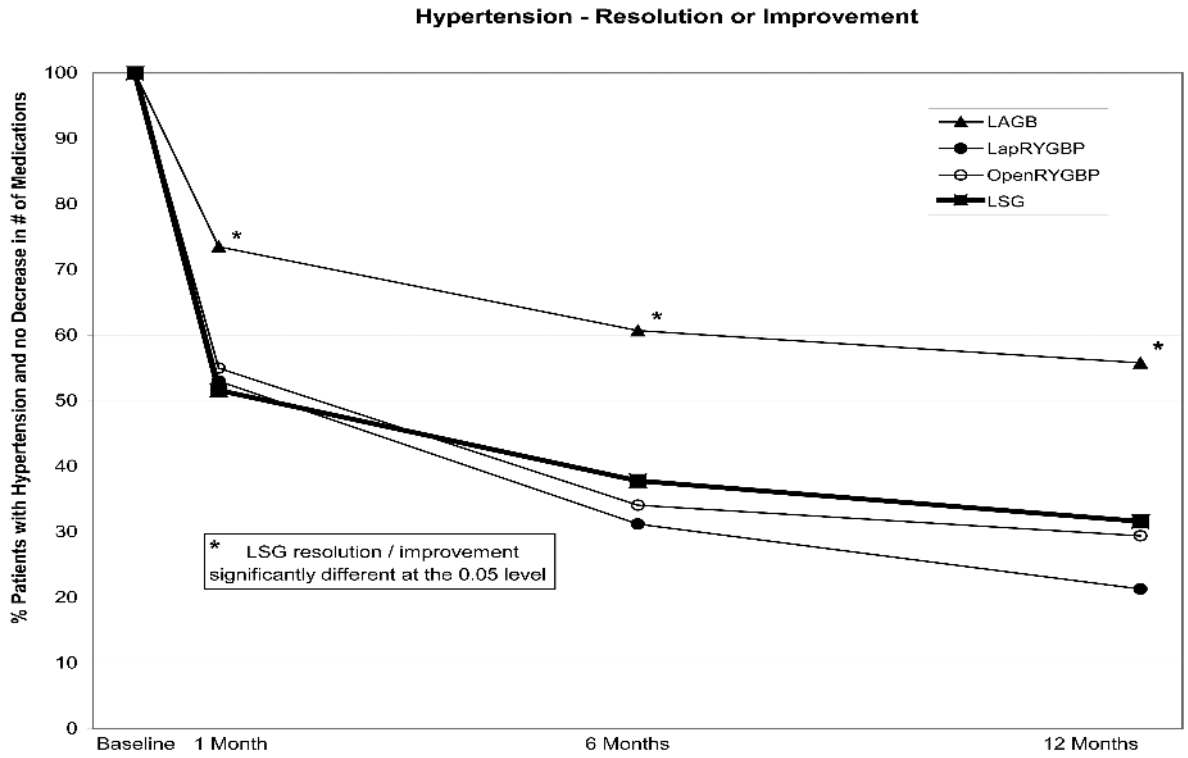
Analysis of Follow-up – Volume and Percent of Eligible Cases

	Baseline	1 month	6 months	12 months
LSG "N" for Analysis	944	826	317	**52**
% Available for follow-up with Data	100%	87%	82%	70%
LAGB "N" for Analysis	12,193	8,697	6,988	2,871
% Available for follow-up with Data	100%	72%	81%	74%
LapRYGBP "N" for Analysis	14,491	12,179	8,585	3,734
% Available for follow-up with Data	100%	80%	79%	71%
OpenRYGBP "N" for Analysis	988	789	563	229
% Available for follow-up with Data	100%	79%	73%	63%

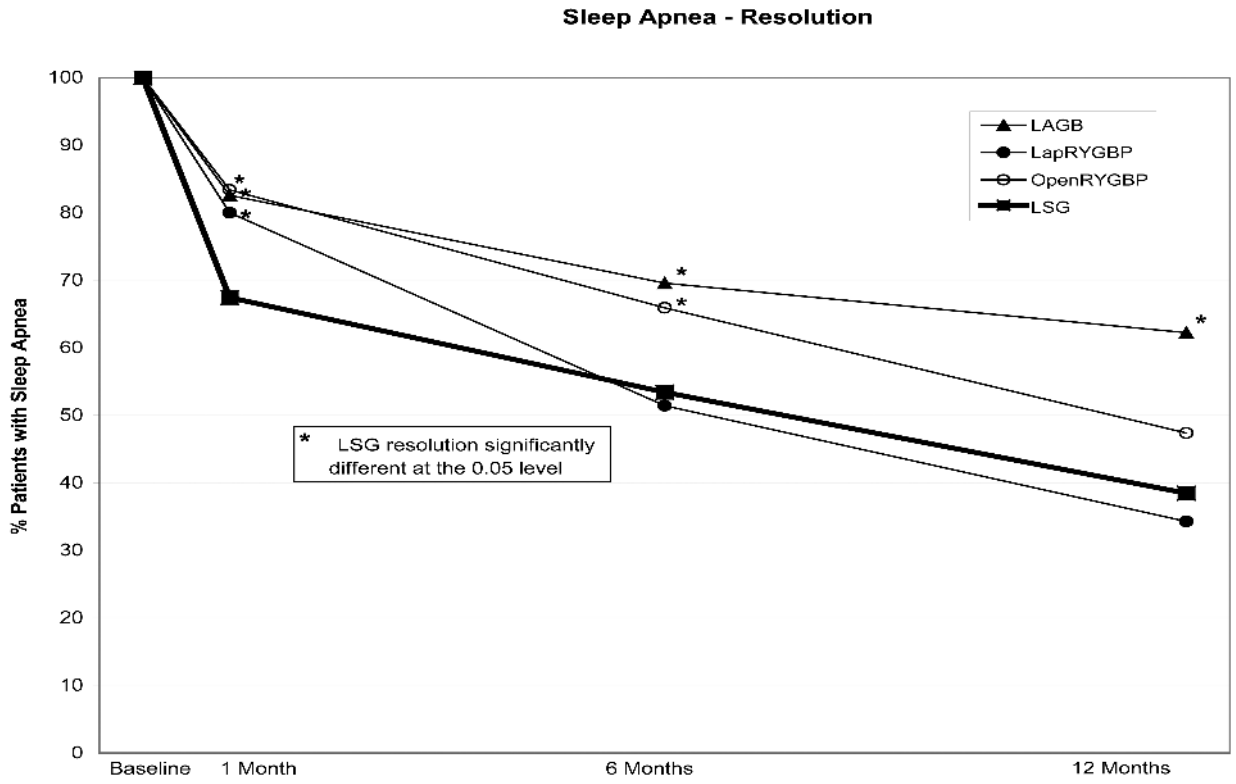
Figure 2.



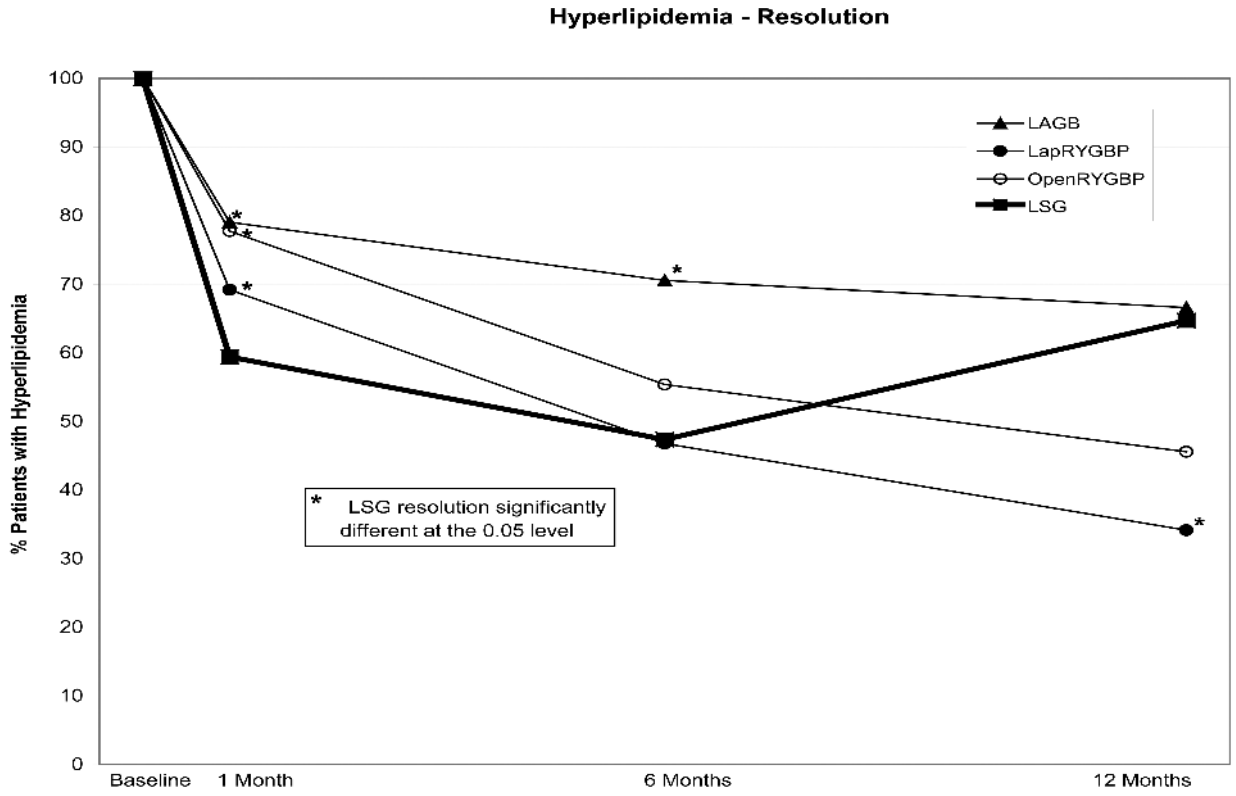
	Baseline	1 month	6 months	12 months
LSG "N" for Analysis	249	202	70	22
% Available for follow-up with Data	100%	85%	82%	79%
LAGB "N" for Analysis	2,558	2,168	1,543	653
% Available for follow-up with Data	100%	87%	84%	77%
LapRYGBP "N" for Analysis	4,452	3,999	2,606	1,088
% Available for follow-up with Data	100%	90%	83%	76%
OpenRYGBP "N" for Analysis	380	301	227	88
% Available for follow-up with Data	100%	79%	76%	67%



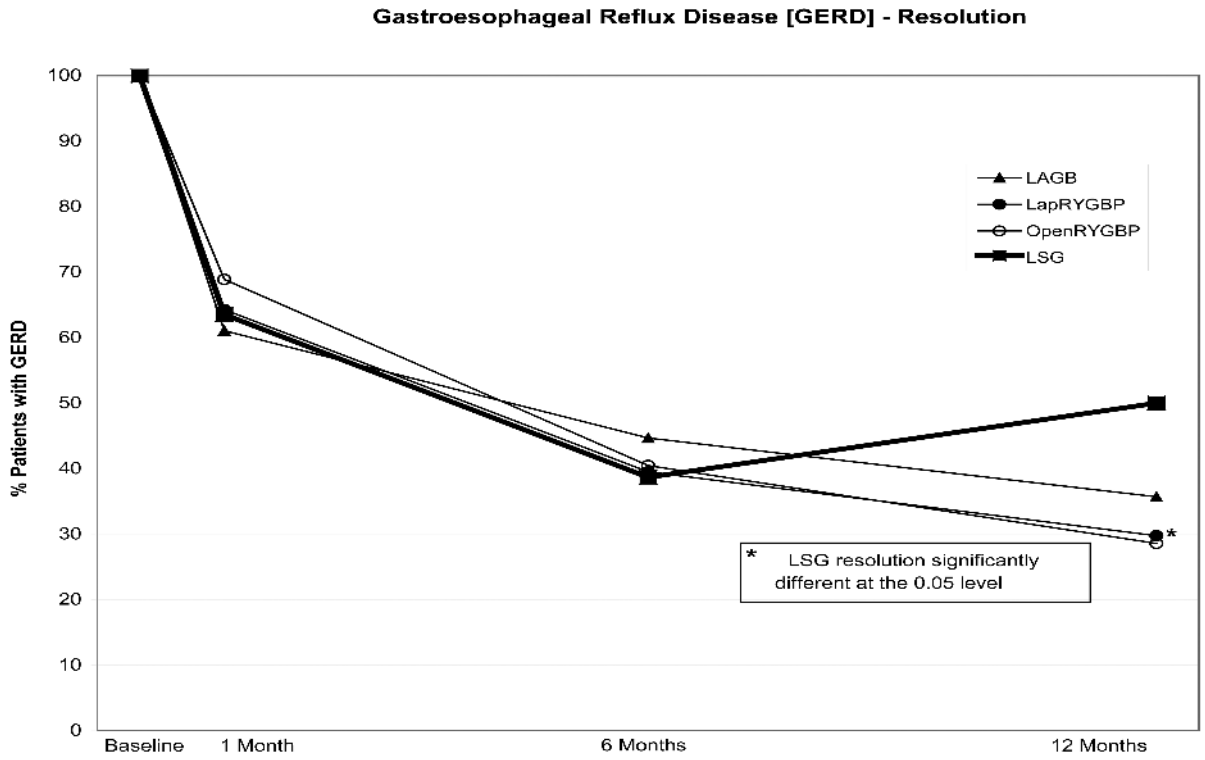
	Baseline	1 month	6 months	12 months
LSG "N" for Analysis	525	407	151	38
% Available for follow-up with Data	100%	81%	79%	81%
LAGB "N" for Analysis	5,641	4,799	3,286	1,405
% Available for follow-up with Data	100%	88%	83%	78%
LapRYGBP "N" for Analysis	7,880	7,029	4,644	2,054
% Available for follow-up with Data	100%	90%	83%	76%
OpenRYGBP "N" for Analysis	583	455	330	143
% Available for follow-up with Data	100%	78%	74%	65%



	Baseline	1 month	6 months	12 months
LSG "N" for Analysis	323	218	88	26
% Available for follow-up with Data	100%	70%	81%	74%
LAGB "N" for Analysis	3,477	2,756	1,781	686
% Available for follow-up with Data	100%	82%	76%	70%
LapRYGBP "N" for Analysis	5,239	4,453	2,862	1,272
% Available for follow-up with Data	100%	86%	78%	74%
OpenRYGBP "N" for Analysis	436	319	217	95
% Available for follow-up with Data	100%	73%	65%	60%



	Baseline	1 month	6 months	12 months
LSG "N" for Analysis	311	202	95	17
% Available for follow-up with Data	100%	66%	75%	74%
LAGB "N" for Analysis	3,139	2,681	1,872	805
% Available for follow-up with Data	100%	88%	83%	77%
LapRYGBP "N" for Analysis	4,611	4,056	2,737	1,274
% Available for follow-up with Data	100%	89%	84%	79%
OpenRYGBP "N" for Analysis	350	274	195	90
% Available for follow-up with Data	100%	79%	68%	63%



	Baseline	1 month	6 months	12 months
LSG "N" for Analysis	231	181	75	22
% Available for follow-up with Data	100%	80%	84%	88%
LAGB "N" for Analysis	2,902	2,451	1,722	773
% Available for follow-up with Data	100%	87%	84%	80%
LapRYGBP "N" for Analysis	4,482	3,934	2,653	1,260
% Available for follow-up with Data	100%	88%	82%	76%
OpenRYGBP "N" for Analysis	334	257	178	77
% Available for follow-up with Data	100%	77%	68%	53%

Figure 3.
Reduction in Obesity Related Diseases

Table 1

Patient Characteristics of 28,616 undergoing bariatric surgery at ACS-BSCN accredited centers.

Characteristic	LSG %	LAGB %	LRYGBP %	ORYGBP %
Total Patients	944	12193	14491	988
Mean Age	46.52	44.31*	44.6*	45.52
Body Mass Index (kg/m2)	46.24	43.91*	46.07	48.8*
<40	24.47	28.84§	19.25§	13.16§
40-49.9	45.34	54.74§	54.79§	47.87§
50-59.9	24.26	13.77§	20.7§	26.01§
≥60	5.93	2.65§	5.25§	12.96§
Female	75.00	78.14*	78.12*	77.94
White	67.48	73.28*	79.89*	83.1*
Non-hispanic	80.83	92.47*	86.09*	84.21*
Renal insufficiency	0.74	0.40	0.50	1.11
Diabetes				
Non-insulin	16.95	14.55§	19.73*	24.29§
Insulin	9.43	6.43§	10.99*	14.17§
Dialysis	0.74	0.20*	0.21*	0.20
Smoker	8.47	10.02	11.04*	14.98*
Functional status				
Partial dependent	0.85	0.27§	0.68	3.04§
Totally dependent	0.00	0.04§	0.08	0§
Mobility device	3.60	1.46*	3.16	8.81*
Musculoskeletal	33.37	24.25*	35.93	47.27*
COPD	2.12	0.89*	1.16*	1.92
Oxygen Dependent	0.85	0.39*	0.71	1.92*
Sleep apnea	34.22	28.52*	36.15	44.13*
Gastroesophageal Reflux	24.47	23.80	30.93*	33.81*
Gallstone disease	19.17	15.16*	22.07*	31.68*
Steroids	1.48	0.81*	0.96	1.32
Previous cardiac disease	1.38	1.35	1.30	2.63*
Previous Myocardial Infarction	2.12	1.25*	1.82	1.82
History Hyperlipidemia	32.94	25.74*	31.82	35.43
Hypertension	55.61	46.21*	54.33	59.01

Characteristic	LSG %	LAGB %	LRYGBP %	ORYGBP %
History PE	1.48	0.71*	1.01	2.23
History DVT	3.18	1.7*	2.35	4.35
Venous stasis	2.54	1.28*	2.64	4.05
Previous operation	8.26	1.32*	2.51*	3.24*
Accreditation Status				
Level I	96.40	61.82	91.30	69.53
Level II	3.60	8.73	8.70	30.47
Outpatient	0	29.44	0	0

LSG, Laparoscopic Sleeve gastrectomy; LAGB, Laparoscopic gastric bypass; LRYGBP, Laparoscopic roux-en-y gastric bypass; ORYGBP, open roux-en-y gastric bypass

*P < 0.05

§Group level *P<0.05*

Table 2

Thirty-day univariate outcomes by procedure type in 28,616 patients undergoing bariatric surgery at ACS-BSCN accredited centers.

Outcome	LSG N (%)	LAGB N (%)	LRYGBP N (%)	ORYGBP N (%)
Total Patients	944	12,193	14,491	988
Conversion to Open[§]	9 (0.10)	30 (0.25)*	207 (1.43)	n/a
30-day Mortality	1 (0.11)	6 (0.05)	21 (0.14)	7 (0.71)*
1-Year Mortality	2 (0.21)	10 (0.08)	49 (0.34)	11 (1.11)*
Readmission	51 (5.4)	208 (1.71)*	937 (6.47)	93 (9.41)*
Reoperation	28 (2.97)	112 (0.92)*	728 (5.02)*	50 (5.06)*
Mean LOS, (days)	2.98	0.76*	2.61*	3.78*
30-day Morbidity	53 (5.61)	175 (1.44)*	857 (5.91)	148 (14.98)*
Coma	0	0	2 (0.01)	0
Stroke	0	1 (0.01)	5 (0.03)	0
Peripheral Nerve Injury	1 (0.11)	0*	4 (0.03)	0
Cardiac Arrest	0	5 (0.04)	13 (0.09)	3 (0.3)
Myocardial Infarction	0	2 (0.02)	9 (0.06)	0
Deep Vein Thrombosis	1 (0.11)	4 (0.03)	21 (0.14)	3 (0.30)
Pulmonary Embolism	3 (0.32)	2 (0.02)*	18 (0.12)	1 (0.1)
Pneumonia	3 (0.32)	6 (0.05)*	58 (0.40)	13 (1.32)*
Unplanned Intubation	3 (0.32)	7 (0.06)*	59 (0.41)	8 (0.81)
Ventilator Dependent (> 48 hrs)	0	2 (0.02)	55 (0.38)*	7 (0.71)*
Acute Renal Failure	0	5 (0.04)	22 (0.15)	6 (0.61)*
Renal Insufficiency	3 (0.32)	2 (0.02)*	12 (0.08)*	3 (0.30)
Urinary Tract Infection	5 (0.53)	20 (0.16)*	104 (0.72)	10 (1.01)
Surgical Site Infection				
Superficial	7 (0.74)	70 (0.57)	219 (1.51)	40 (4.05)*
Deep	2 (0.21)	7 (0.06)	36 (0.25)	23 (2.33)*
Organ Space	10 (1.06)	4 (0.03)*	66 (0.46)*	14 (1.42)
Wound Dehiscence	0	8 (0.07)	27 (0.19)	39 (3.95)*
Sepsis	10 (1.06)	7 (0.06)*	69 (0.48)*	13 (1.32)
Septic Shock	0	4 (0.03)	21 (0.14)	2 (0.20)

LSG, Laparoscopic Sleeve gastrectomy; LAGB, Laparoscopic gastric bypass; LRYGBP, Laparoscopic roux-en-y gastric bypass; ORYGBP, open roux-en-y gastric bypass; LOS, length of stay

*P < 0.05

[§]Conversion to open defined as laparoscopic sleeve gastrectomy, band or roux-en-y gastric bypass converted to an open procedure for unplanned reasons

Table 3

Bariatric specific complication rates requiring a reoperation and/or readmission by procedure type at ACS-BSCN accredited centers.

Occurrence[§]		LSG N (%)	LAGB N (%)	LRYGBP N (%)	ORYGBP N (%)
Anastomotic Leak		7 (0.74)	0*	113 (0.78)	15 (1.52)
	Readmission	2 (0.21)	0*	42 (0.29)	5 (0.51)
	Reoperation	7 (0.74)	0*	99 (0.68)	14 (1.42)
Gastrointestinal Perforation		0	6 (0.05)	17 (0.12)	1 (0.10)
	Readmission	0	3 (0.02)*	7 (0.05)	0
	Reoperation	0	5 (0.04)	14 (0.10)	1 (0.10)
Abdominal Sepsis		1 (0.11)	3 (0.02)	30 (0.21)	2 (0.20)
	Readmission	0	0	11 (0.08)	1 (0.10)
	Reoperation	1 (0.11)	3 (0.02)	25 (0.17)	1 (0.10)
Fluid, electrolyte, nutritional depletion		18 (1.91)	45 (0.37)*	220 (1.52)	21 (2.13)
	Readmission	18 (1.91)	43 (0.35)*	210 (1.45)	21 (2.13)
	Reoperation	1 (0.11)	4 (0.03)	18 (0.12)	1 (0.10)
Stricture causing Obstruction		4 (0.42)	16 (0.13)*	206 (1.42)*	3 (0.30)
	Readmission	1 (0.11)	8 (0.07)	60 (0.41)	0
	Reoperation	3 (0.32)	13 (0.11)	187 (1.29)	3 (0.30)
Intestinal Obstruction		0	4 (0.03)	137 (0.95)*	3 (0.30)
	Readmission	0	4 (0.03)*	76 (0.52)	2 (0.20)
	Reoperation	0	3 (0.02)	113 (0.78)*	1 (0.10)
Anastomotic Ulcer		0	0	68 (0.47)*	4 (0.40)*
	Readmission	0	0	39 (0.27)	0
	Reoperation	0	0	52 (0.36)	4 (0.40)*
Gastric Distention		0	3 (0.02)	8 (0.06)	0
	Readmission	0	3 (0.02)	8 (0.06)	0
	Reoperation	0	0	12 (0.08)	1 (0.10)
Gastrogastric Fistula		1 (0.11)	0*	1*	0
	Readmission	0	2 (0.02)	13 (0.09)	0
	Reoperation	1 (0.11)	0*	0*	0
Gallstone Disease		0	3 (0.02)	19 (0.13)	1 (0.10)
	Readmission	0	2 (0.02)	13 (0.09)	0
	Reoperation	0	3 (0.02)	17 (0.12)	1 (0.10)
Wound Infection/evisceration		2 (0.21)	15 (0.12)	40 (0.28)	26 (2.63)*
	Readmission	2 (0.21)	13 (0.11)	38 (0.26)	19 (1.92)*
	Reoperation	1 (0.11)	5 (0.04)	10 (0.07)	11 (1.11)*

Occurrence[§]		LSG N (%)	LAGB N (%)	LRYGBP N (%)	ORYGBP N (%)
Infection / Fever		6 (0.64)	17 (0.14)*	52 (0.36)	7 (0.71)
	Readmission	5 (0.53)	15 (0.12)*	46 (0.32)	6 (0.61)
	Reoperation	1 (0.11)	9 (0.07)	8 (0.06)	1 (0.10)
Incisional Hernia		0	2 (0.02)	14 (0.10)	1 (0.10)
	Readmission	0	1 (0.01)	7 (0.05)	1 (0.10)
	Reoperation	0	1 (0.01)	11 (0.08)	0
Deep Vein Thrombosis		0	6 (0.05)	14 (0.10)	3 (0.30)
	Readmission	0	6 (0.05)	12 (0.08)	3 (0.30)
	Reoperation	0	0	3 (0.02)	0
Pulmonary Embolism		3 (0.32)	2 (0.02)*	24 (0.17)	2 (0.20)
	Readmission	3 (0.32)	2 (0.02)*	16 (0.11)	2 (0.20)
	Reoperation	0	0	10 (0.07)	1 (0.10)
Pneumonia		1 (0.11)	3 (0.02)	19 (0.13)	5 (0.51)
	Readmission	1 (0.11)	3 (0.02)	17 (0.12)	5 (0.51)
	Reoperation	0	0	3 (0.02)	1 (0.10)
Respiratory Failure		0	3 (0.02)	12 (0.08)	4 (0.40)*
	Readmission	0	1 (0.01)	2 (0.01)	1 (0.10)
	Reoperation	0	2 (0.02)	11 (0.08)	3 (0.30)
Bleeding		6 (0.64)	6 (0.05)*	161 (1.11)	11 (1.11)
	Readmission	4 (0.42)	5 (0.04)*	81 (0.56)	5 (0.51)
	Reoperation	3 (0.32)	4 (0.03)*	104 (0.72)	7 (0.71)
Any Band Problem		n/a	14 (0.11)		
	Readmission	n/a	14 (0.11)	n/a	n/a
	Reoperation	n/a	28 (0.23)	n/a	n/a
Other / Not otherwise specified		25 (2.65)	124 (1.02)*	417 (2.88)	35 (3.54)
	Readmission	17 (1.80)	97 (0.80)*	11 (0.08)	28 (2.83)
	Reoperation	11 (1.17)	42 (0.34)*	133 (0.92)	12 (1.21)

LSG, Laparoscopic Sleeve gastrectomy; LAGB, Laparoscopic gastric bypass; LRYGBP, Laparoscopic roux-en-y gastric bypass; ORYGBP, open roux-en-y gastric bypass; LOS, length of stay

*P < 0.05

§Overall complication rates are included on the first row for each specific complication. Events may be counted twice on the readmission and reoperation rows.

Table 4

Risk-adjusted outcomes of 28,616 cases performed at ACS-BSCN accredited centers.

	LSG	LAGB	LRYGBP	ORYGBP
	n=944	**n=12,193**	**n=14,491**	**n=988**
30-day Mortality	**0.11%**	0.05%	0.14%	0.71%
OR (95% CI)	1 (referent)	0.67 (0.08 – 6.65)	1.62 (0.22 – 12.13)	6.84 (0.83 – 56.29)
1-year Mortality	**0.21%**	0.08%	0.34%	1.11%
OR (95% CI)	1 (referent)	0.53 (0.11 – 2.42)	1.77 (0.43 – 7.33)	4.29 (0.94 – 19.57)
30-day Morbidity	**5.61%**	**1.44%**	5.91%	**14.98%**
OR (95% CI)	1 (referent)	**0.29 (0.21 – 0.40)**	1.06 (0.79 – 1.41)	**2.55 (1.83 – 3.55)**
30-day Readmission	**5.40%**	**1.71%**	6.47%	**9.41%**
OR (95% CI)	1 (referent)	**0.34 (0.25 – 0.47)**	1.25 (0.93 – 1.68)	**1.68 (1.18 – 2.41)**
30-day Reoperation/intervention	**2.97%**	**0.92%**	**5.02%**	**5.06%**
OR (95% CI)	1 (referent)	**0.35 (0.23 – 0.53)**	**1.80 (1.23 – 2.66)**	**1.63 (1.01 – 2.61)**