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Development of a sleeve gastrectomy risk calculator

Ali Aminian, M.D., Stacy A. Brethauer, M.D., Maryam Sharafkhah, M.S., Philip R. Schauer, M.D.*

Bariatric and Metabolic Institute, Cleveland Clinic, Cleveland, Ohio

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Abstract

Background: Laparoscopic sleeve gastrectomy (LSG) is rapidly gaining popularity. Estimating the risk of postoperative adverse events can improve surgical decision-making and informed patient consent. The objective of this study was to develop and validate a risk prediction model for early postoperative morbidity and mortality after LSG.

Methods: Cases of primary LSG in the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) data set at year 2012 (n = 5871) and 2011 (n = 3130) were identified to develop and examine the validity of model. The composite primary outcome was defined as presence of any of 14 serious adverse events within the 30-days after LSG. Multiple logistic regression analysis was performed and a risk calculator was created to predict the primary outcome.

Results: Thirty-day postoperative mortality and composite adverse events rates of 5871 LSG cases were .05% and 2.4%, respectively. Of the 52 examined baseline variables, the final model contained history of congestive heart failure (odds ratio [OR] 6.23; 95% CI 1.25–31.07), chronic steroid use (OR 5.00; 95% CI 2.06–12.15), male sex (OR 1.68; 95% CI 1.03–2.72), diabetes (OR 1.62; 95% CI 1.07–2.48), preoperative serum total bilirubin level (OR 1.57; 95% CI 1.11–2.22), body mass index (OR 1.03; 95% CI 1.01–1.05), and preoperative hematocrit level (OR .95; 95% CI .89–1.00). The risk model was then validated with the 2011 data set and was used to create an online risk calculator with a relatively good accuracy (c-statistic .682).

Conclusions: This risk assessment scoring system, which specifically estimates serious adverse events after LSG, can contribute to surgical decision-making, informed patient consent, and prediction of surgical risk for patients and referring physicians. (Surg Obes Relat Dis 2015;∎:00–00.) © 2015 Published by Elsevier Inc. on behalf of American Society for Metabolic and Bariatric Surgery.

Keywords: Bariatric; Sleeve gastrectomy; NSQIP; Risk; Complication; Morbidity; Mortality; Calculator; Morbid obesity

The growing epidemic of obesity, along with the relative ineffectiveness of conventional weight reduction therapies in severely obese individuals, has led to a remarkable rise in the number of bariatric surgical procedures in the past 2 decades [1]. Among all bariatric procedures, laparoscopic sleeve gastrectomy (LSG) has had a period of rapid growth in recent years. According to some estimates, LSG has become the most common bariatric procedure performed in the United States [2]. The LSG is a safe and relatively simple procedure and is associated with a low complication rate, even in high-risk patients who cannot tolerate a complex surgical procedure due to co-morbidities or anatomic limitations. In addition to achieving significant and durable weight loss, LSG is associated with long-term favorable metabolic effects [3–7].

This study was presented as one of top 10 studies at Obesity Week, Boston, MA, November 2–7, 2014.

*Correspondence: Philip R. Schauer, M.D., Bariatric and Metabolic Institute, Cleveland Clinic, 9500 Euclid Avenue, M61, Cleveland, OH 44195.

E-mail: schauep@ccf.org

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Despite the presence of robust data on safety and efficacy of bariatric surgery, many patients and physicians do not consider surgery to treat the disease of obesity. One reason may be an inaccurate belief of the benefit-to-risk ratio of medical versus surgical treatment of obesity [8,9]. Estimating the risk of postoperative adverse events can improve surgical decision-making and informed patient consent. In addition, there would be a considerable benefit in identifying modifiable preoperative factors that are associated with increased risk of postsurgical adverse events. Limitations of a few available predicted risk models include few baseline variables, combination of open and laparoscopic procedures, or being applicable mainly to gastric bypass [10–13].

The aim of this study was to develop a specific and valid preoperative risk calculator for estimation of early postoperative morbidity and mortality after LSG based on a national data set.

Methods

Data were extracted from the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) database. The ACS-NSQIP prospectively collects data on more than 150 variables, including standardized and audited demographic variables, co-morbidities, laboratory values, and 30-day postoperative mortality and morbidity outcomes for patients undergoing major surgical procedures in the United States (374 participating sites in 2012 and 315 sites in 2011). The ACS has used several mechanisms to ensure that the data collected are of the highest consistency and reliability [14].

Morbidly obese patients aged >18 undergoing LSG with the Current Procedural Terminology (CPT) code 43775 were included. Patients who underwent procedures that are commonly performed along with obesity surgery including concurrent endoscopy, liver biopsy, abdominal wall hernia repair, hiatal hernia repair, cholecystectomy, and procedures to manage intraoperative complications were included. However, revisional bariatric procedures and cases with unrelated concurrent procedures such as appendectomy and hysterectomy were excluded. Cases of LSG at year 2012 and 2011 were identified to make and then to examine the validity of risk model, respectively.

The primary outcome was 30-day postoperative composite adverse events, which was defined as presence of any of 14 serious adverse events, including organ/space surgical site infection, stroke, coma, myocardial infarction, cardiac arrest, acute renal failure, deep vein thrombosis, pulmonary embolism, reintubation, failure to wean from mechanical ventilation, sepsis, septic shock, need for transfusion, and death.

Independent demographic variables were sex, race, age (as a continuous and a categorical variable), height, weight, and body mass index (BMI; as a continuous and a categorical variable). Examined co-morbidities included diabetes (and insulin usage), hypertension, history of pulmonary diseases (dyspnea and chronic obstructive pulmonary diseases), history of cardiac diseases (angina, myocardial infarction, congestive heart failure, cardiac interventions and surgeries), history of peripheral vascular diseases, history of kidney diseases (acute renal failure and being on dialysis), history of cerebrovascular diseases (transient ischemic attack and stroke), recent history of chemotherapy or radiotherapy, steroid use for chronic conditions, and bleeding disorders. Other baseline variables included smoking status, alcohol use, functional status (dependant/independent), and the American Society of Anesthesiologists (ASA) score. Preoperative laboratory variables included serum sodium, creatinine, blood urea nitrogen, albumin, aspartate aminotransferase, bilirubin, alkaline phosphatase, hematocrit, white blood cell count, platelet count, partial thromboplastin time, prothrombin time, and international normalized ratio. The effect of concomitant cholecystectomy was also assessed. All variables were clearly defined in the ACS-NSQIP database user guide [14].

Data analysis was performed using STATA (version 12, StataCorp, College Station, TX). To explore the risk factors associated with the primary outcome, the univariate analysis was performed using the Student's *t* test for continuous variables and Pearson $\chi 2$ test or Fisher's exact test for categorical variables.

Multiple logistic regression with stepwise variable selection was used to construct a model for prediction of the primary outcome. Both the backward stepwise elimination and the forward stepwise selection methods were used to build a model. Independent variables with a significant association ($P < .1$) with the primary outcome in univariate analyses were entered into a model. With backward elimination procedure, only significant risk factors ($P < .05$) were kept in the model. Afterward, a forward stepwise selection was also used to find a stable model.

The calibration of the model was tested using the Hosmer-Lemeshow goodness-of-fit test. The discriminatory capability of the model was assessed using the c-statistic which is the same as the area under the receiver operating characteristic (ROC) curve [10–12]. Then, the risk model based on the 2012 ACS-NSQIP data set was validated using the 2011 data set.

The regression equation used to generate the model was used to construct a free online version of the calculator using the Cleveland Clinic Risk Calculator Constructor (http://www.r-calc.com).

Results

Baseline characteristics and co-morbidities of 5871 patients who underwent LSG in 2012 have been summarized in Table 1. Patients had a mean age of 43.8 ± 11.2 years and BMI of 45.9 ± 8.1 kg/m^2. Eighty percent of the cohort was female, 76% were white, and 22% had diabetes.