ELSEVIER

Surgery for Obesity and Related Diseases 8 (2012) 671–678

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Risk stratification of serious adverse events after gastric bypass in the Bariatric Outcomes Longitudinal Database

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Received April 23, 2012; accepted July 20, 2012

Abstract

Background: There is now sufficient demand for bariatric surgery to compare bariatric surgeons and bariatric centers according to their postsurgical outcomes, but few validated risk stratification measures are available to enable valid comparisons. The purpose of this study was to develop and validate a risk stratification model of composite adverse events related to Roux-en-Y gastric bypass (RYGB) surgery.

Methods: The study population included 36,254 patients from the Bariatric Outcomes Longitudinal Database (BOLD) registry who were 18–70 years old and had RYGB between June 11, 2007, and December 2, 2009. This population was randomly divided into a 50% testing sample and a 50% validation sample. The testing sample was used to identify significant predictors of 90-day composite adverse events and estimate odds ratios, while the validation sample was used to assess model calibration. After validating the fit of the risk stratification model, the testing and validation samples were combined to estimate the final odds ratios.

Results: The 90-day composite adverse event rate was 1.48%. The risk stratification model of 90-day composite adverse events included age (40–64, ≥65), indicators for male gender, body mass index (50–59.9, ≥60), obesity hypoventilation syndrome, back pain, diabetes, pulmonary hypertension, ischemic heart disease, functional status, and American Society of Anesthesiology classes 4 or 5. Our final gastric bypass model was predictive (c-statistic = .68) of serious adverse events 90 days after surgery.

Conclusions: With additional validation, this risk model can inform both the patient and surgeon about the risks of bariatric surgery and its different procedures, as well as enable valid outcomes comparisons between surgeons and surgical programs. (Surg Obes Relat Dis 2012;8: 671–678.) Published by Elsevier Inc. on behalf of American Society for Metabolic and Bariatric Surgery.

Keywords: Bariatric surgery; Roux-en-Y gastric bypass; Gastric bypass; Risk stratification; Adverse events; Mortality

Bariatric surgery is the most effective weight loss intervention for obese patients and enables many patients to discontinue diabetes, hypertensive, and lipid-lowering medications without significant risk of mortality [1]. Unsurprisingly, there has been great demand in the United States for bariatric surgery, which increased from 8,597 procedures in 1993 [2] to >200,000 surgeries in 2007 [3]. Medicare

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1550-7289/12/$ – see front matter Published by Elsevier Inc. on behalf of American Society for Metabolic and Bariatric Surgery.
http://dx.doi.org/10.1016/j.soard.2012.07.020

coverage of bariatric surgery began in 2005, which was followed by improvements in complication rates and shorter lengths of stay [4].

With this growth in surgical volume, there is now sufficient information to compare postsurgical complications and mortality, as has been done by the National Surgical Quality Improvement Program (NSQIP) [5–7], the Michigan Bariatric Surgery Collaborative [8], and the Bariatric Outcomes Longitudinal Database (BOLD) registries of bariatric patients. As noted in a recent article [9], outcomes need to be risk stratified to support meaningful comparisons and avoid implicating centers as providing poor quality when they may simply be performing surgery on higher-risk patients. There are few validated risk stratification systems for characterizing bariatric surgery patients, with the Obesity Surgery Mortality Risk Score (OS-MRS) being the most widely used risk stratification measure to date [10–12].

The purpose of this study was to develop and validate a risk stratification model to predict composite adverse events occurring within 90 days after surgery for patients aged 18–70 undergoing a primary (i.e., not revisional) Roux-en-Y gastric bypass (RYGB) performed by a surgeon participating in the American Society for Metabolic and Bariatric Surgery (ASMBS) Bariatric Surgery Center of Excellence (BSCOE) and tracked in BOLD. This risk model considered a broader array of preoperative patient risk factors and a larger population than have been considered in previous risk stratification models. Identification of predictors of composite adverse events can be used to inform patients and surgeons about the potential for serious complications after RYGB and enables valid outcomes comparisons between surgeons and surgical programs.

Methods

Patients

Details of the preoperative, operative, and postoperative BOLD data have been previously reported [13]. In brief, BSCOE participants enter detailed information on all bariatric surgery patients prospectively for each preoperative, intraoperative, and postoperative patient encounter. BOLD data are used to ensure compliance with the requirements of the BSCOE program and for research purposes to develop general knowledge about optimal bariatric surgery practices; Online Appendix 1 provides a detailed description of variables used in this study.

This study included 101,030 research-consented patients aged 18–70 years who had an initial RYGB performed by a surgeon participating in the BSCOE program between June 11, 2007, and December 2, 2009. After excluding patients who underwent a procedure other than RYGB, had a previous bariatric surgery, or met other exclusion criteria, there were 36,254 patients who had undergone a primary RYGB, who were at least 90 days past the date of surgery when the database was created, and who had complete covariate and outcomes data to enable risk stratification model building (Online Appendix 2). Patients with both open and laparoscopic RYGB were included in the final sample to enable the broadest possible generalizability.

This sample of 36,254 was randomly divided into a 50% testing sample (n = 18,127) and a 50% validation sample (n = 18,127). The testing sample was used to identify significant predictors of 90-day composite adverse events and estimate odds ratios, while the validation sample was used to assess model fit, calibration, and discrimination consistent with methods employed for risk adjustment of cardiac surgery by the Society of Thoracic Surgeons [14–16]. After the specification of the risk stratification model was finalized, the testing and validation samples were combined to estimate final odds ratios from the pooled sample.

Outcome definition

The outcome of interest in the RYGB model was a composite endpoint of 90-day major adverse events, based in part on an algorithm from the LABS team [17]. This composite adverse event outcome included 17 endpoints measured during the index hospitalization and in the 90 days after discharge. These endpoints included intraoperative, predischarge, or postdischarge death, anastomotic leakage, cardiac arrest, venous thromboembolism, evisceration, heart failure, liver failure, multisystem organ failure, myocardial infarction, pneumothorax, pulmonary embolism, renal failure, respiratory failure, sepsis, stroke, systemic inflammatory response syndrome, and intraoperative bleeding requiring blood transfusion. Deaths due to suicide or accidents were excluded, because bariatric surgery is unlikely to be the cause of these deaths. A patient was assigned an outcome value of 1 if any of these 17 endpoints were recorded within 90 days postsurgery, and zero otherwise. Composite adverse events at 90 days were used as the first outcome for risk adjustment using BOLD data, because risk stratification results were consistent between 30-day and 90-day event rates. Mortality, occurring much less frequently than composite adverse events, was difficult to model independently, and this sample was not powered for mortality.

Explanatory variable identification and selection

Before estimating the risk stratification model, a PubMed search of articles published in the English language before June 2010 was conducted to determine which patient risk factors were significant predictors of postsurgical mortality and complications. The search combined terms for bariatric surgery, gastric bypass, Roux-en-Y, and obesity surgery with terms for mortality, morbidity, complications, death, and survival, and generated 47 full-text eligible articles that were extracted from 406 titles and abstracts identified in the search. Predictor variables from 19 articles were systematically assessed, and the primary predictors of mortality or

postsurgical complications included BMI, male gender, age, hypertension, diabetes, previously developed risk scores (e.g., Charlson Co-morbidity Index), and surgical center.

We then examined the prevalence of each risk factor in the overall sample to determine which risk factors might be too rare to model. For example, pulmonary hypertension was rarely (.4%) coded preoperatively but was retained for consideration as a known mortality risk factor [18]. Then, pair-wise correlations were examined to ensure that redundant or highly correlated variables were not included in the final model. By necessity, co-morbidities are largely based on self-report, as patients present for surgery with co-morbid conditions that are under active treatment. To confirm the presence of each co-morbid condition (e.g., pulmonary hypertension), records dating back to the initial diagnosis and initiation of treatment would be required and are generally not available at the time of clinical assessment.

Finally, race and open versus laparoscopic procedure were explicitly excluded from consideration. Race is highly correlated with socioeconomic, insurance, and contextual factors and may not relate well to meaningful clinical physiologic factors that might predict outcomes, which makes outcomes differences by race difficult to interpret [19–21]. In addition, patient outcomes should be similar across race and ethnicity when other preoperative characteristics are accounted for. Therefore, the inclusion of race in the risk stratification model might bias surgeons to operate on patients on the basis of race instead of appropriate risk factors or benefit considerations. The procedure access (open versus laparoscopic RYGB) was also excluded from consideration in the risk stratification model because the surgical procedure is a function of feasibility, patient preference, surgeon experience, surgeon preference, and clinical decision making made intraoperatively in the face of emergent issues at the time of surgery. Procedure access type was excluded to ensure that the risk model included only preoperative factors related to the patient that could not be controlled by the surgeon.

Final model building and testing

Given the large RYGB sample, we were not constrained to select the most parsimonious model that retained the greatest predictive power. However, it was important to ensure that the risk stratification model would be clinically useful to bariatric surgeons, and most of the predictive power was driven by a limited number of risk factors. Model building with the testing sample was conducted in 3 steps. First, bivariate regressions were conducted using logistic regression to generate unadjusted odds ratios and initial P values to identify covariates that were likely to remain highly significant after more complete adjustment. Second, subsets of related patient demographics (e.g., age categories) and preoperative co-morbidities were estimated in restricted logistic regressions to evaluate the sensitivity of ORs from bivariate regressions when clinically related variables were also adjusted. For example, a regression that included several age categories (<40 years, 40–49, 50–59, 60–64, and ≥65) generated similar odds ratios for the 40–49, 50–59, and 60–64 subgroups, and so a single age grouping (40–64 years) was carried forward. Covariates with P values ≤ .10 were carried forward into the final multivariate model, and this generous P value threshold was chosen to account for the fact that the final model was based on the pooling of the testing and validation samples.

The final risk stratification model from the testing sample included a subset of risk factors that satisfied one of two criteria: (1) the risk factor was a statistically significant (no greater than $P < .05$) predictor of the composite adverse event outcome in multivariate regression or (2) the OR of the risk factor was 1.25 or ≤.8, if not statistically significant. The second criterion was included with the expectation that statistically insignificant risk factors with sizable ORs in the current analysis may become statistically significant as the BOLD population grows over time. In addition, risk factors that were not statistically significant on a population level may be important predictors of patient-level outcomes [22]. Goodness of fit was assessed via the c-index (a measure of model discrimination) and the Hosmer-Lemeshow test, which assesses whether the observed event rates match the expected event rates in 5 equally sized subsets of the RYGB cohort.

The initial subset of risk factors was reviewed by a bariatric surgeon (E.J.D.) to ensure face validity, content validity, and construct validity. Odds ratios and 95% confidence intervals for all covariates except one were similar in the testing and validation samples. The obstructive sleep apnea co-morbidity indicator was statistically significant in the testing sample but insignificant in the validation sample, so was excluded from the final risk stratification model. After estimating and validating the risk stratification model using logistic regression, the final model coefficients on the pooled sample of testing and validation patients were estimated using generalized estimating equations (GEE) with a binomial distribution, logit link, independence working correlation matrix, and robust standard errors. A GEE model was estimated to account for correlation among patients treated in the same hospital. All analyses were conducted using Stata MP version 11.0 (College Station, TX), and approval to conduct human subjects research was obtained from the Copernicus Group Institutional Review Board.

Results

Risk profile and event rate of patients having Roux-en-Y gastric bypass

The 36,254 patients in the RYGB cohort had an average age of 43.8 (Table 1). The average body mass index (BMI) was 47.6, and 31.6% were super-obese (BMI ≥ 50). The cohort was predominantly female (79%) and Caucasian (79%). Three percent of

Table 1
Descriptive statistics of patient characteristics and composite 90-day outcome rates for the RYGB cohort

Variable	Mean (SD)
Age at surgery, mean, (SD)	45.8 (11.3)
Female	78.6%
White race	79.3%
Black race	9.1%
Hispanic	7.2%
Other race	4.3%
Body mass index, mean (SD)	47.6 (8.1)
BMI 50–59.9	24%
BMI ≥60	7.6%
ASA class 1	3.3%
ASA class 2	22.7%
ASA class 3	68.7%
ASA class 4/5	5.2%
Hypertension	56.1%
Diabetes	31.2%
Hyperlipidemia	43.4%
Back pain	28.9%
Gastroesophageal reflux disease	49.2%
Pulmonary hypertension	.4%
Obesity hypoventilation syndrome	2.2%
Ischemic heart disease	3.1%
Alcohol use	1.1%
Tobacco use	6.9%
Functional impairment for ambulation	3.6%
Laparoscopic procedure	91.5%
Sample size	36,254

RYGB = Roux-en-Y gastric bypass; BMI = body mass index; ASA = American Society of Anesthesiologists.

patients had an American Society of Anesthesiology (ASA) score of 1, 23% had an ASA score of 2, 69% had an ASA score of 3, and 5% had an ASA score of 4 or 5. Several preoperative comorbidities were highly prevalent, including hypertension (56%), diabetes (31%), hyperlipidemia (43%), gastroesophageal reflux disease (49%), and back pain (29%). Less prevalent preoperative patient factors included ischemic heart disease (3%), obesity hypoventilation syndrome (2%), self-reported alcohol use (1%), self-reported tobacco use (7%), functional impairment requiring an assistive device for ambulation (4%), and pulmonary hypertension (.4%). Finally, 91.5% of the sample had their RYGB performed by laparoscopic access while 8.5% had open RYGB.

The rate of composite adverse events at 30 days was 1.38%, and the event rate at 90 days was 1.48% (Table 2). The most common serious adverse events at 90 days were anastomotic leak (.42%), renal failure (.31%), respiratory failure (.27%), and death (.12%).

Model performance and coefficients

The final risk stratification model for 90-day composite adverse events included 12 covariates (Table 3). These included age 40–64, age ≥ 65, male gender, BMI 50–59.9, BMI ≥ 60, obesity hypoventilation syndrome, back pain, diabetes, pulmonary hypertension, ischemic heart disease, functional impairment to ambulation, and ASA class 4 or 5. Model discrimination based on the c-index was .695 in the testing sample, .662 in the validation sample, and .677 in the pooled final sample. The Hosmer-Lemeshow test was insignificant, indicating that the model was well calibrated.

The most significant predictors in the final risk stratification model were age ≥ 65 (OR = 2.44; $P < .001$), obesity hypoventilation syndrome (OR = 2.12; $P < .001$), functional impairment (OR = 2.01; $P < .001$), pulmonary hypertension (OR = 1.94; $P = .051$), BMI ≥ 60 (OR = 1.91; $P < .001$). The remaining risk factors had ORs between 1.42 and 1.72 (all, $P < .05$ or lower), with BMI 50–59.9 having the lowest OR (1.25; $P < .05$).

Discussion

This study reports the first risk stratification model of patients who had RYGB generated from the BOLD registry, which is the largest cohort of bariatric surgery patients in the world. The model was specifically built to risk stratify patients for composite serious adverse events 90 days after surgery and was conducted using rigorous statistical modeling procedures pioneered in risk adjustment efforts by the Society for Thoracic Surgery [15,16], as called for in a recent article [9]. The BOLD registry is based on standardized prospectively collected outcomes and risk factors from >600 hospitals, which enables development and validation of risk stratification models to support outcomes comparisons that are of interest to patients, surgical programs, and payors.

The rate of 90-day adverse events in this sample of 36,254 patients was low (1.48%), and the 12-factor risk stratification model performed reasonably well (c-index = .677). Many of these risk factors have been shown to be significant predictors of postsurgical mortality or complica-

Table 2
Seventeen 90-day adverse event rates included in composite adverse event outcome

Variable	Combined n (%)
Death, intraoperative, predischarge, or postdischarge	43 (.12%)
Anastomotic leakage	154 (.42%)
Intraoperative bleeding requiring blood transfusion	8 (.02%)
Cardiac arrest	4 (.01%)
Venous thromboembolism	15 (.04%)
Evisceration	3 (.01%
Heart failure	17 (.05%)
Liver failure	2 (.01%)
Multisystem organ failure	5 (.01%)
Myocardial infarction	19 (.05%)
Pneumothorax	6 (.02%)
Pulmonary embolism	29 (.08%)
Renal failure	112 (.31%)
Respiratory failure	99 (.27%)
Sepsis	26 (.07%)
Stroke	6 (.02%)
Systemic inflammatory response syndrome	7 (.02%)
Composite adverse event rate at 90 days	537 (1.48%)

Individual adverse events sum is greater than composite events because patients could have ≥2 distinct events.

Table 3
Comparison of testing, validation, and pooled samples for final model

Variable	Pooled sample coefficient (95% CI)	Testing sample coefficient (95% CI)	Validation sample coefficient (95% CI)
Age ≥65	2.44 (1.70, 3.50)§	2.13 (1.18, 3.81)	2.70 (1.71, 4.25)
Obesity hypoventilation syndrome	2.12 (1.50, 3.00)§	2.29 (1.38, 3.78)	1.96 (1.21, 3.17)
Functional status	2.01 (1.51, 2.68)§	1.98 (1.29, 3.04)	2.04 (1.37, 3.01)
Pulmonary hypertension	1.94 (1.00, 3.77)	2.43 (.96, 6.15)	1.56 (.59, 4.10)
Obese ≥60	1.91 (1.47, 2.50)§	1.94 (1.30, 2.88)	1.90 (1.33, 2.72)
Back pain	1.72 (1.37, 2.16)§	1.92 (1.38, 2.68)	1.56 (1.15, 2.14)
Age 40–64 yr	1.58 (1.26, 1.98)§	1.73 (1.21, 2.48)	1.49 (1.11, 2.00)
Diabetes	1.57 (1.26, 1.94)§	1.68 (1.22, 2.32)	1.46 (1.09, 1.96)
ASA class 4/5	1.53 (1.16, 2.02)†	1.51 (1.00, 2.29)	1.56 (1.07, 2.27)
Male	1.43 (1.19, 1.73)§	1.48 (1.11, 1.96)	1.41 (1.09, 1.81)
Ischemic heart disease	1.42 (1.01, 2.01)*	1.73 (1.07, 2.79)	1.19 (.72, 1.96)
Obese 50–59.9	1.25 (1.02, 1.53)*	1.36 (1.00, 1.84)	1.16 (.88, 1.52)
Sample size	36,254	18,127	18,127
C-statistic	.6773	.6951	.6624

$P < .001$.
ASA = American Society of Anesthesiologists.
* $P < .05$, † $P < .01$, § $P < .0001$.

tions in a wide range of patients and settings. Older age, male gender, and super-obesity have been associated with adverse events in prior studies [10,23–26]. Functional impairment has also been shown to be predictive of 30-day mortality [27] and composite adverse events [17]. Similarly, high ASA class (3 to 5) has been shown to predict 30-day mortality in prior studies [26].

Five co-morbid conditions were also significant predictors of 90-day composite adverse events, including diabetes, back pain, obesity hypoventilation syndrome, ischemic heart disease, and pulmonary hypertension. Diabetes was a strong predictor of mortality in the Swedish Obesity Study [24]. Obesity hypoventilation syndrome was not shown to be a significant predictor of mortality in a previous study [10], so its significance in this cohort is a unique finding. OHS has been theorized to increase patient risk for mortality, but results from prior studies are mixed [28]. Pulmonary hypertension is a particularly noteworthy predictor because it had a sizable odds ratio (1.94, $P = .051$) despite being quite rare in this sample (.4% prevalence). Given the established evidence on the improvement in diabetes, ischemic heart disease, and pulmonary hypertension in the months and years after bariatric surgery [1,29], it is reasonable that these co-morbidities would be significant risk factors for composite adverse events.

Since the publication of the OS-MRS risk stratification model in 2007, there has been great demand for a validated risk stratification measure specific to bariatric surgery. Five predictive risk models for bariatric complications and mortality have been published in 2011–2012 that included several of the same factors as this model (e.g., age, obesity, functional status) [12,30–33]. Several of these models included factors that were not predictive in this BOLD model, including history of hypertension, stroke, myocardial infarction, coronary artery disease, smoking, chronic obstructive pulmonary disease, or venous thrombosis. A validated measure can inform clinical decision making to identify which patients may be more appropriate candidates for bariatric surgery and which patients may require closer postsurgical follow-up. Such a measure could also enable valid comparisons of performance between surgeons and surgical programs. In particular, appropriate risk adjustment will ensure that surgical programs willing to operate on high-risk patients who are likely to benefit the most from surgery are not characterized as poor performers due to high unadjusted event rates. In addition, risk-adjusted outcomes are needed to compare surgical programs for quality improvement purposes [34] and are being demanded increasingly by health insurers that provide coverage for bariatric surgery. We caution that this is the first iteration of a risk stratification model from BOLD data for composite adverse events specifically for RYGB patients, and it is likely that this model will require refinement as the BOLD population grows, the risk profile of patients change over time, and adverse event rates change.

Limitations

Several limitations must be acknowledged. First, the validity of these results is a function of the data quality, which is subject to continuous quality improvement within BOLD. Preoperative patient factors are likely of high quality, and preliminary auditing of BOLD data supports this conclusion. However, several factors (e.g., back pain) are based on patient self-report and may be surrogate measures of unmeasured factors that are more directly related to postsurgical complications. Significant predictors, such as obstructive sleep apnea and pulmonary hypertension, could not be validated with data from original sleep studies or other clinical tests, which may introduce measurement error.

Collection and auditing of all patient outcomes data in the months after surgery to ensure sufficient data capture remains an ongoing challenge. BOLD data are verified

during site inspection, which each BSCOE must undergo initially and every 3 years thereafter to maintain designation. All surgeries reported in BOLD are compared with a hospital-generated surgery list, and an unbiased sampling of 10% of medical records are reviewed for accuracy. In addition, all complications and readmissions occurring within 30 days of surgery are verified. Any unreported reoperations, readmissions, deaths, transfers, or revisions found during chart review trigger a 100% chart review. Inconsistencies noted during site inspections are reported to the Bariatric Surgery Review Committee, which recommends whether the applicant qualifies for or maintains BSCOE designation status. The 90-day rate of composite adverse events reported here (1.48%) is 4 times lower than the composite adverse event rate reported at 30 days postsurgery in a report from LABS [17], although the LABS composite included reinterventions that are not always associated with a "serious complication." Under-reporting of perioperative complications by surgeons or their designee could partially explain the lower 30-day and 90-day adverse event rates in BOLD, which could affect the specification of the risk stratification model in two ways if the patients whose events are not reported are systematically different than the patients who had events. First, the risk factors included in the model may have somewhat different odds ratios. Second, there may be risk factors not included in this model that would have been added to the model. Future work is needed with more current data to replicate these initial results.

Second, the risk factors that were significant in this RYGB cohort may not generalize to patients who have not undergone RYGB. As the Society of Thoracic Surgeons has reported [16], risk factors that are significant predictors of a given outcome in a given population may not be the same predictors that are significant in another outcome or another population. Thus, future work will need to be conducted to extend this risk stratification to non-RYGB procedures (e.g., LAGB, sleeve gastrectomy) that have sufficient volume to enable similar rigorous modeling.

Third, the risk stratification variable included two highly predictive risk factors that were based on self-report by the patient (functional impairment for ambulation) or the physician (ASA class), so this model cannot easily be implemented from administrative claims data. This risk stratification model represents a comprehensive set of preoperative risk factors and suggests that other registries should consider collecting functional status and ASA information.

Conclusion

This risk stratification analysis was based on the largest registry of bariatric surgery patients available today and detailed preoperative patient characteristics and risk factors, intraoperative clinical detail, and postoperative outcome data. With additional validation, this risk model can be used by patients, surgical programs, and payors to evaluate postsurgical outcomes and improve the quality of surgical care, which will demonstrate the value of extensive data collection associated with the bariatric COE program that has been the subject of considerable debate in recent years [35,36].

Acknowledgments

Dr. Maciejewski acknowledges VA HSR&D funding (IIR 05-201, SHP 08-137). We appreciate helpful comments from Richard A. Hansen, PhD, the editor and the reviewers.

Maciejewski: Literature search, figure creation, study design, data construction, data analysis, data interpretation, writing

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Conflicts of Interest

Funding was provided by Surgical Review Corporation. This work was supported by the Office of Research and Development, Health Services Research, and Development Service, Department of Veterans Affairs. Dr. Maciejewski was also supported by a Research Career Scientist award from the Department of Veterans Affairs (RCS 10-391). The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs, Duke University, Surgical Review Corporation, or the University of North Carolina at Chapel Hill. ASMBS acknowledges the surgeons and facilities that enter data into BOLD for their participation in this important initiative.

Disclosure

Drs. Maciejewski and Farley have received consultation funds from Novartis, Takeda Pharmaceuticals, and the Surgical Review Corporation.

Appendix

Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.soard.2012.07.020.

References

[1] Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. JAMA 2004;292:1724–37.

[2] Livingston EH. The incidence of bariatric surgery has plateaued in the U.S. Am J Surg 2010;200:378–85.
[3] Kothari SN, Kallies KJ, Mathiason MA, Baker MT. Excellent laparoscopic gastric bypass outcomes can be achieved at a community-based training hospital with moderate case volume. Ann Surg 2010; 252:43–9.
[4] Nguyen NT, Hohmann S, Slone J, Varela E, Smith BR, Hoyt D. Improved bariatric surgery outcomes for Medicare beneficiaries after implementation of the medicare national coverage determination. Arch Surg 2010;145:72–8.
[5] Khuri SF, Daley J, Henderson W, et al. The Department of Veterans Affairs' NSQIP: the first national, validated, outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care. National VA Surgical Quality Improvement Program. Ann Surg 1998;228:491–507.
[6] Maciejewski ML, Smith VA, Livingston EH, et al. Health care utilization and expenditure changes associated with bariatric surgery. Med Care 2010;48:989–98.
[7] Maciejewski ML, Livingston EH, Kahwati LC, Henderson WG, Kavee AL, Arterburn DE. Discontinuation of diabetes and lipid-lowering medications after bariatric surgery at Veterans Affairs medical centers. Surg Obes Relat Dis 2010;6:601–7.
[8] Birkmeyer NJ, Dimick JB, Share D, et al. Hospital complication rates with bariatric surgery in Michigan. JAMA 2010;304:435–42.
[9] Hutter MM, Jones DB, M. Riley S Jr, et al. Best practice updates for weight loss surgery data collection. Obesity (Silver Spring) 2009;17: 924–8.
[10] DeMaria EJ, Portenier D, Wolfe L. Obesity surgery mortality risk score: proposal for a clinically useful score to predict mortality risk in patients undergoing gastric bypass. Surg Obes Relat Dis 2007;3:134–40.
[11] DeMaria EJ, Murr M, Byrne TK, et al. Validation of the obesity surgery mortality risk score in a multicenter study proves it stratifies mortality risk in patients undergoing gastric bypass for morbid obesity. Ann Surg 2007;246:578–82.
[12] Gupta PK, Franck C, Miller WJ, Gupta H, Forse RA. Development and validation of a bariatric surgery morbidity risk calculator using the prospective, multicenter NSQIP dataset. J Am Coll Surg 2011; 212:301–9.
[13] DeMaria EJ, Pate V, Warthen M, Winegar DA. Baseline data from American Society for Metabolic and Bariatric Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database. Surg Obes Relat Dis 2010;6:347–55.
[14] Shroyer AL, Grover FL, Edwards FH. 1995 coronary artery bypass risk model: The Society of Thoracic Surgeons Adult Cardiac National Database. Ann Thorac Surg 1998;65:879–84.
[15] Shroyer AL, Coombs LP, Peterson ED, et al. The Society of Thoracic Surgeons: 30-day operative mortality and morbidity risk models. Ann Thorac Surg 2003;75:1856–64.
[16] Shahian DM, O'Brien SM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1—coronary artery bypass grafting surgery. Ann Thorac Surg 2009;88:S2–22.
[17] Longitudinal Assessment of Bariatric Surgery (LABS) Consortium, Flum DR, Belle SH, et al. Perioperative safety in the longitudinal assessment of bariatric surgery. N Engl J Med 2009;361:445–54.
[18] D'Alonzo GE, Barst RJ, Ayres SM, et al. Survival in patients with primary pulmonary hypertension. Results from a national prospective registry. Ann Intern Med 1991;115:343–9.
[19] Winker MA. Measuring race and ethnicity: why and how? JAMA 2004;292:1612–4.
[20] Ellison GT, Smart A, Tutton R, Outram SM, Ashcroft R, Martin P. Racial categories in medicine: a failure of evidence-based practice? PLoS Med 2007;4:e287.
[21] Braun L, Fausto-Sterling A, Fullwiley D, et al. Racial categories in medical practice: how useful are they? PLoS Med 2007;4:e271.
[22] Kent DM, Shah ND. Risk models and patient-centered evidence: should physicians expect one right answer? JAMA 2012;307:1585–6.
[23] Livingston EH, Langert J. The impact of age and Medicare status on bariatric surgical outcomes. Arch Surg 2006;141:1115–20.
[24] Sjöström L, Narbro K, Sjöström CD, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med 2007;357:741–52.
[25] Adams TD, Gress RE, Smith SC, et al. Long-term mortality after gastric bypass surgery. N Engl J Med 2007;357:753–61.
[26] Arterburn D, Livingston EH, Schifftner T, Kahwati LC, Henderson WG, Maciejewski ML. Predictors of long-term mortality after bariatric surgery performed in Veterans Affairs medical centers. Arch Surg 2009;144:914–20.
[27] Hutter MM, Kellogg KC, Ferguson CM, Abbott WM, Warshaw AL. The impact of the 80-hour resident workweek on surgical residents and attending surgeons. Ann Surg 2006;243:864–71.
[28] Mokhlesi B, Kryger MH, Grunstein RR. Assessment and management of patients with obesity hypoventilation syndrome. Proc Am Thorac Soc 2008;5:218–25.
[29] Schauer PR, Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. N Engl J Med 2012;366:1567–76.
[30] Turner PL, Saager L, Dalton J, et al. A nomogram for predicting surgical complications in bariatric surgery patients. Obes Surg 2011; 21:655–62.
[31] Sarela AI, Dexter SP, McMahon MJ. Use of the obesity surgery mortality risk score to predict complications of laparoscopic bariatric surgery. Obes Surg 2011;21:1698–703.
[32] Finks JF, Kole KL, Yenumula PR, et al. Predicting risk for serious complications with bariatric surgery: results from the Michigan Bariatric Surgery Collaborative. Ann Surg 2011;254:633–40.
[33] Ramanan B, Gupta PK, Gupta H, Fang X, Forse RA. Development and validation of a bariatric surgery mortality risk calculator. J Am Coll Surg 2012;214:892–900.
[34] Dimick JB, Osborne NH, Hall BL, Ko CY, Birkmeyer JD. Risk adjustment for comparing hospital quality with surgery: how many variables are needed? J Am Coll Surg 2010;210:503–8.
[35] Livingston EH. Bariatric surgery outcomes at designated centers of excellence vs nondesignated programs. Arch Surg 2009;144:319–25.
[36] Pratt GM. Designation does matter. Arch Surg 2010;145:105.

Editorial comment

Comment on: Risk stratification of serious adverse events after gastric bypass in the bariatric outcomes longitudinal database

Ref.: SOARD 12-84R2

Dr. Maciejewski et al. are to be commended for their thoughtful and well-written analysis of risk factors for serious complications following Roux-en-Y gastric bypass. The study benefits from its access to the clinical registry of the Bariatric Outcomes Longitudinal Database (BOLD). This clinically rich data set represents patient data from >600 hospitals nationwide and is the world's largest regis-