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Clinical Outcomes after Bariatric Surgery: A Five-Year Matched Cohort Analysis in Seven US States

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Abstract

Background—Bariatric surgery is the most effective weight loss treatment, yet few studies have reported on short- and long-term outcomes postsurgery.

Methods—Using claims data from seven Blue Cross/Blue Shield health plans serving seven states, we conducted a non-concurrent, matched cohort study. We followed 22,693 persons who underwent bariatric surgery during 2003–2007 and were enrolled at least 6 months before and after surgery. Using logistic regression, we compared serious and less serious adverse clinical outcomes, hospitalizations, planned procedures, and obesity-related co-morbidities between groups for up to 5 years.

Results—Relative to controls, surgery patients were more likely to experience a serious [odds ratio (OR) 1.9; 95% confidence interval (CI) 1.8–2.0] or less serious (OR 2.5, CI 2.4–2.7) adverse clinical outcome or hospitalization (OR 1.3, CI 1.3–1.4) at 1 year postsurgery. The risk remained elevated until 4 years postsurgery for serious events and 5 years for less serious outcomes and hospitalizations. Some complication rates were lower for patients undergoing laparoscopic surgery. Planned procedures, such as skin reduction, peaked in postsurgery year 2 but remained elevated through year 5. Surgery patients had a 55% decreased risk of obesity-related co-morbidities, such as type 2 diabetes, in the first year postsurgery, which remained low throughout the study (year 5: OR 0.4, CI 0.4–0.5).

Conclusions—While bariatric surgery is associated with a higher risk of adverse clinical outcomes compared to controls, it also substantially decreased obesity-related co-morbidities during the 5-year follow-up.

Keywords

Cohort study; Obesity treatment; Bariatric surgery; Outcomes; Complications

Introduction

Obesity is now considered an epidemic by the Centers for Disease Control and Prevention [1–3]. Lifestyle management and medical treatment result in modest weight losses (4–5 kg), but regain is common [4]. Bariatric surgery results in large weight losses [5] and reduces obesity-related co-morbidities, such as diabetes; however, concern about short-and long-term complications remains high.

Many studies have evaluated bariatric surgery complications and clinical outcomes [5–28]; however, few of these studies were nationally representative [12–16, 23, 28–30]. Additionally, most studies have been limited by selection bias [7, 17, 20, 21], sample size [9, 17, 19], and potential confounders.[6–8, 23, 25] The few nationally representative studies [12–16, 23, 28–30] have included only inpatient information [23, 29, 30] or elderly patients [15], had short follow-up [12–14, 23], and limited data on serious complications [12, 14, 16]

or focused only on mortality [28]. Perhaps, most importantly, US studies have lacked comparison groups, which may be especially important for clinical outcomes, such as cardiac events.

We conducted a multistate non-concurrent cohort study with up to 5 years of follow-up using a matched comparison group to more fully evaluate clinical outcomes associated with bariatric surgery. We hypothesized that relative to a control group, persons who underwent bariatric surgery would have (1) a higher risk of adverse clinical outcomes and hospitalizations, which would decline over time; (2) a higher risk of planned procedures, such as skin reduction surgeries; and (3) a lower risk of obesity-related comorbidities.

Materials and Methods

Study Subjects

We collaborated with seven Blue Cross Blue Shield (BCBS) plans (in seven states) to study issues related to obesity. All of these insurance plans covered bariatric surgery for obesity treatment according to standard guidelines [i.e., body mass index (BMI) ≥ 35 kg/m² with an obesity-related comorbidity or BMI ≥ 40 kg/m²] [31]. A limited de-identified data set (as defined by the Health Information Privacy and Protection Act) was created, under Data Use Agreements between the researchers and the health plans, which minimized any risk to the privacy rights of the subjects involved. The study was deemed exempt by the institutional review board of The Johns Hopkins University.

Figure 1 describes how we arrived at our final analytic sample. Out of about 18 million enrollees, we analyzed claims data on subjects who had claims for bariatric surgery between 2003 and 2007 and were enrolled at least 6 months in the year before and after surgery (*N*s in years 1–5 postsurgery were 22,693, 13,889, 7,982, 4,339, and 2,108, respectively). Five of the seven plans provided data from 2002 to 2005, two plans provided data from 2002 to 2007, and one plan provided data from 2002 to 2008. Therefore, we have 2 years of follow-up for all sites, 4 years of follow-up from the two main sites, and 5 years of follow-up from one of the main sites. We selected the comparison group from other insured persons at the same health plans without a claim for bariatric surgery. We matched them 1:1 by age group (18–29, 30–44, 45–64, and ≥ 65 years old), gender, a propensity score for obesity (*c*-statistic, 0.73) [32], prescription benefit coverage, months enrolled, insurance coverage between 2002 and 2008, and BCBS plan site. In brief, the propensity score for obesity was developed using claims data for diagnoses and self-report or measured BMI from health risk appraisal data from the insurance plans [32]. We chose a cut point of BMI ≥ 35 kg/m² for obesity for two reasons: (1) to be inclusive of adults with comorbid diseases having bariatric surgery with BMI ≥ 35 kg/m² and (2) to account for the typical underestimation of BMI when done by self-report [33, 34] since we used self-report or measured BMI in our validation of the propensity score for obesity.

The comparison group subjects were assigned an “index date” equivalent to the date of bariatric surgery for their matched surgical counterpart in order to do pre- and post-analyses without concern for seasonality of outcomes.

For the laparoscopic versus open surgery comparisons, we further excluded persons undergoing the adjustable lap-band procedure ($N=2,554$) since these only occur laparoscopically and could have led to biased analyses.

Data Collection and Outcome Definitions

The following data were provided by the health plans: (1) enrollment files including administrative data (i.e., date of birth, gender, state, and enrollment periods); (2) benefits information indicating medical and pharmacy coverage; and (3) adjudicated inpatient, outpatient and pharmacy claims records containing International Classification of Disease (ICD-9) diagnosis and procedure codes, Current Procedural Terminology (CPT) codes, and National Drug Codes (NDC). These claims were used to identify bariatric surgeries and type of surgery, obesity-related comorbidities, and outcomes of interest. See Appendix Table 3 for specific codes for bariatric surgery.

We categorized the outcomes into four groupings: (1) serious adverse clinical outcomes (e.g., deep venous thrombosis), (2) less serious adverse clinical outcomes (e.g., nutritional imbalances), (3) planned procedures (e.g., skin reductions), and (4) obesity-related comorbidities (e.g., type 2 diabetes) (see Appendix Table 4 for details). These were created based on the prior literature [12, 29, 30] and the team's expertise in medicine, bariatric surgery, obesity, and claims data. We then used CPT codes and ICD-9 codes to determine if these outcomes occurred (a full list of codes is available upon request). We also assessed hospitalizations from any cause in each group.

Statistical Analysis

We used chi-squared tests or t tests as appropriate to determine differences between groups. For each of the four outcomes, we conducted logistic regression analyses by time period using Firth's technique [35] to accurately determine odds ratios and 95% confidence intervals for rare outcomes. We report outcomes by time period postbariatric surgery (e.g., year 1 postsurgery is from the day of discharge from the hospital through day 365; year 2 postsurgery ranges from day 366 to 731). Events within an individual are only counted once for each time period.

We adjusted all models for propensity scores for obesity, age, gender, plan, whether they had the outcome of interest in the 1 year before surgery, year of surgery, 6 months prescription coverage, duration of enrollment in the plan, and comorbidity using the previously validated aggregated diagnosis groups (ADG) morbidity categories, which are part of the Johns Hopkins Adjusted Clinical Groups (ACG) risk adjustment system [36, 37]. The ACG system assigns all ICD-9-CM codes to one of 32 ADGs based on professional judgment, using five clinical dimensions: duration, severity, diagnostic certainty, etiology, and specialty care involvement. Each ADG is a grouping of diagnosis codes similar in terms of severity and likelihood of persistence of the health condition treated over a relevant period. ADGs are not mutually exclusive; individuals can have multiple ADGs (up to 32). Because of model non-convergence, we grouped the 32 ADGs into five similar-sized groups based on number of ADGs, with group five having the highest number of unique ADGs and group one having the lowest numbers of ADGs. Sensitivity analyses that used all 32 ADGs

versus the five groupings of ADGs produced similar results. We used expanded diagnostic clusters (EDCs), which are also part of the Johns Hopkins ACG risk adjustment system [36, 37], to help describe specific diseases, such as type 2 diabetes. The EDC methodology assigns each ICD code to a single EDC; there are 264 EDCs in total. ICD codes within an EDC share similar clinical characteristics and are expected to induce similar types of diagnostic and therapeutic responses. For the laparoscopic versus open surgery comparisons, we adjusted for all the same factors mentioned previously and type of surgery. Stratification by year of surgery produced similar results.

Using a method described by Rosenbaum [38], we conducted sensitivity analyses to determine what strength of unmeasured confounder would change our results. All tests of significance were two-tailed, with an alpha level of 0.05. Data were managed using Microsoft SQL Server 2005, and all analyses were performed using SAS for Windows version 9.2.

Results

Study Subjects

Table 1 describes the characteristics of the bariatric surgery patients and the matched comparison group in the year before surgery. Surgery patients had a mean age of 45 and were 82% female. Gastric bypass was the most common surgery type (70%) followed by lap-adjustable gastric banding (11%). The comparison group was well matched on age categories, gender, and the propensity to be obese. However, type 2 diabetes and hyperlipidemia were slightly higher in the comparison group, while hypertension and sleep apnea were higher in the bariatric surgery group. Most of the comorbidities were also higher in the laparoscopic group compared with the open surgery group.

Serious Adverse Clinical Outcomes

Bariatric surgery patients were almost twice as likely as their matched counterparts to have a serious clinical outcome during the first 365 days following surgery (year 1 OR 1.9, 95% CI 1.8–2.0). The risk remained elevated until year 4 postsurgery (Fig. 2). Table 2 reports the absolute proportions of serious clinical outcomes by time period and group. For a more detailed list of specific serious outcomes, see Appendix Table 5.

While many of the serious outcomes were uncommon (<1%), a few of them deserve further mention. As expected, deep venous thromboses and pulmonary embolism (DVT/PE) were nine times more likely to occur during the hospital admission time frame when compared to nonsurgical controls (OR 9.4, 95% CI 6.6–13.5), remained higher during the first 30 days, and through year 1 (OR 1.5, 95% CI 1.3–1.7). Of note, DVT/PEs were 33% lower in the surgery versus the Other serious adverse outcomes remained higher over the longer term. The risk of abscess or peritonitis was higher in surgery versus control patients during the hospital admission (OR 26.1, 95% CI 13.9–49.2) and remained elevated for 4 years (year 4: OR 2.5, 95% CI 1.6–3.9). Additionally, around 2% of surgery patients required lysis of adhesions each postoperative year compared with around 0.3% per year for the control group (year 5: OR 5.7, 95% CI of 2.7–12.2). Marginal ulcers occurred in 2% of surgery

patients within the first postoperative year (year 1: OR 96, 95% CI 39–240) and remained around 0.5% for the rest of the time. The risk of hemorrhagic complications also remained elevated for 4 years postsurgery when compared to controls (year 4: OR 1.7, 95% CI 1.2–2.6). Ventral/incisional hernia repair with complications, such as gangrene, occurred infrequently, but remained significantly higher in the surgery group through year 4 (year 4: OR 2.2, 95% CI 1.1–4.6).

Lastly, while bacterial or aspiration pneumonia was higher in bariatric surgery patients during the hospital admission (OR 22, 95% CI 13–38), there was a lower risk of pneumonia in the years 2–5 after surgery compared to controls (year 5: OR 0.6, 95% CI 0.4–0.9). The same process occurred for acute renal disease and failure with a higher risk during the hospital admission in the surgery group versus the control group (OR 27, 95% CI 12–57) and a lower risk in the surgery versus control group that became significant at 1 year postsurgery and remained low throughout the 5 years of follow-up (year 5: OR 0.42, 95% CI 0.21–0.84).

Less Serious Adverse Clinical Outcomes

Subjects undergoing bariatric surgery were more likely than their matched counterparts to have a less serious clinical outcome in the 1 year postsurgery (OR 2.5, 95% CI 2.4–2.7), which remained slightly elevated for 5 years (OR 1.6, 95% CI 1.4–1.8) (Fig. 2). Table 2 lists the unadjusted absolute proportions of less serious clinical outcomes by time period and group. For a detailed list, see Appendix Table 6. While the unadjusted proportions of less serious clinical outcomes decreased in year 2 (Table 2), the adjusted odds ratios remained elevated (Fig. 2). The absolute decrease in less serious adverse outcomes is mainly driven by the decrease in upper endoscopies in the years postsurgery compared with the year prior to surgery.

Of the less serious adverse clinical outcomes, two outcomes remained elevated throughout follow-up: nutritional deficiencies (year 1: OR 7.9, 95% CI 7.2–8.6; year 5: OR 4.1, 95% CI of 3.3–5.2) and ventral/incisional hernia repair without complications (year 1: OR 6.1, 95% CI of 5.2–7.2; year 5: OR 9.8, 95% CI of 4.8–20.0).

Several outcomes were much more common in the surgical group in the first 1–2 years postsurgery but dropped to control levels by years 4–5 including: cholecystectomy (year 1: OR 1.4, 95% CI 1.3–1.6), ulcer disease (year 1: OR 2.9, 95% CI 2.4–3.5), gastrointestinal obstruction/ileus (year 1: OR 5.1, 95% CI 4.4–5.9), wound infection (year 1: OR 2.4, 95% CI 2.0–2.8), and abdominal pain, nausea or vomiting (year 1: OR 2.2, 95% CI 2.1–2.3).

Four other outcomes were more common in the surgical group in the first postoperative year but decreased to control levels by year 2, including endoscopy (year 1: OR 2.8, 95% CI 2.6–3.0), hypovolemia/dehydration (year 1: OR 3.4, 95% CI 3.0–3.8), fluid and electrolyte disorders (year 1 OR 2.2, 95% CI 2.0–2.4), and genitourinary complications (year 1: OR 1.4, 95% CI 1.3–1.4).

Hospitalizations

Hospitalizations for any cause were 1.2–1.7 times higher in the surgery group versus the control group throughout the entire 5-year study period and were highest in year 2 (year 2: OR 1.7, 95% CI 1.6–1.8; Table 2, Fig. 2).

Planned Procedures

Planned procedures were more likely in the surgical than the comparison group during the index surgical admission time frame (26% versus 0.1%) as well as in years 2–5 postoperatively (Table 2, Fig. 2). The high proportion of planned procedures during the index admission reflects lysis of adhesions (9%), cholecystectomies (8%), upper gastrointestinal endoscopies (5%), and skin reduction surgeries (3%) done during the bariatric surgery. The higher proportion in years 2–5 mainly reflect skin reduction surgeries (highest in years 2 and 3 at 8% and 6%, respectively) and orthopedic surgeries (3% in years 4 and 5; see Appendix Table 7).

Obesity-related Comorbidity

The bariatric surgery group had a 55% lower likelihood of having an obesity-related comorbidity diagnosis 1 year postsurgery when compared to controls, which remained lower throughout the 5 years of follow-up (Fig. 2). Specifically, the surgery group was less likely to have hypertension (year 5: OR 0.5, 95% CI 0.4–0.6), hyper-lipidemia (Year 5 OR 0.4, 95% CI 0.3 to 0.5), type 2 diabetes (year 5: OR 0.31, 95% CI 0.26–0.38), chronic obstructive pulmonary disease (year 5: OR 0.6, 95% 0.4–0.7), sleep apnea (year 5: OR 0.6, 95% CI 0.4–0.8), and cardiovascular diseases (year 5: OR 0.6, 95% CI 0.5–0.7; see Appendix Table 8).

Open Versus Laparoscopic Surgery

Among patients who underwent bariatric surgery, the open group had an increased risk of serious and less serious adverse clinical outcomes and planned procedures (mainly skin reductions) compared to the laparoscopic group during the index surgical admission, and during the first few years postsurgery (Table 2, Fig. 3). The open group had up to 1.5 times increased risk of hospitalization throughout the 5-year study period (Table 2, Fig. 3). Lastly, the decrease in obesity-related comorbidity diagnoses was similar between the two surgery groups (Table 2, Fig. 3).

Conclusions

In this insured cohort of working aged persons from seven US states, serious and less serious adverse clinical outcomes occurred more often in the bariatric surgery group than in the control group. Serious adverse outcomes remained 1.5–2 times higher in the surgery group until the fourth year postsurgery, while the hospitalizations for any cause and less serious adverse outcomes remained 1.3–1.5 times higher through year 5. Planned procedures were moderately high during the index surgical admission due to concurrent cholecystectomies and lysis of adhesions and remained higher the second year after surgery due to skin reduction surgeries and orthopedic procedures. Obesity-related comorbidity decreased by 55% within the first year postsurgery compared to controls and remained

substantially lower than the control group throughout the study. When comparing open to laparoscopic bariatric surgery, we found that the open group had slightly higher serious and less serious adverse clinical outcomes in the first few years postsurgery, higher hospitalizations throughout the 5 years, yet similar reductions in obesity-related comorbidities.

Since 1990, several national studies have evaluated outcomes after bariatric surgery [8, 12–16, 23, 29]. We found similar proportions of subjects with serious and less serious adverse clinical outcomes: 16% and 62% respectively compared to 10% to 40% [8, 12, 23].

Additionally, the proportions of subjects with specific complications were similar to the findings of other studies that used claims or registry data. For instance, we found that 1.7% of subjects developed DVT/PE and 12% developed nausea, vomiting, or abdominal pain at 30 days postsurgery, which is similar to the range of 0.4–1.7% for DVT/PE [12, 16] and 12.5% for abdominal pain, nausea, or vomiting in other studies [12].

Previously, analyses of complications after laparoscopic versus open procedures have shown mixed results [10, 22]. Our results favored laparoscopic surgery over open surgery in the first few years postsurgery. However, as noted below, there may have been unmeasured confounders.

We also report several novel findings. We found that serious adverse outcomes remain elevated until the fourth year postsurgery and that less serious adverse outcomes and hospitalizations remained elevated throughout the entire 5-year follow-up period. The increases in serious outcomes were predominantly due to abscess/peritonitis, lysis of adhesions, marginal ulcers, hemorrhagic complications, and ventral/incisional hernia with complications. DVT/PE risk was highest in the first 30 days, but remained elevated up to a year postoperatively. While improved care may not be able to decrease all of these undesirable outcomes, others may be preventable. For instance, longer anticoagulation may decrease DVT/PE risk. In addition, repairing hernias during bariatric surgery and developing ways to prevent hernias postsurgery may reduce future need for hernia repairs. Furthermore, several less serious clinical outcomes, including wound infection, cholecystectomy, ulcer disease, and nutritional deficiencies, remained elevated over time. These outcomes warrant investigation to determine if efforts to prevent wound infections and ulcers and to determine if concurrent cholecystectomies to prevent future need for cholecystectomies are beneficial or harmful. Recent guidelines [39] recommend more routine long-term nutritional screening, which may decrease nutritional complications.

As others have shown, we found a strong, early, and sustained benefit of bariatric surgery in reducing obesity-related comorbidities such as chronic obstructive pulmonary disease, type 2 diabetes, hyperlipidemia, hypertension, sleep apnea, and cardiovascular diseases. Christou et al. [8] reported less cardiovascular disease, cancer, endocrine, respiratory, genitourinary, and psychiatric diseases compared with their control group after 5 years of follow-up in Canada and higher rates of digestive diseases. Unlike that study that evaluated potential benefits by organ system [8], we evaluated specific obesity-related diseases, which allows clinicians to discuss potential benefits with individual patients with specific conditions.

Lastly, we found concurrent procedures were relatively common during bariatric surgery. Such procedures might contribute to or prevent future complications.

Several limitations of our study deserve mention. First, the study population, while large and diverse, may lack generalizability to uninsured, elderly, or young populations or to persons who change insurance plans shortly after surgery. While we went to great lengths to select a matched comparison group and to statistically adjust for a range of potential biases (such as baseline comorbidities and baseline occurrence of the outcome of interest), unmeasured confounders may have impacted our results. Sensitivity analyses showed that any unmeasured confounders would have to be moderately associated with our outcomes (OR generally >2 or <0.5 depending on the outcome) to negate several of the large between-group differences we identified. For our laparoscopic versus open analysis, we were unable to adjust for physician or hospital volume because we did not have reliable data on these elements. If higher volume surgeons are more likely to perform laparoscopic procedures compared with open surgeries, the open surgery group would appear to have worse outcomes than the laparoscopic group.

Misclassification bias may also have impacted our results. We only had claims data to determine outcomes after surgery. The comparison group may have been less likely to have a diagnosis of an obesity-related comorbidity compared to their surgical counterparts since patients undergoing bariatric surgery often receive these diagnoses in order to get the surgery covered by their insurance. Since we adjusted for baseline comorbidity in our analyses, our findings represent conservative estimates of the differences. In addition, the comparative comorbidity reduction may be underestimated if practitioners continue to code for diagnoses such as diabetes postsurgery even if the diabetes has resolved. However, this would only strengthen our findings on the benefit of surgery on obesity-related comorbidity. Since there was no CPT code for laparoscopic surgery until 2006, we used other methods to identify laparoscopic cases including separate laparoscopic equipment charges, which may also have resulted in misclassification of laparoscopic as open surgeries. However, this would have biased our results towards the null.

Patients undergoing bariatric surgery may have been seen more often postsurgery increasing the chance of receiving an adverse outcome diagnosis. However, the mean number of follow-up visits was similar between the surgery and control group (4.0 versus 3.3 mean specialty visits and 3.0 versus 2.9 mean primary care visits respectively in the year postsurgery). We did not have BMI in order to select a comparison group or assess weight change over time. While our propensity score for obesity had good accuracy [32], it was based on a BMI >35 kg/m² as opposed to 40 kg/m², which could bias the comparison group to be less obese than the surgery group. This could make the surgery group look slightly worse in complications or slightly better in obesity-related comorbidity reduction postsurgery when compared to the comparison group. However, the pre-postdata for the surgery group presented in the appendix tables supports the conclusions that complications remained higher than baseline over 5 years, while the comparison group tended to remain stable in their outcomes during that same time frame.

In addition, the decreasing number of study subjects by year of the study may be concerning. Most sites gave us data for 2 years of follow-up, while only a few sites gave us data for longer term follow-up accounting for most of the decrease in numbers by year as opposed to loss to follow-up. The actual loss to follow-up was initially <10% but increased to about 10–30% annually after the second year. However, our comparators were matched on months enrolled so we expect our comparative data to be accurate. In addition, most of our results seen at the 4 and 5 year follow-up remain consistent with the 2 year follow-up data where loss to follow-up is much smaller.

Finally, a comparison group analysis may not make intuitive sense for all clinical outcomes. For instance, we realize that no one in the comparison group would be expected to have a DVT/PE during the index surgical admission if they did not have the surgery. Additionally, concurrent procedures would not be expected to occur in the comparison group. However, the comparison group is critical for evaluating long-term outcomes. Additionally, the comparison group highlights the short-term risks for people undergoing surgery versus those who do not.

Despite these weaknesses, our study has several strengths. First, we used a very large database from seven different insurance plans across the USA with 5 years of follow-up. Furthermore, the use of a comparison group is unique and is important in characterizing long-term outcomes, such as cardiac events, which may or may not be related to surgery. Finally, we were able to compare the two cohorts on a wide range of outcomes in a variety of clinical settings.

In conclusion, there was a substantial reduction in obesity-related comorbidities within 1 year of surgery, which remained lower for 5 years. However, a number of adverse clinical outcomes were more common in surgery patients and remained elevated for years postoperatively. The full range of risks, and the time frame in which they can occur, should be discussed with patients. Further efforts to reduce the adverse outcomes after bariatric surgery will enhance the risk–benefit profile for this procedure.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. [Accessed 15 June 2010] US Obesity Trends from 1985 to 2005. <http://www.cdc.gov/obesity/data/trends.html#State>
2. [Accessed 18 Feb 2011] Obesity and overweight—facts. <http://www.who.int/features/factfiles/obesity/en/>
3. Davis MM, Sligh K, Chao C, et al. National trends in bariatric surgery, 1996–2002. *Arch Surg*. 2006; 141(1):71–4. [PubMed: 16415414]
4. Li Z, Maglione M, Tu W, et al. Meta-analysis: pharmacologic treatment of obesity. *Ann Intern Med*. 2005; 142(7):532–46. [PubMed: 15809465]
5. Maggard MA, Shugarman LR, Suttorp M, et al. Meta-analysis: surgical treatment of obesity. *Ann Intern Med*. 2005; 142(7):547–59. [PubMed: 15809466]
6. Agren G, Narbro K, Jonsson E, et al. Cost of in-patient care over 7 years among surgically and conventionally treated obese patients. *Obes Res*. 2002; 10(12):1276–83. [PubMed: 12490672]
7. Angus LD, Cottam DR, Gorecki PJ, et al. DRG, costs and reimbursement following Roux-en-Y gastric bypass: an economic appraisal. *Obes Surg*. 2003; 13(4):591–5. [PubMed: 12935360]
8. Christou NV, Sampalis JS, Liberman M, et al. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. *Ann Surg*. 2004; 240(3):416–23. [PubMed: 15319713]
9. Cooney RN, Haluck RS, Ku J, et al. Analysis of cost outliers after gastric bypass surgery: what can we learn? *Obes Surg*. 2003; 13 (1):29–36. [PubMed: 12630610]
10. Courcoulas A, Perry Y, Buenaventura P, et al. Comparing the outcomes after laparoscopic versus open gastric bypass: a matched paired analysis. *Obes Surg*. 2003; 13(3):341–6. [PubMed: 12841890]
11. Courcoulas A, Schuchert M, Gatti G, et al. The relationship of surgeon and hospital volume to outcome after gastric bypass surgery in Pennsylvania: a 3-year summary. *Surgery*. 2003; 134 (4): 613–21. [PubMed: 14605622]
12. Encinosa WE, Bernard DM, Chen CC, et al. Healthcare utilization and outcomes after bariatric surgery. *Med Care*. 2006; 44(8):706–12. [PubMed: 16862031]
13. Encinosa WE, Bernard DM, Du D, et al. Recent improvements in bariatric surgery outcomes. *Med Care*. 2009; 47(5):531–5. [PubMed: 19318997]
14. Encinosa WE, Bernard DM, Steiner CA, et al. Use and costs of bariatric surgery and prescription weight-loss medications. *Health Aff (Millwood)*. 2005; 24(4):1039–46. [PubMed: 16012144]
15. Flum DR, Salem L, Elrod JA, et al. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA*. 2005; 294(15):1903–8. [PubMed: 16234496]
16. Flum DR, Belle SH, King WC, et al. Perioperative safety in the longitudinal assessment of bariatric surgery. *N Engl J Med*. 2009; 361(5):445–54. [PubMed: 19641201]
17. Gallagher SF, Banasiak M, Gonzalvo JP, et al. The impact of bariatric surgery on the Veterans Administration healthcare system: a cost analysis. *Obes Surg*. 2003; 13(2):245–8. [PubMed: 12740132]
18. Liu JH, Zingmond D, Etzioni DA, et al. Characterizing the performance and outcomes of obesity surgery in California. *Am Surg*. 2003; 69(10):823–8. [PubMed: 14570356]
19. Livingston EH, Liu CY, Glantz G, et al. Characteristics of bariatric surgery in an integrated VA Health Care System: follow-up and outcomes. *J Surg Res*. 2003; 109(2):138–43. [PubMed: 12643855]
20. Martin LF, Tan TL, Horn JR, et al. Comparison of the costs associated with medical and surgical treatment of obesity. *Surgery*. 1995; 118(4):599–606. [PubMed: 7570311]
21. Narbro K, Agren G, Jonsson E, et al. Sick leave and disability pension before and after treatment for obesity: a report from the Swedish Obese Subjects (SOS) study. *Int J Obes Relat Metab Disord*. 1999; 23(6):619–24. [PubMed: 10411235]
22. Nguyen NT, Goldman C, Rosenquist CJ, et al. Laparoscopic versus open gastric bypass: a randomized study of outcomes, quality of life, and costs. *Ann Surg*. 2001; 234(3):279–89. [PubMed: 11524581]

23. Nguyen NT, Paya M, Stevens CM, et al. The relationship between hospital volume and outcome in bariatric surgery at academic medical centers. *Ann Surg.* 2004; 240(4):586–93. [PubMed: 15383786]
24. Sampalis JS, Sampalis F, Christou N. Impact of bariatric surgery on cardiovascular and musculoskeletal morbidity. *Surg Obes Relat Dis.* 2006; 2(6):587–91. [PubMed: 16996318]
25. Sampalis JS, Liberman M, Auger S, et al. The impact of weight reduction surgery on health-care costs in morbidly obese patients. *Obes Surg.* 2004; 14(7):939–47. [PubMed: 15329183]
26. Sjostrom L, Gummesson A, Sjostrom CD, et al. Effects of bariatric surgery on cancer incidence in obese patients in Sweden (Swedish Obese Subjects Study): a prospective, controlled intervention trial. *Lancet Oncol.* 2009; 10(7):653–62. [PubMed: 19556163]
27. Sjostrom L, Narbro K, Sjostrom CD, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. *N Engl J Med.* 2007; 357(8):741–52. [PubMed: 17715408]
28. Adams TD, Gress RE, Smith SC, et al. Long-term mortality after gastric bypass surgery. *N Engl J Med.* 2007; 357(8):753–61. [PubMed: 17715409]
29. Santry HP, Gillen DL, Lauderdale DS. Trends in bariatric surgical procedures. *JAMA.* 2005; 294(15):1909–17. [PubMed: 16234497]
30. Zingmond DS, McGory ML, Ko CY. Hospitalization before and after gastric bypass surgery. *JAMA.* 2005; 294(15):1918–24. [PubMed: 16234498]
31. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults—Executive summary. Bethesda, MD: NHLBI; 2002.
32. Clark JM, Chang HY, Bolen SD, Shore AD, Goodwin SM, Weiner JP. Development of a Claims-Based Risk Score to Identify Obese Individuals. *Popul Health Manag.* 2010; 13:201–7. [PubMed: 20443698]
33. Spencer EA, Appleby PN, Davey GK, et al. Validity of self-reported height and weight in 4808 EPIC-Oxford participants. *Public Health Nutr.* 2002; 5(4):561–5. [PubMed: 12186665]
34. Nyholm M, Gullberg B, Merlo J, et al. The validity of obesity based on self-reported weight and height: implications for population studies. *Obesity (Silver Spring).* 2007; 15(1):197–208. [PubMed: 17228048]
35. Firth D. Bias reduction of maximum likelihood estimates. *Biometrika.* 1993; 80(1):27–38.
36. Starfield B, Weiner J, Mumford L, et al. Ambulatory care groups: a categorization of diagnoses for research and management. *Health Serv Res.* 1991; 26(1):53–74. [PubMed: 1901841]
37. Weiner JP, Starfield BH, Steinwachs DM, et al. Development and application of a population-oriented measure of ambulatory care case-mix. *Med Care.* 1991; 29(5):452–72. [PubMed: 1902278]
38. Rosenbaum, P. *Observational studies.* 2. New York: Springer; 2002.
39. Mechanick JI, Kushner RF, Sugerman HJ, et al. American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery medical guidelines for clinical practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient. *Obesity (Silver Spring).* 2009; 17 (Suppl 1):S1–S70. [PubMed: 19319140]

Fig. 1.

Flow diagram showing identification of study subjects. *Asterisk* We had bariatric surgery cases from all seven plans from 2002 through 2005 ($N=30,965$), but only had two plans with cases in 2006 ($N=5,345$), and only one plan with cases in 2007 and 2008 ($N=7,378$). *Dagger* One site sent enrollees for conditions as specified but selected a 50% random sample of enrollees with hyperlipidemia due to the large number of enrollees with this condition. *Double dagger* The four age groups were 18–29, 30–44, 45–64, and 65 years old

Fig. 2.

Adjusted odds ratio of outcomes, procedures, and diagnoses by time postsurgery in bariatric surgery versus matched comparison group. It depicts the adjusted odds ratios for the entire bariatric surgery group versus the matched comparison group for each year post-surgery. For instance, year 2 postsurgery is the odds ratio of the outcome in between year 1 and 2 postsurgery. Odds ratios are adjusted for age, gender, propensity to be obese, plan site, months enrolled in the plan, comorbidity, and whether the subject had an outcome of interest in the one year prior to surgery. The specific outcomes considered for each of the overall groupings are listed in Appendix Tables 3–6. *Yr* year, *OR* odds ratios, *CI* confidence intervals. The numbers for analysis by year in the surgery and control group are: $N=22,693$ for the first year per group, $N=13,889$ in the second year per group, $N=7,982$ in the third year per group, $N=4,339$ in the fourth year per group and $N=2,108$ in the fifth year per group comparison group by year 3. While the point estimate remained lower in the surgery group for years 4 and 5, the difference between groups was not statistically significant.

Fig. 3.

Adjusted odds ratio of outcomes, procedures, and diagnoses by time postsurgery in open versus laparoscopic surgery groups. It depicts the adjusted odds ratios for the open surgery group versus the laparoscopic surgery group for each year post surgery. Lap-adjustable banding surgeries were excluded since this only occurs in the laparoscopic group and would have biased the analyses. Odds ratios are adjusted for age, gender, propensity to be obese, plan site, months enrolled in the plan, comorbidity, type of surgery, and whether the subject had an outcome of interest in the 1 year prior to surgery. The numbers for analysis in the open surgery group by year are 10,567 in the first year, 9,942 in the second year, 4,973 in the third year, 3,283 in the fourth year, and 1,778 in the fifth year. The numbers for analysis in the laparoscopic group by year are 9,572 in the first year, 7,061 in the second year, 2,512 in the third year, 871 in the fourth year, and 330 in the fifth year. *Yr* year, *OR* odds ratios, *CI* confidence intervals

Table 1

Patient characteristics

Characteristics for 2003–2007 cohorts	All bariatric surgery patients (N=22,693)	Matched comparison group (N=22,693)	Laparoscopic surgery group (N=9,572)	Open surgery group (N=10,567)
Mean age±SD (years)	45.4±10.4	46.8±11.5	45.4±10.4	45.3±10.5
Age categories (years)				
18–29	7.37%	7.37%	7.18%	7.39%
30–44	36.78%	36.78%	36.92%	37.61%
45–64	54.21%	54.21%	53.97%	53.38%
65	1.64%	1.64%	1.93%	1.62%
Gender (% female)	81.9%	81.9%	80.5%	81.3%
Mean propensity score±SD	0.259±0.21	0.255±0.20	0.278±0.22	0.259±0.21
Obesity diagnosis (%)	13.65%	2.56%	16.82%	14.03%
Sleep apnea (%)	5.53%	2.41%	7.33%	5.20%
Gall bladder disease (%)	0.92%	0.78%	1.13%	0.94%
Diabetes (%)	17.99%	22.21%	17.97%	18.31%
Hyperlipidemia (%)	7.58%	8.31%	10.39%	6.78%
Hypertension (%)	35.51%	32.62%	36.23%	34.93%

We chose to report the percentage with a specific comorbidity or disease entity the calendar year prior to surgery since individuals are more likely to get coded with a disease as they get closer to their surgery date in order to ensure their surgery gets covered by their health insurance. Despite choosing this time frame, the higher percent of obese subjects in the surgery group likely represents increased coding for obesity as opposed to actual obesity. The total *N* for lap and open surgeries do not add up to the total number of bariatric surgeries since lap-adjustable gastric banding was excluded from this analysis due to the surgery always occurring as laparoscopic surgery. *SD* standard deviation

Table 2

Unadjusted absolute proportion of subjects with outcomes by time period for bariatric surgery cohort and matched comparison group

Serious clinical outcomes	1 year pre (%)	Same admit (%)	30 days post (%)	First year post (%)	Second year post (%)	Third year post (%)	Fourth year post (%)	Fifth year post (%)
Serious clinical outcomes								
Cases	9.6	12.1	5.5	15.7	13.6	12.3	9.8	9.3
Controls	7.9	0.4	1.1	8.1	7.9	7.9	8.1	7.9
Laparoscopic	7.4	9.5	5.0	15.1	9.4	10.6	10.9	10.0
Open	12.1	16.4	6.8	17.2	12.3	13.1	9.4	9.1
Less serious clinical outcomes								
Cases	51.5	40.2	21.1	61.7	52.4	47.2	46.3	46.3
Controls	32.8	1.5	5.9	34.6	33.0	32.2	33.1	31.9
Laparoscopic	52.4	29.2	21.8	63.3	40.9	44.9	46.2	43.0
Open	51.7	52.5	22.5	63.2	44.3	48.7	46.7	46.9
Hospitalizations								
Cases	9.5	NA	6.3	17.9	19.5	17.7	14.7	14.3
Controls	12.8	NA	1.6	13.4	11.9	12.4	11.7	11.0
Laparoscopic	8.2	NA	5.7	16.8	16.1	15.7	14.0	11.8
Open	11.2	NA	7.7	20.6	22.9	18.8	14.9	14.8
Planned procedures								
Cases	2.6	25.6	0.1	3.0	10.8	9.0	5.4	4.9
Controls	3.0	0.1	0.3	2.9	2.8	2.6	2.7	2.5
Laparoscopic	2.3	23.3	0.02	2.8	6.6	7.6	5.3	3.0
Open	2.7	22.7	0.2	3.3	11.0	9.9	5.5	5.3
Obesity-related comorbidity								
Cases	82.2	NA	26.3	66.4	55.3	52.0	52.3	52.7
Controls	71.7	NA	22.3	74.9	70.9	67.4	67.0	67.4
Laparoscopic	84.8	NA	28.1	68.1	43.8	52.6	53.9	58.5
Open	80.2	NA	25.1	64.4	43.5	50.1	51.2	51.6

The numbers for analysis by year in the surgery and control group are as follows: $N=22,693$ for the first year per group, $N=13,889$ in the second year per group, $N=7,982$ in the third year per group, $N=4,339$ in the fourth year per group, and $N=2,108$ in the fifth year per group. When stating second year post, we are referring to the proportion that occurred between year 1 and 2 postsurgery. The numbers for analysis in the open group are as follows: 10,567, 9,942, 4,973, 3,283, and 1,778 in years 1–5 postsurgery, respectively. The numbers for analysis in the laparoscopic group are as follows: 9,572, 7,061,

2,512, 871, and 330 in years 1–5 postsurgery, respectively. Post refers to postsurgery. Diagnoses are only counted once within each time frame. The first year postsurgery is from the day of discharge to 365 days later, the second year postsurgery is from day 366 through year 2 (day 731). All other postsurgery time frames follow a similar pattern to year 2 postsurgery. NA not applicable