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Original articles

A nationwide safety analysis of bariatric surgery in nonseverely obese patients with type 2 diabetes

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Abstract

Background: Bariatric surgery is more effective than medical therapy in treatment of type 2 diabetes (T2D) in patients with severe obesity. However, surgery is often not advocated for patients with T2D who are overweight or have mild obesity.

Objective: To assess the safety profile of bariatric surgery in patients with T2D and mild obesity.

Setting: Database of the American College of Surgeons–National Surgical Quality Improvement Program.

Methods: Data of 1300 patients with T2D and a body mass index ≥ 25 but < 35 kg/m^2 who underwent bariatric surgery were retrieved from the American College of Surgeons–National Surgical Quality Improvement Program data set (2005–2014) to assess safety profile. Further stratified analyses were carried out between Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG).

Results: The mean operative time and length of hospital stay were 109.4 ± 58.3 minutes and 1.9 ± 1.5 days, respectively. Incidence of all individual major complications was ≤.5% in this cohort except for postoperative bleeding (1.7%). Thirty-day postoperative composite morbidity, serious morbidity, and mortality rates for total cohort were 4.2%, .7%, and .15%, respectively. Smoking (odds ratio = 2.75, 95% confidence interval: 1.34–5.64) and chronic obstructive pulmonary disease (odds ratio = 4.05, 95% confidence interval: 1.51–10.88) were predictors of composite morbidity. Thirty-day morbidity rates were not significantly different between those who underwent RYGB compared with SG.

Conclusion: Bariatric surgery, which is a 2-hour procedure requiring a 2-day hospital stay, is a relatively well-tolerated option in patients with T2D and mild obesity. RYGB and SG had comparable early postoperative morbidity. Smoking can be considered as a modifiable risk factor for early complications after bariatric surgery in patients with T2D and lower body mass index. (Surg Obes Relat Dis 2016;▮:00–00.)

Keywords: Obesity; Body mass index; Overweight; Diabetes; Complication; Safety; Bariatric surgery; Metabolic surgery; Gastric bypass; Mortality; Morbidity; Smoking; NSQIP

ACS-NSQIP Disclaimer: The American College of Surgeons–National Surgical Quality Improvement Program and the hospitals participating in the ACS-NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

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Recent randomized controlled trials (RCTs) have reported the superiority of bariatric surgery over medical therapy for achieving glycemic targets in patients with obesity and type 2 diabetes (T2D) [1–5], which can also lead to complete remission in some surgically treated patients [6,7]. The current eligibility criteria for bariatric surgery originated from the National Institutes of Health consensus panel in 1991, which considers patients with T2D and a body mass index (BMI) ≥ 35 kg/m^2 eligible for bariatric surgery [8].

Over the last quarter century, however, the field of bariatric surgery has significantly evolved with the introduction of new, less invasive surgical approaches (e.g., laparoscopic) and surgical procedures (e.g., sleeve gastrectomy), which have led to improvement in the safety profile of bariatric operations and can potentially expand the indications for surgery [9].

Nonetheless, the safety profile of bariatric surgery performed in multiple centers in a subgroup of patients with T2D who are overweight and mildly obese has not been well characterized. The available RCTs [1–5] cannot clearly resolve the safety concerns of bariatric surgery in this patient population because such small trials are unlikely to reveal uncommon but clinically serious complications. In addition, many of them have screened out low-BMI or high-risk patients deemed unfit for participation in study protocols. This is important because most patients with T2D fall into a BMI category <35 kg/m^2. Therefore, we aimed to assess the safety profile of bariatric surgery in nonmorbidly obese and overweight patients who have T2D using a large national clinical database.

Methods

Data collection and study cohort

Data were retrieved from the American College of Surgeons–National Surgical Quality Improvement Program (ACS-NSQIP) data sets (2005–2014). The ACS-NSQIP prospectively collects data on >300 variables, including standardized and audited preoperative characteristics, laboratory values, and 30-day postoperative mortality and morbidity outcomes for patients undergoing major surgeries in the United States (517 participating academic and community centers in 2014) [10]. ACS-NSQIP uses multiple mechanisms to ensure that the data collected are of the highest reliability and consistency [9,10].

We included patients ≥ 18 years old with BMI ≥ 25 but <35 kg/m^2, who were receiving active medical treatment for T2D and underwent primary bariatric surgery. Surgical procedures including Roux-en-Y gastric bypass (RYGB), adjustable gastric banding (AGB), sleeve gastrectomy (SG), and duodenal switch (DS) were identified using their respective Current Procedural Terminology codes (AGB: 43770; SG: 43775; RYGB: 43644; DS: 43845). All operations were performed laparoscopically except for a small fraction of the DS procedures. We excluded patients who underwent revisional bariatric procedures and those coded as emergent. Patients who had another surgery in the 30 days before the index bariatric surgery were also excluded. To further identify those patients who were at risk for a worse postoperative outcome, we excluded those with any evidence of preoperative sepsis, disseminated cancer, and American Society of Anesthesiology class V (moribund). Data of the subgroup of patients with BMI 25–30 kg/m^2 were detailed separately because there is a paucity of such data in the literature.

Covariates

Independent demographic variables were age, sex, race, BMI, and active smoking status. Examined co-morbidities included dependence on insulin for the treatment of T2D, hypertension, chronic obstructive pulmonary diseases (COPD), history of cardiac disease, history of cerebrovascular diseases as a binary variable representing transient ischemic attack and stroke, dependence on chronic dialysis or need for it beyond 2 weeks, and dependence on chronic steroid/immunosuppressant agents. Preoperative laboratory variables included serum creatinine, albumin, and hematocrit. All variables are clearly defined in the ACS-NSQIP database user guide [10].

Endpoints

The primary endpoints included 30-day postoperative morbidities categorized in 2 different variables representing composite adverse outcomes: (1) composite morbidity defined as presence of any of 16 major adverse events including bleeding (need for transfusion), organ/space surgical site infection, deep vein thrombosis, pulmonary embolism, pneumonia, myocardial infarction, acute renal failure, stroke, sepsis, septic shock, unplanned intubation, prolonged ventilation (>48 hr), cardiac arrest, need for a prolonged hospital stay (>7 d), reoperation, and mortality; (2) serious morbidity defined as occurrence of a class IV or V Clavien-Dindo complication [11]. Class IV Clavien-Dindo complications were defined as organ dysfunction requiring admission to intensive care unit, which includes septic shock, need for dialyses, pulmonary embolism, myocardial infarction, cardiac arrest, and mechanical intubation and reintubation. Class V represents death.

In addition, operative time, hospital length of stay (LOS) after surgery, and 30-day postoperative minor complication rate, including wound infection and urinary tract infection [12], were also assessed.

Statistical analysis

The estimates on the study parameters are expressed as mean ± SD and percentage (%). Because of the low